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## **Global strategy and targets for tuberculosis prevention, care and control after 2015**

### **Report by the Secretariat**

1. WHO's declaration of tuberculosis as a global public health emergency in 1993 ended a period of prolonged global neglect. Together the subsequent launch of the DOTS strategy; inclusion of tuberculosis-related indicators in the Millennium Development Goals; development and implementation of the Stop TB Strategy that underpins the Global Plan to Stop TB 2006–2015; and adoption of resolution WHA62.15 on the prevention and control of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis by the Sixty-second World Health Assembly have all helped to accelerate the global expansion of tuberculosis care and control.
2. In May 2012, Member States at the Sixty-fifth World Health Assembly requested the Director-General to submit a comprehensive review of the global tuberculosis situation to date, and to present new multisectoral strategic approaches and new international targets for the post-2015 period to the Sixty-seventh World Health Assembly in May 2014, through the Executive Board.<sup>1</sup> The work to prepare this has involved a wide range of partners providing substantive input into the development of the new strategy, including high-level representatives of Member States, national tuberculosis programmes, technical and scientific institutions, financial partners and development agencies, civil society, nongovernmental organizations, and the private sector.
3. ***The process.*** WHO's Strategic and Technical Advisory Group for Tuberculosis approved the broad, inclusive scope of the consultative process for the development of the draft strategy. It began with a web-based consultation to seek ways in which to strengthen the current strategy and introduce any new components. During 2012, as part of the annual meetings of national tuberculosis programmes, each regional office organized consultations on the proposed new strategic framework and targets with health ministry officials, national tuberculosis programme managers and partners. In November 2012, officials of countries with a high tuberculosis burden discussed the draft strategic framework, as did 700 stakeholders attending the global symposium at the annual World Conference on Lung Health, held in Kuala Lumpur, Malaysia. In 2013, three special consultations including senior officials of Member States, technical experts and civil society were organized in order to discuss (i) formulation of the post-2015 tuberculosis targets; (ii) approaches to building on the opportunities presented by expansion of universal health coverage and social protection to strengthen tuberculosis care and prevention; and (iii) research and innovation for improved tuberculosis care, control and

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<sup>1</sup> Document WHA65/2012/REC/3, summary record of the sixth meeting of Committee B, section 3.

elimination. In June 2013, the Strategic and Technical Advisory Group for Tuberculosis endorsed the draft, including the global targets and their rationale.

4. The framework of the draft post-2015 global tuberculosis strategy is presented in Figure 1.

**Figure 1. DRAFT POST-2015 GLOBAL TUBERCULOSIS STRATEGY FRAMEWORK**

<b>VISION</b>	A world free of tuberculosis – zero deaths, disease and suffering due to tuberculosis
<b>GOAL</b>	End the global tuberculosis epidemic
<b>MILESTONES FOR 2025</b>	– 75% reduction in tuberculosis deaths (compared with 2015); – 50% reduction in tuberculosis incidence rate (less than 55 tuberculosis cases per 100 000 population) – No affected families facing catastrophic costs due to tuberculosis
<b>TARGETS FOR 2035</b>	– 95% reduction in tuberculosis deaths (compared with 2015) – 90% reduction in tuberculosis incidence rate (less than 10 tuberculosis cases per 100 000 population) – No affected families facing catastrophic costs due to tuberculosis
<b>PRINCIPLES</b>	
<ol style="list-style-type: none"> <li>1. Government stewardship and accountability, with monitoring and evaluation</li> <li>2. Strong coalition with civil society organizations and communities</li> <li>3. Protection and promotion of human rights, ethics and equity</li> <li>4. Adaptation of the strategy and targets at country level, with global collaboration</li> </ol>	
<b>PILLARS AND COMPONENTS</b>	
<b>1. INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION</b>	
<ol style="list-style-type: none"> <li>A. Early diagnosis of tuberculosis including universal drug-susceptibility testing; and systematic screening of contacts and high-risk groups</li> <li>B. Treatment of all people with tuberculosis including drug-resistant tuberculosis; and patient support</li> <li>C. Collaborative tuberculosis/HIV activities, and management of co-morbidities</li> <li>D. Preventive treatment of persons at high risk; and vaccination against tuberculosis</li> </ol>	
<b>2. BOLD POLICIES AND SUPPORTIVE SYSTEMS</b>	
<ol style="list-style-type: none"> <li>A. Political commitment with adequate resources for tuberculosis care and prevention</li> <li>B. Engagement of communities, civil society organizations, and public and private care providers</li> <li>C. Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control</li> <li>D. Social protection, poverty alleviation and actions on other determinants of tuberculosis</li> </ol>	
<b>3. INTENSIFIED RESEARCH AND INNOVATION</b>	
<ol style="list-style-type: none"> <li>A. Discovery, development and rapid uptake of new tools, interventions and strategies</li> <li>B. Research to optimize implementation and impact, and promote innovations</li> </ol>	

## ACHIEVEMENTS

5. **Steady progress.** WHO-coordinated global efforts to control tuberculosis led by Member States and supported actively by technical and financial partners have produced remarkable results. Target 8 of Millennium Development Goal 6, “to have halted and begun to reverse the incidence of tuberculosis” by 2015, has already been achieved. Between 1995 and 2012, 22 million lives were saved and 56 million people were successfully treated for tuberculosis. The burden of tuberculosis has been declining in all WHO regions since 2001. The tuberculosis mortality rate has decreased 45% since 1990 and the world is on track to achieve the Stop TB Partnership’s global target of a 50% reduction in the mortality rate by 2015. In 2012, 6.1 million newly diagnosed cases notified to national tuberculosis programmes were reported to WHO. Globally, treatment success rates have been maintained at 85% or more since 2007.

6. **Evolving response.** The response to the global tuberculosis situation has evolved in line with countries’ situations and needs. The 2009 ministerial meeting in Beijing and the adoption of the subsequent commitments made by the World Health Assembly in resolution WHA62.15, stimulated renewed commitment by Member States with a high-burden of drug-resistant tuberculosis to address the problem. Data on the magnitude of the problem of drug resistance are now available for all countries with a high burden of tuberculosis. Global mechanisms have been set up to procure quality-assured medicines and diagnostics and to strengthen laboratory networks equipped with mycobacterial culture and drug susceptibility testing facilities. WHO-recommended tuberculosis/HIV collaborative activities are a widely accepted global norm implemented across countries. Public–private mix approaches have helped diverse public, voluntary, private and corporate care providers in many settings to align their practices with international standards, and partnerships with communities and civil society have grown in strength. Programme-based operational research has allowed a swift translation of evidence into national policies and field practices.

7. **New technologies and tools.** Noteworthy progress has been made in the development of new tools. Seven WHO-endorsed new diagnostics are being rolled out. The launch of Xpert MTB/RIF, a rapid and sensitive molecular test to diagnose tuberculosis and rifampicin resistance, has been particularly impressive. By mid-2013, 1402 GeneXpert machines and 3.2 million cartridges had been procured by 88 of the 145 low- and middle-income countries eligible for concessional pricing. The pipeline of new tuberculosis medicines has expanded substantially and bedaquiline, the first new tuberculosis medicine in four decades, has recently been recommended by WHO for the treatment of severe cases of drug-resistant tuberculosis. Twelve candidate vaccines are also in the pipeline.

## CHALLENGES

8. **Persisting burden.** The achievements over the past two decades are far from enough to ensure progress towards elimination of tuberculosis. The latest data on the global tuberculosis epidemic are available from WHO’s *Global tuberculosis report 2013*. In 2012, there were an estimated 8.6 million new cases and 1.3 million people died from tuberculosis, including 320 000 among people living with HIV. Notably, in the same period, 410 000 women, 160 000 of them HIV-positive, died of tuberculosis, making it a top infectious killer of women. There were also an estimated 500 000 cases of tuberculosis and at least 74 000 deaths in children. Africa and Eastern Europe are not on track to achieve the 2015 target of halving tuberculosis deaths compared with the level in 1990. The poorest countries are worst affected, and in all countries the poorest and most vulnerable bear the greatest burden of tuberculosis.

9. **Stagnating case notifications.** After a steady rise until 2006, notifications of tuberculosis cases have now stagnated. Many of the notified cases have been detected only after long delays. Data from tuberculosis prevalence surveys from many countries have revealed a large hidden burden of asymptomatic tuberculosis cases. This finding underscores the limitations of the current methods of case detection. There remains much scope to activate and institutionalize engagement with civil society organizations, communities and people with tuberculosis in order to drive demand for tuberculosis care that is accessible to all who need it. In most high-prevalence settings, mapping at-risk populations and providing priority attention to the most affected still needs to be undertaken.

10. **Multidrug-resistance.** The problem of resistance to medicines poses a great threat to tuberculosis control and remains a major concern for global health security. In 2012, there were an estimated 450 000 new cases of multidrug-resistant tuberculosis, defined as resistance to at least isoniazid and rifampicin (the two most important medicines used in the treatment of tuberculosis). However, only about 94 000 cases were notified and 82% of those patients were reported to have been started on treatment. Among the patients treated, the reported treatment success rate globally was only 48%. Extensively drug-resistant tuberculosis, a more severe and lethal form resistant also to the most active second-line medicines, has been reported by 92 countries. Several health system barriers persist, preventing the rapid expansion of programmatic management of drug-resistant tuberculosis.

11. **HIV-associated tuberculosis.** The HIV epidemic continues to fuel the tuberculosis epidemic especially in Africa, which accounted 75% of the world's HIV-positive tuberculosis cases in 2012. Globally, nearly 50% of all tuberculosis patients did not know their HIV status and only a little over 50% of those with associated HIV infection received antiretroviral treatment in 2012. A significant proportion of people living with HIV are not screened regularly for tuberculosis. Chemoprophylaxis for tuberculosis is still not provided to all who could benefit from it. Importantly, in the absence of appropriate care and prevention, a large proportion of people living with HIV die from undiagnosed tuberculosis.

12. **Noncommunicable diseases and tuberculosis co-morbidities.** Risk-factors of tuberculosis such as diabetes, tobacco-smoking, silicosis, alcohol and drug misuse, and undernutrition hamper tuberculosis control, especially in low- and middle-income countries. A large pool of latently infected people contributes to a growing proportion of future tuberculosis cases. The increasing prevalence of noncommunicable diseases also changes the profile of tuberculosis co-morbidities, complicating clinical management and worsening health outcomes. Few links currently exist between health services for communicable and noncommunicable diseases.

13. **Weak health systems.** Inadequate coverage and weak performance of health services limit access to high-quality tuberculosis care. Many public and private health providers remain delinked from national tuberculosis control efforts. Absence of universal health coverage aggravates the economic burden on the poor. This hardship is compounded by a lack of social protection mechanisms to address associated income loss and non-medical costs. Regulatory mechanisms essential to ensure effective infection control, rational use of tuberculosis diagnostics and medicines, mandatory disease notification, functioning vital registration systems, and protection of the legal rights of people with tuberculosis remain weak. Data collection, quality and use need to be improved at all levels. The weaknesses in health systems have limited the linkages that are required across social sectors in order to address poverty, undernutrition and risk factors that adversely influence people's vulnerability to tuberculosis, and the health outcomes of people with tuberculosis.

14. **Slow decline in incidence.** The fall in incidence at an average annual rate of some 2% globally is too slow to achieve tuberculosis elimination in the foreseeable future. Ending the tuberculosis epidemic will entail early diagnosis and proper treatment of all cases of active tuberculosis as well as a

gradual removal of the pool of latent tuberculosis infection in some 2000 million people. Diagnosis of tuberculosis remains demanding in the absence of a point-of-care test, and the duration of treatment remains too long in the absence of shorter and better regimens for drug-susceptible and drug-resistant tuberculosis, as well as for latent tuberculosis infection.

15. **Funding gaps.** There has been a substantial increase in financing for tuberculosis in disease-endemic countries – from less than US\$ 2000 million in 2002 to about US\$ 6000 million in 2013 – dominated by major enhancements in domestic funding and external funding through the Global Fund to Fight AIDS, Tuberculosis and Malaria. However, global tuberculosis control efforts remain under-funded. To supplement growing domestic funding, international donor funding of about US\$ 2300 million per year is needed for implementation of existing interventions up to 2015 and US\$ 2000 million per year is needed for research and development. Estimated gaps amount to about US\$ 2000 million per year for implementation and US\$ 1300 million per year for research between 2013 and 2015. Funding requirements are likely to increase in the immediate post-2015 period, for two reasons. Accelerated progress towards the goal of universal health coverage is required to ensure that all people with tuberculosis can access diagnosis and treatment without facing catastrophic costs.<sup>1</sup> Increased investments in research and development are required to deliver the technological breakthroughs that can help to end the global tuberculosis epidemic. Funding requirements may subsequently fall as reductions in tuberculosis incidence accelerate and outweigh the costs associated with improved coverage of tuberculosis prevention, diagnosis and treatment interventions.

16. **Underlying determinants.** Overall, global and national political choices will determine the future impact of social, economic and environmental determinants of tuberculosis. Tuberculosis care and prevention will continue to benefit from general economic growth. The important underlying determinants of the tuberculosis epidemic that need to be addressed include poverty and inequity, food insecurity, adverse effects of population movements and complex emergencies. Specifically, effective tuberculosis prevention will require actions resulting in poverty reduction, improved nutrition, and better living and working conditions as well as strategies to mitigate the impact of migration, ageing populations, and chronic diseases such as diabetes that are risk factors for tuberculosis.

## APPROACHES

17. **Expanding care, strengthening prevention, and intensifying research.** Addressing the above challenges will require innovative, multisectoral, and integrated approaches. The DOTS strategy strengthened public sector tuberculosis programmes to help to tackle a large burden of drug-susceptible disease. The Stop TB Strategy,<sup>2</sup> built on DOTS, helped to begin addressing drug-resistant tuberculosis and HIV-associated tuberculosis while promoting research to develop new tools. It also helped to expand partnerships with all care providers, civil society organizations and communities, in the context of strengthening health systems. Ending the tuberculosis epidemic will require further expansion of the scope and reach of interventions for tuberculosis care and prevention; institution of systems and policies to create an enabling environment and share responsibilities; and aggressive pursuit of research and innovation to promote development and use of new tools for tuberculosis care

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<sup>1</sup> Out-of-pocket expenditure on health care exceeding 40% of discretionary household expenditure has been defined by WHO as a catastrophic level. The threshold for catastrophic total cost (including indirect costs) has not yet been established.

<sup>2</sup> The six components of the Stop TB Strategy are : (i) pursue high-quality DOTS expansion and enhancement; (ii) address TB/HIV, MDR-TB and other special challenges; (iii) contribute to health system strengthening; (iv) engage all care providers; (v) empower people with tuberculosis, and communities; and (vi) enable and promote research.

and prevention. It will also require a provision for revisiting and adjusting the new strategy based on progress and the extent to which agreed milestones and targets are being met.

18. ***Eliciting systemic support and engaging stakeholders.*** In practical terms, continuing progress beyond 2015 will require intensified actions by and beyond tuberculosis programmes within and outside the health sector. The new strategy envisages concrete actions from three levels of governance in close collaboration with all stakeholders and engagement of communities. At the core are national tuberculosis programmes or the equivalent structures that are responsible for coordination of all activities related to delivery of tuberculosis care and prevention. Above them are the national health ministries that provide critical systemic support, enforce regulatory mechanisms, and coordinate integrated approaches through interministerial and intersectoral collaboration. Above all, the national governments have to provide the overall stewardship to keep tuberculosis elimination high on the development agenda through political commitment, investments and oversight, while making rapid progress towards universal health coverage and social protection.

19. ***Elevating leadership and widening ownership.*** Tuberculosis care and control need to be strengthened further and expanded to include prevention of tuberculosis. For this purpose, in-country leadership for tuberculosis control ought to be elevated to higher levels within ministries of health. This is essential in order to effect coordinated action on multiple fronts and to accomplish three clear objectives: (1) achieving universal access to early detection and proper treatment of all patients with tuberculosis; (2) putting supportive health and social sector policies and systems in place to enable effective delivery of tuberculosis care and prevention; and (3) intensifying research to develop and apply new technologies, tools and approaches to enable eventual tuberculosis elimination. The three pillars of the global tuberculosis strategy are designed to address these objectives.

20. ***Specific actions proposed for Member States.*** The 10 components of the draft global tuberculosis strategy contain specific country-level actions. These specifically focus on adapting, implementing and monitoring a substantially enhanced and holistic response to countering the tuberculosis epidemic and ending it by 2035. The role of the WHO Secretariat is focused on providing support to Member States through normative guidance, policy advice and monitoring and evaluation.

## **VISION, GOAL, MILESTONES AND TARGETS**

21. The vision for the draft post-2015 tuberculosis strategy is “a world free of tuberculosis”; also expressed as “zero deaths, disease and suffering due to tuberculosis”. The goal is to end the global tuberculosis epidemic.

22. The Millennium Development Goal target “to halt and begin to reverse the incidence of tuberculosis by 2015” has already been achieved. The related Stop TB Partnership targets of reducing tuberculosis prevalence and death rates by 50% relative to 1990 are on track to be achieved by 2015. Under this draft strategy, new, ambitious yet feasible global targets are proposed for 2035. These include achieving a 95% decline in deaths due to tuberculosis compared with 2015, and reaching an equivalent 90% reduction in tuberculosis incidence rate from a projected 110 cases/100 000 in 2015 to 10 cases/100 000 or less by 2035. These targets are equivalent to the current levels in some low incidence countries of North America, Western Europe and the Western Pacific. An additional target proposed to ascertain progress of universal health coverage and social protection is that by 2020, no tuberculosis-affected person or family should face catastrophic costs due to tuberculosis care.

23. Milestones that will need to be reached before 2035 are also proposed for 2020, 2025, and 2030. Table 1 presents key global indicators, milestones and targets for the draft post-2015 strategy.

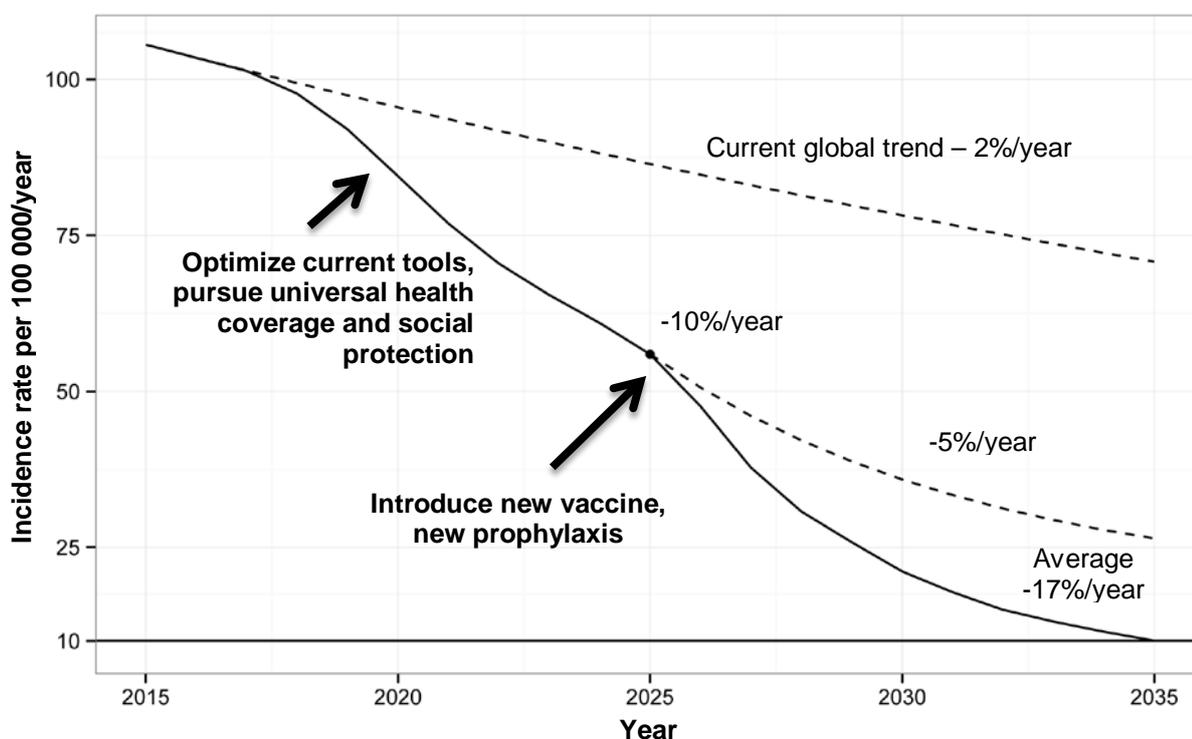
24. A milestone is a 75% reduction in tuberculosis deaths by 2025, compared with 2015. This will require two achievements. First, the annual decline in global tuberculosis incidence rates must accelerate from an average of 2% per year in 2015 to 10% per year by 2025. A 10% per year decline in tuberculosis incidence is ambitious yet feasible; it has been projected on the basis of the fastest rate documented at national level, which occurred in the context of universal access to health care and rapid socioeconomic development in Western Europe and North America during the second half of the past century. Secondly, the proportion of incident cases dying from tuberculosis (the case-fatality ratio) needs to decline from a projected 15% in 2015 to 6.5% by 2025. It has been modelled that rapid progress towards universal access to existing tools combined with socioeconomic development can lead to a 75% reduction in tuberculosis deaths. Furthermore, improved tools, such as a rapid point-of-care test and improved tuberculosis treatment regimens are likely to emerge soon from the research and development pipeline thus facilitating achievements of the milestones.

**Table 1. Key global indicators, milestones and targets for the draft post-2015 tuberculosis strategy**

Indicators with baseline values for 2015	Milestones			Targets
	2020	2025	2030	2035
<i>Percentage reduction in deaths due to tuberculosis</i> (projected 2015 baseline: 1.3 million deaths)	35%	75%	90%	95%
<i>Percentage and absolute reduction in tuberculosis incidence rate</i> (projected 2015 baseline 110/100 000)	20% (<85/100 000)	50% (<55/100 000)	80% (<20/100 000)	90% (<10/100 000)
<i>Percentage of affected families facing catastrophic costs due to tuberculosis</i> (projected 2015 baseline: not yet available)	Zero	Zero	Zero	Zero

25. In order to sustain progress beyond 2025 and achieve by 2035 a reduction in tuberculosis deaths of 95% and a 90% reduction in the incidence rate from 110 cases/100 000 to less than 10 cases per 100 000, there must be additional tools available by 2025. In particular, a new vaccine that is effective pre- and post-exposure, and better diagnostics as well as safer and easier treatment for latent tuberculosis infection will be needed. Achievements with existing tools complemented by universal health coverage and social protection would be remarkable but not sufficient to maintain the rate of progress required to achieve the 2035 targets. For new tools to be available for introduction by 2025, greatly enhanced and immediate investments in research and development will be required. Figure 2 shows the projected acceleration of the decline in global tuberculosis incidence rates with optimization of current tools combined with progress towards universal health coverage and social protection from 2015, and the additional impact of new tools by 2025.

**Figure 2. Projected acceleration in the decline of global tuberculosis incidence rates to target**



levels

26. The milestone that no families affected by tuberculosis face catastrophic costs implies minimizing direct medical costs, such as fees for consultations, hospitalization, tests and medicines as well as direct non-medical costs such as those for transport and any loss of income while under care. It requires that tuberculosis patients and tuberculosis-affected households have access to appropriate social protection schemes that cover or compensate for direct non-medical costs and income losses. With sufficient political commitment, tuberculosis-related costs could be rapidly reduced in all countries, and therefore many countries may be able to reach the target by 2020.

## THE PRINCIPLES OF THE DRAFT STRATEGY

### Government stewardship and accountability with monitoring and evaluation

27. Activities under the draft tuberculosis strategy span the health and social sectors and beyond, including finance, labour, trade and development. Stewardship responsibilities should be shared by all levels of the government – local, provincial, and central. The central government should remain the “steward of stewards” for tuberculosis care and prevention, working with all stakeholders.

28. The success of the draft post-2015 global tuberculosis strategy will depend on effective execution of key stewardship responsibilities by governments in close collaboration with all stakeholders: providing the vision and direction through the national tuberculosis programme and the health system; collection and use of data for progressive improvements in tuberculosis care and prevention; and exerting influence through regulation and other means to achieve the stated goals and objectives of the strategy.

29. To ensure accountability, regular monitoring and evaluation need to be built into strategy implementation. Progress will need to be measured against ambitious national targets and indicators. Table 2 presents an illustrative list of key global indicators that should be adopted and adapted for national use and for which country-specific targets should be set. These indicators should be supplemented by others considered necessary to capture progress in the implementation of all essential activities. Examples of targets that could apply in all countries include a treatment success rate of at least 85%, and testing of 100% of tuberculosis patients for drug susceptibility and HIV.

### **Strong coalition with civil society and communities**

30. The affected communities must also be a prominent part of proposed solutions. Community representatives and civil society must be enabled to engage more actively in programme planning and design, service delivery and monitoring as well as in information, education, support to patients and their families, research and advocacy. To this end, a strong coalition that includes all stakeholders needs to be built. Such a coalition of partners can assist people in both accessing high-quality care and in demanding high-quality services. A national coalition can also help drive greater action on the determinants of the tuberculosis epidemic.

### **Protection and promotion of human rights, ethics and equity**

31. Policies and strategies for the design of the overall national tuberculosis response, and the delivery of tuberculosis care and prevention, have to explicitly address human rights, ethics and equity. Access to high-quality tuberculosis care is a right. This strategy is built on a rights-based approach that ensures protection of human rights and promotion of rights-enhancing policies and interventions. These include engagement of affected persons and communities in facilitating implementation of all pillars and components of the draft strategy with special attention to key affected populations.

32. Tuberculosis care and prevention pose ethical dilemmas. National tuberculosis programmes should acknowledge and address these with due respect to relevant ethical values. These may include, for example, the conflict between the public interest in preventing disease transmission and patients' rights to demand a supportive care environment or refuse treatment; the response to the stigmatization attached to the disease and the discrimination against those affected; the lengthy treatment and the challenges of adherence to treatment; ensuring patient-centred service provision and balancing the risk of infection to health care workers; the care to be offered when there are not effective treatment options; and setting of priorities for research and for delivery of interventions. Ways to address these dilemmas should be guided by globally recognized principles and values, should be sensitive to local values and traditions, and should be informed by debates among all stakeholders.

33. The draft strategy aims to promote equity through identification of the risks, needs and demands of those affected, to enable equal opportunities to prevent disease transmission, equal access to diagnosis and treatment services, and equal access to means to prevent associated social impacts and catastrophic economic costs. The process through which to meet the targets, and achieve the goals of the strategy will be better served by applying a rights-based approach, developing and maintaining the highest ethical standards in every action taken, and ensuring that inequities are progressively reduced and eliminated.

### **Adaptation of the strategy at country level, with global collaboration**

34. No global strategy can apply similarly to all settings across or within countries. The tuberculosis strategy will have to be adapted to diverse country settings, based on a comprehensive national

strategic plan. Prioritization of interventions should be undertaken based on local contexts, needs and capacities. A sound knowledge of country-specific disease epidemiology will be essential, including mapping of people at a greater risk, understanding of socioeconomic contexts of vulnerable populations, and a grasp of health system context including underserved areas. Adoption of the global strategy should be immediately followed by its national adaptation and development of clear guidance on how the different components of the strategy could be implemented, based on local evidence when possible.

35. In a globalized world, diseases like tuberculosis can spread far and wide via international travel and trade. Tackling tuberculosis effectively requires close collaboration among countries. Effective intercountry collaboration also requires global coordination and support to enable adherence to the International Health Regulations (2005) and ensure health security. Countries within a region can benefit from regional collaboration. Migration within and between countries poses challenges and addressing them will require collaborative action. Global coordination is also essential for mobilizing resources for tuberculosis care and prevention from diverse multilateral, bilateral and domestic sources. WHO's global tuberculosis report, which annually provides an overview of the status of the tuberculosis epidemic and implementation of global strategies, demonstrates and symbolizes the benefits of close collaboration and global coordination.

## **PILLAR ONE: INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION**

36. *Strengthening and expansion of core functions of tuberculosis programmes.* Pillar one comprises patient-centred interventions required for tuberculosis care and prevention. The national tuberculosis programme, or equivalent, needs to engage and coordinate closely with other public health programmes, social support programmes, public and private health care providers, nongovernmental and civil society organizations, communities and patient associations in order to help ensure provision of high-quality, integrated, patient-centred tuberculosis care and prevention across the health system. Pillar one is meant to help countries to progress from previous strategies and to embrace new strategies and technologies for providing universal access to drug susceptibility testing; to expand services to manage tuberculosis among children; to provide additional outreach services to underserved and vulnerable populations; and to embark on systematic screening and preventive treatment of relevant high-risk groups – all in partnership with relevant stakeholders. Use of innovative information and communication technologies for health (eHealth and mHealth) could particularly help to improve tuberculosis care provision including logistics and surveillance.

### **Early diagnosis of tuberculosis including universal drug susceptibility testing, and systematic screening of contacts and high-risk groups**

37. *Ensure early detection of tuberculosis.* Currently an estimated two thirds of global incident tuberculosis cases are notified to national tuberculosis control programmes and reported to WHO. Ensuring universal access to early and accurate diagnosis of tuberculosis will require the strengthening and expansion of a network of diagnostic facilities with easy access to new molecular tests; information and education to prompt people with symptoms of tuberculosis to seek care; engagement of all care providers in service delivery; the abolition of barriers that people encounter in seeking care; and systematic screening in selected high-risk groups. Although the current most frequently used test for tuberculosis – sputum-smear microscopy – is a low-cost option providing specific diagnosis, it significantly lacks sensitivity. As a result, health services miss many tuberculosis patients or identify them only at advanced stages of the disease. Screening for symptoms alone may not suffice; additional screening tools such as a chest radiograph may facilitate referral for diagnosis of bacteriologically negative tuberculosis, extrapulmonary tuberculosis and tuberculosis in children.

38. ***Detect all cases of drug-resistant tuberculosis.*** Diagnosis of drug resistance remains a particular challenge for laboratory systems in many low- and middle-income countries. Capacity to diagnose drug-resistant tuberculosis is limited in most places where it is sorely needed. Only a fraction of the estimated cases of multidrug-resistant tuberculosis receive a laboratory test to confirm their disease. Adequate capacity to diagnose all cases of drug-resistant tuberculosis is essential to make further progress in global tuberculosis care and control.

39. ***Roll out new diagnostics.*** Wide introduction of new molecular diagnostic testing platforms will allow early and accurate diagnosis of tuberculosis and drug resistance. It could help diagnose less advanced forms of tuberculosis and facilitate early treatment, contributing potentially to decreased disease transmission, reduced case fatality, and prevention of adverse sequelae of the disease. Introduction of the new molecular diagnostics will require change of diagnostic policies and training at all levels. More sensitive and rapid diagnostics will increase the number of reliably diagnosed patients. The new realities of the additional workload will mean lining up additional human and financial resources.

40. ***Implement systematic screening for tuberculosis among selected high-risk groups.*** The burden of undetected tuberculosis is large in many settings, especially in high-risk groups. There can be long delays in diagnosing tuberculosis and initiating the appropriate treatment among people with poor access to health services. Many people with active tuberculosis do not experience typical symptoms in the early stages of the disease. These individuals may not seek care early enough and may not be identified for testing for tuberculosis if they do. Mapping of high-risk groups and carefully planned systematic screening for active disease among them may improve early case detection. Early detection helps reduce the risks of tuberculosis transmission, poor treatment outcomes, undesirable health sequelae, and adverse social and economic consequences of the disease. Contacts of people with tuberculosis, especially children aged five years or less, people living with HIV, and workers exposed to silica dust should always be screened for active tuberculosis. Other risk-groups should be identified and prioritized for possible screening based on national and local tuberculosis epidemiology, health system capacity, resource availability, and the feasibility of reaching the identified risk-groups. A screening strategy should be monitored and assessed continuously, to inform a re-prioritization of risk groups, re-adaptation of screening approaches, and discontinuation of screening if indicated. Screening strategies should follow established ethical principles for infectious disease screening, should protect human rights, and minimize the risk of discomfort, pain, stigma and discrimination.

### **Treatment of all people with tuberculosis including drug-resistant tuberculosis, and patient support**

41. ***Treat all forms of drug-susceptible tuberculosis.*** The new draft tuberculosis strategy will ensure provision of services for early diagnosis and proper treatment of all forms of tuberculosis affecting people of all ages. New policies incorporating molecular diagnostics will help to strengthen management of smear-negative pulmonary tuberculosis and extrapulmonary tuberculosis as well as tuberculosis among children. Key affected populations and risk groups with suboptimal treatment uptake or treatment success will need to be given priority attention in order to accelerate the decline in case fatality required in order to reach the ambitious targets for reductions in tuberculosis mortality.

42. ***Treat all cases of drug-resistant tuberculosis.*** Resistance to medicines poses a major threat to global progress in tuberculosis care and prevention. Globally, about 4% of new tuberculosis patients and about 20% of patients receiving retreatment have multidrug-resistant tuberculosis. Providing universal access to services for drug-resistant tuberculosis will require a rapid scale up of laboratory services and programmatic management. New models of delivering patient-centred treatment will need to be devised and customized to diverse settings and contexts. Ambulatory services should be

given preference over hospitalization, which should be limited to severe cases. Expansion of services for management of drug-resistant tuberculosis will require bold policies and investments to abolish health system bottlenecks that impede progress.

43. ***Strengthen capacity to manage drug-resistant cases.*** The proportion of drug-resistant tuberculosis patients successfully completing treatment varies substantially between countries and averaged 48% globally in 2012. Currently available treatment regimens for drug-resistant tuberculosis remain unsatisfactory in terms of duration, safety, effectiveness and cost. New safer, affordable and more effective medicines allowing treatment regimens that are shorter in duration and easier to administer are key to improving treatment outcomes. Linkages with existing pharmacovigilance mechanisms will contribute to promoting safer use and management of medicines. Interventions to improve quality of life for patients while enabling adherence to treatment include management of adverse drug reactions and events; access to comprehensive palliative and end-of-life care; measures to alleviate stigmatization and discrimination; and social support and protection. Importantly, all care providers managing drug-resistant tuberculosis should have access to continued training and education, enabling them to align their practices with international standards.

44. ***Address tuberculosis among children.*** With an estimated 500 000 cases and 74 000 deaths occurring annually, tuberculosis is an important cause of morbidity and mortality among children. In countries with a high prevalence of tuberculosis, women of childbearing age also carry a heavy burden of the disease. Maternal tuberculosis associated with HIV is a risk factor for transmission of tuberculosis to the infant and is associated with premature delivery, low birth-weight of neonates, and higher maternal and infant mortality. National tuberculosis programmes need to address systematically the challenges of caring for children with tuberculosis, and child contacts of adult tuberculosis patients. These may include, for instance, developing and using child-friendly formulation of medicines, and family-centred mechanisms for enabling adherence to treatment.

45. ***Integrate tuberculosis care within maternal and child health services.*** Proper management of tuberculosis among children will require development of affordable and sensitive diagnostic tests that are not based on sputum specimens. Tuberculosis care should be integrated within maternal and child health services to enable provision of comprehensive care at the community level. An integrated family-based approach to tuberculosis care would help remove access barriers, reduce delays in diagnosis and improve management of tuberculosis in women and children.

46. ***Build patient-centred support into the management of tuberculosis.*** Patient-centred care and support, sensitive and responsive to patients' educational, emotional and material needs, is fundamental to the new draft global tuberculosis strategy. Supportive treatment supervision by treatment partners is essential; it helps patients to take their medication regularly and to complete treatment, thus facilitating their cure and preventing the development of drug resistance. Supervision must be carried out in a context-specific and patient-sensitive manner. Patient-centred supervision and support must also help identify and address factors that may lead to treatment interruption. It must help to alleviate stigmatization and discrimination. Patient support needs to extend beyond health facilities to patients' homes, families, workplaces and communities. Treatment and support must also extend beyond cure to address any sequelae associated with tuberculosis. Examples of patient-centred support include providing treatment partners trained by health services and acceptable to the patient; access to social protection, use of information and communication technology for providing information, education and incentives to patients; and the setting up of mechanisms for patient and peer groups to exchange information and experiences.

## **Collaborative tuberculosis/HIV activities; and management of co-morbidities**

47. *Expand collaboration with HIV programmes.* The overall goal of collaborative tuberculosis/HIV activities is to decrease the burden of tuberculosis and HIV infection in people at risk of or affected by both diseases. HIV-associated tuberculosis accounts for about one quarter of all tuberculosis deaths and a quarter of all deaths due to AIDS. The vast majority of these cases and deaths are in the African and South-East Asia regions. All tuberculosis patients living with HIV should receive antiretroviral treatment. Integrated tuberculosis and HIV service delivery has been shown to increase the likelihood that a tuberculosis patient will receive antiretroviral treatment, shorten the time to treatment initiation, and reduce mortality by almost 40%.

48. *Integrate tuberculosis and HIV services.* Although there has been an encouraging global scale-up of collaborative tuberculosis/HIV activities, the overall coverage of services remains low. Further, the level and rate of progress vary substantially among countries. There remains a mismatch between the coverage of HIV testing for tuberculosis patients and that of antiretroviral treatment, co-trimoxazole preventive treatment, and HIV prevention. Reducing delays in diagnosis, using new diagnostic tools and instituting prompt treatment can improve health outcomes among people living with HIV. Tuberculosis and HIV care should be further integrated with services for maternal and child health and prevention of mother-to-child transmission of HIV in high-burden settings.

49. *Co-manage tuberculosis co-morbidities and noncommunicable diseases.* Several noncommunicable diseases and other health conditions including diabetes mellitus, undernutrition, silicosis, as well as smoking, harmful alcohol and drug use, and a range of immune-compromising disorders and treatments are risk factors for tuberculosis. Presence of co-morbidities may complicate tuberculosis management and result in poor treatment outcomes. Conversely, tuberculosis may worsen or complicate management of other diseases. Therefore, as a part of basic and coordinated clinical management, people diagnosed with tuberculosis should be routinely assessed for relevant co-morbidities. WHO's *Practical Approach to Lung Health*<sup>1</sup> is an example of promoting tuberculosis care as an integral part of management of respiratory illnesses. The local situation should determine which co-morbidities should be systematically screened for among people with active tuberculosis. A national collaborative framework can help integrated management of noncommunicable diseases and communicable diseases including tuberculosis.

## **Preventive treatment of persons at high risk; and vaccination against tuberculosis**

50. *Expand preventive treatment of people with a high risk of tuberculosis.* Latent tuberculosis infection is diagnosed by a tuberculin skin test or interferon- $\gamma$  release assay. However, these tests cannot predict which persons will develop active tuberculosis disease. Isoniazid preventive therapy is currently recommended for the treatment of latent tuberculosis infection among people living with HIV and children under five years of age who are contacts of patients with tuberculosis. It has a proven preventive effect but severe side effects can occur, especially among the elderly. Although regimens with similar efficacy and shorter duration have been studied, more evidence on efficacy and safety are needed. More studies are also required to assess the effectiveness and feasibility of undertaking preventive treatment among other high-risk groups such as, for example, people in congregate settings like prisons and workplaces, health care workers, recent converters of a test of infection, and miners exposed to silica dust. Management of latent tuberculosis infection in people

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<sup>1</sup> Document WHO/HTM/TB/2008.410; WHO/NMH/CHP/CPM/08.02.

with a high risk of developing active tuberculosis could be an essential component of tuberculosis elimination, particularly in low tuberculosis-incidence countries.

51. ***Continue BCG vaccination in high-prevalence countries.*** The BCG (Bacillus Calmette-Guerin) vaccination prevents disseminated disease including tuberculosis, meningitis and miliary tuberculosis, which are associated with high mortality in infants and young children. However, its preventive efficacy against pulmonary tuberculosis, which varies among populations, is only about 50%. Until new and more effective vaccines become available, BCG vaccination soon after birth should continue for all infants except for those persons with HIV living in high tuberculosis prevalence settings.

## **PILLAR TWO: BOLD POLICIES AND SUPPORTIVE SYSTEMS**

52. ***Sharing of responsibilities.*** The second pillar encompasses strategic actions that will enable implementation of the components under pillar one through sharing of responsibilities. These include actions by and beyond national tuberculosis programmes, from across ministries and departments. Such actions address medical and non-medical needs of those ill with tuberculosis and also help to prevent tuberculosis. This will require a well-resourced, organized and coordinated health system with government stewardship backed up by supportive health policies and regulations as well as broader social and development policies. National tuberculosis programmes, their partners and those overseeing the programmes need to engage actively in the setting of broader social and economic development agenda. Similarly, leaders in development must recognize tuberculosis as being among the social concerns that deserve priority attention.

53. ***Social determinants of tuberculosis.*** Pillar two further includes actions beyond the health sector that can help to prevent tuberculosis by addressing underlying social determinants. Proposed interventions include reducing poverty, ensuring food security, and improving living and working conditions as well as interventions to address direct risk factors such as tobacco control, reduction of harmful alcohol use, and diabetes care and prevention. Tuberculosis prevention will also require actions on the part of governments in order to help to reduce vulnerabilities and risks among people most susceptible to the disease.

54. ***Multidisciplinary and multisectoral approach.*** The implementation of pillar two components demands a multidisciplinary and multisectoral approach. Accountability for pillar two will rest not only with health ministries, but also other ministries including finance, labour, social welfare, housing, mining and agriculture. Eliciting actions from across diverse ministries will require commitment and stewardship from the highest levels of government. This should translate into ensuring adequate resources and accountability for optimal and integrated clinical care; protection from catastrophic economic burden due to the disease; social interventions aimed at reducing vulnerability to the disease; and protection and promotion of human rights.

## **Political commitment with adequate resources for tuberculosis care and prevention**

55. ***Develop ambitious national strategic plans.*** Scaling up and sustaining interventions for tuberculosis care and prevention will require high-level political commitment along with adequate financial and human resources. Continuous training and supervision of personnel are fundamental to sustain significantly expanded activities for tuberculosis care and prevention. Central coordination under government stewardship is essential. This must lead to, as a first step, development of a national strategic plan embedded in a national health sector plan, taking into account tuberculosis epidemiology, health system structure and functions including procurement and supply systems,

resource availability, regulatory policies, links with social services, the role of communities, civil society organizations and the private sector; and coordination with all stakeholders. A national strategic plan should be ambitious and comprehensive, and incorporate five distinct sub-plans: a core plan, a budget plan, a monitoring and evaluation plan, an operational plan and a technical assistance plan.

56. ***Mobilize adequate resources.*** The expansion of tuberculosis care and prevention across and beyond the health sector will be possible only if adequate funding is secured. The national strategic plan should be properly budgeted with clear identification of gaps in finances. A well-budgeted plan should facilitate resource mobilization from diverse international and national sources for full implementation of the plan. In most low- and middle-income countries, the currently available resources are inadequate or sufficient only for modestly ambitious plans. Coordinated efforts are required to mobilize additional resources to fund truly ambitious national strategic plans with a progressive increase in domestic funding.

### **Engagement of communities, civil society organizations, and all public and private care providers**

57. ***Engage communities and civil society.*** A robust response to end the tuberculosis epidemic will require the establishment of lasting partnerships across the health and social sectors and between the health sector and communities. Informed community members can identify people with suspected tuberculosis, refer them for diagnosis, provide support during treatment and help to alleviate stigmatization and discrimination. Civil society organizations have specific capacities and tuberculosis programmes can benefit from harnessing them. Their competencies include reaching out to vulnerable groups, mobilizing communities, channelling information, helping to create demand for care, framing effective delivery models and addressing determinants of the tuberculosis epidemic. National tuberculosis programmes should reach out to unengaged civil society organizations, encourage them to integrate community-based tuberculosis care into their work, and widen the network of facilities engaged in tuberculosis care and prevention. Civil society should also be engaged in policy development and planning as well as periodic monitoring of programme implementation.

58. ***Scale up public-private mix approaches and promote International Standards for Tuberculosis Care.*** In many countries, tuberculosis care is delivered by diverse private care providers. These providers include pharmacists, formal and informal practitioners, nongovernmental and faith-based organizations as well as corporate health facilities. Several public sector providers outside the purview of national tuberculosis programmes also provide tuberculosis care. These include large public hospitals, social security organizations, prison health services, military health services etc. Leaving a large proportion of care providers out of an organized response to tuberculosis control has contributed to stagnating case notification, inappropriate tuberculosis management, and irrational use of tuberculosis medicines leading to spread of drug-resistant tuberculosis. National tuberculosis programmes will have to scale up country-specific public-private mix approaches already working well in many countries. To this effect, close collaboration with health professionals' associations will be essential. The *International Standards for Tuberculosis Care*, other tools and guidelines developed by WHO as well as modern information and communication technology platforms can be used effectively for this purpose.

## **Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control**

59. ***Move with urgency to universal health coverage.*** Universal health coverage, defined as, “the situation where all people are able to use the quality health services that they need and do not suffer financial hardship paying for them” is fundamental for effective tuberculosis care and prevention. Universal health coverage is achieved through adequate, fair and sustainable prepayment financing of health care with full geographical coverage, combined with effective service quality assurance and monitoring and evaluation. For tuberculosis specifically, this implies: (a) expanding access to the full range of high-quality services recommended in this strategy, as part of general health services; (b) expanding the coverage including costs of consultations and testing, medicines, follow-up tests and all expenditures associated with staying in complete curative or preventive treatment; and (c) expanding access to services for all in need, especially vulnerable groups faced with the most barriers and worst outcomes.

60. ***Strengthen regulatory frameworks.*** National policy and regulatory frameworks for health care financing and access, quality-assured production and use of medicines and diagnostics, quality-assured health services, infection control, vital registration and disease surveillance systems are powerful levers that are essential for effective tuberculosis care and prevention. In countries with a high tuberculosis burden, these frameworks need to be urgently strengthened and enforced. The draft strategy calls for improvements in several areas outlined below.

61. ***Enforce mandatory notification of tuberculosis cases.*** Many tuberculosis cases are not notified, especially those managed by private care providers that are not linked to national tuberculosis programmes. Under-notification of cases hampers disease surveillance, contact investigation, outbreak management, and infection control. An effectively enforced infectious disease law, or equivalent, that includes compulsory notification of tuberculosis cases by all health care providers, is essential.

62. ***Ensure recording of tuberculosis deaths within vital registration.*** Most countries with a high burden of tuberculosis do not have comprehensive vital registration systems and the quality of information about the number of deaths due to tuberculosis is often inadequate. An effective vital registration system has to be in place to ensure that each death due to tuberculosis is properly recorded.

63. ***Regulate the production, quality and use of tuberculosis diagnostics and medicines.*** Poor quality tuberculosis medicines put patients at great risk. Irrational prescription of treatment regimens leads to poor treatment outcomes and may cause drug resistance. Use of inappropriate diagnostics such as serological tests leads to inaccurate diagnosis. Regulation and adequate resources for enforcement are required for the registration, importation and manufacturing of medical products. There should be regulation of how medical products are subsidized and a determination of which types of health professional are authorized to prescribe or dispense tuberculosis medicines.

64. ***Undertake comprehensive infection control measures.*** Appropriate regulation is required to ensure effective infection control in health care services and other settings where the risk of disease transmission is high. Managerial, administrative, environmental and personal measures for infection control should be part of infectious disease law, and regulations related to construction and organization of health facilities.

## **Social protection, poverty alleviation and actions on other determinants of tuberculosis**

65. **Relieve the economic burden related with tuberculosis.** A large proportion of people with tuberculosis face a catastrophic economic burden related to the direct and indirect costs of illness and health care. Adverse social consequences may include stigmatization and social isolation, interruption of studies, loss of employment, or divorce. The negative consequences often extend to the family of the persons ill with tuberculosis. Even when tuberculosis diagnosis and treatment is offered free of charge, social protection measures are needed to alleviate the burden of income loss and non-medical costs of seeking and staying in care.

66. **Expand coverage of social protection.** Social protection should cover the needs associated with tuberculosis such as: (a) schemes for compensating the financial burden associated with illness such as sickness insurance, disability pension, social welfare payments, other cash transfers, vouchers or food packages; (b) legislation to protect people with tuberculosis from discrimination such as expulsion from workplaces, educational or health institutions, transport systems or housing; and (c) instruments to protect and promote human rights, including addressing stigma and discrimination, with special attention to gender, ethnicity, and protection of vulnerable groups. These instruments should include capacity building for affected communities to be able to express their needs and protect their rights, and to call to account those who impinge on human rights, as well as those who are responsible for protecting those rights.

67. **Address poverty and related risk factors.** Poverty is a powerful determinant of tuberculosis. Crowded and poorly ventilated living and working environments often associated with poverty constitute direct risk factors for tuberculosis transmission. Undernutrition is an important risk factor for developing active disease. Poverty is also associated with poor general health knowledge and a lack of empowerment to act on health knowledge, which leads to risk of exposure to several tuberculosis risk factors. Poverty alleviation reduces the risk of tuberculosis transmission and the risk of progression from infection to disease. It also helps to improve access to health services and adherence to recommended treatment.

68. **Pursue “health-in-all-policies” approaches.** Actions on the determinants of ill health through “health-in-all-policies” approaches will immensely benefit tuberculosis care and prevention. Such actions include, for example: (a) pursuing overarching poverty reduction strategies and expanding social protection; (b) improving living and working conditions and reducing food insecurity; (c) involving diverse stakeholders, including tuberculosis affected communities, in mapping the likely local social determinants of tuberculosis; and (d) preventing direct risk factors for tuberculosis, including smoking and harmful use of alcohol and drugs, and promoting healthy diets, as well as proper clinical care for medical conditions that increase the risk of tuberculosis, such as diabetes.

## **PILLAR THREE: INTENSIFIED RESEARCH AND INNOVATION**

69. **Enhancing investments in research.** Progress in global tuberculosis control is constrained not only by the lack of new tools to better detect, treat or prevent tuberculosis but also by the weaknesses of health systems in delivering optimal diagnosis and treatment with existing tools. Ending the tuberculosis epidemic will require substantial investments in the development of novel diagnostic, treatment and prevention tools and their optimal uptake in countries alongside better and wider use of existing technologies. This will be possible only through increased investments and effective engagement of partners, the research community and country tuberculosis programmes.

70. ***Embarking on research for tuberculosis elimination.*** Revolutionary new technology and service delivery models are needed to achieve tuberculosis elimination. This will require an intensification of research – from fundamental research to drive innovations for improved diagnostics, medicines and vaccines, to operational and health systems research to improve current programmatic performance and introduce novel strategies and interventions based on new tools. To highlight the need for reinvigorated tuberculosis research and catalyse further efforts, an International Roadmap for Tuberculosis Research has been developed. The road map outlines priority areas for future scientific investment across the research continuum. It provides a framework for outcome-oriented research. A mapping of the efforts carried out in the various research areas will also be necessary, so as to follow up on progress made. Embarking on research for tuberculosis elimination will require a multi-dimensional approach informed by stakeholders including scientists, public health experts, tuberculosis programme managers, financial partners, policy-makers and civil society representatives. Guided by clinical and programmatic needs, such an approach should not only help undertake public health oriented research for the development of new tools and strategies but also facilitate their seamless integration into ongoing programmes. It is important that tuberculosis becomes a key domain of investigation within national health research agendas.

### **Discovery, development and rapid uptake of new tools, interventions and strategies**

71. ***Develop a point-of-care rapid diagnostic test for tuberculosis.*** Since 2007, several new tests and diagnostic approaches have been endorsed by WHO, including: liquid culture with rapid speciation as the reference standard for bacteriological confirmation; molecular line probe assays for rapid detection of multidrug-resistant tuberculosis; non-commercial culture and drug-susceptibility testing methods; light-emitting diode fluorescence microscopes; and Xpert MTB/RIF for rapid diagnosis of tuberculosis and rifampicin-resistant tuberculosis. However, an accurate and rapid point-of-care test that is usable in field conditions is still missing. This requires greater investments in biomarker research, and overcoming technical difficulties in transforming sophisticated laboratory technologies into robust and accurate point-of-care platforms.

72. ***Develop new drugs and regimens for the treatment of all forms of tuberculosis.*** The pipeline of new drugs has expanded substantially over the last decade. There are nearly a dozen new or repurposed tuberculosis drugs under clinical investigation. Bedaquiline, the first new tuberculosis drug for decades, was approved in 2013 by WHO for the treatment of multidrug-resistant tuberculosis. Novel regimens including new or repurposed medicines; adjuvant and supportive therapies are being investigated and early results appear promising. In order for further progress to be made, investments are required in both research and capacity building to implement trials in accordance with international standards, and to identify means of shortening the duration of tuberculosis medicines trials.

73. ***Enhance research to detect and treat latent infection.*** Globally, more than 2000 million people are estimated to be infected with *Mycobacterium tuberculosis*, but only 5% to 15% of those infected will develop active disease during their lifetime. Ending the tuberculosis epidemic will require eliminating this pool of infection. Research is needed to develop new diagnostic tests to identify people with latent tuberculosis infection who are likely to develop tuberculosis disease. Further, treatment strategies that could be safely used to prevent development of tuberculosis in latently infected persons will also need to be identified. These strategies should include new medicines or combinations as well as interventions to identify and mitigate risk factors for progression. Further research will be required to investigate the impact and safety of targeted and mass preventive strategies.

74. ***Aim for an effective vaccine against tuberculosis.*** The century-old BCG vaccine is useful to protect against severe forms of tuberculosis in infants and young children but has limited efficacy against other forms of tuberculosis. Much progress has been made in the development of new vaccines; currently there are 12 vaccine candidates in clinical trials. More research and investments are required to address a series of major scientific challenges and identify priorities for future tuberculosis vaccine research. A post-exposure vaccine that prevents the disease in latently infected individuals will be essential to eliminating tuberculosis in the foreseeable future.

### **Research to optimize implementation and impact; and promote innovations**

75. ***Invest in applied research.*** Investments in fundamental research need to be complemented with those for applied research that supports rapid adoption, adaptation, and implementation of evidence-based policies. Research aimed at improving understanding of the challenges and developing interventions that result in improved policies, better design and implementation of health systems and more efficient methods of service delivery is critical to produce evidence for improving current strategies and introducing new tools. Research is also needed to identify and address bottlenecks to implementation of existing and new policies, and to provide evidence from the perspective of patients as well as from health systems.

76. ***Use research to inform and improve implementation.*** Most innovations cannot be translated into effective local action without careful planning and adaptation, and partnership with stakeholders. In addition to routine surveillance, well-planned and well-conducted research is required to assess national and local epidemiological and health system situations, socio-behavioural aspects of health care seeking, adherence to treatment, stigmatization and discrimination, and to evaluate different implementation models.

77. ***Create a research-enabling environment.*** Fostering better and more relevant operational, health system and social science research will help implementation and contribute to the development of national and global policies. For this purpose, good systems for research prioritization, planning and implementation need to be in place at country level. Indicators to measure progress should include investments in outcomes as well as in the impact of research activities. A broad-based, concerted effort is needed to develop research capacity, allocate appropriate resources, and encourage stakeholders to work together. An enabling environment for performing programme-based research and translating results into policy and practice is necessary to achieving the full potential of tuberculosis programmes.

## **ADAPTING AND IMPLEMENTING THE STRATEGY**

### **Initiating and sustaining strategic dialogue**

78. ***Engage all stakeholders in strategy adoption and adaptation.*** A first step in adapting and implementing the strategy would be for Member States to hold inclusive national consultations with a wide range of stakeholders, including communities most affected by tuberculosis, in order to consider, adopt and prepare for adaptation of the strategy. Blanket application of a global strategy could be inappropriate if it does not adequately respond to an assessment of local needs that is derived from the nature of the tuberculosis epidemic, the health system context, the social and economic development agenda and the expressed demands of the populations at risk. Furthermore, it must build on the capacities of health systems and those of partners.

79. ***Use a multi-disciplinary approach.*** A meaningful implementation of this strategy will demand the involvement of many actors and their sharing of responsibilities. The scope of existing tuberculosis advisory panels will need to be expanded beyond clinical, epidemiological and public health expertise. It will need to include a wider range of capacities from civil society and from the fields of finance and development policy, human rights, social protection, regulation, health technology assessment, the social sciences, and communications. The work to adapt the new global tuberculosis strategy to national contexts may be an adjunct to overall national health strategic planning, but will need a significant and specific effort.

80. ***Prepare to develop new strategic plans.*** Countries follow different development planning cycles. Existing strategic and operational plans may need to be modified building on any new approaches. Detailed national strategic plans are also essential to mobilize funding from domestic and international sources. Development of new national strategic plans or modifications to existing ones should take into consideration the recommended framework of the new draft strategy.

### **Epidemiological and health systems mapping**

81. ***Undertake a detailed epidemiological and health system context assessment.*** A prerequisite for adoption of the strategy and preparation for its adaptation will be a detailed assessment of the national epidemiological and health system situation. Proper mapping should provide important information such as population groups most affected by the disease and most at risk of developing it; age and sex characteristics and trends; prevalence of different forms of tuberculosis and dominant co-morbidities including HIV, undernutrition, diabetes, tobacco use, and alcohol misuse; important subnational and urban–rural variations; distribution and types of care providers; available social protection schemes and their current and potential linkages for the benefit of tuberculosis care and prevention.

82. ***Collect and use data to improve systems mapping.*** Some of the information for context assessment can be derived from routine reporting and, in some countries, from national or regional tuberculosis prevalence survey results. Other required information may have to be obtained from review of periodic national programme evaluations, field assessments and local quantitative and qualitative studies. For this purpose, countries need to build capacities in order to establish an information system that monitors the characteristics of the tuberculosis epidemic, and make appropriate use of the data generated from the system at all levels.

### **MEASURING PROGRESS AND IMPACT**

83. Target setting and monitoring of progress in implementing each component of the global strategy are essential. Monitoring should be done routinely using standardized methods based on data with documented quality. Table 2 provides examples of the indicators that can be used to monitor progress in implementing different components and subcomponents of this strategy. The main indicators of disease burden are incidence, prevalence and mortality. Given the overarching 2025 targets of the draft strategy, particular attention to measurement of trends in mortality and incidence is required.

84. Mortality data are critical in order to enable prioritization of public health interventions and the measurement of progress made in disease control and the overall health of the population, including health inequalities. A robust national vital registration system that includes recording of data on causes of death is essential for measurement of trends in mortality due to tuberculosis. Vital registration data can also be used to identify subgroups of the population that have higher mortality over case-notification ratios, thereby allowing targeting of interventions. The quality of these data is documented globally by WHO<sup>1</sup> and statistical methods can be used to account for incomplete coverage or miscoding. Countries that already have vital registration systems need to ensure that data are of sufficient quality. Those without such systems need to introduce them. An interim solution being adopted by an increasing number of countries is the introduction of a sample vital registration system.

85. Globally, incidence is estimated to be declining slowly, at a rate of about 2% per year. The 2025 and 2050 targets mean that, in the post-2015 period, great attention will need to be given to measuring how fast incidence is falling. In high-income countries with high-performance tuberculosis surveillance and health systems, case notification systems capture all, or almost all, incident cases. However, in other countries, routine case notifications provide biased data due to under-diagnosis (cases not diagnosed) and under-reporting (cases diagnosed by health practitioners but not reported to public health authorities). In such settings, inventory studies and capture–recapture modelling may be used to estimate tuberculosis incidence.

86. Accurate measurement of trends in tuberculosis incidence requires the performance of tuberculosis surveillance systems to be strengthened so that they cover all providers of health care and minimize the level of under-reporting. WHO has developed a tuberculosis surveillance checklist, the “standards and benchmarks for tuberculosis surveillance and vital registration systems”, to assess a national surveillance system’s ability to measure tuberculosis cases accurately. The checklist defines 10 surveillance standards that must be met in order for notification and vital registration data to be considered as a direct measurement of tuberculosis incidence and tuberculosis mortality, respectively. Countries that meet all standards can be certified as having an appropriate surveillance system. The WHO checklist should be used to improve tuberculosis surveillance progressively towards the ultimate goal of measuring trends in tuberculosis cases directly from notification data in all countries.

87. Tuberculosis prevalence is a very useful indicator of the tuberculosis disease burden. It is directly measurable through population-based surveys.<sup>2</sup> Prevalence surveys also provide information that is useful for policy improvements, in particular those related to access to health and to tuberculosis diagnosis. Measurement of tuberculosis prevalence using nationwide surveys is not feasible everywhere. Nationwide prevalence surveys are important for high-burden settings and will be especially relevant and useful for direct measurement of impact in countries that implemented a repeat or baseline survey around 2015. The WHO Task Force on TB Impact Measurement has set criteria for prioritization of prevalence surveys at country level and works with countries and other partners to support implementation and analysis of surveys. The Task Force closely monitors the implementation of all surveys to ensure international comparability through the use of WHO-recommended methods and standards. The Task Force also assesses progress towards prevalence reduction targets.

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<sup>1</sup> Mathers CD, Fat DM, Inoue M, Rao C, Lopez AD. Counting the dead and what they died from: an assessment of the global status of cause of death data. *Bulletin of the World Health Organization*. 2005;83(3):171-7.

<sup>2</sup> World Health Organization. *Tuberculosis prevalence surveys: a handbook*. Geneva 2011. [http://www.who.int/tb/advisory\\_bodies/impact\\_measurement\\_taskforce/resources\\_documents/thelimebook/en/index.html](http://www.who.int/tb/advisory_bodies/impact_measurement_taskforce/resources_documents/thelimebook/en/index.html).

**Table 2. Illustrative list of key global indicators for the draft post-2015 global tuberculosis strategy**

<b>COMPONENT</b>	<b>ILLUSTRATIVE INDICATORS</b>
<b>PILLAR ONE: INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION</b>	
<b>A. Early diagnosis</b>	<ul style="list-style-type: none"> <li>– % of people with suspected tuberculosis tested using WHO recommended rapid diagnostics</li> <li>– % of all tuberculosis patients for whom results of drug susceptibility testing were available</li> <li>– % of eligible index cases of tuberculosis for which contact investigations were undertaken</li> </ul>
<b>B. Treatment</b>	<ul style="list-style-type: none"> <li>– Tuberculosis treatment success rate</li> <li>– % of patients with drug-resistant tuberculosis enrolled on second-line treatment</li> </ul>
<b>C. TB/HIV and co-morbidities</b>	<ul style="list-style-type: none"> <li>– % of tuberculosis patients screened for HIV</li> <li>– % of HIV-positive tuberculosis patients on antiretroviral therapy</li> </ul>
<b>D. Preventive treatment</b>	<ul style="list-style-type: none"> <li>– % of eligible people living with HIV and children aged under-five who are contacts of tuberculosis patients being treated for latent tuberculosis infection</li> </ul>
<b>PILLAR TWO: BOLD POLICIES AND SUPPORTIVE SYSTEMS</b>	
<b>A. Government commitment</b>	<ul style="list-style-type: none"> <li>– % of annual budget defined in tuberculosis national strategic plans that is funded</li> </ul>
<b>B. Engagement of communities and providers</b>	<ul style="list-style-type: none"> <li>– % of diagnosed tuberculosis cases that were notified</li> </ul>
<b>C. Universal health coverage and regulatory frameworks</b>	<ul style="list-style-type: none"> <li>– % of population without catastrophic health expenditures</li> <li>– % of countries with a certified tuberculosis surveillance system</li> </ul>
<b>D. Social protection, social determinants</b>	<ul style="list-style-type: none"> <li>– % of affected families facing catastrophic costs due to tuberculosis</li> <li>– % of population without undernutrition</li> </ul>
<b>PILLAR THREE: INTENSIFIED RESEARCH AND INNOVATION</b>	
<b>A. Discovery</b>	<ul style="list-style-type: none"> <li>– % of desirable number of candidates in the pipelines of new diagnostics, drugs and vaccines for tuberculosis</li> </ul>
<b>B. Implementation</b>	<ul style="list-style-type: none"> <li>– % of countries introducing and scaling-up new diagnostics, drugs or vaccines</li> </ul>

## **THE ROLE OF THE WHO SECRETARIAT**

88. The WHO Secretariat, at all levels of the Organization, will provide support to Member States in reviewing, adopting, adapting and implementing their post-2015 tuberculosis strategies, building on the framework provided in the draft strategy. WHO will draw on its comparative advantages in areas of the core functions outlined below and use its Strategic and Technical Advisory Group for Tuberculosis and regional advisory bodies, as well as the Organization's governing bodies, in order to guide, support and evaluate its work.

89. WHO will continue its policy and norms-setting work, building on a range of available and future guidance documents on tuberculosis. The Secretariat will provide the strategic guidance and tools needed for adaptation and implementation of the strategy in diverse country settings. These tools will need to be iterated as further evidence on effective approaches and best practices becomes available. Periodic guidance will be needed on the use of new tuberculosis diagnostics, medicines susceptibility testing methods, and new treatment regimens as they become available. WHO will work with partners to stimulate further evidence generation and policy recommendations on how national tuberculosis programmes can engage in the development agenda to address social determinants of tuberculosis.

90. To enable this strategy to have a rapid impact and to support Member States, the Secretariat will pursue its core function of technical support coordination. It will continue to stimulate contributions from partners, at global, national and local levels. The tuberculosis technical assistance mechanism (TBTEAM) managed by WHO helps to facilitate and mobilize financing for technical assistance by partnering with major development agencies. The gaps in technical expertise among supporting agencies will need to be filled by collaborating with experts working in global health disciplines beyond tuberculosis, and by drawing more young collaborators into the field.

91. WHO will continue to strengthen its stewardship role in generating global demand for research, prioritizing among tuberculosis research needs, and supporting with partners the effective conduct of research to inform global and national strategy and policy design and implementation. This will entail further work with basic scientists, epidemiologists, social scientists, innovators in the public, private and academic communities, as well as affected populations. It will also mean that national tuberculosis programmes need to work with academic partners and associated research institutions, research-focused public partnerships and public-private partnerships.

92. WHO will foster effective partnerships to support the work proposed under the three pillars of the new draft strategy. This work in partnership aims to support Member States in achieving universal access to tuberculosis care and prevention and in reaching out to vulnerable populations and communities most affected by the tuberculosis epidemic worldwide. WHO will work with the Stop TB Partnership, and will seek out new partnerships that can leverage effective commitment and innovation in the non-health sector driven elements of the strategy.

93. The launch of the Stop TB Strategy 2006–2015 by WHO led to its swift translation into a comprehensive, costed global plan of action by the Stop TB Partnership that is hosted and administered by WHO. Similarly for the draft post-2015 global tuberculosis strategy, WHO will actively support the development of a global investment plan by the Stop TB Partnership, outlining activities and defining financing requirements to meet the ambitious targets while achieving the stated milestones on the way. WHO will work closely with the Stop TB Partnership and will contribute to preparing the global action and investment plan to guide post-2015 efforts for tuberculosis care and prevention by providing the required strategic, scientific and technical input.

## **ACTION BY THE EXECUTIVE BOARD**

94. The Board is invited to consider the draft post-2015 global tuberculosis strategy and targets.

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