

# EXPANDING DOTS

*in*



## THE CONTEXT *of* A CHANGING HEALTH SYSTEM



WORLD HEALTH ORGANIZATION

WHO/CDS/TB/2003.318

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### **Acknowledgements**

The preparation of this document was initiated by WHO's Regional Office for the Western Pacific. Valuable comments were provided by members of the Strategy and Technical Advisory Group for TB (STAG-TB).

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## INTRODUCTION

In 2000, the World Health Assembly, recalling resolutions WHA44.8 and WHA46.36, restated two global targets for TB control: to treat successfully 85% of detected smear-positive TB cases; and to detect 70% of all such cases (1). Meanwhile, country-specific data suggested that in 2000 90% of the world's population was living in countries that had adopted DOTS, the internationally recommended strategy for TB control. However, only approximately 27% of the estimated number of new smear-positive cases were detected under DOTS (2). To reach the global targets, it is widely recognized that DOTS implementation must be expanded (3).

The international community has responded to this call. In 2000, for example, governments of countries with the highest burden of TB signed the “Amsterdam Declaration to Stop TB”, committing to expansion of DOTS to reach the global TB control target of at least 70% detection of infectious TB cases by 2005. Similarly, a summit of the G8 countries committed to increasing resources for the control of TB. The Stop TB Partnership has brought together countries, technical partners, funding agencies, and civil society to fight this scourge collaboratively. A Global Fund to Fight AIDS, Tuberculosis and Malaria has been established and is being operationalized.

Despite these advances, the priority given to reaching global targets for TB control must be considered in context. Tuberculosis is not the only priority public health concern, nationally or internationally. Other diseases of poverty, such as malaria and HIV/AIDS, as well as prevention efforts, such as those available through immunizations and interventions such as IMCI (integrated management of childhood illness), and reproductive health activities are also priorities. Health systems are challenged to respond to these multiple priorities with limited human and financial resources and other operational constraints. In considering how to expand DOTS further, therefore, it becomes important to consider the context in which DOTS is being expanded. This context includes multiple priorities, limited resources, and changing political environments.

The context calls for consideration of how control of TB will contribute to the overall aim of strengthening health systems. It also requires consideration of how giving priority to TB control can be balanced with the need to simultaneously address other health and development concerns. In this light, DOTS expansion will require careful strategic planning that embraces multiple priorities, builds on the strengths of current health systems, and promotes TB control as a mechanism to further improve the overall quality of health services delivery.

In conjunction with mounting responses to the various public health priorities, many countries are striving to strengthen their health systems to make them more equitable, effective, efficient, responsive, and sustainable. These health sector

reforms - or health system strengthening efforts - often result in changes in the way disease control is prioritized, planned, delivered, and monitored; the changes offer both opportunities and challenges, in terms of maintaining current TB control efforts and in expanding DOTS.

Fortunately, the DOTS strategy has proved itself to be adaptable, enhancing the capacity of the primary health care network to detect, diagnose, and treat TB patients. Successful DOTS delivery has been achieved in a range of health system contexts including those that use community-based care networks, primary care facilities, hospitals, and nongovernmental organization (NGO) networks; those that channel financing directly to the TB programme and those that finance via a sector-wide approach; and those that engage a mix of public and private sector providers. The modalities for planning and implementing DOTS may be as diverse as the health systems in which they are operationalized while still yielding quality outcomes.

The DOTS strategy incorporates proven technical and managerial norms in an implementation framework (4). The challenge is to ensure that the framework is moulded into a DOTS implementation plan that reflects the priorities and strategies of the overall health system, builds on the strengths of the primary health care network for delivery of TB control, and ensures that all components of DOTS are incorporated into the functioning of the health system.

Public health specialists working in TB control and/or managing NTPs have cited challenges to balancing the proven technical norms of the DOTS strategy with the operational realities of changing health systems (5-7).<sup>1</sup> This document offers some considerations that may facilitate increased involvement of the NTP in a health sector reform process, encourage increased technical inputs into health systems planning, and promote the strategic positioning of TB control in the context of changing health systems.

Lessons learned from Cambodia, Ghana, Kenya, Kyrgyzstan, Malawi, Mexico, Philippines, South Africa, Uganda, and Zambia are the foundation for these considerations and are cited throughout the document. It is recognized that the future of health sector reform will differ markedly from country to country, depending on a host of variables including the aim of the government, the influence of donors and other partners, and the present stage in the process.

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<sup>1</sup> Also, meeting of the Strategic and Technical Advisory Group, 2001.

## BACKGROUND: HEALTH SECTOR REFORM AND TB CONTROL

Health sector reform is most appropriately described as a process. Reforms undertaken to strengthen the health system reflect a continuous process of needs assessment and identification, system enhancement, and evaluation. While the approaches that countries take to the reform process are as varied as national health systems themselves, there are commonalities in terms of reform objectives and the modalities that have emerged.

### 2.1 Objectives

The objectives for reform may include a desire to:

#### **Promote equity**

Public health systems are designed to ensure the availability of health care for a country's population. By definition, public health systems are the responsibility of government.<sup>1</sup> Government financing of TB control, through salaries, drug supplies, buildings, technical guidance, or other commodities, enables the provision of services that are affordable, accessible, and technically appropriate.

The primary responsibility of the public health system can be seen as a means of ensuring health care for all, including the poor. However, studies have demonstrated that the poor have significantly lower rates of utilization within public health facilities than the rich (8). Similarly, utilization can vary significantly by sex, ethnicity, and geography. Reforms can attempt to correct these inequities by increasing access for, and utilization by, marginalized populations by focusing on diseases of poverty, or through other means (9).

#### **Enhance effectiveness**

Effectiveness relates to the outputs and results achieved by the health system and may be considered in most aspects of health system functioning. Reforms may aim, for example, to improve the regular availability of drugs, strengthen the quality of service delivery, or improve the impact of health system activities on the health of the population. Improving effectiveness is often cited as a requirement to increasing utilization and consequently, the public health impact of the health sector (10).

#### **Improve efficiency**

Efficiency reflects a "best buy" - maximizing the public health benefit through the best use of existing resources. A health system aims to ensure both technical and allocative efficiency.

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<sup>1</sup> From an economic perspective, government intervention in public health make sense where it corrects for market failures (e.g. ensuring health services in remote areas where no private providers exist), where it addresses externalities (i.e. curing a TB patient also prevents additional cases), and where it protects the poor.

Technical efficiency can be defined as “doing things right”, which would be achieved for a given disease by selecting a treatment regimen that is effective in curing the disease, that is feasible to deliver through the public health network, and that reflects good value for money. For TB control, the DOTS strategy is hailed as a cost-effective strategy, i.e. efficient, and one of the best buys in public health (9).

Allocative efficiency refers to the evidence-based prioritization of public financing to achieve the maximum health gains for the least costly combination of inputs. Allocative efficiency can be defined as “doing the right things”, in terms of the budget allocation to health in the context of all public spending, of budget allocations within the health sector, or of allocations for TB control.

For prioritization of budget allocations within the health sector, criteria that balance strict allocative efficiency with considerations such as spending to correct market failures, support public goods, and enhance equity have been suggested (11, 12).

### **Nurture responsiveness**

Recognizing that variations in health status, health-seeking behaviour, health care preferences, and quality perceptions occur within countries, health systems may seek to nurture context-specific approaches to health service delivery. For example, in response to a high prevalence of TB among a nomadic population, the health system may engage outreach workers in the provision of directly-observed treatment (DOT) for TB. To ensure that this type of flexibility or adaptability is possible, the health sector may explore systemic changes to enable local responses to local needs.

### **Increase sustainability**

Maintaining a public health system is costly. The World Bank estimates that, globally, public expenditures for health account for 2.5% of GDP (range 0.2-7.9%) (13).<sup>1</sup> Many governments in developing countries rely on bilateral and multilateral donor support and loans to supplement the available national budget for health. While improvements in efficiency could be seen as a modality to increase sustainability, health sectors may adopt other modalities to directly address the question of sustainability.

In general, increasing sustainability will require either an increase in budget or a decrease in cost. These changes may be effected, for example, by further expanding the resource base from which funds are drawn to support the health system or by limiting the costs to the government, i.e. reducing subsidies.

<sup>1</sup> In low-income countries, public expenditure on health accounts for 1.3% of GDP.

## 2.2 Modalities

The modalities to effect these improvements include:<sup>1</sup>

### Integration<sup>2</sup>

Integration refers to the combining of responsibility or activities at any level of the health system, thereby reducing any overlap or duplication of activities. Its primary aim is to improve efficiency for providers and patients. Examples of integration might include:

- Central ministry of health level: all communicable disease programmes are integrated under a single administrative unit to eliminate parallel drug distribution, separate health worker training sessions, or to promote collaboration.
- Provincial or state level: joint supervisory visits to decentralized levels are conducted to reduce the costs associated with multiple visits and the distractions to health workers by limiting the number of teams that visit.
- Health facility level: health workers become multi-task workers, responsible for delivering a variety of care packages.

DOTS enables TB case detection and treatment to occur within primary care facilities, as an integral part of essential services.

### Decentralization<sup>3</sup>

Decentralization refers to a shift in responsibility and accountability for planning, administration, and implementation of public health functions from central (or provincial/state) levels to lower levels of the health system. It may or may not include the devolution of financial and human resources to support the increased responsibility and accountability of public health functions.

By bringing decisions, and the power to act on them, closer to the population, decentralization aims to nurture health system responsiveness to local needs, increase demand for effective services, and promote equity. In addition, decentralization may stimulate community-level ownership of and engagement in public health issues such as TB control. Furthermore, a policy of decentralization may aim to improve efficiency by reducing the administrative costs associated with a hierarchical system.

<sup>1</sup> For further discussion of these modalities see: Weil DEC. Advancing tuberculosis control within reforming health systems. *International Journal of Tuberculosis and Lung Disease*, 2000, 4(7):597-605. Note that, for each modality, footnotes provide suggestions for further reading

<sup>2</sup> For more information on integration: (1) Barrett B. Integrated local health systems in central America. *Social Science and Medicine*, 1996, 43:71-82. (2) James DM. An integrated model for inner-city health-care delivery: the deaconess center. *Journal of the National Medical Association*, 90:35-39. (3) Nagappaul DR. *Why integrated tuberculosis programmes have not succeeded as per expectations in many developing countries - a collection of observations*. Geneva, World Health Organization, 1981 (document WHO/TB/81.122). (4) van Praag E et al. Can HIV/AIDS care initiatives be part of integrated health care? Lessons from developing countries. In: *XI International Conference on AIDS, Vancouver, 7-12 July 1996*. Vancouver, Conference Secretariat, 1996 (Abstract ThB400).

<sup>3</sup> For more information on decentralization: (1) *Health system decentralization in Africa: an overview of experiences in eight countries*. Geneva, World Health Organization (background document for Regional Meeting on Decentralization in the Context of Health Sector Reform in Africa. (2) *Decentralization and health systems change: a framework for analysis*. Geneva, World Health Organization, 1995 (revised working document).

**Cost-recovery<sup>1</sup>**

Cost-recovery, also called cost-sharing, refers to user fees that may be charged to patients for consultations, diagnostic services, or drugs. These fees allow patients to share with the government the expense of operating the public health system, thereby improving sustainability.

User fees are generally based on an assessment of the population's ability and/or willingness to pay for health care services. In general, the fees still represent a cost-savings to patients when compared with the local private sector, where health outcomes are similar. User fees may be tiered, meaning that the price for a consultation in a basic primary health care facility is less than the price for a consultation in a secondary or tertiary care facility. In this way, user fees may be used to encourage use of lower-level facilities, thereby promoting efficiency.

National policy may be introduced to exempt poor patients from user fees and may exclude certain services that carry positive externalities,<sup>2</sup> such as TB treatment and immunizations, from charging schemes. Cost-recovery may be introduced to enable health facilities to generate their own income. It is hypothesized that this offers an incentive for health facilities to offer quality services in order to further increase revenues and to afford additional inputs and labour costs.

**Social insurance<sup>3</sup>**

Another form of cost-sharing is initiated through social insurance - larger groups that are able to risk-pool contribute to the cost of providing health services through the establishment of health insurance plans. For the public health sector, the introduction of health insurance schemes improves sustainability by adding to the financial resource base.

Examples of social insurance range from full national insurance coverage (100% population coverage) founded in the social security system (e.g. Costa Rica), to mandatory, employer-based insurance where employers contribute to insurance premiums, to community risk-pooling.

There has been little debate concerning how or whether to require that TB control services be covered in social insurance schemes. Two of the major challenges are extending coverage to those most in need, and ensuring that providers serving the insured deliver quality care.

<sup>1</sup> For more information on cost-recovery: (1) Hammer JS. Prices and protocols in public health care. *World Bank Economic Review*, 1997, 11:409–432. (2) Ainsworth M, Shaw RP, eds. *Financing health care through user fees and insurance: case studies from sub-Saharan Africa*. Washington, DC, World Bank, 1996.

<sup>2</sup> Externalities refer to the “spill-over” effects of an intervention. TB treatment cures the individual patient and also prevents further spread of the disease to the population.

<sup>3</sup> For additional information on social insurance: Ron A. *Planning and implementing health insurance in developing countries: guidelines and case studies*. Geneva, World Health Organization, 1993 (document WHO/ICO/MESD.7).

### **Privatization<sup>1</sup>**

The role of the public health sector may be narrowly or broadly defined. The public health sector may, for example, act only where there is a comparative advantage in doing so, to correct market inefficiencies, to protect the poor, or in all facets of health care delivery.

During reforms, the scope of responsibility of the public health sector may change. This may result in some services being privatized or contracted out where the government no longer has the capacity or will to offer the services, or where a decision is made that there would efficiency gains in privatizing certain functions. An example is the privatization of reference hospitals that provide specialized care. One of the main challenges during privatization is ensuring consistent quality (e.g. maintaining standardized treatment regimens and recording/reporting systems in public and private facilities providing TB care).

### **Increased role of private and NGO sectors**

Discussion of health sector reform tends to focus on the public health system. However, the reform process often involves a strategic assessment of all functions of health care delivery demanded by the population, and consideration of how all partners - public, private, and NGO - can best collaborate to meet these demands. As this occurs, private and NGO sectors may be drawn more closely into the planning and implementation of public health functions. Closer examination of the activities of all players in the health system may highlight inconsistencies in the control strategies being employed by the various sectors. The public sector may take a lead in streamlining technical norms and standards such that care across the sectors becomes more seamless and consistent. Challenges may emerge where there is little motivation for private and NGO sectors to collaborate.

### **Sector-wide approach<sup>2</sup>**

A sector-wide approach refers to a planning and/or financing strategy that is founded on evidence-based priority setting with a comprehensive view of the health sector. This approach suggests, that for the health system to best balance multiple priorities and to address them despite limited resources, the health sector must be evaluated, planned, and/or financed as a whole. If TB control, for example, is a priority public health intervention, it will figure prominently in the overall health sector plan and be granted a budget that not only reflects its priority position but also considers the other financing needs of the health sector. The approaches taken to financing sector plans vary widely. There are examples of TB

<sup>1</sup> For additional information on privatization: Bennett S, Ngalande-Banda EE. *Public and private roles in health: a review and analysis of experience in sub-Saharan Africa*. Geneva, World Health Organization, 1994 (document WHO/ARA/CC/97.6).

<sup>2</sup> For additional information on sector-wide approaches: (1) Cassels A. *A guide to sector-wide approaches for health development: concepts, issues and working arrangements*. Geneva, World Health Organization, 1997 (document WHO/ARA/97.12). (2) Cassels A, Janovsky K. *Reform of the health sector in Ghana and Zambia: commonalities and contrasts*. Geneva, World Health Organization, 1996 (document WHO/SHS/CC/96.1.)

programmes that are financed through “mini-baskets”, whereby all partners interested in financing TB control pool their funds in support of the NTP workplan. In other countries, all health financing is pooled, with the NTP receiving an allocation from the “general basket”. Still other models finance TB control through a combination of pooled resources and earmarked funding.

**Prioritization of core primary care functions**

To increase efficiency and sustainability, and to free up resources for an increased focus on effectiveness and equity enhancements, the health sector reform process may shift resources from tertiary care to primary health care. In terms of TB care, this may provide further motivation for programmes to move from hospitalizing patients during the intensive phase of treatment to a system of ambulatory DOT.

Table 1 provides hypotheses of opportunities and threats that health sector reform present for TB control.

Sections 3-11 focus on maximizing the opportunities for sustaining and/or expanding DOTS in the context of a changing health system. Each section considers those aspects of the health sector reform process that may impact a core function of an NTP and offers some practical considerations to capitalize on the change process for DOTS expansion or improvement. The core functions explored are:

- strategic planning
- normative functions
- financing
- human resource capacity
- drug supply
- service delivery
- monitoring and evaluation
- Information, Education, Communication (IEC), social mobilization, and advocacy
- operational research.

A country example is provided in each section.

*Table 1. TB control and reform strategies: potential opportunities and risks<sup>a</sup>*

REFORM STRATEGY	OPPORTUNITIES	RISKS <sup>a</sup>
Decentralization programme integration	<ul style="list-style-type: none"> <li>• Regional and local needs analysis and response</li> <li>• Increased local ownership and commitment to selected priorities</li> <li>• Increased involvement of NGOs and community groups in case-finding and case-holding</li> <li>• Innovative planning for coordinated delivery of essential services</li> </ul>	<ul style="list-style-type: none"> <li>• Insufficient political recognition of TB problem</li> <li>• Insufficient technical or administrative capacity (procurement, training, supervision)</li> <li>• Loss of accountability</li> <li>• Problems in enforcing norms, standardized surveillance</li> <li>• Insufficient capacity and expertise remains at central unit</li> </ul>

Table 1. (continued)

REFORM STRATEGY	OPPORTUNITIES	RISKS <sup>a</sup>
Cost-recovery/ user-fees	<ul style="list-style-type: none"> <li>• More resources for local service delivery</li> <li>• TB services may be exempted</li> <li>• Subsidies or exemptions for the poor</li> <li>• Patients may perceive that services improve with payment</li> </ul>	<ul style="list-style-type: none"> <li>• TB care may be charged or patients may expect charge-disincentive to seek care or complete care</li> <li>• Less access for the poor</li> <li>• Providers focus on revenue-generating patients</li> </ul>
Extension of essential services coverage	<ul style="list-style-type: none"> <li>• Increased resources for case-finding and treatment extension</li> <li>• Economies of scale with integrating training, supervision, and/or delivery of essential services</li> </ul>	<ul style="list-style-type: none"> <li>• TB may not be selected as an element of the essential services package</li> <li>• Insufficient resources to finance all services</li> <li>• Insufficient attention given to how to deliver services coherently</li> </ul>
Sector-wide approach (SWAp)	<ul style="list-style-type: none"> <li>• Increased national ownership of health priority-setting, plans and programmes</li> <li>• Increased sustainability</li> <li>• Reduced duplication or conflicts in donor interventions</li> <li>• Coherent plans for resolving systemic problems</li> <li>• Increased flexibility in use of resources</li> <li>• Allowance for ring-fencing for priorities</li> </ul>	<ul style="list-style-type: none"> <li>• Focus on process rather than outcomes</li> <li>• Priority-setting more politicized</li> <li>• Lack of involvement in planning efforts</li> <li>• Loss of resources for key disease control inputs</li> <li>• Dedicated funds removed before new resource flows secured</li> <li>• Transitional problems have long-term effects, e.g. drug resistance, loss of credibility</li> </ul>
Privatization of hospitals and services	<ul style="list-style-type: none"> <li>• Incentives for most cost-effective care (e.g. less X-ray; more smears)</li> <li>• Contracts for TB care with payment contingent on results</li> </ul>	<ul style="list-style-type: none"> <li>• Faulty drug procurement</li> <li>• Less motivation to serve TB patients</li> <li>• Incentive to charge patients or restrict hospitalization</li> <li>• Managers have less public health knowledge, interest, or incentive to follow norms</li> </ul>
Involving the private sector	<ul style="list-style-type: none"> <li>• Improve involvement of private sector to increase quality of TB treatment</li> <li>• Increased accountability through performance-based contracts</li> </ul>	<ul style="list-style-type: none"> <li>• Insufficient incentives to collaborate in TB control, respecting national technical norms</li> <li>• Insufficient enforceability or clarity in contract terms</li> <li>• No improvement in technical capacity</li> <li>• Poor outcomes, drug resistance</li> </ul>
Insurance schemes	<ul style="list-style-type: none"> <li>• Increased overall service coverage of the poor</li> <li>• Increase in timely health-seeking behaviour</li> <li>• Reduced or no fees for service</li> <li>• TB indicators can measure quality</li> </ul>	<ul style="list-style-type: none"> <li>• Public health interventions may not be identified for coverage</li> <li>• Reduced care of remaining uncovered populations</li> <li>• Lack of support for technical oversight and capacity-building</li> </ul>
Civil service reform	<ul style="list-style-type: none"> <li>• Increased health worker numbers and/or pay increases motivation</li> <li>• Increased workforce in poorer areas</li> <li>• Performance-based evaluation might improve quality and focus on TB indicators</li> </ul>	<ul style="list-style-type: none"> <li>• Overall reduction in staffing</li> <li>• Reduced staff security is demotivating</li> <li>• Contracting may increase rather than decrease turnover</li> </ul>

<sup>a</sup> From: Weil DEC. Advancing tuberculosis control within reforming health systems. *International Journal of Tuberculosis and Lung Health*, 2000, 4:597-605.



## STRATEGIC PLANNING

Strategic planning refers to the responsibilities of the NTP to: advocate TB control as a public health priority; nurture a policy, financing, and operating environment that will support full implementation of DOTS through the health system; perpetuate a needs assessment and response cycle that includes ongoing monitoring of programme performance; and foster collaboration between all levels of the health system and among all partners involved in TB control.

### Policy recommendations

- An NTP, with an authoritative central unit, remains explicit within the structure of the ministry of health.
- A comprehensive and costed multi-year plan for TB control is available.
- Tuberculosis control activities consistent with the multi-year TB control plan are reflected in the health sector strategy, budget, and workplans, the health plans of all district levels, and development plans that include health, such as poverty reduction strategies.

### 3.1 Health sector reform issues

Effective strategic planning is perhaps the most challenging and vital aspect of NTP involvement in the change process. During health sector reforms, strategic planning will be required to maintain the smooth functioning of the NTP as it currently exists while designing/promoting an implementation framework for TB control that will enable it to excel in the emerging health system. Active strategic planning will also be required during any transition process - ensuring participation and ownership for decisions by all partners in and implementers of TB control. Any modality for effecting health system change that is considered within a country will call for strategic planning on behalf of TB control. The issues may include:

#### 3.1.1 Decentralization

Authority for strategic planning, priority setting, budget utilization, drug procurement, and other implementation functions may be devolved to lower levels of the health system. Decentralization may also include the elimination of intermediary levels of the health system, thereby linking the district level (or equivalent) directly with the central level. If well supported, the greater authority of lower levels of the health system for planning and implementing TB control may stimulate increased ownership for managing the TB epidemic throughout the health system. Decentralization also offers the opportunity for local levels to focus on implementation mechanisms most relevant to the local population. To capitalize on these opportunities, decentralization may command intense

collaboration between the central and lower levels to ensure political commitment for TB control reflected in local plans and budgets, and quality monitoring. Unless well managed, decentralization may result in differing priority being given to TB control in different geographical regions despite similar epidemiological realities. Issues related to inconsistent quality and compliance with technical norms may arise.

### 3.1.2 *Integration*

At the central level, the NTP may be merged with other communicable disease programmes under a common umbrella within the ministry of health. At central and decentralized levels, this may result in broader terms of reference for all individuals (i.e. multi-purpose workers) and a decline in the number of TB-specific personnel. However, there may be an increase in the overall number of health workers whose mandate includes TB control, thereby offering an opportunity to consider wider DOTS delivery. An integrated communicable disease programme may also result in a common budget for many aspects of programme implementation, such as training or supervision. The integration of functions such as drug procurement may shift responsibility for some core functions away from the central TB unit. In the case of drug procurement, anti-TB drugs may be procured and distributed within the essential drugs package. Integration need not mean that the normative technical role of the TB programme is lost. In the case of an integrated essential drugs package, the central TB programme still has a responsibility to advise on the quantification of national drug needs, elaborate the technical specifications, and plan and monitor drug distribution and drug stocks<sup>1</sup> (see section 4).

At the service delivery level, the delivery of TB care may be fully integrated within primary health care. The challenge is to maintain a balance between the efficiency of integrated service delivery and the need to ensure the highest quality of care in view of the technical/operational specificity of TB control. Strategic planning is the mechanism through which the NTP can plan how to make best use of the existing TB expertise at central and other levels to support and monitor the quality of service delivery.

### 3.1.3 *Cost-recovery*

User fees may be introduced for various primary care services. Generally, TB control will be excluded from the user fee structure because of the externalities associated with TB (i.e. since TB is infectious, the benefits of TB control extend beyond the individual receiving the treatment in the form of reduced transmission in society). Where user fees are seen as an incentive for providers to improve the

<sup>1</sup> See Ghana profile (page 31) for an example.

quality of service delivery, excluding TB control from the fee structure may serve as a disincentive for providers to diagnose and treat TB cases. To counter this phenomenon, it may be useful to consider alternative incentive schemes for patients and/or providers.<sup>2</sup> The strategic planning function may require wide awareness-raising of and support for the rationale for maintaining free TB services.

#### **3.1.4** *Social insurance*

Where social insurance schemes are being introduced or expanded, TB diagnosis and treatment may not be automatically included in the benefits package. In many countries, TB control is fully subsidized by government and donors to ensure free treatment for patients and may not be considered in the planning of insurance benefits. However, social insurance could prove to be an important financing source for TB control if TB treatment is included in the benefits package.

#### **3.1.5** *Privatization*

Several functions of a TB control programme may be privatized for anticipated efficiency gains. Some examples include drug quality control or procurement and distribution, hospital services, and reference laboratory functions. Careful consideration may be given to determining whether there is a comparative advantage to the NTP conducting some of the functions being considered for privatization, such as quality control. Where privatization can complement the strengths of the NTP and/or increase the efficiency of operations, the ministry of health may consider contracting these private providers or facilities to conduct activities of relevance for the TB programme. For example, where the national reference laboratory has been privatized, the NTP may contract with the laboratory to conduct quality assurance activities.

#### **3.1.6** *Increased role of private and NGO sectors*

To broaden the base of public health providers, private sector and NGO providers may be more systematically drawn into the public health network during a reform process. This presents an opportunity for improvements in access to TB control services. However, coordination by the NTP will be required to ensure technical consistency and quality throughout the provider network. Planning for the inclusion of private and NGO sector facilities in the network of TB providers adds another dimension to DOTS expansion. Linking the private and public providers into a cohesive and standardized network of TB service providers will require consideration of, among other things, the knowledge, attitudes, and

<sup>2</sup> See Cambodia profile (page 45) for an example.

practices (KAP) of the new providers (i.e. consistency with technical norms); balance of authority; diagnostic and drug supply quality and price; and recording and reporting. In its strategic planning role, the NTP can be engaged in policy decisions regarding these factors.

### 3.1.7 *Sector-wide approach*

Planning and/or financing of TB control may be considered in the broad context of the health sector and public health in general. The sector-wide approach process often begins with an assessment of priorities based on a desire to identify the package or mix of public health services that will maximize the benefit to society and minimize future risk to societal welfare. The NTP's strategic planning role involves the provision of inputs to the process (e.g. burden of TB in the country, status and plans for expanding or sustaining DOTS coverage, evidence of the cost-effectiveness of DOTS) to ensure the appropriate positioning of TB control within broad priorities, such as communicable diseases. Control of TB will be considered in the context of its contribution to the overall impact of the health system in achieving public health aims.<sup>1</sup> Securing a position of priority for TB control within the plan, maintaining a budget line for TB control (explicit or implicit), and ensuring that TB indicators are monitored as part of evaluating the move to a sector-wide approach are central to the strategic planning role.

## 3.2 **Considerations for DOTS expansion**

### 3.2.1 *Understanding the reform agenda*

Each country will have its own aims for reform and modalities for effecting change. A clear understanding of the reform agenda is needed to guide the NTP in the change process. Practical steps in gaining the background knowledge on the reform process include the following:

Review existing strategy documents regarding reforms

Existing documents that elaborate the national policy and direction for reforms are frequently used as the framework for future decisions, including how TB control will be operationalized (even if TB control is not mentioned explicitly). The documents may include:

- strategic direction or policy statement on the reform process or expected outcomes of health systems development;
- national health plan;

<sup>1</sup> The aims may vary by country, with one country focusing on improving equity, for example, and another country on efficiency.

- poverty-reduction strategy paper (PRSP);
- new organigrams highlighting staff placement;
- revised terms of reference for responsibilities of health staff at various levels;
- policy statements regarding the financing of the health system, including documents on social insurance plans and benefits packages if applicable;
- essential drugs list and supporting documents on procurement and distribution of anti-TB drugs and essential drugs (if different);
- indicators of health system performance.

Review these documents to identify the components of reform (e.g. decentralization, integration) relevant to the country. Note where sound TB control components have been included and where they are missing.

Identify the players in the reform process (central and decentralized levels)  
To facilitate the reform process, many countries establish a health systems strengthening or health sector reform division within the ministry of health, which may serve as a temporary or fixed resource. Depending on the role of donors and other partner agencies in the country, these agencies may also be important players in the strategic phase of health sector reforms, during transition periods, and in implementing and financing health sector activities.

It is important to ask various partners for their views on the role of TB control in the changing health system and suggestions for the involvement of the NTP at all levels in the change process. While advocacy for TB control is vital for building political support, it is also important to listen openly to the perceptions and viewpoints of various players. This will enable the NTP to focus on its perceived strengths and comparative advantages and to modify areas that are not perceived as consistent with the reform agenda.

### 3.2.2 *Conceptualization*

Adequate background on the reform aims, modalities, agenda, and players will equip the NTP to visualize how the emerging health system might function. The NTP can thus offer inputs that reflect a willingness to participate in the changes and support the aims. In practical terms, the NTP can design a DOTS implementation framework that makes the best use of the opportunities of the reform process while minimizing the risks to effective TB control. This framework should highlight, in detail, how each component of DOTS will be implemented and identify those responsible or accountable for its success in the changing environment.

The aim is to conceptualize DOTS implementation such that it becomes an invaluable strength of the overall health system and a successful indicator of public health outcomes. Two types of conceptualization are generally needed:

### **Implementation plan**

The implementation plan is the broad, medium-term DOTS implementation framework that answers the question “What will TB control look like in the changing health system environment?” Some considerations include:

#### *Components of DOTS implementation that must be safeguarded*

Despite efforts to adapt DOTS implementation to the context of the changing health system, some technical and operational norms may remain that, if not maintained at the central level, could threaten the quality, sustainability, or feasibility of effective TB control. If, after careful consideration, it is recognized that the risk of altering some principles of DOTS implementation is not countered by the potential benefits of the change, a limited number of norms may be highlighted as requiring safeguarding and discussed with policy-makers.

In the context of decentralization, for example, a country may devolve all responsibility for drug procurement to lower levels. The risk for TB control of creating drug-resistant strains of TB is high where non-standardized regimens, drug shortages, or substandard drug qualities exist. The NTP may wish to recommend that drug planning and distribution be decentralized while procurement and quality control remain centralized. Fully decentralized responsibility for strategic planning provides another example. A district or region may de-emphasize the importance of TB control and therefore not budget adequately for DOTS implementation. The NTP may advocate a continued role in strategic planning of TB control activities; further, it may suggest a policy of giving central technical programmes the authority to confirm that national priorities are reflected in decentralized plans.

#### *Aspects of reform through which DOTS can be strengthened or expanded*

Consider how the changing role of facilities can increase access to DOTS; identify criteria (e.g. availability of anti-TB drugs, access to a laboratory, trained health worker, regular supervision and monitoring, etc.) for a facility to be considered a DOTS delivery point.

#### *Support for decentralized levels to plan for TB control*

Determine whether TB control activities are included in the overall plan of the decentralized primary health care networks (e.g. provincial or state health plans). If TB control is currently planned separately, discuss the rationale for this and whether it will be continued in future. Encourage the inclusion of TB control activities in all integrated district- and provincial-level health plans. Make available the cohort analysis of the district or province and promote evidence-based decision-making that prioritizes TB control founded on an accurate needs assessment and status summary (estimated cases, trends in TB incidence, coverage with DOTS, treatment completion rates).

*Determination of how other core components of DOTS can be implemented in the context of the changing health system*

Consider the movement of a TB patient through the reforming health system to identify points where TB detection, diagnosis, and treatment are possible. Similarly, consider points where patients may experience delays or be lost from the system. Modify the implementation plan to address such constraints to case-finding and case-holding. Propose at which levels of the health system recording and reporting forms should be placed, and indicate where inputs (i.e. drugs, transfer of sputum) are needed.

*Capacity that needs to be built to effect change*

Where reform modalities include decentralization, integration, and the involvement of private and NGO sectors, the implication for the NTP is that capacities maintained by health workers currently engaged in TB control (e.g. recording and reporting) and the central NTP (e.g. strategic planning and budgeting) need to be extended. The most frequently neglected areas of capacity-building for decentralized levels include priority-setting based on evidence and available resources, strategic planning, and budgeting or accounting.

*Risks to TB control*

It may be useful to prepare a summary of the likely risks to effective TB control during the change process for discussion with policy-makers and as a focus for operational research (how to avoid the risks) and monitoring (whether the risks becoming reality).

**Transition**

The process of health sector reform involves a period of transition during which effective TB control must be maintained and new ways of working introduced. The transition period is often short, poorly planned, and under-funded. In parallel with planning how DOTS implementation can be delivered effectively in the changed health system, the NTP can develop a transitional plan that highlights the intensive capacity-building, supervision, operational research, advocacy, and strategic planning required at central and decentralized levels to maximize the potential for successful reforms.

*Building or maintaining political commitment for TB control*

The reform process will probably be a time of priority-setting and efficiency assessments. To position TB control, it is vital that the evidence base be compiled. It may be valuable, for example, to demonstrate the cost-effectiveness of the DOTS strategy, the country's performance in TB control in the context of reaching the global targets endorsed by the World Health Assembly, and the potential impact of sustained or expanded TB control efforts in contributing to the public health aims set out in the reform agenda. Cost-effectiveness analyses from various countries have been published (14, 15) and guidelines for conducting a cost-effectiveness analysis are available from WHO (16).

Other considerations relevant to priority-setting include the association between TB and poverty in many countries, TB and HIV interactions, and worsening rates of drug resistance. These concerns may be balanced with the success of DOTS globally or nationally. Such evidence in support of TB control as an efficient public health intervention, combined with an operational plan that reflects DOTS implementation as a strength of the changing health system, will provide the tools with which political commitment can be encouraged.

#### *Participation in the process*

Equipped with sound knowledge of the reform agenda, a plan for the success of DOTS in the changing health system (including a statement of concerns and proposals for ensuring that all core TB control functions are taken into account in the new structure), and evidence for TB control as a priority public health intervention, the NTP - if not already involved - is prepared to fully engage in the change process. The suggestions that follow may facilitate what is often a challenging entry into the various policy debates and decisions.

- *Seek partners.* The most obvious partners for the NTP are other communicable disease programmes that are experiencing the same frustrations, expectations, and hopes regarding the reform process. In addition, the decision-makers may welcome more unified inputs from the technical divisions of the ministry of health. The technical programmes may decide to establish an advisory committee to guide national policy on disease control issues. For example, a consortium of technical programmes can jointly offer to: identify a set of selected indicators that can be used to monitor health impact; design laboratory and service delivery networks; or specify the terms of reference for health workers in decentralized facilities or for joint monitoring and supervision. In this manner, collaboration is enhanced for priority-setting of interventions and safeguarding of key operational aspects.
- *Identify the forum or mechanisms for providing inputs*
  - Inquire from the health ministry's health systems development team, and from other partners, how the NTP should provide inputs into the process.
  - Find out when the health systems development team(s) meet and whether participation of the NTP is welcome.
  - Request that the NTP be offered the opportunity to comment on policy documents before their publication.

**Case study: strategic planning, Philippines**

In 1991, the Philippines initiated reforms in the health sector aimed at strengthening the autonomy of local government by decentralizing public health services. The functions of the formerly centralized TB control programme were to be devolved. To ensure the smooth transfer of functions and assets to the periphery, the NTP manager was involved in planning and implementing the decentralization. Through this involvement, the NTP was able to ensure that TB control indicators were monitored during the transition to a more decentralized system and that TB remained a core indicator of overall health system performance. The NTP was also able to support the Department of Health (DoH) reform efforts by quickly responding to constraints that emerged related to logistics management, monitoring and supervision, and maintenance of a national information system.

In 1999, the DoH initiated further reforms, highlighting the slow progress being made in reducing key public health problems and a worsening inequity in access to health services. Through a consultative process, the DoH stimulated NTP involvement in the formulation of objectives, strategies and resource requirements to address these concerns. The multi-year plan for TB control was an important input for the development of the reform agenda. While the NTP was merged with other infectious disease programmes at central level, at the operational level TB control was highlighted as one of three priority activities to be included in the public health units of hospitals.

The re-engineering of the health sector is both offering opportunities for the expansion of DOTS at peripheral levels and raising concerns that quality cannot be maintained with weakened supervisory capacity. The NTP and its partners, including the Philippine Coalition Against TB and international agencies, have been able to express their concerns to the DoH and have influenced the reform process. Perhaps the most important outcome of NTP participation in the process has been the maintenance of TB control as a priority activity, having a safeguarded multi-year budget and with its indicators being monitored as part of health system performance.



## NORMATIVE FUNCTIONS

Normative functions refer to the responsibilities maintained by the NTP for establishing technical policy, providing tools such as guidelines and manuals, building human resource capacity, and ensuring quality.

### **Policy recommendation**

The central unit of the TB programme maintains authority for defining and ensuring compliance with technical standards for diagnostics, drugs, reporting and recording, and treatment delivery (i.e. DOT).

### 4.1 Health sector reform issues

In the context of a changing health system, it is probable that much responsibility and authority will be devolved from central to lower levels or encompassed in a wider context (e.g. TB control within communicable disease programmes). Core normative functions, however, must still be carried out to ensure a cohesive and consistent national response to TB control. Determination of how and where to best promote the normative functions becomes a key policy discussion. Among the considerations are the following:

#### 4.1.1 Decentralization

Responsibility and accountability for normative functions such as strategic planning, training, and supervision may be devolved as part of encouraging local ownership and a local response to the TB epidemic. Balancing the benefits of decentralized normative authority for some functions with the need to maintain consistent quality nationwide can help to define the degree to which normative functions are decentralized. During the reform process, the NTP may advocate central authority for normative functions such as the determination of treatment regimens, elaboration of service delivery norms, monitoring of national trends in TB control, and regulation of drug quality. Where some normative functions are decentralized, the central unit may continue to provide inputs for local decision-making, build local capacity for planning, and monitor the implementation of norms.

#### 4.1.2 Integration

Where the NTP becomes a component within a more integrated division, consideration for how to best maintain effective normative functions will be needed. The control of tuberculosis has certain technical specificities that make it unique - for example, the need for directly-observed treatment to improve compliance/results; the need for multi-drug therapy, the high risk of drug

resistance, the public health risk of not curing patients, etc. These specificities can be highlighted within integrated norms and policies.

#### 4.1.3 *Increased role of private and NGO sectors*

While public health facilities are bound by definition to the normative policies of the central ministry of health, the same is not necessarily true of the private and NGO sectors. A decision to engage the private and NGO sectors in TB control will include exploration of how to achieve alignment with the technical and operational norms of the public sector.

#### 4.2 **Considerations for DOTS expansion**

The NTP will be required to carefully balance the need to maintain technical specificity and authority on certain issues with respect for the aims and modalities of the health sector reform agenda. Maintaining an evidence-based approach that relies on proven technical approaches and lessons learned from other countries will support an effective distribution of normative functions. Other technical programmes will be engaged in similar normative activities. Working jointly with other programmes can further enhance the efficiency of certain functions of the NTP (e.g. training) while adding more weight to its decisions. The normative functions inherent in the DOTS strategy include:

- ensuring that political commitment is reflected in adequate funding of TB control;
- adoption of technical norms with proven efficiency, namely sputum smear microscopy for diagnosis and short-course chemotherapy for treatment, and consistent application throughout the country;
- drug procurement and quality assurance;
- standardized recording and reporting forms for monitoring patient progress at an individual level and for epidemic control at a national level (note: standardized forms are important to facilitate continuity when patients move within the country);
- building and maintaining human resource capacity for DOTS implementation.

**Case study: normative functions, South Africa**

South Africa adopted the DOTS strategy in 1996 and began implementation in the context of a rapidly evolving, post-apartheid health care system. Key issues that influenced DOTS expansion during this period included:

- district health system in a nascent phase;
- boundaries for political and health districts being demarcated; and
- general devolution of responsibility from the central level.

The South African system is characterized by decentralized authority; the NTP therefore lacks line authority to directly compel provinces and districts to implement activities or to allocate specified levels of resources. Other means of achieving the aim of DOTS expansion had therefore to be adopted. Examples of approaches used include:

- ministerial declaration that TB is a priority programme; regular TB status reports are presented to the provincial health ministers' forum;
- promotion of DOTS as a “best practice” by highlighting international as well as South African small-scale pilot projects and their successes;
- designation of “demonstration and training” districts that receive intensified training and support;
- promulgation of a training manual health care worker and practical guidelines for establishing a “gold standard of care”;
- development of a central (national-level) tender for drug procurement from which provinces purchase their drugs, enabling the NTP to ensure that provinces used fixed-dose combinations widely and reserved single drugs for tertiary treatment sites;
- a district-based recording and reporting system, introduced in two pilot provinces, is now being expanded nationwide;
- development of treatment guidelines for multidrug-resistant TB to rationalize procurement of second-line drugs and to promote an evidence-based standard of care;
- generation of a national medium-term development plan and subsequent provincial implementation plans that adhere to the national framework.

South Africa is still facing a burgeoning TB epidemic fuelled by co-infection with HIV. However, progress has been achieved in establishing broad support for and acceptance of the concept of DOTS. As performance is widely variable across provinces and districts, ongoing efforts are aimed at supporting well-performing areas and bolstering areas that have experienced slower implementation of DOTS.



## FINANCING

Political commitment for TB control is reflected, in part, through adequate financing of DOTS implementation. The financing function involves active partnership with donors and financing agencies where government resources are insufficient to support needed TB control activities. It also includes ensuring smooth financial flows, uninterrupted financing, and appropriate prioritization of financing.

### Policy recommendations

- TB control services are free of charge in the public sector.
- An explicit budget, consistent with the budget of the national TB plan, is delineated at national level and at decentralized levels to which budgets are allocated; the central unit has access to all information regarding the availability of financial resources for TB control.
- TB diagnostic and care services are covered in the benefits package of all insurance schemes.
- An interagency coordinating committee for TB control is established and maintained to ensure cohesive financing of the national TB plan. (*Note:* in the context of basket funding or sector support, this may not be applicable. TB control may be represented in the broader discussion of sector financiers.)

### 5.1 Health sector reform issues

#### 5.1.1 Decentralization

A policy of decentralization may include the devolution of some or all of the budget for TB control activities to lower levels. This devolution may include full responsibility for budget planning or enumeration (i.e. how much is needed for TB control), budget allocation, and reporting on expenditures, and highlights a need to build capacity at the level to which finances will flow for budgeting, accounting, and reporting. Regardless of whether or not funds are decentralized, the comprehensive national plan for TB control must be budgeted to ensure adequate financing for a cohesive approach to TB control or to prioritize spending where resources are insufficient. As follow-up to the enumeration of a national budget, the NTP may map out the distribution of budget according to the decentralized financing structure. In this way, the devolution of funds need not limit the ability of the TB programme to know what is budgeted for TB at decentralized levels. The central unit can continue to monitor the sufficiency and technical appropriateness of financial flows and spending, correcting for constraints as possible. A proactive approach to budgeting as part of the strategic planning process may help the NTP to balance its technical normative function

and the ownership of the budget at decentralized levels. If responsibility for financial decisions and ownership of budgets is decentralized, the way in which the central level is able to reinforce its normative role may have to change to reflect less of a link to finances.

### 5.1.2 *Integration*

A policy of integration may affect financing in various ways (also see “Sector-wide approach” below). Integration of the NTP with other technical programmes under a common disease control division, for example, may suggest the combining of budgets (i.e. loss of a TB control line-item in the budget). Maintaining or increasing the budget for TB control activities may require advocacy within a broader communicable disease framework. Integration may also result in the flow of finances based on function rather than by disease. For example, the budget for anti-TB drugs may become integrated with that of the Ministry of Health’s drug procurement agency rather than disaggregated from the general budget for essential drugs. Integration of budgets will require that advance consideration be given to the prioritized allocation of funding. If, for example, the resources needed to fully fund an approved communicable diseases workplan are not mobilized and only 80% of the budget is available, which activities will be funded? Policy may suggest that every activity and drug supply be subjected to a 20% reduction, or it may ensure full funding for priority activities with other areas absorbing the budget cuts. In the case of TB control, it is critical that a sufficient and stable budget be guaranteed for drugs and TB control operations.

### 5.1.3 *Cost-recovery*

In general, TB control services are excluded from cost-recovery schemes. This is consistent with the WHO recommended policy that TB treatment be available free of charge. However, it is important to note that TB patients will seek initial consultations and diagnostic procedures in a context of cost-recovery. There is little evidence related to the impact of user fees for general health services on TB case detection. Where reforms suggest a change in fees to patients or revenues to providers, operational research and intensified monitoring of TB case detection may be indicated to guide future policy decisions.

### 5.1.4 *Social insurance*

Employer-based or social insurance schemes may represent an important financial resource for the public health network in general and providers in particular. Benefits for TB control services are frequently excluded from insurance benefits packages because TB patients are not usually charged for treatment in the public

sector. Excluding TB services from the benefits package and providing free TB treatment in public facilities mean that government is subsidizing the insurance scheme - either deliberately or unintentionally.

#### 5.1.5 *Sector-wide approach*

Financiers of the public health system may agree to reflect the government's policy of integration in their budget allocations, grants, or loans. In some countries, government, donors, and other partners have channelled funding into a common basket to support the broad health sector workplan. Governments adopting a sector-wide approach to financing may dissuade earmarking of funds to specific programmes or seek a mix of financing options that include basket funding and programmatic funding. One of the aims of basket funding is to improve sustainability by limiting the risk inherent in a programme dependent on one donor or a limited number of donors. It also offers the government an opportunity to distribute resources based on national rather than external priorities. The importance of having TB control well reflected in the national health plan is magnified in the context of sector-wide financing, particularly where earmarked funding for TB control is discouraged or prohibited.

#### 5.1.6 *Global initiatives*

Several global initiatives have the potential to increase financial resources for the health sector, and notably for TB control. Grants of anti-TB drugs are available to selected countries through the Global Drug Facility (GDF), coordinated through the Stop TB partnership. The awards (i.e. drug supply) are contingent on the willingness of a country's health sector to reinvest the funds previously allocated for anti-TB drugs in other aspects of DOTS expansion. Since anti-TB drugs account for a large proportion of the TB control budget in most countries, such assistance may represent a significant contribution to the national TB budget. Countries may apply to the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria to support expanded prevention and control activities. This support can be channelled across sectors and among governmental and nongovernmental partners, thereby enhancing the potential to coordinate a strategic and seamless network of providers and activities for TB control.

Governments (and specifically ministries of finance) and development partners have become increasingly interested in ensuring that development assistance and government subsidies for the social sectors are benefiting the poor - either proportionally or in a targeted manner. This is consistent with the aims of health sector reform to improve equity and enhance efficiency. Many countries are developing PRSPs in response to a multisectoral process of evidence collection, priority-setting, and strategic planning. Highly-indebted poor countries are required to prepare and successfully implement one-year poverty-reduction plans

in order to be considered for full debt relief. Successful implementation is measured against a variety of indicators, including those for health. To date, indicators for TB control have rarely been used to gauge progress in reaching the poor with health services. Where debt relief results in increased availability of funds for the health sector, TB control may also receive an increased budget if it is seen as a priority activity that benefits the poor.

## 5.2 Considerations for positioning TB control

Ensuring that TB control is well financed will require that it is highlighted as a priority activity within the national health plan and in decentralized health plans. Advocacy using epidemiological and cost-effectiveness evidence may be beneficial to building commitment to TB control. Effective advocacy may target financiers, including government, donors, and partners, as well as budget planners and budget holders, including integrated disease control departments and/or decentralized health management units.

In the context of poverty-reduction strategies, evidence of the performance of the DOTS programme in reaching the poor and identification of mechanisms to strengthen its impact will be needed.

In the context of integration or of a sector-wide approach, increasing the level of funding available for TB control may require that the emphasis of advocacy shifts from increasing support from a select group of donors, partners and government to increasing support for TB control within the context of overall health sector priorities. In all instances, the availability of a strong, costed, national plan for TB control will greatly facilitate application for grants and participation in broader sectoral support discussions.

While increased availability of resources through global initiatives is welcome, consideration must be given to the sustainability of this financing and the compensatory actions (i.e. increased government allocation or increased donor base) to be taken at the conclusion of the grant period.

To clarify potential avenues for funding of TB control activities, discussions with government, donors and partners might focus on:

- *Donors or partners that have traditionally supported TB control*: how financing of TB control will be channelled in future (i.e. whether they will continue to fund TB control directly or participate in basket funding).
- *Donors/partners supporting the general health system*: how TB control activities will be financed in future (i.e. how priorities will be determined, how advocates of TB control can proceed).
- *Government (i.e. ministry of finance, ministry of health)*: to review and discuss national financing mechanisms for health care and the financing of TB control in this context.

- *Insurance providers:* how to include TB control services in benefits packages.
- *Global initiatives:* compiling the local evidence and preparing proposals.
- *Poverty-reduction strategies:* evaluate the socioeconomic profile of TB patients currently benefiting from DOTS in various sectors, consider how DOTS might be adapted to better reach the poor or otherwise marginalized populations, and advocate this strategy within the context of improving access to and use of health services by the poor.

The NTP might also stimulate discussions related to the monitoring of financial flows and the possible linkages with TB control indicators. This may be achieved by monitoring the link between (1) financing flows and TB control inputs such as drugs, supervisory activities, training, laboratory equipment and reagents, and (2) financing flows and TB control outcomes such as cases recorded and treatment outcomes. Tying changes in financing mechanisms to programmatic indicators will be particularly useful during the transition phase. The health system may consider performance-based disbursement of funds linked to programmatic indicators or may simply monitor the programmatic indicators in order to ensure quality and sustained activity by all levels of the NTP.

#### **Case study: financing, Ghana**

One of the primary aims of the health sector reforms initiated in Ghana in 1995 was to “improve” financing of the health sector. The Ministry of Health sought to establish common financial management and implementation arrangements with all partners. A sector-wide approach was adopted, with government, donors, and other financial partners pooling resources in support of the health sector. Another key feature of the reform strategy was the decentralization of budgets and responsibility for planning and implementation to districts.

Cost-recovery was introduced to enable revenue generation at the facility and district levels, although TB treatment remained free of charge. This was seen as a disincentive for health providers and facilities to provide quality TB care, because it does not generate income.

Funds allocated to districts are not earmarked; districts can therefore plan, and disburse funds, according to local priorities. Before the reforms, the NTP provided direct funding to the districts for TB control activities. The change in financial flows and lack of earmarking of funds have resulted in many districts not allocating funds for TB control from their general health services budgets. Since the central unit does not know the allocation for TB control at district level, wide disparities in the quality of TB control between districts have emerged. Anti-TB drugs, and laboratory supplies and equipment are financed within line-items for essential drugs and equipment. There are reports of delays in the release of funds to districts.

No specific budget line exists for TB control at the national level. The central unit of the NTP can budget for its own activities but cannot plan or budget comprehensively for the implementation of DOTS nationally.

A mid-term review of the health sector reforms acknowledged the constraints facing the NTP and other programmes as a result of some of the changes. In response, key changes taken into account in the 2002-2006 plan for the health sector includes:

- TB control highlighted as a national priority;
- a package of essential public health services, including TB control, defined and to be implemented by the primary care network;
- cost-recovery system to be replaced by community health financing and insurance schemes;
- plans for strengthening the monitoring and supervision of TB-related activities.

## HUMAN RESOURCE CAPACITY

The NTP retains responsibility for building and maintaining human resource capacity for the planning and implementation of DOTS at all requisite levels of the health system. This responsibility is tied to the NTP's normative function and therefore implies collaboration with public, private, and NGO sectors including universities and training centres.

### Policy recommendations

- At central level, sufficient staff capacity exists to coordinate all core functions of DOTS implementation (i.e. strategic planning, normative functions, financing, human resource development, stable drug supply, service delivery, monitoring and evaluation, IEC, advocacy operational research) and to engage financial and technical partners in TB control.
- At regional or provincial and district levels, sufficient staff capacity exists to prepare decentralized strategic plans; plan and manage drug supplies and equipment; maintain treatment registers; conduct supervisory visits; train lower-level staff; monitor DOTS implementation; support laboratory services; plan and conduct relevant operational research; and coordinate activities with partners.
- At health facility level, sufficient staff capacity exists to detect and diagnose cases; administer treatment; maintain recording and reporting forms; provide health education to patients and communities; oversee TB treatment supporters; trace patients who default from treatment; monitor drugs and other supplies; and coordinate activities with partners.

### 6.1 Health sector reform issues

#### 6.1.1 Decentralization

Decentralization of responsibility to lower levels of the health system implies that additional staff or new cadres of health staff may be given responsibilities related to TB control. These staff may have little or no experience or training in DOTS implementation. Furthermore, the decentralization of responsibility, budget, and accountability for service planning and delivery to lower levels may also imply a shift in human resources from central or provincial level (i.e. mid-level) to lower levels, thereby limiting capacity at these levels during the work-intensive process of health systems strengthening. Consequently, the need to provide technical and managerial training can be expected to increase dramatically during a period of health systems change.

### 6.1.2 *Integration*

Under a policy of integration, human resources may be pooled and used in the service of overall public health goals, including TB control. As with decentralization, integration may result in an increased need for training. With integration, the NTP can anticipate the emergence of a cadre of health workers that have, or will have, TB control functions added to their terms of reference, at varying intensities. This will make it necessary to train additional people in DOTS implementation. Integration policies may further suggest that training for the control of communicable diseases be combined or minimized, allowing fewer opportunities for detailed specific training in TB control. Opportunities for expanding or maintaining training in TB control through supplementary channels, such as with on-the-job training tools or by mentoring during supervisory visits, may need to be explored.

### 6.1.3 *Increased role of private and NGO sectors*

Since the private and NGO sectors are engaged in the provision of public health, training on the technical and managerial norms for DOTS implementation will be needed to ensure standardized and high-quality service delivery.

## 6.2 *Considerations for positioning TB control*

In a context of decentralization and integration, the number and profile of health providers engaged in TB control activities will change – perhaps dramatically. The result may be fewer health staff with TB control as their sole or primary responsibility and more health staff with TB control as one among many responsibilities. This may increase the number of facilities able to offer TB control services but may diffuse TB expertise. The response of the NTP may be to:

- Tailor training materials, course formats, and the content of supervisory visits to meet the needs of the changing profile of human resources, and specifically to provide basic DOTS implementation training to many general health workers and increase technical support to facilities.
- Identify opportunities to provide training in DOTS implementation through integrated training and during supervisory visits. Modalities can be identified to ensure that, where integrated training is envisaged, it will include the essential components of TB control commensurate with staff job descriptions.
- Ensure that pre-service training is consistent with national policies for TB control. The NTP may review the TB-related curriculum for medical and nursing schools and schools of public health to ensure that pre-service training reflects the changing terms of reference of health staff and that technically sound training on TB control is included.
- Develop on-the-job tools to reinforce the technical messages provided in training, especially for microscopists and treatment providers.

- Encourage on-the-job training and mentoring as a focus of supervisory visits.
- Map human resource capacity for TB control within the changing health system. As part of the strategic planning for DOTS implementation, the NTP may usefully engage in a mapping of human resource placement to ensure that health workers already trained in TB case detection, diagnosis, and treatment management are strategically positioned throughout the district and provincial networks. Mapping of the anticipated human resource needs that will emerge as the health system and patterns of DOTS delivery change will enable the NTP to develop plans for training and capacity-building.

Strengthening human resource capacity to effectively manage the health systems change process is crucial to the success of any reform process. This may require intensive training and supervisory activities, which must be included in the transitional and longer-term plans of the NTP and health sector, with adequate budgetary support.

WHO recommends that each level of the health network has one person identified as the focal point for TB control activities. Even in a context of integration, WHO recommends that the equivalent of district, provincial, and national TB coordinators be maintained. These focal points are particularly important during a process of change in the health system because they can monitor the technical and managerial aspects specific to TB control. They can guide TB control implementation strategies to reflect the changing environment and address emerging issues to ensure that case notification and treatment outcomes are sustained or continue to improve as the health system context changes.

#### **Case study: human resource capacity building, Kyrgyzstan**

Before the health reforms initiated in 1996, TB control services were provided through a specialized network of TB facilities staffed by TB experts. TB patients were hospitalized for 12 months, with over 4000 beds allocated for TB patients.

The reforms aim to facilitate access to quality health care by the population. To achieve this, the reform strategy has emphasized strengthening primary health care, and decentralizing and improving the efficiency of service delivery. Within this context, TB control is being gradually integrated into the general health services network. This change has required a new cadre of health worker, positioned at decentralized levels and in general hospitals, and the retraining of many specialists for primary health care activities, including TB control. As part of the decentralization and integration of TB control, more than 3000 general practitioners have been trained for DOTS delivery.



## DRUG SUPPLY

WHO recommends that a standardized regimen of anti-TB drugs be included in the national essential drugs list. It is the responsibility of the NTP to ensure a stable and quality supply of anti-TB drugs.

### Policy recommendations

- The central TB programme maintains technical oversight for the specification of drug formulations, quantification, drug distribution, and stock monitoring.
- To ensure a standardized, technically appropriate, and high-quality drug supply, anti-TB drug tendering and procurement are centralized.

**Note:** Decentralized levels may specify the quantities of drugs needed and transfer payment for them. A central procurement agency may procure anti-TB drugs within essential drugs packages or through alternative mechanisms, but should the central TB programme in review of technical specifications, quantities, drug distribution plans, stock monitoring, etc.

### 7.1 Health sector reform issues

#### 7.1.1 Decentralization

Policy decisions related to decentralization may emphasize the need to devolve responsibility for planning drug supply quantities and distribution to lower levels. This may be accompanied by a decision to devolve budgets for drug supply to enable local procurement. WHO emphasizes the need to ensure standardized anti-TB drug regimens, drug combinations, and drug quality throughout each country. Many countries have faced the challenge of identifying mechanisms that support decentralization while maintaining a stable and quality drug supply nationwide, or of striking a balance between the two objectives.

#### 7.1.2 Integration

Many countries procure and distribute anti-TB drugs in parallel to the essential drugs programme. A policy of integration may emphasize the need for streamlining of drug procurement and distribution mechanisms for all essential drugs - including anti-TB drugs.

### 7.1.3 *Cost-recovery*

Cost-recovery schemes may be introduced to collect a proportion or all of the expense of drugs from patients who use them. It is expected that patients will benefit from low prices, achieved through bulk purchasing, and high quality standards. The revenue generated through cost-recovery should enable sustainable local purchasing of drugs needed to serve the population. Even where cost-recovery for most essential drugs is introduced, WHO recommends that anti-TB drugs be excluded from such schemes and remain free of charge in the public sector.

### 7.1.4 *Privatization*

Privatization may extend to functions such as procurement, operation of the central medical stores, and distribution, with variable implications for the anti-TB drug supply.

### 7.1.5 *Increased role of private and NGO sectors*

As private and NGO sectors are brought into the network of DOTS providers, variability will be encountered in drug specifications available through public providers, private pharmacies, and NGO facilities or pharmacies. Consideration of how best to ensure standardized, high-quality, affordable drugs through all providers will be necessary.

## 7.2 *Considerations for positioning TB control<sup>1</sup>*

WHO emphasizes the need to ensure standardized drug regimens, drug combinations, and drug quality throughout each country. This suggests centralized bulk procurement and quality control of anti-TB drugs. In a context of decentralization, responsibility for planning quantities of anti-TB drugs and prioritizing a budget for these drugs within the context of an overall health plan can be effectively devolved with adequate capacity-building and technical assistance. It is recommended, however, that anti-TB drugs be procured in bulk by a central agency or unit for purposes of efficiency and quality control. An alternative approach is to capitalize on the strengths of the GDF for bulk procurement. A policy enabling decentralized levels to order and purchase drugs through the GDF would support the aims of decentralization while ensuring a stable supply of high-quality drugs.

<sup>1</sup> For further discussion on drug supply: Valasquez G, Madrid Y, Quick JD. *Health reform and drug financing: selected topics*. Geneva, World Health Organization, 1998 (document WHO/DAP/98.3) (Health economics and drugs, DAP series, no. 6).

Where a policy of integration supports the procurement and distribution of anti-TB drugs within the context of the essential drugs package, special consideration must be given to the transition from a specialized (i.e. anti-TB drugs only) procurement and distribution network to an integrated system. Anti-TB drugs might, for example, be phased into the integrated package. This could be accomplished by jointly engaging experts in the procurement of anti-TB and in essential drugs procurement to ensure that the technical and operational specifications of anti-TB drug supply are understood and accounted for. In addition, criteria for joint monitoring of the stages of anti-TB drug procurement and distribution may be established for ongoing collaboration between the anti-TB and essential drugs experts. Alternatively, anti-TB drugs may be included in select stages of the integrated procurement process. For example, the quantity and technical specifications for procurement may be prepared by the central unit of the NTP, tendering completed in conjunction with the essential drugs package, distribution handled by provincial and/or district TB coordinators, and inventory maintained jointly.

Decentralization and the involvement of other sectors in TB control may result in additional service points for DOT delivery. As TB patients access additional facilities for TB care, drugs will need to reach these additional sites. Expanded distribution or innovative mechanisms for ensuring that each diagnosis of TB is matched with an adequate supply of anti-TB drugs can be discussed with local health providers and TB supervisors.

The capacity of the public sector to procure a stable, low-cost and quality-assured supply of anti-TB drugs may represent a comparative advantage that the public sector can use to engage the private and NGO sectors as DOTS providers. For example, the public sector might offer to provide anti-TB drugs to the other sectors at cost (which will likely represent a large cost savings to private and NGO providers) in exchange for case recording and reporting.

#### **Case study: drug supply, Guinea**

The NTP in Guinea benefits from the financial and technical inputs of numerous partners. The DOTS implementation network includes NGOs working in partnership with government. Ensuring a consistent national drug supply requires coordination of these partner inputs. Under the leadership of the NTP, partners jointly enumerate the country's anti-TB drug quantity and supply needs. Through collaboration, they define the procurement plan for each agency. Drugs are received, stored and monitored by the central unit of the NTP. All partners engaged in DOTS implementation draw from the cooperative drug supply for their drug needs. In this way, a delayed procurement by one agency can be covered by the supply of another.

Guinea has had no drug stock-outs since 1986.



## SERVICE DELIVERY

The diagnosis of TB and provision of treatment can be considered under the umbrella of service delivery. In a changing health system environment, effective DOTS delivery is the crux of all policy decisions related to TB control in the context of the health system. While there are few policy debates that directly address service delivery, most policy debates and decisions aim to facilitate accessible and effective service delivery. Service delivery may be considered from the perspective of patients and their communities, such that patient and social satisfaction are primary aims. Service delivery must also be considered from the perspective of health providers, who need to be empowered and enabled to provide high standards of TB care.

### **Policy recommendation**

The DOTS strategy is an integral part of the essential services package delivered through the primary health care network.

### **8.1 Health sector reform issues**

#### **8.1.1 Decentralization**

As responsibility for core functions, such as planning and budgeting, are decentralized, the decentralized level will need to balance its managerial responsibilities with service delivery responsibilities. Decentralization policies may encourage patients to make better use of the health facilities nearest to them rather than specialized clinics in more central locations, resulting in an increase in the number of patients or severity of illness being dealt with by local health facilities.

#### **8.1.2 Integration**

Integration policies may call on certain facilities to provide a wider variety of preventive and curative services. This may change (and probably increase) the number of DOTS service points. The profile of health care providers will respond by becoming more multi-purpose, with knowledge of TB control becoming one of many technical requirements. In addition, laboratories may provide a broader base of diagnostic services. Again, this may increase the number of laboratories capable of conducting smear examinations to diagnose TB. At the same time, however, the technical expertise of microscopists may become more diffuse.

### 8.1.3 *Cost-recovery*

In an environment where cost-recovery is introduced, the impact on the ability or willingness of patients to pay for treatment in the public sector may change. While TB treatment may continue to be free of charge, patients will probably have to pay for the initial consultations before a diagnosis of TB is made. Careful monitoring of TB case notifications will enable the health system to identify and address any reduction in TB case detection rates as a result of a change in price.

### 8.1.4 *Increased role of private and NGO sectors*

To expand service availability without increasing the network of government-run facilities, health sector reforms may promote closer collaboration with the private and NGO sectors. (The implications for the public sector have been discussed in sections 4 and 6 on normative functions and human resource capacity respectively.) Ensuring the quality of service delivery through the private and NGO sectors should be the primary focus of the public sector.

## 8.2 **Considerations for positioning TB control**

The technical specifications of the DOTS strategy have proved their effectiveness in a variety of country contexts and are applicable in changing health system environments. Many successful programmes provide TB care as a fully integrated function of primary health care. The policy discussions related to service delivery can focus on the technical aspects that will impact the quality of service provision. In particular, the designation of TB diagnostic service points should reflect the recommendations WHO and the International Union Against Tuberculosis and Lung Disease (IUATLD) for laboratory networks. To maintain technical expertise, WHO suggests that a microscopist should 10-15 smear examinations each week.<sup>(17)</sup> Guidelines, consistent with the aims of decentralization and integration, for planning the laboratory network for TB control as an integral component of the general laboratory service of a country are available from WHO and IUATLD (17, 18).

As part of its strategic planning function, a mapping of the existing and future (anticipated) service delivery network is recommended to plan how best to support this network in terms of training, supplies, and supervision. The NTP may want to develop criteria that would qualify a health facility as a TB treatment service point, such as: availability of anti-TB drugs; access to a laboratory with smear microscopy capacity; regular supervision; and trained health workers. These criteria could be used to prioritize interventions (e.g. training) that need to be conducted to add service delivery points to the network. In addition, by mapping facilities that meet all the necessary criteria, a plan could be developed for geographical targeting of areas with limited TB service delivery points.

Further consideration might be given to expanding DOTS through other formal and informal service delivery channels, such as community health networks.

**Case study: service delivery, Cambodia**

In 1994, the NTP was revitalized and the DOTS strategy adopted. TB control was one of the first successful health service delivery programmes to be introduced since the dismantling of much of the health network in the 1970s. With little existing health infrastructure, TB control was provided initially through the hospital network. However, the NTP developed its medium-term strategic plan with the anticipated reforms and the establishment of a primary care network in mind. The NTP envisaged DOTS delivery through decentralized primary care facilities, as a core component of general health services.

In 1996, the Ministry of Health introduced organizational and financial health sector reforms to rebuild the health infrastructure and revitalize health services dismantled during the so-called “Khmer Rouge” period. The NTP was a key partner in the technical and policy discussions related to shaping the reform agenda. The reforms emphasized a decentralized model that would bring essential health care services to rural, underserved populations. Operational districts were established with 10-15 health centres each. A “minimum package of activities” was defined for implementation by the health centres and included TB control services.

TB control was one of the first activities introduced in the new health centres. By 2002, DOTS was available in more than half of the functional health centres, as well as in 75 referral and national hospitals. Since 1997, TB case detection rates have increased from 50% to 70% among the populations covered by DOTS.



## MONITORING AND EVALUATION

The recording and reporting system inherent in the DOTS strategy is an effective tool for patient monitoring, drug planning, and national trend observation. Most importantly in terms of health systems development, DOTS provides indicators for monitoring health system performance in general. Where DOTS has been in place for several years, baseline data exist for the success of TB control before any health system changes. These data can be readily shared with health systems planners as a simple means of evaluating the impact of reforms and the reform process on the delivery and outcomes of TB care. Where DOTS is being introduced or expanded, the recording and reporting system is a job-aid for health providers - ensuring knowledge of the medications to be provided and that patient progress is followed, problems in treatment highlighted, and cure confirmed.

### Policy recommendations

- TB indicators are included among the core indicators for monitoring health system performance.
- Standardized TB case recording and reporting forms are adopted nationwide, with responsibility for national surveillance maintained by the central unit.
- Monitoring of select TB control indicators is included in integrated supervisory activities and integrated surveillance systems.
- TB-specific monitoring and supervision are maintained to ensure the quality of the programme, complementing integrated supervision activities.

### 9.1 Health sector reform issues

#### 9.1.1 Decentralization

Where TB diagnosis and treatment are decentralized, decisions will need to be made regarding the levels at which patient recording, reporting, and data compilation occur.

#### 9.1.2 Integration

Where integration of communicable disease prevention and control and primary health care activities is promoted as a component of reform, integrated supervision is often suggested. The aim is to assess the overall performance of the health system and to address weaknesses or problems in a more comprehensive manner. While this approach cannot fully substitute for specific technical

monitoring of TB control activities, it is a rational and resource-efficient way to monitor the health system. It is critical that TB control be included in any such integrated supervision. This can be complemented by more in-depth TB-specific supervision on a periodic basis. TB experts can provide guidance on the indicators to be monitored and activities to be assessed during integrated supervision.

### **9.1.3** *Increased role of private and NGO sectors*

Engaging the private and NGO sectors in recording and reporting of TB cases in a manner consistent with the public sector norms will enable the monitoring of national trends in TB and facilitate quality control of service delivery.

## **9.2** *Considerations for positioning TB control*

### **9.2.1** *Case recording and reporting*

Case recording and reporting of TB, as is currently endorsed by WHO in the DOTS strategy, can be maintained in decentralized, integrated, changing health systems. TB-specific recording and reporting provides a “snapshot” of the overall quality of health service delivery through data on case detection and treatment outcomes. Simplified data on the number of TB cases may be extracted from the more complete data set for inclusion in overall communicable disease surveillance.

Where health systems are moving towards decentralization and a greater focus on primary health care facilities, the DOTS recording and reporting system can follow. A careful assessment of where patients are being detected, diagnosed, and treated will offer a map of how patients access and utilize services in the changing health system. This information can be matched with that on the laboratory network and drug distribution systems to identify the most efficient (in terms of time and access) mechanism for recording and reporting patients. The organization of the recording and reporting system should reflect changes in the DOTS delivery network and be linked to key inputs (i.e. provision of drugs, transfer of sputum).

### **9.2.2** *Supervision*

There will be a continuing need for intensive review of TB control activities and for technical support to health workers through supervisory visits. If decentralization leads to additional facilities assuming responsibility for TB control activities, the need for supervision will increase. Where integrated

supervision is introduced, TB experts can provide a supplementary focus on the technical and operational specifics of TB control not addressed in integrated supervision. The advent of integrated supervision should be a welcome addition to TB-specific supervision. It is important to rationalize which components of DOTS are reviewed by whom (integrated team or TB supervisor) and how often. Integrated supervision offers an opportunity for the complexities of TB control to be understood and appreciated as a priority public health activity by a wider constituency. When balanced with technical TB-specific supervision, the overall health system should benefit from improved TB service delivery at all levels. Principles that will ensure effective supervision of TB activities include the following:

- Use all opportunities for supervision: TB-specific supervision supplemented by integrated supervision activities.
- Review the terms of reference, team make-up, and frequency of visits for all mechanisms of supervision.
- Discuss the role of supervision with health providers, TB experts, health systems decision-makers.
- Propose rational division of supervision responsibilities. The TB teams at all levels are still responsible for reviewing all integrated supervision reports and focusing on any problems identified through further assessments.

*Table 2. Division of responsibility: example*

	INTEGRATED SUPERVISION	TB-SPECIFIC SUPERVISION
Frequency <sup>a</sup>	Quarterly	Every 6 months
Laboratory	Check that laboratory register is completed correctly  Check that follow-up sputum examinations are being done	Review smears: quality control  Match laboratory register to patient register
TB treatment facility	Check that patient register is completed correctly  Check that drug regimens are correctly prescribed	Review treatment cards and concordance with patient register  Analyse cohort analysis of treatment outcomes
Treatment point	Check that patient cards are completed  Check drug supply	Review knowledge of TB practices  Observe staff providing DOT

<sup>a</sup> Frequency to be flexible depending on country norms and transport feasibility.

**Case study: monitoring and evaluation, Peru**

The NTP in Peru was one of the first to reach the global targets for case detection and treatment success rates. Following 10 years of sustained quality DOTS implementation, the country is experiencing a decline in TB incidence. Peru acknowledges the role of its strong management and supervision system in this success. The DOTS system for case recording and reporting was adopted and the data were used to ensure appropriate planning, monitoring, and implementation of activities. To ensure widespread ownership and understanding of the data and its implications, over 250 health workers engaged in TB control meet twice yearly to review and analyse the data collected through the health system. Based on the evidence, the NTP and network of providers are able to identify priorities to be addressed in the following year.

## IEC, SOCIAL MOBILIZATION, AND ADVOCACY

As with any institutional or organizational change, changes in the health system will be met with uncertainty and resistance unless the goals, objectives, and strategies can be fully communicated to the population concerned such that the potential benefits are apparent and begin to motivate the change process. Changes in the health system will affect society at all levels - individual, household, community, and national. Designing and introducing a system that benefits all stakeholders, including providers and patients, will require proactive sharing of information, consistent participation of stakeholders, and the building of ownership for the changes.

### 10.1 Health sector reform issues

#### 10.1.1 Decentralization

Where responsibilities are decentralized, local governments may have additional power to set priorities for health care spending. In the absence of clear information on national priorities or the needs for and benefits of expanding DOTS locally, TB control may not receive sufficient budget or human resource allocations for ideal implementation. In a decentralized setting, advocacy to stimulate political commitment is needed at both national and at provincial or district levels - wherever priorities are set and budgets allocated.

### 10.2 Considerations for positioning TB control

Advocacy, IEC, and social mobilization can be used to stimulate political commitment at the decentralized level or among new partners in health services delivery for DOTS expansion. To ensure continuity of DOTS implementation and to identify opportunities for further enhancement of DOTS delivery, an ongoing exchange of information related to service delivery realities (i.e. the impact of reforms on the capacity of the health system to deliver DOTS) will be needed to inform policy discussions regarding the positioning of TB control in the emerging environment. This might best be accomplished through social mobilization techniques that build demand and ownership for DOTS among provider, political, and social communities. In a changing health system, the role of TB coordinators and other providers of TB control services may change. To maintain ownership for TB control by these providers and to expand ownership for TB control to the broader health sector, it may be effective to engage all coordinators in local advocacy and social mobilization activities.

Stimulating ownership for TB control by the broader health system, and possibly among new or different stakeholders, may require some changes in perception of DOTS or of TB in general. Where TB programmes previously operated in parallel with the primary health care network, for example, TB control may be perceived as well funded, as the responsibility of others, or as a specialized service. In addition, stigma associated with TB may act as a disincentive for general health providers and or communities considering how to prioritize TB control activities. It may be interesting to ask microscopists, health care providers, and community leaders whether TB control is part of primary health care or whether it is any way “different”. Is caring for TB patients seen as an additional burden and, if so, why? TB patients may be seen as undesirable or their care as expensive or time-consuming. These concerns may be addressed through IEC, social mobilization, or advocacy. Further operational research may also be required to explore mechanisms for motivating and/or supporting health workers in their efforts to control TB and for reducing the stigma associated with TB.

#### **Case study: social mobilization, Uganda**

Since 1995, DOTS has been available nationwide in Uganda through the primary health care network. However, case detection remains low because of limited accessibility to and utilization of health services. The NTP recognized that, to stimulate demand for TB care and facilitate access to TB services, it needed to engage communities in the detection and treatment of TB patients. The NTP developed a community-based care strategy and tested it in Kiboga district. The community-based approach improved cure rates from 59% in 1997 to 78% in 1998, and halved the costs of TB care for the health system and patients alike. On the basis of this success, the NTP began rapidly expanding the community-based approach to TB care.

Simultaneously, the Ministry of Health began discussing health sector reforms. The success of the NTP in mobilizing civil society to take ownership of a public health problem piqued the interest of policy-makers. It was noted in particular that community-based DOTS promoted strong partnerships between the formal health system and communities, while also building capacity at decentralized levels of the health system for planning and monitoring of activities. Community-based care became part of the national health sector reform strategy, making social mobilization systemic.

## II

**OPERATIONAL RESEARCH**

In the context of a changing health system, operational research becomes a tool for charting the course of DOTS implementation. Modalities for implementing DOTS in a “new” way or through untried mechanisms can be tested, refined, and adapted through operational research before being applied nationally. Operational research can build the local evidence needed to appropriately guide policy decisions.

**11.1 Health sector reform issues**

Health sector reform is a process that involves a cycle of problem identification or needs assessment, exploration of potential solutions, application of the solutions, and evaluation of the outcomes. Throughout the change process, decisions will need to be made on the basis of local evidence. Where local evidence is not available, operational research becomes the basis for policy decisions. However, policy decisions may also be made based on evidence from other country experiences, in which case operational research techniques may be engaged to monitor the impact of new policies or working methods on DOTS implementation.

**11.2 Considerations for positioning TB control**

Within each of the normative functions highlighted previously, operational research might be considered to substantiate a policy decision. An example is operational research aimed at better defining and improving the efficiency of the flow of patients between diagnostic, treatment, and referral centres in a newly decentralized system. This might include an assessment of the movement of patients through the local health network system to identify any delays or potential transfers where patients are lost from the system. The results might suggest policy changes to provide incentives to patients for a more efficient flow through the system (e.g. lower cost of consultations at the local health facility than at a hospital). Again, operational research techniques can be engaged to test and analyse the results of proposed policy changes.

**Case study: operational research, Malawi**

Malawi established its NTP in 1964 and was one of the first countries to implement what is now called “DOTS”. The NTP uses operational research to define problems and test interventions to solve them. Between 1996 and 2001, various research projects were carried out on health-seeking behaviour, equity in access to TB care, diagnostic practice, delivery of treatment, collaboration with other public health programmes, NTP management capacity, and supervisory and monitoring systems. Some 60 research papers have been published, the majority in peer-reviewed

journals, plus 14 articles and a number of chapters in textbooks or international documents. An example of how operational research in Malawi has been used to test and analyse the results of proposed policy changes in TB control is given below.

In 1984, the IUATLD provided the NTP with drugs for short-course treatment of smear-positive TB patients, and established a standardized reporting and evaluation system in all districts of the country. Cure rates rose from 74% in 1984 to 90% in 1987 (19). However, since 1988 this success has been compromised by the HIV epidemic. Annual TB cases started to increase sharply and the pattern of TB started to change; smear-negative cases exceeded smear-positive cases and there was an increase in the proportion of extrapulmonary TB. Cure rates decreased and mortality rates increased. The increased case-load strained laboratory services and congested TB wards raised concern over the quality of patient care since there had always been limited numbers of health staff on each ward. Morale among TB programme staff fell and donors threatened to withdraw funding unless performance improved.

The problem of hospital congestion was worst in urban areas where, in the mid-1990s, bed-occupancy rose to reach 160-200% of previous levels. NTP policy involved hospitalization in the initial intensive phase of treatment of all TB patients so that health care staff could carry out DOT. The period of hospitalization varied from one to three months. It was thought that involving the community in DOT delivery for the initial intensive phase of treatment would reduce the workload for staff and contribute to better patient care. However, a policy change required research that would show favourable results. Between 1998 and 1999, the NTP conducted operational research in decentralizing TB treatment in five districts in Malawi. In the study districts, community DOT options were offered to newly diagnosed patients. Choices included hospital outpatient department, health centre, guardian, and community health volunteer supervision. Fully oral regimens were introduced to replace those involving injections to facilitate community DOT. Of 6335 patients recruited in the study, 68% chose community DOT for the initial phase of treatment. The cure rate for new smear-positive patients was 62% - the same rate experienced at national level with the system of hospitalization.<sup>1</sup> (see below) WHO supported studies on cost-effectiveness and affordability of community DOT in one of the study districts. Involving the community in DOT was shown to be cost-effective and cheaper for the health service, the patient, and the community.<sup>2</sup> The results prompted the NTP to recommend countrywide expansion of community-based DOT to the Ministry of Health and Population; this has been adopted as national policy.

The operational research programme of the NTP has benefited from the technical and/or financial support of the College of Medicine of Malawi, WHO, Liverpool School of Tropical Medicine, London School of Hygiene and Tropical Medicine, Department for International Development of the United Kingdom, Norwegian Agency for Development Cooperation, and the Royal Netherlands Tuberculosis Association.

<sup>1</sup> Nyirenda T et al. Decentralisation of tuberculosis services in an urban setting, Lilongwe, Malawi. *International Journal of Tuberculosis and Lung Disease* (in press).

<sup>2</sup> Skeva J et al. Cost and cost-effectiveness of increased community and primary care facility involvement in tuberculosis care in Lilongwe District, Malawi. *International Journal of Tuberculosis and Lung Disease* (in press)

## CONCLUSIONS

A changing health system demands the attention of the NTP and all partners concerned with TB control. The mechanisms of health care service delivery will probably continue to change, with or without the involvement of the NTP. Clearly, changes that do not take into account the operational and technical requirements of an effective NTP will compromise a country's TB control efforts, with negative implications for years to come. "Health sector reform" does not inherently threaten the effectiveness of TB control; rather, it signals change and demands participation to ensure that the components of the DOTS strategy are well-positioned and incorporated in health service activities.

Incorporating an assessment of the health systems development process into standard monitoring missions for TB control programmes can strengthen the role of the NTP. In addition to planning adequately for operationalizing TB control in the context of the changing health system, this type of assessment can help to formalize partnerships between the TB programme and agencies or programmes involved in the reform or health systems development process.



## SUMMARY CHECKLISTS

### Summary checklist 1: Components that suggest successful positioning of TB control within a health system

#### National level

- Operational plan for implementing DOTS during the transition; i.e. short-term.
- Five-year operational plan for implementing DOTS in the changing health system (i.e. implementation framework that takes into account reform priorities and modalities such as decentralization).
- TB control indicators included in the summary of indicators that will be periodically monitored to assess the impact of the reforms.
- Budget for TB control is transparent and reflects priority status of TB control.
- TB drugs are included in the essential drugs package and a plan for their procurement and distribution is in place.
- Policies elaborated by the NTP and endorsed by the ministry of health, delineating the functions of the NTP that will remain unchanged and those that will change in accordance with reform aims (e.g. drug supply will continue to be procured centrally although planning of quantities will be decentralized with central level support).
- Terms of reference highlighting TB control functions or responsibilities of various levels of the health system.
- Terms of reference for supervision and monitoring visits, including the role of integrated supervision in monitoring TB control activities.
- Staffing pattern supports operational plan - both during transition and in the longer term.
- Plan for human resource capacity-building to reflect expanded and/or changing workforce (e.g. schedule and curriculum for training multi-purpose workers for DOTS implementation).
- Plan for building capacity of decentralized levels particularly in the areas of strategic planning and budgeting.
- NTP involvement in the decision-making process; for example, NTP is engaged in meetings of the health sector development team, provides technical inputs to reform process and reform documents.
- Noted collaboration with other communicable disease programmes, national HIV/AIDS committee, and health sector development team of the ministry of health.
- Noted collaboration with donors and other partners in the reform process

#### Lower levels

- Mapping of the health facilities that will offer TB control services, including a mapping of the laboratories and drug distribution mechanisms to support TB detection and treatment by facilities.
- Ownership for TB control reflected in plans for DOTS implementation within overall health plans.
- Budget for TB control is transparent and reflects priority status of TB.
- Staffing pattern supports DOTS implementation plan.
- Plans for building technical capacity of health workers to detect, diagnose, and treat TB, and managerial capacity to monitor patient care.
- Schedule of supervisory visits, including integrated supervision and TB-specific supervision.
- Availability of a six-month buffer stock of anti-TB drugs, laboratory reagents, and supplies.

## Summary checklist 2: Partners engaged in positioning TB control within the changing health system

Meet with:

1. Ministry staff involved in planning reforms or health systems development. Discuss:
  - How TB control can best be planned for as part of overall health system.
  - Inclusion of TB indicators for monitoring health system performance.
  - Level of involvement of technical programmes in decision-making process.
  - Plan for transition (training, funding, placement of staff).
  - Role of TB control programme in changing health system.
  - Forum or mechanisms for TB programme input into change process .
  - Inclusion of TB in national insurance or financing schemes.
2. WHO, World Bank, and other partners involved in TB control and/or health systems development. Discuss:
  - Perception of structure of future aid, how TB control can be best supported.
  - Role of technical programmes in decision-making process.
  - Inputs needed from TB programme.
3. HIV/AIDS programme staff. Discuss:
  - Perceptions of TB control programme and role of TB control in improving the care of people living with HIV/AIDS.
  - Identification of opportunities for stronger collaboration.
4. National council on HIV/AIDS. Discuss:
  - Enhanced collaboration with TB programme (20)
5. Established medical associations, where active, in reform process. Discuss:
  - TB control in the private sector; how to promote stronger collaboration with public sector.
  - Identification of constraints to providing effective TB control and negotiate possible solutions.
6. Decision-makers (i.e. provincial medical officers) at lower levels. Discuss:
  - How TB control is planned for and provided; how to strengthen role of TB programme in functioning of overall health system.
  - Ownership of TB control.
7. District health management teams. Discuss:
  - Level of priority being given to TB control.
  - How TB control is planned for, provided and financed. Role of TB control as core activity of health system.
  - How to promote effective TB control through public health and community channels.
8. Health workers. Discuss:
  - Constraints to providing effective TB control.
  - Importance of providing TB control among other activities.
9. TB patients. Discuss:
  - Accessibility of TB services (including fees).

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Printed in Italy

Design and printing: Jotto Associati s.a.s. - Biella - Italy





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