Key bottlenecks in M/XDR-TB control and patient care - executive summary

In preparation for this meeting, WHO has prepared a series of briefing papers that describe the key bottlenecks to controlling M/XDR-TB and providing care to M/XDR-TB patients, and how they can be addressed. The 10 papers are incorporated in this document and conclude with tables summarizing for each bottleneck the actions required and by whom.

Surveillance data on TB provided by WHO and partners enable the future epidemic to be modelled. These data show, in **Paper 1: Forecasting the control of MDR-TB epidemics**, that both prevention of MDR-TB ("turning off the tap" through improving basic TB control) and diagnosis and effective treatment of MDR-TB cases (reducing transmission in the community of drug-resistant strains) are necessary to reducing rates of MDR-TB in countries where MDR-TB is already established and the rate is high. This can be achieved with existing diagnostics and treatment regimens, but new technology and approaches to diagnosis and treatment are needed to reduce cases and deaths more quickly. There are at least four reasons to intensify case finding and treatment for MDR-TB in all countries: to give the best possible chance of cure to all patients, whether they have drug-susceptible or drug-resistant TB; to accelerate TB decline, and move as quickly as possible towards elimination; to prevent the build-up in populations of drug-resistant, latent infection; and to plan for worst outcomes in the face of uncertainty (be risk averse).

Significant gaps remain in basic TB control. Three of the key ones are outlined in **Paper 2**: **Addressing the gaps in TB control**. Too often hospitals are a barrier to patients in accessing proper care for TB; a wide array of providers exists, in both private and public sectors, and many give substandard care, while the potential to enlist patients and communities in the provision of proper care is ignored. Mechanisms are laid out to harness the potential of patients and communities, as well as identify all care providers and link hospitals and providers of care of all kinds with NTPs.

Paper 3: Providing M/XDR-TB management and care reflects the complexity of the steps needed to manage, that is diagnose, treat and care for, people with MDR-TB. The paper is not prescriptive but lays out the issues that need to be considered to facilitate decision-making on the best mix of sites to care for patients, whether in hospital or in the community. The ethical dimension of provision of care is addressed because in managing MDR-TB it is imperative to ensure that the rights and duties of patients are assured as well as those of the community. Collaboration in delivery of care for MDR-TB is recommended with all non-governmental structures, including the private sector. HIV is a major problem for people with MDR-TB, and the collaborative engagement of AIDS control programmes with their TB counterparts, in the problem of MDR-TB, is essential.

Paper 4: Addressing the health workforce crisis calls for countries to develop strategic and operational plans for health workforce development to both strengthen basic TB control and scale up management of M/XDR-TB. Plans need to go beyond traditional training activities and address staffing, motivation, retention and support systems issues. NTPs need to collaborate and coordinate with other health programmes to ensure that health workforce needs for TB control are included in overall health workforce development.

Until WHO's Stop TB Strategy was launched in 2006, global TB control efforts underplayed the need for laboratories. **Paper 5: Responding to the laboratory bottleneck** addresses the gap which has built up and calls for TB laboratory needs to be addressed in strategic plans for the national health laboratory system as a whole. Meeting this gap will require an additional 2000 new or revitalized laboratories capable of culture and drug sensitivity testing to be established and more than 20,000 new laboratory technicians to be trained and deployed. A systematic approach at country level to planning of laboratory costs is essential, starting with clear policies for screening of patients at risk of MDR-TB and applying appropriate diagnostic algorithms using the different modalities available.

Not all countries are insisting on anti-TB medicines that are of proven quality based on WHO standards, or stringent regulatory authority standards according to **Paper 6: Ensuring access to quality-assured anti-TB medicines**. Fixed-dose combinations of first-line medicines are insufficiently used given that they are proven to be at least as effective as loose pills in curing patients of TB and in addition they offer significant practical and logistic advantages. If countries were truly averse to the risk of creation of resistance they would use them much more. WHO and the GDF offer several services to help national drug procurement. With respect to the second-line medicines, insufficient amounts are being produced, even for the relatively few patients enrolled for treatment. Pharmaceutical companies are not yet convinced that there is a return to be made from investing in this market. To break this cycle, governments should commit to scaling up treatment for MDR-TB, thus creating greater demand, enabling more accurate forecasts, and bringing more companies into the supply network.

The unregulated availability of anti-TB medicines, whether first-line or second-line, is fuelling the development of MDR and XDR-TB. **Paper 7: Restricting the availability of anti-TB medicines** calls for governments to ban immediately "over-the-counter" sales of such products. It further advises the accreditation of practitioners in the public and private sectors to prescribe anti-TB medicines and restrictions in the right to carry out prescribing practices to accredited practitioners.

Neglected until outbreaks of MDR-TB and XDR-TB forced the issue of infection control onto the agendas of public health and TB control, **Paper 8: Prioritizing TB infection control** calls for urgent development of national plans, in line with the new WHO policy on TB infection control, to upgrade all health-care facilities to make them safe for

patients and health-care workers. This requires a national approach which can be based on existing infection control structures, and administrative, environmental and personal protection measures in all facilities.

Against the backdrop of static research funding for TB, **Paper 9: Maximizing research opportunities to address M/XDR-TB** calls for greater involvement of all governments, especially those of the emerging economies, and funding agencies in research on MDR-TB. Multi-agency and country coordination is recommended to develop new rapid methods for detection of M/XDR-TB and field test them. Similarly, new medicines are urgently needed, as well as the design and funding of randomized controlled trials for treatment and prevention of MDR-TB using both new and available compounds. In addition, opportunities are clearly being missed, to make full use of the funds available for operational research within existing Global Fund grants. One essential area where such funds could be used is in investigating the causes of drug resistance in different settings.

To achieve the target set out in the Global Plan to Stop TB 2006–2015, 1.4 million cases of M/XDR-TB will need to be treated in the 27 countries with the highest burden in the seven years 2009–2015, according to **Paper 10: Financing M/XDR-TB control and care**. The total cost of diagnosing and treating 1.4 million cases (including infection control) amounts to US$ 16.9 billion over seven years, rising from US$ 0.7 billion in 2009 to US$ 4.4 billion in 2015; the latter figure is 61 times the funding available in 2009. Most funding is required in the European Region (US$ 8.9 billion), followed by Asia (US$ 7.1 billion). The first step, in order to mobilize the required funding, is the preparation of country-specific budgets as part of national strategic plans for TB control. WHO has prepared a planning and budgeting tool for this purpose. Domestic resources need to be accessed especially in middle income countries. If sufficient domestic funding cannot be mobilized, countries should make full use of resources available from the Global Fund, UNITAID, and other donor agencies and financial mechanisms.

Table. **The Stop TB Strategy at a glance, 2009**

VISION	**A world free of TB**
GOAL	To dramatically reduce the global burden of TB by 2015 in line with the Millennium Development Goals and the Stop TB Partnership targets
OBJECTIVES	• Achieve universal access to quality diagnosis and patient-centred treatment • Reduce the human suffering and socioeconomic burden associated with TB • Protect vulnerable populations from TB, TB/HIV and drug-resistant TB • Support development of new tools and enable their timely and effective use
TARGETS	• MDG 6, Target 8: Halt and begin to reverse the incidence of TB by 2015 • Targets linked to the MDGs and endorsed by Stop TB Partnership: – 2005: detect at least 70% of infectious TB cases and cure at least 85% of them – 2015: reduce prevalence of and deaths due to TB by 50% – 2050: eliminate TB as a public health problem
COMPONENTS OF THE STRATEGY AND IMPLEMENTATION APPROACHES	
1. Pursue high-quality DOTS expansion and enhancement a. Secure political commitment, with adequate and sustained financing b. Ensure early case detection, and diagnosis through quality-assured bacteriology c. Provide standardized treatment with supervision, and patient support d. Ensure effective drug supply and management e. Monitor and evaluate performance and impact	
2. Address TB/HIV, MDR-TB, and the needs of poor and vulnerable populations a. Scale-up collaborative TB/HIV activities b. Scale-up prevention and management of multidrug-resistant TB (MDR-TB) c. Address the needs of TB contacts, and of poor and vulnerable populations	
3. Contribute to health system strengthening based on primary health care a. Help improve health policies, human resource development, financing, supplies, service delivery, and information b. Strengthen infection control in health services, other congregate settings and households c. Upgrade laboratory networks, and implement the Practical Approach to Lung Health (PAL) d. Adapt successful approaches from other fields and sectors, and foster action on the social determinants of health	
4. Engage all care providers a. Involve all public, voluntary, corporate and private providers through Public-Private Mix (PPM) approaches b. Promote use of the International Standards for Tuberculosis Care	
5. Empower people with TB, and communities through partnership a. Pursue advocacy, communication and social mobilization b. Foster community participation in TB care, prevention and health promotion c. Promote use of the Patients' Charter for Tuberculosis Care	
6. Enable and promote research a. Conduct programme-based operational research b. Advocate for and participate in research to develop new diagnostics, medicines and vaccines	