

# Discussion

## Detection and treatment of TB cases

Two hundred and one countries reported to WHO on the TB epidemic in 2002, more than in any previous year. The number of countries that had adopted the DOTS strategy increased to 180, and 69% of the world's population had access, in principle, to DOTS. Adding the 2002 case notifications to those of previous years, a total of 13.3 million TB patients, and 6.8 million smear-positive patients, were treated in DOTS programmes between 1995 and 2002.

The most critical markers of progress are case detection and treatment success rates. The smear-positive case detection rate increased to 37% globally, just over half way to the 70% target. Of 1.2 million smear-positive cases registered in the 2001 cohort, 82% were successfully treated, close to the 85% target, but no better than for the 2000 cohort. India reported the biggest gains in case detection among countries that provided data for both 2001 and 2002; the additional 59 858 smear-positive cases reported by the Indian DOTS programme represent 28% of the global improvement in case detection, in a country that has 20% of the world's case load. Other major increases in case detection were reported in South Africa, Indonesia, Pakistan, Bangladesh, and the Philippines.

Better case finding represents progress in TB control only when accompanied by high cure rates. Of the countries that have been most progressive on case detection, South Africa still reports a very low rate of treatment success (65%). If low treatment success means frequent treatment failure in this country, then drug resistance will be the outcome:

the 2001–2 survey of resistance across South African provinces found MDR-TB prevalence rates of up to 14% among previously treated patients.<sup>6</sup>

The six countries listed above were together responsible for over 60% of the increase in cases detected, and mostly responsible for the acceleration in case finding. An additional 214 656 cases were reported during 2002, as compared with 2001, which is 60% greater than the average increase between 1995 and 2000. The step-up in recruitment to DOTS programmes is even more pronounced in the numbers of all TB cases (smear-positive and smear-negative) reported. However, even with this acceleration, the 2002 data show that the world's TB control programmes are not yet on course, collectively, to meet the 70% target by 2005. That would require an annual increase of about 433 000 smear-positive cases in each of the years 2003–5.

Among the HBCs, only Viet Nam has reached both targets, though Cambodia, Myanmar and the Philippines appear to be close. By the end of 2002, 63 countries lay in the penumbra of the target zone (case detection > 50%, treatment success > 70%), but together accounted for only 15% of the smear-positive case load globally.

Some gains in case detection (as defined by WHO) could be made rapidly in countries and regions where many cases are already known to public health authorities (assuming they are really TB cases), but are not treated under DOTS. Data from the Americas and Europe indicate that the target for case detection could be met, or closely approached, just by ensuring that the diagnosis and treatment of known TB patients meets DOTS standards. Significant gains in case detection could be made in

South-East Asia for the same reason. Although there is little scope for making similar gains in Africa, the Eastern Mediterranean and Western Pacific regions (where most patients are already reported under DOTS), the combined total of all such patients would push global case detection from 37% up to around 50%, the same as the fraction of all TB cases found in 2002.

To go beyond 50% case detection will be challenging, if the pattern of DOTS expansion observed from 1995 to 2002 persists. The data in this report identify two obstacles en route to the 70% target. The first is the relatively sluggish increase in case notifications from all sources (DOTS and non-DOTS). The number of smear-positive cases notified to WHO by public health authorities increased by just 4% per year between 1996 and 2002, and the total number of TB cases has not increased at all. Consequently, the proportion of all notified smear-positive cases that come from DOTS programmes has been increasing since 1995. If this trend continues, all TB cases reported to WHO in 2005 will be notified and treated by DOTS programmes. This means that all TB patients reported in the public sector will, by 2005, receive the internationally recommended standard of care. But it also means that, to reach the 70% target by 2005, DOTS programmes must recruit cases that would not otherwise have been notified in the public sector. The rate of recruitment of TB cases to health programmes that participate in the public case notification system has hitherto been slow.

The second impediment is that the smear-positive case detection rate within DOTS areas, as measured by the ratio of case detection to population coverage, has remained roughly

constant since 1996, averaging 49%. That is, almost all of the gains in case detection made under DOTS have been made through geographical expansion, and not by improving case finding in established DOTS areas. If this continues to be true, the smear-positive case detection rate will still be roughly 50% even when, according to measures of population coverage, the whole world has access to DOTS. Some HBCs do show improvements in case finding within DOTS areas, especially India, Indonesia, Bangladesh, and the Philippines, but these are much slower than the improvements made by extending DOTS to new areas.

Among the 1.2 million smear-positive cases treated under DOTS in the 2001 cohort, 82% were reported to have successful outcomes. HIV co-infection is blamed for relatively poor results in Africa (71%), and HIV may indeed contribute to the high death rate (7%). However, African NTPs could do substantially better by cutting the proportion of patients lost from DOTS cohorts, which amounted to 21% of patients in 2001. In eastern Europe, relatively high rates of drug resistance could help to explain why 12% of patients failed treatment and 7% died. But these data need closer examination: it is possible that a proportion of the "failures" had not completed treatment after 6 months because, for example, longer regimens are used to treat patients with resistant bacilli. For these patients, the final outcome of treatment is not known.

In summary, the global, smear-positive case detection rate was 37% in 2002, over half way to the 70% target, and rising more quickly than at any time since 1995. Given recent trends, we expect the smear-positive case detection rate by DOTS programmes to be about 50% in 2005, by which time all TB patients notified and treated in the public sector will receive the internationally recommended standard of care. Case detection could be increased from

37% to 50% by ensuring that the diagnosis and treatment of known TB cases in the Americas, South-East Asia, and the Western Pacific Regions conforms with DOTS standards. To get above 50% case detection will be demanding because the notification rate of all TB cases by public health authorities has been stable at about this level for many years, and because DOTS programmes will probably have exhausted this supply of cases by 2005.

Two years ago, we forecast that the smear-positive case detection rate would accelerate after year 2000, and then saturate below 50% around 2005.<sup>24</sup> The latest data suggest a somewhat brighter future, but remain consistent with the notion that saturation will follow acceleration. To escape that future, DOTS programmes and public health authorities must now do something different. They must recruit patients from non-participating clinics and hospitals, notably in the private sector in Asia, and from beyond the present limits of public health systems in Africa. These are the regions of the world that account for the vast majority of cases that are not seen, and therefore not yet "detected", by public health authorities.

### **Planning and DOTS implementation**

All 22 HBCs have strategic plans for DOTS expansion, though the plan for Thailand has still not been made available to WHO. However, the transition from planning to implementation, and from implementation to improvements in coverage and case detection has been slower than anticipated. The constraints described in this report are disappointingly similar to those identified in 2003,<sup>5</sup> though financial shortages have become a lesser concern for some countries. NTP staff interviewed for the present report listed 13 constraints in the HBCs. Dominant among them was the lack of adequately trained staff; followed by poor monitoring

and evaluation; inadequate infrastructure; weak laboratories; the failure of DOTS programmes to engage private practitioners and other public providers; and ineffective decentralization.

Short- and long-term strategic planning, with regular reviews of the plans and assessment of interventions, would help ensure commitment to a sustained course of action, even in the face of other crises that threaten to consume resources reserved for TB control. Viet Nam – the only HBC to have reached the targets – offers a good example of sustained commitment. Firm NTP leadership and careful planning, reinforced by strong political will, have guided the methodical expansion of DOTS.

NTPs will find it hard to act independently of other factors that influence TB control. The lack of qualified personnel needs to be addressed through Human Resource Development Plans, generated within the context of national plans to strengthen the health workforce. The plans must include mechanisms to improve staff recruitment, retention, and motivation, to ensure better in-service and pre-service training, and to make use of secondments of staff from academic institutions. PPM projects, and schemes to involve other public providers and facilities (NGOs, communities, hospitals, and workplace or corporate health care systems), should bring many more clinical staff and health facilities into the ambit of DOTS programmes. NTPs must also make the case for improved infrastructure – working with government outside the health sector – to help improve the access of patients to health services.

The decentralization of health systems has left some countries unable to improve the quality of TB control. Responsibility for planning and

<sup>21</sup> Dye C, Watt CJ, Bleed DM, Williams BG. What is the limit to case detection under the DOTS strategy for tuberculosis control? *Tuberculosis* 2003; 83: 35–43.

financing has been fully transferred to peripheral health services, but without sufficient technical capacity or political support to handle added responsibilities at the periphery.

While the DOTS strategy must remain at the heart of TB control policy, a wider range of interventions will be needed to reduce TB burden in the countries most affected by HIV/AIDS, especially those in eastern and southern Africa.<sup>16</sup> These interventions will need to be offered through better collaborations between TB and HIV/AIDS control programmes. Most collaborative TB/HIV activities are so far being implemented in districts or regions, rather than on a national scale. Some NTPs have determined that DOTS programmes must perform more effectively before attention is paid to the TB/HIV interaction. And yet the case detection targets for 2005 are unlikely to be met without, for example, the systematic referral of TB suspects from VCT centres, and from other facilities that provide services for HIV/AIDS patients. High cure rates will not be guaranteed for HIV-infected TB patients unless there is better access to ART and cotrimoxazole preventive therapy, and better treatment of other opportunistic infections.

Among other constraints to DOTS expansion are the failure of drug supplies, inconsistent drug quality, and undeveloped drug policies. Appropriate drug policy depends, in part, on the prevalence of drug resistance, and vice versa. The WHO/IUATLD global DRS project currently includes all or part of 14 HBCs.<sup>6</sup> It must be expanded to more areas within those countries, and to the remaining 8 HBCs, to obtain a true assessment of the magnitude of the problem worldwide. Poor laboratory networks remain a major obstacle to establishing high-quality surveillance systems. The control of MDR-TB will require the implementation of all components of the DOTS strategy, extended where appropriate as DOTS-Plus, to include the use of standardized regimens of second-line

drugs for patients with resistant strains. Ultimately DOTS-Plus and testing for drug sensitivity will become an integral part of the DOTS strategy, and planning for MDR-TB control will become a routine component of NTP programme activities.

### **Financing DOTS expansion**

The total cost of TB control in the HBCs was about US\$ 850 million in 2002, with a large increase in planned expenditure to US\$ 1 billion in 2003. In both years, funds came primarily from governments (through domestic revenues and loans), and to a lesser extent from grants. The funding shortfall reported by HBCs in 2003 was only US\$ 41million, about 4% of the total, and lower than in 2002.

But summary statistics of this kind conceal a diversity of financial needs among the countries that carry the largest burdens of TB. Our analysis of budgets and expenditures puts the 22 HBCs into broadly three groups. The first, most progressive group contains 10 countries that have planned to significantly increase spending from 2003 onwards, in order to meet the global targets for case detection and treatment success by 2005. Encouragingly, this group includes four of the countries with the most TB cases: India, China, Indonesia, and Bangladesh. India's projected budgetary growth should allow the rapid increase in patient recruitment to continue, while maintaining the same per patient expenditure that has yielded high cure rates under DOTS. China, Indonesia and Bangladesh aim to improve case detection while spending more on the management of each patient. In Ethiopia, Kenya, Cambodia, Uganda, and Myanmar, the total increases in planned costs are smaller but, as for the larger countries, they are linked to plans for scaling up and improving the quality of DOTS. The Russian Federation plans a major increase in activities and costs in 2004. All of these forward-looking countries, with the exception

of India, will need some extra money to put their plans into action. Kenya, Cambodia, Uganda, and Myanmar report the largest budgetary shortfalls relative to their needs. However, once approved funding from the GFATM is disbursed in full, the deficits in Myanmar and Uganda will be eliminated. Some of the country budgets are well-reasoned and consistent with recommended policy; others are less so. The Russian Federation errs towards the latter, where a large part of the need is generated by the purchase of X-ray equipment and by the costs of refurbishing hospitals.

In the second group of countries are Brazil, the Philippines, Thailand and Viet Nam, where a large proportion of patients are already treated in the public sector, either by DOTS or non-DOTS programmes. They probably do not require large budget increases to meet targets, and funding gaps are low or non-existent.

The remaining eight countries are in a third group, where NTPs are not yet close to reaching targets, and apparently have neither plans nor budgets that will get them to the targets by 2005. Some of these countries provided no data either for 2002 or 2003; for others the planned increase in costs was small. Some members of this group did plan budgetary increases, but without explanation. If the 13 constraints that emerged from our review of planning are genuinely obstacles to TB control, we would expect to see large and well-justified budgets to overcome them. In the absence of new sources of money, we would also expect to see larger funding gaps.

In general, the governments of richer countries pay a larger fraction of the costs of TB control. For the poorer countries that have identified greater needs, progress in TB control will be closely linked to the flow of funds from grants, especially those recently awarded by the GFATM. The GFATM has rapidly become a major donor for TB control, but our analysis raises difficulties of two kinds.

First, payments from the Fund have so far been small compared with the size of grants awarded. During 2003, only 16% of the total approved for TB and TB/HIV activities in the first 2 years was paid to countries. Second, it is questionable whether large influxes of new money can be immediately and effectively used in countries that have little experience of rapidly scaling up health interventions, and weak capacity for developing effective plans. The HBCs have together planned a sizeable 18% increase in expenditure for 2003. The GFATM grants to Bangladesh, Ethiopia and Myanmar would (at least) double the annual funding available for TB control in these countries in 2004. As external donors contribute more to TB control, filling the current holes in budgets, attention will turn to the absorption capacity of the poorest countries.

A strength of comparative, cross-country analysis is that it suggests various ways in which TB control in the HBCs could be improved. For example, the government contribution to funding is lower in China than in Viet Nam, even though China has a higher GNI. The comparatively high costs per patient treated in South Africa and the Russian Federation can be explained by their over-reliance on hospital care and expensive diagnostics. In other HBCs, a higher proportion of patients are successfully treated at lower cost outside hospitals and clinics. Although the Russian Federation has a relatively high GNI, the government foresees a large funding gap for 2004 and 2005. Some of these need could perhaps be met from domestic resources.

There remains much variation among HBCs in the way they report data on budgets and expenditures. Several countries, including India, Brazil, China, Viet Nam, and Indonesia, provided complete data and little or no follow-up was required from WHO. For others, much discussion with NTP managers and WHO country staff was needed to satisfac-

torily complete the questionnaire. During 2003, a large number of low-burden countries submitted data, but the poor quality of some of these data made them unusable. The reporting problems in high- and low-burden countries included the following: aggregate budget and expenditure totals were given with no breakdown by line item and funding source; information about GFATM proposals and awards was excluded, and data contained in GFATM proposals was inconsistent with data submitted to WHO; loans providing support to the health sector as a whole (e.g. from the World Bank in Brazil, Indonesia, and Tanzania) were not mentioned; the costs of dedicated NTP staff were not accurately calculated, or not calculated at all; and drug budgets were apparently inconsistent with the number of patients to be treated (often due to the existence or purchase of a drug buffer stock). The budgeting exercise has been made difficult in some countries with decentralized TB control, because funds for TB control are allocated at sub-national level and there is limited transparency or reporting of line items to national level.

While some of these complications are understandable, they raise questions about the capacity of NTPs to plan strategically, and to adequately fund and implement a DOTS programme. During 2004, WHO will address the difficulties that respondents faced in completing the financial questionnaire. The questionnaire itself will need revision: it is not yet clear, for example, what countries are budgeting for TB/HIV activities and for the treatment of MDR-TB cases, because they are not line items on the questionnaire. For the same reason, it is generally unclear what countries would wish to budget for external technical assistance. Technical assistance is needed to support a variety of activities, including the effective use of grants from the GFATM. Based on the observation that many proposals to the GFATM appear to be rich in financial data, there is

no doubt that it will be possible to gather more budgetary data of higher quality from more countries, and with greater efficiency.

As the WHO database grows, the investigative techniques applied to these data will need to be refined and developed. On refinement, the projections of costs for 2004 and 2005 in the 22 HBCs assume, among other things, that the cost per patient treated will remain constant as the number of cases detected increases. This would underestimate resource requirements if the cost per patient increases as additional cases become harder to find, or more difficult to treat. On development, there is no general procedure, as yet, for calculating the expected percentage of a country's total health spending that should be used for TB control. These are two examples of the analytical challenges facing the financial monitoring project.

In summary, the estimated cost of TB control in the HBCs was about US\$ 1 billion in 2003, and rising. Ten of the 22 HBCs project budgetary increases that are in line with plans for a major expansion of DOTS coverage. But some of these countries need to find significantly more money, and to find ways of efficiently disbursing this money, if they are to turn these plans into patients diagnosed, treated and cured. Four of the HBCs probably do not need much more money to reach the targets because most TB patients are already treated in the public sector, if not always under DOTS. The stated funding needs and funding gaps for the remaining Eight countries are almost certainly too low. These countries need sharply-focused strategic plans to overcome the constraints laid out in this report. For some of these countries, the planning and implementation of DOTS will come too late to reach the targets by 2005.