Following the endorsement of the End TB Strategy by the Sixty-seventh WHA in 2014, the focus is now on enabling adaptation and implementation of the strategy at the country level. The post-2015 End TB Strategy for tuberculosis prevention care and control has a bold vision of a world without tuberculosis. It aims to end the global tuberculosis epidemic by 2035 by reducing deaths due to tuberculosis by 95%; reducing tuberculosis incidence by 90%, and eliminating catastrophic costs for tuberculosis-affected households. The strategy addresses government stewardship and accountability; coalition-building with affected communities and civil society, human rights and ethics; adaptation to fit the needs of each epidemiological, socioeconomic and health system contexts and global collaboration. It builds on three pillars: integrated, patient-centred care and prevention; bold policies and supportive systems; and intensified research and innovation.

Ending the TB epidemic will require an expansion of the scope and reach of interventions for TB 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 TB care and prevention.

The High-Level Preparatory (HLP) Meeting held at the Regional Office in New Delhi, India, from 29 June to 2 July 2015 reviewed the attached working paper and made the following recommendations:

**Actions by Member States**

1. Reaffirm commitment to eliminate TB as a public health problem by adapting the End TB Strategy;

2. Revise and implement the national tuberculosis strategic plans in line with the three pillars of the End TB Strategy: integrated, patient-centred care and prevention; bold policies and supportive systems and intensified research and innovation;

3. Secure adequate financing for implementing and monitoring all tuberculosis-specific, health sector-related and multisectoral actions proposed in the End TB Strategy, taking into consideration the variations in the epidemiological, socioeconomic and health system contexts;
(4) Engage a wide range of stakeholders in the implementation of the strategy, including local, national, regional and international partners, as well as stakeholders from within and beyond the health sector.

**Actions by WHO**

(1) Advocate for the highest level political commitment and increased funding from national and international sources to support TB elimination efforts in the Region;

(2) Provide guidance to Member States on how to adapt and operationalize the End TB Strategy, including the development of a regional strategic plan for interventions in the period 2016–2020 towards TB elimination;

(3) Assist Member States with implementation of the strategy, and evaluate the impact in terms of progress towards set milestones and targets;

(4) Promote equitable access to new tools and medical products for the prevention, diagnosis and treatment of tuberculosis and multidrug-resistant tuberculosis.

The working paper and HLP recommendations are submitted to the Sixty-eighth Session of the Regional Committee for its consideration.
Introduction

1. In May 2014, the Sixty-seventh World Health Assembly WHA 67.1 endorsed resolution on global strategy and targets for tuberculosis prevention, care and control after 2015 with its (1) bold vision of a world without TB and its targets of ending the global TB epidemic by 2035 through a reduction in TB deaths by 95% and incidence by 90% (or to fewer than 10 cases per 100 000 population), as well as elimination of associated catastrophic costs for TB-affected households; (2) associated milestones for 2020, 2025 and 2030; (3) principles addressing: government stewardship and accountability; coalition-building with affected communities and civil society; equity, human rights and ethics; adaptation to fit the needs of each epidemiological, socioeconomic and health system context; and (4) three pillars of integrated, patient-centred care and prevention; bold policies and supportive systems; and intensified research and innovation.

2. The resolution urges all Member States to: (1) adapt the strategy in line with national priorities and specificities; (2) implement, monitor and evaluate the TB-specific health sector and multisectoral actions proposed in the strategy with high-level commitment and adequate financing, taking into consideration local settings; and (3) seek, with the full engagement of a wide range of stakeholders, to prevent the persistence of high incidence rates of TB within specific communities or geographical settings.


4. Evidence shows that the progress, though significant, is not enough. Several challenges persist in reducing the global burden of TB and the pace of its reduction. Even though these may vary according to country contexts, addressing them effectively calls for adoption of a holistic approach in all contexts.

Current responses, achievements and challenges

5. TB remains a major global health problem affecting 9 million people each year and causing 1.5 million deaths, thus competing with HIV/AIDS as the top infectious killer worldwide. The WHO South-East Asia Region had an estimated 4.5 million prevalent and 3.4 million incident cases in 2013 and carried about 38% of the global TB burden, making it by far the most affected region in the world.

6. The Region is on track to meet the MDG targets; although notified TB cases have been steadily increasing, a decline in the prevalence is seen in all Member States, some reporting more than 50% decline since 1990. The target of halving the TB mortality rate has already been attained. The MDG of halting and reversing TB incidence in the Region by 2015 has also been achieved. The TB treatment success rate has continued to be more than 88% since 2009. Case notification is also increasing: in 2013 (reported in 2014), Member States notified a total of 2.1 million cases of TB. This represents an increase over cases notified in 2012 and implies a rise in access to quality TB care services.

7. Noteworthy progress has been made in the development of new tools. Seven WHO-endorsed new diagnostics are being rolled out. The recent introduction of a rapid molecular test to diagnose TB and rifampicin resistance simultaneously has been particularly impressive, with
application in low- and middle-income countries eligible for concessional pricing. The pipeline of new TB medicines has expanded substantially.

8. The Region, achieving high treatment success rates, has resulted in maintaining the slow but steady decline in TB incidence rates during the past decade. This has also led to low levels (2.2, range: 1.6–2.8%) of multidrug-resistant (MDR) TB among newly detected cases. Among previously treated cases in the Region, the MDR-TB rate is estimated to be higher, about 16% (range: 11–21%) and the Region has the second lowest proportion of MDR-TB among retreatment TB patients. Extensively drug-resistant TB (XDR-TB) has also been reported from six countries (Bangladesh, India, Indonesia, Myanmar, Nepal and Thailand) in the Region.

9. India initiated a national TB drug resistance survey in July 2014. An estimated 5214 patients from 120 clusters are expected to submit sputum specimens to the National TB Reference Laboratory (NTRL) and the National TB Institute, Bangalore (NTI). As part of the survey, a 13-drug susceptibility testing (five first-line drugs and eight second-line drugs) for 5214 patients are being carried out. The survey is ongoing with more than 90% intake completed. Analysis and results will become available in March–June 2016.

10. An estimated 1.1 million (13%) of the 9 million people who developed TB in 2013 were HIV-positive globally and the South-East Asia Region accounted for about 15% of the global burden of new HIV-positive TB cases. National TB/HIV policies and guidelines, and a comprehensive package of interventions are being implemented in all countries except the Democratic People's Republic of Korea, where HIV testing in select TB cases with history of travel is being undertaken; however, the pace of implementation and outcomes differ across countries.

11. Since 2006, WHO is putting emphasis on childhood TB by issuing guidance on management and treatment of TB in children. WHO also published the "Childhood TB: training toolkit".

12. While achievements over the past two decades are substantial, they do not suffice to ensure progress towards elimination of TB: inadequate coverage and weak performance of health services limit access to high-quality TB prevention and care. Over 1 million people with TB are "missed" each year by health systems and many, therefore, do not get the TB care that they need. The scaling up of programmatic management of drug-resistant TB (PMDT) and TB/HIV collaborative activities is insufficient, and many public and private health providers remain delinked from national TB control efforts. The 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 critical to ensure effective infection control; rational use of TB diagnostics and medicines; mandatory disease notification; functioning vital registration systems; and protection of the legal rights of people with TB remain weak. In addition, data collection, quality and use at all levels need improvement.

13. Noncommunicable diseases and TB comorbidities: Risk-factors of TB such as diabetes, tobacco smoking, silicosis, alcohol and drug misuse, mental illness, and under-nutrition hamper TB control, especially in low- and middle-income countries. A large pool of latently infected people contributes to a growing proportion of future TB cases.
Strategic issues and the way forward

14. Ending the TB epidemic is not merely a biomedical, but a developmental challenge. An inclusive global-, regional- and country-level response designed to meet the global development goals is necessary to end the TB epidemic. The progress towards ending the TB epidemic will depend as much on achieving overall health improvement as on optimizing current strategies, developing new tools and technologies to diagnose, treat and prevent TB, and making them accessible to all in need.

15. Implementing the strategy will require intensified actions elaborated under the three pillars of the End TB Strategy from the three levels of governance in Member States to close collaboration with all stakeholders. The three levels include NTP, health ministry, and higher levels in government responsible for setting the social development agenda, resource allocation and interministerial coordination. NTP should be responsible for coordination of all activities related to delivery of services for TB care and prevention. The national health ministries should provide critical systemic support, enforce regulatory mechanisms, and coordinate integrated approaches through interministerial and intersectoral collaboration. The national governments should provide the overall stewardship to keep TB elimination high on the development agenda through political commitment, investments and oversight, while making rapid progress towards universal health coverage and social protection. This is also captured in the four cross-cutting principles of the strategy.

16. Member States consider establishing high-level national mechanisms involving actors within and beyond governments to effectively coordinate a multisectoral response that ensures the adaptation and implementation of the End TB Strategy.

17. Ensuring universal access to early and accurate diagnosis of TB will require the strengthening and expansion of a network of diagnostic facilities with easy access to new molecular tests. Screening for symptoms alone may not suffice; additional screening tools such as a chest radiograph may facilitate referral for diagnosis of bacteriologically negative TB, extrapulmonary TB and TB in children. The burden of undetected TB is large in many settings, especially in high-risk groups. Mapping of high-risk groups and carefully planned systematic screening for active disease among them may improve early case detection. Contacts of people with TB, especially children aged five years or less, people living with HIV, and workers exposed to silica dust should always be screened for active TB. Other risk groups such as prison inmates, refugees and migrants should be identified and prioritized for possible screening based on national and local TB epidemiology, health system capacity, resource availability, and the feasibility of reaching the identified risk groups.

18. Providing universal access to services for drug-resistant TB 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 and community-based services should be given preference over hospitalization, which should be limited to severe cases. Expansion of services for management of drug-resistant TB will require bold policies and investments to abolish health system bottlenecks that impede progress. Introduction of newer drugs and shortening the period of treatment is recommendable through operational research. Currently available treatment regimens for drug-resistant TB 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.

19. The new strategy emphasizes on treatment of all people with tuberculosis including drug-resistant TB, children TB, TB/HIV co-infection and management of co-morbidities. The strategy will aim to ensure provision of services for early diagnosis and proper treatment with support and supervision for all forms of TB affecting people of all ages. New policies incorporating molecular diagnostics will help to strengthen management of smear-negative pulmonary TB and extrapulmonary TB as well as TB among children.

20. Proper management of TB among children will require development of affordable and sensitive diagnostic tests that are not based on sputum specimens. TB 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 TB care would help remove access barriers, reduce delays in diagnosis and improve management of TB in women and children.

21. There remains a mismatch between the coverage of HIV testing for TB patients and that of antiretroviral treatment, cotrimoxazole 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. TB 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.

22. 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 TB. Presence of comorbidities may complicate TB management and result in poor treatment outcomes. Conversely, TB may worsen or complicate management of other diseases. Therefore, as a part of basic and coordinated clinical management, people diagnosed with TB should be routinely assessed for relevant comorbidities. WHO’s Practical Approach to Lung Health is an example of promoting TB care as an integral part of management of respiratory illnesses. The local situation should determine which comorbidities should be systematically screened for among people with active TB. A national collaborative framework can help integrated management of noncommunicable diseases and communicable diseases including TB.

23. Latent TB infection is diagnosed by a tuberculin skin test or interferon release assay. However, these tests cannot predict which persons will develop active TB disease. Isoniazid preventive therapy is currently recommended for the treatment of latent TB infection among people living with HIV and children under five years of age who are contacts of patients with TB.

24. Tackling the global TB epidemic effectively also requires close collaboration among countries. Global and regional coordination and support is essential to ensuring national health security. Countries within the Region can benefit from regional collaboration. Migration within and between countries poses challenges, and addressing them will require both in-country coordination and cross-border collaboration.
25. To scale up and sustain interventions for TB care and prevention will require high-level political commitment along with adequate financial and human resources. Central coordination under government stewardship is essential. Coordinated efforts are required to mobilize additional resources to fund truly ambitious national strategic plans with a progressive increase in domestic funding.

26. A robust response to end the TB epidemic will require the establishment of lasting partnerships across the health and social sectors and between the health sector and communities. Civil society organizations have specific capacities, and TB programmes can benefit from harnessing them. Civil society should also be engaged in policy development and planning as well as periodic monitoring of programme implementation.

27. In many countries, TB care is delivered by diverse private care providers. These providers include pharmacists, formal and informal practitioners and nongovernmental and faith-based organizations, as well as corporate health facilities. National TB 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 TB Care, other tools and guidelines developed by WHO as well as modern information and communication technology platforms can be used effectively for this purpose.

28. 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 TB 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 TB 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 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.

29. 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 TB care and prevention. In countries with a high TB burden, these frameworks need to be urgently strengthened and enforced. An effectively enforced infectious disease law or equivalent that includes compulsory notification of TB cases by all health care providers is essential.

30. Most countries with a high burden of TB do not have comprehensive vital registration systems, and the quality of information on the number of deaths due to TB is often inadequate. An effective vital registration system has to be in place to ensure that each death due to TB is properly recorded.

31. 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
infection disease laws as well as regulations related to construction and organization of health facilities.

32. A large proportion of people with TB face a catastrophic economic burden related to the direct and indirect costs of illness and health care. Poverty, as such, is a powerful determinant of TB. 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 TB. Even when TB diagnosis and treatment is offered free of charge, social protection measures are needed to alleviate the burden of income loss and nonmedical costs of seeking and staying in care.

33. Social protection should cover the needs associated with TB 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 TB 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.

34. Actions on the determinants of ill health through "health-in-all-policies" approaches will immensely benefit TB 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) addressing the health issues of migrants and strengthening cross-border collaboration; (d) involving diverse stakeholders, including TB-affected communities, in mapping the likely local social determinants of TB; and (e) preventing direct risk factors for TB, 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 TB, such as diabetes.

35. It requires greater investments in biomarker research, and overcoming difficulties in transforming sophisticated laboratory technologies into robust, accurate and affordable point-of-care platforms. The pipeline of new drugs has expanded substantially over the last decade. There are nearly a dozen new or repurposed TB drugs under clinical investigation. Bedaquiline, the first new TB drug for decades, was approved in 2013 by WHO for the treatment of multidrug-resistant TB. A second new drug, delamanid, also for the treatment of multidrug-resistant TB, is in the process of review by WHO. Research is needed to develop new diagnostic tests to identify people with latent TB infection who are likely to develop TB disease. Further, treatment strategies that could be safely used to prevent development of TB in latently infected persons will also need to be identified. 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 TB vaccine research. A post-exposure vaccine that prevents the disease in latently infected individuals will be essential to eliminating TB in the future.

36. 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.