

Expert Paper Series

Expert Paper **Infectious** **One Disease**

Expert Paper Series

Infectious Disease



Secretariat of the International Task Force on Global Public Goods



Infectious Disease

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ISBN: 0-9788790-2-3

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For hard copies of this report, please contact the Secretariat of the International Task Force on Global Public Goods, PO Box 16369, SE-103 27 Stockholm, Sweden. After 31 December 2006, please contact the Department for Development Policy, Ministry for Foreign Affairs, SE-103 39 Stockholm, Sweden.

Printing: Erlanders Infologistics Väst AB, Stockholm, Sweden

Design: Grundy & Northedge, London, United Kingdom

Editing and layout: Communications Development Incorporated,
Washington, D.C., United States

This publication may be reproduced in full or in part if accompanied with the following citation: Secretariat of the International Task Force on Global Public Goods. 2006. *Expert Paper Series One: Infectious Disease*. Stockholm, Sweden.

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Michael Kremer is the Gates Professor of Developing Societies in the Department of Economics at Harvard University and a senior fellow at the Brookings Institution. He is a fellow of the American Academy of Arts and Sciences and a recipient of a MacArthur Fellowship and a Presidential Faculty Fellowship. Kremer's recent research examines education and health in developing countries, immigration and globalization. He and Rachel Glennerster have published *Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases*. His articles have been published in *American Economic Review*, *Econometrica* and the *Quarterly Journal of Economics*.

Ronald Ridker received a Ph.D. in economics and international relations from the University of Wisconsin in 1958. Since then he has taught at Washington University in St. Louis and Syracuse University in New York State; was responsible for a research program in population, resources and the environment at Resources for the Future; served as economic adviser to the USAID Mission in India; and was a senior adviser in the Operations Evaluation Department of the World Bank, where he was responsible for human resource sectors. Since retiring from the World Bank in 1994, he has served as a consultant for various international agencies. His publications include *Economic Cost of Air Pollution Damage*; *To Choose a Future: Resource and Environmental Consequences of Population Growth*; *Population and Development: The Search for Selective Interventions*; and numerous journal articles.

Pasi Penttinen is a public health professional working as medical/public health adviser for International SOS in the Indonesian province of Papua. His current activities include implementation of HIV, TB and malaria control programs at a district level. He previously worked at the Swedish Institute of Infectious Disease Control as a senior medical officer in surveillance and outbreak response for communicable diseases. His training includes a medical degree and a PhD in epidemiology from Kuopio University and an MPH in quantitative methods from Harvard University. He is a fellow of the European Program on Intervention Epidemiology Training. His current research interests are in applying time-series methodology in communicable diseases, describing functional public-private partnerships and developing survey methodology for challenging environments.

Christopher Murray is the director of the Harvard University Global Health Initiative and the former executive director of the Evidence and Information for Policy Cluster at the World Health Organization. A physician and health economist, his early work focused on tuberculosis control and the development of the pioneering Global Burden of Disease project at Harvard University. Recently he has initiated major new approaches to the measurement of population health, cost-effectiveness analysis and the conceptualization, measurement and national application of health systems performance assessment. He has authored or edited 14 books, many book chapters and more than 120 journal articles in internationally peer-reviewed publications.

Uma Lele is a visiting professor in the Department of Food and Resource Economics at the University of Maryland and has published extensively on the issues of development. She is a fellow of the American Agricultural Economics Association. Before retiring from the World Bank as a senior adviser in the Bank's Independent Evaluation Group, she occupied various positions in its research and operational departments. She is currently a core team member of the Independent External Evaluation of the Food and Agricultural Organization of the United Nations, with responsibility for evaluation of the FAO's technical activities.

Jagadish Upadhyay joined the World Bank in 1971 after serving as an under-secretary in the National Planning Commission of Nepal and as a consultant to the Center for Economic Development and Administration in Kathmandu. From 1987 to 1992 he held the position of senior project officer of health and education in the West Africa region. From 1992 to 2004 he served as the lead project officer, East Asia and the Pacific region, responsible for overall management of the World Bank's health sector operations in China. After retiring from the World Bank in 2004, he has served as a consultant for various international organizations.

Acronyms and Initials

ACT	artemisinin-based combination therapy
AMC	advanced market commitment
APC	advance purchase commitments
ARV	antiretroviral
CCM	country coordinating mechanism
CDC	Centers for Disease Control
CDR	case detection rate
CGIAR	Consultative Group on International Agricultural Research
DALY	disability-adjusted life year
DFID	Department of International Development
DOTS	directly observed treatment-short course
EU	European Union
FDA	Food and Drug Administration
GAVI	Global Alliance for Vaccines and Immunization
GDF	Global Drug Facility
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GNP	gross national product
GPG	global public good
HPTN	HIV Prevention Trials Network
HRP	Special Programme of Research, Development and Research Training in Human Reproduction
IAVI	International AIDS Vaccine Initiative
IDA	International Development Association
IFF	International Finance Facility
IFFim	International Finance Facility for Immunization
IHR	International Health Regulation
IPT	intermittent preventive treatment

IPV	inactivated polio vaccine
MAP	multicountry AIDS programme
MDG	Millennium Development Goal
NGO	non-governmental organization
NIH	National Institutes of Health
ODA	official development assistance
OECD	Organisation for Economic Co-operation and Development
OPV	oral polio vaccine
PSDP	Primary School Deworming Project
PSDP	Public Sector Development Programme
R&D	Research and development
RBM	Roll Back Malaria
RNTCP	Revised National TB Control Programme
SARS	severe acute respiratory syndrome
STD	sexually transmitted disease
STI	sexually transmitted infection
SWAP	sectorwide approaches
TB	tuberculosis
TDR	Special Programme for Research and Training in Tropical Diseases
UN	United Nations
UNAIDS	The Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNESCO	United Nations Educational, Scientific and Cultural Organisation
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHA	World Health Assembly
WHO	World Health Organization
WTO	World Trade Organization

Preface

The control of communicable diseases is a global public good. Microbes do not respect national boundaries. They can just as easily infect across national borders as within them. Increased speed of travel has decreased the time it takes for an infection to spread around the world, as seen most recently with the SARS and the avian flu. Typically epidemics begin and endure as regional affairs, with infections criss-crossing poor countries' borders in difficult times, often emerging from isolated endemic zones. This reflects the underlying poverty and associated deprivation in those countries—also most prone to civil war and failed state conditions—in which disease flourishes while public health capacity withers. Helping these countries strengthen their systems and capacities is clearly in the international public interest, alongside global public good concerns about research on infectious diseases and early warning systems.

The strategies and partnerships the international community has adopted to prevent the spread of infectious diseases have evolved in line with the challenges it has faced. Early steps included an 1851 meeting in Paris on cholera and an 1881 meeting in Paris on yellow fever. Reflecting the strong partnership between the global public good pillars of health and

knowledge, these efforts took flight in the 1880s with the invention of the microscope and the subsequent confirmation of the germ theory of infections and the efficacy of quarantines. Since then, knowledge and health have remained closely intertwined, with advances in knowledge through research the major cause of dramatically improved health outcomes over the past 50 years. This connection goes to the heart of what is the global public good in this area. Other instruments—of surveillance and avoidance of the spread of drug resistance—also produce major global benefits. Local capacity building has properties of global public goods as well, given the importance of local systems as a basis for international surveillance and monitoring and for minimizing and mitigating systemic risks.

The pursuit of the international public interest in preventing and controlling the spread of infectious diseases is at the heart of the World Health Organization's (WHO) mandate. It is charged with supporting the intergovernmental process by which the international community agrees on rules to regulate members' conduct and monitor implementation. The complexity of managing the global health system has increased with globalization characterized by the explosion of air travel. The emergence of pandemics such as AIDS and the resulting proliferation of institutional players on the global health scene, the outbreak of SARS in 2003 as well as the recent worries about a possible avian flu outbreak are signals that the world needs a strong WHO focused on the big picture to provide leadership and direction to the many efforts that will be needed. The WHO has already taken the leadership on some important challenges like the revision of the International Health Regulations to include diseases of importance for the international community and the creation and reinforcement of the international surveillance system at the national, regional (such as the European Centre for Disease Control) and international levels (such as the Global Outbreak Alert and Response Network).

The Secretariat of the International Task Force on Global Public Goods has commissioned papers to further analyse these issues. The papers review the causes and consequences of these issues and propose solutions. The papers also analyse the financing, institutional and capacity building aspects of these challenges. The papers are summarized below.

Papers commissioned by the Secretariat of the International Task Force on Global Public Goods

In “Transnational Public Goods for Health” Scott Barrett identifies the transnational public goods for health, and explains why they tend to be underprovided and how their provision might be enhanced. Barrett starts by differentiating public health issues of international concern and transnational public goods. Then Barrett considers the following transnational public goods for health in detail: surveillance, the control of infectious diseases, the eradication of infectious diseases, the control of the spread of resistance and knowledge, particularly with regard to new vaccines. He then answers the following question: “For which transnational public goods is provision likely to yield the greatest benefits?” Barrett argues that in the past the eradication of smallpox may have yielded a higher return than any other single public investment, but opportunities like this are unlikely to be available again. According to Barrett, surveillance and knowledge are the two areas that would yield the highest returns. Barrett focuses his recommendation on surveillance. Barrett proposes *inter alia* to organize a systematic review of the gap in the global infrastructure for surveillance, especially of outbreaks of new diseases, and how this gap should be filled.

The focus of Michael Kremer’s “Global Public Goods in Communicable Disease Control” is on one of the two highly beneficial health interventions identified by Barrett: knowledge, particularly R&D for new vaccines. In his contribution Kremer starts with a short description of the institutional landscape of international public health. He then turns to a brief analysis of the different global public goods in the health area: surveillance, avoiding the spread of drug resistance, generation of knowledge and dissemination of knowledge. The main part of the paper is focused on the generation of knowledge—that is, R&D for new vaccines. To encourage the global public good of research and development, Kremer proposes “push” programmes that subsidize research inputs, such as providing a research grant, and “pull” programmes that reward research outputs, such as committing in advance to purchase a specified amount of a desired product at a specified price. He argues that each approach has strengths and limitations, but pull programmes are relatively underused. Donors should consider making legally binding commitments that if certain new products are developed, they will either fully or partially finance purchases. According to Kremer, making a commitment in advance to buy vaccines if and when they are de-

veloped would create incentives for industry to increase investment in research and development. This innovative financing proposal is called “advance purchase commitment.”

Ron Ridker’s “Ensuring Markets for New Drugs and Vaccines for Poor Countries: Institutional Requirements and Possibilities” goes one step further by exploring which institutions would be most appropriate to take the lead in implementing an advance purchase commitment. The paper begins by reviewing a proposed advance purchase commitment designed for this purpose. It then asks what functions need to be accomplished to implement it, what institutions would be able to fulfil these functions, and what changes in their operating procedures might be necessary to do so.

Investing in R&D for new vaccines would bring very high returns to the international community but the development of new vaccines is a very long and expensive process. Other interventions such as R&D for microbicides which are less expensive to develop than vaccine could be very effective in preventing HIV/AIDS. Pasi Penttinen’s “Microbicides as an Option for HIV Prevention” focuses on the great gains the international community could receive from more investment in microbicides. Pasi Penttinen recommends that clinical research should be supported, and financial and logistical solutions for production and marketing activities should be sought.

Barrett, Kremer and Penttinen recognize the importance of the WHO as the leading institution in the control of communicable diseases. Christopher Murray’s “The Role of the World Health Organization in the Control of Communicable Diseases” looks at the institutional aspects in greater detail. In the first part of his contribution, Murray identifies six functions that he considers the WHO should perform. Then, Murray analyses WHO strengths and weaknesses in addressing these six challenges. Murray argues that the organization is uniquely positioned to lead the efforts regarding advocacy, norms and standards, and epidemic outbreak and response, as well as political pressure that might arise in the event of an epidemic, because of its credibility with Ministries of Health. Murray adds that the organization, despite this unique position, has some difficulties in performing these functions because of the lack of resources. In the area of monitoring and evaluation, Murray considers that the WHO has limited capacity. He proposes the creation of an independent organization that would focus mainly on this area of work.

All the authors recognize the huge importance of strengthening national health systems for better control of communicable diseases. Uma

Lele, Ronald Ridker and Jagadish Upadhyay's "Health System Capacities in Developing Countries and Global Health Initiatives on Communicable Diseases" looks at the capacity-building aspects in more detail. It analyses seven international health programs addressing communicable diseases representing considerable diversity in age, scope and approaches to global collective action. This contribution draws on existing evaluations and on four country-case studies—China, India, Kenya and Malawi—as well as reviews of reports and interviews with stakeholders. The authors give a general overview of the effects of global programs on national health capacities. They argue that global programs are relevant to health needs but that they cannot address the challenges on their own. Lele and her team show that global programs impose heavy transaction costs on developing countries. The authors also argue that the recent proliferation of uncoordinated agencies and programs increase transaction costs and further threaten the capacities of national health systems.

This assessment is followed by a more detailed review of the effectiveness of the different global programs in addressing tuberculosis, malaria, HIV/AIDS, R&D and immunization in the four countries. Uma Lele and her team make several recommendations. They recommend, among other things, improving the balance between disease-specific and sectorwide programs, between treatment and prevention, and among the roles of public, private and community organizations. They also recommend that the World Bank become more proactive in building country-level health system capacities and coordinating the activities of bilateral donors in this field.

Transnational Public Goods for Health

1

Chapter

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This paper examines the transnational public good dimension of global health. It argues that supplying public goods for health has two advantages: the obvious efficiency advantage of supply and a related advantage for economic development. Because the discrepancy in health between rich and poor nations is so large, the second advantage is likely to be especially important for this public good, compared with the others being examined by the Task Force. Five public goods are studied in detail: surveillance, the control of infectious diseases, the eradication of infectious diseases, the control of the spread of resistance and knowledge, particularly for new vaccines. The paper briefly examines the incentive problems associated with each area and the institutional actions taken so far to correct them.

This paper identifies the transnational public goods for controlling communicable diseases and explains why interventions may be underprovided and how their supply might be enhanced. There are two pure global public goods: eradicating disease and preventing resistance. For both, no country can be excluded from the benefits of provision, and no country's consumption reduces the amount available to other countries. Both are discrete public goods. Eradication either happens or it does not. Resistance develops or it does not.¹ Both also require interventions by a large number of countries—and in some cases, by all. The important difference is that eradicating disease is time limited, though surveillance and precautions must continue indefinitely. Preventing resistance requires ongoing intervention (see table 1.1).

Surveillance for emerging diseases (such as SARS) and the knowledge of how to control a disease are both potential public goods, but

Table 1.1 Policy interventions for infectious diseases

Intervention	Global public good	External benefits
Surveillance	Yes, if reported	Allows informed countries to take steps to limit imports and consequences of imports
Knowledge	Yes, if access unrestricted	Can be used to control a disease or as an input to further scientific progress
Control	Yes, partially	Breaks international transmission
Treatment	Yes, partially	Reduces international transmission but may also hasten resistance
Resistance/avoidance	Yes	No risk of importing resistant pathogens; current treatments remain effective
Elimination	Yes	Breaks international chain of transmission
Eradication	Yes	Yields every country a dividend of avoiding both future infections and the need to control them

access to them can be restricted. Surveillance is of little benefit to other countries unless accompanied by an obligation—or, better yet, an incentive—to report. The essential problem revealed by the SARS outbreak was less a failure of surveillance than a failure to report the disease. Similarly, knowledge is a public good when users are allowed access. Sometimes, however, potential users are excluded; knowledge can be kept secret or embodied in patented products.

Control of a disease has some attributes of a public good. If a disease is controlled, the likelihood of its being transmitted to susceptible persons is reduced somewhat. But whether this reduction yields transnational benefits depends on the circumstances. Measles, for example, has been eliminated in the United States, so that further control of this disease in developing countries is of little benefit to the United States.

Similarly, treatment of a disease such as tuberculosis reduces transmission and so offers a measure of protection to others. But treatment can also hasten the onset of resistance, especially if the drug is used inappropriately.

Elimination of a disease involves high rates of control so that a disease stops being transmitted. Where a disease is eliminated, it ceases to be endemic and imported cases cannot spark an epidemic. Elimination is location specific—it is a local public good and, in some cases, a regional public good. Whether elimination benefits other countries depends on the levels of control adopted elsewhere. Measles elimination in the Americas, for example, is of little if any benefit to African countries, where the disease remains endemic.

For which transnational public goods is provision likely to yield the greatest net benefit? The eradication of smallpox may well have yielded a higher return than any other single public investment, but opportunities such as that are unlikely to be available again. The greatest gains are likely to come from two kinds of interventions:

- Surveillance, reporting and controlling of newly emerging and re-emerging diseases and resistance.
- Knowledge—particularly of new vaccines, combination vaccines, antibiotics and antiretrovirals, and vector control—coupled with an efficient system for production and distribution.

To illustrate, one area where both interventions would yield enormous benefit is the early identification of a new pandemic flu, coupled with measures to protect susceptible populations from infection—including the rapid development, production and distribution of a new vaccine. Other fruitful interventions are discussed in what follows.

This paper identifies the transnational public goods for health and explains why they tend to be underprovided and how their provision might be enhanced. The focus is on controlling communicable diseases. Other public goods, such as protecting the ozone layer, have implications for global health but are addressed in the companion paper on the global commons. Other public health issues that are not global public goods, such as smoking, are not addressed in this paper, even though they may be of international concern.²

Global public goods have two characteristics: no state can be prevented from consuming them, and consumption by one state does not diminish the amount available to others. As will be explained, control of communicable diseases can be a global public good. But it will not always be so—and understanding when it is and when it is not is important to the design of policies and institutions. Where countries are very different and health is a global public good, it may pay some countries to finance health improvements in other countries. Where countries are very different and health is not a global public good, financing may be undertaken for humanitarian or development reasons—but not because the countries paying for health improvements benefit directly from the investment.

The distinction is emphasized because much recent literature has combined or conflated the two motivations, or stressed the humanitarian and development dimension. The World Health Organization (WHO) Commission on Macroeconomics and Health, for example, produced an excellent report on global public goods for health, but

Box 1.1 Not all global health issues are global public goods

Private health is concerned with the health of individuals. Public health, by contrast, is concerned with the health of a community: the control of infectious disease, improvement of the physical environment (sanitation, pollution), nutrition, safety in the workplace and on the roads, smoking—anything that affects the health of a population at large.

Public health is determined in part by private choices, such as the choice to vaccinate oneself, to sleep under a bednet at night (to ward off mosquito vectors) or to wear a seat belt. It is also determined by public infrastructure investments (sanitation, road safety), regulation (pollution, workplace safety, cigarette advertising) and policies that affect individual behaviour and the provision of medical care.

Public policy is needed because some incentives prevent individual choices from sustaining efficient outcomes. Individuals have strong incentives to be vaccinated when an effective vaccine exists and is safe and affordable and the disease against which the vaccine offers protection poses a substantial risk. When an individual is vaccinated, it becomes that much harder for a disease to be transmitted to unprotected persons in a community—a phenomenon known as “herd immunity”. But individuals have little if any incentive to take this effect into account, with the consequence that, from the perspective of the collective good, too few people will be vaccinated. Policies of mandatory vaccination and vaccination subsidies are intended to correct for these incentive problems.

Public health is local, national, regional and global—and policy must address public health on all these levels. And just as individual choices have implications for the community, so policy choices at each level have implications for the other levels of collective decision-making. Control of the malaria vector, for example, exhibits mass effects at the village level and across national boundaries. By definition, disease eradication must be achieved globally, and yet success depends on whether a targeted disease can be eliminated from its last stronghold—perhaps a small village in a remote, war-torn region.

Many public health issues are of international concern; only a subset consists of transnational public goods. The distinction is important because different issues reflect different underlying incentive problems. They also call for different remedies.

Two public health issues have attracted substantial interest in recent years but are not global public goods. The explosive spread of HIV/AIDS in developing countries is among the greatest of all public health concerns today, and the inequity of antiretrovirals being available to infected persons in rich countries but beyond the budgets of HIV-positive persons in developing countries has attracted global attention. It has also attracted funding, including a \$15 billion pledge by the Bush administration to supply antiretrovirals to 14 countries. Supplying antiretrovirals to the poor in poor countries is largely a humanitarian concern. It will not reduce the global spread of the disease.^a There may, however, be indirect effects. Perhaps humanitarian assistance is itself a public good (perhaps all countries benefit from the knowledge that an HIV-positive person and his or her family is being helped by the provision of antiretrovirals). Perhaps it will aid international security—another public good—by avoiding a future source of state failure (National Intelligence Council 2000).

Intervention may also be needed to ensure that the trading system benefits all countries, and is seen to do so.^b The problem is not only that infected persons in developing countries cannot afford the cost of antiretroviral therapies available in rich countries. The problem is that a one-price policy for patented drugs is inefficient.

The price of antiretrovirals is high because the research and development costs need to be recouped by the companies that risked capital in the effort. Allowing companies to charge a high price is thus justified from the perspective of intertemporal efficiency. But the marginal cost of producing these treatments is a small fraction of the price charged. Because the research and development costs are already being recouped in rich countries, the companies making these drugs should be willing to sell them in developing countries for a price close to marginal costs. And an efficient system would allow this to happen.^c

Box 1.1 Not all global health issues are global public goods (continued)

But the international trading system blocks such transactions. Arbitrage—normally the friend of efficiency—could create a gray market for the drugs, causing cheap drugs sold in poor countries to be shipped back to rich countries and so depressing the profits of manufacturers in these markets. Even in the absence of trade, differential pricing may put downward pressure on prices in rich countries, where charging high prices may be seen (by consumers and politicians) to be unfair. To avoid these problems, manufacturers have incentives not to offer antiretrovirals at a low price in poor countries. But maintaining a high price in all markets only encourages entry by copycat producers—a development that also cuts into the profits of the original innovator. This helps explain why several companies have offered their products to developing countries on a no-profit basis.^d

To sum up, there are many reasons for providing international assistance for health, and for adopting international health policies. The focus of this paper is on the provision of transnational public goods for health—most especially surveillance, control and eradication of infectious diseases, control of the spread of resistance and knowledge.^e

a. There is some evidence that antiretroviral therapy may reduce viral loads and, hence, the probability of sexual transmission (Ahrin-Tenkorang and Conceicao 2003). However antiretrovirals also keep HIV-positive persons alive for longer, possibly creating more opportunities for transmission. As well, the availability of therapy lowers the costs to an individual of getting infected, and so may promote risky behaviour.

b. See WHO and WTO (2001).

c. Economic efficiency requires that a product be available to every person willing to pay more than it costs to produce. This requires that marginal willingness to pay equal marginal cost; it does not require that every person actually pay marginal cost.

d. See WHO Commission on Macroeconomics and Health (2001, p. 88).

e. Working Group 2 of the Commission on Macroeconomics and Health (2002) also emphasizes standardized data collection, and Kremer (2004) notes the importance of randomized evaluations of health programmes.

its main report stresses the need to improve the health of the world's poorest people—a worthy goal, for sure, but not necessarily a global public good (WHO Commission on Macroeconomics and Health 2001) (see box 1.1).

In contrast to ordinary development assistance, the supply of global public goods yields benefits to both developing and industrialized countries (see box 1.2). If industrial countries gain enough from a public good, they might be willing to finance its supply—for their own benefit, even though doing so also aids developing countries. An example illustrated later in this paper is eradicating disease.

Disease eradication is a disease-specific programme. The alternative is to invest in basic public health infrastructure—a capability for controlling a range of diseases. Eradication often suits the countries supplying aid, but infrastructure is typically of greater benefit to aid recipients. As explained later, aid targeted to combating particular diseases can be—and arguably should be—constrained to reinforce basic public health services. This need not benefit only developing countries. A key public good is improved surveillance and control of emerging diseases. Such a capability is of great benefit to industrial countries, but it requires investment in basic infrastructure.

There are two views of the relationship between health and development, each correct but each very different. One view is that life expectancy improves with increases in per capita income (World Bank 1993). The other is that economic growth is helped by improvements in public health (WHO Commission on Macroeconomics and Health 2001).^a It is this last view that is especially relevant for the Task Force, since one of the criteria for priority-setting identified in the Secretariat's "Meeting Global Challenges" is net poverty reduction.

Two examples may suffice to emphasize the importance of improvements in health to development: Fogel (1990) estimates that improvements in nutrition and health account for as much as 30% of the growth in per capita income between 1790 and 1980 in Western Europe. Gallup and Sachs (1998) estimate that, if the burden imposed by malaria were lifted, income per head in the malaria-prone countries of Africa would rise by a third.

The decline in mortality over the past century—according to Fogel (1990, p. 44), "one of the greatest events of human history"—had several causes: improved nutrition, public health and personal hygiene; decontaminated food and water; improved housing; and technological advances. It is easy today to forget the progress that has been made. In France, at the end of the eighteenth century, "the bottom 10% of the labour force lacked the energy for regular work and the next 10% had enough energy for less than 3 hours of light work daily" (Fogel 1990, p. 22). It was not until the second quarter of the nineteenth century that per capita daily caloric consumption reached the levels prevailing in India today (Fogel 1990, p. 45).

The contrast between the rich and poor countries today is striking, but so is the contrast between the rich countries today and these same countries one to two centuries before. Of course poor countries today have an advantage over the rich countries of yesterday: the availability of technologies such as vaccines, antibiotics and drugs, not to mention knowledge of the causes of disease. But the ecological circumstances of poor countries today are very different, and as we shall see, the challenge is not just to bring the technologies developed for the rich countries to the aid of the poor. It is also to develop new technologies to address endemic tropical diseases.

a. See Bradley (2001) for a preliminary sketch of the relationships discussed here.

Disease control—always a global public good?

One might think that the control of an infectious disease must be a global public good. However the situation is actually more complicated.³

To begin, consider a situation in which an infectious disease is endemic everywhere. If the disease were highly infectious, almost every person could expect to be infected. Under these circumstances, a small increase in control by one country would have no effect anywhere else. That control would not be a global public good.

Now imagine that the disease existed in only one country, and that the persons in every other country were susceptible. If the country with the disease took steps to control it, there would be real benefits to the rest of the world, for control would reduce the risk that other countries would import the disease and spark an epidemic. No country could be

excluded from receiving this benefit. Nor would any country's consumption of this benefit reduce the consumption available to others. In this case, control would be a global public good. The obvious example would be control of a new disease, such as SARS.

Suppose now that control is achieved by means of a vaccine. Suppose, too, that rich countries vaccinate so thoroughly that the disease is eliminated in these countries but is endemic everywhere else. In this case, though prevalence of the disease would be near zero in the rich countries, a little extra control in one poor country would not be a global public good. The rich countries would not benefit because high levels of vaccination make them invulnerable to an epidemic triggered by imports. And the other poor countries would not benefit, because the disease is already endemic in these countries. An example might be measles.

As suggested by these examples, whether control of an infectious disease is a global public good depends on the circumstances. Most especially it depends on the vulnerability of countries to being harmed by imports.

An example of a programme supplying the regional public good of disease control is the Southern Cone Initiative—an agreement signed by Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay and Peru. The aim was to limit the cross-border spread of the vector transmitting Chagas disease—a regional disease involving a protozoan parasite, *Trypanosoma cruzi*, transmitted to humans by triatomine insects. After a long asymptomatic period, Chagas disease can cause organ failure, especially of the heart and digestive and nervous systems. According to Dias and others (2002, p. 605), the initiative was projected to cost \$190–\$350 million over 10 years (1991–2000). It has proved an economic success, with financial returns estimated at 30% for Brazil and more than 64% for Argentina.

Surveillance, notification and control

It is interesting that countries are not obligated under international law to control any disease. This presumably reflects two beliefs: first, that the countries with domestic cases have a strong unilateral incentive to control it, and second, that the countries with no domestic cases have strong incentives to protect against imports. Both presumptions are partially true. But only partially.

First, as suggested by the preceding discussion, in some situations control by one country confers real benefits on other countries. Put differently, if the costs of control were high enough, unilateralism could not be relied upon to supply enough control.

Second, control presumes identification of the disease, and identification requires surveillance. Just as countries have incentives to control too little, so they may have incentives to conduct too little surveillance. To take just one example, the BSE (mad cow) inquiry in the United Kingdom noted incentive problems in reporting surveillance of this disease.⁴

Of course, in some cases, the incentive to conduct surveillance may be strong. In August 1997 an outbreak of *E. coli* (*Escherichia coli* O157:H7) identified by the Colorado Department of Public Health and Environment was traced to a meat-processing plant in Nebraska. The company recalled 25 million pounds of ground beef—the largest meat recall ever. According to Elbasha and others (2000), the cost of the surveillance system to discover the outbreak would have been recovered if this discovery had prevented just 15 cases of infection. By comparison, a 1993 recall of just 25,000 pounds of ground beef was estimated to have prevented 800 cases of *E. coli*. While the benefits of surveillance may exceed the costs for some countries, the global benefits will be larger still, and in some cases the costs of surveillance will lie between the domestic and global benefits.

Third, protection against imports is costly. It essentially involves raising trade barriers. If control abroad were weak, trade barriers might be the best response but their use would still be costly. Except when the threat of importing a disease looms large, countries can gain by lowering trade barriers and avoiding the terms of trade externality of protection. But how accurately can a country assess the risk of disease imports? If it were notified immediately of all outbreaks, it could erect trade barriers only as needed. But the trade restrictions would be directed at the country suffering the outbreak, so the incentive for this country to notify is dulled. Making matters worse, countries at risk may have an incentive to overreact to the threat of imports, taking the opportunity to improve their terms of trade. This tendency to overreact only shrinks the incentive others have to notify.

Countries are obligated to notify the WHO of outbreaks under the International Health Regulations (IHR), the only legally binding international agreement on infectious diseases. The IHR also prescribe the maximum measures that can be taken to limit imports. But the IHR are inadequate for several reasons. They apply only to three diseases—cholera,

plague and yellow fever. (China was under no legal obligation to notify the WHO of the SARS outbreak.) Compliance with the IHR is poor—partly because of the incentive problems already noted. And they do not address the related incentive problems of underinvestment in surveillance and the ability to control a new outbreak. These require a basic infrastructure.

Surveillance is needed for new diseases such as SARS, emerging diseases and resistant strains. A surveillance system must do three things (Henderson 1993):

- Detect unusual cases—a task requiring both clinical and epidemiological expertise.
- Report its findings, through either formal or informal channels, to an organization or system capable of seeing broader patterns or trends.
- Investigate these unusual cases.

Investigation often requires special expertise—a facility few countries, and certainly few developing countries, can call on. Currently, that role is often played by the Centers for Disease Control and Prevention (CDC). Believing that the WHO could not fulfil such a function itself, Henderson (1993) argues that the CDC should be acknowledged officially as having this function. Essentially, investigation is a best-shot public good—one that the United States presumably supplies because it is better off supplying it than not, given that others do not supply it.

As Henderson (1993) explains, the institutional demands depend very much on the outbreak. A sudden increase in cases in a particular area is rather easily detected—such as an outbreak of Ebola virus. A more gradual increase in cases, dispersed over a wide area, is harder to detect—an example being the emergence of HIV. The CDC is effective at investigating sudden increases in cases, but Henderson argues that a network of internationally supported health centers is needed—with particular attention to densely populated areas in the tropics. As expressed by Working Group 2 of the Commission on Macroeconomics and Health (WHO Commission on Macroeconomics and Health 2002, p. 53), “Weaknesses in developing countries constrain the world’s ability to detect and respond globally to the threat of infectious disease. This situation points to an interesting, and unresolved, feature of global public goods: the solution to their adequate provision and supply rests at local, national and sometimes regional levels.”

Countries may respond to an outbreak by raising trade barriers—a matter not handled well by the IHR but that should be handled

adequately by the Sanitary and Phytosanitary Measures Agreement under the World Trade Organization (WTO). The most effective approach is to contain and control the disease at its source—rapidly. Developed countries likely have the capability to do so at home. Developing countries often do not. And because the benefits would be diffused throughout the global system, such assistance may not arise spontaneously (Giesecke 2003, p. 203).

Surveillance is essential not only for new diseases but also for old diseases that have been eradicated. In both cases, even one case could amplify into a pandemic. As noted by Lederberg (2002, p. 11), “Given the biological variability of vaccine strains, and the innumerable array of samples in frozen storage, it is not a question of whether a disease outbreak will occur in the post-eradication era but, rather, when and where.”

Because of the problems with the IHR already highlighted, the regulations have been revised. The revisions, which will enter into force in June 2007, contain six improvements:

- A focus not on specific diseases but on events “posing a serious and direct threat to the health of human populations”. Such a focus obviously imposes an obligation to report a new disease such as SARS.
- A requirement that states develop and maintain surveillance capacity and “report and respond effectively to public health risks and events potentially constituting public health emergencies of international concern” (Fidler 2004).
- A requirement that states notify the WHO of “events potentially constituting a public health emergency of international concern”.
- Provision for the WHO to take account of informal sources of information, and not just information provided by official sources.
- Authorization for the WHO to determine independently whether an event constitutes a public health emergency of international concern.
- Authorization for the WHO to take steps to prevent or reduce the international spread of disease by such means as travel recommendations.

Notice that most of these changes reflect actions already taken by the WHO in the wake of the SARS crisis.

Elimination and eradication

According to the Dahlem Workshop on the Eradication of Infectious Diseases, eradication means the permanent reduction to zero of the worldwide incidence of infection caused by a specific agent. Essentially, it means that a disease ceases to exist in the wild. But eradication is not the same as extinction. The smallpox virus, for example, has been eradicated from nature but still exists in laboratories. Eradication is also to be distinguished from elimination—the reduction to zero of the incidence of disease in a defined geographic area.

Elimination provides a local public good: herd immunity. If a large enough fraction of a population is vaccinated, the rest of the population becomes protected because high vaccination rates break the chain of infection. An import may infect an unprotected person, but it would not trigger an epidemic.

Elimination also provides a benefit to other countries where the disease is no longer endemic. It breaks the chain of transmission.

Eradication of an infectious disease is a pure global public good. Every country benefits from it. But any country can also prevent eradication from being achieved. Right now the global polio eradication initiative risks failure after investing over \$3 billion and involving some 20 million volunteers over 15 years. In the Kano state of Nigeria, Muslim leaders have claimed that the polio vaccine is tainted with the AIDS virus and sterility drugs—a global conspiracy against Islam. The Kano government declined to participate in a national immunization days programme in 2003, and the European Union then declined to pay for the national programme in Nigeria, believing the money would be wasted (Roberts 2004, p. 1,967). One consequence has been a leakage of the virus, with nine polio-free countries importing polio from Nigeria in 2003 (Brown 2004).

This underlines that eradication is a weakest link public good. It succeeds or fails depending on whether the disease is eliminated from its last holdout. The economics of eradication are interesting and important. If a disease is eradicated, not only is the number of infections reduced to zero but there is also no longer a need to vaccinate susceptible persons. That means every country can benefit from eradication: the rich countries that previously eliminated the disease and the endemic countries still suffering from infections.

This is sometimes misunderstood. For example, Working Group 2 of the Commission on Macroeconomics and Health claims that, “Although

Table 1.2 Benefits and costs of smallpox eradication

(millions of US dollars)

	Amount
Annual benefit to India	722
Annual benefit to all developing countries	1,070
Annual benefit to the United States	150
Annual benefit to all industrial countries	350
Total annual benefit	1,420
Total international expenditure on eradication	98
Total national expenditure by endemic countries	200
Combined total expenditure on eradication	298
Benefit-cost ratio of international expenditure	483:1
Benefit-cost ratio of combined total expenditure	159:1

Note: The benefit-cost ratio is found by dividing the annual benefit by 0.03 (3% discount rate) and dividing that number by the one-time expenditure estimate.

Source: Fenner and others (1988), pp. 1364–66.

all countries benefit, the enormous financial gains that accrued to the United States in the case of smallpox eradication, for example, were not matched by similar gains in most developing countries. The greatest beneficiaries were likely to be the developed countries that needed eradication to consolidate the gains of their national immunization programmes” (WHO Commission on Macroeconomics and Health 2004, p. 52). According to estimates in Fenner and others (1988, pp. 1364–65), this view is wrong: India gained more from smallpox eradication than did the United States (see table 1.2). True, the United States saved more in avoided vaccination costs, but India saved more in avoided infections costs.

Estimates of the benefits and costs of smallpox eradication are shown in table 1.2. The benefits, as just noted, reflect avoided vaccination and infection costs. These are annual estimates. Assuming that the annual savings would be realized forever and discounting future benefits at 3%, the present value benefit of eradication would be about \$47.3 billion in 1967 US dollars.⁵ The costs in table 1.2 are the additional costs over routine vaccination necessary to achieve eradication. Taking this cost to be a one-time expenditure, the benefit-cost ratio is 159:1 if all costs are included (\$47,333/\$298) and 483:1 if international finance is counted (\$47,333/\$98). International finance is the money given by industrial countries to finance smallpox elimination programmes in developing countries. These numbers are plainly extraordinary.

Because eradication is essentially an investment (Barrett and Hoel 2004), its economics can be unusually attractive. But there still are

incentive problems. Eradication may yield every country a windfall, but the last country to eliminate the disease would get only a fraction of the global benefit, and under some circumstances it may not pay this last country to eliminate the disease, even though the entire world would be better off if it did (Barrett 2003). This is especially so when countries are highly asymmetric, and the last country is a poor developing country. In this case, eradication will have to be financed by the rich countries or private foundations.

This is precisely how the smallpox and polio campaigns have been financed. For smallpox, international financing essentially paid to increase the control programmes already in place in endemic countries to a level sufficient to eliminate the disease domestically (this is the cost of \$98 million in table 1.2). Some contributions were bilateral. Some were through a special fund, agreed to by a vote by the World Health Assembly. Some were voluntary. For polio the contributions are much greater. The total cost will exceed \$3 billion, whether the effort succeeds or fails (WHO 2003). One difference between the two initiatives is the injection of private foundation funding. Rotary International has contributed more than \$500 million, and the Bill & Melinda Gates Foundation and the United Nations Foundation have contributed more than \$25 million each (WHO 2003).

Since eradication is a global public good, financing has been difficult, as might be expected. The incentives to free-ride are strong. Elsewhere (Barrett 2004) it is shown that the United States had a strong incentive unilaterally to fund the entire smallpox effort, and yet financing proved difficult. As explained by Fenner and others (1988, p. 423), financing “constituted a serious, continuing problem”. One reason may be that each country preferred that others pay—and that enough effort was devoted to coordinating the burden-sharing problem. Another reason may be the lack of strong domestic political interests promoting financing. Though everyone would benefit from eradication, the benefit would be diffused (Barrett 2004).

The polio eradication initiative has learned from this, identifying the “fair shares” that countries should pay. And yet, financing has proved difficult (Aylward and others 2003, p. 48):

[Of the 22 WHO Member States who are members of the OECD’s Development Assistance Committee that makes up the community of ‘traditional’ ODA donors, only 16 have contributed to the eradication initiative. Of these, only seven contributed the equivalent or

more than their estimated 'share,' six are 'free-riders' in that they made no financial contribution to eradication, while the remaining nine contributed substantially less than their estimated 'share' of the total budget of \$2,750 million dollars between 1985 and 2005.

The polio eradication initiative is underfunded by \$130 million for 2004–05 (WHO 2003).

While the financing of polio eradication has been successful, the economics of polio eradication are not as attractive as the economics of smallpox eradication. Indeed, polio eradication may be technically infeasible in the sense that vaccination may need to continue even after wild polio viruses have been eliminated globally. The reason is that the live vaccine used to eliminate polio in developing countries—the oral polio vaccine, or OPV—is excreted into the environment by vaccinated persons and can revert to a pathologic state, causing the disease's re-emergence. Such outbreaks have already occurred several times. Partly because of this risk, industrial countries intend to continue vaccinating with the inactivated polio vaccine (IPV) indefinitely. But doing so compromises the economics of eradication.

Box 1.3 **Vertical versus horizontal programmes: do they conflict?**

While eradication can benefit every country, implementation of an eradication programme can also distract endemic countries that may have higher priorities. As noted by Aylward and others (2003, p. 47), "An often heated debate has flared between and within ODAs, academics, NGOs, and the United Nations itself as to whether the massive opportunity costs of eradication, particularly to conduct national immunization days, were simply too high to merit the production of this [global public good for health]."

The polio eradication initiative is a "vertical" disease-specific programme. It is distinguished from horizontal approaches that cut across diseases. Eradication may be best achieved by national immunization days, but basic health is better provided by the primary health care system.

In general, vertical approaches both weaken and strengthen horizontal systems. The Taylor Commission, convened by the Pan American Health Organization in 1995, concluded that polio eradication had "contributed positively to overall strengthening of health systems in the Americas" (Loevinsohn and others 2002, p. 19). Two follow-up studies drew mixed conclusions. One found that the "health system effects of polio eradication had been mostly positive but that there were "threats" that had to be recognized explicitly and dealt with pre-emptively" (Loevinsohn and others 2002, p. 20). The other concluded that "polio eradication had not had a very significant impact, either positive or negative, on health systems" (Loevinsohn and others 2002, p. 20).

This evidence warns that pursuit of a global public good may undermine development. But the choice is not between one and the other. The challenge, rather, is to design vertical programmes in a way that supports horizontal health systems.

The current plan adopted by the WHO is to stop vaccination with OPV after global elimination has been certified. But such a policy runs the risk of reintroducing the disease. If OPV is then used to extinguish an outbreak, the problem will be compounded because opportunities for reintroduction of the disease will increase. If IPV is used, interventions will be costly—not only because the vaccine is more expensive to administer but also because it is less effective in suppressing outbreaks. For all these reasons, stopping OPV will prove risky. By contrast, continued vaccination of OPV may not be sustainable: once the disease is eliminated, there will be an incentive to divert resources to the control of other diseases.

Plainly, the polio eradication initiative must proceed carefully, and the current plan for ceasing vaccination may need to be reconsidered. A more important point to emphasize is that the World Health Assembly needs to be much more careful before embracing future eradication efforts. The feasibility of eradication needs to be demonstrated. Plans for the post-certification period need to be developed. And an agreement should be reached for financing such an effort even before the first dollar is spent. Since eradication succeeds or fails depending on whether the last case of infection can be isolated and future vaccination avoided, any eradication policy must project into the distant future before taking even a first step towards realizing such an ambition.

Limiting resistance

Many public health interventions develop resistance with (inappropriate) use, and so become less and less effective. Examples include resistance to antibiotics such as penicillin, antimalarials such as chloroquine, treatments for tuberculosis, and antiretrovirals for HIV; resistance by the malaria vector to DDT; and resistance by the hepatitis B virus and the pertussis (whooping cough) bacterium to vaccine. Interventions impose “selective pressure” on target organisms, causing them to adapt or die. The organisms that survive can pass on their genetic advantage, and so render the interventions less effective.

Resistance is a growing problem today for several reasons. The scale of interventions has increased, thus increasing selective pressure. The discovery of new interventions has slowed. And little action has been taken to stop resistance. In rich countries, resistance develops from over-

use of antibiotics. In poor countries, it develops from underuse of antibiotics, antimalarials and other medicines.

Because resistance creates an externality, we should expect too little to be done to slow or stop resistance by countries acting independently. But the incentive problem is more interesting than this. As noted in a recent WHO document (2002) on resistance to antimicrobials, resistance is a global problem, and a special one at that:

No single nation, however effective it is at containing resistance within its borders, can protect itself from the importation of resistant pathogens through travel and trade. Poor prescribing practices in *any* country now threaten to undermine the potency of vital antimicrobials *everywhere* [emphasis added].

In other words, resistance is unlike disease control. A country that vaccinates against measles is protected from imports. A country that prevents resistance is not protected from imports of resistant strains.

Resistance can be slowed. When a single drug is used—and used widely over a long period—the chances of resistance developing can be high. Consider malaria. The antimalaria drug chloroquine, inexpensive and once highly effective against the *Plasmodium falciparum* parasite, began losing its potency in the 1960s. A substitute drug, derived from artemisinin, a traditional Chinese herbal medicine, is more expensive—and so is rarely used in Africa, where most malaria deaths occur. To slow or even stop resistance, a combination of artemisinin-based drugs must be used: a combination dramatically reduces the chance of a mutation conferring resistance. However, for the reasons mentioned previously, this intervention only works if it is applied universally. If just one country uses an artemisinin in monotherapy, resistant strains may develop and spread around the world, undermining the efficacy of the combination drug. Monotherapies using artemisinin are being used in Asia, threatening the spread of resistance globally.

What is the net benefit of adopting artemisinin-based combination therapies (ACTs)? According to Arrow and others (2004, p. 81), “It is impossible to assign a dollar value to this international public good, but it must include both the ability to treat hundreds of millions of cases of malaria with these drugs (over the number of years of extra effective life produced), and potential moderation of future R&D costs for first-line antimalarials.” The cost of adopting ACTs is easier to

quantify. Arrow and others (2004, p. 101) estimate this cost to be about \$300–\$500 million a year.

Addressing this problem will likely require a centralized approach. The challenge is to make it one that both individuals and states will want to adhere to. To ensure compliance by individuals will require making the combined drug at least as inexpensive as the alternative, and doing that will require a subsidy. To ensure full international participation, the programme will need to be organized centrally, perhaps under the WHO or UNICEF (or both). Countries would need to pledge to rely on the combined drugs. If each country were assured that all others would use only the combination drug, the incentive for each to use only that drug would be increased.

It will nonetheless remain true that each country will receive only a fraction of the global benefit associated with fulfilling its pledge, and so it may be necessary to subsidize participation by some countries. Arrow and others (2004, p. 100) note that most “African countries are unlikely to be able to contribute large amounts directly to a global antimalarial subsidy”, so they recommend that international assistance be made available. (Details for how this might be administered, and how the incentive problems of international financing might be corrected, are not addressed in their report.)

As with the other global public goods for health, there are important connections between the global and local levels—not only in creating the incentives discussed above but also in complementing this approach with environmental controls, such as using bednets, spraying walls with insecticide, draining breeding areas and so on.

Another connection is with a related public good: the creation of knowledge. When resistance can only be slowed, new drugs must be developed to substitute for the old line once it becomes ineffective.

Knowledge

One reason for the improvement in global health over the past century has been the availability of technologies such as antibiotics and vaccines, derived from knowledge about the underlying biology of infection. Other kinds of knowledge have also helped, including knowledge of the Guinea worm life cycle, which makes eradication feasible using only cloth water filters.

Knowledge has public good characteristics (Stiglitz 1999). One person's use of knowledge does not deprive others of the knowledge, nor can others always be excluded from certain kinds of knowledge—such as the knowledge of how and why to use water filters. Patented knowledge, of course, is exclusive by design, but patents are essential. If knowledge could not be patented, firms would have little incentive to invest in research and development. Though the pricing of antiretrovirals has been criticized—with some justification, as noted earlier—were it not for the patent system, these drugs would not be available in the first place. Weakening patent laws favours the current generation but harms the future.

Many vaccines were developed only to help particular countries or markets but have been widely used elsewhere. Developing countries have benefited hugely from the technologies developed by and for industrial countries. But this observation exposes another truth: that little research has gone into developing technologies to protect people against diseases endemic to the poor countries only—such as malaria, Chagas disease, African sleeping sickness and schistosomiasis. To prove the point, one of the great successes in public health in developing countries has been the elimination of river blindness (onchocerciasis) from many parts of Africa—a feat made possible using a drug (ivermectin, donated by Merck) developed for the veterinary market in developed countries.

One reason for the lack of innovation in tropical medicine is that patent protection in developing countries has typically been weak. Another is that patent protection would likely need to apply to a lot of developing countries to create strong incentives to innovate. Allied to this is the need for basic research into the underlying science—the kind of role performed by the National Institutes of Health in the United States. Here again, an international approach to tropical medicine research is likely to be needed.

A different approach is to make innovation an arm of development assistance. Michael Kremer's "Global Public Goods in Communicable Disease Control" in this volume has proposed using advance purchase commitments to supply the pull incentive for innovation. The basic idea is that if countries were committed to purchasing new vaccines at a price high enough to reward successful innovation, the pharmaceutical industry would innovate, the vaccines would be distributed and health in developing countries would improve. This approach may hold some promise but it also suffers deficiencies. One is that it is difficult for governments to make commitments (Schelling 1960). Another is that

the financing of the advanced purchase would itself be a public good and so would be vulnerable to free-riding. Numerous other proposals have been made, including modified “orphan drug” legislation and private-public partnerships (WHO Commission on Macroeconomics and Health 2002, p. 38). They suffer similar incentive problems.

Conclusions

This paper has identified several priority areas for action:

- A systematic review is needed of the gap in the global infrastructure for surveillance, especially of outbreaks of new diseases, and how this gap should be filled and financed.
- The IHR revisions are to be welcomed. The trade restrictions objective is now covered by the Sanitary and Phytosanitary Measures Agreement under the WTO, but this agreement applies only to the 147 WTO members. This leaves out about 50 countries. Because infectious disease control must be comprehensive, the IHR revisions will improve protection for all countries, even for the trade dimension.
- The revised IHR also affirm the international legal obligation of countries to notify the WHO of outbreaks or suspected outbreaks of any disease (even though modern communications allow outbreaks to be reported through informal channels). They also empower the WHO to issue global warnings directly, as the organization did in the wake of the SARS outbreak.
- A systematic review is also needed of the gap in resources available for responding to new outbreaks. It is much more efficient to control a disease at the source than to erect trade barriers globally to prevent its spread. The offer of such assistance would also increase the incentive for countries to report and for other countries not to overreact in their trade policies. Rules would need to be devised for the rights and obligations of states in allowing entry into their country of an outbreak response team, and for the team’s rules of engagement.
- Full support should be given to the polio eradication initiative at this critical time, but this support needs to take account of the risks associated with the initiative. Full support should also be given to the Guinea worm eradication initiative, particularly interventions in the remaining war-torn endemic regions. But

before embarking on future eradication initiatives, a careful review is needed to establish criteria for selecting future candidates for eradication, to delineate the rights and obligations of participating states and to develop an effective financing mechanism. Eradication succeeds only if the last case can be isolated, so planning needs to extend to this last case—and beyond, given that certification, surveillance and possibly other interventions will be needed indefinitely.

- A review is needed of the design of vertical systems and of the balance of development assistance for the vertical and horizontal dimensions of health programmes (see box 1.3). International initiatives typically involve vertical programmes (disease-targeted programmes, for example). Public health in developing countries, however, is often better supplied by horizontal systems (basic public health infrastructure). Moreover, strong horizontal programmes aid surveillance and control in the event of new outbreaks, to the benefit of all countries.
- Resistance is already a problem, one that will get worse unless major changes are made in the use of drugs (and pesticides) worldwide. As with surveillance and eradication, a centralized approach is needed, particularly for the use of combination therapies. If just one country fails to cooperate in stopping resistance, all will be more vulnerable. In addition to establishing rules for slowing resistance, specific mechanisms will be needed for financing such efforts.
- A number of initiatives are under way to promote research and development for new vaccines and drugs needed by poor countries, especially in the tropics. A systematic review is needed of the effectiveness of these approaches in stimulating investment.
- Ways must be found to ensure the efficient distribution of essential drugs and vaccines, not just their efficient supply. The international pricing of pharmaceuticals is not a global public good issue, but it does have a bearing on the incentives for research and development investment and on the support given broadly to a liberalized trade regime.

Notes

1. Where resistance has a fitness cost, it may develop but would not survive—provided use of the drug were low enough.
2. Article 19 of the Constitution of the WHO authorizes the body to initiate treaty negotiations. However the WHO has exercised this authority only once—in 2000 when it launched political negotiations on the WHO Framework Convention on Tobacco Control. This agreement, adopted in 2003, will enter into force in February 2005. Control of smoking is not a global public good. Smoking impairs the health of smokers and of people who consume their smoke second-hand; smoking is addictive (smoking now makes it harder for an individual to stop smoking in the future); and smoking is also a social activity (people are more inclined to smoke—and find it harder to quit—when others around them are smoking). There are thus a number of reasons why public policy may be needed to discourage smoking. But if one state bans smoking, the welfare of other states is pretty much unaffected. What makes smoking policy an international issue is primarily trade, including smuggling and advertising. If one state controls smoking—say, by imposing a very high tax on cigarettes and by banning advertising—the effectiveness of these policies may be undermined by the policies of other countries (see Taylor, Bettcher and Peck 2003).
3. Herlihy (1997) offers a more complex hypothesis of a singular event: the Black Death of 1348–49, an epidemic that cut the population of Europe by as much as 70% or 80%. His thesis is that the shock of this event “elicited a social response that protected the European community from comparable disasters until the present” (Herlihy 1997, p. 17). Loss of labour created incentives for factor substitution—of land and capital for labour, and of new technologies for old. Chiefly because of the Black Death, Herlihy (1997, p. 49) argues, “the Middle Ages were a period of impressive technological achievement.” McNeill (1998) makes a more sweeping assessment of the role of disease in shaping development.
4. See www.bseinquiry.gov.uk/report/volume2/chapter4.htm.
5. Adjusting for inflation only, this is about \$268 billion in current dollars. (The consumer price index inflator of 5.67 is taken from <http://minneapolisfed.org/Research/data/us/calc/hist1800.cfm>.)

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Global Public Goods in Communicable Disease Control

2 Chapter

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The control of communicable diseases presents a significant challenge to the global community. This paper argues that many of the benefits of administering existing drugs and vaccines are realized primarily within national borders, but that many of the other tools for combating communicable diseases are global public goods. National governments and private producers do not reap the full social benefits of their investment in these tools, so there is a tendency to under-invest.

Communicable disease control is sometimes set forth as the archetypical example of a global public good. However, in reality, the extent to which benefits of disease control cross borders falls on a continuum. The benefits of providing drugs and vaccines typically accrue overwhelmingly to people inside the national borders of the country administering the treatment or vaccine. However if a disease is close to eradication—like polio is today—then a large fraction of the benefit of vaccination or treatment may accrue outside the country.

Turning to other tools for disease control, disease surveillance is important for monitoring and stemming the spread of communicable diseases. However individual countries have an incentive to free-ride off international efforts, and in some circumstances to underreport disease activity. Surveillance on diseases like SARS or the flu, for which active efforts could contain their spread and the provision of early information is essential, has a large global public good component.

Avoiding the spread of drug resistance is another global public good, because drug-resistant disease strains can cross borders and undermine global disease control efforts. International efforts to encourage appropriate drug use are necessary.

Disseminating knowledge about disease control is also a public good. It is costly for countries to develop public health strategies and inefficient for countries to duplicate work. The World Health Organization's (WHO's) essential medicines list and policy guidelines are therefore valuable global public goods.

National governments and private companies also tend to under-invest in research and development (R&D) for drugs and vaccines. No single country internalizes the full benefits of a malaria vaccine, for example. Furthermore, were a private company to invest in developing a vaccine, countries would have an incentive to try to obtain the vaccine at a price as close to manufacturing cost as possible. Programmes to encourage the global public good of R&D could take the form of “push” programmes that subsidize research inputs, such as providing a research grant, or “pull” programmes that reward research outputs, such as committing in advance to purchase a specified amount of a desired product at a specified price. Each approach has strengths and limitations, but pull programmes are relatively under-utilized. Donors should consider making legally binding commitments that if certain new products are developed, they would either fully or partially finance purchases. For example, they could commit to guarantee a price of \$20 per person for the first 250 million people immunized with a malaria vaccine meeting certain technical specifications.

A final global public good is research on the effectiveness of health programmes. Randomized prospective evaluations are particularly useful to policy-makers, because differences in outcome between treatment and comparison groups can be attributed to a particular intervention. Such knowledge is beneficial to policy-makers globally. The global community should consider creating a new institution, specifically charged with promoting and financing randomized evaluations. This organization would encourage, conduct and finance rigorous impact evaluations, and also disseminate both positive and negative results.

The control of communicable diseases presents a significant challenge to the global community. This paper argues that in many contexts, the benefits of administering existing drugs and vaccines are realized primarily within national borders, but that many other tools for combating communicable diseases have benefits predominantly across national borders. National governments and private producers do not reap the full social benefits of their investment in these tools, so there is a tendency to under-invest.

This paper begins with a brief overview of the institutional and financial context of disease control, laying out the architecture and roles of the major global health institutions and funding sources. It then presents several examples of global public goods in communicable disease control and discusses how policy-makers can most effectively promote these goods. Finally it highlights two forms of global public goods related to knowledge: R&D for new drugs and vaccines and knowledge about the effectiveness of health programmes. It discusses the incentive issues surrounding each of these goods and outlines reform scenarios.

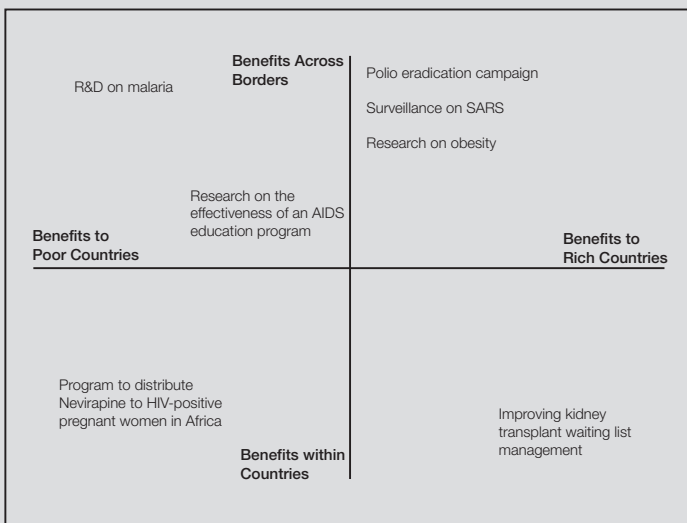
This paper focuses on global public goods. While it is important for analytical clarity to differentiate global public goods from other kinds of health interventions, it is also important to recognize that many programmes to control disease that are not global public goods may nonetheless be justified on other grounds. For example the benefits of providing nevirapine, a drug used to prevent mother-to-child transmission of the HIV virus, are primarily national in scope. However implementing such a programme in Sub-Saharan Africa would save many lives. Even though the global public good element of such a programme is modest, it is amply justified on equity grounds.

Figure 2.1 illustrates how international disease control efforts can be evaluated according to two different criteria: first, whether the benefits of a particular programme or intervention flow mainly to those within national borders, and, second, whether the benefits of a particular disease control effort primarily accrue to rich countries or poor countries.

Institutions

A myriad of multilateral, regional and national institutions work on issues related to communicable diseases. The lead international public health agency is the WHO. The WHO is the United Nations special-

Figure 2.1 **Benefits of international disease control efforts**



ized agency for health and is governed by 192 member states through the World Health Assembly. The WHO enjoys a broad mandate with six core functions: articulating health policy and advocacy positions; managing information and promoting R&D; providing technical and policy support nationally and internationally; negotiating and sustaining national and global health partnerships; setting norms and following up on their implementation; and stimulating the development and testing of new technologies, tools and guidelines for disease control, service delivery, healthcare management and risk reduction.

In recent years the WHO has emphasized improving the effectiveness of its country programmes. It has highlighted the link between health and poverty reduction and taken a greater role in establishing national and international consensus on health policy, strategy and standards. It has also negotiated partnerships to improve health access and outcomes (WHO 2001). In the context of communicable diseases, the WHO has prioritized combating malaria, tuberculosis and HIV/AIDS, all of which pose a serious threat to health and development, have a disproportionate impact on the lives of poor people and are in need of resource mobilization and new and cost-effective technologies. It has also prioritized providing support in the development of effective and sustainable health systems.

Recent WHO initiatives on communicable diseases include the “3 by 5” campaign, in collaboration with the Joint United Nations Programme on HIV/AIDS (UNAIDS). This plan calls for the provision of antiretroviral (ARV) treatment to three million people living with AIDS in developing and transitional countries by the end of 2005. It is unclear whether this target is realistic. The WHO has also highlighted the linkages between HIV and tuberculosis. In January 2004 it launched “Interim Policy on Collaborative TB/HIV Activities” guidelines, a plan to expand the collaboration between national tuberculosis and HIV/AIDS programmes. The guidelines call for the rapid expansion of voluntary HIV testing and counselling in TB programmes, with the aim of identifying and referring more than 500,000 TB patients who are HIV positive for ARV treatment in the next two years.

Other international agencies also play major roles in combating communicable diseases, though none with the broad mandate of the WHO. For example, the United Nations Children’s Fund (UNICEF) does significant work on child immunization, supplying about 40% of the world’s vaccines for children. In 2002 it procured over 2 billion doses of vaccine for nearly 100 developing countries. The World Bank

commits about \$1.3 billion each year in new lending for health, nutrition and population projects in the developing world and has been one of the largest financial supporters of HIV/AIDS programmes in developing countries. UNAIDS is the joint United Nations programme on HIV/AIDS, co-sponsored by UNICEF and the World Bank, as well as by WFP, UNDP, UNFPA, UNODC, ILO, UNESCO and the WHO.¹ It is an advocate for global action on HIV/AIDS, providing leadership and advocacy, as well as resource mobilization and partnership building, strategic information and tracking, monitoring and evaluation of the epidemic and responses to it. Regional development banks, like the Inter-American Development Bank and African Development Bank, also fund health-related programmes to combat communicable diseases.

The Global Fund to Fight AIDS, Tuberculosis and Malaria provides grants to strengthen local public health infrastructure and scale up efforts to prevent and treat these diseases. It does not implement programmes directly, but rather acts as a financial instrument. Since 2001, the Global Fund has attracted \$4.7 billion in financing through 2008. In its first two rounds of grant-making, it has committed \$1.5 billion in funding to support 154 programmes in 93 countries.

The Global Alliance for Vaccines and Immunization focuses on increasing children's access to vaccines in poor countries. Its Vaccine Fund provides countries with resources to strengthen routine immunization services and pay for vaccines and safe injection materials. The fund also provides a small one-time investment to help support introduction activities.

Finally, organizations that focus on medical research, such as the US National Institutes of Health (NIH), also play an important role in the fight against communicable diseases, as do national health systems, regional institutions and humanitarian and philanthropic agencies. A number of programmes currently subsidize research on diseases of the poor, including the International AIDS Vaccine Initiative (IAVI), the Medicines for Malaria Venture and the Malaria Vaccine Initiative.

Administering drugs and vaccines

Communicable disease control is sometimes set forth as the archetypical example of a global public good. However, in reality, disease control falls on a continuum. In some circumstances disease control activities in

one country have a large benefit for people in other countries, while in other circumstances the spillover is relatively small.

The prevalence of a disease is a major determinant of the level of global spillover from administering drugs and vaccines. Standard epidemiological models imply that if the net reproductive rate of a disease (the number of secondary infections caused by a single primary infection) within a country is less than one, then cross-border disease transmission will only lead to a limited number of cases before the chain of infection dies out. If it is substantially greater than one, then the long-run spread of the disease within the country will be almost the same regardless of how many cases cross the border each year. Thus in normal circumstances, the prevalence of a disease within a country depends primarily on conditions within that country. Cross-border externalities from drugs or vaccines will only be quantitatively large if it is possible to completely eliminate these cross-border seed infections, or if the reproductive rate is extremely close to one. Such a situation is rare. However, if a disease is close to eradication, like polio is today, then it may be possible to completely eliminate the seed infections flowing across borders. Thus, while the benefits of most forms of communicable disease control, like AIDS treatment or flu vaccinations, are likely to accrue overwhelmingly to people inside the national borders of the country administering the treatment or vaccine, polio eradication is a true global public good.

Rich countries, which must vaccinate their populations against polio, would benefit greatly from global eradication. However, given polio's low prevalence and the many other pressing public health concerns that poor countries face, polio eradication may not be a high priority for individual developing countries. Governments may also face high political costs for polio vaccination campaigns; for example, northern Nigeria has been beset by rumours that the vaccine spreads HIV and leaves girls infertile. Given the spillover effects of polio eradication and its costs to developing countries, it is appropriate for high-income countries to pay for these campaigns in developing countries. The trust fund recently established by the Bill & Melinda Gates Foundation, Rotary International and the United Nations Foundation to buy down IDA loans for polio eradication may be a good example to follow.

Other tools to combat communicable diseases

The previous section showed that the benefits of administering existing drugs and vaccines are usually national in scope. However many of the other tools to combat the spread of communicable diseases have a large global public good component. This section highlights some of these global public goods.

Surveillance as a global public good

Disease surveillance is important for stemming the spread of some communicable diseases. If an outbreak is caught early in some circumstances, it may be possible to isolate and contain the disease before it spreads globally, assuming the disease's net reproductive ratio is not too much greater than one. Surveillance can also be valuable for national disease control efforts by providing advance notice to governments to prepare for an outbreak (for example, by obtaining appropriate flu vaccines). Thus, while national disease control efforts, like the provision of drugs or vaccines, usually do not have large global spillover, the information gained from surveillance can provide benefits that are global in scope. However individual countries have an incentive to free-ride off the surveillance efforts of their neighbours and the international community, without contributing a globally efficient share of the effort. Furthermore national governments may be reluctant to share information about disease activity due to domestic concerns about adverse publicity and the implications for economic activity. Monitoring problems in China during the 2004 SARS epidemic highlighted how national incentives may not align with global public interest.

Surveillance is perhaps most important for identifying new diseases and unusual outbreaks. For example, the US flu vaccine for 2004 did not protect as well as possible against a new strain that became predominant in the United States (CDC 2004). Better surveillance might have allowed the Centers for Disease Control and Prevention to respond to this new strain earlier and more effectively.

While the adoption of the new IHR signals the international community's desire for stronger surveillance, it does not guarantee compliance. Countries still have an incentive to free-ride on this new agreement. Since much of the benefits of surveillance for small countries flow beyond their borders, they may require additional subsidies to put this in place.

Avoiding the spread of drug resistance

Misuse of pharmaceuticals can facilitate the development of drug-resistant disease strains, creating negative externalities for the rest of the world. Once evolved, a drug-resistant strain can cross borders and infect individuals in other countries. More broadly global disease control is threatened by ineffective treatments that leave patients contagious.

Drug overuse and misuse speed the development of drug-resistant disease strains, because the most resistant parasites may not be eliminated during treatment. These parasites can then be transmitted to others. Fighting drug resistance requires appropriate monitoring of patients, patient support to ensure adherence to treatment and timely introduction of alternative drugs and treatment regimens when resistance begins to emerge. However budgetary pressures can make it difficult for governments, particularly in developing countries, to implement such policies. Healthcare systems in developing countries are typically weak, and qualified medical personnel scarce. For example, while the United States has 2.7 trained physicians per thousand people and Europe has 3.9, Sub-Saharan Africa has only 0.1 (World Bank 2001).

In some situations healthcare providers may face a trade-off between increasing access to drugs and discouraging the emergence of drug-resistant strains. To the extent that drugs will be used anyway, however, international efforts to encourage appropriate drug use will slow the development of resistance, creating a global public good. Donors may therefore wish to fund programmes that encourage the proper use of drugs, budgeting sufficient resources for not just outreach and pharmaceutical costs, but also for support personnel and patient follow-up. It is critical to evaluate such programmes rigorously to make sure they are effective.

Dissemination of knowledge

The setting of global norms for disease control, and the development of health policy recommendations, is another example of a global public good. It is costly for countries to develop public health strategies and inefficient for countries with similar health needs to duplicate work. The WHO's essential medicines list, and its policy guidelines, such as the advocacy of school-based deworming in at-risk areas, are therefore valuable public goods.

It has been argued (see, for example, Jameson and others 1998) that the WHO may be best suited to promoting truly global public goods in health, while organizations like the World Bank and UNICEF have a comparative advantage in providing support for goods that are primarily national. For example, the WHO might take the lead on promoting research and development, facilitating information sharing across countries, harmonizing norms and standards and building consensus on health policy. The World Bank might support national health programmes and capacity building in countries that lack resources and require international collective action to successfully deliver services to their citizens. It certainly makes sense for the WHO to take the lead in facilitating information sharing and building consensus on health policy. However, given the WHO's much smaller budget, there may also be a role for the World Bank in the provision of some expensive global public goods, such as R&D on new drugs and vaccines. Donors could switch support to the WHO. However, given that donors have a smaller share of votes in WHO governance than IDA governance, it is unclear how much they will be willing to do so.²

Generation of knowledge

Knowledge creation is another example of a global public good to fight communicable diseases. Many countries would benefit from a vaccine for malaria or from evidence about the most effective AIDS-prevention programmes. As a result, the full social value of such goods is not internalized by private or national providers. The next two sections look at two forms of knowledge creation in more detail: R&D on vaccines and drugs and research on which health programmes and health delivery systems are most effective.

R&D for vaccines and drugs

R&D as a global public good

R&D for vaccines and drugs is a global public good. Once developed, many countries would benefit from a schistosomiasis or malaria vaccine, for example. Because no single country internalizes the full

benefits of such vaccines, however, there is no incentive to invest at the globally optimal level. Moreover, were a private company to invest in developing a vaccine, once the firm's R&D costs were sunk, no individual country would have incentive to pay an amount for the vaccine commensurate with the value of the vaccine to its citizens. Instead each country would have incentives to try to obtain the vaccine at a price as close to manufacturing cost as possible. In rich countries patents offer some protection to companies. But these returns to patents can only be realized by charging prices that far exceed manufacturing costs. As a result many poor countries have chosen to limit patent protection for pharmaceuticals. Thus there is a large gap between the returns that potential developers of needed vaccines or drugs could expect and the benefits the product, if developed, would provide for society. Indeed many vaccines and drugs sold in developing and middle-income countries sell for a fraction of their social value.

There is evidence of a gross under-investment in R&D for drugs in low- and middle-income countries. For example, of the 1,233 drugs licensed worldwide between 1975 and 1997, only 13 were for tropical diseases. Two of these were modifications of existing medicines, two were produced for the US military, and five came from veterinary research. Only four were developed by commercial pharmaceutical firms specifically for tropical diseases of humans.

Vaccines fare even worse than drug treatments. Companies may be more inclined to invest in drug treatments than in vaccines, even when the social benefit is greater for vaccines (see Kremer and Snyder 2003). This market distortion is particularly detrimental for developing countries, because much more medical infrastructure is required to deliver drug treatments. Creating incentives for vaccine research is therefore particularly pressing for developing countries.

Push vs. pull programmes

Programmes to encourage the provision of R&D could take two broad forms. "Push" programmes subsidize research inputs, for example, through grants to researchers or R&D tax credits. "Pull" programmes reward research outputs, for example, by committing in advance to purchase a specified amount of a desired product at a specified price. Under pull programmes, the public pays nothing unless a viable product is developed. Each approach has strengths and limitations, but given the

importance of R&D for vaccines and drugs, there is an important role for both approaches.

Push programmes are subject to asymmetric information, both between researchers and programme administrators and between these groups and the public. This asymmetry gives rise to moral hazard and adverse selection. Moral hazard arises because funders cannot perfectly monitor the actions of grant recipients. Thus researchers may have incentives to devote their efforts to other research or to the preparation of future grant applications, rather than focusing on the development of the desired product. In contrast, under a pull programme, money changes hands only when a useable product is delivered, so researchers' incentive is to focus on developing the desired product. Adverse selection in push programmes arises because researchers have more information than funders do about the probability that their research will lead to successful products. Research administrators may not be able to determine which research projects are worth pursuing, nor which diseases and products should be targeted. Decision-makers may therefore end up financing ideas that only have a slight chance of success, or worse, they may fail to fund promising research because they do not have confidence that its backers are presenting objective information on its prospects. In contrast, under a pull programme where developers are rewarded only if they successfully produce the desired product, there is a strong incentive for firms considering research investments to be realistic in assessing their prospects for success.

Under pull programmes, money changes hands once a viable product is developed. For example, a sponsor could commit to guarantee a price of \$20 each for the first 200 million people immunized with a malaria vaccine, subject to a \$2 co-pay from developing countries or other donors. These programmes have several advantages in encouraging the later stages of product development. They give researchers incentives to self-select projects with a reasonable chance of yielding a viable product and to focus on developing a marketable product. A key limitation, however, is that these pull programmes require sponsors to specify their output in advance. Thus pull programmes may not work well in encouraging basic research, because it is usually difficult to specify the desired results in advance, and because a key objective of basic research is to provide information to other researchers rather than to develop specific products. However it should be possible to define technical specifications for needed drugs and vaccines. Existing regulatory institutions are already charged with making safety and

efficacy determinations, and the information generated in these trials could be used in pull programmes. Another issue is that pull programmes could potentially lead to duplication of research activities. Of course it is often appropriate to pursue many different leads simultaneously in searching for solutions to important problems. However in cases where policy-makers believe that promising alternatives are being neglected under pull programmes, they could address the problem through push programmes.

Thus both push and pull programmes have important and complementary roles in encouraging R&D. More could be done on the side of “push” financing to encourage research. For example, the NIH and its counterparts in other high-income countries could agree to treat researchers from developing countries on the same basis as their own researchers in awarding grants. However, as mentioned in Section II, a number of push programmes to encourage such research do already exist. In contrast, pull incentives are relatively under-utilized. How, then, might a viable pull programme be designed?

Designing a pull programme

The most attractive way to design a pull programme is through an explicit, legally binding commitment to fully or partially finance product purchases if the product is developed. The credibility and design of this purchase commitment will be a critical determinant of its effectiveness. Potential developers of a vaccine or drug must believe that once they have sunk funds into developing the desired product, the sponsors will not renege on their commitments by paying a price that covers only the cost of manufacturing, and not research. Courts have held that similar public commitments to reward contest winners or to purchase specified goods constitute legally binding contracts and that the decisions of independent parties appointed in advance to adjudicate such programmes are binding. The credibility of a purchase commitment can be enhanced by clearly specifying eligibility and pricing rules and insulating decision-makers from political pressure through long terms of service, and perhaps by including former industry officials on the adjudication committee.

Product eligibility conditions would probably include some minimal technical requirements, such as clearance by a regulatory agency like the US Food and Drug Administration (FDA). Products that pass these requirements could then be subject to a market test; nations wishing to

purchase products (or donors acting on their behalf) might be required to provide a modest co-payment tied to their per capita income.

Kremer and Glennerster (2004) discuss the design of a purchase commitment. Using figures on pharmaceutical sales revenue and marketing, they note that sales with a net present value of \$3.12 billion would provide a market comparable to that associated with commercial products. For a malaria vaccine, a price of \$20 for the first 200 million doses would give a total net present value in this range. A commitment at this level to purchase vaccines for malaria would be extremely cost effective, costing nothing if a useable product was not developed and less than \$20 per disability-adjusted life year (DALY) saved if a vaccine were developed.

Reform scenarios

A number of organizations—including the World Bank, national governments and private foundations like the Bill & Melinda Gates Foundation—have the resources to create credible vaccine and drug purchase commitments.

A private foundation would be well suited to sponsoring a purchase commitment. Foundations' continuity of leadership and relative freedom from interest groups would make them good candidates for making credible purchase commitments. However only a few foundations would have the resources needed to take on a commitment for a complex disease like HIV, malaria or tuberculosis on their own.

Multilateral organizations like the World Bank have the resources and expertise to promote a large-scale purchase commitment. However the commitment would need to be designed to meet the organization's institutional requirements. One option would be for the World Bank to commit to provide IDA loans to any member states that wanted to purchase a sponsored vaccine or drug, as long as a number of pre-specified conditions, like price and efficacy, were met. IDA loans at below-market rates carry an implicit subsidy of roughly 60%, and the World Bank could further subsidize the loans by off-setting part of the vaccine purchase price through grants. Other donors—either governments or foundations—could also make commitments to give recipient countries money to repay IDA loans, depositing promissory notes in a World Bank trust fund now.

Moving to concrete proposals

The Center for Global Development and the Bill & Melinda Gates Foundation sponsored a working group to examine ways to operationalize pull mechanisms and develop model pull contracts.³ The group's report (2005), "Making Markets for Vaccines", explains why Advanced Purchase Commitments (APC) are effective tools for stimulating R&D on vaccines for neglected diseases. It also shows that APC can be pursued within the existing budgetary and legal framework, making them a viable option for policy-makers. Efforts now need to focus on developing concrete proposals for APC and on securing adequate sponsor participation.

The G-8 has already begun the process. At its recent June 2005 summit, the G-8 finance ministers asked Italy to confer with all relevant parties in the public and private sector and to develop concrete proposals for APC programmes by the end of 2005.

Knowledge about health programme effectiveness

The need for randomized prospective evaluations

Just as R&D is an essential tool for combating communicable diseases, it is also necessary to understand which kinds of health interventions are most effective. Research conducted to optimize healthcare delivery systems in one country can often be useful to others, particularly when the countries are from the same region and share similar cultures and levels of development.

While many development projects typically include an evaluation component, these often consist simply of audits, interviews with stakeholders or before-and-after comparisons. However audits do not measure effectiveness and stakeholder satisfaction is no guarantee of effectiveness. Before-and-after comparisons can also be problematic because changes external to the project can influence the project's measured impact. For example, it would be difficult to measure the impact of a school-based AIDS education project on students' knowledge if the government had simultaneously introduced a new radio campaign providing information about AIDS. Comparing programme participants with non-participants is also problematic. The correlation

of inputs and outcomes may be misleading if the measured inputs are correlated with other unmeasured variables that also affect outcomes. For example, families that participate in a programme that distributes deworming medicine might be more concerned about health issues and better aware of the effects of intestinal worms than families that do not participate in the programme. If these unobserved factors also improve health and reduce worm infection rates, then a researcher might overestimate the effects of the programme. On the other hand, families that participate in the programme might tend to be in worse health than families that do not participate. In this case, the programme's impact on health might be underestimated.

One way to address these concerns is to conduct randomized prospective evaluations. In these evaluations, before the project is implemented, all suitable participants are randomly assigned to treatment and comparison groups. With random assignment and sufficient sample sizes, the two groups should be comparable in all aspects other than the effect of the project. Thus differences in outcome can be attributed to the project itself. Studies that have compared estimates from randomized prospective evaluations with the effects estimated in a non-experimental framework suggest that omitted-variable bias is often a significant problem in the latter (see, for example, Glazerman and others 2002).

Randomized prospective evaluations of drug effectiveness revolutionized the field of medicine, and they could have a similar impact in policy analysis. Randomized evaluations are often feasible for health programmes. Indeed, when resources are limited due to budget or personnel constraints, it may be necessary to phase in project implementation rather than rolling out the project in all areas simultaneously. In such cases randomization may be the fairest way to determine the order of phase-in. With prospective randomized evaluations, the effects of the programme can be measured directly, and the results will be transparent to policy-makers.

Examples: PROGRESA and PSDP

The PROGRESA programme in Mexico and the Primary School Deworming Project (PSDP) in Kenya are two examples of programmes that were evaluated using a randomized prospective design. PROGRESA provides cash grants to women that are conditional on children's school attendance and preventative health measures (nutritional supplementation, healthcare visits and participation in health education

programmes). When the programme was launched in 1998, government officials chose to take advantage of the fact that budgetary constraints made it impossible to reach the 50,000 potential participant communities immediately. Instead they began with 506 communities, half of which were randomly assigned to receive the programme. Researchers collected data from both treatment and comparison communities. The subsequent evaluation showed that PROGRESA was effective in improving health and education outcomes; for example, children had on average a 23% reduction in the incidence of illness (see Gertler and Boyce 2001). In part because the randomized phase-in of PROGRESA allowed such a clear documentation of its positive effects, the programme has been maintained and expanded to other parts of Mexico and Latin America.

The Primary School Deworming Project in Kenya provided twice-yearly, school-based mass deworming treatment for whipworm, roundworm and schistosomiasis. Miguel and Kremer (2003) found that the treatment was an extremely cost-effective way of improving children's health and education outcomes and generated significant externalities in reducing infection rates in the surrounding community. They estimate that the programme cost is only \$5 per DALY and \$3.50 per additional year of school participation, making it one of the most cost-effective interventions of its kind. The introduction of a small fee led to a sharp 80% reduction in treatment rates relative to free treatment, highlighting the need for deworming medicine to be subsidized (Miguel and Kremer 2004). The Primary School Deworming Project evaluation results suggest that donors should prioritize the subsidization of deworming medicine internationally.

Potential applications

Randomized trials of health policy interventions could be taken in a number of areas. One area in which experimentation and evaluation would be particularly helpful is in developing strategies to reduce health worker absenteeism. Chaudhury and others (2003) observed absenteeism rates of over 40% in health clinics in several developing countries, highlighting the urgency of this issue for communicable disease control. To take another example, there are few randomized evaluations examining the effects of improved water supply on health outcomes. A randomized prospective evaluation would help policy-makers determine what priority to give water and sanitation projects in controlling

diseases, as opposed to alternative approaches, such as immunization against rotavirus. Randomized trials could be used to test a variety of approaches to the fight against HIV/AIDS, ranging from testing HIV/AIDS education curricula in schools to examining the effect of voluntary counselling and testing on behaviour, to the effect of provision of bednets as an incentive for antenatal visits by pregnant women on take-up of nevirapine.

Reform scenarios

Under current institutions, development agencies and national governments do not have sufficient incentives to conduct randomized evaluations. The global community should consider either creating new structures within existing organizations or creating a new institution specifically charged with promoting and financing randomized evaluations. This structure or institution would encourage, conduct and finance rigorous impact evaluations, and also disseminate both positive and negative results. Successful programmes could then be taken to scale by donors. An independent committee would evaluate results from the trials. Creating a new agency would allow independence from existing agendas. A ready-made supply of potential evaluators already exists within existing international agencies, as well as within academia, and collaborations with non-governmental organizations (NGOs) offer many opportunities for evaluating policies of wide relevance. One reason for the current dearth of randomized evaluations is that no one considers conducting such evaluations to be their job. Evaluations also have common features and would benefit from a specialized agency with specific expertise. The agency could also serve as a more general resource centre by developing and diffusing training modules, tools and guidelines for randomized evaluations.

Finally, this institution could work to disseminate reputable evaluation findings through policy briefs and in an accessible searchable database space. An evaluations unit could conduct systematic searches for all impact evaluations and assess their reliability; the organization would report on both successful and unsuccessful interventions. The database could promote a virtuous circle, with donors demanding credible evaluations before funding or continuing projects, more evaluations being conducted and the general quality of evaluation work—and projects—rising.

Conclusion

This paper argued that while provision of drugs and even vaccines against communicable disease typically creates benefits that flow primarily to residents of the country where provision takes place, many other tools for combating communicable diseases are global public goods. National governments and private firms have a tendency to under-invest in these goods because they do not reap their full social benefits.

This paper looked at the circumstances under which provision of drugs and vaccines has strong global spillovers and highlighted polio eradication as such a case. It discussed several of the tools for communicable disease control, including surveillance, avoiding the spread of drug resistance and disseminating knowledge about disease control. It then focused on two global public goods related to knowledge: R&D on drugs and vaccines and research on the effectiveness of health programmes.

The WHO plays an important role in promoting global public goods for combating communicable diseases, particularly in setting global norms for disease control and in developing health policy recommendations. It is costly for developing countries to develop public health strategies, and the WHO's stature and global legitimacy puts it in a unique position to advise countries on disease-control efforts. However its limited budget and mandate makes it essential that national governments, private foundations and other multilaterals also play a role in promoting global public goods for communicable disease control. This paper makes the following recommendations:

- High-income countries should finance polio-eradication efforts in developing countries, due to its high global spillover. The trust fund recently established by the Bill & Melinda Gates Foundation, Rotary International and the United Nations Foundation to buy down IDA loans for polio eradication may be a good example to follow.
- From a global public goods perspective, disease surveillance is most important for diseases like SARS or the flu, for which active efforts could potentially contain their spread, and the provision of early information is essential. The WHO is best placed to organize and facilitate surveillance efforts.
- To discourage the emergence of drug-resistant disease strains, donors should consider funding programmes that encourage proper use of drugs, budgeting sufficient resources for not just outreach and pharmaceutical costs, but also for support per-

sonnel and patient follow-up. Evaluation is critical to ensure these programmes are effective.

- To encourage the global public good of R&D for vaccines and drugs, donors should finance purchase commitment programmes. These programmes would serve as a “pull” incentive; the public pays nothing unless a viable product is developed, and researchers are given an incentive to self-select projects with a reasonable chance of yielding the desired product. Private foundations, multilateral organizations and national governments are all capable of sponsoring a purchase commitment programme. One option would be for the World Bank to legally bind itself to provide IDA loans to any member states that wanted to purchase a sponsored vaccine or drug, while other governments and foundations commit money to recipient countries to help repay these loans. Organizations like the G-8 are currently putting together concrete proposals involving APC. Stronger efforts need to be made to pursue these proposals and to line up adequate sponsor participation.
- The global community should consider creating a new institution, specifically charged with promoting and financing randomized evaluations. This organization would encourage, conduct and finance rigorous impact evaluations, and also disseminate both positive and negative results.

Notes

1. UNAIDS is co-sponsored by the Office of the United Nations High Commissioner for Refugees, United Nations Children’s Fund, World Food Programme, United Nations Development Programme, United Nations Population Fund, United Nations Office on Drugs and Crime, International Labour Organization, United Nations Educational, Scientific and Cultural Organization, World Health Organization and World Bank.
2. The WHO’s operating budget for communicable diseases was \$369 million in 2002–2003. In contrast, the World Bank approved \$3.4 billion in loans and grants for health and social services projects in 2003.
3. See www.cgdev.org for more information on the Pull Mechanisms Working Group.

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Ensuring Markets for New Drugs and Vaccines for Poor Countries: Institutional Requirements and Possibilities

3 Chapter

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The purpose of this paper is to consider the institutional and other arrangements required to implement an advanced market commitment (AMC) to induce more significant investments in the development of drugs and vaccines specifically designed for use in developing countries. It begins by reviewing a proposed AMC developed for this purpose. It then asks what functions need to be accomplished to implement it, what institutions would be able to fulfil these functions and what changes in their operating procedures might be necessary to do so.

The proposed AMC was developed by a working group of the Center for Global Development and published in April 2005 (Levine and others 2005) under the title Making Markets for Vaccines.¹ The concept was further elaborated in documents prepared for the G-8 Ministers of Finance (Tremonti 2005) titled “Advanced Market Commitments for Vaccines”. At their December 2005 meeting, the G-8 endorsed the idea and announced that they will work with others to develop a pilot AMC for a vaccine specifically designed for use in developing countries. That decision makes the topic of this paper especially timely.

This paper should be considered first thoughts on institutional arrangements for implementing this proposal. It is based on a review of relevant documents and discussions with a few key individuals. There was no opportunity to undertake serious brain-storming discussions with representatives of the various organizations that might be involved. The focus is on the development of drugs and vaccines in earlier stages of development (for example, vaccines for HIV/AIDS, tuberculosis and malaria and second- or third-generation drugs for treating these diseases). Although the specifics of an appropriate commitment differ depending on the disease, the form of product (a vaccine or a drug) and technical and market characteristics, the general principles focused on here remain the same.

The essence of the proposal is to provide developers with the same kind of market inducements they face when deciding to develop a new product primarily

for sale in industrial country markets and to do so in a way that minimizes costs to donors. This is to be accomplished by guaranteeing that a certain quantity of the product will be purchased at a relatively high price (equivalent to what they would receive in an industrial country market), after which the companies receiving the guarantee would be obligated to sell to eligible countries at a cost close to that of production, and by searching for a mechanism that allows donors to make convincing commitments without setting money aside in advance. If the latter is accomplished, donors would have no cost (except for a small administrative cost) in the event the product is not developed. If the desired product is developed, the cost is unlikely to be greater than what donors are likely to contribute to health problems of developing countries anyway. Indeed, in the long run it is likely to cost less because it would substantially improve the efficiency of whatever level of foreign assistance they provide. The section on organizational consideration discusses possible ways that the guarantee might be provided without putting money aside in advance.

An AMC may be a necessary condition to induce pharmaceutical companies to invest in developing desired products, but it is not sufficient. Other requirements include an adequate scientific base, effective demand in developing countries and the capacity to test, distribute and deliver the product to those who need it—none of which can be taken for granted. The appendix provides a stark example of a case where the bottleneck displays a lack of secure and effective demand (caused by lack of capacity, among other things, to introduce, gain acceptance, procure and distribute a new product), rather than the availability of an acceptable product or the funds to purchase it.

Several institutional arrangements are considered. The most likely would involve a division of labour between international institutions. The World Health Organization (WHO) is probably best placed to take on several anchor and core functions—convening and housing a unit that develops the terms of the AMC offer, modifying these terms as new information is acquired, deciding when the terms have been met and monitoring and evaluating the experience thereafter. The World Bank, the Global Fund to Fight AIDS, Tuberculosis and Malaria or (if considering a vaccine) the Vaccine Fund of the Global Alliance for Vaccines and Immunization (GAVI) could serve as the guarantor representing donors who would provide the underlying guarantee. Lead responsibility for planning and providing demand-side capacity building is probably best assigned to the World Bank, but it would need the assistance of other, more specialized, institutions already working in this field.

Agencies involved in providing the commitment would have to modify operating procedures to participate, but that would be a small price for the enormous benefit to the world if these products are developed.

To inspire biotech and pharmaceutical companies to invest in products designed to tackle the major diseases of developing countries and to do so in a way that minimizes the cost to donors, the working group settled on an approach that tries to reproduce the incentives that have induced such companies to invest in the diseases of the industrial world. To accomplish this, the proposal includes the following elements:

- *A description of the desired product in terms of output characteristics—for example, a minimum degree of efficacy, specification of permissible side-effects, number of required treatments per patient and storage characteristics—leaving it to developers to decide how best to achieve these goals.*
- *The prices and quantities that would be guaranteed.* A relatively high minimum price (adjusted for inflation) would be guaranteed for up to a maximum number of treatments sold to eligible countries. Thereafter the supplier would have to agree to sell subsequent doses to these countries for a substantially lower price, perhaps a modest mark-up over the cost of production. This arrangement is necessary to ensure there is a specific end to a donor's financial commitment, while assuring developing countries that they will have access at much lower prices. This two-tier price structure is roughly comparable to what drug companies face in the open market—a high price for sales in developed countries, allowing them to recoup investment outlays and receive reimbursement for the risks they have assumed, and a substantially lower price for sales in poor countries.
- *A legal document, here called a commitment letter, that commits the donor(s) to award a contract to one or more firms that develop and demonstrate the capacity to produce the desired product.* It would include other terms—for example, stating that the offer can be withdrawn after a certain number of years if no acceptable product is forthcoming and that the offer can be modified if conditions change, but only in the direction of lowering the performance bar or improving the financial terms. Firms that take up the challenge would have the opportunity to sign this letter along with the donor. Doing so would turn the commitment into a bilateral contract, making it easier to prove damages if the donor does not perform properly.
- *The contract between the donor(s) and the suppliers of the desired product.* This document would commit donors to guaranteeing that the suppliers receive a certain price for as many units as they can sell to eligible

countries up to a specified maximum and commit the suppliers to sell at a lower price once the quantity target has been met.

Particularly for early-stage drugs and vaccines, such as those for HIV/AIDS, tuberculosis and malaria, it will not be easy to come up with an acceptable set of technical and financial parameters. It is nearly certain that best guesses today will turn out to be far off the mark of what is feasible and desirable 5 years from now, let alone 10 or 15. There are three considerations here that can help. First, pharmaceutical companies and venture capitalists make judgements of this sort every time they decide on an investment. Designing an offer in a way that takes into account their way of thinking could help greatly. Second, some useful impressions can be obtained from studies of the costs and revenues associated with similar products. For example, the working group found studies suggesting the social value of vaccines typically far exceeds the cost of development and production, even in the case of vaccines that have been especially costly to develop; and the background papers for the report to the G-8 presented the results of simulations that demonstrate that an AMC would be cost effective compared to other interventions, even under unfavourable assumptions, such as the time to develop and size of market. Third, the initial offer should allow room for adjustments. The price and quantity targets should not be set so high that there is little room to raise them if necessary.²

To keep donor costs down, the commitment should be backed by promissory notes or a borrowing authority that can be exercised when needed, rather than up-front payments into an account. If such an arrangement can be worked out, donors would have no cost (except for the services of a monitoring and implementation unit) if an acceptable product is not developed. This is quite different from “push” mechanisms in which a donor helps finance research and development (R&D) expenditures with no guarantee that a useful product will emerge. Moreover, if an acceptable product is forthcoming, the cost to donors would not be greater—indeed, likely to be considerably less in the long run—than what donors would probably contribute in the same period without a guarantee.³ The challenge is to find a way that a potential donor can provide a convincing commitment without putting money up front.

Two other ways to keep donor costs down are built into the proposal. First, the guarantee is not that the donor will pay a specific price, but that the supplier will receive a specific price. In other words, the donor is responsible for the difference between the target price and

what the country, its citizens and other donors are willing to pay. It guarantees a floor under the price the supplier receives, but the donor may pay only a fraction of this amount.

Second, this proposal does not guarantee that a certain number of units will be purchased, only that the donor will pay for however many units are purchased by qualified countries up to a specified maximum. This specification was introduced to ensure that donors do not end up paying for quantities of a vaccine that are not used. This is a controversial specification that could adversely affect risk assessment by investing companies. While it is true that developers are accustomed to absorbing this risk in developed markets, they may be reluctant to do so in unfamiliar markets with uncertain demand.⁴ A simple solution, should it prove necessary, is to share the risk—for example, by guaranteeing the sale of the first third of the target quantity.

The contract guarantees the direct or indirect purchase of a vaccine. A direct purchase involves the donor procuring the product or contracting procurement out to an agent such as the United Nations Children's Fund (UNICEF). Under an indirect arrangement, the funds are provided to the eligible countries or to their donors, which they then use to purchase supplies through their usual procurement channels. This is least disruptive to the current system, allows for co-financing and might increase the probability that supplies procured this way would be used. This arrangement would work well in cases where there is no quantity guarantee. Where there is a quantity guarantee, and the guaranteed amount is not purchased by the country, the donor issuing the guarantee would have to step in and purchase the difference (or arrange for the purchase by others).

Other necessary conditions

An AMC may be a necessary condition to induce developers and producers to devote substantially more financial and human resources to these diseases, but it is not a sufficient condition. First, there must be an adequate scientific base on which pharmaceutical companies can build. If these companies feel that this base is inadequate, “push” funding programmes to fill in gaps in scientific understanding will be needed to complement their R&D work.⁵ Second, these companies must be convinced that effective demand will exist when the proposed product is ready for market. Governments, the medical community and consumers

may be reluctant or slow to adopt a new product, no matter how good it is, for many reasons. A programme should be in place to make sure these barriers are cleared away in a timely fashion. Third, a substantial programme of capacity building for testing, distribution, delivery and training is likely to be needed and will have to operate in parallel with the R&D effort to ensure that these capacities are available when needed. A comprehensive programme that includes these three elements along with market incentives for manufacturers has a much higher probability of success than a programme of market incentives alone.⁶

The appendix provides an example of how serious some of these problems can be. Producers of a relatively new but expensive drug are reluctant to expand production; although the WHO has recommended adoption, and the Global Fund has offered to finance its purchase because of uncertainties about when governments will adopt it and place orders. These uncertainties stem from governments' need to decide between different formulations (which may require building capacity to undertake large-scale field trials), to make difficult social policy decisions (for example, whether to adopt, since the Global Fund guarantees to fund for only two years, and national policy to adopt, given that subsidies are available only for the publicly distributed portion of demand) and to establish training and delivery programmes. The time lags and uncertainties inherent in these processes would have been substantially less had planning and capacity-building activities started sooner.

Organizational considerations

This discussion suggests that the following functions must be assigned to one or more agencies so as to implement a scheme of this sort:

- *Provision of the guarantee.* A donor, a group of donors or an organization empowered by them has to provide a credible long-term guarantee.
- *Specification of commitment terms.* The target product characteristics and purchase terms must be specified.
- *Monitoring and implementation.* A independent unit that monitors progress, proposes changes in the commitment terms if necessary and certifies if and when the product specifications have been met must remain in business as long as the AMC offer is outstanding.
- *Contract implementation.* The disbursement of funds under the terms of the contract must be monitored.

- *Dispute adjudication.* The commitment letter and subsequent contract must specify how disputes will be settled. An independent agency willing to take on this function is also needed.
- *Other functions, as needed.* These might include assistance with developing an adequate scientific base and demand-side capacity building (that is, assisting eligible countries to ensure they are willing and able to introduce the new product in a timely fashion). In addition, some agency is needed to perform anchor functions—to take the lead in promoting, monitoring, overseeing and troubleshooting. This function is not independent of the others; an agency that performs some of the other functions would naturally assume this leadership role.

The guarantee provider

To narrow the field of organizations that might provide the guarantee, we start with the following criteria. The organization should be a legal entity, so it can enter into binding contracts and be sued for non-performance. It should have an independent source of assets or income, or at least access to such funds from its contributors. It should have experience and a good track record of managing funds and accounts. And it should have experience and a good track record in providing grants or loans in the health field to developing countries. Without making a fine point of how well these criteria are met, the following candidates are worth considering: one or more bilateral donors, a private foundation operating in the global health field, the multilateral development banks, the Global Fund and the GAVI's Vaccine Fund. Other agencies such as the WHO, UNICEF and the International AIDS Vaccine Initiative (IAVI) might be called on to help with other functions, but would not be in a position to provide the kind of guarantee required. A new organizational arrangement—the International Financing Facility for Immunization (IFFim), which is being administered by the Vaccine Fund—should also be considered. Some of its funding authority is likely to be used to establish advance purchase commitments for late-stage products.

Bilateral donors. Directly or indirectly, bilateral donors must be involved. One or more donors would establish and sign a commitment letter, or they would make a commitment to an organization that would do so on their behalf. For example, several donor members of the Global

Fund's board might decide to authorize its organization to establish an AMC. This paper considers the pros and cons of these two approaches when discussing the Global Fund later. Here the discussion is limited to how the donors might establish a credible commitment.

The working group considered two bilateral donors, the US and UK governments, asking in each case whether there are institutional or legal impediments to making commitments and how such commitments would be treated in the budget process. Of course money could always be taken out of the current budget and held in escrow, but tying up money for as long as 10 or 15 years that could be used for other purposes in the interim would be very expensive, politically as well as economically. The challenge is to find some way to use these funds in the interim⁷ or some mechanism that permits a commitment made today to be scored against the relevant future budget.

The US government would have a difficult time signing a contract for future delivery without putting money aside now. Its annual budget process sets targets for both the authority to spend and the actual outlays. Although the projected expenditure would score against outlays in some future year, the authority to enter into such a commitment must be sought from Congress and limits the extent to which authority can be allocated to other ends at the time it is granted. There are some ways around this problem—for example, requesting legislative approval outside the appropriations process. But significant political capital would have to be used to follow such routes, and currently signs of interest in doing so are weak.

Of course the US government has entered into programmes making advance purchase commitments in other fields. A recent example is the BioShield programme to develop anti-biological weapon products. But Congress has decided these programmes are of such high priority that it is willing to bear the opportunity cost of setting funds, or funding authority, aside now.

The UK government would have a much easier time making a commitment for future expenditures without affecting current budget authority. The working group concluded that no legislative approval would be needed for the government to enter into a legally binding commitment as long as the commitment were deemed an “executory contract”—that is, a contract in which both parties have not yet fully performed their obligations. In this case there would be no impact on the UK Department for International Development's departmental expenditure limit until payments were made. Moreover the UK govern-

ment has been in the forefront of developing and promoting innovative financial arrangements like the AMC and the IFFim for use in the international health field. It thus appears to be willing as well as able to enter into an AMC, unilaterally or multilaterally.

Both governments have agencies with the proper technical skills and experience working with developing countries to set up and manage the programme and assist developing countries in preparing for the introduction of new products.

Private foundations. Pharmaceutical companies are likely to find an AMC issued by a private foundation such as the Bill & Melinda Gates Foundation or the Rockefeller Foundation more credible and attractive than one issued by a national government. Such foundations typically have assets to back up their commitments, cannot legislate away their commitments, have greater continuity of leadership and strategic focus and are less vulnerable to lobbying from special interest groups.⁸ No single foundation is likely to sponsor an AMC by itself or to take on the management and capacity-building functions required, but contributions to a pool of funds or to another organization that takes the lead in managing the enterprise would be very valuable.

The World Bank. The World Bank (and other multilateral development and financial institutions) could also make credible forward commitments. Its loan and credit repayment flows provide it with a reliable source of income. International Development Association (IDA) pledges from its donors, though not as predictable, have been forthcoming for more than 50 years. And it can borrow to take care of cash flow problems. But its operating procedures tend to restrict how these funds can be used. It typically does not make commitments beyond five years,⁹ avoids earmarking future sources of income, provides most of its funds to governments and has limitations on the circumstances under which it can provide grants instead of loans.

With board approval, these limitations could be overcome. For example, the board might commit itself to provide IDA funds for this purpose if and when needed. At that time, IDA country allocations might have to be reduced by the amount of the subsidies needed to honour the AMC in a given year. To compensate countries for this reduction, IDA members could be asked for a supplemental contribution. Alternatively, the board might try to borrow against future IDA commitments (somewhat like the IFFim). While it might seem far fetched to imagine that IDA members would agree to anything like this today, it may not

appear that way when an effective vaccine for HIV/AIDS or malaria becomes available.

Another possibility that has been suggested is an IDA “buy-down”, which has been used in polio eradication projects in Pakistan and Nigeria. Such an arrangement would involve providing a client country with an IDA credit to finance any demand-side capacity building needed, with the bulk of the funds not becoming effective until the desired drug or vaccine is ready for purchase. At that point a willing donor would buy down the IDA credit to the country and cancel the debt, thereby turning the credit into a grant. This arrangement might require substantial changes in World Bank procedures; it might also be cumbersome because arrangements would have to be established with each eligible country.

Yet another possibility is the International Finance Corporation, an affiliate of the World Bank that provides loans, equity capital and guarantees to private companies, mostly but not exclusively, in developing countries. Its guarantees are meant to stimulate private enterprise by absorbing some risks of doing business in or with developing countries. In effect they are options that can be exercised at some unspecified date if certain events occur. As such, they are no different in principle than an AMC. Here again some changes in operating procedures would have to be authorized.

But no change would be required for the World Bank to serve as a facilitator for donor commitments to an AMC. The donors could put funds or promissory notes into a trust fund established specifically for implementing an AMC. Alternatively, they could make contributions or commitments to the World Bank’s Development Grant Facility, which spends about \$125 million per year on global programmes, including a variety of global health initiatives. A final possibility would be the establishment of a global partnership managed by the World Bank, to which the Bank, as well as bilateral and other donors, might contribute.

The World Bank would have no difficulty serving as an implementing agency and assisting eligible countries with capacity-building and demand creation tasks. It is in the business of building capacity. It could also use its convening power to pull together assistance from other organizations.

The Global Fund to Fight AIDS, Tuberculosis and Malaria. In its short life span, the Global Fund has become the largest single financer of medicines for AIDS, tuberculosis and malaria. If a new drug or vac-

cine for one of these diseases is developed, it will certainly be heavily involved in funding it through its recipients in developing countries—whether or not there is an AMC for the product. In contrast to the World Bank, the Global Fund does not have an independent source of income, cannot issue bonds or borrow for the long term and does not yet have a long successful history of raising funds for its operations. Its standard operating mode is to provide funds to its clients for projects they want to undertake; it does not (or at least has not yet) entered into any contracts directly with suppliers.

Thus the Global Fund has neither the resources nor the mandate to commit to enter into a contract with a supplier. However, if donors provided the commitments, the Global Fund could serve as a facilitator. First, it might commit to providing funds to its clients for their purchase of a new drug or vaccine. This commitment would not guarantee that countries would make the required purchases, but there is a strong presumption that they would, especially in well established markets (for example, where a new drug or vaccine is replacing an old one). But if the product requires a change in national policy or behaviour of consumers, such a presumption is unlikely to be sufficient for producers. The appendix describes a case where the Global Fund has so far been unsuccessful in convincing manufacturers and growers to produce sufficient ACT for its malaria programme without a purchase guarantee.

Short of agreeing to purchase the product itself, the only other thing the Global Fund could do is to persuade its clients to provide commitments to purchase the product with funds it provides. Suppose, for example, that the Global Fund signed an agreement with India that committed that country to purchase a certain quantity of a new product using the Global Fund's money for this purpose when it is available. If it were clear that these funds will not be available to India under any other circumstances, the opportunity cost to India of making the requested purchase would be negligible. This possibility has not been explored.

The only other possibility is for the board of the Global Fund to change its rules to permit the secretariat to enter into advance purchase or market commitments on behalf of its donors. In effect, the Global Fund would serve as an intermediary for donors willing to provide commitments for future purchases. Most likely donors would make individual commitments to the Global Fund, which in turn would make a commitment to the producer. This arrangement has two advantages over donors providing guarantees directly. First, commitments could be pooled together, thereby spreading risks and reducing the required

size of any one donor's commitment. Second, the arrangement should comfort manufacturers because the Global Fund could serve as an intermediary, helping resolve problems before they get out of hand.

There would also be advantages for the Global Fund since, if donors were willing, it would begin to acquire some longer term sources of financing. The changes in operating procedures required might be a small price for this benefit—to say nothing of the lives saved by introducing new drugs and vaccines more rapidly.

GAVI, the Vaccine Fund and the IFFim. GAVI is an alliance between the private and public sector from industrial and developing countries that promotes the widespread use of vaccines. It is not a legal entity that can enter into long-term contracts. It would certainly be a good vehicle for promoting the concept of an AMC for vaccines. It could help create appropriate committees or agencies to implement such a scheme, though it may not want to take on these functions.

The Vaccine Fund operates much like the Global Fund, providing grants on request from its clients, in this case focused on the purchase of vaccines especially for children. But there is nothing in its bylaws or operating procedures that inhibits it from providing long-term commitments for new products. The limiting factor is the purposes for which its donors have provided their contributions. To date, contributions have been provided for expanding the use of vaccines already in the market, not for generating new vaccines. But the establishment of the IFFim is changing this picture in some ways.

The IFFim, which was established in September 2005 with commitments totalling \$4 billion from the governments of the United Kingdom, France, Italy, Spain and Sweden, and which is being implemented by GAVI, has the power to borrow against future streams of donor financing for foreign assistance. Since this borrowing authority could be exercised at any time, the IFFim could guarantee drug and vaccine developers that funds would exist to honour a future market commitment without having to set them aside in advance. The funds will be used to encourage more widespread use of several vaccines already in use in developing countries and to speed up the introduction of two—for rotavirus and for pneumococcus—that are in late-stage development. Because a variety of “push” and “pull” activities will be financed, it may be difficult to determine the independent effects of any AMC that is established. But it should be possible to learn a great deal about how best to establish and manage such schemes.

Specification of commitment terms and related plans

It can be argued that the specification of commitment terms is best left to the donor(s), because they will ultimately fund an AMC. But if the scheme is to work, pharmaceutical companies must be convinced that the scientific base for promising R&D efforts is adequate (or will be developed in a timely fashion), that the financial terms are attractive and that an adequate market for the product is likely after the guaranteed purchase target has been met. This suggests using an agency viewed by all parties as independent, with the convening power to pull together disparate views and interests and the capacity to develop a more comprehensive plan.

The WHO comes closer to meeting these criteria than any other agency. It is already in the business of setting standards for drugs and vaccines and pre-qualifying new products, and it has extensive experience in the developing world. More specialized agencies, such as IAVI, the Roll Back Malaria Partnership, the Medicines for Malaria Venture, the Stop TB Partnership and the Special Programme for Research and Training in Tropical Diseases (TDR), should be called on for assistance as needed. It will be important to involve developing countries in the product specification process, to ensure that the specifications work for them and to enhance the credibility of the offer. Indeed the greatest strengthening of credibility will come from developing countries committing to use some of their funds to purchase the product.¹⁰ It also will be important to obtain reactions from potential developers to ensure that the offer is at least in the ballpark of what some firms might consider attractive.

Monitoring and implementation (before initiation of purchase contract)

Because conditions are bound to change unpredictably while the commitment letter is outstanding, there needs to be an agency responsible for monitoring developments and proposing changes in the product specifications or financial terms. This agency must also be empowered to make the final decision on when the terms of the commitment letter have been satisfied.¹¹ For these purposes, it must be seen as independent and objective by the parties involved and must be accepted by them to fill these roles. These functions are best fulfilled by the same body that manages the development of the original commitment terms. It would be in the best position to understand the intent of the

originators, to adjust the offer terms to meet the final objectives and to judge between different interpretations of whether the first phase has been satisfactorily met.¹²

To allow room for improvements in the vaccine of interest and to encourage competition, there should be no presumption that the terms of the commitment letter will be satisfied by the first firm to meet the specifications. Until the total subsidy that the donors have committed to provide has been exhausted, the offer should be kept open to allow other firms that might come along with a better product to participate in the subsidy. While this could raise complications that need to be worked out, the institutional issue is clear: the agency responsible for making decisions about this subsidy must remain in existence so long as the offer remains outstanding.

Contract implementation and monitoring

After the terms of the contract are agreed to, implementation could be handled by the donor(s) or a representative—for example, the Global Fund or the Vaccine Fund. The agency that managed the project up to this point should turn to monitoring and evaluation to derive as many lessons as possible from the experience.

Other functions

A variety of agencies are involved in monitoring and promoting basic research in relevant fields. Examples include the International AIDS Vaccine Initiative and the TDR. They should be called on to judge whether additional “push” financing is needed in specific areas. The World Bank, the largest financer of projects aimed at developing health system capacity, is in a good position to assist with demand-side capacity building. The WHO, the largest provider of technical assistance in the health field, plus more specialized agencies focusing on specific diseases, should be called on to help. The WHO is also in a good position to serve as the anchor institution for this enterprise. The parties, or potential parties, to the AMC contract can decide who should be called on to help settle disputes.

Conclusions

The essence of the argument for an AMC for an early stage drug or vaccine is that it will reduce uncertainty about future markets, thereby speeding up the production of global public goods such as knowledge and products to attack communicable diseases. If the product is never developed, the cost to donors is minimal. If it is developed, the cost is unlikely to be greater than what donors are likely to contribute to health problems of developing countries anyway; indeed, in the long run, it is likely to cost less because it will substantially improve the efficiency of whatever level of foreign assistance they provide.

How might responsibility for the functions required to implement this proposal be assigned? While an individual donor or foundation could undertake many of these functions and outsource the others, the decision by the G-8 Ministers to proceed with a pilot programme makes collective action much more likely. Given that, one possibility is to establish a new global partnership dedicated to managing this enterprise. This would be an attractive option for those who believe that organizations like the WHO and World Bank are too bureaucratic, conservative and risk-averse to meet the challenges that an AMC is likely to pose. But the cost, especially in terms of time, required to establish an effective new organization is always underestimated; it is likely to be far too high given the urgency of this task. Moreover, there are some good options among existing institutions.

For reasons noted in the previous section, the WHO is in the best position to host a unit that would take on the core functions—managing the process of collecting the diverse inputs required to develop the technical and financial specifications of the offer, modifying the offer if necessary and determining when these specifications have been met. By virtue of these responsibilities, this unit would be in a good position to take on monitoring and evaluation responsibilities as well. This unit might need a degree of independence from some of the WHO's standard bureaucratic practices, and it must be in a position to call on other WHO offices, as well as outside experts, to help. With careful consideration to placement in the hierarchy and good leadership, these requirements should not be difficult to meet. Again, for reasons noted in the previous section, the World Bank is in the best position to lead, coordinate and monitor demand-side capacity-building activities; but responsibilities for country-level programmes should vary depending on which agency—UNICEF, UNDP, the World Bank or one of the

health partnerships—has the best contacts and programmes already established. Specialized technical agencies would monitor scientific developments and make recommendations—probably to the WHO—about whether assistance is needed to help fill gaps in scientific understanding or adjust target product specifications over time. Decisions about how to undertake the adjudication function are best left to the parties that sign the contracts.

This leaves the selection of a guaranteeing agency—an agency that, on behalf of the donors, issues the guarantee and signs and implements any contracts that result—to be decided. There are several good possibilities here. The Global Fund or (if a vaccine is involved) the Vaccine Fund of GAVI could serve these functions based on promissory notes provided by donors. The World Bank could also serve these functions using its own financial resources along with those of various donors. Use of its own resources would make the World Bank especially attractive because it would further enhance the confidence that potential developers have in the offer. But any of these agencies could serve these functions well so long as the donors give them the authority to do so. They would have to modify their operating procedures to some extent, but that would be a small price to pay for the enormous global benefits that would result from the development of new drugs or vaccines to fight the neglected diseases of developing countries.

Now that the IFFim has come into existence, some have suggested that efforts to find a home for and implement an AMC for early-stage products should wait to see how well the concept works for late-stage products. The experience could make future efforts easier and reduce the risk of failure. But the IFFim will have several limitations. First, the interest of its donors seems to be to pull money out of the expected stream of foreign assistance quickly, not to acquire borrowing power to be used at some unspecified future date. Second, as proposed, any commitment issued by the IFFim can be outstanding only for 10–15 years. For early-stage products, it could take that long before a contract for future deliveries could be initiated. Third, several problems involved in applying the AMC approach are quite different for early-stage products. The firm or firms that eventually enter into the contract are not known in advance, and the appropriate market price is more difficult to determine. Such differences suggest that an AMC for a late-stage product is unlikely to be an adequate test of an AMC for an early-stage product. It would be better to work on both fronts simultaneously.

Appendix: Global health partners' efforts to expand production of artemisinin-based combination therapy products for treating malaria

This case illustrates many of the points made in the text and provides a concrete example of the challenges faced by the Global Fund and other organizations in trying to induce countries to switch to new drugs and manufacturers to increase supply.

Artemisinin-based products (artemisinin-based combination therapies or ACTs) to treat malaria came onto the market in the late 1990s. Because they cost 10–14 times more than older drugs such as chloroquine and sulfadoxine with pyrimethamine, they are rarely used in public health programmes—despite growing resistance to the older drugs and recommendations from the WHO to switch. It was only in January 2004, after the Global Fund announced that it would fund the new compounds, that governments began to seriously consider their use.

Changing national policy on a drug can take a year or more. It requires clinical, pharmacological and surveillance studies to determine which combination is best suited to local conditions—that is, which has the highest efficacy rate, lowest number of detrimental side effects, slowest growth rate of resistance and so on. (There are four formulations.) It also requires difficult and politically sensitive decisions on social policy. The Global Fund, along with most other donors, finances only the public use of drugs, which often accounts for less than 20% of total consumption. A blanket switch in policy from the older drugs to ACTs could increase the price of treating malaria for the vast majority of the population to unaffordable levels. So countries consider other possibilities, such as sanctioning use only for pilot studies or for children under five. Countries are also concerned about long-term funding. Funds from the Global Fund are guaranteed initially for only two years. Faced with the need to choose between different formulations, the need to make difficult decisions on social policy and uncertainties about external funding, it is understandable that national policy is slow to change, and the timing of change is unpredictable.

The result: demand for new drugs such as ACT is difficult to predict even when funds are available from donors for their purchase. Producers know this and react by being cautious about increasing production, which results in shortages, drives up prices and makes demand even harder to predict.

During 2004 the concerned partners tried several approaches to deal with these problems. First, the WHO, UNICEF and Global Fund presented producers with detailed demand and supply projections. Taking all the uncertainties of demand into account, they estimated that the Global Fund would be called upon to finance 70–80 million treatments in 2005 and 120–130 million treatments in 2006 for the public sector, whereas only 50 million treatments are likely to be produced in 2005 and—unless farmers planted substantially more seed before the end of the December 2005/January 2006 planting season—only 70 million treatments in 2006. (This projection of supply leaves out new plantings just beginning in East Africa, which are not expected to be significant in 2006 but could be in subsequent years.)

Industry representatives responded by saying that timing is as important as demand. Because the shelf life of artemisinin is only 18–24 months, and most buyers will not buy the product unless at least 75% of the shelf life remains, sales must occur within 4–6 months of production. Moreover, the yield of artemisinin from its leaves drops sharply after harvest, so extraction must occur rapidly. Until they have firm purchase contracts with sufficient lead time, manufacturers indicated that they would refuse to sign contracts with farmers for substantially greater output, even if they believed that the demand is there and will eventually materialize.

The Global Fund tried to provide more certainty by establishing a memorandum account in which it deposited \$205 million, about two-thirds of what it estimated its clients needed to purchase ACTs during 2005 and 2006. It called a conference of all stakeholders to explain this account, review the demand and supply projections and discuss various other solutions. Industry still insisted on a guarantee, saying that this arrangement did nothing to protect them from the timing uncertainties.

Thereafter, Zambia and several other countries began working with the Roll Back Malaria Partnership to develop a proposal to the Global Fund that it provide a guarantee for a substantial portion of the projected demand. This has proved to be a non-starter. Because the Global Fund was established to provide funds directly to countries and has no mandate to purchase commodities itself—which it would have to do if called upon to honour the guarantee—the secretariat must seek board approval for a change in policy before it can honour this request, even though funds have already been set aside.

The first draft of this appendix, written in April 2005, concluded that “time is running out. Because of the lead times required for planning

and growing the raw material, a solution must be found by next September or October in order to avoid the shortage projected for 2006.” In fact, just the opposite has happened during the last 10 months. Because of procurement problems, internal supply management problems and delays in adjusting policies, enough of the projected demand has failed to materialize that there are now surpluses—supplies in national warehouses that are not moving into the field and inventories building up in producers’ warehouses that are not being delivered to countries—with the result that instead of expanding orders for raw materials for this growing season, some manufacturers have cut back, which of course will lead to another round of shortages after this growing season.

This sad story is not unique. With variations, wild swings from shortages to temporary surpluses occur every time a new drug is introduced to a developing country market. Would a short-term advance purchase guarantee result in a higher and more stable flow of products to final users? It would if it bought sufficient time to resolve the demand-side capacity problems before the shelf life of the products it finances expires. This would probably be the case in some countries but not in others. It would behoove the Global Fund to consider each such case on its merits, rather than sticking to a fixed policy of never providing a purchase guarantee.

Notes

1. The idea was put forward in a 1998 World Bank document (see references), but the CGD document is the first elaboration of it into a practical, implementable proposal.
2. Based on revenues generated by new medicines introduced into the United States in the 1990s and a wide variety of assumptions—for example, about the efficacy of a new product—the working group suggested that an offer for a malaria vaccine of \$15 per person for the first 200 million people immunized and a commitment to sell to eligible countries at \$1.00 per person immunized thereafter might be enough of an incentive (in 2004 prices) for developers and producers to take up the challenge. But even if the price were doubled, this intervention would still be cost effective compared with many other interventions (including the provision of bednets). See Levine, Kremer and Albright (2005, pp. 55 ff) and Tremonti (2005b, pp. 8 ff).

3. If a vaccine for one of these diseases were ever developed, unless it were exorbitantly expensive, donors would almost certainly help developing countries acquire it. What the guarantee does is to reduce the uncertainty of this happening and speed up the development (perhaps by as much as 5–10 years considering how long it has taken in the past for new medicines introduced into industrial countries to begin being widely used in developing countries). There would be a cost to donors in having to provide subsidies sooner, but they would be more than offset by the reduction in costs for treatment, care and prevention by less effective means—to say nothing of the savings in lives and other social costs the disease imposes.
4. This could be the case even for products that are already in the market. The appendix provides an example of such a case.
5. The two programmes should proceed simultaneously; there is nothing to be gained by waiting to establish the APC until scientific gaps are filled. The worst that happens is that no one rises to the challenge thrown out by the commitment letter for a few additional years. The best that happens is that some companies decide to proceed with R&D anyway.
6. It is noteworthy that even in a country like India, with relatively good administrative and health structures extending down to the village level, the authors of a working paper designed to estimate the potential demand for an HIV/AIDS vaccine in southern India emphasize that difficult constraints must be overcome before much of this projected demand can be expected to result in actual use; the stigma associated with HIV/AIDS must be reduced before high-risk populations will be willing to be vaccinated; low public awareness and ownership must be overcome; both the vaccine delivery infrastructure and the overall public health delivery system must be substantially strengthened; a plan to involve the private sector must be developed and implemented; the national capacity for vaccine trials must be upgraded; funding for HIV prevention must be increased; and the capacity to design, implement, monitor and evaluate programs must be developed. See Seshadri, Subramaniam and Jha (2003).
7. One possibility would be to put the money aside now but lend it out for other uses and make the loans callable on demand. This possibility sounds like a non-starter. It does not get around the problem of having to score the allocation against the current budget, and it might not be considered a highly credible commitment by developers since, if it were politically inconvenient, the government might not call the loan, and the developers would have no way to force the government to do so.

8. See Levine, Kremer and Albright (2005, p. 74).
9. However, it does establish programmes consisting of several loans or credits that cover a 10-year period.
10. It would signal that they have seriously investigated the appropriateness of the specifications, are truly interested in using the product and are likely to take the steps necessary to ensure timely distribution and delivery.
11. This same agency might also assist donors and producers in negotiating the final purchase contract.
12. The proposal to the G-8 elaborates on these functions and suggests that the unit assigned these functions be called the Independent Assessment Committee.

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Microbicides as an Option for HIV Prevention

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Heterosexual transmission—particularly affecting women—is driving the HIV epidemic today in many resource-poor countries, where most of the infections are occurring. During 2004 the Joint United Nations Programme on HIV/AIDS (UNAIDS) estimated that 4.9 million new HIV infections occurred in the world. In many affected communities women have little negotiating power in matters of contraception and sexual life. The biggest potential for preventing HIV today lies in methods controlled by the female sex partner, particularly in high-risk groups. Topical microbicides offer one promising alternative.

Topical microbicides are pharmaceutical products that disrupt the transmission or the life cycle of HIV. Some microbicides also have properties that make them effective against other sexually transmitted infections or make them effective contraceptives. There are no microbicides on the market today, but clinical trials in humans have begun for 18 preparations, and several others are in preclinical research. It seems realistic to assume that within 5–10 years a few preparations will have finished phase 3 studies and, if successful, been accepted by regulatory authorities.

Several aspects specific to topical preparations need to be assessed during the clinical studies, including questions of formulation, application and effectiveness in specific sexual acts and ethical questions surrounding clinical trials in developing countries. After regulatory approval major challenges remain related to cost-effective production, distribution in resource-poor areas and cultural acceptability.

Microbicides are some of the most promising options likely to be available for preventing HIV transmission in the near future. Clinical research (and research targeting specific issues of topical preparations) should be supported, and financial and logistical solutions for production and marketing activities should be urgently sought.

The need for prevention options

Heterosexual transmission in resource-poor countries of Sub-Saharan Africa and Asia is driving the HIV epidemic today. According to UNAIDS estimates 4.9 million people were infected with HIV during 2004. Women are being increasingly affected. In Sub-Saharan Africa 57% of people infected were female.

In the communities where HIV spreads most rapidly women have little power of negotiation on sexual issues. Therefore the decision on using the only available prevention method, the male condom, is often a decision of the male in a sexual relationship. It is likely that an effective prevention method that could be used discreetly by women would provide some of the impetus needed to combat the HIV epidemic. Medical preparations—microbicides—that kill the virus and possibly other microbes causing other sexually transmitted infections are one such prevention option.

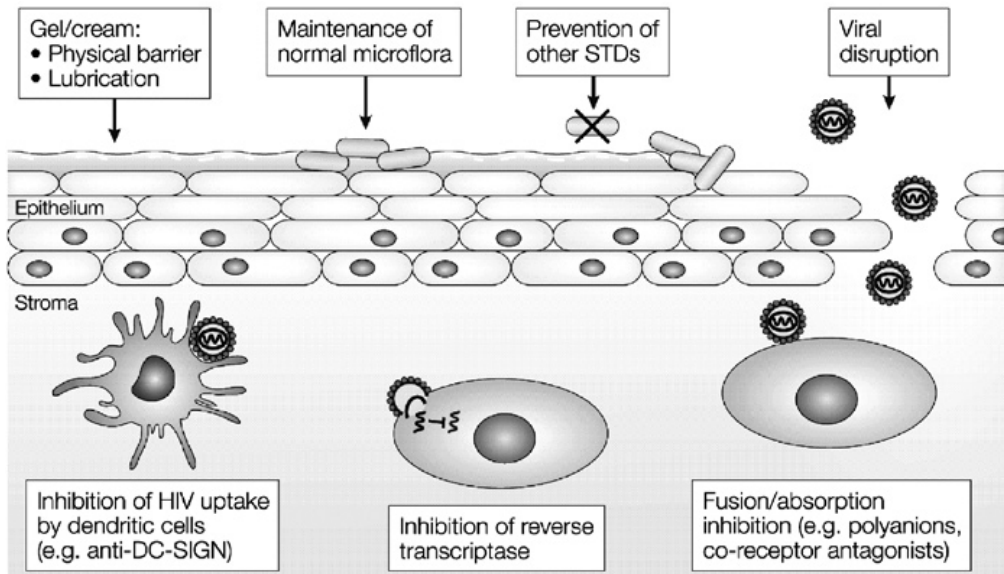
Mechanisms of action

After it became clear that many detergent-based spermicides used for contraception have potent activity against HIV and some sexually transmitted infections (STIs) in laboratory conditions, active research was undertaken on nonoxynol-9 (N-9)-based products in the late 1990s. Unfortunately several randomized controlled trials on humans failed to show beneficial effects of these compounds and even suggested negative effects on transmission owing to damage to the vaginal epithelium (WHO 2001).

After the disappointment of the first studies research interest in microbicides has gained momentum during recent years (see annex 1), and currently about 65 potential compounds have been identified in preclinical studies (in the laboratory). These compounds may be characterized by their mechanism of action (see figure 4.1).

Maintaining, mobilizing or enhancing normal vaginal defence mechanisms in the cervicovaginal environment. A healthy intact mucosa is a good natural protective barrier against infection in women. This barrier may be supported by gels and creams that provide lubrication and additional physical barriers for viruses and bacteria. An acid pH, normal vaginal microflora, natural antibodies and antimicrobial peptides are other natural mechanisms that microbicides can support or strengthen.

Box 4.1 Possible action mechanisms for microbicides



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Source: Stone (2002).

Directly inactivating sexually transmitted pathogens (HIV and other STIs) by non-specific surface-acting agents. HIV, some other viruses and bacteria have a protective membrane or envelope. Some microbicides disrupt this membrane. The challenge in developing microbicides with this mechanism is that they often are active against human cells as well. The right balance between the side-effects and the microbicidal effect must be found. N-9 belongs to this group. Many of these agents are also spermicidal and can therefore be used as contraceptives.

Inhibiting early steps in the viral cycle of HIV and entry into the mucosal cells. To be able to replicate in humans HIV must enter human cells after bypassing protective mechanisms. This process includes attaching to the cell membrane, fusing into the membrane and entering into the cell. At any of these stages the process can be blocked specifically by binding surface proteins on the virus or by binding the receptors on the human cells. Some microbicides function also by non-specifically coating the virus or the human cell with “charged interactions”.

Interrupting the viral life cycle after infection. Some antiviral medications already used for therapeutic use may also be used as topical microbicides. These agents inhibit viral replication or local spread of the infection. Some of these agents are likely to have spermicidal activity.

Table 4.1 Overview of microbicides in clinical trials during 2004

Phase	TOTAL #	Microbicide candidates	Sponsor/developer	Mechanism of action	Potentially spermicidal
1	8	Acidform™/Amphora™	Topcad, Cernicamp; GMP	1	
		Benzalkonium chloride	Biofem	2	
		Cellulose acetate phthalate/CAP	New York Blood Center	multiple	
		Human monoclonal antibodies (C2F5, C2G12, C4E10)	Polymun Scientific	2	
		Lactin-V capsule	University of Pittsburgh; NIAID	2	
		Polystyrene sulphonate/PSS	GMP	3	
		Tenofovir/PMPA	Gilead	4	No
		UC-781	Biosyn	4	No
1/2	1	VivaGel/SPL7013TM	Starpharma	3	
2	2	Invisible Condom™	Laval University	2	Yes
		<i>Lactobacillus crispatus</i> suppository (CTV-05)	University of Pittsburgh	1	
2/2B	2	Protected <i>Lactobacillus</i> in combination with BZK		1	
		BufferGel™	ReProtect; HIV Prevention Trials Network (HPTN) and National Institute for Child Health and Human Development (NICHD)	1	No
2/3	1	PRO2000/5 /Naphtlane sulfonate polymer (will be tested with Emmelle™ in phase 3)	Indevus Pharmaceuticals; HPTN	3	
3	5	Praneem Polyherbal	IRR India	unknown	
		Carraguard™	CDC; Population Council	3	
		Ushercell/cellulose sulfate/CS	Polydex; GMP	1	Yes
		Emmelle™/dextrin-2-sulfate	ML laboratories; MRC, ITM	3	
		Sawvy™/C-31G	Biosyn; GMP and NICHD	2	Yes
TOTAL	19				

Source: www.microbicide.org.

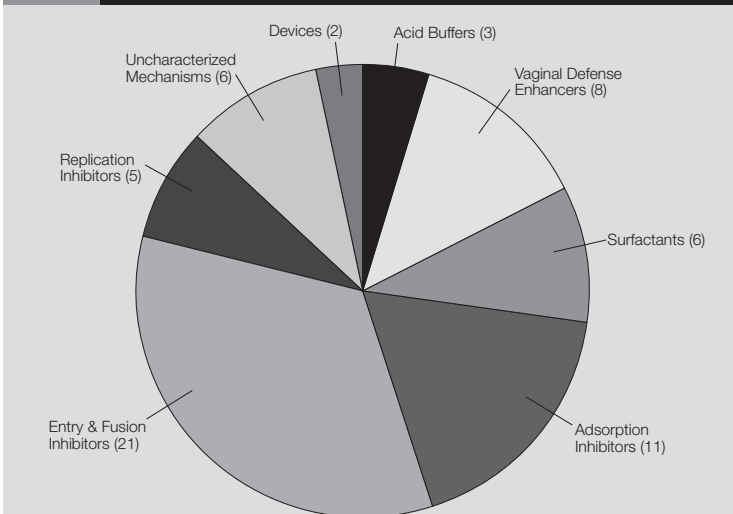
Research pipeline

Research on new pharmaceutical preparations is a slow process because of issues such as safety and efficacy testing. The time for a compound to receive approval is estimated at more than 10 years. The development process is normally divided into four phases. Phase 1 trials are carried out in small numbers of healthy women to assess any possible serious adverse effects. Phase 2 trials are traditionally expanded safety studies where researchers also try to obtain preliminary evidence of efficacy. Because this is very difficult for HIV prevention, some groups are now working with phase 2/3 studies directly. Phase 3 studies assess effectiveness, safety, product acceptability and patient adherence to the regimen. Phase 4 studies assess many aspects of the compound after it is introduced.

More than 62 agents are being studied at a preclinical level in the laboratory (see table 4.1). Clinical studies in humans have begun for 19 agents (see table 4.1; annex 2). Microbicides with all action mechanisms have entered phase 1. Agents from all therapeutic groups except the therapeutic antivirals have also entered phases 2 and 3. These studies are being carried out by public stakeholders or by smaller pharmaceutical companies.

It has been suggested that a microbicide combining several action mechanisms would be more effective or have less adverse effects than single preparations, but most current research concentrates on single-

Figure 4.2 Mechanisms of action of microbicides under development in 2004



Source: www.microbicide.org.

action mechanisms (see figure 4.2). This is caused by scientific problems in evaluating efficacy and the associated regulatory problems.

Research: opportunities and challenges

Little attention is being paid to formulation and delivery technology— aspects of this kind of vaginal preparation that could enhance the efficacy and acceptability of the microbicide.

Almost all research on microbicides concentrates on effects on transmission between the penis and the vagina. However in many heterosexual relationships couples also engage in anal sex. Given the structural and physiological differences between the anus and the vagina, specific studies on the efficacy of microbicides in anal sex are warranted.

Clinical trials for HIV prevention in resource-poor countries share two ethical challenges: large study populations and a need to provide a high standard of prevention and treatment.

Epidemiology

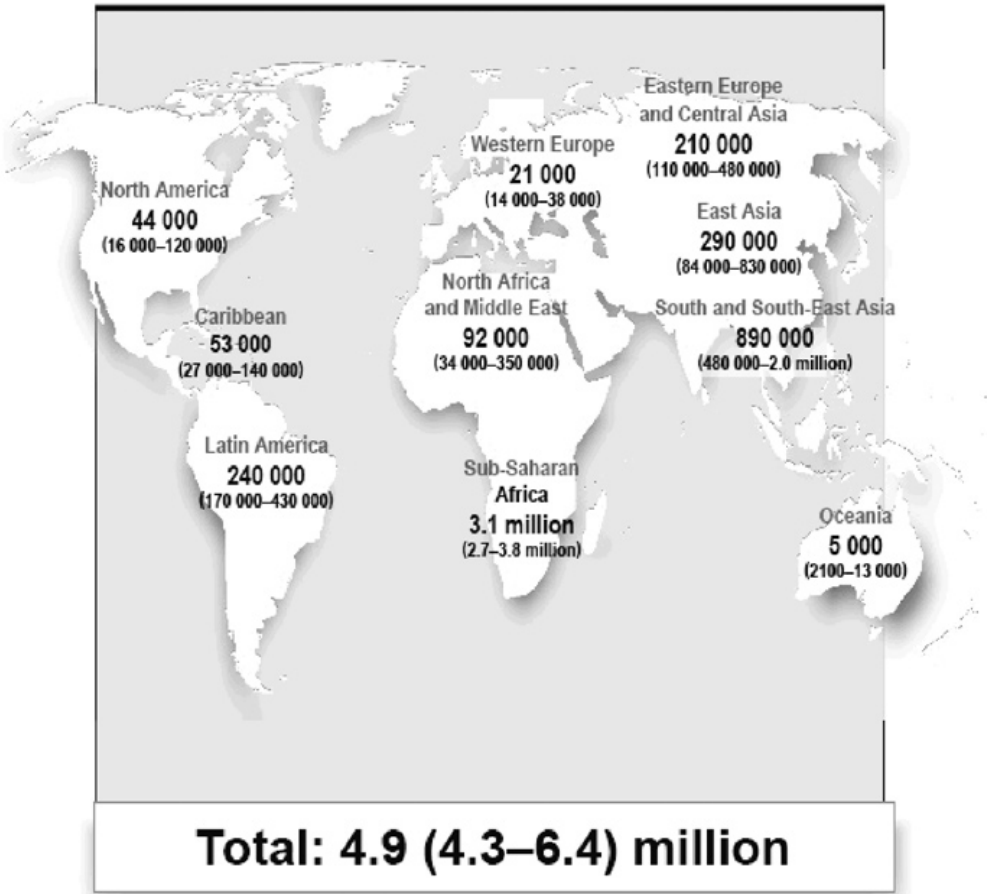
UNAIDS estimates that 4.9 million new infections of HIV occurred during 2004. Of these, 3.1 million infections occurred in Sub-Saharan Africa where 57% of people living with HIV are female. Another 1.2 million infections occurred in Asia (excluding central Asia) where 22–30% of people living with HIV are female (see figure 4.3).

Currently 39.4 million people are infected with HIV, of which 17.6 million are female. Three-quarters of women living with HIV live in Sub-Saharan Africa.

Public health and economic impact

Charlotte Watts and her co-workers studied the public health and economic impact of microbicide use in resource-poor countries. They used country-specific epidemiological and economic models to assess effects. Seventy-three countries with a GNP of less than \$1,200 per year and all Sub-Saharan African countries were included. For each country the number of HIV infections averted was calculated for four separate risk groups (sex workers, adolescents, injecting drug users and women

Figure 4.3 Estimated number (estimate boundaries) of new HIV infections during 2004



Source: UNAIDS (2004).

in regular partnerships) with a realistic level of access to microbicides. Only direct cost savings in the healthcare system (not including retroviral therapy) and productivity gains were considered as economic benefits.

Assuming a 60% effective microbicide reaching 20% of the at-risk population, the results of Watts's analysis suggest 2.5 million HIV infections could be averted over a three-year period, with total economic benefits of \$3.73 billion (see tables 4.2 and 4.3). These benefits are sensitive to assumptions of effectiveness against HIV, effectiveness against other STIs and consistent use of the microbicide.

Another study, commissioned by the Rockefeller Foundation, found that the potential market for microbicides ranges widely from \$0.1 bil-

Table 4.2

Three-year cumulative HIV infections averted and associated health and productivity gains from distributing a 60% efficacious microbicide to 20% of groups in contact with services in 73 low-income countries

	Three-year cumulative HIV infections averted	Present value of direct cost savings to health systems (2002; \$billions)	Present value of productivity gains (2002; \$billions)
East Asia and Pacific	793,577	1.3	0.43
Eastern Europe and Central Asia	128,246	0.2	0.04
Latin America and the Caribbean	50,444	0.06	0.03
South Asia	882,642	0.65	0.17
Sub-Saharan Africa	682,790	0.48	0.36
Total	2,537,700	2.69	1.04

Source: Watts and others (2003).

lion to \$5 billion, depending mostly on consumers' acceptability of the product. The development costs of the current microbicide portfolios are estimated to be \$775 million over five years. This is roughly equal to the estimated current development costs of HIV vaccines over two years (\$350 million). The total cost of any product depends strongly on the time needed to successfully finalize phase 1–3 clinical trials. The distribution costs of microbicides will depend on whether the product is marketed over the counter or as a prescribed medicine. For over-the-counter products the distribution costs will likely be comparable to condoms and cosmetic products. For prescribed medicines a large part of the cost will be determined by the costs incurred in the healthcare system. Private investment in microbicide research has been minimal, mainly because of the high uncertainty about the market size.

Challenges ahead

After finalizing phase 3 clinical studies several essential hurdles remain before any public health benefits from microbicides can be achieved. The developers and large governmental agencies have already discussed specific problems in regulatory approval, and the will appears to be there for relatively rapid approval. Large-scale production will entail a large financial investment and a risk that must be taken by some stakeholder if the products are to be launched. Wide distribution to allow access for large parts of populations in some of the poorest economies is a chal-

Table 4.3 Three-year impact and economic benefits of introducing a microbicide with different HIV and STD efficacy to 20% of groups in contact with services in 73 low-income countries

Efficacy scenarios	Three-year cumulative HIV infections averted	Present value of direct cost savings to health systems	Present value of productivity gains
		(2002; \$billions)	(2002; \$billions)
40% HIV, 0% STD	1,662,344	1.77	0.67
40% HIV, 40% STD	1,856,885	1.96	0.76
60% HIV, 0% STD	2,537,700	2.69	1.04
60% HIV, 40% STD	2,735,177	2.88	1.13

Source: Watts and others (2003).

lenge in itself, and all these steps must happen in a cost-efficient way so that the end user can afford the product.

Final challenges include ensuring proper and consistent use by people with little previous sexual education through education and advertisement campaigns. All stakeholders need to be involved in this process (see annex 3). This should be done in a way that also promotes common use to minimize any switch from condoms to microbicides, although the effects of this switch are thought to be minimal.

Conclusions

Microbicides appear to provide a new option for preventing HIV that could be introduced rapidly and have considerable public health and economic effects in resource-poor countries. Challenges ahead include finalizing phase 3 clinical trials for as many preparations as possible, securing a cost-efficient production and distribution system, securing wide access (that takes into account cultural sensitivities) for the product in Sub-Saharan Africa and Asia and providing sufficient education for users specifically to promote condom and microbicide use.

Microbicides hold the promise of a prevention tool women can control. Modelling indicates that even a 60% efficacious microbicide could have substantial impact. If such a product were used by only 20% of women in 73 low-income countries, 2.5 million new infections could be averted over three years among women, men and children.

A first-generation microbicide could be ready for distribution in five to seven years. But for that to happen, investment in microbicide research and development needs to expand rapidly and dramatically so

that highly potent yet affordable microbicides with novel mechanisms of action can be tested in experienced high-incidence sites. Currently the incentive structure of the private market is not funneling sufficient investment towards microbicides, despite the fact that estimates point to a potential \$1.8 billion market for a successful product by 2020 (Access Working Group 2002). Substantially increased resources are required to ensure that testing of the most promising candidate microbicides proceeds without delay and that the groundwork is laid now for efficient distribution of successful products.

Note

Much of the information appearing in this paper originated from UNAIDS on World AIDS Day, 1 December 2004 and from information provided by two advocacy groups: the Alliance for Microbicide Development (www.microbicide.org) and the Global Campaign for Microbicides (www.global-campaign.org).

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Annex 1: Timeline of developments in microbicide research

1987

This year marks the first instance in which US Agency for International Development (USAID) funds awards for HIV transmission and microbicide development.

1990

South African epidemiologist Zena Stein publishes seminal article titled “HIV Prevention: The Need for Methods Women Can Use” in *American Journal of Public Health*.

1992

The International Conference on Population and Development Plan for Action calls for the development of “virucides” to protect women against HIV and other STIs.

First topical microbicides meeting sponsored by the Population Council is held.

1993

UK Medical Research Council (MRC) establishes virucidal working group to promote microbicide research.

US Department of Health and Human Services (DHHS) Secretary Shalala identifies \$10 million for the National Institutes of Health (NIH) Topical Microbicides Initiative.

First Topical Microbicides Workshop sponsored by NIH and the Food and Drug Administration (FDA) takes place.

World Health Organization (WHO) holds first international scientific consultation on microbicides.

NIH establishes HIV Network for Prevention Trials (HIV/NET), government-funded clinical trials infrastructure, which becomes the major sponsor of trial sites for microbicides.

1994

NIH issues first Request for Proposals (RFP) to support microbicide research.

The first inclusion of microbicides is found in US House and Senate report language.

The International Working Group on Microbicides (IWGM) is established.

1995

NIH issues first grants for microbicide-specific research.

The National Institutes of Allergy and Infectious Diseases (NIAID) complete pre-clinical guidelines.

1997

IWGM publishes recommendations for the clinical development of microbicides.

At an International AIDS Conference in Vancouver, US DHHS Secretary Shalala commits to spend \$25 million per year on microbicides over the next four years.

The first clinical studies of PRO2000 begin.

1998

The Alliance for Microbicide Development is founded, and the first and second meetings are held.

Advocates launch Global Campaign for Microbicides.

CONRAD (Contraceptive Research and Development), Family Health International and IWGM host meeting on opportunities for industrial collaboration in microbicides/spermicides.

First clinical studies of Carraguard™ by Population Council take place.

1999

First clinical studies of cellulose sulfate (CS) begin.

First clinical studies of Savvy™ (C31G) begin.

2000

Rockefeller Foundation convenes international group of scientists, research organizations, advocates and industry representatives to explore ways to accelerate microbicide development.

Preliminary data from COL-1492 study is presented at 13th International AIDS Conference in Durban, South Africa.

First major international scientific conference on microbicides is held in Washington, D.C.

Bill & Melinda Gates Foundation awards \$25 million to CONRAD, and the Global Microbicide Project is established.

2001

Bill & Melinda Gates Foundation awards \$20 million to the Population Council.

Crompton-Uniroyal and Biosyn sign licensing agreement for UC-781.

2002

Microbicides named by Joint Center for Bioethics of University of Toronto as one of the “Top 10 Biotechnologies for Improving Global Health”.

Second major international scientific conference on microbicides is held in Antwerp, Belgium.

International Partnership for Microbicides (IPM) is launched.

The WHO and CONRAD release the nonoxynol-9 report.

Bill & Melinda Gates Foundation awards \$28 million to the University of California at San Francisco to test the diaphragm as an HIV-prevention tool.

2003

Bill & Melinda Gates Foundation awards \$60 million to the International Partnership for Microbicides (IPM).

FDA Advisory Committee holds meeting on microbicides clinical trial design.

2004

Third major international scientific conference on microbicides is held in London.

First microbicide plenary at 15th International AIDS Conference takes place in Bangkok, Thailand.

Global HIV Prevention Working Group recommends increased funding for microbicide R&D.

IPM takes on development of Tibotec’s TMC-120.

Five microbicide candidates enter six late-stage clinical trials.

Annex 2: Descriptions of candidate microbicides

BufferGel™ keeps the vagina acidic even during intercourse and creates a physical barrier that inhibits the passage of pathogens into the vaginal and cervical epithelium. *Acidform™* is also an acid-buffering agent.

Carraguard™ is made from carrageenan, an inexpensive substance derived from seaweed that is widely used as an additive to foods and cosmetics (for example, to thicken ice cream). Carraguard is a fusion inhibitor. Based on laboratory work, Carraguard is assumed to not be contraceptive.

Invisible condom is a non-toxic polymer-based gel that serves as a barrier against viruses and bacteria.

Lactin vaginal capsules recolonize the vagina with *Lactobacillus* (LB). LB helps keep the vagina free from infection by producing hydrogen peroxide, a highly acidic substance. When the ecology of the vagina is somehow disrupted—through infection, douching or poor hygiene—the LB bacteria can die off, leading to a condition known as bacterial vaginosis (BV). BV has been linked to increased risk of HIV infection.

PMPA gel works in the same way as some of the antiretroviral drugs currently used for therapy; it interrupts the replication of the virus once it enters cells. The hope is that PMPA could be absorbed by cells in the vaginal epithelium and then stop the virus once it enters the outer cells of the vaginal wall. Many antiretroviral drugs that were initially explored as potential AIDS therapies were abandoned because they could not be absorbed easily into the bloodstream; these same compounds might be perfect candidates for a microbicide because they could be applied topically and not absorbed systemically.

Pro-2000 contains a synthetic polymer that binds to the HIV virus, thereby disrupting binding of the virus to target cells. The gel probably works in a similar fashion to block chlamydia and HSV-2 (herpes) infections. Other fusion inhibitors include *Emmelle™*, *cellulose sulfate* and *polystyrene sulfonate*.

Savvy™ is a surfactant that disrupts the outer surface of pathogens. Other such products being explored as potential microbicides include *sodium dodecyl sulfate* (common in shampoos and toothpastes) and benzalkonium chloride (frequently used in contact lens solution to prevent bacteria growth). The surfactant *nonoxynol-9*, the active ingredient in most over-the-counter spermicides, was once explored as a possible microbicide, but has recently been shown to be ineffective.

Annex 3: Who's who in the microbicides field (some of the major entities involved in microbicide advocacy as of 2004)

Please note that this information has been compiled by the Global Campaign for Microbicides to help microbicide advocates develop increased familiarity with the field. It is by no means a complete list of all entities involved in microbicide advocacy and research. Omissions have been made for the sake of brevity and carry no implication about the entities omitted.

Alliance for Microbicide Development (www.microbicide.org)

The alliance is a consortium working to advance the needs and interests of the people (scientists, small biotechs, nonprofit research groups) doing the hard work of developing and testing candidate microbicides. It does this by monitoring developments in the field, facilitating information exchange, collaborating in key advocacy activities and convening policy dialogue on critical scientific and research issues. Through its interactive Web site, product development databases, weekly bulletins, quarterly journal, annual meetings and other information channels, the alliance is a comprehensive neutral resource for discussion, problem-solving and information for microbicide developers, the wider microbicide community and the general public.

Family Health International (www.fhi.org)

FHI is among the largest international public health non-governmental organizations managing research and field activities in more than 70 countries to meet the public health needs of some of the world's most vulnerable people. In addition to serving as the Coordinating and Operations Center for the HIV Prevention Trials Network (HPTN), FHI is also conducting a range of non-HPTN microbicide trials. They include a trial of cellulose sulfate (in collaboration with the Global Microbicides Project) in Nigeria, two trials of Savvy™ to occur in Ghana and Nigeria and a pre-exposure prophylaxis study of Tenofovir (PMPA) in Cameroon, Ghana, Nigeria and Cambodia.

Global Campaign for Microbicides (www.global-campaign.org)

The Global Campaign for Microbicides generates and unifies advocacy efforts to build support among opinion leaders, policy-makers and the general public for increased investment in microbicides and other user-controlled HIV and STD prevention options. Through its 25 partner organizations and 170 endorsing groups, the campaign equips advocates worldwide with a growing body of free resources, training and materials. Supported by campaign subgrants, affiliates in 10 US cities and in Canada, India, South Africa, Uganda, Ireland and the UK work to catalyse local advocacy activities. Under the campaign's umbrella activists, non-governmental organizations and residents of clinical trial site communities are able to mobilize—as empowered civil society actors—to accelerate microbicide development, plan for widespread access and protect the interests of end users throughout the research process.

Global Microbicides Project (www.gmp.org)

The Global Microbicides Project is a project of CONRAD (Contraceptive Research and Development), a programme of the Eastern Virginia Medical School in Norfolk, Virginia, U.S.A. The GMP was established with funding from the Bill & Melinda Gates Foundation to help develop new microbicides that specifically address the needs and perspectives of women. It is now fielding clinical trials on three candidate microbicides: Acidform™, cellulose sulfate (Ushercell™) and polystyrene sulfonate.

HIV Prevention Trials Network (www.hptn.org)

The HPTN is a worldwide collaborative network of clinical trials that develops and tests the safety and efficacy of non-vaccine interventions designed to prevent HIV transmission. Established and funded by the US government, the HPTN supports the efforts of a network of expert scientists and investigators from more than two dozen international sites partnered with US-based institutions. The Microbicide Science Working Group of the HPTN is fielding seven clinical trials involving the following candidate microbicides: BufferGel™, PRO 2000/5™, cellulose sulfate (Ushercell™) and Tenofovir (PMPA). The HPTN is also working with other public health organizations involved in microbicide

research to ensure a uniform approach to protocol development and design.

International Family Health (www.ifh.org.uk)

International Family Health (IFH) was an international non-governmental organization in the United Kingdom dedicated to improving the sexual and reproductive health and rights of disadvantaged people in resource-poor settings. In a project funded by the European Community, the UK Department for International Development and the International Partnership for Microbicides, IFH collaborated with the Global Campaign for Microbicides and other partners on efforts to raise awareness of microbicides among European donors, scientists, industry and regulatory bodies. IFH developed country policy-makers and HIV/AIDS, women's health, international development and other activist organizations in Europe, Africa and Asia. The organization closed in September 2004.

International Partnership for Microbicides (www.ipm-microbicides.org)

The International Partnership for Microbicides (IPM) serves as a “virtual pharmaceutical company” to accelerate product development and testing through milestone-driven agreements with key collaborators. As a public-private partnership the IPM serves as a centralized mechanism for donors to invest in the field. The IPM also finances the development of infrastructure for conducting clinical trials, makes targeted investments to develop resources and technologies that will be shared with the entire field and advances an access agenda to ensure effective microbicides will be made accessible to women at the highest risk in the poorest regions of the world as soon as possible.

Microbicide Development Project (www.mdp.mrc.ac.uk)

The Microbicides Development Programme (MDP) is a five-year research collaboration sponsored by the UK Department of International Development and administered by the Medical Research Council Clinical Trials Unit and Imperial College London. In collaboration with institutions in South Africa, Tanzania, Uganda, Cameroon and Zambia, the MDP is fielding trials of two candidate microbicides—Dextrin-2-Sulfate (Emmelle™) and PRO-2000/5™. The MDP also aims to

develop new products to enter safety studies in the United Kingdom and Africa.

Population Council (www.popcouncil.org)

The Population Council is an international NGO with staff in 18 developing countries dedicated to improving the well-being and reproductive health of current and future generations around the world and to achieving a humane, equitable and sustainable balance between people and resources. Its Contraceptive Development Programme has developed a candidate microbicide, Carraguard™, which is about to enter phase 3 effectiveness trials in South Africa. The Population Council also administers and participates in the Rockefeller-funded Microbicides Basic Science Network, which consists of five scientists charged with working on different but complementary aspects of research to facilitate microbicide development.

The Role of the World Health Organization in the Control of Communicable Diseases¹

5 Chapter

Christopher J.L. Murray

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This contribution discusses the potential of the World Health Organization (WHO) to be an anchor institution for communicable disease control global public goods (GPGs). It identifies six categories critical to this role: research and development of new technologies; multi-country disease control efforts; advocacy for funding and action; developing norms and standards; epidemic surveillance and response; and monitoring disease levels and trends and evaluating what works and what does not. With this framework, the WHO's governance and organization, its strengths and weaknesses and potential solutions to problems are analysed.

Despite needing more resources to better face the challenges of advocacy, norms and standards and epidemic outbreak and response—as well as political pressure that might arise in the event of an epidemic—the WHO is the only organization able to support these GPGs. It is uniquely positioned to lead efforts because of its credibility with ministries of health and potential to recruit highly qualified staff. A critical priority is to stop the trend of increasing shares of the WHO's budget flowing to regional and country offices.

The WHO is not a major funder of research and development (R&D), and its effectiveness in this area can be limited because of its governance and organizational structure. But the success of the Bill & Melinda Gates Foundation demonstrates that research for communicable diseases does not necessarily require the political legitimacy of the WHO. Therefore, new R&D efforts should be made in close partnership with this organization.

The WHO is crucial in leading and catalysing multi-country disease control efforts, as proven by the control programmes for malaria, smallpox, onchocerciasis and polio. At the same time, it can be argued that the organization does not have a strong tradition in implementing communicable disease control programmes at the country level and that partnerships would be more effective at it.

The WHO's headquarters carries out most of the work on global public goods. However its staff is separated into global, regional and national offices. This structure seriously complicates the capacity of the organization to act as one institution for effective delivery of GPGs and creates tension between the centre and the regions, both for duplication and conflict on the creation of some GPGs and for control of resources. The steady increase in the share of the regular budget and, with J.W.Lee's administration, the extrabudgetary funds directed to regional offices threaten the future capacity of headquarters to deliver GPGs effectively.

Finally, in the area of monitoring and evaluation of what works and what does not in communicable disease control, the WHO is structurally limited. The solution proposed here is the creation of an independent organization that would focus mainly on this area of work.

This contribution elaborates on this set of six GPGs; reviews the WHO's basic governance, organization, strengths and weaknesses to provide a basis for analysis; discusses the WHO's potential role with respect to these GPGs; and provides an overall discussion of challenges and potential solutions.

Global public goods for communicable diseases

Several authors have proposed definitions and lists of GPGs associated with communicable diseases (Kremer 2006; Barrett 2006; Smith and others 2003). For the purpose of this evaluation, it is useful to identify six categories of public goods.

- *Research and development.* This can lead to new technologies for disease control, including diagnostics, drugs, vaccines, insecticides and other control methods.
- *Coordinated multi-country control efforts.* These include eradication programmes and efforts requiring multi-state action because of ecological or political reasons—for example, efforts to contain the spread of drug resistance across national borders.
- *Advocacy for funding and action.* The WHO currently plays a major role in these efforts.
- *Developing norms and standards.* The WHO has historically played a critical role in formulating global norms and standards that have been effectively used by many low- and middle-income countries.
- *Epidemic surveillance and response.* The WHO is a critical actor in this area, as shown by efforts to combat the spread of SARS in 2003 and the avian flu (Heymann and Rodier 2001; Enserink 2004).

- *Monitoring and evaluation.* This includes monitoring communicable disease levels and trends and evaluation of what works and what does not in communicable disease control. Structural aspects of the WHO's governance may limit its capacity to support this GPG.

The underlying principle in this analysis is that the benefits (or harm) of these GPGs do not accrue strictly in units within nation states. Many other aspects of communicable disease control may have dimensions that are GPGs. And each of the six categories used in this contribution can be further subdivided. Nevertheless, this framework allows a reasoned assessment of the WHO's capacity to support or deliver these GPGs.

WHO background

Governance

The WHO is a voluntary association of 192 member states. Decision rights are vested in the World Health Assembly (WHA), which meets each year in May, normally in Geneva at the Palais des Nations. Heads of delegations are usually ministers of health or, in some cases, other senior government representatives. Delegations often include ministry of foreign affairs representatives who take the lead on issues of budget or membership. In practice the WHA functions as a political forum that brings to the fore a combination of current technical priorities for ministries of health and issues with a strong geopolitical dimension such as health and trade.

The WHA approves each biennial budget as well as the scale of assessment for member states. Member states with effective delegations can influence the budget and establish clear mandates to pursue certain activities. An example is the series of discussions in the last three assemblies on human resources and the impact of nurse migration, which in Africa has been raised as both a political and a technical issue. The secretariat has responded with a range of programmatic activities. Another example is the passage of the Framework Convention for Tobacco Control after several years of negotiations.

The WHO also has in its constitution an executive board (EB) of 32 member states elected from each region to a three-year term on the board. The EB plays a critical role in governance. It meets every January and just after the WHA in May, and it reviews in much greater detail

the budget and technical work. It also establishes the assembly agenda. Resolutions should in principle go through the board before being discussed at the WHA, but there are mechanisms for introducing them from the floor of the assembly. The power and influence of the EB are also increased because it nominates a new director-general every five years. As illustrated several times in the past 10 years, one member state on the board can substantially influence the technical direction of the WHO. With each new administration, the role of the EB in relation to the secretariat of the WHO evolves. Its potential role in technical oversight has important implications for the WHO's capacity to deliver communicable disease GPGs.

Structure

Counting all types of employment contracts, including national programme officers and local staff, the WHO has about 8,000 staff organized into global, regional and national offices. The WHO's headquarters is in Geneva with about 2,000–3,000 staff on site—the number fluctuates under different administrations and on the basis of extrabudgetary funding. The headquarters undertakes most of the efforts related to global public goods, except for regional and country offices support of communicable disease control efforts such as polio eradication.

A unique and critical aspect of the WHO is its six regional offices, each with an elected regional director. Five regional offices—the European in Copenhagen, the Eastern Mediterranean in Cairo, the African in Brazzaville, the South-East Asian in New Delhi and the Western Pacific in Manila—receive all their funding from the regular WHO budget. The sixth, the American Regional Office, is also the Pan-American Health Organization, which was founded several decades before the WHO. It collects independent funds from its member states in addition to funding received from the regular WHO budget.

Because they are elected by the member states of regional offices, regional directors have an independent power base from the director-general and headquarters. The WHO's capacity to act as a single organization is severely complicated by the regional structure (Godlee 1994). To date, there is little staff rotation across regions or between regions and headquarters. Therefore staff members in regional offices are loyal primarily to the regional director, which strengthens further the independence of the regional offices. The result is often duplication and conflict on the creation of some GPGs. For example, some regional of-

fices have issued technical guidance for communicable disease control that conflicts with guidelines issued by headquarters.

The WHO also has country offices in more than 120 countries. These offices are run by a country representative or liaison officer, and they range from very small units of two to three staff members to much larger offices in countries with substantial extrabudgetary resources. WHO representatives (WRs) are selected by the director-general in consultation with the regional director and the national government. Recently, headquarters has been trying to have more influence on the selection of WHO representatives, but has had varying success.

Compared with the United Nations Children's Fund (UNICEF) or the United Nations Development Programme (UNDP), the WHO does not have a strong history of programme implementation in developing countries through its country offices. Most efforts of the WRs and their staff have been focused on advocacy and technical advice. The country office annual budget cycle is often managed closely with the ministry of health, so some ministers view the budget as under their direct control. This means that the WHO is a trusted adviser to the minister, but also that it can be extremely difficult for the country office to have independence or distance from the minister or ministry.

Budget

The approved biennial budget for 2006–07 is \$995,315,000 from the regular budget, based on assessed contributions from member states. The scale of assessment generally follows the UN scale; although in the 2002–03 biennium, the scale of assessment was highly controversial and the subject of intense conflict between the Group of 77 and the West (WHO 2003). The second half of the budget comes from voluntary contributions of member states, foundations and private companies. The bulk of these extrabudgetary funds comes from bilateral aid agencies in the main Western powers. For 2006–07, an extrabudgetary budget of \$2,398,126,000 was estimated (WHO 2006). Given that contributions have been substantially below expectations, the total extrabudgetary resources are likely to be smaller.

Traditionally, the executive board and WHA oversee the regular budget. The majority of funds went to costs for staff with fixed-term posts. The executive board and WHA had little oversight over the extrabudgetary funds that pay for most of the WHO activity streams. This situation has been evolving. Under the Brundtland administration there

was an explicit attempt to present to the governing bodies an integrated budget of regular and extrabudgetary resources. This increased transparency has led to more demands from regional offices for control of a larger share of resources. The following director-general, J.W. Lee, committed to increasing the share of both regular and extrabudgetary resources that would be controlled by regional offices (Kapp 2003). This change in how resources are allocated and controlled has profound implications for the potential effectiveness of the WHO in delivering or supporting GPGs for communicable diseases.

Strengths and weaknesses

As a global health institution, the WHO has tremendous strengths and some weaknesses. First, it has extremely high credibility with ministries of health. The source of this credibility is in part related to its democratic governance and close relationship at the country level. Most developing countries see it as their organization, thus technical norms and standards, advocacy and programme guidance have immediate credibility. Technical and political legitimacy have been fostered over the past decades by the secretariat's efforts to base technical recommendations and programme initiatives on sound science with a reasonable degree of support from the academic community. As health has occupied an increasingly important role in development dialogue, there has also been increased controversy over many WHO recommendations. Debates about tobacco control, diet and chronic disease, health systems performance and primary treatment of clinical malaria are just a few examples of increased discussion and response to WHO efforts (Muggli and Hurt 2003; Boseley 2003; Ndiaye and others 2004; Navarro 2001). It is unclear how these debates will ultimately affect the WHO's technical credibility.

Second, as a corollary to its political legitimacy and technical credibility, the WHO has the capacity to recruit the best individuals from around the world. But this has not always been used effectively. In fact there is a fundamental tension for human resource development between global normative work and country implementation. The global normative roles such as research and development, epidemic surveillance and response, monitoring and evaluation and advocacy often require the expertise of individuals who have already developed the necessary skills in their national contexts or in the research community. An organization that is effective at country implementation may need to recruit cohorts of public health professionals

at a younger age and create a range of experiences in different field conditions as part of career development. Combining these needs into one coherent recruitment strategy is a major challenge that has not been resolved.

Third, regional and country offices could be an important asset, but in practice they often decrease the WHO's effectiveness in some regions (Peabody 1995). A good regional office enhances the effective delivery of GPGs, but a poorly led and disorganized regional office has the opposite effect. In addition, a poorly run regional office can lead to a high level of politicization of strictly technical decisions. Many administrations have tried to explore options to increase the effectiveness of the regional offices, but have had little success. Over the past three decades there has been a steady increase in the share of regular budget resources allocated to regional and country offices. Under J.W. Lee's administration there were efforts to formalize the share of resources going to regional and country offices as well. The steady reduction of the budget spent in headquarters over time seriously threatens the WHO's capacity to deliver GPGs.

Fourth, the WHO has less legitimacy and credibility in high-income countries than in developing countries. This is particularly true for the United States and Canada and to a lesser extent for Western Europe. Its main influence in these countries is on the development community. This can be a weakness in leading efforts for setting research and development agendas or evaluating what works and what does not. The WHO's lower profile in Organisation for Economic Co-operation and Development (OECD) countries does not have a structural cause but may simply be a reflection of the main thrust of its work over the past 50 years. As the epidemiological profiles of developing and developed countries converge, WHO norms and standards would naturally be relevant to all nations. Enhancing the organization's credibility in high-income countries is a major challenge for the future.

Fifth, the WHO's heavy dependence on extrabudgetary funds from a handful of bilateral agencies means that these agencies have a great deal of influence on political and technical decision-making at the organization. This has not historically been a major problem, but such financial dependence creates the possibility of exaggerated influence.

Sixth, because of its governance, it is difficult for the WHO to criticize or act against the interests of the government of an influential member state. This means that taking actions necessary to support GPGs which may not benefit such member states can be difficult. This problem has

critical implications for epidemic surveillance and response and for global monitoring and evaluation. Both of these activities can have immediate or long-term political consequences in member states (Brown 2004).

Relationships with other agencies

Over the past 15 years there has been a dramatic growth in the number and importance of other organizations, initiatives and partnerships active in global health. In the 1980s UNICEF and the World Bank emerged as major actors. At the country level UNICEF became the dominant health implementation agency in the UN family. By adding health sector loans to its portfolio, the World Bank began to have substantial policy influence in low- and middle-income countries. This decreased the WHO's influence, particularly in such areas as health finance.

Recent global health initiatives and partnerships include such major institutions as the Global Alliance for Vaccines and Immunization (GAVI) or the Global Fund to Fight AIDS, Tuberculosis and Malaria, among almost 50 other efforts for different diseases and programmes. Two types of responses are now emerging to this change in the global health architecture. First, as health is becoming the largest segment of the global economy, it is natural and inevitable that the global architecture will become much more pluralistic. This can be viewed as good for global health, preventing concerted global action from becoming captive to any one organization. The alternative view is that the transaction costs of running so many partnerships are extremely high. At present there is a real sense of donor fatigue with new initiatives and partnerships. In addition, some argue that the position of the WHO is being progressively eroded by their rise.

Both views may be fundamentally correct. Many global health initiatives and partnerships are likely to stay, and new ones may emerge. Likewise, there may be a move towards fewer, more clearly defined roles so that duplication is reduced. To survive as an effective organization the WHO must navigate this complex territory and focus on areas where it has a strong comparative advantage.

Research and development

The WHO is not a major funder of R&D. Many technical programmes support small research projects and policy analyses, but financially significant efforts to support communicable disease research are largely restricted to three major undertakings: the Special Programme for Research and Training in Tropical Diseases (TDR), the Special Programme of Research, Development and Research Training in Human Reproduction (HRP) and the research policy group. The WHO's performance in supporting R&D is mixed.

Both the TDR and HRP have been successful in raising funds and supporting research in underfunded areas. They have been able to leverage their small resources to have significant influence on research agendas. The TDR in particular—and to some extent the HRP—has been dwarfed in recent years by the activities of the Bill & Melinda Gates Foundation. The latter's success in shifting the attention of the biomedical research community to certain high-burden diseases indicates that one of the major limitations of R&D has been resources (McCarthy 2004). Its success also shows that efforts to foster R&D for communicable diseases do not necessarily require the political legitimacy of the WHO (Butler 2004).

It is interesting to note that some commentators believe the success of the TDR and HRP has been in part because they have had some autonomy through the governance mechanisms created for special programmes. Independent donor forums and scientific advisory bodies have allowed them to work directly with researchers in developing and developed countries without having to route resources through regional and country offices. One interpretation is that they have tried to leverage the legitimacy of the WHO, but have opted for alternative governance structures. They demonstrate that such organizational hybrids can succeed, although the transaction costs can be rather high both financially and politically.

These programmes have at various phases of their history been criticized for having no relationship to WHO staff, which leads to duplication of efforts. Several institutional solutions have been attempted in recent years. Relevant for this discussion is that it may be difficult to maintain a divide between staff working on funding R&D and staff advising countries on solutions. Integrating these functions brings other complications. It may be increasingly difficult to have independence and perspective on R&D funding if one is also heavily engaged in country implementation.

The WHO's health research policy group has increased its advocacy efforts at the global and national levels. In November 2004 it released a report at the Mexican Summit on Health Research. Such efforts have increased the profile of health research, but it is too early to tell if there will be any lasting effect on investments.

If there is consensus among donor countries that there should be increased investment in R&D, what should be the role of the WHO? While this is a complex subject with much written about different options (Currat 2002; TDR 2003), one conclusion appears to be clear: regular organizational mechanisms are ill suited for funding R&D because of the potential for political influence on decision-making. On the other hand, with sufficient resources, affiliated institutional arrangements such as the TDR or HRP can effectively harness the legitimacy of the WHO. The main problem with these efforts is the high transaction cost. If an affiliated organization is to play a role in communicable disease R&D, then there are economies of scale that should be considered.

Multi-country disease control programmes

The WHO has at various times led a number of major multi-country disease control efforts (Bruce-Chwatt 1987; Hopkins 1988; Thylefors 2004). The most notable are the unsuccessful malaria eradication efforts in the 1960s, the successful smallpox eradication programme in the 1970s and the ongoing Onchocerciasis Control Programme and polio eradication efforts. The failure with malaria and the success with smallpox provide important insights into technical and political challenges of these efforts. All four cases illustrate that the WHO has a unique capacity to galvanize and lead multi-country efforts. Successful efforts have used the organization to establish the legitimacy of the overall goal, convene the world's scientific community to develop a consensus-based strategy, advocate for funding and political action by member states and, in some cases, coordinate action and implementation.

How much should the WHO be involved in programme implementation at the country level? Unlike UNICEF, the WHO does not have staff recruitment or development that emphasize the skills set required to be effective at country programme implementation. It does not have a strong tradition or reputation of programme implementation at the country level. Nevertheless, for polio eradication, the WHO has

taken on large numbers of national programme staff using extrabudgetary resources. An important issue for future investments in multi-country communicable disease control programmes is the extent to which the WHO should implement them at the country level. The current emphasis on delivering antiretrovirals for HIV has increased the WHO's efforts at supporting country implementation. It is too early to evaluate whether the organization has increased its capacity to implement programmes at the country level.

No other institution is positioned to globally take on the critical functions of advocacy, setting technical norms and standards and coordinating action. And it is difficult to imagine future efforts requiring multi-state coordinated action without the WHO playing a critical anchor role. However implementation at the country level should probably be undertaken by other partners or networks.

Advocacy

The WHO is in a unique position to provide the world with advocacy material on the magnitude of communicable disease problems and the potential to act on them. Its combination of political legitimacy and technical credibility means that it can effectively reach the media and scientific journals. Because most advocacy material is not country specific but often presented for groups of countries, there is less potential for political pressure from member states or other organizations to influence content.

The main issue for the WHO in pursuing effective advocacy is not to stray from the available scientific evidence and undermine its own technical credibility. This is fundamentally an issue of leadership, which must continue to reinforce the underlying culture of science so that it is unacceptable for advocacy material produced by the WHO to stray far from legitimate scientific underpinnings.

In the early 1990s the Global Burden of Disease Study was initiated in part because the sum of deaths claimed by different WHO technical programmes exceeded the total number of deaths in the world by severalfold (Murray and Lopez 1996a). As part of the effort to create a unified set of epidemiological assessments of mortality and disability, the intense pressure on technical programmes to keep their figures as large as possible was evident. Crudely, the larger the problem, the more money from donors. The study published in 1996 set new benchmarks

for internal consistency, comparability and comprehensiveness of epidemiological information (Murray and Lopez 1996b).

During the period 1998–2003 the Global Burden of Disease approach to producing coherent epidemiological information was institutionalized in the WHO. Given the importance of figures for advocacy, technical programmes would exert intense competitive pressure on the Epidemiology and Burden of Disease Team charged with bringing together annual assessments. These pressures were withstood because of the strong commitment of the senior management to provide valid, reliable and comparable information. This process, while imperfect, meant that internally consistent, comparable and comprehensive information on incidence, prevalence, mortality and disabling sequelae by age and sex for 14 epidemiological subregions was published each year. Over the period 2003–05 the team has been reduced from 22 staff members to 2, and it appears unlikely that the WHO will continue to produce such information.

The danger of not basing WHO advocacy work on sound evidence is not a structural problem. One solution is to call on the leadership to ground its advocacy work on sound science and to raise the standard of transparency in how advocacy work is undertaken. A telling illustration of this problem is the ongoing debate on the various efforts to develop cost estimates for the global response to HIV/AIDS, tuberculosis and malaria. The expansion of coverage of such interventions as antiretrovirals has been much slower than hoped for. Nevertheless, advocacy figures for funds required in the next two to three years have not been revised to account for this. If there are open public calls for more transparency and sound science in the advocacy work, WHO leadership is likely to respond in a constructive manner.

Norms and standards

A critical function of the WHO is establishing norms and standards for a range of health-related activities—diagnosis, treatment, prevention, surveillance and health information. As shown by such efforts as the International Classification of Diseases and Injuries and the Essential Drugs List, the WHO can be highly effective in setting widely used international norms and standards. It has the attributes that are necessary for such a function: political legitimacy and the capacity to convene the scientific community. As norms and standards take on more political significance—for example, in food safety through the Codex Alimen-

tarius—there has been increased discussion in the executive board on how experts are selected and the procedural rules for development.

There has been increased concern over the balance of power between the secretariat, member states and expert advisers in establishing science-based guidelines (such as the controversies around hypertension management guidelines). The role of networks like the Cochrane Collaboration in providing the GPG of summary information on the available intervention trials has raised issues about the unique role of the WHO. When it sets norms and standards, many countries automatically pay attention. This reality, however, does not indicate what should be its role in setting norms and standards vis-à-vis networks or other global coalitions. It seems reasonable to argue that the WHO should remain the primary standard setter for most areas of health, but that it should pursue this role in a highly transparent fashion and engage as partners existing and future networks in the background analytical work required for setting standards.

Epidemic surveillance and response

Epidemic surveillance and response—detecting, reporting and responding to epidemics—is a classic GPG because of the obvious potential of epidemics to spread across national borders. Controlling the spread of epidemics has an extremely long history in public health action. In fact quarantine has been one of the organizing principles of global health action for more than one century. But during much of the twentieth century the incidence of major epidemics declined. Vital registration data available for high-income countries and some middle-income countries demonstrated a major reduction in mortality from epidemics after the 1950s. In the past 20 years, however, communicable disease epidemics have returned to centre stage (Piot 2000; Kaiser 2004; Feldmann and others 2004).

Recent experience with epidemics includes HIV/AIDS, cholera, ebola, SARS and avian flu. From a GPG perspective, however, it is important to distinguish rapidly progressing epidemics from those that unfold over years, such as HIV/AIDS and tuberculosis. The pace of transmission and development matters because it dictates the urgency of response. Does action in the first days, weeks or months dramatically alter the course of the epidemic? If it does, then the response must have particular attributes. In the rest of this discussion, we focus

on rapidly progressing epidemics that require immediate detection and response. Slower epidemics are addressed in the section on monitoring and evaluation.

Given the centrality of rapidly progressing epidemics to the history of public health, it is not surprising that the WHO has long had a role in detection and response. The importance of this role has increased as the risk of inter-state transmission has increased due to globalization. More travel and communication means that epidemics more likely spread faster and are more likely to be detected. In the 1980s and 1990s the WHO increased its capacity for epidemic detection and response (WHO 1995). This was seen as legitimate and consistent with its constitutional mandate.

Epidemic detection and response requires four critical components: access to information on outbreaks, laboratory capacity to characterize the outbreak, ability to respond to outbreaks, and authority and capacity to take inter-state actions. Each of these factors has both resource implications and institutional/governance issues which are addressed below.

Information. Because outbreaks can lead to immediate economic consequences such as reduced tourism or even total travel bans, there are rather powerful incentives for national authorities to delay or refrain from reporting outbreaks to the WHO. National authorities may also fail to report outbreaks because of breakdowns in the flow of information from peripheral facilities to the central government or because most countries do not collect any case reports from private sector providers. The WHO has long recognized this reality and has developed methods to collect information from non-governmental sources. Nearly half the possible outbreaks reported to the organization come from these sources. The WHO uses software to scan local media for articles on outbreaks and also receives potential outbreak information through the Internet. This global surveillance strategy was adopted by the WHO's Global Outbreak Alert and Response Network established in 1998. Although some national authorities are unhappy that the organization uses these non-official sources, with the approval of the new International Health Regulations (IHRs) by the World Health Assembly in May 2005, the WHO's legal authority to continue this approach was firmly established. Because many outbreak reports are picked up from local media reports and not national governments (Heymann and Rodier 2001; Enserink 2004) and because of the intense media focus on outbreaks, the time available for political pressure on WHO leadership is much shorter, making it more difficult for countries to influence

reporting. It seems that the WHO can, especially with the revised and strengthened IHRs, fulfil the need for global outbreak reporting.

Laboratory capacity. Outbreak investigation and pathological agent identification require the support of an effective laboratory network. The WHO has with partners supported such a development, but new investments are urgently needed in many countries and regions. Some bilateral efforts such as those funded by the US Centers for Disease Control may strengthen laboratory capacity in selected countries. In addition, new investments will be needed.

Response. Effective detection and response requires an appropriate global, regional and national capacity (Heymann 2004). Having identified a potential outbreak, an outbreak response team needs to be mobilized with a short turnaround. There appear to be few structural or political limitations for this within the WHO or the networks it coordinates. The main limitation is resources.

Authority. The legal authority and effective leadership for the WHO to take inter-state action is perhaps the most complex component. In some cases the organization needs to issue travel bans or invoke quarantine. It may need to allocate stockpiles of vaccines. These critical actions entail major political risks to WHO leadership. If a powerful country is affected, the director-general can face intense pressure not to take action or to reverse action already taken.

Given its governance, can we expect the WHO to withstand political pressure at critical junctures? The experience of the SARS epidemic in 2003 illustrates that the organization can act decisively and take actions resisted by powerful countries such as China and Canada. When it issued recommendations against travel in these two countries, both lobbied hard against the measure. In subsequent negotiations on the IHRs some representatives of China sought to curtail the WHO's right to take such action. A US comment on the first draft of the proposed revision of the IHRs states: "We are concerned that any provision that purports to authorize the WHO to conduct on-the-spot studies in a member state in the absence of a member state's request and/or requires that a member state 'collaborate with the WHO in assessing the severity of the threat' in-country, in the absence of an invitation to the WHO, is an infringement on that member state's sovereign prerogatives." ("Second US government comments on the first draft of the proposed revision of the IHRs," 27 April 2004.)

Two factors meant that the WHO was effective in the SARS case. First, strong leadership of the organization meant that it was willing to

take political risks in the interest of the public good. Second, the intense media focus on the SARS epidemic meant that in the short to medium term it would be hard for a country to resist the WHO's efforts or to take too strong a retaliatory action against its leadership. For these reasons it appears that the WHO can be an effective organization in the future in leading outbreak detection and response in a world of increasing transparency and accountability.

The decade-long revision of the IHRs culminated with the adoption of the new regulations by the World Health Assembly on 23 May 2005. With the purpose and scope of the new IHRs "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade" (article 2), the WHO's legal basis for action is strengthened, and its capacity to resist political pressure is enhanced. Using a "decision instrument" each state party has to determine if an event in its territory could potentially "constitute a public health emergency of international concern" (article 6) and has to inform the WHO of this event. In addition, the revised regulations permit the WHO to "take into account reports from sources other than notifications or consultations" with a given state party and then request verification of this information by that state party (articles 9.1 and 10.1), while having the right to also "communicate information to other states parties that might help them in preventing the occurrence of similar incidents" (article 11). It is finally the director-general's responsibility to decide if a disease event reported by a state party is an international public health emergency and, if yes, to issue recommendations on the measures to be taken in response (article 15). As Fidler and Gostin point out, the new IHRs "establish important new powers for the WHO" (2006), and, although the implementation of the regulations may face financial and state compliance difficulties, they have the potential to successfully guide global health governance for prevention of the international spread of diseases. The reality is that for epidemic detection and response, there is no effective alternative to the WHO. No other organization could possibly have the legitimacy or credibility to take necessary inter-state actions.

Monitoring and evaluation

Sound information on financial and human resources invested in health, health interventions delivered to those in need and the impact of these efforts on population health is critical for monitoring progress and evaluating what works and what does not.² Although all countries devote substantial efforts to collecting a wide range of health information through registries, surveys and vital registration systems, huge gaps hinder our ability to respond to global health challenges. At a time when global investments in HIV/AIDS, tuberculosis and malaria are increasing, and when there is renewed focus on health goals as exemplified by the UN Millennium Declaration (UNDP 2003), the extraordinary gaps in critical health information are alarming.

The availability of valid, reliable and comparable health information to inform local, regional, national and global decisions can be increased through four interconnected efforts:

- Improve the technology and methods for population health measurement.
- Strengthen national capacity and motivating governments to collect and analyse useful data.
- Establish global norms and standards for core measurements and how to measure them.
- Report valid, reliable and comparable assessments of inputs, service delivery and achievements.

While there are many challenges and initiatives under way for the first three components, the fourth is currently the weakest—and getting worse.

Technology and methods of health measurement

For a number of critical measures of health, health intervention delivery and resources for health systems—including many identified in the Millennium Development Goals—the current measurement technology is inadequate. For example, in settings where vital registration is incomplete or non-existent, survey methods have been developed to measure child mortality through household surveys (Boerma and Sommerfelt 1993). These methods have been validated (Hill and Brass 1992) and are widely applied in the Demographic and Health Surveys (USAID and Macro International) and other survey programmes. Despite intense focus on diseases that kill adults in poor countries, particu-

larly AIDS and tuberculosis, there is no adequate method to measure adult mortality in these settings (Gakidou, Hogan and Lopez 2004). While antibody tests for HIV/AIDS mean that population prevalence of infection can be ascertained from sample surveys (Boerma, Ghys and Walker 2003), affordable and feasible methods are not yet available to assess tuberculosis in a community. Advances in immunology, proteomics, genomics, metabolomics, survey science and statistical methods hold out the prospect of new technologies and methods coming on line in the next decade that will dramatically improve our ability to monitor population health. Recognizing this potential, the Bill & Melinda Gates Foundation included technology for population health measurement in its Grand Challenges competition (Varmus and others 2003). This is an important step, but further investments in developing effective and affordable technologies and methods will likely be needed.

Strengthening national capacity and commitment to collect and analyse health data

In the long run, strengthening national capacity to collect and analyse data is essential. The development of vital event registration in developed countries is an example of the slow progress of health measurement. While there have been intense efforts to strengthen data collection for particular vertical disease programmes such as polio eradication (Heymann and Aylward 2004) or selected sentinel communities (INDEPTH Network 2002), there has been slow progress in low-income and many middle-income countries. An exception is the Thai Health Promotion Foundation, where a 2% excise tax on tobacco and alcohol funds a major programme for improving the national health information system. Investments and technical assistance efforts to build national health information capacity have continued over the past 30–40 years with only limited success (Cash and Narasimhan 2000; Malison and others 2000).

Efforts may be invigorated by the leading institutions, including the WHO, UNICEF, the World Bank, bilateral donor agencies and the Bill & Melinda Gates Foundation, which have created the Health Metrics Network to catalyse the development of health information systems in developing countries. In current plans, they will focus on capacity building in some five to seven countries a year. The WHO, along with other partners, must lead in providing technical assistance and guidance. Strengthening national health information systems, however, will

require sustained long-term government commitment and substantial external resources. Progress is impeded by the difficulty of demonstrating that the currently weak systems have occasionally generated useful data for decision-making. Our experience has been that enhanced global reporting will increase government commitment to collect high-quality data.

Norms and standards

Global norms and standards must be established on key indicators for different health programmes and for health systems overall; the best measurement methods for these indicators given current technology and analytical methods; and standardized definitions and classification systems. As shown by the *International Classification of Diseases and Injuries* over the past 50 years, the WHO can play a powerful role in this area (WHO 1992). For both overall health statistics and many disease-specific or risk factor-specific areas, it can and should remain the leading institution. Its potential role, however, depends critically on maintaining—and in some cases expanding—resources for this type of work. Given Lee's administration's shift away from work on global norms and standards to country implementation (Lee 2003), the WHO's leadership in this area may be undermined. If the organization continues to withdraw from this area, other institutions will need to fill the void.

Global reporting

Critical to health information having local, national or global effects is the creation and dissemination of gold standard information on key indicators of inputs, achievements and impacts of health interventions. Reporting information that is valid, reliable and can be meaningfully benchmarked is essential for monitoring progress and evaluating what works and what does not. In fact, unless health information is disseminated through multiple channels—including the media, scientific journals and other documents to the public, the scientific and public health community and decision-makers—it more often than not remains unused in statistical abstracts or spreadsheets in ministries of health.

Because it is the leading agency in the UN system working on health and because in many cases there is no credible alternative, the WHO is the major actor in global health reporting. In some cases it reports in partnership with UNICEF or the Joint United Nations Pro-

gramme on HIV/AIDS (UNAIDS), but at present there is a default expectation that it should report gold standard information to the world. However, due to its many other roles in global health, the WHO is not well suited as an institution for this crucial role.

Over time and across technical areas, the WHO's performance in global reporting has varied tremendously. For example, in the last six *World Health Reports*, it has made systematic efforts to collate and analyse all available data sets on child and adult mortality (WHO 2000–2006) and has published abridged life tables for all countries (Lopez and others 2002). In contrast, for one of the Millennium Development Goal indicators, the prevalence of malaria, it simply reports country statistics irrespective of a wide range of known biases. For example, Nigeria reports a rate of 30 cases per 100,000 people per year, while Guatemala reports 386 per 100,000. The fluctuation in resources committed to global reporting and achievement in this area can be traced to many factors. But at a more fundamental level there is an essential flaw in the architecture of global institutions regarding monitoring and evaluation that must be addressed. The rest of this contribution identifies the core reasons for this problem and potential solutions. Addressing the problems with global reporting will also fuel greater country commitment to strengthening national health information systems.

Advocacy, technical assistance, monitoring and evaluation

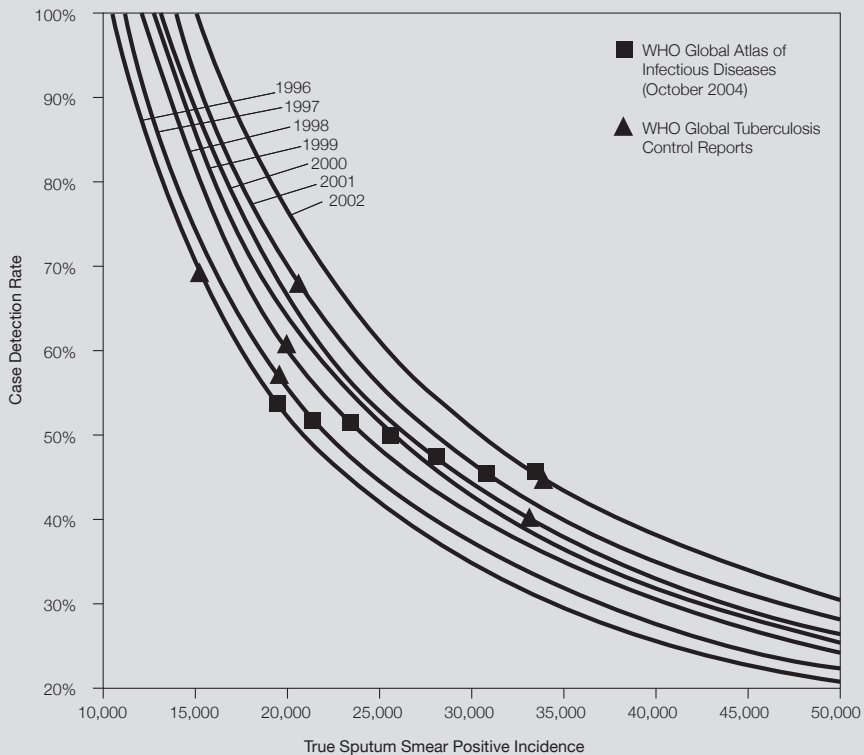
The WHO very often finds itself in the multiple roles of global advocate, provider of technical assistance to countries, monitor of progress towards targets and evaluator of what works and what does not. The same cluster or department serves as prosecuting attorney, judge and jury. The commitment and dedication of staff working in the technical departments is unquestionable. The problem is that staff members inevitably feel the tension between advocacy, monitoring and evaluation. In other arenas such as business, it would be unthinkable to ask a company to audit itself.

The WHO's tuberculosis programme provides an example of the inevitable tensions of an organization simultaneously developing advocacy material, providing countries with technical assistance, monitoring progress towards the global targets and evaluating its own DOTS strategy. Direct measurements of tuberculosis in populations come from four potential sources: registered tuberculosis deaths, notified new cases

of tuberculosis, purified protein derivative (PPD) skin testing of BCG scar-negative children and sputum prevalence surveys. For most low-income countries, the only source is case notifications. The WHO has worked carefully to estimate true incident cases from case notifications (Corbett and others 2003; Raviglione 2003). Such estimates are useful for planning purposes, but should not be used for monitoring progress or evaluating the DOTS strategy. In many countries case notifications are being used both to calculate the numerator of the case detection rate and to estimate the denominator. Trends in the case detection rate (CDR) (one of two key indicators for tuberculosis programmes) are derived exclusively from changes in the assumptions.

Figure 5.1 illustrates, by using isoquants, all possible combinations of true incidence and case detection rates that are consistent with the

Figure 5.1 **The relationship between case detection rate and true incidence, Mozambique, 1996–2002**



Note: Isoquants represent all possible combinations of true incidence and case detection rates that are consistent with the number of notified smear-positive cases for each year.

Source: WHO. 2004. "Global Atlas of Infectious Diseases." See www.who.int/globalatlas/; and WHO. 2002. "Global Tuberculosis Control Reports." Geneva: World Health Organization.

number of notified smear-positive cases for each year for the period 1996–2002 in Mozambique. The choice of a unique combination of true incidence and CDR from each year's isoquant is completely arbitrary. The WHO has a set of (unrevealed) assumptions on which it bases the CDR for each year. As estimates for a given year are arbitrary there is no empirical basis to derive estimates of trends over time—the isoquants in figure 5.1 are consistent with increasing or decreasing trends in CDR, and no information is available on the true trend. It should also be noted that the WHO's guesses of the CDR and true incidence for the same year differ in the *Global Tuberculosis Reports* and on their Web site (WHO 2005). Serial guessing is not a sound basis for monitoring progress towards a global target of 70% case detection. Because of the pressure of being the global advocate for tuberculosis control, the WHO's TB programme cannot and does not draw attention to the fact that it has essentially no empirical basis to assess the trend in case detection in regions where tuberculosis is most prevalent, including Sub-Saharan Africa.

National politics and performance-related disbursements

Because of the nature of the WHO's governance discussed above, if a powerful country disputes country-specific figures produced by the WHO, it can pressure the organization to change the data. Senior UN officials recognize this problem.

A standard compromise used in the United Nations, including the WHO, is to report regional figures that have been carefully analysed and corrected for known biases and national figures that simply regurgitate those sent by member states. This situation produces many bizarre results. For example, regional totals of disease incidence or cases put on treatment often do not equal the sum of published country-specific figures. Another example is the publication of nonsensical figures. The WHO reports case detection rates for smear-positive tuberculosis of more than 100% for Oman, Chile, Honduras and Algeria, among others (WHO 2005). The obvious question: how can we believe any of the national figures published for case detection if rates greater than 100% are accepted without scrutiny?

As novel institutions such as the Global Alliance for Vaccines and Immunizations (GAVI) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) propose to link disbursements to achievements in intervention delivery, the pressure at the national level to provide biased data will intensify. Even before GAVI was created there was no

relationship between reported changes in immunization coverage and changes as measured through household surveys (Murray and others 2003). GAVI recognizes the potential problem of providing performance-related disbursements and asking grantees if they have achieved their targets (GAVI 2004). Its Data Quality Audits (LATH Consortium 2001) demonstrate profound problems and opportunities for distortion. Still there is no independent assessment of vaccine coverage. The same problems will inevitably apply to Global Fund investments.

Country pressure on WHO leadership means that there is always the possibility of monitoring and evaluation being politically influenced. Although it may be able to resist political pressures for brief periods, the WHO might cave in the long run. However, for monitoring inputs to health systems, delivering health interventions and making progress on overall health, the dynamics are different. As the time frame is longer, the potential for data manipulation is much greater.

A strong leader can withstand outside pressure, but the WHO might not always have leadership willing to take on this challenge. We should recognize the organization's importance in building national capacity for health information, establishing norms and standards for measurement and setting agendas for R&D on new technologies and methods. At the same time we have to recognize that the WHO is ill suited for the role of global monitoring and evaluation of health.

Potential solutions

It seems clear that to sustain increased investments in global health, gold standard information is essential. In the long run gold standard information will require better measurement methods and technologies, strengthened capacity in developing countries, and global norms and standards. To fulfil the need in the near term and to fuel government commitment to better health information in the long run, the institutional problems of global reporting by the WHO and other UN agencies must be solved.

The need for independence in monitoring and evaluation is not new. The same issue emerges for national governments. Many different solutions have been developed in various countries. Most have involved creating semi-autonomous government institutions with independent boards and fixed terms for directors. A characteristic of mature democracies has been to sustain investments in these independent entities. The diversity of national experience also demonstrates that effective moni-

toring and evaluation requires reliable resources, a stable institutional environment and considerable autonomy.

At the international level, both the World Bank and the International Monetary Fund have independent arms that evaluate internal activities and directly report to boards. For monitoring and evaluation of their member states' development progress, these functions have not been as insulated. In these organizations, however, single member states, particularly developing countries, have much less capacity to influence leadership. This distinction is largely because of the nature of the governance of these organizations, which is not one nation one vote. Rather there are small boards with dominant permanent members that reflect financial contributions to the organizations.

In response to criticism of its educational statistics, the United Nations Educational, Scientific and Cultural Organization (UNESCO) chose to create the independent UNESCO Institute for Statistics (UIS) to meet the need for "a wider range of policy-relevant, timely and reliable statistics in the fields of education, science and technology, culture and communication" (UIS mission, www.uis.unesco.org). Twelve international statistical experts comprise the UIS governing board, which is charged with approving the institute's yearly programme and budget, its functions, as well as monitoring, evaluation and control of its operations. As such, it is an affiliated institution that has been designed to have functional autonomy from the rest of UNESCO. Despite the institute's mission, it is not clear that it has successfully increased the quality and availability of educational statistics.

The range of national and international models suggests several options for enhancing the global institutional architecture for health monitoring and evaluation. First, the WHO could create an autonomous division whose head reports directly to the executive board, not the director-general. This division would also need to have a separate budget line and would probably require a constitutional amendment. Such an arrangement would secure some independence from country political pressure. Even in the unlikely event that it were voted by the WHA, this solution still has considerable risks. The staff in this division might have the reasonable expectation to rotate to other parts of the WHO in the future. This will make it likely that, if pressured, they would not want to do anything that the director-general was against. Countries that were not pleased with information on monitoring and evaluation could attempt to reduce or eliminate this division's budget during the biennial budget cycle.

Second, an affiliated entity in the model of a special programme like the TDR or HRP could be created. In this model there would be an independent board that would choose a director—or at least be consulted in the selection of one. Such affiliated models, as noted above, have been successful in reducing some centre-region tensions and political interference. However these affiliated models have not been successfully used in circumstances directly affecting member states' ministers or ministries of health. Given that the WHO has extensive mechanisms to control staff movement and behaviour even when the staff members work for affiliated entities, this model is unlikely to work effectively.

The only viable solution will be to create a new independent health monitoring organization. The objective of this body would be to regularly report on spending on health, delivery of services and the impact of these efforts on population health. This would be a small organization, its main role to collate, analyse and disseminate the best available evidence. Much of this work would be in close partnership with various actors such as WHO technical programmes, GAVI and the Global Fund. To be effective the organization would need to be sheltered from advocacy on the one hand and from political interference on the other.

Those familiar with the complex governance issues that such new entities face will recognize that solving the governance and financing issues for this organization will not be an easy task. But it can be done. Success of such an organization would depend on three key factors. First, all representatives from the key stakeholders in global reporting would need to have a voice in the governance of this effort. Key stakeholders would include national governments, multilateral institutions (WHO, UNICEF, UNAIDS, UNDP, World Bank, EU and others), bilateral donor agencies, a range of non-governmental organizations and the research community.

Second, to be effective such a health monitoring organization would have to be committed to the principles of validity, reliability, comparability, an explicit data audit trail and open consultation. As health information reaches a wider audience and touches on issues salient to everyone's life, scrutiny will intensify. The debates around the publication of the *World Health Report 2000* and the subsequent recommendations of the Scientific Peer Review Group highlight the importance of total transparency in the process of measurement (Almeida and others 2001; Williams 2001; Anand and others 2003).

Validity and reliability are familiar concepts in health measurement. Comparability means that results should be reported in a way that al-

allows meaningful comparisons to be made between countries and over time. Committing to an explicit data audit trail is costly but essential. This means that every step in the development of a figure should be made publicly available, including primary data, all calculations to correct for known biases and appropriate commentary. The extraordinary commitment of the Human Genome Project to put all primary data in the public domain with effectively no time lag is a model to follow. Open consultation means that both governments and the scientific community at large should be able to comment and critique published figures. Fostering healthy debate on measurements will lead to better data collection and analysis.

Third, an independent monitoring organization—while it could be a relatively small undertaking of the order of \$50–70 million a year—would require stable core resources. Securing the right combination of governance and resources is the main challenge for creating such an organization. Without them, any organization, regardless of governance structure, could be captured by its soft money funders. A number of financing models are possible, ranging from endowment to assessed contributions from entities that would benefit from the dissemination of gold standard information, to revenue-generating services such as accreditation of figures.

In an era when the credibility of global health organizations is under attack, providing the public with credible, clear and comparable health information will strengthen the commitment and resolution to scale up global health efforts. At the Bangkok AIDS Conference in July 2004, a journalist asked whether WHO figures on antiretroviral delivery were “Enron-like” (Naik 2002). While such accusations are clearly unfair, it is in the best interest of the WHO and the global community to invest in rock-solid independent monitoring and reporting of global health.

Discussion

The WHO’s main asset as an anchor institution for communicable disease GPGs is its political legitimacy and capacity to convene the scientific community. For each of the six GPGs analysed in this contribution, there is a spectrum of possibilities for the WHO. For advocacy, norms and standards, and epidemic outbreak and response, it appears to be well positioned to take the lead. The main challenge for these GPGs is the

need for increased resources. The situation for other GPGs, however, is more complicated.

For an expanded global effort on communicable disease R&D, new efforts should be made in close partnership with the WHO. For a range of structural reasons related to governance and organization, it is not well positioned to undertake major new R&D programmes. Successful affiliated models such as the TDR provide a viable option. Options that do not involve the WHO or involve it as part of a network could also be successful.

The WHO has a major role in leading and catalysing multi-country disease control efforts. However it can be argued that it should not be charged with country implementation, although it has been able to fulfil this function for diseases such as smallpox and polio. In general, country implementation of multi-country communicable disease control efforts would be better pursued through partnerships.

As noted in the body of this contribution, an important challenge for effective delivery of many GPGs within the WHO framework is the tension between headquarters and the regional offices. Most of the work on GPGs is undertaken by headquarters staff. The steady increase in the share of the regular budget and now the extrabudgetary resources going to regions and country offices seriously threatens the WHO's capacity to deliver GPGs in the future. This trend is extremely hard to reverse. No candidate for director-general is likely to run and be elected on a platform that would increase resources for headquarters over the regions or those directly controlled by ministries of health. There is unfortunately a slow but steady dynamic that will erode the capacity of the WHO to deliver GPGs. The solution to this problem will only come through broad recognition of the organization's critical role in delivering GPGs and the need for extra resources to support these functions at the global level. In the absence of a firm commitment from the governing bodies of the WHO to strengthen the GPG functions, second best solutions based outside of the organization may be ultimately required.

Finally, it is in the area of monitoring and evaluation of what works and what does not that the WHO has major structural limitations. Expanded efforts in the evaluation of what works for communicable diseases control should be undertaken by an entity independent of the organization.

Notes

1. The arguments contained in this contribution were published in the *British Medical Journal* in 2004.
2. The material in this section has been used as the basis for Murray, Lopez and Wibulpolprasert (2004).

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Health System Capacities in Developing Countries and Global Health Initiatives on Communicable Diseases

6 Chapter

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Nearly 14.5 million people die annually from preventable communicable diseases, and tens of millions more have their lives impaired by these diseases on a daily basis. More than 90% of this burden is borne by the poorest populations in developing countries. Over the past several decades, this burden has grown, new diseases have been added and drug resistance has undermined some of the progress that has been made. These trends and the threats they pose for all nations in this increasingly interconnected world have resulted in far-reaching changes in the global health sector. Among other things, a growing share of foreign aid is being devoted to health issues even though overall aid levels have increased little; much of this increase has gone to new programmes and organizations established independently of the traditional organizations like the World Health Organization (WHO) and the World Bank; and the focus has been on a few communicable diseases with cross-border spillovers, resulting in a relative neglect of other health issues of importance to developing countries.

These new programmes have increased demand for technical inputs from the WHO and UNICEF, induced other UN agencies such as the International Labor Organization to establish complimentary programmes and challenged the World Bank to expand its financial and policy/advisory activities with respect to these diseases. They have also placed tremendous pressure on the health delivery systems of developing countries, greatly complicating their lives by asking them to add new programmes to their already over-burdened list of activities. Resources at the disposal of developing countries are limited. Therefore it is important to exploit economies of scale and scope and to avoid wasteful expenditures.

The International Task Force on Global Public Goods, for which this background paper was prepared, asked the study team to assess these trends in global

health expenditures and, in particular to analyse the effectiveness of international health programmes in building the capacity of national health systems to prevent communicable diseases and to assess the coherence of the new and existing programmes with one another. This background paper is the result of that request. It focuses on seven of these non-traditional programmes (see table 6.1) and three communicable diseases—malaria, tuberculosis and HIV/AIDS.

Effectiveness of the global programmes in building national capacities

Much of the recent emphasis in global health interventions has shifted away from general preventive measures designed to improve well-being—through promoting such elements as better nutrition, education, public health, a clean water supply and family planning—and towards the prevention and treatment of specific communicable diseases. The shift to disease-specific measures is often associated with global programmes. These programmes have introduced new technologies for addressing communicable diseases on a scale not known before and vastly increased the supply of vaccines and drugs to treat these diseases. But their impact on countries' health systems as a whole has not always been positive.

Global programmes vary enormously in size and impact. The Global Forum for Health Research is too small to have much impact. Stop TB, while still small, has had quite significant impacts on policy in some countries. The Global Alliance for Vaccine and Immunization (GAVI) is a significant presence in more countries than is the World Bank in the field of immunization. The budget of the Global Fund for AIDS, Tuberculosis and Malaria (GFATM) is larger than that of the World Bank for the diseases it covers and has at times overwhelmed country health budgets and absorptive capacity, distorting national priorities and shifting scarce skilled personnel and managerial attention away from areas of importance for a balanced country health system.

Global programmes are relevant to needs, but cannot do the job on their own. Typically they do not supply the skills or the resources necessary to build the system capacity necessary to support their programmes. Nor do they deal with the fundamental changes outside the health sector—for example, sanitation, sexual mores, education, nutrition and maternal, child health and family planning practices—necessary for control and prevention of the diseases on which they focus. The

additional funds these programmes bring to the table are necessary but far from sufficient.

Global programmes impose heavy transaction costs on developing countries. All too often they try to solve similar constraints by using their own procedures without building on existing procedures of governments or donors. There are scale economies in improving systems for a number of communicable diseases simultaneously, rather than attempting to strengthen systems disease by disease. The challenge is to make the quick improvements needed to prevent epidemics from rapidly worsening, while not creating parallel systems unless absolutely necessary.

Much more can be achieved if the programmes work in long-term strategic partnerships, especially at the operational country level, with key international organizations such as the World Bank and the WHO. These traditional international organizations have many limitations, but they are the only ones able to provide the range of policy/strategy and technical inputs needed in developing countries based on their global reach, mandates and experience to achieve sustainable, global results.

Progress against specific diseases

The fight against tuberculosis (TB) has been relatively successful, particularly in large countries like India and China with better health infrastructures, thanks in large part to the effective implementation of the strategy known as DOTS (directly observed treatment—short course). The strategy, endorsed by the WHO and promoted by the Stop TB partnership, moves from a clinical approach to TB to a public health approach that is built on and seeks to improve the primary care foundation for sustainable treatment programmes. But globally the problem of TB is growing in scope and complexity, among other reasons, due to the emergence of drug-resistant strains, the spread of HIV/AIDS, which lowers resistance to TB, and financial barriers. New drugs and vaccines, new strategies involving collaboration between TB and HIV/AIDS programmes and significantly greater funding will be necessary to reverse present trends.

Malaria control is less of a success story, particularly in Africa, which has four-fifths of malaria-related deaths. The problem in Africa is especially acute because of widespread resistance to traditional drugs, the high cost and unreliability of supply of alternatives and weak national capacities for targeted interventions. The standard prescription for malaria control is the promotion of insecticide-treated nets, intermittent

preventive treatment of pregnant women and artemisinin-based combination therapy (ACT) to address drug resistance to chloroquine. More successful programmes have included strong surveillance and location-specific, multisectoral strategies focused on malaria-endemic regions. The Roll Back Malaria Partnership played a major role at the global level by ensuring that funding for malaria control is included in the Global Fund, but it had limited impact at the country level in helping to develop effective operational strategies.

The prevention of HIV/AIDS calls for fundamental changes in human behaviour, including sexual practices. Treatment can manage but not cure the disease; it is justified on developmental, economic, humanitarian and ethical grounds, but its impact on prevention is unclear and controversial. Information and education campaigns of varying intensities are now present in nearly all countries, and availability of drugs for treatment is expanding, thanks to dramatically increased international funding. There is a general consensus that a multisectoral approach focused on high-risk groups and community participation is necessary, and many variants of this theme can be found on the ground. But there is very little systematic evidence about the effectiveness of these various approaches and only hints about why the progress of the disease seems to be slowing in some countries like Brazil, Thailand and Uganda and accelerating in others. A much greater focus on monitoring and evaluation is needed to derive useful lessons from the accumulating experience.

UNAIDS has been highly effective in political mobilization at the global level, and it played an important role in the establishment of the Global Fund for AIDS, Tuberculosis and Malaria and expansion of the World Bank's HIV/AIDS programme. It has been less effective in mobilizing support of stakeholders at the country and local levels.

The Global Fund is distinctive because of its size and its operating procedures. These procedures have created strong country ownership by putting nationals in the driver's seat of designing disease control strategies. But its efforts to involve NGOs have met with mixed results so far. Its activities and procedural requirements have spawned huge demands for technical assistance (which are being met with difficulty by organizations such as the WHO and UNAIDS), exacerbated aid-coordination problems (for example, by duplicating institutional arrangements at the country level) and introduced complex and changing application, procedural and reporting requirements that have greatly slowed down disbursement and implementation. A large fraction of its funds finance the

importation of drugs, which raises ethical problems about scaling up or indeed even continuing treatment for those now being supplied drugs given uncertainties about future funding levels. Some governments have begun reacting to these problems by taking charge of donor coordination efforts or applying sector-wide approaches. Some of the latter bring donors together disease by disease, as with TB in India, while others incorporate disease-specific assistance into the health sector reforms as a whole, as in Malawi.

Other issues

The main report also draws on the findings from the case studies and interviews regarding immunization, health research, drug procurement and supply and human resource shortages. It finds that global programmes are helping to make progress in some of these areas, especially in immunization, but all are, or will soon be, running into diminishing returns unless the capacity of health and related non-health systems are substantially improved. The principal bottleneck is of system-level shortages including of well trained doctors, nurses and health administrators. These shortages cannot be overcome from within specific disease control programmes—except perhaps at the expense of other important health programmes.

Conclusions and recommendations

Global health programmes need to shift away from a tendency for crisis management to a greater focus on longer term strategic planning and implementation. The crisis mentality, stimulated in part by very effective advocacy programmes, has resulted in a justifiable shift in resources towards treatment of communicable diseases. But it has been based on estimates of need rather than of absorptive capacity, and that has resulted in inefficient use of resources and neglect of critical components such as prevention, system capacity building (reflected most dramatically in shortages of professional health workers), surveillance, research, monitoring and evaluation and the role of non-health sectors, all of which affect health outcomes. The crisis mentality has also resulted in a proliferation of uncoordinated agencies and programmes that increase transaction costs and further reduce the effectiveness of foreign assistance. These problems are particularly severe in small, low-income countries that depend heavily on aid. Without a change to a longer term ap-

proach, disappointment with results will eventually lead to donor fatigue that will threaten the financing and ultimately the sustainability of global health programmes.

These conclusions lead to the following recommendations.

- *Develop an effective mechanism for greater coherence and coordination at both the strategic and the country operational level, especially among the three core organizations—the WHO, the World Bank, and GFATM—but also other related partners and funders.* There is a natural division of labour between the core organizations, with the WHO setting standards and providing technical assistance, the World Bank providing assistance for systemwide policy planning and capacity building, and GFATM providing large-scale funding. The global system cannot work well without active and effective collaboration between all three at both the global and the country levels. Some agency must take the lead to make this happen, as well as to ensure that the other anchor functions are satisfactorily provided. Given the roles it now plays, the WHO would seem to be the logical agency to do this.
- *Increase the core funding of the WHO* (as opposed to funding from extrabudgetary sources that are ad hoc and of questionable sustainability) so that the organization can properly serve as an anchor institution and satisfy the growing technical assistance needs of developing countries.
- *Make the World Bank more proactive in building country-level health system capacities and coordinating the activities of bilateral donors in this field.* As the only agency with significant operational capacity in all sectors, the World Bank has a relative advantage in assessing the appropriate balance between disease-specific and overall health system approaches, bringing into play non-health sectors, viewing health in a macroeconomic context and helping design and support country-specific capacity-building programmes relevant to the health sector. It is also in the best position to provide leadership at the country level in coordinating bilateral donor programmes for building health system capacity.
- *Continue evolving the Global Fund towards becoming a true funding agency.* Building on the steps it has already taken in this direction in some countries, GFATM should scale up its support for country-wide disease-specific strategies supported by

other donors without weakening its laudable outcome-based approach to funding.

- *Improve the balance between disease-specific and sectorwide programmes, between treatment and prevention and among the roles of public, private and community organizations.* The most serious imbalance arises from the relative neglect of systemwide programming and capacity-building efforts, especially in small, poor countries, where it is hurting health programmes for non-communicable diseases. Donors and international organizations have a special responsibility to help these countries develop the capacity to correct these imbalances.
- *Sharpen the focus of some programmes and consolidate others.* Agencies that focus mainly on advocacy (for example, UNAIDS) have been more successful at the global than at the country level; they need to consider ways to work more successfully at the country and local level. In the research field TDR and the Global Forum need to consider merging to achieve a critical mass of impact.
- *Establish programmes aimed at overcoming shortages of skilled and motivated professionals for the health system as a whole.* This will require policies and programmes that cut across various disease-specific programmes. Donors need to be willing to ramp up investments in health training and research institutes and to assist governments in funding adequate salaries for public health workers.
- *Enhance substantially monitoring and evaluation, research and data gathering capacity at both the global and the country level.* Apart from critical humanitarian and development considerations, one of the reasons for emphasizing treatment is that available strategies and technologies for prevention are few, complex and difficult to implement and to evaluate for impact. Operationally useful lessons need to be derived from the few success cases in preventing the spread of HIV/AIDS and TB. Operations research is also needed, using randomized experimental designs to test different strategies for inducing behavioural change. Medical research and design (R&D) is needed to develop vaccines for communicable diseases, new and more effective barrier methods and ways to contain the growth of drug resistance. Funding for such research and related data-gathering and surveillance activities is much lower than benefit-cost estimates suggest is

appropriate. Innovative mechanisms to induce private sector investments in these areas should be considered and piloted. Any analysis and policy discussion must take account of factors that are outside the health sector but affect the incidence of communicable diseases. Much of the needed capacity should be created in developing countries. Many issues—for example, the appropriate choice among different drug formulations and ways to change behaviour—are country specific. Sooner or later all new products must be tested in the settings where they are to be used.

The research for this paper was completed in the spring of 2005. Since then awareness has increased among donors of the importance of building health system capacities of developing countries. Several initiatives are underway to increase support for health systems, although they have not yet been put in place. The recognition of the need for harmonization of procedures and practices among the many diverse disease-related donor-funded initiatives has also increased. Nevertheless, past experience suggests that donors are slow to change. Hence many of the observations and conclusions of this paper remain valid. Furthermore, future studies can treat this study as the baseline and track improvements in donor harmonization.

The challenge posed by communicable diseases

Nearly 14.5 million people die each year from preventable communicable diseases (WHO 2000b). Tens of millions more have their lives impaired by these diseases every day. More than 90% of the world's communicable disease burden and 90% of related deaths hit the poorest populations of developing countries. Each year they endure more than 500 million cases of malaria and more than 1.1 million deaths from it, 85% of them children under five (WHO 2002a). Drug resistance is on the rise both for malaria and tuberculosis (TB). TB is spreading in many African countries and in Russia, a result of the breakdown in public health services. Tuberculosis afflicts 8.8 million people each year and kills nearly 2 million, mostly adults in their most productive years. Almost 40 million people are living with HIV, about 4.9 million of them newly infected. In 2004 AIDS claimed 3.1 million lives, mostly in the developing world—two-thirds in Sub-Saharan Africa and about a fifth in South and South-East Asia (UNAIDS 2004). HIV is spreading rap-

idly to rural areas and affecting higher proportions of women. And each year more than 30 million children, mostly in Africa and Asia, remain unvaccinated against any disease.

The challenge is most severe in Africa and South Asia. Parts of Sub-Saharan Africa have been losing ground on key health indicators. South Asia's large share of the world's poor gives it commensurately large shares of people with poor health indicators.

But some drug- and vaccine-based strategies have been quite successful in eradicating or controlling specific diseases. Even Malawi, with its low per capita income, has successfully overcome measles, and the developing world is on the verge of eradicating polio. Great progress has been made in child immunization, TB control—notably in China and India—and malaria control in India, drawing greater attention to disease control programmes. But without continued vigilance and nurturing even these achievements can evaporate quickly.

Health systems in developing countries

National capacity is often the weakest link in preventing cross-border spread of diseases. The World Health Organization (WHO) framework for analysing a health system, as adapted for this review, captures many dimensions that either are addressed by disease-specific programmes or need to be (see box 6.1).

Public sectors tend to have weak capacities in formulating and overseeing health policy and strategy, planning, budgeting, management and monitoring and evaluation, and in accountability to the public. They also typically suffer from insufficient access to recurrent finance, inadequate human capital, poor incentives for performance and poor governance. Surveillance systems and epidemiological research capacities tend to be inadequate.

The private sector can be a large resource for scaling up services, because consumers (even among the poor) tend to rely heavily on the formal or informal private sector for curative and symptomatic care.¹ But studies of TB in India suggest that private providers often lack critical information to share with patients and incentives to promote prevention. Effective public-private partnerships that improve the quality of service would help control and prevention scale up enormously. Active public-private partnerships can accelerate programmes more quickly than either sector working alone. Another way to help scale up pro-

Global inputs

- *Advocacy* (knowledge, standards, guidelines, technical assistance, global policy rules (for example, for aid and trade): International organizations and donors, international NGOs, international professional organizations, pharmaceuticals and consumables
- *Finance*: Financing policies, lending or grant-making policies and procedures, economic and sector analysis, procurement and disbursement policies, technical assistance, training and capacity building

National health system inputs

Domestic knowledge, technology and human resources

Sources of financing

- *National*: Central, state, provincial and local
- *Private*: Consumer and institutional
- *International*: Multilateral banks, bilateral donors, the GFATM and philanthropic sources

Service delivery

- *Public*: Roles of central, provincial or state and local governments including health ministries and departments and related subsidiarity issues; research institutions, medical colleges and other human capital and training institutions
- *Private*: For-profit and non-profit community-level organizations (traditional, informal, indigenous and allopathic), health educational and training institutions, financial and human resource policies, management systems and related incentives

Government oversight functions

- Policy setting, information, disclosure and advocacy; regulation and standard-setting and strategic incentives; public-private partnerships; monitoring and evaluation; establishing routine feedback loops to actors

Some characteristics of the operating environment

Market failures, government failures and civil society failures

Systems of accountability and governance

Within national governments to scientific professional community, donors and consumers

grammes is to outsource some elements of service delivery by building capacities of all partners.

Innovations in providing global public goods for health

The dramatic worsening of the disease burden—and the risks to global health, economic development and security—are producing rapid and far-reaching changes in the global health sector, with many potentially positive results. Four important trends:

- Put global health on a “war footing” as a major global concern and an integral part of the Millennium Development Goals (MDGs).
- Direct a growing share of development aid to health, even though overall aid levels have increased little.
- Promote more health aid through new global health programmes outside the key traditional international and national organizations.
- Focus global health efforts on a few communicable diseases with cross-border spillovers, even though the health systems of developing countries must concurrently address nationally and locally important challenges with extremely scarce resources.

Factors prompting these trends include recognition of the high global economic costs of cross-border spillovers and the rapid development and delivery of new drugs and vaccines made possible by biomedical research and advances in information technology. Intense political activism by influential leaders, stressing the large share of the disease burden borne by developing countries and the poorest within them and the need to mobilize resources, has played a key role.²

In the global health sector emphasis has shifted away from general preventive measures (improved nutrition, education, clean water and family planning) towards preventing and treating specific communicable diseases. The shift is often associated with new global partnerships among traditional intergovernmental and bilateral organizations, civil society organizations and the private sector. Not only are UN agencies and the World Bank engaged in partnerships, but the Bill & Melinda Gates Foundation is now a major player, as are foundations associated with pharmaceutical companies. The new partnerships result from the opportunity to use technological advances to rapidly scale up the pace of work and, at least implicitly, from the perceived failure of traditional international organizations and governments to respond quickly enough.³

The new global programmes address communicable diseases on a scale not known before, with a strong emphasis on vaccines and drugs. They have revived the 40-year-old debate about the merits of disease-specific, or vertical, programmes versus general health services programmes. A consensus has now emerged that each approach has its merits and weaknesses, and the two need to be seen as mutually complementary (Mills 2005).⁴

Some potential positive effects of disease-specific programming include greater political awareness of specific diseases; augmented financial resources to combat those diseases; aid coordinated around a disease-specific approach; development of disease-specific strategies; mobilization of cutting-edge technical knowledge from diverse sources; efforts to address issues of disease-specific global drug supply, distribution and pricing; global networking among professionals; development of technical guidelines and performance indicators; improved surveillance; support for epidemiological and operational research; and support for disease-specific planning and implementation, monitoring and evaluation, education and training of professionals and development of incentive systems.

Negative effects include competition for resources; a lack of effort to develop single-purpose staff into multipurpose health workers; a failure to build the capacity of national health systems so they can sustain the achievements of disease-specific campaigns; fragmentation of multipurpose health services; distorted allocation of scarce human and financial resources and distorted incentive systems; and lack of evidence on the cost-effectiveness of disease-specific approaches.

The institutional innovations have included some critical changes in global trade rules—particularly with regard to intellectual property—dramatically expanding the possibility of producing generic drugs in developing countries.⁵ New rules have also reduced the prices of antiretroviral drugs and vaccines and opened up the possibility of increasing their availability to the world's poorest populations on a scale large enough to offer immense positive effects. This situation may change as more developing countries abide by the WHO rules on copying patented drugs.

The institutional innovations have had positive results; they have mobilized large-scale new financing, increased global and national awareness of health issues at the highest political levels and attracted global expertise and knowledge from a variety of fields. They have challenged the capacities and procedures of the WHO and World Bank to deliver financial aid and technical assistance. They have expanded the roles of such UN agencies as the International Labour Organization in spreading disease-specific information in the workplace. And by shifting the balance from shareholder models of governance (in which those who pay for the actions of an organization are on the executive board) to stakeholder models (in which those who are affected are on the board), the new programmes are shaping

the global health agenda and indirectly influencing the activities of the WHO and World Bank.⁶

Seven global programmes for control of communicable diseases

Global programmes are partnerships and initiatives whose benefits cut across more than one region and in which the partners reach explicit agreements on objectives, establish a new (formal or informal) organization, generate new products or services and contribute dedicated resources. The seven programmes assessed in this paper include three that either have their own financing or are supported by a financing mechanism—the Special Program for Tropical Disease Research (TDR); GAVI, supported by the Vaccine Fund; and GFATM—and four for information transfer and policy advocacy, broadly defined—the Global Forum for Health Research, UNAIDS, the Stop TB partnership and Roll Back Malaria (RBM) partnership (see table 6.1).

The programmes with financing mechanisms support activities at either the global level to achieve global objectives (as with the research by TDR and GAVI's Vaccine Fund to develop drugs and vaccines), or the national level to achieve national—and indirectly some global—objectives (as with GAVI's child immunization programmes and the GFATM). *The advocacy programmes* undertake political mobilization; collect and disseminate information at the national and global levels; mobilize resources for global R&D; develop—and build consensus around—disease-specific global strategies, standards and norms; support scientific networking among professionals; develop consensus on harmonizing donor financing policies and practices to support action against specific diseases; and establish facilities for financing drugs and supplies.

Most of these new global programmes are mobilizing expertise and knowledge for problem-solving from a variety of fields. Through advocacy they have increased global and national awareness of communicable diseases at the highest political levels. Indeed the Global Fund and GAVI (with the help of the Vaccine Fund) are now bigger sources of finance for communicable disease treatment and control and for child immunization than the World Bank.

Donors may see the GFATM and GAVI/Vaccine Fund as all-purpose assistance partners and may not perceive their implications for existing agencies. Though the traditional institutions have adapted their

Table 6.1 **Global health programmes: main features**

Programme	Start Date	Latest Expenditure (\$ millions)	Sponsors	Goals
FINANCING MECHANISMS				
Special Program for Tropical Disease Research (TDR)	1975	47.4	UNDP, the World Bank and the WHO. The programme is housed in the WHO.	Develop new and improved approaches to prevent, diagnose, treat and control neglected infectious diseases and to strengthen the capacity of developing countries to undertake research supporting disease control.
Global Alliance for Vaccines and Immunization (GAVI)	1999	124.1	Co-sponsored by the Bill & Melinda Gates Foundation, UNICEF, the WHO, the Vaccine Fund and the World Bank.	Save children's lives and protect people's health through the widespread use of safe vaccines, with a particular focus on the needs of developing countries. Increase immunization coverage at global, regional and national levels; provide technical expertise to support national programmes, capacity building and policy reforms and to accelerate development of new vaccines. GAVI's Vaccine Fund is a separate fund with its own governance and management structure that finances GAVI-approved proposals on immunization.
The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)	2002	1,009.0	An independent international fund co-sponsored by the UN, Group of Eight, developing countries, private foundations and others. The WHO provides administrative support for the secretariat, and the World Bank acts as trustee.	Dramatically increase resources dedicated to fighting HIV/AIDS, tuberculosis and malaria for prevention, treatment, care and support. Provide resources to buy commodities to prevent and treat the three diseases and associated support for strengthening comprehensive commodity management systems at the country level.

Continues

responses, their resources nowhere match the growth in demand—or the consequent need—that the new financing programmes have stimulated. The programmes have also placed considerable pressure on the health delivery systems of developing countries, challenging them to

Table 6.1 Global health programmes: main features (continued)

Programme	Start Date	Latest Expenditure (\$ millions)	Sponsors	Goals
ADVOCACY PROGRAMMES				
Global Forum for Health Research	1996	3.10	An independent international foundation co-sponsored by the World Bank.	Help bridge the so-called 10/90 gap (whereby diseases that account for 90% of the global burden of disease receive 10% of the funding for health research) by focusing research efforts on the health problems of the poor. Improve allocation of health research funds. Facilitate better collaboration on health research between public and private sectors.
UNAIDS	1996	95.0	UNDP, UNICEF, UNFPA, the World Food Program, UNODC, the ILO, UNESCO, the WHO and the World Bank.	Foster unprecedented global political mobilization on HIV/AIDS; stimulate UN and bilateral donors to increase their funding for HIV/AIDS activities; build consensus on and acceptance of a global strategy with which to approach agreed global goals and targets; and develop new approaches to partnerships, including the pharmaceutical industry and civil society.
Global Partnership to Stop Tuberculosis (Stop TB)	1998	20.8	A network of international organizations, countries, private and public financial donors, governmental and nongovernmental organizations and other entities (NGOs, research institutions, technical health agencies and individuals). Co-sponsored by the World Bank, UNICEF and the WHO, which serves as lead international agency.	Eliminate TB as a public health problem and, ultimately, obtain a world free of TB. Ensure that every TB patient has health-seeking behaviour and has access to effective diagnosis, treatment and cure. Stop the transmission chain. Reduce the inequitable social and economic toll of the disease. Develop and implement new preventive, diagnostic and therapeutic tools and strategies.

Continues

Table 6.1 **Global health programmes: main features (continued)**

Programme	Start Date	Latest Expenditure (\$ millions)	Sponsors	Goals
Roll Back Malaria (RBM)	1998	11.4	Co-sponsored by the World Bank, UNDP, UNICEF and the WHO, which serves as host agency.	Halve the world's malaria burden by 2010. Communicate the RBM concept, strategy, approach and progress for sustainable implementation. Coordinate technical and programmatic assistance programmes. Disseminate and promote best practices for scaling up malaria control interventions. Promote rational drug treatment policies and remove taxes and tariffs on essential malaria commodities. Establish and strengthen capacities in national malaria control programmes at the service delivery level.

respond in unprecedented ways and to accommodate global priorities with extremely limited national capacities and resources.

Study method and information sources

The analysis underlying this chapter was based on a standard set of questions (see table 6.2).

Not surprisingly many methodological challenges arise in using standard evaluation frameworks to evaluate global health programmes. Result chains linking inputs, outputs, outcomes and effects tend to be non-linear, complex and not well articulated. Often programmes are designed before enough evidence is available, as with the GFATM or RBM. In principle outcomes and effects are easier to measure, causality is easier to establish, and outcomes are easier to attribute to specific activities for financing mechanisms than they are for advocacy programmes, because financing mechanisms tend to promote concrete activities.

Five of the programmes had independent external evaluations at the time of writing this paper. The GAVI and GFATM have been evaluated by specific donors or their own management on specific programme aspects. Effects are known with confidence only for the TDR, which has developed tools for tropical disease control and

Table 6.2 Questions addressed and evaluation criteria used

Questions	Evaluation criteria
How relevant are the declared objectives of the specific global health initiatives to preventing or controlling communicable diseases on a sustainable basis?	Relevance
How and how well are the programmes implemented at the country level?	Efficacy
How evaluable are programme outcomes and impacts?	Evaluability of outcomes and impacts
What have the programmes achieved in relation to their declared objectives, and what impacts have they had on the capacities of developing countries?	Impacts including on capacities of developing countries
How sustainable are their outcomes and impacts?	Sustainability of financing, outcomes and impacts

scientific research capacity; GAVI, which measures the numbers of children's lives saved; and Stop TB, which measures the numbers of patients treated and cured. There is stronger evidence of positive process outcomes (or potential) from UNAIDS and the GFATM than from RBM or the Global Forum, which are too new and have weak monitoring and evaluation systems.

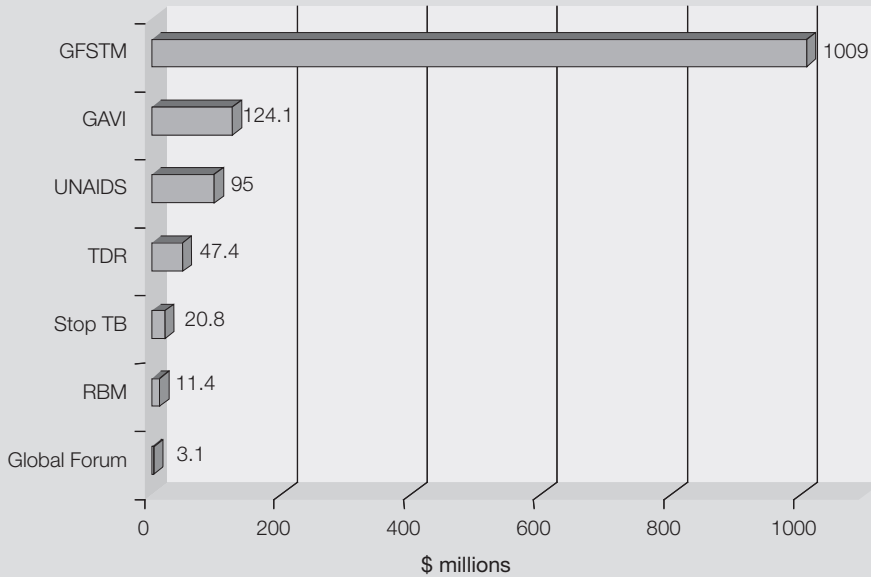
Effects of global programmes on national health systems

Controlling or preventing communicable diseases requires four ingredients:

- Sound technical approaches based on research and development, using technologies and products relevant to local circumstances.
- Political commitment.
- Financing to ensure that scientific, institutional and other capacity exists in countries to carry out programme activities, evaluate results and adapt solutions to ensure long-term sustainability. More financing is necessary, but not sufficient. A key challenge is to deploy financing to alleviate the most binding constraints.
- Inputs from other sectors and actors such as agriculture, water supply and sanitation, education and community participation.

From this perspective the objectives and missions of the seven global programmes are highly relevant to needs.

Figure 6.1 Size of programmes in terms of annual expenditures, including grant disbursements



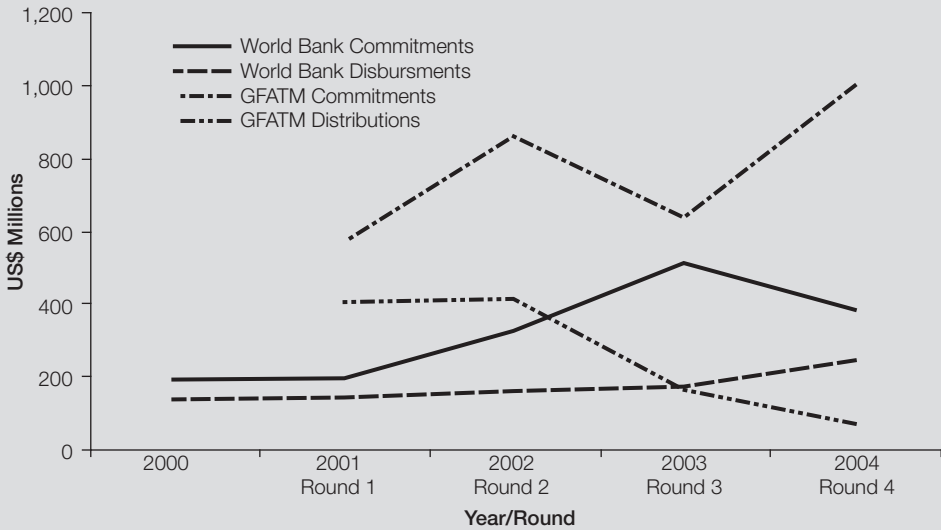
Note: Expenditures for GAVI and Stop TB include disbursements from the Vaccine Fund and the Global Drug Facility, respectively. Data for the GFATM pertain to grants made by the fund. All expenditures are for the latest year in which data are available.

Are the programmes large enough to make a difference? They range in size from the Global Fund, which committed well over \$1 billion to the three communicable diseases in fiscal year 2004 alone, to the Global Forum for Health Research, which spent \$3.1 million in that year (see figure 6.1).

The Global Fund is large even compared with the World Bank in its commitments to the three diseases. It has disbursed slightly more than \$1 billion to 123 countries—an impressive performance by any account—with 56% of funding allocated for HIV/AIDS, 13% for TB and 31% for malaria. By comparison, the World Bank’s cumulative commitments and disbursements (including for projects approved before the GFATM was established) over the same period went to 78 countries—\$1.5 billion for HIV/AIDS and \$835 million for other communicable diseases (see figure 6.2).

The GAVI has provided significant finance for child immunization, committing \$124 million for this purpose in 2004. GAVI has been financing immunization in 70 countries, compared with the World Bank’s 40 countries. Until IDA 13 was approved, the World Bank was unable to provide grant funding, and even today it is limited to the lowest income

Figure 6.2

Commitments and disbursements for communicable diseases: a comparison of World Bank financing and Global Fund grants, 2000–04


Note: Disbursement data for the GFATM and World Bank are not strictly comparable. They provide only orders of magnitude and should be interpreted with caution. The World Bank disbursements involve commitments made before 2000. GFATM disbursements to principal recipients are more like advances and do not indicate the extent of implementation. Local Fund agents play an important role in approving applications and giving the green light to proceed with disbursements to subrecipients. Bank disbursements more closely reflect the rate of project implementation, although the World Bank also establishes revolving funds in its investment programmes and makes fast-disbursing adjustment loans, mostly in Latin America.

countries. Hence the demand for World Bank loans and IDA credits for health interventions, including for immunization, has been limited.⁷

Global programmes are relevant to needs, but cannot do the job on their own

Global programmes provide only a few of the many ingredients needed to control or prevent each disease, and only a few do so on a scale commensurate with the problems. While global programmes such as the Stop TB partnership, TDR and GAVI have helped build capacity in specific areas, that is not their declared mission—nor do the programmes supply either the skills or the resources needed to build capacity. Therefore how the programme mission and goals are incorporated into the health systems of developing countries is a vital determinant of results.

Furthermore the factors leading to the spread of communicable diseases call for fundamental changes outside the health sector. For example, education, changes in sexual mores, better nutrition and population policy are often needed for HIV/AIDS control and prevention. Changes in behaviour, sanitation and environmental policy are obviously important for fighting malaria and TB, and women's education is important

for reducing child mortality.⁸ Hence more funds for specific drug-based disease programmes, while necessary, are not sufficient.

Collectively, global programmes impose heavy transaction costs on developing countries

The global programmes vary in their procedures, reporting requirements and performance indicators. They often require the establishment of special units, addressing similar constraints by using separate their own procedures, seldom building on existing procedures. Their requirements for preparing proposals, procuring supplies and setting up institutional arrangements differ dramatically. To use the additional funds expeditiously and efficiently calls for knowledge, expertise and skills that are typically in extremely short supply in developing countries.

The goals of all seven programmes are highly relevant to the problems of preventing or controlling communicable diseases. Yet developing countries must reconcile global priorities and local needs with extremely scarce resources. Countries can incur high transaction costs from the lack of coherence between disease-specific programmes and the other health activities of traditional international organizations, which combine disease-specific with systemwide interventions to strengthen general health systems.

Towards a better balance between improving health system capacity and attacking each disease separately

Disease prevention and control are part of the public health agenda, not a separate agenda. While successful disease-specific programmes help build capacity for controlling or eradicating specific diseases, they do not always take account of some generic, system-level issues that need support. Such issues include human capital development, overall drug and vaccine procurement and distribution systems and laboratory capacity to serve more than one disease. In several cases focusing on controlling and eradicating specific diseases inadvertently entails “robbing Peter to pay Paul”—siphoning resources away from the rest of the health system.

The biggest toll in this respect is on human resource development. Shortages of well trained doctors, nurses and health administrators block more rapid progress in fighting communicable diseases. These shortages

cannot be overcome from within programmes to control specific diseases (except perhaps at the expense of other important health programmes).

The experience of GAVI in India offers another example. The Indian government concluded that a nationwide immunization programme using multivalent vaccines would be financially and institutionally unsustainable without assured external funding—funding provided as long-term, predictable grants on a large scale. India's polio eradication programme, well on the way to achieving its target, has placed enormous strains on the immunization delivery system.⁹ India has a relatively large financial and institutional capacity. Its experience suggests that most low-income countries would be unable to sustain such an immunization programme unless they too were assured of similar funding.¹⁰

At the country level synergy between global health programmes, and between their activities and those of the traditional international organizations, remains weak. The various sources of assistance are not well coordinated. Often the lost opportunities and resulting costs to developing countries are hidden and qualitative, not easily measured and not even sufficiently articulated by them. The challenge is to make quick improvements to prevent epidemics from rapidly worsening, without creating parallel systems unless absolutely necessary.

Because the global programmes cannot be sustained without health system infrastructure, most developing countries urgently need help in building the capacities of their systems. The WHO offers the most potential to provide technical assistance on a global scale, but its regular budget has not grown. It has increased its reliance on temporary extra-budgetary resources from donors to fund activities, but it cannot meet the growing demands. The World Bank has rapidly increased its financial assistance for communicable diseases, particularly HIV/AIDS and TB, but its assistance for developing health sector capacity has grown only slowly. Overall a larger share of support for health in developing countries has gone to control communicable diseases—partly in response to the growing need and partly because of strong external advocacy for efforts against specific diseases.

Much more can be achieved if the global programmes work in long-term strategic partnerships, at the national operational level, with key organizations such as the World Bank and the WHO. They have the resources, experience, track record and relative advantage to scale up programmes effectively. They are the only ones in a position to provide

The World Bank remains the largest overall funder of health development in developing countries, and thus its activities form an important part of the context for evaluating global programmes. Moreover, it remains an important partner both in searching for solutions to communicable disease problems and in helping its client countries build their health systems.

The World Bank can apply sector-specific, multisectoral and macroeconomic expertise to health issues at the global and national levels in a way that more specialized agencies cannot. Its *World Development Reports* on population in 1984 and health in 1993 made major contributions to health strategies in developing countries.

Between 1990 and 2004 the World Bank lent nearly \$20 billion and disbursed \$15 billion for health. Its lending for the health sector (including investment and adjustment finance) has increased by 3.4% a year since 1990 and has fluctuated around \$1.4 billion a year in nominal terms.

Global advocacy has had a striking effect on patterns of World Bank lending. Commitments to HIV/AIDS alone have grown by an average of 16.7% a year since 1992, mostly for multicountry HIV/AIDS programmes (MAPs) in Africa. New commitments for all communicable diseases have grown by an average of 8.6% a year since 1992. Lending for child health has increased by 5.2% a year (mostly in East Asia and the Pacific and in South Asia), and commitments to population and reproductive health and to nutrition and food security have declined at 0.2% and 0.7% a year, respectively. Improvements in health system performance, though still the largest component of health sector lending, increased by only 2.2% a year and fluctuated around \$500 million a year.

Global advocacy has also led the World Bank to address HIV/AIDS as a multisectoral issue, leading to the promotion of national AIDS councils in several countries, with various ministries represented and the necessary clout for interministerial coordination. The importance of a multisectoral approach has also led to a retrofitting of World Bank-funded projects in other sectors with HIV/AIDS components, particularly in Africa.

There is a growing view within the World Bank, however, that the multisectoral approaches may inadvertently have undermined the capacities of health ministries, disempowering them and resulting in the loss of qualified staff to other ministries.^{a,b} Completion and audit reports of HIV/AIDS projects suggest that World Bank operations that helped strengthen the capacity of the ministries of health in Brazil and India may have been more effective in building capacity than its support for multisectoral projects.^c The completion reports on “component projects” suggest that including HIV/AIDS components in non-health projects (for example, in transport projects, to provide information to truck drivers) did not ensure effectiveness except when associated with well informed design, implementation and oversight, and accompanied by strong technical inputs—which can come from ministries of health.

The changing composition of World Bank financing for health raises a question. Can sustainable outcomes in communicable diseases be achieved if the World Bank, other major donors and governments do not make more investments in health system support to increase the capacity of developing countries to use new resources?^d

Notes: a. See the 2004 Regional HIV/AIDS Treatment Acceleration Project for Africa, which tries to empower ministries of health; b. Bilateral donors in the 1990s preferred to bypass ministries of health and finance NGO activities directly on the grounds of poor governance by the ministries (as, for example, in Kenya). This preference contributed to the loss of health ministry staff and capacity; c. See the World Bank Operations Evaluation Department (OED) audits of the Indian National AIDS Control Project, as well as the audits of the First and Second Brazilian AIDS and STD Control Projects; d. The 1999 evaluation of the World Bank's health sector lending by the OED also stressed this need (OED 1999).

policy, strategy and technical inputs in the health sector on the scale needed to achieve global results (see box 6.2).

The disease-by-disease approach makes it difficult for developing countries to realize economies of scale and integrate disease-specific approaches into their systems, even though some of the infrastructure and capacities needed to achieve control and prevention are common across diseases. Better integration of the disease control programmes with countries' health system capacities is needed. Such a systemwide focus would help ensure the needed balance in developing primary, secondary and tertiary services; upgrading facilities for training, research and surveillance; improving the financial and logistical aspects of sector management; and strengthening capacities to plan and evaluate disease-specific and systemwide policies and strategies.

Some programmes have been quite successful in achieving their objectives and even in building disease-specific capacity. But synergy among programmes could be improved in three dimensions:

- First, at both the national and the global level, economies of scale and scope in dealing with more than one disease could be better exploited.
- Second, the activities of disease-specific programmes and those of key international institutions, such as the World Bank and the WHO, should be made more coherent because they are pivotal elements of the global health architecture.
- Third, complementary policies, strategies and investments—in research and development, country capacity, prevention and treatment, drug procurement and distribution and pricing and subsidies—are needed to enhance the effectiveness of the global programmes and to achieve greater coherence between the work of traditional international organizations and that of the new financing mechanisms.

Successful programmes learn from their own and others' experience. Yet despite the demonstrated results of well coordinated disease-specific strategies and the rhetoric of harmonization, collective action problems often prevent organizations from using their comparative advantage through disease-specific programmes.

To deliver quality assistance such advocacy programmes as UN-AIDS, Roll Back Malaria and Stop TB must work with agencies that provide financing and technical assistance. The GFATM and GAVI are not purely financing mechanisms, nor do they perform traditional developmental functions. These programmes do not have large enough ad-

ministrative budgets to deliver the capacity-building aspects of assistance on a long-term, predictable basis. They do not have the WHO's advantages in surveillance, guidelines and standards development or technical assistance, or those of the World Bank in advising on health policies and strategies at the sector level to countries. Nor do they fully exploit those agencies' advantages. (Nor are those advantages acknowledged by many donors that contribute to disease-specific programmes.)

In field visits and donor interviews the team noted a weak strategic link between the country-level assistance of bilateral donors and their contributions to disease-specific programmes. Donors' roles in funding these global programmes and in assisting countries need to be independently and objectively assessed, adjusted and consolidated. Unnecessary duplication, overlap, gaps and confusion exist in both roles.

Tuberculosis: the Stop TB partnership

Effective implementation of DOTS has made TB control an example of great success against a communicable disease. DOTS ensures that people suffering from tuberculosis are fully treated with a powerful combination of drugs under the regular supervision of health workers or community volunteers. The treatment costs about \$13 for six months of drugs and uses primary care services. When implemented well it can effectively cure patients.

The DOTS-based strategy is being implemented in 182 countries, and DOTS coverage extends to 69% of the world's TB-affected populations. The TB Global Drug Facility (GDF), an important component of the Stop TB partnership's strategy, has now provided treatment to 4.4 million patients in more than 65 countries. The global TB case detection level is now 45% and the treatment success rate is 82%.

One of the most successful global health partnerships, Stop TB, offers important lessons for global TB control, for application to other communicable diseases and for effectively linking advocacy to financing mechanisms. The Stop TB partnership has mobilized complementary actions by all relevant partners to achieve control in some large countries and to pave the way in others—for example, by promoting greater World Bank investment in TB control and by actively lobbying for the inclusion of TB in the Global Fund, thus increasing the resources available to countries.

The Stop TB partnership has mobilized the use of the DOTS package by all relevant partners to achieve control in some large countries,

most notably China and India, using vertically organized managerial and support functions for integrated delivery systems. The good results have engendered ownership of DOTS among aid partners supporting the TB programme.

In China and India the successful DOTS strategies enjoy a relatively good balance among primary, secondary and tertiary services, and between research and surveillance. In China the World Bank and the WHO have worked with the Department of International Development (DFID) to increase the grant component of financial aid for TB to meet China's reluctance to borrow for health programmes. In India the central government developed the Revised National TB Control Programme (RNTCP) with funding from a World Bank loan, supplemented by funds from the Danish International Development Agency, DFID, USAID, GFATM and Stop TB partnership (see box 6.3). But even in these two countries, with their relatively strong health systems, the disease-specific and systemwide infrastructure policies and strategies need better integration.

Thanks to political mobilization by Stop TB, all 22 high-burden countries have developed national plans to combat TB, and the number of people treated has risen by 23%. Preventing TB has been recognized as a critical factor for mitigating the effects of HIV/AIDS, and guidelines have been developed for collaborative arrangements between TB and HIV projects. The guidelines call for managing co-infection, but progress in promoting collaborative arrangements has been slow. For people with multidrug resistance, pilot projects and the Green Light Committee for approving DOTS applications have facilitated streamlined access to life-saving second-line drugs. Progress is also being achieved with new lines of promising drugs.

The four country case studies indicate that Stop TB's performance is uneven, with considerable scope for expanding access to health services and to DOTS in Kenya and Malawi. Although these countries have

Box 6.3 The Global Drug Facility in India

Given the large TB burden in India, substantial resources are required for drugs even though the cost has fallen sharply (Rs. 500 or \$13 for a full course). Stop TB contributed drugs in kind through the Global Drug Facility for three years (2001–04) for the state of Orissa and for 200 million people outside Orissa, meeting approximately 25% of India's drug requirements. The government appreciates the contribution of GDF as a useful addition to the RNTCP. Procurement through the GDF has been smooth, and all procurement of TB drugs (even drugs not funded by the GDF) is being done through the GDF.

two of the stronger TB control programmes in Africa, barriers remain to their broader use of DOTS: weak public health systems, a shortage of trained personnel, a large number of vacancies, poor infrastructure, decentralization and the need for closer cooperation with other disease control programmes, such as those for leprosy and HIV/AIDS. Problems reported in Kenya include the poverty of patients, the large HIV disease burden, a rising urban slum population, high proportions of nomadic and semi-nomadic populations beyond the reach of services, inadequate facilities and equipment, lack of knowledge and awareness among health workers, a large private health care sector that is not involved (especially in urban areas) and inadequate funding of proposed DOTS expansion activities.

Reasons for success

Several factors explain the quick success of the Stop TB partnership in using the DOTS strategy:

- It has been more successful in large countries with strong national health system capacity than in small countries with weak capacity.
- It gave high priority to developing a shared global plan.
- It further developed concrete, cost-effective DOTS-based approaches for diagnosis and treatment with detailed technical guidelines that are relatively easy to implement and monitor.
- It actively helped countries such as China and India to mobilize funding on attractive terms from the World Bank, DFID and other donors.
- It developed concrete, realistic, short-, medium- and long-term objectives ranging from R&D to field implementation, country by country.
- It made available treatment guidelines and free access to drugs and high-quality technical assistance.
- It established the GDF.
- It worked closely with countries to take advantage of World Bank loans and credits and, more recently, GFATM funds.

This combination of factors has made the control of TB more of a success than the control of malaria or HIV/AIDS. The TB control programme is technically easier to implement than the multisectoral approach needed to control HIV/AIDS or malaria. In China and India success depended partly on the strong partnership between the govern-

Box 6.4 DOTS success in China and India

China's success in combating TB reflects major investments by the World Bank in TB control, strong political support, general acceptance of the DOTS technical packages and financing from the Global Fund to extend the programme to the remaining eight poor provinces. But the financial sustainability of TB control is not assured, because the programme supports free diagnosis for all patients and free treatment for at least infectious (smear-positive) patients. This departure from China's fee-for-service health finance system adds a substantial financial burden at the local and provincial levels. In the first World Bank-assisted project some provinces ended free service as soon as the Bank's financing ended—adversely affecting the control programme. Thus, despite official commitments, the GFATM and other international agencies need to continue strong advocacy through effective policy dialogue.

In India, one of the most successful TB programmes, DOTS covers about 886 million people, distributed over 80% of the country. The government expects to scale up coverage to 100% by March 2005. With funding of \$142 million from the World Bank, the RNTCP has expanded DOTS coverage 40-fold in the past five years, treated more than 2.5 million patients, trained 300,000 health workers and established public-private partnerships to upgrade private sector knowledge of the DOTS strategy. The cure rate for TB in India under DOTS is 84%. The WHO has played a key role in providing technical assistance.

In the interests of uniformity and accountability, the government is managing and mediating all donor inputs. However, if state TB control officers had better information on the objectives of the Stop TB programme and more support, they could contribute more. For example, Karnataka's floundering TB programme needs greater targeting of Stop TB inputs, particularly advocacy, monitoring and capacity building at the state level and an enabling environment. Rather than focus on the RNTCP, which is on track, the Stop TB partnership needs to respond to state-level needs. These needs involve departments of health, whose capacity and commitment tend to be low and to require support. State finances are in considerable disarray in India, and the long-term sustainability of the programme, whose dependence on external assistance has increased, is in question.

ment and the WHO (see box 6.4). The World Bank also played a role. With the WHO, Stop TB gained consensus on the technical control package and developed technical strategies to respond to HIV/TB and multi-drug-resistant TB, leading to successes in such countries as Cambodia, Peru and Vietnam, as well as Moldova and Latvia. The partnership's strong consensus building on science and strategy and its defined measures of performance may offer a model for other programmes.

Current issues: inadequate finance and prevention

The TB problem is growing in scope and complexity because of drug-resistant strains, financing barriers and a host of other factors. In several countries cure rates are below the global average of 82%. TB is spreading in many African countries, driven mainly by AIDS, and in Russia

as a result of the breakdown in public health services and social and economic challenges of transition.¹¹ Stop TB has given special attention to creating responses to these challenges, but the implementation of collaborative activities at the country level is slow relative to the accelerated pace of the HIV/AIDS epidemic. TB and HIV/AIDS programmes need to collaborate more effectively in the field.

Originally Stop TB estimated that TB control would cost \$9.1 billion over five years (or \$1.8 billion a year), but it identified funding of only \$6.1 billion (\$1 billion a year) or a funding gap of \$3.8 billion (\$0.8 billion a year). That estimate has since increased to \$2.2 billion a year (WHO 2004). Securing long-term financing for the GDF is also crucial (WHO 2004).

Containing new outbreaks and eradicating TB are multisectoral challenges. Stop TB's focus on treatment needs to be widened to the removal of root causes, many related to poverty, gender, nutrition, ignorance, stigma and the living conditions of the poor.

Malaria: the Roll Back Malaria partnership

Malaria control is less of a success story than TB control, particularly in Africa, where four-fifths of malaria-related deaths occur.

Available knowledge and technologies should prevent and cure malaria, but progress has been slow. Despite scientific and political consensus, strategies for choosing remedies have not yet been well planned or implemented. A multisectoral and decentralized delivery system is needed. A large part of the problem lies in the shortage of funds and the slow development of planning and implementing capacity in countries.

Though monitoring and evaluation data are weak on the outcomes and impacts of the RBM partnership, the country case studies for this review confirm the findings of the independent external evaluation of RBM (Malaria Consortium 2002), the OED Global Review (OED 2004) and the World Bank malaria strategy paper (2005). Certainly RBM has increased global awareness and political support and helped mobilize greater funding for malaria prevention, treatment and control, particularly from the Global Fund. But RBM has so far had very little effect on outcomes. It has been less successful than Stop TB in engendering concrete national strategies and in mobilizing financial and policy support from the World Bank. Only recently has the RBM partnership sought support for malaria control from relevant partners.

World Bank lending for malaria interventions lost ground. Commentators suggest that the World Bank assumed that poverty reduction support credits and sectorwide approaches (SWAP) alone would work. Yet none of the stellar performers of the past decade used SWAP; Brazil, Eritrea, India and Vietnam all had focused malaria control programmes, even while the World Bank's Malaria Fact Sheet explicitly asked countries to avoid such programmes. Internal World Bank critics argue that this advice unwittingly discouraged countries from effective approaches while promoting approaches that did not work and, in some instances, produced bad results. Building on the global knowledge base and lessons learned, the World Bank developed a global strategy to upgrade its support for malaria control in collaboration with multiple partners (World Bank 2005). But it was too new to know its results.

At the country level there is more agreement on strategy than on how to apply the instruments that RBM promotes on the ground. RBM's standard prescription includes insecticide-treated bednets, intermittent preventive treatment (IPT) of pregnant women to prevent mothers from getting malaria and to prevent low birth weight and artemisinin-based combination therapy (ACT) to address the widespread resistance to commonly used drugs such as chloroquine. Bednets require subsidies and effective targeting because it is a challenge for the poor to obtain and use them. IPT requires a strong, well-organized public sector health delivery system and an effective community-level delivery mechanism. Combination therapy, which African countries have adopted at the urging of the WHO despite concerns about financial feasibility, costs \$1 to \$3 per episode—many times the cost of chloroquine, even though the cost is subsidized. Most countries with weak delivery systems cannot undertake diagnostic tests. Moreover, RBM relies on its donor partners to operationalize solutions in small, malaria-endemic, low-income countries where monitoring and evaluation of outcomes and effects are weak.

The case studies concluded that RBM has not been a significant funder of malaria control efforts or of health policy and programmes in India or China.¹² In India's Enhanced Malaria Control Programme, RBM had little effect on disease awareness, approach to malaria control, financing, programme implementation or monitoring and evaluation. Nor has it had much effect on India's human resources for malaria control, on procurement of drugs or other products, on health policy or on the nation's health system. The limited effect may result from the rela-

tively small burden of malaria in India, RBM's focus on Africa and the timing of India's own efforts relative to those of the global programme.

The success of Brazil, Eritrea and India in malaria control (World Bank 2005) may offer relevant lessons for the design of RBM's operational approaches. Because these three countries do not face drug resistance they could deviate considerably from the standard prescription. In all three countries the national vertical programmes entailed strong surveillance, a focus on malaria-endemic regions and effective decentralized multisectoral strategies at the local level, stressing the importance of national technical capacity to adapt location-specific solutions. These factors have applied in the successful TB control programmes and also show what is needed for HIV/AIDS strategies to succeed:

- Changes were flexibly adapted to countries' specific conditions. They were not fully in line with the global malaria control guidelines issued by the WHO and promoted by the World Bank. Programme managers based implementation on their extensive knowledge of what worked for malaria control in their country—not, as some observers contend, on reluctance to adopt newer strategies with more costly drugs.
- Interventions were targeted to high-risk areas, using a significant portion of World Bank loan proceeds.¹³
- The countries invested heavily in improving surveillance systems, making targeting to high-risk areas possible. Laboratory capacity was strengthened, and case reporting was streamlined, integrated and computerized—improving both the completeness and timeliness of case reporting.
- Capacity was developed at the subnational level, both to manage programmes and to analyse and interpret data, which then influenced decision-making at the appropriate level.
- Strong integration and decentralization of implementation strategies to local public health facilities increased local commitment. Before this change was made, village-level functionaries were paid by national malaria control programmes and worked solely on malaria control. The most extreme example is in Brazil, where malaria treatment was provided by free-standing malaria clinics with no formal link to local public health facilities.¹⁴ The decentralization of responsibility and resources stimulated local governments to become more involved, a factor pivotal to success in Brazil, India and, to some extent, Eritrea.

As with the Stop TB partnership, RBM's experience with malaria control suggests that a strong vertical national control programme should be a key part of implementation. Brazil, Eritrea and India effectively integrated elements of their decentralized health systems with the work of national programmes that provided technical support and procurement of essential commodities, including drugs, insecticides, bednets and laboratory equipment. Experience managing vertical programmes helped develop strong skills, extensive networks and the basic infrastructure necessary to implement activities efficiently and effectively. In Africa the supply of drugs is unreliable, and national capacities for targeted interventions are much more limited than in Brazil or India.

In Brazil, Eritrea and India the well developed public health infrastructure was crucial, including its skilled technical staff at state, district and local levels and its strong leadership by native directors with both technical and managerial skills. Technical personnel understood the systems and could move things quickly through their bureaucracies, even though the targeted areas often had much weaker infrastructure.

Public-private partnerships played a key role at the local level. In India local health departments have often partnered with tribal welfare, education and agricultural departments, as well as with NGOs, community groups, local governments and private providers. These partnerships generally focus on specific activities. For example, NGOs distribute and retreat bednets, and tribal welfare workers offer malaria treatment to their communities. In Brazil's mining areas private shopkeepers also played an important part in expanding treatment.

Roll Back Malaria has played a limited role in the successful control of malaria in Brazil and India, although overall it has played a major one by ensuring that funding for malaria control is included in the Global Fund.

Current issues: need to focus on country capacity building

RBM has been substantially restructured on the basis of recent evaluation recommendations. It now has a clearer strategy and a focus on selected countries and has put in place a stronger governance structure with clearer roles, responsibilities and accountabilities between its board, secretariat, working groups and regions, and more focused participation of beneficiary countries in its governance. The roles of the WHO and RBM are being clarified, and a Malaria Medicines and Supplies Service is established. RBM is encouraging the development of new

malaria drugs, diagnostics and vaccines, in conjunction with others. It is working more than before at the country level and trying to learn more about and disseminate best practices. It is exploring with the Global Fund and others how ACT can be purchased in sufficient quantities and at reasonable prices.

However these efforts do not speak to the most important problem for malaria: the lack of national capacity to deal with the disease. GFATM experience suggests that the World Bank and the WHO can be active in institutional and technical capacity building. The WHO has not only developed standard guidelines for malaria interventions, but is also working on developing support for timely supply of ACT. The World Bank can similarly help mobilize national capacity, including drug supply and distribution and design and administration of pricing, subsidies and targeting.

HIV/AIDS: UNAIDS and the Global Fund (GFATM)

Preventing HIV/AIDS calls for fundamental changes in human behaviour, including sexual practices. Information campaigns made possible by increased international aid have attempted to slow the increase in the number of HIV-positive cases. But except in a few countries (Brazil, Thailand and Uganda, and in parts of India), monitoring and evaluation have not been strong enough to yield a clear verdict on the effects of campaigns. Diverse factors led to the successes in Brazil and Thailand, including a focus on high-risk cases in terms of potential for spread; a clear emphasis on changing behaviour; and strong national leadership, planning and implementation (Ainsworth and Chamberlin 2000).

Treatment of HIV/AIDS is justified on developmental, economic, humanitarian and ethical grounds, but its effect on prevention is unclear and controversial. Prevention programmes in most countries are less focused than in Brazil or Thailand. Several authorities expressed a concern that HIV/AIDS prevention may even be being sidelined, perhaps inadvertently, because capacity is very limited, and national policy-makers have now shifted their attention to scaling up treatment.

Scaling up treatment has been made possible by major structural changes: dramatically reduced drug prices, growing international trade in generic drugs following the agreement brokered by the Clinton

Foundation and the growing amount of finance available under the GFATM and the US President's Emergency Plan for HIV/AIDS Relief (PEPFAR). The WHO's "3 by 5" (treating 3 million by 2005) campaign is playing a catalytic role in accelerating treatment and prevention.

In most countries interventions have had less than a decade to mature, and treatment has been provided only since the emergence of the Global Fund.¹⁵ It is too early to know the extent to which more international aid has reduced HIV-positive cases. Determining the counterfactual—that is, how many more cases would have occurred without the activities of UNAIDS, the World Bank or the GFATM and why—will be increasingly important as the global community moves further towards performance-based assistance.

Yet countries are ambivalent about substantially scaling up treatment, concerned about the national fiscal implications and uncertain about the size and sustainability of external support. Recipient countries lack clarity about the criteria donors would use to assess performance, and hence the conditions under which donor assistance would continue to flow.¹⁶ Countries expressed different expectations of the GFATM, as distinct from bilateral donors, whose decision-making on assistance to the health sector is partly influenced by factors extraneous to the control of disease such as overall quality of governance and level of corruption.

The sudden large increase in finance for HIV/AIDS, in the face of limited institutional capacity in both international agencies and developing countries, has posed challenges for ensuring performance and for clarifying conditions. This is why a coordinated approach to monitoring and evaluation, accepted by all donors, is essential. It is generally accepted that monitoring and evaluation and donor coordination are weak. A common monitoring and evaluation framework has been developed for the GFATM, PEPFAR, World Bank, WHO and other partners. But OED's evaluation of six global health programmes (OED 2004) shows how difficult it has been to implement this common framework.

The potential for HIV/AIDS programming to help strengthen health systems with strong referral systems and intersections between primary, secondary and tertiary levels is critical. The benefit for other areas of service delivery would be enormous, including the maintenance of patients' records and provisions for managing chronic conditions.

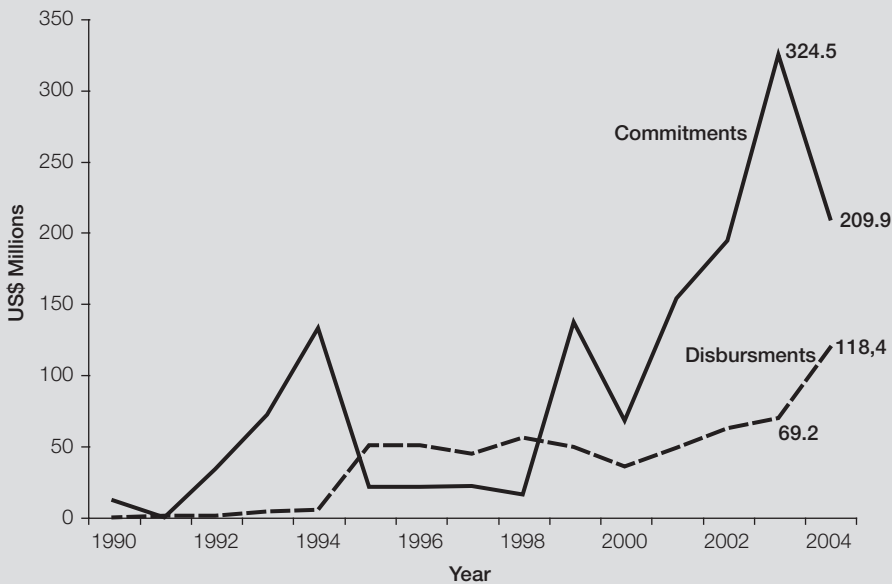
Disease-specific strategies against HIV/AIDS need greater attention. They are not well focused on high-risk groups. National AIDS councils, community participation and multisectoral approaches are

evolving, but there is no systematic evidence on how well they are working. Countries where the disease is being rolled back are few, and developing-country stakeholders suggest that there is more scope to learn transferable lessons within and across countries. All these aspects call for global programmes to focus on action at the country level.

UNAIDS

UNAIDS, co-sponsored by nine UN organizations and the World Bank, is designed to achieve global and national consensus on fighting HIV/AIDS as a multisectoral challenge rather than simply a health issue. The UNAIDS partnership has been highly effective in mobilizing global political support for increased World Bank lending for HIV/AIDS efforts and establishing the GFATM. The UNAIDS Secretariat needs to continue leading activism at the global level, but it also needs to find a way to advocate more effectively at the national and even the local

Figure 6.3 World Bank lending for HIV/AIDS, 1990–2004



Source: World Bank Business Warehouse. Commitments are new commitments in each year, typically disbursed over five to seven years. These annual disbursements are associated with commitments approved in previous years. Disbursements in the early 1990s are understated, because projects approved before 1990 were not recorded when the World Bank changed its sectoral and thematic coding system for projects in 2002.

levels. In this regard, UNAIDS performance varies across the four case-study countries.

Because many of its messages have been translated into donor actions, it is easy to overlook the secretariat's key role in a number of outcomes. World Bank staff and managers interviewed for this study stressed that UNAIDS's collection and dissemination of knowledge on the changing epidemiology of HIV/AIDS, and its advocacy, helped make World Bank managers aware of the disease and overcome denial among policy-makers in developing countries. This made it possible for the World Bank, first in Africa and later elsewhere, to open dialogue on the sensitive issues surrounding HIV/AIDS. Before the establishment of UNAIDS, only \$289.3 million of the \$7.25 billion committed to the health sector by the World Bank had been allocated to HIV/AIDS, while \$800.1 million had gone to other communicable diseases. Between 1996 and 2004 (that is, after the establishment of UNAIDS and the GFATM), the World Bank committed \$948.9 million for HIV/AIDS and \$638.1 million to other communicable diseases (see figure 6.3).

Many seemingly good ideas inspired by UNAIDS have been difficult to implement, especially in Africa. In the first generation of projects, national AIDS strategies and World Bank projects supporting them were criticized for lack of clarity and lack of focus on such high-risk groups

Box 6.5 The Global Fund and MAPs

The MAPs in Africa approved by the World Bank in 2000 were prompted by concerns that the HIV/AIDS pandemic was a disaster of extraordinary proportions needing an emergency response. They were designed to achieve many of the same objectives as the GFATM. The World Bank expedited its project preparation and approval process (MAPs could be approved at the vice presidential rather than the board level) and made disbursement procedures more flexible. Disbursements for HIV/AIDS projects in 2000–04, at \$332.8 million, were more than three times what they had been in 1990–96 (\$110 million).

MAPs have made progress (with disbursement levels comparable with those in health and social sector projects at the same stage), but they face a variety of challenges similar to those faced by the Global Fund—disappointing implementation of projects and subprojects, lack of national monitoring and evaluation, inadequate governance of national AIDS councils, complex procedures for community-based projects and weak health responses. The World Bank has produced a generic operational manual for preparing and implementing multi-sectoral HIV/AIDS programmes. However implementation of a harmonized national monitoring and evaluation system remains a challenge.

Source: Brown, Jonathan, Didem Ayvalikli and Nadeem Mohammad. 2004. "Turning Bureaucrats into Warriors: Actafrica." World Bank, Washington, D.C.; Interim Review of the Multi-Country HIV/AIDS Programme for Africa, October 2004.

as sex workers and on monitoring beneficiaries' behaviour. Many national AIDS councils suffered from lack of effectiveness and some from outright scandal. Community-driven services drawing largely on NGOs have encountered at best weak local capacity for delivery, and at worst lack of fiduciary accountability. This has led some governments—as in Kenya—to question the usefulness of these services, though others—as in Brazil or India—have welcomed their role in scaling up.¹⁷ The World Bank's multicountry AIDS programmes (MAPs) in Africa have also experienced implementation difficulties, partly because the early ones were prepared in a rush to get the resources out. The World Bank has since devoted considerable resources to supervision, with greater country presence than the GFATM. Disbursements have picked up; yet disbursing for MAPs remains a challenge.

UNAIDS has pressed for coherence in efforts against HIV/AIDS through the “Three Ones” principle: one action programme, one national authority and one monitoring and evaluation system. But none of the “ones” has been easy to implement, even in the few countries where governments have taken charge of their national strategies. Indeed the establishment of the GFATM may have compounded the difficulty of developing a unified country strategy against AIDS.

UNAIDS has also helped highlight the multisectoral character of the disease. But multisectoral strategies have not yet been successful. The realization of other aspects of the UNAIDS mission is a long way off—namely, reducing transmission; providing affordable, cost-effective care for persons living with the disease; mitigating the effect of HIV/AIDS on individuals, households and communities; and building consensus on and acceptance of a global strategy with which to approach agreed global goals and targets.

Current issues: extend advocacy down to the country level

After the success of the UNAIDS Secretariat in advocacy at the global level, the establishment of the Global Fund has helped move action to the country level. The Fund's considerable resources have provided UNAIDS with a number of roles, including harmonizing the World Bank's MAPs with country programmes (including those of the Global Fund) and developing a single integrated work plan and monitoring and evaluation, as in Malawi.

Nevertheless the experience of the four case-study countries suggests that the country-level activities of the UNAIDS Secretariat have

been opportunistic, varying with the level of support from other donors. To make better progress towards the unmet goals, the secretariat may need to define a clearer niche for itself at the country level, supporting greater collection and dissemination of local information and applying it to reduce stigma and engage households more in testing and counseling. This delineation of responsibilities is important, since the WHO's 3 by 5 initiative emphasizes treatment for HIV/AIDS along the lines of the Stop TB partnership, which has provided substantial technical inputs in the 20 high-incidence countries.

The Global Fund for AIDS, Tuberculosis and Malaria

As of January 2005 GFATM had approved 294 proposals from 129 countries. Of those, 264 were signed as grant agreements between the principal recipient—responsible for implementing the grant—and the GFATM secretariat, a signing rate of about 90%. Most unsigned proposals were from round four and still in negotiation; others involved principal recipients that had not yet met GFATM's criteria or reflected unresolved disagreements within country coordinating mechanisms (CCMs—see Box 6.5). Generally, once a grant agreement has been signed, the GFATM may begin to make disbursements. It had begun disbursing funds for 255 proposals.

The short interval between rounds one and two occurred because the GFATM was quick to establish itself on the international scene. But

Box 6.5 Membership of the Global Fund's country coordinating mechanisms

A critical element in the structure of the Global Fund is the country coordinating mechanism (CCM). CCMs are intended to be multisectoral, involving broad representation from government agencies, non-governmental organizations, community- and faith-based groups, private sector institutions and bilateral and multilateral agencies. Their composition varies greatly. At the time of writing this paper NGOs and civil society groups were present in almost every CCM, but in rounds one and two, only 12% of the suggested principal recipients came from civil society. Roughly 73% of all CCMs included representatives from the WHO and UNAIDS secretariat, and about half included bilateral donors; the World Bank was a member of roughly 14% of the CCMs.

Almost all CCM chairs were from national government ministries, and fewer than a fourth of vice chairs were from outside government. The Global Fund was taking steps to correct the pro-government slant. In round three the number of vice chairs from outside government increased to 23%, and the percentage of NGOs and private sector organizations proposed as principal recipients increased to 21%. In round four nearly 60% of the CCMs were composed of civil society and private sector representatives. Persons living with the diseases are still only marginally represented in all regions.

after realizing that the programme was moving too quickly, the GFATM changed the deadlines for rounds three and four to at least a year apart. Still it has established a new, innovative mechanism for rapidly delivering resources to recipients such as NGOs, national governments, private sector entities and community groups.

The GFATM stresses the need for increased coherence among key international organizations, at both the global and national levels, to ensure that the increased financing helps build both a quality pipeline of investments and the national development capacities of its grant recipients.

Some of GFATM's challenges arose because its first grant proposals were invited even before the Fund was formed, reflecting both the speed at which GFATM operations have grown and its sheer size. Others are the teething problems of any new organization; and still others are systemic, where the GFATM's role as financing mechanism has come up against development realities.

Both the GFATM and the World Bank have focused assistance on small, poor countries in greatest need, but the country case studies suggest that, at least at this early stage, additional resources may be more effectively used by large middle-income countries with stronger institutional capacity for implementation of programs.

The case studies also suggest that initially the GFATM may have achieved strong country ownership rapidly by putting countries in the driver's seat for disease control and prevention strategies. World Bank staff members acknowledged that the Global Fund had diversified stakeholder participation more widely and more quickly than has the World Bank by opening participation in its CCMs and by providing direct access to its financial resources to all stakeholders in countries, rather than to governments alone. However the lion's share of GFATM resources still went to government organizations at the time of writing of this paper, and the Fund's CCMs were still dominated by government ministries, even though they are intended to have broad representation. The capacity of non-governmental organizations to prepare and implement sound projects for the GFATM was weak, and GFATM's strategies to bolster this capacity were not clear.

The presence of the GFATM has compounded the aid coordination challenge. It has considerably duplicated institutional arrangements—for example, between national AIDS councils meant to have multisectoral government representation and the CCMs. This has raised transaction costs for countries accessing resources and for such country-supporting international organizations as the WHO and UNAIDS. Country

authorities have difficulty with the GFATM's complex and changing procedures for grant preparation, approval and disbursement. Absorptive capacity problems seem to be slowing the implementation of other donor programmes, particularly in the small countries with greatest need. As a result some donors were reassessing future commitments of resources to the health sector.

The Global Fund has also spawned a huge demand for technical assistance for project preparation, execution, monitoring and evaluation. Although the demand was being met by the WHO, UNAIDS and others, the demand for technical assistance far exceeds supply. WHO, UNAIDS and USAID were also frequently represented in the CCMs. The World Bank was present in far fewer cases, perhaps reflecting the weak coordination between the Global Fund and the Bank at both the strategic institutional level and the country level.

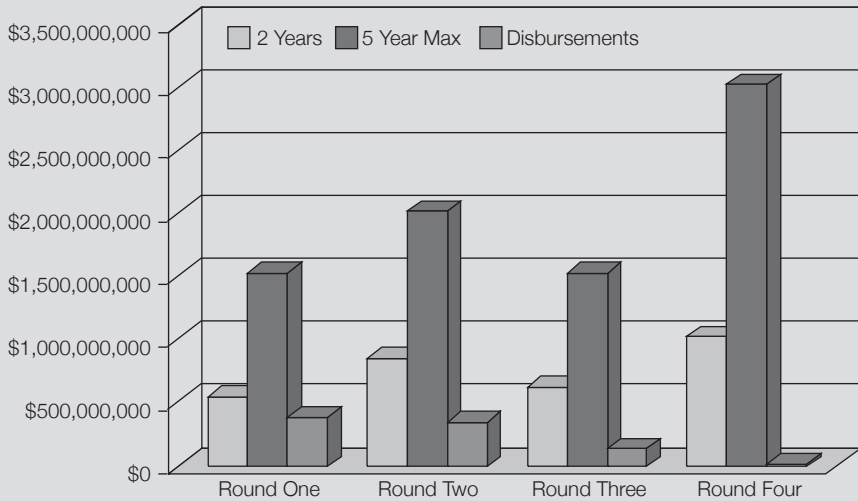
Another weakness is the insufficient links between GFATM-funded programmes and other donors' disease control strategies, particularly in small countries where health system capacities are weak. Countries argue that this reflects the Fund's Geneva-based organization, its modest presence at the country level, donors' lack of well integrated disease control strategies and a focus on treatment that several country stakeholders suggested diverts attention from prevention. Besides long-term uncertainty about external resources for scaling up treatment, countries are anxious about the fiscal, financial, political and ethical implications of that uncertainty.

Authorities in some developing countries have begun to coordinate disease programmes across donors in their countries and even to use sectorwide approaches. Some such approaches bring donors together by disease, as for TB in India, while others bring disease-specific assistance under the health sector reforms as a whole, as in Malawi.

Benefits and costs to developing countries of GFATM's approach

The responsibility for preparing, submitting and implementing proposals lies with the beneficiary countries. By getting all relevant stakeholders actively involved the Fund had earned strong ownership of its approach in the countries relatively quickly after its establishment. The nationals interviewed considered GFATM proposals as country-driven and initially liked their fast approval—compared, for example, with those funded by the World Bank or bilateral donors, whose procedures they considered more time consuming and more

Figure 6.4 Global Fund grant commitments and disbursements, by round



Source: See www.theglobalfund.org/en/.

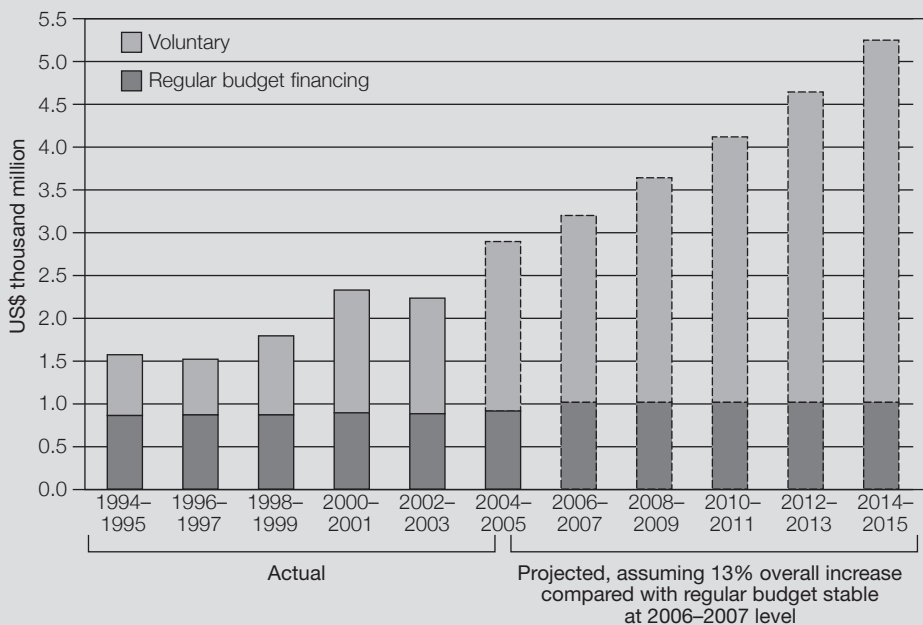
bureaucratic. For China, for example, the GFATM approved more than \$272 million of funding in its first three years of operation and its first two years in that country. This contrasts with the World Bank's approval of less than \$1 billion for health in its 20 years of operations in China.¹⁸

The size and the grant element of its funding also make the GFATM a significant player, at least for now (see figure 6.4), but the slow disbursements of GFATM grants was a source of considerable frustration in recipient countries. The GFATM opened large-scale access to international aid funds for NGOs.¹⁹ But the Fund acknowledged that ensuring the effective participation of civil society members and people living with HIV/AIDS had been more difficult than anticipated. Governments dominated the Fund's CCMs and were the majority recipients of funding (see box 6.5). Nevertheless, its approach had already influenced the way the World Bank, DFID and USAID provide financial assistance, and the way the WHO (see figure 6.5) and UNAIDS provide technical and other support, as well as the way in-country stakeholders perceive these actions.²⁰

The Global Fund's reported operating costs of about 3% may be low, but they do not include the costs incurred by developing countries and international partners in preparing proposals and accessing Fund finance. The transaction costs of preparing proposals and access-

ing GFATM funds might not seem high if funds flowed rapidly once programmes were approved, but this was not the case. The GFATM appraises the capacity of institutions to spend resources *after* it approves the grant proposals. This is one reason the Global Fund seemed so attractive to developing countries in its early stages. By contrast, the World Bank and most other donors conduct appraisals of implementation and technical capacity *before* they approve funding. Large amounts of GFATM funds were committed but relatively little had been disbursed, as seen in Kenya and Malawi. Other donors argued that ministries of health and national AIDS councils devoted so much time to meeting GFATM requirements for accessing approved grants that they had too little time left for implementing other externally funded programmes; leading donors to reassess their future commitments to the health sector. Some recipient countries were not meeting their agreed counterpart funding levels for those other programmes and, in some cases, may have used GFATM funds to do so.²¹ It was too early to assess the net increase in resource commitments and disbursements when this paper was pre-

Figure 6.5 WHO: Trend of voluntary contributions and regular budget, 1994–2015



Source: World Health Organization. Proposed Programme Budget 2006–07. Available at www.who.int/gb/ebwha/pdf_files/PB2006/P1-en.pdf.

pared. These issues should be monitored country by country, given the diversity of circumstances.

The GFATM has also led to considerable duplication in requirements, procedures and institutional arrangements at the country level. The Fund's concepts of CCMs, principal recipients, local Fund agents and development partners are all new and were being tested in the field. This learning by doing increased the transaction costs of accessing resources for both countries and the international organizations that supported them.

GFATM procedures have been overhauled several times. Assessments of the fiduciary capacity of principal recipients and the choice of local Fund agents have been sources of controversy. In the case-study countries, interviewees consistently commented that the Fund's rules remain unclear and poorly communicated. GFATM staff members acknowledged this in part, indicating that in the first two years some staff members in charge of country programmes did not fully appreciate the extent to which the board meant the rules to be applied flexibly. Such discrepancies, across countries and over the rounds, created confusion and high transaction costs for developing countries and for such technical assistance partners as the WHO and UNAIDS.²² The GFATM claims that it is simplifying and clarifying its procedures. Authorities in case-study countries suggest that more needs to be done; indeed, a few argue that GFATM staff members need to be located in the field to solve this problem satisfactorily.

Despite the high calibre of its technical review committee, the Global Fund's review process receives considerable criticism in developing countries for being ad hoc and non-transparent. A widely shared view is that better packaged proposals win, rather than those that are likely to be implementable. In principle the CCMs screen proposals. But while their processes are improving, they have been fraught with difficulties, and the Fund's responses may be insufficient to improve their capacity.²³

In some cases the GFATM also approves proposals that supplement or scale up programmes that are already well developed, appraised and funded by other donors and have a sound record of results on the ground, using well tested technical approaches and effective implementation methods, but lack financial resources. This has been the case for TB programmes in China and India.

Most proposals that the GFATM approves should be those that have proven to be effective as pilots and are scalable. Through an improved, effective CCM process, the GFATM should encourage governments,

NGOs and international and bilateral agencies with strong country presence to collectively fill a pipeline with quality proposals well worth scaling up.

Financial instrument or implementing entity?

The Global Fund seems caught between being a pure financing agency and a full development agency. As a financing agency, it could co-finance other donors' projects and rely on their procedures when appropriate. As a development agency, it would directly or indirectly (through other development agencies) provide substantially more assistance for building capacity in health systems. The organization faces pressures to move in both directions.

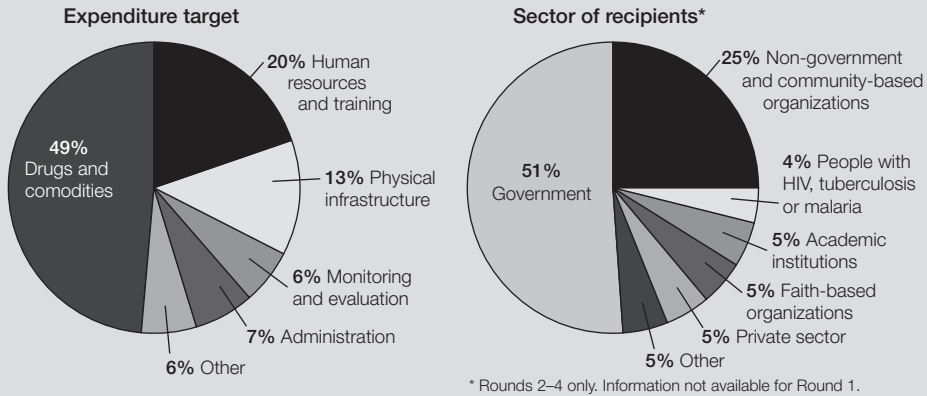
The Fund's decision to provide capacity development grants starting in round five is a good one, but it is not equipped to help with capacity development. The Fund argues that countries should mobilize resources for planning and implementing proposals, at least initially. It does not indicate where those funds should come from. Lately, however, it has been making a case for more financial support for international organizations that help countries prepare and implement projects.

The issues of a financing mechanism and the developmental functions of aid are worth considering from an additional perspective. Even in China, with its relatively well developed health sector, finance is less a constraint than the capacity to develop sound policy initiatives and manage the delivery system. Financial assistance combined with assistance for policy development and technical and managerial inputs is likely to have greater benefit than financial assistance alone. In countries that are less advanced, the need to accompany finance with policy assistance and investment oversight is even greater.

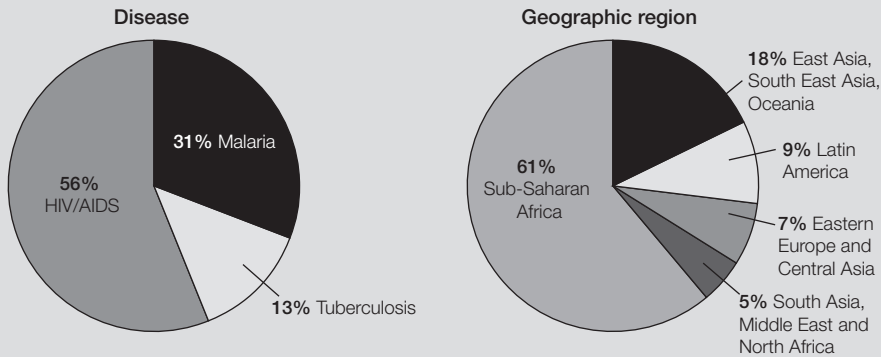
Fund partners—particularly the WHO and UNAIDS Secretariat, but also bilateral agencies and the World Bank—provide substantial support of this kind. The World Bank, the WHO and bilateral donors also collectively need to provide long-term, sustainable assistance in developing capacity-building proposals. An important question is which agency should provide such assistance and which should fund the cost of preparation.

Figure 6.6 **Distribution of GFATM commitments**

GFATM expenditure by components and recipient



GFATM expenditure by diseases and geographic region



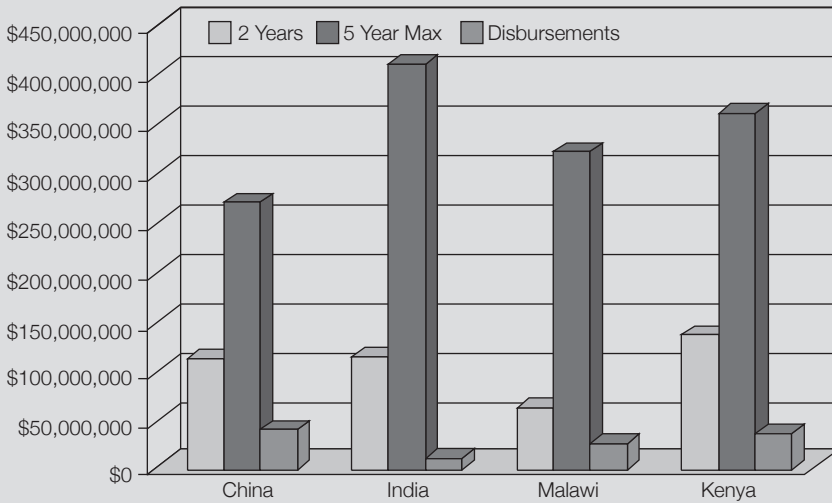
Source: www.theglobalfund.org/en/

Allocation of GFATM funds

The allocation of GFATM funds among the three diseases—56% for HIV/AIDS, 13% for TB and 31% for malaria—seems reasonable, considering the burden of disease in the affected areas. Funding goes to a wide variety of recipients: slightly more than half to national governments, one-fourth to NGOs and the rest spread out among several groups (see figure 6.6).

Sub-Saharan Africa has received a larger share of GFATM resources than the rest of the world, reflecting Africa's need more than its capacity to implement. The Fund has approved grants of \$112 million to China and \$114 million to India, compared with \$137 million to Kenya and \$62 million to Malawi (see figure 6.7). Disbursements have been much slower than commitments.

Figure 6.7 GFATM grant commitments and disbursements in the four case-study countries



Source: www.theglobalfund.org/en/

World Bank funding followed a similar broad pattern. The Bank's MAPs in Sub-Saharan Africa were already in preparation when the GFATM was established. During a period in which nearly 60% of GFATM commitments and 50% of its disbursements were made to Sub-Saharan Africa, the World Bank targeted 39% of its health sector commitments to the region.

By concentrating their resources simultaneously in Africa, the region with the weakest institutional capacity, and using separate approaches and procedures, the Global Fund and the World Bank have compounded the problems of absorptive capacity, resource transfers and the pace of implementation.^{24,25} Other regions with stronger planning and implementation capacity received smaller shares of the resources committed by both organizations.

Why did this happen? World Bank staff members, including some of the strongest supporters of MAPs, seem to agree that the substantial allocations to Africa were driven by the need to act. The Global Fund, by contrast, observes that it does not give priority to the most affected countries and communities. Rather its board approves proposals that are "technically sound". This assessment may "include having adequate capacity and readiness for implementation, but more importantly requires planned responses to the three diseases to be appropriate and therefore technically sound. No weighting is given to the disease burden in a

given country, nor to strong capacity or readiness of implementation as a formal criteria.”²⁶ As noted earlier, however, many of those interviewed for this chapter questioned the capacity of the Fund’s Geneva-based Technical Review Committee and its current local Fund agent arrangements to assess capacity or readiness for implementation.

The Global Fund promotes a balanced approach to treatment versus prevention. Yet it has no requirement for and no way to assess whether countries have strong prevention strategies. And the balance between treatment and prevention is difficult to assess from the evidence. In the third round, the Fund provided half its resources to purchase drugs, stressing its emphasis on scaling up treatment. Nearly half of GFATM funds go to procuring drugs and purchasing commodities.

Current issues: use of sectorwide approaches and need for empirical research

If the Global Fund accepted a country-wide, disease-specific approach to aid for communicable diseases, that would have substantial implications for the Fund, donors and countries.²⁷ Funds could flow into a common pool and be used to implement an agreed disease control and prevention programme. Priorities, both geographic and thematic, could be agreed across the board; common procurement procedures and monitoring formats could be developed.

The GFATM says it supports the inclusion of its funds in common pooled funding mechanisms. It is participating in the SWAP in Mozambique and intends to participate in SWAP in Uganda and other countries. According to the Fund, it has made a major change in its operating procedures to facilitate participation in SWAP: independent assessments of principal recipients are no longer conducted before grants are signed. Rather an assessment of the SWAP is conducted or assessments undertaken by other donors are accepted to fulfil precondition requirements. From the viewpoint of building capacity, this is a positive development and more such changes need to happen.

Empirical work is needed on two important questions that bear on intercountry resource allocation. First, are small countries with limited internal capacity able to spend the resources committed to them as quickly as large countries? This question could not be answered because the Fund’s disbursements to principal recipients do not reflect the rate of implementation. Second, consider a country where resources for recurrent expenditures are extremely scarce, and the government is under pressure to give priority to maintaining externally funded, mainly com-

municable disease control programmes. How does that situation affect the rate of implementation of communicable disease programmes and of health system programmes more generally? What can be done to help with implementation issues in small countries? Investigations to answer such questions should be carried out as soon as possible.

Immunization: Global Alliance for Vaccines and Immunization

By bringing substantial resources to the table, GAVI has been able to rekindle enthusiasm for immunization, which was declining because of a lack of resources. It has committed more than \$1 billion to 71 countries for immunization and is also financing work to develop new vaccines. A measure of its success: the fund is estimated to have prevented 670,000 deaths of children born in 2001–03 from a range of childhood diseases. In addition to augmenting the supply of funding and technical assistance in support of immunization, GAVI has made two important contributions: introducing new and improved vaccines, such as for hepatitis B, and initiating an effort to stimulate the market for new multivalent vaccines by guaranteeing funding, while helping refine the details of the delivery system.

GAVI's programmes have boosted immunization efforts, particularly in poor regions of the countries assisted; reduced child morbidity and mortality; improved capacity for preparing and implementing projects; and incorporated new vaccines and technologies while increasing immunization coverage. GAVI has introduced performance-based systems known as data quality audits, increased awareness of injection safety through the use of auto-disposable syringes and linked disbursements to performance based on incremental reporting of immunizations.

GAVI has sought to accelerate the integration of the hepatitis B vaccine into an expanded programme of immunization designed to provide this vaccine to all infants in defined areas, to promote safe injection practices for all routinely administered immunizations and to reduce the prevalence of the hepatitis B surface antigen (HBsAg) and the incidence of hepatitis B. Though one of GAVI's declared objectives was to expand the coverage of immunization programmes in developing countries, the alliance has focused on promoting new multivalent vaccines, whose unit costs are many times those of the cheaper, older, single vaccines typically used in poor countries.

Experience in case-study countries

GAVI has two channels: for countries with immunization coverage of less than 50% or more than 50%. China and India fall in the second category, thus qualifying only for assistance with new vaccines such as for *H. influenzae* type b (Hib) and hepatitis B. Both countries have substantial immunization programmes—covering tuberculosis, diphtheria, pertussis, tetanus (DPT), measles and polio—that they fund largely from their own resources. Most Chinese and Indian programmes have sought to reach all children with routine immunizations and to reduce morbidity and mortality caused by vaccine-preventable diseases. They give high priority to keeping their countries polio-free. Before GAVI's arrival coverage varied, with low rates of immunization in the states or provinces with lower incomes and lower levels of institutional development.

GAVI has provided support for hardware and vaccines and limited funding for systems support, but securing recurrent resources—which GAVI does not provide—has been a challenge. In both China and India GAVI's record in integrating immunization programmes into the larger health system has been mixed. GAVI has focused on its own financial sustainability, but has not been sufficiently involved in debates on overall health policy issues or on issues of domestic resource availability and allocation to immunization relative to other health sector activities.²⁸ Even with considerable price reductions the costs of the new multivalent vaccines are too high for most developing countries without continued predictable external assistance or sacrifices of other health goals.

GAVI's programme in China has been considered highly successful, but even GAVI has assessed its success in India as limited. Three reasons were cited by all sources:

- Polio eradication takes a large share of resources.
- India considers the new vaccines too expensive and did not think it politically viable to pilot them in one area without agreeing to provide them elsewhere.
- Neither Hib nor hepatitis B are regular parts of the Indian immunization programme—there is considerable debate in India as to the need for universal immunization for hepatitis B, and hence no strong policy consensus on its delivery.²⁹

With GAVI's assistance India has piloted a programme in Andhra Pradesh for the hepatitis B vaccine and taken responsibility for financing larger shares of the immunization costs.

Although GAVI has placed considerable emphasis on financial sustainability and asked countries to take on an increasing share of vaccination costs, financial viability remains the biggest challenge for the programmes GAVI assists. Kenya's Expanded Programme of Immunization (KEPI) initially cost about \$1 per child, but the introduction of the new pentavalent vaccines with GAVI support has pushed the cost up to \$10 per child. Each year KEPI has received about KSh 100 million (about \$1 million) from the central government for immunization support, but it will now require about 12 times that amount. In Malawi the case study indicates that 90% of the cost of immunization is for improved vaccines.

GAVI's experience has shown that a timely, reliable and sufficient supply of new vaccines can be generated if there is enough purchasing power. But countries' capacity to use the vaccines can take a long time to develop, requiring the programme to scale back its expectations. GAVI has learned other important lessons on institutional capacity building and monitoring and evaluation of results, but it is unclear if they are sufficient to ensure the programme's financial sustainability without injections of external resources over the long term.

Many of the interviewees in India, Kenya and Malawi suggested that the programmes GAVI has supported might now be easier to scale up and financially more sustainable if GAVI had done three things:

- Promoted the traditionally more affordable vaccines, with new vaccines only where appropriate, according to its original goals.
- Worked to improve the effectiveness of vaccine delivery within the public delivery system.
- Simultaneously tried to increase the supply and further reduce the decreasing prices of the newer improved vaccines.

Current issues: continued international funding for immunization?

GAVI is phasing out in 2006. Its partners have launched a global campaign through the International Finance Facility (IFF) to mobilize funding specifically for an immunization programme (known as IFFim). GAVI has developed scenarios based on potential levels of funding between \$4 billion and \$8 billion over 10 years. The details of criteria for funding and disbursement mechanisms, financial architecture, the ex-

tent of future reductions in vaccine prices and the absorptive capacity of poor countries will evolve. Some donors have already expressed interest in providing the resources to underwrite IFFim. It is unclear whether IFFim will reflect the lessons of experience or guarantee resources on the scale needed to increase coverage using new vaccines on a scaled-up, sustainable basis. In the meantime a positive development is that the Bill & Melinda Gates Foundation has committed additional resources to the immunization programmes.

Systemwide issues: research, procurement and human resources for health

Health research

Research, development and affordable access to new products and technologies are crucial for preventing and containing communicable diseases in developing countries. Investments in international surveillance and health research—including, for example, microbial resistance—have high pay-offs and have expanded at the global level. But coordination, prioritization and global and national links with research efforts and funding are still weak. Public sector funding is needed for R&D of drugs and vaccines for communicable diseases; market-based approaches may not work fast enough. Funding is also needed to strengthen the international and domestic public procurement arrangements for drugs, vaccines and health-related products.

Most international discussion focuses on technical research that can be both financed and implemented at the global level—a necessary but insufficient goal. Preventing the spread of communicable diseases also calls for applied, adaptive, policy and operational research in public health at the regional, national and local levels, supported by long-term predictable sources of funding. Among the needs are biological research to detect microbial resistance, research to assess the adoption and efficacy of new products and technologies, epidemiological research to understand and control the spread of communicable diseases and operations research and evaluation to better understand the effectiveness of interventions. Experts have stressed three areas needing attention:

- The large need for investments in product development once research begins to deliver promising results.
- Epidemiological and operations research, again at the national level.
- More investment in surveillance to detect current or latent outbreaks.

The outbreaks of SARS and avian flu in East Asia and of cholera in India have shown not only the personal cost, but also the high global economic cost when developing countries' capacity for surveillance fails and the need to make relevant information freely and widely available.

Investment in surveillance and in epidemiology and operations is insufficient, requiring the public sector to fund (and sometimes carry out) research that could easily be done by private research institutions and NGOs. Neither developing country governments nor donors yet appreciate the importance of these investments and the need for long-term predictable funding.

The gap between developed and developing countries in research spending is wider in health than in agriculture. In agriculture developing countries undertake almost half the research, reflecting a substantial increase in donor investments in self-standing agricultural research projects.³⁰ Such investments have not materialized for health research, even in large countries. The source of sustained finance for such research in developing countries, on the scale needed, remains unresolved.

Surveillance can be seen as both a global and a national public good. As the leading technical agency the WHO has advocated for increased surveillance funding, but money has not been forthcoming on the scale needed. Some financing for national surveillance components is typically included in health sector investments by the World Bank; estimates are not readily available, but interviews for the OED study of global health initiatives suggest this financing is limited. The World Bank and the WHO need to work with other partners as the Bank and private foundations and bilateral donors did with the UN Food and Agriculture Organization for agricultural research, substantially enhancing investment in national agricultural research systems to complement investments in the Consultative Group on International Agricultural Research (CGIAR).

Initiatives are under way to develop vaccines for HIV/AIDS and for malaria. At least a decade of research and testing is likely before a vaccine will be commercially available for either. Research and testing

can be accelerated substantially by strengthening the weak and sporadic links between global and national research institutions and through increased public funding of R&D at the international level.

The costs of developing drugs to treat diseases of the poor will not be recovered from sales in the market, so research on these diseases has been severely underfunded. A growing number of public–private partnerships support increased research of relevance to these diseases, adding to the efforts of established programmes, but the gap in research funding remains large.³¹ Neither the Special Program for Research and Training in Tropical Diseases (TDR) nor the Global Forum for Health Research, nor the newly emerging public–private partnerships are large enough to meet the health research challenge.

Special programme for research and training in tropical diseases. The oldest of the global health programmes, TDR has been an important and effective agency for research, training and institutional capacity building in tropical health science. It is underfunded because it primarily deals with researchers and research institutions; it does not engage in public

Box 6.6 Linking global research to country problems: TDR in Malawi and China

Malawi: Malawi has one of the world's highest child mortality levels. According to Malawian researchers, perhaps one of TDR's most important contributions is its support for research into severe malaria among children in Blantyre. The researchers devised a means of staging the severity of malaria in comatose children—the Blantyre Coma Score—and examined the safety and efficacy of artemether and artesunate in treating severe malaria. They also investigated the safety and efficacy of LapDap in treating uncomplicated malaria.

Leprosy research supported by TDR has had significant effects on research and treatment methods. Chemotherapy studies led to the adoption of a multidrug therapy for leprosy. Studies that evaluated vaccines showed that a BCG vaccine was superior to the killed *M. leprae* preparation; they also provided some of the most complete demographic and clinical data available on a large population. The leprosy studies led to the establishment of an excellent research facility in northern Malawi. TDR has also supported the evaluation of the safety and efficacy of ivermectin for treating onchocerciasis and using it communitywide. The results were important for scaling up community-based drug distribution in other endemic regions in Africa and also formed the basis of a relatively successful control programme in Malawi.^a

China: With China's improved capacity, TDR's research focus shifted to funding research projects based on scientific merit. Given the size and diversity of China's needs, TDR's capacity-building efforts concentrate mainly on malaria and schistosomiasis control with some funding for leishmaniasis, leprosy and, more recently, TB control. TDR research has also influenced the quality of World Bank lending in China (for example, for schistosomiasis control) and improved the design of specific World Bank operations.

a. See Salaniponi (2006).

advocacy nor package its programmes and progress well for interested parties.

Independent evaluations and investigations conducted for this chapter show that with relatively small amounts of funding TDR has achieved substantial effects on several key communicable diseases that afflict the poor. It has leveraged support for developing candidate vaccines for malaria, leishmaniasis and schistosomiasis and strengthened research capacity in developing countries through collaborative research involving scientists in developing and advanced countries (see box 6.6). TDR's publications have an impressive record of citation in scientific journals.

Case studies provide evidence, as in China and Malawi, that in several diseases and disciplines TDR support for basic training and capacity building has helped develop research leadership among individuals and institutions. Kenya has a long-standing record of collaborative research with TDR, reflecting its strategic location as a regional research centre. However researchers there stressed that external support is sporadic and that it focuses on issues of interest to international organizations that do not necessarily match needs on the ground (OED 1999; OED 2003b).

With expenditures of \$47.4 million in 2003, TDR's funding has stagnated in real terms over the past 10 years and more of it is earmarked. Meanwhile the programme's research mandate has expanded to 10 tropical diseases. Donors have become less willing to provide funding and more demanding of quick results with wide effects.

In response to the rapidly changing environment for health research and financing and some internal constraints, TDR has addressed fundamental issues of its scope, strategic objectives, role in global research and funding and partnership strategies. It has been enhancing the quality of its technical reviews, method of work, governance and management and achieving improved accountability for results. It has also been striving to achieve greater autonomy from the WHO—a move that partner agencies have advocated to allow TDR the speed, flexibility and responsiveness it needs to better exploit new opportunities (for example, in public-private partnerships).

Going forward, the control of communicable diseases would benefit if TDR were to refocus its efforts on scientific health research, where it has strong experience and comparative advantage, rather than spreading itself too thinly to developmental activities, as donors seem to be demanding.

Global forum for health research. With spending of just over \$3 million in 2003, the Global Forum is an example of a small donor responding

to a large need. Most sources consider its efforts too small relative to its objectives and the needs it serves.³²

The Global Forum generates information on trends in research funding. It finances some public-private partnerships, promotes networking among scientists and develops new tools for setting research priorities. The forum lacks its own research funding mechanisms (except on a very small scale) and offers developing countries little leverage over other sources of funds. It lacks its own scientific capacity and does not have the ability of TDR or the CGIAR to muster scientific advice through technical advisory committees.

Networking by the Global Forum is a useful source of information on international best practice, but more funding, more effective long-term predictable support and more sustained global-national links are needed.

New public-private research partnerships. In the past five years new public-private research partnerships have pledged some \$2 billion to new not-for-profit ventures for research on diseases of the poor (Widdus and Wright 2004). These partnerships now provide some \$200 million annually (Global Forum, private communication).

Looking ahead through 2007, the additional financing required for health research by drug- and vaccine-related partnerships is estimated to exceed \$1 billion. Long-term assurance of sufficient funding is essential to ensure that products will come to market from the promising results of those current initiatives. Drug development can take much more than 10 years and require hundreds of millions of dollars. As more candidate products enter the final stages of development, the guarantee of sufficient funding becomes more critical. Vaccine development takes even more resources.

Large middle-income developing countries that have scientific capacity, such as India and Brazil, are beginning to expand their health research and collaborate with new public-private initiatives, such as those supported by the Bill & Melinda Gates Foundation.³³ One positive development is the proposed global network linking medical research institutions in advanced and developing countries, being considered by scientists with the support of the Global Forum and the Rockefeller and Bill & Melinda Gates Foundations. The purpose is to undertake joint projects of mutual interest. Such a network is well worth supporting, provided issues of priority-setting are addressed.³⁴

Current issues: links between global and local levels; need for long-term research funding. Resources for R&D on the diseases of the poor remain extremely scarce. Stronger links between activities at the global and the

local levels are needed to exploit economies of scale and scope. Despite the substantial catalytic efforts of the Bill & Melinda Gates Foundation, the lack of a long-term funding mechanism is still a major constraint on such research. The creation of a well structured international financing mechanism has been recommended by the Commission on Macroeconomics and Health.³⁵ But bilateral aid agencies and the domestic research agencies of industrialized countries have not been willing to support new efforts, and current donors are at the limit of their funding, given other priorities for their resources.³⁶

Because of economies of scale and scope and limited resources, global priority setting and a financing plan to back the priorities are both important. But there is no broadly shared process for deciding what research should be carried out, how it should be financed or conducted at different levels and how global research should be linked to national and local research. Appropriately adapted, the model used by the CGIAR—with its 15 autonomous international research centres throughout the world, a secretariat in the World Bank and a Science Council (previously called the Technical Advisory Committee) in the UN Food and Agriculture Organization—is perhaps overdue to be applied to health research (see box 6.7).

The development of a global health research system faces many obstacles. Major funding from donors is unlikely to materialize without the

Box 6.7 Consultative Group on International Agricultural Research (CGIAR)

CGIAR was established with a strategic mission and a science-based organization to mobilize the best of science in advanced countries to develop technologies for the benefit of food-deficit countries and populations. Its mandate has expanded substantially to achieving food security and poverty reduction through research, partnerships, capacity building and policy support, promoting sustainable agricultural development based on sound environmental management of natural resources. CGIAR has:

- Conducted strategic research with global or regional public goods features, with large transnational spillovers.
- Brought the best of known science to address the problems of food security in developing countries.
- Funded productivity-enhancing research that has had sizeable effects on reducing poverty through employment, incomes, food prices and land savings.
- Established gene banks and plant and animal breeding that are unique global public goods assets with large global spillovers.

Ongoing reforms are attempting to address the challenges arising from the radically changed external and internal environment.

Source: OED (2003b).

collective leadership of the World Bank, the WHO, and other concerned international organizations. Scientists tend to resist a strong donor role in setting research priorities, concerned that research organizations can become donor-driven rather than science-driven. Donors worry that research and expenditure priorities may reflect the interests of more powerful segments of society, whether the urban elite or scientists. Yet TDR has shown that a public organization can successfully undertake research on the diseases of the poor and have a considerable leveraging effect.

The World Bank lacks a mechanism beyond its small Development Grant Facility (DGF) to finance health research at the global level. DGF funds—limited to about \$150 million a year—would need to be diverted from other activities, including agricultural research.

The IFF is a potential source of financing for health research. Increased international funding on a stable, long-term basis would establish an assured market and stimulate production of drugs and vaccines, but is unlikely to stimulate research on communicable diseases. The IFF could possibly fund research directly by establishing a window for health research or by helping guarantee markets for drugs and vaccines. TDR and the Global Forum need to consider merging to achieve a critical mass.

Drug purchase arrangements at global and country levels

Drug purchase arrangements constrain efforts to scale up disease prevention and control. For example, since the WHO revised its guidelines to promote ACT to treat drug-resistant malaria, there is a considerable shortage of ACT drugs, and prices of the raw materials have risen.

Fairness, competition, corruption and governance associated with the large-scale procurement of services and commodities are also issues. The procurement procedures of the World Bank, UNICEF, GFATM and bilateral donors have been strongly criticized by developing countries as well as by international technical advisers working in the case-study countries. They were perceived to suffer from excessive centralization of approval authority in the donors' capital cities and to be complex, tedious, slow and unresponsive to borrower needs. As part of its support for sectorwide approaches the World Bank is simplifying its procurement procedures.

Drug purchasing in the global programmes. Most disease control programmes would be sustainable if additional long-term external grant funding were available consistently and predictably. But even with reduced prices the outcomes of many disease-specific drug and vaccine de-

livery approaches promoted by the global programmes may be sustained only if considerably more funding becomes available. There is considerable scope for establishing similar infrastructure at the country level for arrangements to procure and distribute drugs.

The Global Fund commits nearly half of its funds to procurement of drugs and commodities. Stop TB's Global Drug Facility (GDF) was established to enable developing countries' health ministries implementing DOTS programmes to procure quality drugs at reliable, competitive prices. Developing countries support such purchase arrangements because they increase the reliability and quality of supply and lower the price of drugs. An evaluation by McKinsey and Company generally gave the facility high marks (see box 6.8). It suggested that the facility should specialize in drug procurement, clarify the roles and responsibilities of its partners in the governance of the facility and leave funding for drugs to other donors (including the Global Fund). At \$15.6 million in 2003, GDF is grossly underfunded; indeed McKinsey identified a need for an additional \$20 to \$30 million for 2003 alone. The Roll Back Malaria partnership has similarly embarked on establishing a facility to ensure a more reliable supply of quality drugs and bednets. The World Bank, through its lending operations, has strengthened procurement procedures in China, India and Malawi, including helping draft new legislation in Malawi and helping build the capacity of Malawi's ministries to

Box 6.8 The Global Drug Facility (GDF)—A changing focus

The GDF, launched in 2001 with start-up funding from the Canadian government, is an initiative of the Stop TB partnership hosted by the WHO. It is designed to increase access to high-quality drugs for tuberculosis. Its objectives are to provide grants, procure drugs and mobilize partners for technical assistance for DOTS expansion. It has contracted with the United Nations Development Programme Inter-Agency Procurement Services Office (UNDP/IAPSO) to purchase TB drugs for DOTS programmes.

McKinsey's evaluation of the GDF's performance and organizational effectiveness in its first two years found that "GDF has been able to achieve reduction in drug prices of up to 30% for developing countries and a positive effect beyond access to quality drugs and low prices by catalysing expansion of DOTS plans, and securing additional support from donors and technical partners." It emphasized that GDF's grant-making role is necessary for continued impact.

The evaluation concluded that although GDF's governance model—with the WHO providing a legal entity and administrative support and the Stop TB partnership providing an advisory board and funding—had functioned acceptably, "the roles of WHO, the Stop TB partnership and the working committees should be more clearly specified, and GDF should explore ... mutually beneficial relationships with the Global Fund and other key donors."

Source: McKinsey (2003b).

procure health supplies. The Indian state of Tamil Nadu uses competitive processes to procure drugs at prices even lower than those obtained through international arrangements.

Some interviewees argued that the Roll Back Malaria partnership and efforts against HIV/AIDS should adopt the vertically integrated DOTS model, including establishing an international drug facility for those diseases. But they also recommended that efforts be made concurrently to ensure that developing countries develop national and state or provincial capacities for competitive international procurement. They offered several reasons:

- International procurement arrangements such as the GDF ensure quality supplies at competitive prices, but they also cost developing countries about 4–10% of the costs of drugs procured. Developing countries could save by building domestic or regional capacities.
- Even for highly aid-dependent countries, national drug procurement involves much larger quantities and expenditures and a wider range of goods than typical aid-related procurement.
- Establishing capacity for transparent and accountable procurement of drugs, vaccines and materials helps improve the management of domestic delivery systems. Several Indian states, for instance, have developed improved competitive processes as well as domestic distribution systems that balance drug supplies over several months.
- National procurement capacity can also help improve overall domestic supply management and make domestic delivery systems more efficient.
- Using multiple sources of financing and following procurement procedures for different donors entails huge transaction costs, delayed procurement and disbursements, duplicative training and monitoring efforts and multiple logistical requirements.
- With improved domestic procurement capacity, purchases can be better tailored to domestic needs.

Developing countries argue that target dates could be established to phase out international arrangements, providing an incentive to build national capacities to procure drugs and vaccines. The international community could facilitate this process in two ways: by providing technical assistance for legislation and its implementation, as well as for training, and by establishing international standards of good practice in procurement, including transparency and accountability, thereby pro-

viding incentives for developing countries to adopt these processes and practices.³⁷ International agencies should increase efforts to help developing countries establish procurement capacity.

Current issues: harmonize procurement arrangements. Developing countries favour improving procurement arrangements such as those of the GDF rather than establishing new ones. The World Bank, the Global Fund and the GAVI should harmonize their procurement standards and practices.³⁸ As the discussion of HIV/AIDS illustrated, each new arrangement entails competition among agencies, learning by doing and unnecessary costs to developing countries in learning new or changing rules.

The lessons from developing countries should be taken on board by programmes such as the Global Fund and disseminated more broadly. Addressing the procurement issues head-on will increase the appropriateness, timeliness and affordability of purchases by developing countries and the scope for scaling up.

Human resources for health: the neglected critical factor

At various points in this paper the importance of underpinning specific disease control programmes with substantial health system capacity has been stressed. There can be no better illustration than a focus on health system personnel issues. Shortages of well trained doctors, nurses and health administrators are the principal barriers to more rapid progress. These shortages cannot be overcome from within specific disease control programmes—except perhaps at the expense of other important health programmes. As Lincoln Chen (2004) has noted, “irrespective of money and drugs, health achievements depend upon frontline health workers who connect people and communities to technologies and services ... pouring money and drugs at a problem is wasteful if workers are not available, motivated, skilled and supported.”

The availability of such health workers, particularly for public health programmes, was never great in most developing countries and has generally worsened in the past two decades. First, the spread of HIV/AIDS and TB has taken its toll, directly through death and absenteeism due to illness and indirectly by reducing the attractiveness of working in the sector. Second, budgetary constraints, in some cases linked to structural adjustment and health sector reform programmes, have resulted in underinvestment in professional health training programmes and facilities—with the result that today’s training pipeline is narrow and cannot

easily be expanded without a serious deterioration in quality. Third, demand for health workers in affluent countries and relaxed migration policies have swelled the exodus of better trained workers from developing countries. Fourth, the perennial problem of recruiting health professionals to work in the public sector and in rural areas has worsened because of constraints on civil service salaries and hiring policies and attractive offers from the private sector and donor-supported NGO programmes. All these issues are coming to a head as the AIDS epidemic dramatically increases the need for more and better trained health workers.

These problems are most severe in Africa. For Sub-Saharan Africa to improve the ratio of health workers to 1,000 people from its current level of 1 to the target of 2.5 (needed to reach the Millennium Development Goals by 2015), the region needs to add 1 million health workers between now and 2015 (Joint Learning Initiative 2004).

Among the four case-study countries health worker shortages are most severe in Malawi, where vacancy rates for funded positions in the public health system are at least 25% for nurses and as high as 80% for specialists; indeed it is alleged that there are more Malawian doctors in Manchester, England, than in Malawi.³⁹ Kenya is much better endowed with human resources, but donor support to NGOs and the unattractive salaries and working conditions in the public service have led to considerable loss of qualified staff to the private sector. The consequences can be seen most clearly in Kenya's rural health centres, where mortality and morbidity rates are increasing as the result of neglect and inadequate treatment of birth complications, respiratory infections and diarrhoea, as well as the continued spread of HIV/AIDS and related infections. The situation in India and China is less severe, partly because the infrastructure for training doctors and nurses is better developed, but also because efforts to recruit, train and deploy para-professionals—community health workers and volunteers in India, “barefoot doctors” in China—have been more successful. But even in those two countries the quality of care, especially in rural public clinics, is poor in the less developed regions and has deteriorated.

There are no simple common fixes. Issues that need to be addressed, besides the most obvious one of appropriate budget allocation, include civil service regulations and salary reforms, housing in rural areas, agreements with receiving countries to help sending countries recover the costs of training emigrants and donor policies on financing the recurrent costs of public programmes on a long-term basis.

Funding for vertical disease control programmes cannot solve these problems; in some situations such funding adds to the problem. Donors should consider funding training programmes on a large scale, as they did in the agricultural sector when food shortages threatened many developing countries in the 1970s.

Using a sectorwide approach. Meeting myriad donor requirements on a disease-by-disease basis is often difficult and wasteful and can dilute the ability of recipient countries to maintain national health priorities. A sectorwide approach to communicable diseases can in principle strengthen the stewardship role of ministries of health, promote greater cohesion in the sector, harmonize donor support and channel the limited capacities of developing countries to achieve results. These potential benefits, combined with demand from bilateral donors and some governments, have led the World Bank to participate in 30 health-related SWAP in nearly 20 countries over the past decade.⁴⁰

Using SWAP provides an opportunity to support a country's health sector development through time-slice financing, rather than earmarking support for particular activities or inputs. The approach requires broad-based ownership and partnership in the implementation of the health system strategy.

The GFATM supports the inclusion of its funds in common pooled funding mechanisms such as the ongoing SWAP for health in Mozambique. Malawi was negotiating SWAP with the World Bank, and GFATM funding could be folded into it. The government of India was considering developing SWAP for disease prevention by building on its successful TB programme that, although focused on a single disease, calls for a sectorwide approach. The GFATM affirmed that it would support India's initiative, including accepting the procedures and formats suggested by the government. For India this would be a major breakthrough in harmonizing approaches among donors for a specific disease, and eventually for more than one disease, enabling the government to be in the driver's seat.

Sceptics in the World Bank and in developing countries think SWAP could tie up considerable committed resources if donors fail to agree on certain issues. They note that there is no cross-country evidence that SWAP for malaria control have resulted in better outcomes or greater efficiency. They also raise questions about the technical rigor and strategic relevance of the programmes on which donors are harmonizing processes.⁴¹ In short, they are demanding more evidence that SWAP can improve outcomes.

Certainly SWAP may not be appropriate in all cases—particularly where there is no agreed-on strategy, where demand is not initiated by the government or where opinions differ between a government and donors. But where the approach works well it can be an effective way to improve the efficiency, quality and equity of a country's health system while ensuring a minimum package of essential health services. There has been no independent evaluation of health SWAP, and one is needed urgently, given their potential to contribute to sectorwide strategies.

Conclusions and recommendations

Global health programmes need to shift away from a tendency towards crisis management to focus more on longer term strategic planning and implementation. The crisis mentality, stimulated partly by very effective advocacy programmes, has produced a justifiable shift in resources towards treating communicable diseases. But it has been based on estimates of need rather than of absorptive capacity, resulting in inefficient use of resources and neglect of critical components such as prevention, system capacity building, surveillance, research, monitoring and evaluation and the role of other sectors. All affect health outcomes. The crisis mentality has also produced a proliferation of uncoordinated agencies and programmes that increase transaction costs and further reduce the effectiveness of foreign assistance. These problems are particularly severe in small low-income countries that depend heavily on aid. Without a change to a longer term approach, disappointment with results will eventually lead to donor fatigue that will threaten the sustainability of global health programmes.

These conclusions lead to the following recommendations.

- *Develop an effective mechanism for greater coherence and coordination at both the global strategic and the country operational levels, especially among the three core organizations—the WHO, World Bank and GFATM—but also among other related partners and funders. There is a natural division of labour between the core organizations, with the WHO setting standards and providing technical assistance, the World Bank assisting in systemwide policy planning and capacity building and the GFATM providing large-scale funding. The global system cannot work well without active and effective collaboration between all three at both the global and the national levels. Some agency must take*

the lead to make this happen, as well as to ensure that the other anchor functions are satisfactorily provided. Given the roles it now plays, the WHO seems the logical choice.

- *Increase the core funding of the WHO* (as opposed to funding from extrabudgetary sources of questionable sustainability) so it can properly serve as an anchor institution and satisfy the growing technical assistance needs of developing countries.
- *Make the World Bank more proactive in building national health system capacities and coordinating the health activities of bilateral donors.* As the only agency with significant operational capacity in all sectors, the World Bank has a relative advantage in assessing the appropriate balance between disease-specific and overall health system approaches, bringing into play other sectors, considering health in a macroeconomic context and helping design and support country-specific capacity-building programmes relevant to the health sector. It is also in the best position to lead countries in coordinating bilateral donor programmes for building health system capacity.
- *Ensure that the Global Fund continues evolving towards a true funding agency.* Building on steps it has taken in some countries, the GFATM should scale up its support for countrywide disease-specific strategies supported by other donors, without weakening its laudable outcome-based approach to funding.
- *Improve the balance between disease-specific and sectorwide programmes, between treatment and prevention and among the roles of public, private and community organizations.* The most serious imbalance arises from the relative neglect of systemwide programming and capacity-building efforts—especially in small, poor countries, where this neglect is hurting health programmes for non-communicable diseases. Donors and international organizations have a special responsibility to help these countries develop the capacity to correct these imbalances.
- *Sharpen the focus of some programmes and consolidate others.* Agencies that focus mainly on advocacy—for example, UNAIDS—have been more successful at the global level; they need to consider ways to work more successfully at the national and local levels. In research, TDR and the Global Forum should consider merging to achieve critical mass.
- *Establish programmes aimed at overcoming shortages of skilled and motivated professionals for the health system,* with policies and pro-

grammes that cut across disease-specific programmes. Donors must be willing to ramp up investments in health training and research institutes and to help governments fund adequate salaries for public health workers.

- *Substantially enhance monitoring and evaluation, research and data-gathering capacity at both the global and national levels.* Apart from critical humanitarian and development considerations, one reason for emphasizing treatment is that strategies and technologies for prevention are few, complex and difficult to implement and evaluate. Operationally useful lessons need to be drawn from the few successes in preventing the spread of HIV/AIDS and TB. Operations research is also needed, using randomized experimental designs to test strategies for inducing behavioural change. Medical R&D is needed to develop vaccines for communicable diseases, new and more effective barrier methods and ways to contain the growth of drug resistance. Funding for such research and related data-gathering and surveillance activities is much lower than benefit-cost estimates suggest is appropriate. Innovative mechanisms to induce private sector investments should be considered and piloted. Analysis and policy discussions must take account of factors outside the health sector that affect the incidence of communicable diseases. Much of the capacity needed should be created in developing countries. Many issues—for example, the appropriate choice of drug formulations and ways to change behaviour—are country-specific.

Acknowledgements

This paper is a collaborative effort by Uma Lele, Ronald Ridker and Jagadish Upadhyay. Major substantive inputs were also provided by Richard Skolnik and many others. Uma Lele retired as senior adviser to the World Bank's Operations Evaluation Department, now called the Independent Evaluation Group, and the other co-authors were consultants to the Secretariat of the International Task Force on Global Public Goods. The views expressed in this paper are those of the authors and do not necessarily represent the views of the World Bank, its Independent Evaluation Group or the International Task Force on Global Public Goods.

Notes

1. The few exceptions include immunization services. The universal characteristics of the private sector include its wide range in quality—often from the best in high-income urban areas to the very weak in poor regions and rural areas—leaving considerable scope for knowledge sharing and quality enhancement.
2. The Report on Macroeconomics and Health (WHO 2001), the appeals of the UN Secretary-General at recent meetings and the Group of Eight Okinawa meeting are examples.
3. By the time the Global Fund began operating, however, the World Bank had committed \$550 million to HIV/AIDS in 16 countries and approved the second phase of the MAP (MAP2).
4. Disease-specific programmes are typically organized vertically, that is, they are directed, supervised and executed by specialized agencies with dedicated resources and workers. This contrasts with multipurpose, or horizontal programmes, which integrate different aspects of health sector development within individual countries.
5. The breakthrough global agreement on antiretroviral drug supply, pricing and trade forged by the Clinton Foundation, the World Bank, UNICEF and the Global Fund based on WHO guidelines in 2003 allows many of the world's poorest countries to buy HIV drugs but also confronts the challenge of the weak delivery systems, increased aid dependency for treatment and perhaps the most significant issue—long-term sustainability.
6. The WHO, for example, is the major supplier of technical assistance for the GFATM proposals funded in developing countries and an observer on the GFATM board, and the World Bank is the trustee of Global Fund resources. Both the World Bank and UNAIDS Secretariat are observers on the GFATM board. The World Bank is a co-sponsor of UNAIDS with 10 UN agencies, has observer status on its board and receives funds from UNAIDS to operationalize several UNAIDS messages in World Bank operations.
7. In China the World Bank helped mobilize grant funds from DFID to make its overall lending terms attractive to the health sector.
8. A careful statistical study of the effects of education, especially of girls, may indicate a stronger negative effect on HIV infection rates than do information, education and communication or condom distribution programmes. Improved nutrition, which education as well as other policies can affect, is likely to increase resistance to become-

ing infected by communicable diseases. Some legal and institutional arrangements—perhaps laws regulating prostitution, needle exchanges, marriage, labour relations and policies regarding national service—may also result in lower infection rates.

9. India's polio eradication campaign is one of the largest ever efforts at social mobilization. According to the health officials interviewed, polio eradication is highly staff intensive. Nevertheless, if India can sustain its current rate of progress, it will be declared polio free in 2005.

10. Some commentators on an earlier draft stressed that in India, as in China, the share of health in public budgets is among the lowest in developing countries. India has recently announced its intention to double the health budget. Yet questions about priorities among competing demands remain daunting and decisions are driven in part by local needs and a political process.

11. Elsewhere in the world, including other countries of the former Soviet Union, TB incidence is falling or stabilizing.

12. RBM launched the Mekong Project in China in October 2000 with a one-time allocation of about \$200,000, with the expectation of implementing the project for 10 years. This regional project combined local development activities in four other countries along the Mekong River: Viet Nam, Laos, Cambodia and Thailand. The project stopped because no further funds were provided. Another project influenced by RBM was the elimination of malignant malaria in the mountain areas of Wuzhishan in Hainan Province, a research project started in July 2003 for three years with a budget of about \$50,000. The modified regimen was recommended by the WHO as the standard regimen to eliminate malignant malaria. A first round GFATM grant enabled China's Tenth Five-Year Plan (which included programmes for malaria control in remote counties of Yunnan and Hainan) to be realized. The possibility of implementation in remote counties was not clear because of inadequate funds.

13. Investments were highly targeted to high-risk municipalities in the Amazon basin in Brazil and the 15 high-burden provinces in Viet Nam. Even in Eritrea, where targeting was not central to the project design, control efforts focused more on the most heavily affected zones.

14. Brazil decentralized most government functions during the first few years of the malaria control programme, shifting the responsibility and resources for malaria control to municipalities. In Eritrea and India much of the responsibility for implementation was shifted to zonal and state health authorities, respectively.

15. Even the World Bank's financing of antiretroviral therapy is relatively recent and was prompted by a combination of decline in prices of generic drugs, external advocacy, the vast need and the perceived success of a pilot effort in the Caribbean. For additional information, see the Bank's Regional Treatment Acceleration Program for Africa (2004).

16. The GFATM was reviewing its first two years' performance while this contribution was being finalized.

17. Government questioning of NGOs is viewed sceptically by some as being politically motivated and driven by the desire of governments to monopolize resources. The truth usually lies in the middle. Not all NGOs are able and incorruptible and governments do like to control resources.

18. \$786.6 million of IDA, \$129 million of IBRD and probably another \$50 million of health components in multisectoral projects.

19. NGOs argue that if the Global Fund learns from its experience and becomes more responsive to their needs, it will help them strengthen their capacity to prepare and submit proposals for funding. An alternative view is that since only a small share of the proposals submitted get funded, and the bulk of GFATM funds inevitably goes through the public sector, a competitive process wastes the limited internal capacity of developing countries. Some commentators also note that it has proven easy to recruit well qualified consultants to write good GFATM proposals, but often the consultants or the international agency staff who write the proposals are not responsible for their implementation, and the recipients often lack implementing capacity.

20. For example, the World Bank has shortened and expedited its project preparation and approval process and made its disbursement procedures more flexible.

21. China, for example, has not been able to meet counterpart funding requirements in the health sector in several provinces that face funding shortages. The implication is that GFATM funds are being used to fill shortfalls.

22. A Kenyan NGO obtained a GFATM grant even though the proposal missed the deadline for submission to the CCM. There may be other examples of such inconsistencies with the declared rules.

23. In India, for example, the demands on the government to review and help improve the huge number of proposals coming from various groups are considerable. More generally NGOs are demanding more capacity-building assistance, which the government does not have the

resources to provide. Local Fund agents provide a case in point. There is a consistent view in developing countries that they are strong on fiduciary matters but weak on a variety of developmental aspects. Similarly they cannot always supply the complementary skills and knowledge of development that the staff of other agencies are able to provide.

24. Unlike those of the World Bank, GFATM disbursements tend not to reflect the actual rate of implementation. This is because GFATM funds are transferred to the principal recipients but not to the actual recipients until they meet the Fund's demanding requirements for disbursements. This is a good fiduciary practice, yet its result is that disbursements overstate implementation outcomes.

25. For example, the GFATM approved a large proposal in Malawi while discouraging the grant applicants from including capacity-building components, even though human capital constraints in Malawi are legendary. Malawi's frustration with the slow disbursements was all the greater because it was aware of the human capital constraints but was discouraged from including a response to them in the proposal that was approved. As noted above, the GFATM is proposing to make human capital development an important part of its fifth round for financing.

26. Comments by the GFATM on 24 March 2005.

27. Some country-based donor agency staff members feel there is a lack of congruence between the stated commitment of their agencies to supporting SWAP and donor support for the GFATM.

28. Establishing baselines and assessing performance based on subsequent monitoring and evaluation and timely supplies in the right doses at the right time have also been challenges for GAVI. Both China and India have also had serious problems of injection safety.

29. Pediatricians interviewed in India confirmed that they recommend multivalent vaccines to their patients in the cities who can afford to pay the nearly Rs. 900 cost of the vaccine, which includes hepatitis B. However they do not see the use of such costly vaccines as financially sustainable in rural areas. Moreover, there is a considerable debate among health specialists in India about how widespread the incidence of hepatitis B is among children, underscoring the need for epidemiological research.

30. Even for agricultural research, however, donor investments appear to have peaked.

31. The Commission on Macroeconomics and Health recommended that \$3 billion be spent annually on health research. Some sources con-

sidered this level unrealistic in the current aid climate, while others questioned the assumptions underlying the estimate.

32. A view expressed by the Secretary to the Commission on Macroeconomics and Health in India, among others.

33. Investments in health research by middle-income developing countries such as Brazil and Cuba reach almost 2% of health expenditures. India has adopted the same target. Brazil and Colombia are searching for new sources of research funding—for example, taxes on alcohol and tobacco. But their health expenditures go disproportionately to the tertiary sector and perhaps so do health research expenditures.

34. For details on this initiative, see Keusch (2003). Who and what should determine research priorities and how scientific probabilities of success and science quality should be balanced with societal needs and preferences in allocating resources have been challenges for health research. Even at the national level, setting research priorities based on the burden of disease and research gaps relative to the needs of politically more powerful urban populations remains a challenge. The Global Forum has developed a methodology for research priority setting by national health research systems, but it is unclear how many countries are using it. In developing countries the priorities of national councils of medical research, much like the priorities reflected in public health spending, tend to be driven by the disease burden of the urban and elite populations, and they tend to focus on medical rather than social science research. There is no global process for setting priorities for health research for development and too little is known about national priority-setting processes.

35. Jamison (2001) has argued that rivalries among research and control communities in health and among different disease professionals have prevented them from cooperating, whereas agricultural scientists working at the international level were willing and able to overcome these rivalries for a common purpose of establishing a global agricultural research network.

36. Public funding for research takes place through “push” programmes, while “pull” mechanisms ensure markets for the products of research once they are developed. Both approaches are at work in global health initiatives. Kremer (2001) has stressed the many benefits of the pull approach: greater efficiency, fewer risks and research that is more precisely targeted to the end user. The pull approach has become attractive to aid donors.

37. It could award them internationally recognized certificates of good practice in much the same way that Transparency International announces a ranking of countries on corruption.

38. The World Bank is doing this in several countries, including the four studied here, but these efforts should be enhanced.
39. World Bank staff estimates. A *New York Times* article of 12 July 2004, “An Exodus of African Nurses Puts Infants and the Ill in Peril”, quotes from a report indicating that two-thirds of public health nursing positions in rural areas are vacant and a report that claims there are more Malawian doctors in Manchester, England, than in Malawi.
40. For the World Bank, SWAP can cover major subsectors or have multisectoral involvement in which health is an input; several modalities have been used to finance them. Other donors may sometimes use different definitions.
41. In Zambia, for example, the World Bank OED report on the Health Sector Support Project (IDA Credit 003239) noted that while there was progress on the reforms and harmonization agendas, “there is no clear evidence that the overall quality of, and access to, a national package of essential health services had improved.” Furthermore, the local perception prevailed of “too much emphasis on process and not enough on achieving visible results on the ground.” Drug shortages were common, especially in the urban health centres. In another example, while the Malawi Joint Program of Work (2004/2010) for the SWAP recognized malaria as the leading case of outpatient visits (30%), malaria outcomes were not among the 42 indicators in the SWAP indicator matrix. And in Uganda the coverage of insecticide-treated bednets is only about 15% despite the SWAP.

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