

# Regional Framework for Action on Implementation of the **End TB Strategy** in the Western Pacific, 2016–2020





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## ABBREVIATIONS

<b>AIDS</b>	acquired immunodeficiency syndrome
<b>ART</b>	antiretroviral treatment
<b>BCG</b>	bacille Calmette–Guérin (vaccine)
<b>CPT</b>	co-trimoxazole preventive therapy
<b>DST</b>	drug susceptibility testing
<b>DOT</b>	directly observed therapy
<b>DOTS</b>	directly observed treatment, short-course
<b>GDF</b>	Global Drug Facility
<b>HIV</b>	human immunodeficiency virus
<b>HiAP</b>	health in all policies
<b>IPT</b>	isoniazid preventive therapy
<b>ISO</b>	International Organization for Standardization
<b>ISTC</b>	International Standards for Tuberculosis Care
<b>LED</b>	light-emitting diode
<b>LPA</b>	line probe assay
<b>LTBI</b>	latent TB infection
<b>MDGs</b>	Millennium Development Goals
<b>MDR-TB</b>	multidrug-resistant tuberculosis
<b>NCDs</b>	noncommunicable diseases
<b>NMRA</b>	national medicine regulatory authority
<b>NSP</b>	national (TB) strategic plan
<b>NTP</b>	National Tuberculosis Programme
<b>PAF</b>	population attributable fraction
<b>PATLAB</b>	Pacific TB Laboratory Initiative
<b>PMDT</b>	programmatic management of drug-resistant tuberculosis
<b>RFLP</b>	restriction fragment length polymorphism
<b>rGLC</b>	regional Green Light Committee
<b>SRL</b>	supranational reference laboratory
<b>TB</b>	tuberculosis
<b>UHC</b>	universal health coverage
<b>VNTR</b>	variable number tandem repeats WHO World Health Organization
<b>WRDs</b>	WHO-recommended diagnostics
<b>XDR-TB</b>	extensively drug-resistant tuberculosis

# FOREWORD

Progress in reducing the burden of tuberculosis (TB) in the Western Pacific Region has been remarkable. Since 1990, concerted efforts have reduced TB prevalence by over 55% and TB deaths by over 78%. An estimated 9.5 million lives have been saved since 2000. Today, 1.4 million patients are treated annually. With incidence continuously declining, the Western Pacific Region has achieved the TB-related targets associated with the Millennium Development Goals.

However, much work remains to be done to further reduce the burden of TB. Despite big reductions, TB continues to claim more than 100 000 lives every year in the Region. In 2014, 1.6 million people fell ill with TB, shattering lives and livelihoods. In May 2014, the World Health Assembly adopted a new global strategy for TB, the *End TB Strategy*. The strategy sets ambitious targets: a 90% reduction in incidence and a 95% reduction in mortality by 2035, with no families facing catastrophic costs due to TB by 2020.

Drug-resistant TB is a growing threat to global and regional health security. Health systems with weak drug regulations and substandard care continue to generate drug-resistance. Despite substantial investment, the majority of drug-resistant TB cases are undiagnosed or treated with a low rate of success.

TB concentrates in vulnerable populations, among those least able to cope with the financial burden of illness. Basic TB services are free in nearly all countries in the Region; nevertheless, patients often still suffer heavy financial burden. The *End TB Strategy's* target of “no affected families facing catastrophic costs due to TB” must be achieved through ensuring financial risk protection for TB patients in line with national efforts towards universal health coverage.

Weak regulatory mechanisms diminish TB control by allowing inadequate TB treatment. Ministries of health are best positioned to coordinate and guide national responses. Under government stewardship, strong regulatory mechanisms should be in place to support TB control, including mandatory disease notification, harmonized drug regulatory policies and standards of care that include infection control.

To achieve the End TB Strategy, intensified research and development are also required. Globally and regionally, a critical need exists for continued advocacy, information-sharing platforms and enhanced TB research investment. Building national research capacity is essential, especially in low- and middle-income countries with substantial TB burden.

The Regional Framework for Action on Implementation of the *End TB Strategy* in the Western Pacific 2016–2020 aims to adapt the End TB Strategy to the particular circumstances of countries and areas in the Region. The endorsement of this framework by the sixty-sixth Regional Committee for the Western Pacific represents the strong commitment of Member States to build and maintain bold national efforts for TB control until the vision of zero deaths, disease and suffering due to tuberculosis is achieved.



Shin Young-soo, MD, Ph.D.  
Regional Director



# EXECUTIVE SUMMARY

Progress in reducing the tuberculosis (TB) burden in the Western Pacific Region has been remarkable, with millions of lives saved and drastic reductions in prevalence and mortality in the past two decades. Throughout the Region, national tuberculosis programmes (NTPs) have expanded the basic TB services package and centred its focus on the most cost-effective, high-impact interventions at little or no cost to patients. Furthermore, accurate epidemiological information and programmatic evidence have provided a rich base for informed decision-making.

Despite unprecedented achievements, TB remains a leading killer in the Region, claiming more than 100 000 lives every year. Detecting TB cases in vulnerable populations such as migrants, prisoners, children, older people and the poor can be difficult, and many have limited capacity to cope with the burden of illness. Although basic TB services are available free of charge in almost all countries, TB patients continue to suffer from a heavy financial burden. Loss of income and direct expenses trigger a downward spiral, whereby patients are less able to complete treatment and may develop drug resistance. Annually, on average, there are an estimated 71 000 new cases of multidrug-resistant TB in the Region, with only 11 412 (16%) cases notified in 2013 and 6926 (10%) patients placed in treatment. Notably, the treatment success rate in the Region was only 52% for patients enrolled in treatment in 2011. Weaknesses in health systems and regulatory mechanisms result in limited services, inadequate treatment, irrational drug use and discrimination against people with TB.

In 2014, the Sixty-seventh World Health Assembly endorsed the *Global strategy and targets for tuberculosis prevention, care and control after 2015*, also known as *The End TB Strategy*. The strategy aims to “end the global TB epidemic” by 2035, bringing the level of disease burden in the whole world down to the level seen now in countries with the lowest TB burden. Within the scope of this 20-year time span, this regional framework focuses on the implementation of *The End TB Strategy* in the coming five years. The indicators and targets of *The End TB Strategy* are reinforced, especially ensuring no families face catastrophic costs due to TB. Based on extensive consultation, the regional framework aims to provide policy options for consideration in order to update national strategies and plans and strengthen national efforts to advance TB control.

The **End TB Strategy** contains five elements that are particularly relevant to the regional situation:

1. A paradigm shift in the structure and operation of NTPs from a limited view of service provision to an expanded holistic approach;
2. A focus on equity to ensure all people receive quality care despite disparities resulting from socioeconomic development and changing epidemics;
3. An emphasis on health system strengthening and promotion of multisectoral actions within the context of universal health coverage (UHC) and social protection;
4. Universal application to all countries covering the spectrum of TB epidemiology; and
5. People-centred health care as an approach that consciously adopts the perspectives of individuals, families and communities, and sees them as participants as well as beneficiaries of trusted health systems.

## **PILLAR 1**

### **INTEGRATED, PEOPLE-CENTRED CARE AND PREVENTION**

Many people with TB disease are undiagnosed. The poor and marginalized populations are among them, as well as children and older people whose disease is more difficult to detect. Furthermore, the majority of drug-resistant TB cases are either undiagnosed or treated with a low rate of success.

The *End TB Strategy* calls for particular attention to high-risk and vulnerable populations. This may require complex interventions including screening for active disease and latent infection, tailored treatment support, co-morbidity management and social protection measures. Against a backdrop of decreasing TB incidence among the general population, successful TB control in the coming decade will depend on effective, strategic and setting-specific interventions to address TB among high-risk and vulnerable populations.

Several new tools for global TB control have been developed and many more will follow. Laboratory strengthening, along with rapid and rational adoption of these innovations, is critical to the successful roll-out of the *End TB Strategy*. Establishing high-quality diagnosis and care with state-of-the-art technologies, in line with humane and responsive people-centred care, will substantially improve health system performance in addressing the needs of patients, families and communities.

Ministries of health are encouraged to proactively lead in the full implementation of the *End TB Strategy*, expanding services to high-risk and vulnerable populations and progressively implementing new diagnostics while maintaining high treatment success rates.

## PILLAR 2

### BOLD POLICIES AND SUPPORTIVE SYSTEMS

Strengthened and coherent health and social sector policies, as well as empowered and mobilized civil society, are essential in forming a bold societal response to the TB epidemic. In each country, the ministry of health will continue coordinating and stewarding the overall national TB response, as elaborated in a national TB strategic plan. Under this government stewardship, more regulatory approaches should be employed to support control efforts including mandatory disease notification, strong and harmonized drug regulatory policies, and standards of care including infection control. Building on previous public–private mix approaches, new tactics are needed to effectively engage all care providers by balancing regulatory and partnership methods, and focusing on the quality and continuum of care. Engaging patients, families and communities in programme planning and service delivery will not only increase community awareness, but also nurture an enabling environment for patients and families, and potentially lead to a bold community-based response.

The target of “no affected families facing catastrophic costs due to tuberculosis” must be achieved by ensuring sufficient financial risk protection while allowing people to enjoy access to quality services in the context of UHC. As the disease disproportionately affects vulnerable populations, minimizing direct medical expenses may not be sufficient to prevent households from falling into poverty. Continued advocacy and negotiation will be needed for better and expanded social protection coverage that favours TB patients. Many risks stem from various social determinants. To address these determinants requires a multisectoral approach in collaboration with a wide range of governmental and nongovernmental entities.

## PILLAR 3

### INTENSIFIED RESEARCH AND INNOVATION

To reach the ambitious targets of the *End TB Strategy*, intensified research and development is required to better detect, treat and control TB. The strategy places emphasis on the development of a point-of-care rapid diagnostic test, new drugs and regimens for the treatment of all forms of TB, better detection of and treatment for latent infection, and effective vaccines including a post-exposure vaccine that prevents disease progression from a latent state.

As in the other pillars, the *End TB Strategy* proposes a paradigm shift in TB research. NTPs are encouraged to progressively promote TB research in countries beyond programmatic operational research and contribute to the global evidence base for research and development. Proposed actions include establishing a national TB

research network, developing a national TB research strategic plan and research priorities, building the capacity of related human resources, and increasing TB research funding through diversified funding sources. A radical boost in global TB research will only be possible when all countries, including low- and middle-income countries with substantial TB burdens, form national movements in TB research promotion.

## REGIONAL FRAMEWORK FOR ACTION AT A GLANCE

### **PILLAR 1** INTEGRATED, PEOPLE-CENTRED CARE AND PREVENTION

#### 1.1 Treatment and care for all TB patients

- ▲ Drug-resistant TB
- ▲ TB among children
- ▲ TB among high-risk populations
- ▲ Collaborative TB/HIV activities
- ▲ Management of co-morbidities

#### 1.2 Strong laboratory networks to find all TB cases

#### 1.3 Latent TB infection and BCG vaccination

### **PILLAR 2** BOLD POLICIES AND SUPPORTIVE SYSTEMS

#### 2.1 Governance and stewardship

- ▲ Robust national TB strategic plans supported by strong political commitment and adequate resources
- ▲ Sustainable TB care delivery and financing mechanisms in the context of universal health coverage
- ▲ Drug regulatory and management systems to support TB control
- ▲ Disease notification and surveillance systems

#### 2.2 Engagement and partnerships

- ▲ Engaging patients, families, communities and civil society organizations
- ▲ Engaging all public and private care providers

#### 2.3 Addressing social determinants and social protection

- ▲ Social protection mechanisms to support patient and families affected by TB
- ▲ Addressing poverty and social determinants by promoting the HiAP approach

### **PILLAR 3** INTENSIFIED RESEARCH AND INNOVATION

#### 3.1 Enhancing TB research capacity for development, rapid uptake and optimum use of new interventions

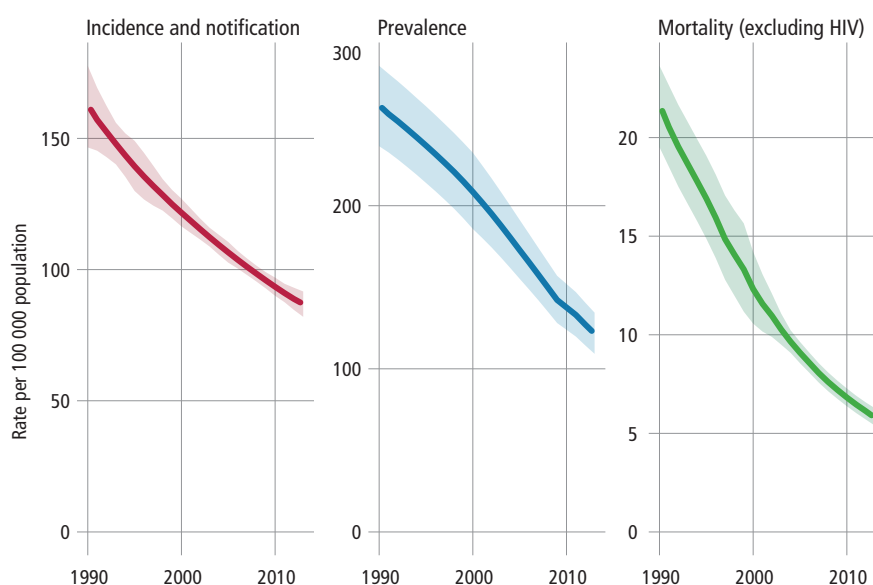
# PART A. Background

## 1. Regional progress

### Impact on tuberculosis burden

Progress in reducing the burden of tuberculosis (TB) in the Western Pacific Region is remarkable. The rapid adoption and regionwide expansion of the global TB strategy, namely the directly observed treatment, short-course (DOTS) strategy, which was later expanded in 2006 as the *Stop TB Strategy*, resulted in substantial health impacts. Since 2000, 9 million lives have been saved from this deadly disease, and around 1.35 million patients are treated every year. Concerted efforts have succeeded in reducing TB deaths and prevalence by more than 73% and 53%, respectively, since 1990 (Fig. 1). TB incidence has been in continuous decline, and the Western Pacific Region has achieved the TB-related targets linked to the Millennium Development Goals (MDGs) set for 2015.

**FIGURE 1.** Estimated TB incidence, prevalence and mortality in the Western Pacific Region, 1990–2013



## Programme expansion and improvement

Supported by strong political commitment, national tuberculosis programmes (NTPs) in the Region have expanded nationwide the basic TB services package with a strong focus on the most cost-effective, high-impact interventions at little or no cost to patients. Extensive laboratory networks have provided timely diagnosis for TB patients with smear microscopy as a prime tool. These networks have provided patients and health-care workers with confirmation of TB disease that also contributed to reliable surveillance and a strong evidence base for assessing the burden and trends of TB in the community.

The long duration of TB treatment relies heavily on a constant supply of high-quality drugs. Supply chains ensuring an uninterrupted stock of first-line drugs have been established throughout the Region. These drugs are provided to patients without charge. Through community engagement and public–private mix schemes, patients receive supportive supervision for treatment completion. Over 85% of enrolled patients in six high-burden countries in the Region were treated successfully in 2012.

Programmatic management of drug-resistant TB (PMDT) has moved beyond the pilot phase and is now being rolled out in all national programmes. Enrolment has more than tripled since 2010 with tens of thousands of patients receiving life-saving treatment courses.

## Accurate epidemiological information and programmatic evidence

Along with programme expansion in the past decade, country-based epidemiological information and programmatic evidence have been much enriched. The Western Pacific Region is the only World Health Organization (WHO) region in which all countries with a high burden of TB have conducted TB prevalence surveys, including some countries with repeat surveys.

The information obtained through those surveys has provided valuable insight into national TB situations and guided informed decision-making. Additionally, many countries significantly developed operational research capacity, and research studies conducted in the Region have provided evidence to improve national and global TB control.

## 2. Challenges

Despite unprecedented achievements in past decades, TB remains a leading killer in the Region, claiming more than 100 000 lives every year. In 2013, 1.6 million people fell ill with TB, seriously disrupting their lives and livelihoods. Formidable challenges must be overcome if a region free from TB is to be realized.

### High-risk and vulnerable populations

TB is related to poverty, under-nutrition and poor immune function and concentrates in vulnerable populations, such as migrants, prisoners, children, and older and poor people. Detecting these cases can be more difficult than detecting cases in the general population, and many of these people have the lowest capacity to cope with the burden of illness. Other groups, including people living with human immunodeficiency virus (HIV) or silicosis, smokers and diabetics, are at higher risk of developing TB, have more complications and have worse outcomes. An estimated 270 000 people in the Region who develop TB every year are not notified or not diagnosed due to weak health system capacity in diagnosis and surveillance. As TB control progresses, a greater proportion of cases present very minor symptoms and are not detectable using symptomatic screening and smear microscopy. Further progress is contingent on more proactive case-finding approaches and the development of more sensitive diagnostics.

### Catastrophic economic burden to patients

Although basic TB services are available free of charge in almost all countries, TB patients continue suffering from a heavy financial burden. A systematic review showed that families with TB patients in low- and middle-income countries lost more than half of their household annual income due to TB. Importantly, about half of the financial burden is incurred before patients are diagnosed.<sup>1</sup> Loss of income and direct expenses trigger a downward spiral whereby the patient is less able to complete treatment, more likely to have repeat episodes, and more likely to develop drug resistance resulting in more expensive and arduous treatment.

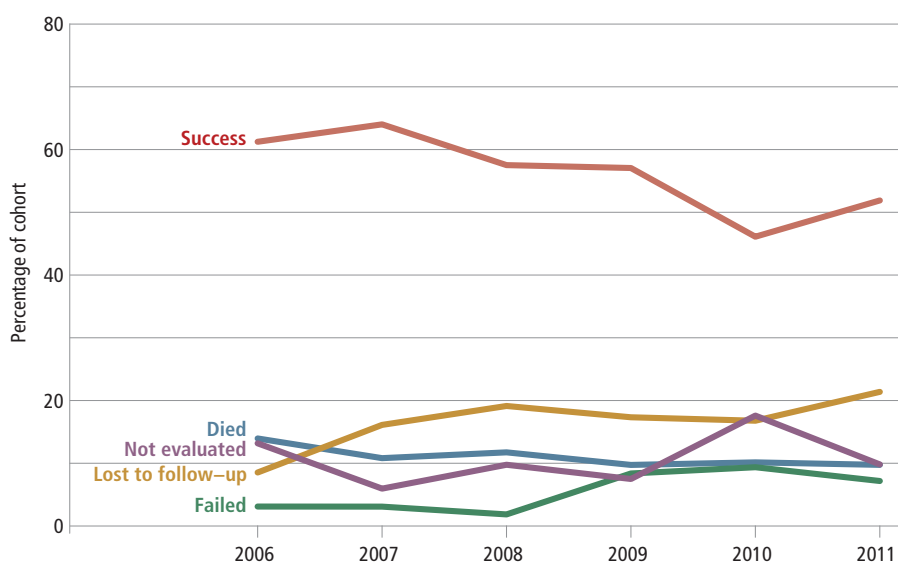
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1. Tanimura T, Jaramillo E, Weil D, Raviglione M, Lönnroth K. Financial burden for tuberculosis patients in low- and middle-income countries: a systematic review. *European Respiratory Journal*. 2014.

## Drug-resistant TB

The problem of drug resistance poses a great threat to TB control and remains a major concern for regional health security. In 2013, there were an estimated 71 000 new cases of multidrug-resistant TB (MDR-TB), defined as resistance to at least isoniazid and rifampicin – two of the most important drugs used in the treatment of TB. Extensively drug-resistant TB (XDR-TB), a more severe and lethal form of TB that is also resistant to the most active second-line drugs, has been identified in up to 10% of notified MDR-TB cases. Despite substantial investment and effort, only 11 412 (16%) of the estimated 71 000 MDR-TB cases were notified in 2013, and among those notified cases, only 6926 (61%) were enrolled in treatment. More disappointingly, only 52% of patients enrolled in treatment in 2011 (latest available data) were successfully treated (Fig. 2).

**FIGURE 2.** Treatment outcomes of TB patients enrolled in MDR-TB treatment in the Western Pacific Region, 2007–2011



## Health system response

Limited access to health services, insufficient quality of care, and lack of financial and social protection are hampering further advancement of TB control. Weak health systems prevent the establishment of links across social sectors to address poverty, undernutrition and risk factors that adversely influence people's vulnerability to TB and health outcomes of people with TB. Persistent health system barriers prevent the rapid expansion of vital services such as the treatment of MDR-TB.



Regulatory mechanisms essential to ensure effective infection control, rational use of TB diagnostics and drugs, mandatory disease notification, functioning vital registration systems and protection of the legal rights of people with TB remain weak, resulting in inadequate TB treatment in the public and private sectors, over-the-counter sale of TB drugs and sale of TB drugs that are not quality assured, and discrimination against people with TB.

All of these challenges directly and indirectly impact the lives of people affected by TB. Overcoming them will require a people-centred approach to health care that includes elements of prevention, diagnosis, treatment and recuperation.

### **3. The End TB Strategy, global targets and operational indicators**

#### **The End TB Strategy and global targets**

The Sixty-seventh World Health Assembly endorsed the *Global strategy and targets for tuberculosis prevention, care and control after 2015* through resolution WHA67.1. The strategy, also known as the *End TB Strategy*, envisions a world free of TB, with zero deaths, disease and suffering due to the disease, and ambitiously proposes to “end the global TB epidemic” by 2035.

Ending the TB epidemic entails lowering the levels of the disease burden globally to the current level of countries with the lowest TB burden. This can be numerically translated as a 90% reduction in TB incidence and a 95% reduction in TB deaths. Achieving such a drastic impact will require not only delivering adequate TB services, but also pursuing universal access to health care and social protection while rapidly improving nutrition and economic conditions. To this effect, elimination of catastrophic costs that TB-affected families face has also been included as an important target to be achieved under the *End TB Strategy*.

Within the scope of the 20-year strategy, spanning from 2015 to 2035, the regional framework focuses on implementing the *End TB Strategy* in the coming five years. Agreed milestones for 2020, along with baseline and targets in the regional context, are presented in Table 1.

## The End TB Strategy: global targets and operational indicators

**VISION:** A world free of TB – zero deaths, disease and suffering due to tuberculosis

**GOAL:** End the global TB epidemic

### INDICATORS

- Reduction in number of TB deaths compared with 2015
- Reduction in TB incidence rate compared with 2015
- TB-affected families facing catastrophic costs due to TB

	MILESTONES		TARGETS	
	2020	2025	2030*	2035
Reduction in number of TB deaths compared with 2015	35%	75%	90%	95%
Reduction in TB incidence rate compared with 2015	20% (< 85/100 000)	50% (< 55/100 000)	80% (< 20/100 000)	90% (< 10/100 000)
TB-affected families facing catastrophic costs due to TB	0	0	0	0

\* Targets for the United Nations Sustainable Development Goals

### PRINCIPLES

1. Government stewardship and accountability, with monitoring and evaluation
2. Strong coalition with civil society organizations and communities
3. Protection and promotion of human rights, ethics and equity
4. Adaptation of the strategy and targets at country level, with global collaboration

### PILLARS AND COMPONENTS

#### PILLAR 1: INTEGRATED, PEOPLE-CENTRED CARE AND PREVENTION

- A. Early diagnosis of TB including universal drug-susceptibility testing, and systematic screening of contacts and high-risk groups
- B. Treatment of all people with TB including drug-resistant TB, and patient support
- C. Collaborative TB/HIV activities, and management of co-morbidities
- D. Preventive treatment of persons at high risk, and vaccination against TB

#### PILLAR 2: BOLD POLICIES AND SUPPORTIVE SYSTEMS

- A. Political commitment with adequate resources for TB care and prevention
- B. Engagement of communities, civil society organizations, and public and private care providers
- C. Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control
- D. Social protection, poverty alleviation and actions on other determinants of TB

#### PILLAR 3: INTENSIFIED RESEARCH AND INNOVATION

- A. Discovery, development and rapid uptake of new tools, interventions and strategies
- B. Research to optimize implementation and impact, and promote innovations

**TABLE 1.** The End TB Strategy milestones for 2020 in the Western Pacific Region

Target indicators	Baseline*	2020 milestones
• Reduction in number of TB deaths compared with 2015	110 000	77 000 (30% reduction)
• Reduction in TB incidence rate compared with 2015	87 per 100 000	70 per 100 000 (20% reduction)
• TB-affected families facing catastrophic costs due to TB	To be established	0

\* Tentatively figures from 2014 were used and will be updated after 2015 values are made available.

While all three high-level target indicators are relevant to all countries, targets and milestones can be adapted by countries according to national contexts, especially for the first two epidemiological indicators. Since the planning cycle of national strategies generally spans several years, medium- and long-term epidemiological projections are necessary to define appropriate target levels. For the third global target indicator, it is critical for all countries to establish a nationally appropriate methodology to periodically measure household expenditure associated with TB by adapting the generic protocol that was developed by WHO. Ensuring no family faces catastrophic costs due to TB by 2020 is among the most critical indicators in the implementation of the regional framework.

## 4. Rationale, purpose and target audience

In response to the World Health Assembly's endorsement of resolution WHA67.1, the regional framework has been prepared to facilitate adaptation and adoption of *The End TB Strategy* in countries and areas of the Western Pacific Region. The framework was developed by WHO based on discussions and outcomes of a series of regional meetings in 2014 in consultation with NTPs, international partners and regional TB expert bodies, such as the WHO TB Technical Advisory Group and the regional Green Light Committee (rGLC) of the Western Pacific.

The regional framework provides policy options for NTPs and policy-makers to consider in updating national strategies and plans to strengthen efforts to advance TB control. The regional framework is also a resource for international and national partners in TB control in the Region.

## 5. Regional relevance and focus

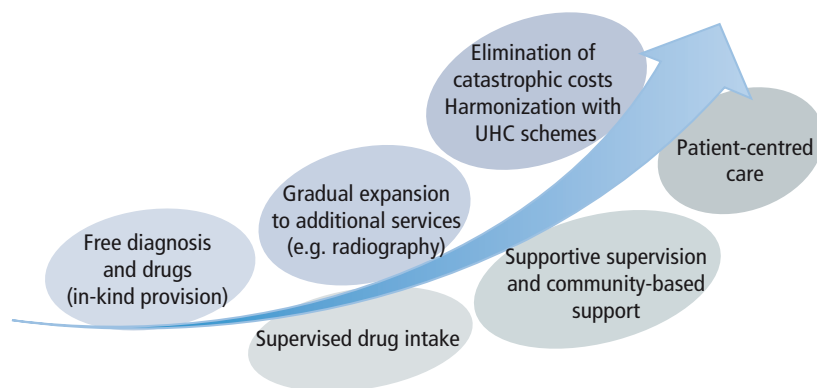
In formulating the regional framework, particular consideration was given to qualities in *The End TB Strategy* that are highly relevant to the regional TB control situation.

### Paradigm shift in TB control

*The End TB Strategy* contains a number of health system strategies, concepts and frameworks that were not fully elaborated in previous strategies. While building on the foundation of earlier TB control strategies, the *End TB Strategy* has the potential to bring about a significant paradigm shift in the structure and operation of TB control programmes. Figure 3 illustrates the conceptual evolution of selected components of TB control programmes from the past to the future.

To provide guidance and policy options in areas beyond the conventional TB control approach, the regional framework elaborates strategies, concepts and frameworks that are not fully employed in conventional TB control policies and practices.

**FIGURE 3.** Examples of conceptual evolution of components of the TB control programme (free treatment policy and patient support)



### Equity focus

Among many important components of *The End TB Strategy*, promoting a whole-of-system approach for the equitable delivery of quality health services is critically relevant to the regional context. Despite rapid economic growth and socioeconomic development in the Western Pacific Region, disparity among different segments of the population is widening and inequitable distribution of health services is commonplace. The nature of TB epidemics is also changing with the burden of disease concentrated more in socially vulnerable populations. A focus on equity is vital.

## Emphasis on health system strengthening and promotion of multisectoral actions

Ongoing health sector reforms demand public health programmes to be streamlined to improve efficiency and sustainability, especially in the context of diminishing donor investment in communicable disease control. TB control programmes have to evolve to adapt to this changing environment and respond to the needs of patients and communities, taking into account the harmonization and integration with the overall health system. There are numerous opportunities to strengthen TB control policies and services by taking advantage of ongoing and forthcoming system-wide changes. Regulatory approaches have to be fully utilized to ensure safety and quality of care.

As countries move towards universal health coverage (UHC), NTPs are better equipped to provide access to quality TB services without financial risk to patients and families. Many countries in the Region are progressively expanding social protection, which can be fully utilized in favour of TB control policies. Multisectoral collaboration needs further expansion to create a whole-of-society response to the TB epidemic that involves government and nongovernmental stakeholders, the private sector, and empowered patients, families and communities.

## Covering the whole spectrum of TB epidemiology and addressing Region-specific needs

Another important quality of the *End TB Strategy* is its universality. Unlike previous global strategies that focused primarily on countries with a high burden of TB, The *End TB Strategy* defines core necessities and ambitions in TB care and control that transcend to all epidemiological settings. It is within this context that the WHO Framework towards TB elimination in low-incidence countries was developed as the first operationalization document based on the *End TB Strategy*.

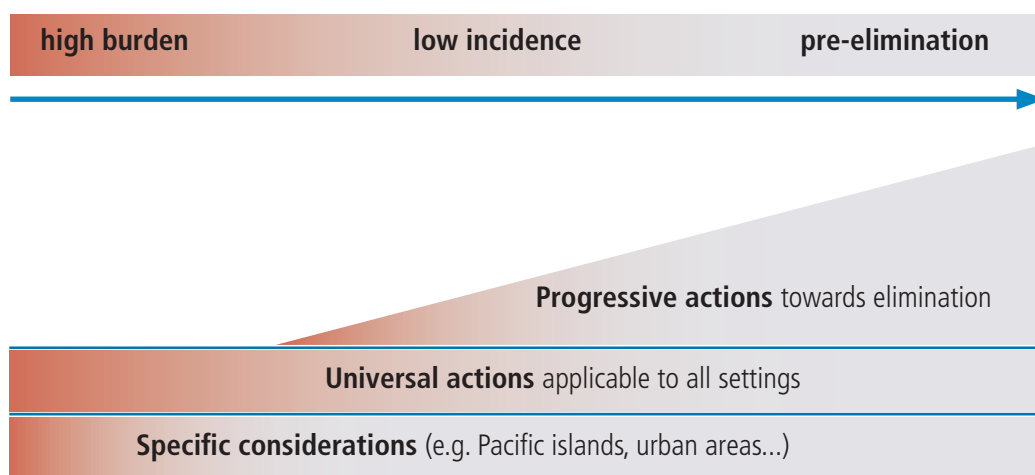
The Western Pacific Region is comprised of 37 countries and areas with varying levels of TB endemicity and diverse socioeconomic situations. Taking advantage of the universality of the *End TB Strategy*, the regional framework proposes policy options for NTP consideration by taking into account the full spectrum of TB epidemiology as well as some setting-specific challenges.

To reflect this diversity, the actions proposed in the regional framework are grouped into three tiers: (1) universally applicable actions for all settings; (2) actions towards TB elimination that can be considered by countries with a relatively low disease burden; and (3) actions to be considered for specific settings, for example Pacific island countries and areas, ageing societies and urban areas (Fig. 4). This approach is also highly relevant in considering subnational approaches in TB control, especially

in countries where TB epidemiology and socioeconomic conditions are highly diverse. By taking this three-tiered approach, the regional framework intends to serve as a resource for all countries and areas in the Region.

**FIGURE 4.** Three-tiered approach to TB control

**SPECTRUM OF TB EPIDEMIOLOGY**



## People-centred care

People-centred health care is an approach that sees individuals, families and communities as participants in and beneficiaries of trusted health systems that respond to their needs and preferences in humane and holistic ways. People-centred care requires that people have the education and support they need to make decisions and participate in their own care. It is organized around the needs and expectations of people rather than diseases.

Although people-centred health care must be realized progressively through an integrated, whole-of-system approach rather than merely within a vertical programme, TB control programmes are encouraged to proactively take action to contribute to the realization of people-centred care. Effective TB control requires and even benefits from the attributes and core values envisioned in people-centred health care.

## **BOX 1. Actions to promote people-centred care in the context of TB services**

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*The time came when I couldn't take it anymore. I was in so much pain. Physically, mentally, emotionally and spiritually, everything seemed so dark.*

*[Health workers] should not learn purely the technical side, but also learn the proper care, how to be friendly to patients, no matter what their illness.*

— Testimonies of patients who underwent MDR-TB treatment

In the past, TB control programmes emphasized supportive supervision or directly observed therapy (DOT) by health-care workers or treatment partners by engaging volunteers, families and communities. While supportive supervision will remain a foundation of effective TB control, it only partially addresses patient needs. We must go further – towards comprehensive people-centred TB care that is sensitive and responsive to the medical, psychosocial and financial needs of all patients and families affected by TB. Many of the challenges faced by NTPs require actions that increase people-centredness and the continuum of TB services. The journey towards people-centred health care requires change within four domains: (1) individuals, families and communities; (2) health-care workers; (3) health-care organizations (facilities); and (4) health systems.<sup>2</sup> The following list illustrates potential actions that can lead to the realization of people-centred health services in the context of TB care.

### **1. Informed and empowered individuals, families and communities**

- Enable patients, families, community representatives and civil society organizations to be actively engaged in TB programme planning, implementation, service delivery and monitoring, as well as research and advocacy.
- Facilitate the exchange of information among patients, families and peer support groups.
- Promote and empower patient organizations and peer support groups at national, subnational and community levels.
- Disseminate experiences of TB patients, families and communities through media and public events.
- Build a strong coalition of stakeholders that advocate equitable access to people-centred quality TB services, as well as to eliminate stigma and discrimination associated with TB at all levels of society.
- Build a national coalition to drive actions towards addressing the social determinants of TB.
- Empower people and communities to demand quality services to meet their needs and expectations.

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2. People at the centre of health care: harmonizing mind and body, people and systems. Manila: WHO Regional Office for the Western Pacific; 2007.

## 2. Competent and responsive health-care workers

- Review methods and materials for the training of health-care and TB care workers taking into account the core competencies<sup>3</sup> that are relevant to people-centred care.
- Adequately prepare all TB care workers to provide holistic care including basic communication and counselling skills, and skills to address non-TB morbidities and psychosocial issues through service coordination.
- Establish patient–provider relationships built on respect, compassion and principles of non-discrimination and equity.
- Disseminate the *International Standards for Tuberculosis Care (ISTC)*, *The Patients' Charter for Tuberculosis Care* and other tools to promote quality TB services appropriate to local contexts.
- Ensure regular, supportive and integrated supervision, including feedback mechanisms, to guide and empower health workers and to instil greater confidence in TB care.
- Ensure workforce sufficiency in terms of quantity and quality, taking into account staff turnover.
- Build a supportive environment for health workers to provide services to TB patients by offering appropriate training and provider incentives, setting up infection control measures and taking steps to eliminate stigma and discrimination against TB care workers.

## 3. Efficient and humane health-care organizations (facilities)

- Build capacity to offer psychological, welfare and legal support for TB patients through strong service coordination.
- Support easy referral and continuity of care (one-stop approach).
- Improve access to TB diagnosis and treatment with particular attention to the poorest and most vulnerable population groups, e.g. expanding treatment outlets in the poorest rural and urban settings, involving providers who practise close to where patients live.
- Identify and address discrimination, gender and equity issues.
- Ensure facility design with emphasis on access, people and family friendliness, while ensuring patient safety and proper infection control.

## 4. Supportive health-care systems

- Ensure TB services are free of charge or heavily subsidized and patient financial burden is minimized.
- Ensure quality and safety of TB care through appropriate, effective mechanisms such as facility standards (e.g. infection control, diagnostic capacity and quality) and professional standards (i.e. ISTC) through certification, accreditation, registration and renewal of licenses.
- Establish and strengthen mechanisms for feedback, such as routine collection of service evaluation, patient satisfaction surveys and community dialogue.

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3. WHO defines the core competencies of health-care practitioners as the ability to: (a) organize care around the patient; (b) communicate effectively to facilitate partnerships with patients and his/her family; (c) ensure continuous improvements in the quality and safety of health care; (d) monitor patients across time, using and sharing information through available technology; and (e) consider patient care and the provider's role in the broadest perspective, taking into account psychosocial aspects of care, compassionate and ethical practice (Preparing a health care workforce for the 21st century. Geneva: WHO; 2005).



# PART B.

## Implementation of the Regional Framework

### **PILLAR 1**

#### **Integrated, people-centred care and prevention**

This is a matter of social justice, fundamental to our goal of universal health coverage. Each and every man, woman or child with TB should have equal, unhindered access to the innovative tools and services they need for rapid diagnosis, treatment and care.

—Dr Margaret Chan, WHO Director-General

Many people with TB disease are undiagnosed in the community, especially those who are among the poor and marginalized, as well as children and older people whose disease is more difficult to detect. Despite substantial investments and efforts in PMDT expansion, the majority of MDR-TB cases are either undiagnosed or treated with a low rate of success. Several new tools, particularly new diagnostics, have come into the picture of global TB control and many more will follow. Laboratory strengthening, along with rapid and rational adoption of these innovations, is critical to the successful roll-out of the *End TB Strategy*, which substantially improves early and increased detection of drug-susceptible and drug-resistant TB among children, adolescents and adults.

The *End TB Strategy* calls for attention to high-risk and vulnerable populations. This may require complex interventions including co-morbidity management, screening for active TB disease, management of latent TB infection (LTBI), tailored treatment support mechanisms and social protection measures. Against a backdrop of decreasing TB incidence among the general population, setting-specific interventions to address TB among high-risk and vulnerable populations are key to successful TB control for the upcoming decade.

Establishing high-quality TB diagnosis and care with state-of-the-art technologies in a form of humane and responsive people-centred TB care will substantially improve health system performance in addressing the needs of patients, families and communities.

# 1.1 Treatment and care for all TB patients

## Strategy

Early diagnosis of all forms of TB, as well as timely initiation of patient-centred treatment and care, continues to be a prime strategy for TB control. Currently only an estimated two thirds of the global incident tuberculosis cases are notified to NTPs. Ensuring universal access to early and accurate diagnosis of TB will require multi-faceted actions: (a) improve health communication and community awareness to prompt people with TB symptoms to seek care; (b) minimize physical, financial and social barriers that people encounter in seeking care; (c) engage all care providers in service delivery; (d) improve diagnostic algorithms and tools including strengthening and expanding a network of diagnostic facilities with easy access to sensitive diagnostic algorithms and tools; and (e) systematically screen selected high-risk groups.

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## PROPOSED ACTIONS

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### ■ Proposed actions for all settings

In the regional framework, actions for early diagnosis and patient-centred care are contained in multiple sections transcending all three pillars of *The End TB Strategy*.

Therefore, the following action points serve as anchors and more detailed actions are elaborated in each referenced section.

- Improve health communication and community awareness (Section 2.2.1)
- Minimize physical, financial and social barriers (Sections 2.1.2, 2.3.1 and 2.3.2)
- Engage all care providers (Section 2.2.2)
- Improve diagnostic algorithms and tools (Section 1.2)
- Systematically screen selected high-risk groups (Sections 1.1.3, 1.1.4 and 1.1.5)

## 1.1.1 Drug-resistant TB

### Strategy

Drug-resistant TB is a growing threat for global health security. Globally, approximately 480 000 people developed MDR-TB in 2013. However, only about 136 000 cases were notified, and of those only 97 000 started treatment. Among the patients treated, the treatment success rate was 48%. Furthermore, XDR-TB has been reported by 100 countries.

Considerable progress in the global response is evident – most countries have scaled-up PMDT by moving from pilot projects to national programmes. Nonetheless, the response to the crisis has been insufficient. Despite the introduction of new rapid diagnostic tests, the vast majority of patients in need still lack access to quality diagnostic and treatment services. Several health system barriers persist, preventing rapid expansion.

Scaling-up PMDT requires improvements in the following critical steps in the cascade of services: (1) stepwise increase of the proportion of TB cases who receive drug susceptibility testing (DST); (2) all diagnosed patients promptly notified and enrolled in treatment; and (3) all enrolled patients complete their treatment with effective patient-centred support.

#### **a. Stepwise increase of the proportion of TB cases who receive DST**

Adequate capacity to diagnose all cases of drug-resistant TB is essential to further progress. Ensuring universal access to early and accurate diagnosis of TB, including drug-resistant forms, 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 to seek care; and engagement of all care providers and removal of barriers in seeking care. Addressing new realities with additional workloads will require additional human and financial resources and will need a stepwise approach towards universal DST provision.

#### **b. All diagnosed patients promptly notified and enrolled in treatment**

Increasing diagnostic capacity must be aligned with drug and treatment provision and political commitment. New models of delivering patient-centred care 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. In addition, underlying causes for the high level of initial loss to follow-up need to be identified and addressed. Integrated patient-centred TB care and prevention, and bold policies and supportive systems are needed to address these challenges.

### c. All enrolled patients complete their treatment with effective patient-centred support

It is imperative that all enrolled MDR-TB patients receive quality care and complete their treatment with effective patient-centred support. The development and introduction of drugs that are safe, affordable and effective in shortening treatment duration and easy to administer are key to improving treatment outcomes. Links with pharmacovigilance mechanisms will contribute to promoting safer use and management of drugs. Interventions to improve the 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 stigma and discrimination, and social support and protection. Importantly, all care providers managing drug-resistant TB should have access to continued training and education, enabling them to align their practices to patient-centred approaches that adhere to international standards and ensure safety.

## Regional situation<sup>4</sup>

In the Western Pacific Region, 4% of new and 22% of previously treated TB cases were estimated to have MDR-TB. This means that in 2013, there were 71 000 MDR-TB cases among notified pulmonary TB cases. Three quarters of these were new cases, which poses a huge challenge in case detection. The Region includes countries with very high MDR-TB caseloads, such as China, the Philippines and Viet Nam, as well as several Pacific island countries with few, irregular cases and low capacity to manage treatment.

Countries are also at different stages of PMDT implementation. The introduction of WHO-recommended diagnostics (WRDs) has enabled a drastic increase in diagnostic capacity. However, access to WRDs is uneven and only highly selected cases are being tested. In 2013, the coverage of DST among new cases and previously treated TB cases was 3% and 20% respectively.

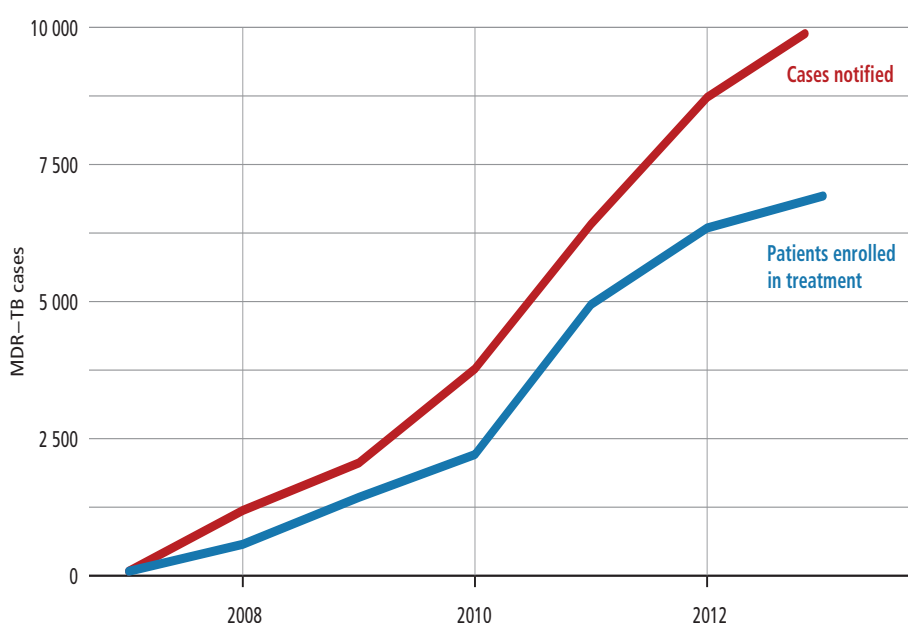
In 2013, only 11 153 MDR-TB cases, including those confirmed resistant to rifampicin only, were notified – 16% of the estimated MDR-TB cases. Among the notified cases, 6926 or 62% were enrolled in treatment. The 2011 cohort of MDR-TB resulted in 52% treatment success. Over the last five years, case notification and enrollment saw a fivefold increase, while the gap between notification and enrolment further widened (Fig. 5).

The rGLC of the Western Pacific has been assisting Member States with responsible PMDT scale-up since 2011. The rGLC has assisted countries with formulation of

4. Islam T et al. Drug-resistant tuberculosis in the Western Pacific Region. *Western Pac Surveill and Response J.* 2014;5(4):34–46.

national PMDT action plans, PMDT programme evaluation, critical review of mission reports, and the establishment and operation of a quality-assured second-line drug repository for the Pacific island countries and areas. The rGLC has also contributed to regional capacity-building with ongoing strategic and technical guidance.

**Figure 5.** Notified MDR-TB cases, including cases confirmed resistant to rifampicin only, and patients enrolled in treatment in the Western Pacific Region, 2007–2013



## PROPOSED ACTIONS

### ■ Proposed actions for all settings

1. Increase the proportion of TB patients who receive DST in a step-wise manner
  - Maximize the use of WRDs while maintaining and strengthening laboratory capacity for culture and DST at least for first-line drugs (also in Section 1.2).
  - Improve access to laboratory services (culture, phenotypic and genotypic DST) through decentralization or strengthening of specimen transport systems, in alignment with the expansion of treatment facilities (also in Section 1.2).
  - Ensure all TB patients at high risk of drug-resistant TB – as defined by the respective country receive DST at least for rifampicin resistance.

- Engage all service providers and set up a proper referral mechanism for diagnosis.
- Critically analyse loss to follow-up during the referral process and address identified gaps.

## **2. Promptly notify all diagnosed patients and enrol in treatment**

- Strengthen treatment referral mechanisms, timely release of results and prompt treatment initiation by streamlining information systems in laboratory and treatment facilities.
- Expand treatment services to bring them closer to patients and communities.
- Ensure rigorous infection control is in place in treatment facilities and in ambulatory and home-based care settings.
- Ensure patient-centred pre- and post-test counselling and provide psychosocial support.
- Ensure availability of quality-assured second-line drugs.
- Enforce mandatory notification of all forms of TB with particular attention to facilitate MDR-TB notification and treatment initiation (Sections 2.3 and 2.5).

## **3. Ensure a supportive environment to complete the treatment of all enrolled patients**

- Explore ways to address psychosocial, nutritional and financial needs of patients (Section 2.3).
- Pursue decentralization and integration with general TB services (e.g. community-based TB care) to improve access to and quality of care.
- Ensure referral and hospitalization capacity for severely ill patients with proper infection control measures, co-morbidity management (Section 1.1.5) and palliative care.
- Explore and establish mechanisms to provide incentives for community-based patient support activities including treatment partners.
- Continue training, education and supportive supervision for health-care providers to ensure quality of care consistent with international standards.
- Empower patients, communities and civil society organizations and engage them in patient support activities and in creating demand for quality services (Section 2.2.1).
- Identify and implement actions to reduce stigma and to eliminate discrimination associated with TB and MDR-TB.
- Introduce recommended new drugs and regimens as they become available (Section 2.1.3).

## ■ Proposed actions towards elimination

### 1. Ensure universal DST

- Periodically review diagnostic algorithms and testing criteria to progressively expand testing coverage towards universal DST.
- Develop DST capacity for the full spectrum of TB drugs (also in Section 1.2).

### 2. Ensure universal treatment coverage

- Ensure treatment services are available close to patients' homes, as much as possible, while maintaining necessary expertise by centralizing specialized services. This can be challenging particularly in low-incidence settings.
- Provide treatment options, including surgery, for all forms of drug resistance, including fluoroquinolone-resistant MDR-TB and XDR-TB.

### 3. Ensure quality of care for all patients

- Effectively link with pharmacovigilance system for prompt response.
- Provide palliative care for those in need.

## ■ Proposed actions for setting-specific considerations

1. In the Pacific, maintain a mechanism to ensure availability of culture, DST and molecular diagnostics as an inter-country, subregional service, e.g. the Pacific TB Laboratory Initiative (PATLAB) (Section 1.2).
2. In the Pacific, ensure uninterrupted access to quality-assured second-line TB drugs by sustaining subregional mechanisms (e.g. subregional stockpile of second-line TB drugs for the Pacific island countries and areas managed by WHO).

### *Key documents*

- Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis. Geneva: WHO; 2014.
- Policy implementation package for new TB drug introduction. Geneva: WHO; 2014.

## 1.1.2 TB among children

### Strategy

TB is a significant cause of morbidity and mortality among children. Globally, over half a million children fall ill with TB each year and up to 80 000 die. While the vast majority of childhood deaths are preventable with early diagnosis and treatment, TB illness in children is often missed or overlooked due to non-specific symptoms and difficulties in diagnosis. After decades of being relegated to the shadows, the childhood TB epidemic is now in the spotlight. The goal of zero TB deaths in children has been endorsed by the international TB community and has united key stakeholders to make this goal a reality.

NTPs need to systematically address the challenges of diagnosis and treatment of TB in children. Childhood TB can only be effectively addressed by NTPs in collaboration with other health programmes (particularly maternal and child health, nutrition, and immunization services), tertiary and secondary health facilities, private and public health-care providers, professional associations, nongovernmental organizations, and community organizations. 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 will help remove access barriers, reduce delays in diagnosis and improve management of TB in children.

### Regional situation

Almost all countries with a high TB burden have updated national guidelines for managing TB among children. However, the level of implementation varies significantly between and within countries. Only a few countries have successfully formed effective partnerships beyond NTPs, and links between NTPs, paediatricians, and maternal and child care services remain weak. Contact screening and provision of isoniazid preventive therapy (IPT) are still limited.

A regional childhood TB task force was formed in 2014 to accelerate regional efforts to address TB among children. The task force is advocating recognition of the significant child TB burden in the Region, supporting the development of bold national actions, and providing education resources and venues for exchange to facilitate regional collaboration.

#### **BOX 2. Country efforts in addressing TB among children**

From 2012 to 2014, Viet Nam carried out community-based contact screening with provision of IPT for eligible child contacts in four pilot provinces. The pilot included training in child TB diagnosis in hospitals and development of health education materials that



explain the rationale for contact management. With successful results from the pilot, a national plan for childhood TB management was developed with four main objectives: (1) increase awareness through advocacy and health communication; (2) improve detection and management of childhood TB; (3) improve contact investigation and preventative treatment among children; and (4) conduct monitoring, evaluation and research. Viet Nam identified a priority research agenda for childhood TB and embarked on several collaborative research activities with national and international partners to increase understanding of childhood TB epidemiology and improve programme performance.

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## PROPOSED ACTIONS

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### ■ Proposed actions for all settings

1. Ensure political commitment and collaboration with various stakeholders for integrated approaches across the health system to address TB in children, adolescents and pregnant women.<sup>5</sup>
2. Implement effective contact screening including the wider use of WRDs (Sections 1.1.3 and 1.2).
3. Revise treatment guidelines to include fixed-dose combination drugs suitable for children made available in 2015.
4. Improve clinical management and social support serving the particular needs of children and families.
5. Maintain high bacille Calmette–Guérin coverage (except in low-incidence settings), increase the use of IPT, and improve infection control practices (Section 1.3).
6. Strengthen recording, reporting and data analysis by all care providers, especially hospitals and the private sector (Sections 2.1.4 and 2.2.2).
7. Improve awareness in the community and build the capacity of health-care workers.
8. Incorporate child-related operational research questions in the national TB research agenda and national TB research strategic plan (Section 3.1).

### *Key documents*

- Report of the meeting on the development of childhood tuberculosis action plans in the Western Pacific Region. Manila: WHO Regional Office for the Western Pacific; 2014.
- Guidance for national tuberculosis programmes on the management of tuberculosis in children, second edition. Geneva: WHO; 2014.
- Roadmap for childhood tuberculosis: towards zero deaths. Geneva: WHO; 2013.

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5. Detjen A, Gnanashanmugam D, Talens A. A framework for integrating childhood tuberculosis into community-based child health care. Washington, DC: CORE Group; 2013.

## 1.1.3 TB among high-risk populations

### Strategy

As incidence falls in a country, TB often becomes concentrated in specific high-risk and vulnerable groups, including people who are poor, malnourished, old or homeless, migrants, people living with HIV, people exposed to silica, people who use tobacco or illicit drugs or engage in the harmful use of alcohol, prisoners and other marginalized groups – many of which often overlap. The relative importance of high-risk groups progressively increases as TB among the general population is successfully controlled.

Mapping TB high-risk populations is an important step to identify and prioritize risk groups and interventions. Setting-specific epidemiological information is a valuable source of information for risk-group mapping. High-risk populations often face poor access to health services, resulting in a significant delay in diagnosis and ongoing transmission in the community.

When exploring intervention options to improve health access for high-risk populations, it is important to first explore ways to improve general health access for the risk population rather than providing TB services in isolation. Coordination with authorities and other health programmes will provide opportunities for accessing and providing TB services for specific risk groups while pursuing sustainability and programmatic convergence.

TB screening is an important complement to routine TB case finding. The WHO guidelines, *Systematic screening for active tuberculosis*, recommend that systems should be in place to provide screening for active TB among close contacts of pulmonary TB patients, people living with HIV and workers exposed to silica dust. Other risk groups should be identified and prioritized for possible screening activities based on national and local TB epidemiology, health system capacity, resource availability and feasibility of reaching the risk groups. A screening strategy should be monitored and assessed continuously to inform re-prioritization of risk groups, re-adaptation of screening approaches and discontinuation of screening, if merited.

The risk of treatment interruption, loss to follow-up and relocation during treatment is greater for TB high-risk groups, which means the risk of unfavourable treatment outcomes and the development of drug-resistant TB is also increased. To ensure treatment completion, patient-centred support mechanisms that are tailored to a specific risk population may need to be developed. Examples include peer support groups for key affected populations, cross-border referral systems for mobile populations, and enablers such as food and transportation for the poor and other socially vulnerable populations.

Historically, TB presents as a social disease – implying that a range of social determinants increase vulnerability to the disease. Addressing social determinants and the vulnerability of populations will contribute to not only TB control, but also general public health and greater equity in health. For this reason, NTPs are in a good position to promote a whole-of-society approach, namely, health in all policies (HiAP),<sup>6</sup> and provide concrete evidence on the impact of such an approach (Section 2.3.2).

## Regional situation

The *Regional Strategy to Stop Tuberculosis in the Western Pacific 2011–2015* called for a robust, systematic approach to address TB high-risk populations. Since the endorsement of the strategy, many high-burden countries intensified their national efforts to address TB among high-risk populations. Several countries organized national workshops to develop multisectoral strategies to address TB among high-risk populations by engaging a wide range of stakeholders (Box 3). Initiatives were embarked upon to conduct systematic TB screening among a range of high-risk groups such as prisoners, internal and cross-border migrants, diabetes patients, smokers, ethnic minorities, older people, people living in urban slums and other endemic geographical pockets. WHO has developed ScreenTB, a web-based tool to assist countries with risk-group prioritization and cost-effective planning for TB screening activities.<sup>7,8</sup> These initiatives have contributed to in-country evidence bases that inform national policy formulation.

Understandably, TB programmes in lower-burden countries have been more proactive in addressing TB among high-risk populations. Although priority risk groups vary across countries, some risk groups are commonly seen in upper-middle- and high-income countries such as the homeless, the urban poor and migrants from high-burden countries.

Migration poses a significant challenge to TB control including ensuring continuity of care through intercountry collaboration. WHO has developed *Tuberculosis control in migrant populations: guiding principles and proposed actions in the Western Pacific* with close consultation with experts and Member States.<sup>9</sup> The document proposes a set of policy options that will continue to be relevant in the coming years with increasing population movement in many parts of the Region.

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6. Health in all policies has been defined as “an approach to public policies across sectors that systematically takes into account the health and health systems implications of decisions, seeks synergies, and avoids harmful health impacts, in order to improve population health and health equity”. A HiAP approach is founded on health-related rights and obligations. It emphasizes the consequences of public policies on health determinants, and aims to improve the accountability of policy-makers for health impacts at all levels of policy-making.

7. Nishikiori N, Weezenbeek CV. Target prioritization and strategy selection for active case-finding of pulmonary tuberculosis: a tool to support country-level project planning. *BMC Public Health*. 2013;13:97.

8. Systematic screening for active tuberculosis: an operational guide. Geneva: WHO; 2015.

9. Report of the consultation on tuberculosis and migration in the Western Pacific Region. Manila: WHO Regional Office for the Western Pacific; 2013.

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## PROPOSED ACTIONS

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### ■ Proposed actions for all settings

1. Review, identify and map priority TB high-risk populations at national and subnational levels by assessing their TB risk, social vulnerability and access to health care.
2. Explore ways to improve access to and quality of TB services for each high-risk population.
  - Extend health system reach to each of the high-risk populations in coordination with relevant authorities and health programmes.
  - Collaborate with governmental and nongovernmental partners who have experience in working with specific high-risk populations (e.g. social welfare ministry and institutions, city governments, authorities in charge of prisons, immigration and illicit drug use).
  - Conduct systematic screening of active TB among close contacts, people living with HIV and people with a history of silica exposure.
  - Consider systematic screening of active TB among identified priority high-risk populations.
3. As required, consider specific patient-support mechanisms including enablers and treatment support tailored to specific high-risk populations and settings.
4. Promote operational research to assess the TB burden and evaluate interventions to address TB among high-risk populations.
5. Collaborate with other countries to establish an international referral network for TB patients.<sup>10</sup>

### ■ Proposed actions towards elimination

1. Integrate diagnosis and management of LTBI into systematic screening of active TB among prioritized high-risk populations (Section 1.3).
2. Continuously improve health system capacity for concurrent management of co-morbidities (Section 1.1.5).
3. Promote HiAP to address social determinants of TB (Section 2.3.2).

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10. WHO will explore possible mechanisms for intercountry notification and referral for TB among migrants.

## ■ Proposed actions for setting-specific considerations

1. In countries where TB among migrants is regarded as an important challenge, national TB control policies and TB services may be reviewed and updated in line with the four principles outlined in *Tuberculosis control in migrant populations: guiding principles and proposed actions*.

### **BOX 3. National workshops to address TB among high-risk and vulnerable populations**

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Addressing TB among high-risk populations requires strong collaboration within and outside the health sector. Collaborative arrangements are essential as reaching high-risk populations requires a combination of strong NTP technical capacity and access to target populations through other governmental and nongovernmental entities. It is also important to systematically identify priority risk groups in specific local settings. A national stakeholder workshop can establish good collaborative arrangements between partners for priority-risk populations.

To facilitate such national processes, WHO in the Western Pacific Region has developed a workshop package for TB high-risk populations including lectures and group work materials and a risk group prioritization tool for TB screening.

Cambodia was the first country to organize a workshop using the WHO package in 2011. The workshop was attended by 68 participants from 25 organizations in government and nongovernmental sectors. Some participants had already played important roles in TB control in the country, while others, especially those from non-TB health programmes or non-health sectors, had little engagement in TB control but had the potential to provide access to priority risk populations. As a result of intensive discussions among all stakeholders, seven priority risk populations were identified and collaborative actions were agreed among partners. Many activities that emerged through the workshop resulted in concrete project formulation, which were successfully funded and implemented. The experience further informed national strategic plan formulation followed by successful application to the Global Fund to Fight ADIS, Tuberculosis and Malaria.

With some variety in methodology and outcomes, similar workshops have been organized in China, Mongolia, the Philippines and other countries. These activities always confirmed that collaborative arrangements are a powerful means to expand TB control efforts beyond the realm of NTPs. The more collaboration, the more people with TB can be reached.

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#### **Key documents**

- Systematic screening for active tuberculosis: principles and recommendations. Geneva: WHO; 2013.
- Systematic screening for active tuberculosis: an operational guide. Geneva: WHO; 2015.
- Recommendations for investigating contacts of persons with infectious tuberculosis in low- and middle-income countries. Geneva, WHO; 2012.
- Tuberculosis control in migrant populations: guiding principles and proposed actions. Manila: WHO Regional Office for the Western Pacific; 2015.

## 1.1.4 Collaborative TB/HIV activities

### Strategy

The overall goal of collaborative TB/HIV activities is to decrease the burden of TB and HIV in people at risk of or affected by both diseases. Globally, HIV-associated TB accounts for one quarter of all TB deaths and one quarter of all deaths due to AIDS. Integrated service delivery increases the coverage of antiretroviral treatment (ART), shortens the time to treatment initiation, and reduces mortality by almost 40%. TB and HIV care can be further integrated with maternal and child health services. NTPs and national AIDS programmes are urged to strengthen the commitment in delivering TB/HIV collaborative services in a coordinated manner from the central level down to peripheral levels.

### Regional situation

There has been encouraging progress made in the scale-up of TB/HIV collaborative activities in the Region. However, progress varies between countries, and service gaps remain in HIV testing and provision of ART, co-trimoxazole preventive therapy (CPT) and IPT. In 2013, 35% of TB patients received HIV testing. Among patients found to be coinfected with TB and HIV, 58% received CPT and 60% received ART. Treatment success among HIV-associated TB patients was only 55% compared to 94% for all TB patients. The excess mortality among HIV-associated TB patients can be partly attributed to the low ART coverage.

Despite a gradual reduction in the rate of new HIV infections in the Region, the estimated number of people living with HIV reached 1.3 million in 2013, up from 840 000 in 2001. Only one third of people living with HIV are receiving ART. The majority of people living with HIV do not know their status and are not enrolled in care, and hence are failing to start ART. Scaling up TB/HIV collaborative activities could substantially contribute to closing these gaps.

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## PROPOSED ACTIONS

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### ■ Proposed actions for all settings

1. **Strengthen WHO-recommended TB/HIV collaborative activities.**
  - Improve mechanisms for collaboration between NTPs and national AIDS programmes.

- Decrease the burden of TB among people living with HIV through systematic TB screening, IPT and effective infection control.
- Decrease the burden of HIV among TB patients through HIV testing, HIV prevention, CPT, ART, and HIV care and support.
- Strengthen recording and reporting, as well as monitoring and evaluation, at the care level while adhering to confidentiality.

## **2. Further reduce delays in diagnosis of HIV and TB.**

- Promote decentralization and integration of services, including community-based HIV testing and counselling for key populations.
- Introduce and apply new diagnostics.
- Promptly initiate ART for TB/HIV patients (regardless of CD4 count).
- Conduct systematic screening of people living with HIV to detect TB and LTBI.

## **3. Promote the principles of people-centred care, reduction of stigma and discrimination, community engagement, and social protection (Sections 2.2 and 2.3).**

### *Key documents*

- Guidelines for intensified tuberculosis case-finding and isoniazid preventive therapy for people living with HIV in resource-constrained settings. Geneva: WHO; 2011.
- WHO policy on collaborative TB/HIV activities: guidelines for national programmes and other stakeholders. Geneva: WHO; 2012.

## **1.1.5 Management of co-morbidities**

### **Strategy**

While most TB cases can be treated by a standard regimen without much difficulty, it is also known that a range of other conditions can complicate diagnosis, treatment and care of TB patients. Co-morbidities often become significant issues among vulnerable populations who carry multiple risk factors for TB and concurrent illnesses, such as malnutrition, alcohol and drug abuse, tobacco use and noncommunicable diseases (NCDs) including diabetes, cancer, kidney and liver diseases. The importance of co-morbidity management becomes far greater among older people due to multiple underlying diseases and decreased coping capacity.

Under the leadership of NTPs, countries should strengthen health system capacity for concurrent management of TB and multiple co-morbidities. Ideally, as part of basic and coordinated clinical management, people diagnosed with TB should be routinely assessed for relevant co-morbidities, and efforts should be made to reduce modifiable risk factors. In relatively advanced health-care settings, many of the important co-morbidities are managed in different specialized care settings. Thus, sensitization, collaboration and coordination between TB specialists and other expert groups are critical in effectively addressing TB among patients with co-morbidities.

## Regional situation

A comprehensive study of TB and co-morbidities is yet to be undertaken as efforts to describe and address co-morbidities of TB patients are insufficient, especially in countries with a high burden of TB. Among important co-morbidities, diabetes causes significant morbidity and mortality in the Region. As such, co-management of TB and diabetes has been identified as a critical component of NTPs especially in Pacific island countries and areas (Box 4). In countries where older people constitute a majority of TB cases, co-morbidity management is identified as a critical cornerstone of national TB control strategies (Box 5).

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## PROPOSED ACTIONS

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### ■ Proposed actions for all settings

1. Collaborate with the clinical sector and relevant professional bodies to periodically assess important co-morbidities among TB patients and identify gaps in concurrent management.
2. Incorporate guidance on co-morbidity management into the national TB guidelines, including guidance on screening co-morbidities, strategies to reduce modifiable risks (e.g. treatment of malnutrition, control of diabetes,<sup>11</sup> advice on smoking cessation and smoke-free environments<sup>12</sup>), as well as dosage guidelines for people with renal and hepatic dysfunctions.
3. Engage and collaborate with experts and stakeholders to develop management strategies for TB and important co-morbidities. Joint guidelines or cross-linking guidelines can be used to promote standards of care among expert communities.
4. Use selected co-morbidities as markers for TB risk, and, where appropriate, consider active TB case finding and management among people with these conditions (Section 1.1.3).

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11. Chiang CY, Bai KJ, Lin HH, Chien ST, Lee JJ, Enarson DA, et al. The Influence of Diabetes, Glycemic Control, and Diabetes-Related Comorbidities on Pulmonary Tuberculosis. *PLoS ONE* 10(3).

12. Bam TS, Aditama TY, Chiang CY, Rubaeah R, Suhaemi A. Smoking cessation and smokefree environments for tuberculosis patients in Indonesia—a cohort study. *BMC Public Health*. 2015;15:604



## ■ Proposed actions towards elimination

1. Continue effective collaboration with experts and stakeholders to develop management strategies for TB and important co-morbidities including patient triage and infection control.
2. Advocate facility enhancement and staff education in some special care settings, such as specialized care facilities and nursing homes.
3. In line with the latest WHO guidelines, explore expanding diagnosis and management of LTBI among people at high risk of acquiring TB infection and developing the disease (Section 1.3).

## ■ Proposed actions for setting-specific considerations

1. In settings where TB/diabetes co-morbidity is known to be widespread, such as Pacific island countries and areas, establish and strengthen TB/diabetes collaborative activities such as bidirectional screening and effective concurrent management of both conditions in line with WHO guidelines.
2. In settings where local transmission is effectively controlled and TB morbidity is predominantly seen among the older population, consider developing a strategy for TB control among older people with special attention to co-morbidity management, which may include:
  - clinical guidance and increased health system capacity to address challenges of diagnosis, treatment and care of TB among older people including co-morbidity management;
  - approaches for early case detection including systematic TB screening through regular health check-ups and facility-based screening (e.g. nursing homes), where appropriate; and
  - approaches to prevent TB transmission within care facilities including installing proper infection control measures, systematic entry screening and procedures for outbreak management.

### **BOX 4. Diabetes as a critical co-morbidity in managing TB in the Pacific island countries and areas**<sup>13,14,15</sup>

The Western Pacific Region is home to 36% of the people living with diabetes worldwide. In particular, diabetes is highly prevalent in Pacific island countries and areas, with the highest prevalence rate found in Tokelau (37.5%), followed by the Federated States of Micronesia (35.0%), the Marshall Islands (34.9%), Kiribati (28.8%), Cook Islands (25.7%), Vanuatu (24.0%) and Nauru (23.0%). These seven countries and areas are among the top 10 for diabetes prevalence in the world. TB is also prevalent in Pacific island countries and

13. Viney K, Brostrom R, Nasa J, Defang R, Kienene T. Diabetes and tuberculosis in the Pacific islands region. *Lancet Diabetes Endocrinol.* 2014;2(12):932.

14. *International Diabetes Atlas*, 6th edition. Brussels: International Diabetes Federation; 2013.

15. Brostrom R. TB-DM implementation update. Presentation at the Seventh TB Control Meeting for the Pacific Islands, Nadi, Fiji; 2014.

areas, posing a substantial dual burden of TB and diabetes. An analysis of the population attributable fraction (PAF) of diabetes in TB cases (i.e. the proportion of TB cases that would not occur in a population if diabetes is eliminated) shows that 10 out of 15 countries with the highest PAF are Pacific island countries, demonstrating the considerable impact of diabetes on the TB epidemic in the Pacific. Among others, the Federated States of Micronesia and the Marshall Islands showed an extremely high PAF (more than 40%).

Local surveillance data show that diabetes is found in 34% of TB cases in the Pacific, and the proportion is higher in those aged 40–60 years (57%). Compared with TB patients without diabetes, TB patients with diabetes are 54% more likely to be smear-positive and 41% more likely to have cavitory chest radiography in the Pacific setting, suggesting that diabetes increases the severity of TB. It has been also reported that diabetes further increases the risks of non-conversion of sputum culture at two months, death during TB treatment and relapse after receiving standard treatment.

It is clear that diabetes is not merely a TB risk factor in the Pacific island context, but also a co-morbidity that must be actively managed. It is imperative to establish health-system capacity to provide quality concurrent management of TB and diabetes in order to provide patient-centred TB services.

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#### **BOX 5. Co-morbidity management as a core element of TB control in an ageing society<sup>16</sup>**

TB among the older population remains a significant public health issue in Japan. The proportion of people aged 65 years and over among all TB cases increased from 37% in 1987 to 59% in 2010. Older TB patients tend to have much milder symptoms compared with patients in the general population. For example, about one third of TB patients over 85 years do not have any respiratory symptoms, and TB is often diagnosed at a very late stage of the disease when patients are managed for other health conditions. The TB management of older patients can be highly complex as most of them carry multiple co-morbidities that require intensive medical care such as cancer, NCDs, kidney and liver dysfunction, and cognitive disorders. The need for nursing care for many older patients poses another operational challenge in arranging treatment support and care, as well as infection control in care institutions.

In responding to these challenges, co-morbidity management is a core element in the TB control strategy of Japan. For example, it is critical to secure an integrated treatment facility that can manage infectious TB patients who present with other serious medical conditions (e.g. a facility that can provide concurrent treatment for TB and renal failure, cardiovascular events or mental disorders). With the foreseeable ageing societies in many countries, this phenomenon may become a common agenda for TB control in the Region.

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#### **Key documents**

- Collaborative framework for care and control of tuberculosis and diabetes. Geneva: WHO; 2011.
- Improving tuberculosis prevention and care through addressing the global diabetes epidemic: from evidence to policy and practice. Lönnroth K, Roglic G, Harries AD. *Lancet Diabetes Endocrinol*, 2014.

16. Uchimura K, Ngamvithayapong-Yanai J, Kawatsu L, Ohkado A, Yoshiyama T, Shimouchi A et al. Characteristics and treatment outcomes of tuberculosis cases by risk groups, Japan, 2007-2010. *Western Pac Surveill Response J*. 2013;4(1):11–8.

## 1.2 Strong laboratory networks to find all TB cases

### Strategy

A high-performing laboratory network is essential to reach the ambitious targets of the *End TB Strategy*. The global priority for TB care and control is to improve case finding of all cases through early diagnosis, including smear-negative TB, and to enhance the capacity to diagnose MDR-TB. All elements of Pillar 1 of the *End TB Strategy* are highly dependent on the rapid adoption of emerging policy advice for new diagnostics. These elements also depend on continuous striving for quality assurance within the TB laboratory network, making full use of integrated diagnostic platforms and opportunities for collaboration in the context of health system strengthening.

While the most frequently used test for diagnosing TB, sputum-smear microscopy is a low-cost option that lacks sensitivity, resulting in health services missing many TB patients or identifying them only at an advanced stage of the disease. Screening for symptoms alone may not suffice; additional screening tools such as chest radiography would facilitate referral for diagnosis of bacteriologically negative TB, extrapulmonary TB and TB in children.

The effective and rational use of all existing diagnostics facilitates early diagnosis and treatment, contributing to decreased disease transmission, reduced case fatalities and prevention of adverse sequelae of the disease. New molecular diagnostic testing platforms allow earlier and more accurate diagnosis of TB including drug-resistant forms of TB. Introduction of new molecular diagnostics would require additional resources to institute changes in diagnostic policies and training at all levels.

Diagnostic algorithms should start with appropriate screening policies to identify people at risk. Recommended diagnostics are not mutually exclusive and should be combined based on country epidemiology, the existing laboratory network and available resources. Even with new, rapid diagnostics, conventional laboratory capacity, i.e. microscopy, culture and DST, must be maintained for monitoring patient response to treatment and detecting resistance to drugs other than rifampicin. Scale-up of diagnostic capacity must be matched with access to appropriate treatment and care.

### Regional situation

Throughout the Region, quality-assured TB laboratory networks are being strengthened along with the development of TB programmes. All national reference laboratories in high-burden countries are linked with supranational reference laboratories (SRLs). Technical support provided by SRLs has contributed significantly to the strengthening of laboratory capacity in countries in the Region. Laboratories are increasingly focused

on internal and external quality management, and several national reference laboratories have already been successful in gaining international accreditation.

Following WHO guidance, countries have been replacing conventional light microscopy with the more sensitive light-emitting diode (LED) fluorescence microscopy in phases. The Xpert MTB/RIF assay (Cepheid, Sunnyvale, California, United States of America) has also been rolled out with more than 1700 machines procured by 2014. Countries have rapidly adopted Xpert MTB/RIF as the initial diagnostic test for detecting rifampicin resistance in people with a high risk of MDR-TB and people living with HIV. However, the use of Xpert MTB/RIF in paediatric and extrapulmonary diagnosis has not yet been fully implemented.

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## PROPOSED ACTIONS

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### ■ Proposed actions for all settings

1. **Review and update diagnostic policies including the timely roll out of newer WHO-recommended diagnostics (WRDs).**
  - Develop or update a strategic plan for establishing a laboratory system that combines different diagnostics and optimizes the efficient use of all diagnostic methods based on country epidemiology, the existing TB laboratory network, opportunities for shared diagnostic platforms, integration and collaboration in the context of health system strengthening and available resources.
  - Define country-specific diagnostic algorithms. The choice of algorithms will dictate current and future diagnostic and laboratory capacity needs. A recommended diagnostic need not be used exclusively; rather multiple tools can be utilized relevant to the needs of each screening group.
  - Maintain capacity of conventional techniques and reposition them in the diagnostic algorithm.
  - Ensure availability of laboratory capacity for routine monitoring of MDR-TB patients to detect and manage adverse effects.
2. **Increase accessibility.**
  - Maximize the use of WRDs while maintaining and strengthening laboratory capacity for culture and DST to rifampicin and isoniazide.
  - Improve access to laboratory services through decentralization or strengthening of specimen transport systems, in alignment with the expansion of treatment facilities.
  - Develop DST capacity to specific second-line drugs in settings where populations and patients have had significant exposure to second-line drugs.

### 3. Ensure quality standards.

- Provide adequate human resources and training.
- Ensure equipment validation and maintenance.
- Strengthen laboratory quality management systems (internal and external) for all procedures.

### 4. Strive to achieve international standards of laboratory accreditation (Box 6).

- Strengthen laboratory management.
- Establish or strengthen laboratory information management systems.
- Maintain appropriate infrastructure and biosafety.

## ■ Proposed actions towards elimination

1. Develop DST capacity for the full spectrum of TB drugs.
2. Prepare for capacity development in molecular technologies beyond currently recommended diagnostic tools, i.e. Xpert MTB/RIF and line probe assay (LPA), in light of emerging technologies such as whole genome sequencing.
3. Gradually develop and expand capacity to conduct molecular techniques that can assist cluster detection and outbreak investigation.

## ■ Proposed actions for setting-specific considerations

1. In the Pacific island countries and areas, ensure availability of culture, DST and molecular diagnostics by strengthening and further developing PATLAB,<sup>17</sup> a subregional mechanism for laboratory services, through continued coordination and commitments of all partners.

### **BOX 6. Strengthening laboratory management towards accreditation**

Accreditation is a means to recognize the quality and competence of a laboratory. Accreditation is achieved when a laboratory has a quality management system in place that complies with ISO 15189:2012, an international standard that specifies requirements for quality and competence in medical laboratories.

National laboratories are encouraged to meet all of the requirements of this International Organization for Standardization (ISO) standard. At a minimum, lower-level laboratories are required to implement internal and external quality-improvement mechanisms.

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17. Since 2004, PATLAB, a collaborative mechanism between WHO and five supporting reference laboratories in Australia, New Zealand and the United States of America, has been supporting the Pacific island countries and areas to: (a) strengthen quality assurance for smear microscopy; (b) expand drug resistance surveillance; (c) support the definition of minimum essential requirements for laboratory design, layout and biosafety; (d) advise on rational uptake of rapid diagnostic tools; and (e) ensure access to quality-assured culture and DST.

All diagnostic techniques used in a laboratory should be quality-assured. Supervision and technical support should be routinely provided from the upper level of the laboratory network to the lower level to ensure that the network operates effectively.

Among the priority countries, the national TB reference laboratories in the Philippines and Viet Nam have achieved ISO 15189:2012. Using the Global Laboratory Initiative accreditation tools, it is proposed to engage and support more public TB laboratories in the priority countries as they embark on the challenging journey towards ISO 15189:2012 accreditation.

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#### *Key documents*

- The Global Laboratory Initiative. A roadmap for ensuring quality tuberculosis diagnostics services within national laboratory strategic plans. Geneva: WHO; 2010.
- Tuberculosis laboratory biosafety manual. Geneva: WHO; 2012.
- Xpert MTB/RIF assay for the diagnosis of pulmonary and extrapulmonary TB in adults and children: policy update. Geneva: WHO; 2013.

## 1.3 Latent TB infection and BCG vaccination

### Strategy

As much as one third of the world's population is infected with TB, which serves as a continuous reservoir of the disease. The vast majority of infected individuals have LTBI with no signs or symptoms of TB disease. They are not infectious, but they are at risk for developing active TB disease. The lifetime risk of developing active disease from LTBI is estimated to be 10–20%, with half of these cases developing within the first five years after initial infection.

The development of TB disease from LTBI, or reactivation, can be averted by preventive treatment. However, population-wide mass LTBI testing and treatment are not advisable due to imperfect tests, risk of serious side effects and the very high cost. The cost of systematic testing and treatment can be justified, and the benefits may be greater than the harm, if only selected risk groups are targeted. To facilitate expansion of LTBI services, WHO has developed *Guidelines on the management of latent tuberculosis infection* for high- and upper-middle-income countries with an estimated TB incidence rate of less than 100 per 100 000 population. The guidelines include evidence-based practices for testing, treating and managing LTBI in individuals with the highest risk of progression to active disease.

The BCG vaccine prevents fatal disseminated diseases (i.e. meningitis and miliary TB) in infants and young children. However, its preventive efficacy against pulmonary TB is limited and it does not prevent reactivation of LTBI. In settings with high TB prevalence, until new and more effective vaccines become available, BCG vaccination soon after birth should be continued for all infants except for those with HIV.<sup>18,19</sup>

## Regional situation

With diverse epidemiological and health system situations, countries in the Region are at varying stages in handling LTBI. In most settings, LTBI management has been implemented among people living with HIV and children who are TB contacts. Countries are expected to gradually expand the target population for diagnosis and treatment of LTBI, taking into account the risks and benefits to individuals and specific groups, overall TB epidemiology and available resources. Expanding LTBI management is one of the critical interventions needed to achieve the ambitious target of 90% reduction in TB incidence under the *End TB Strategy*.

Universal BCG coverage has been maintained in the vast majority of countries in the Region. With the exception of countries with a low incidence of TB, BCG vaccination is likely to remain part of the national immunization schedule until new and more effective vaccines become available.

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## PROPOSED ACTIONS

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### ■ Proposed actions for all settings

1. Ensure services for LTBI diagnosis and treatment are in place for young children who are close contacts of pulmonary TB patients and people living with HIV after active TB disease is excluded. The policies should be in concert with those on screening for active TB in high-risk populations, contact investigation (Section 1.1.3), childhood TB diagnosis and care (Section 1.1.2), and TB/HIV collaborative activities (Section 1.1.4).
2. Establish and periodically review the diagnostic and management algorithms for LTBI, taking into account the balance between benefits and harms, resource implications, and the availability and rational use of diagnostic tools.
3. Establish or strengthen recording and reporting systems for LTBI, particularly focused on contacts, people living with HIV and other high-risk groups taking into account local epidemiology.

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18. BCG vaccine. WHO position paper. Wkly Epidemiol Rec. 2004;79(4):27–38.

19. Revised BCG vaccination guidelines for infants at risk for HIV infection. Wkly Epidemiol Rec. 2007;82(21):193–6.

## ■ Proposed actions towards elimination

1. Gradually expand the target population for LTBI diagnosis and treatment appropriate to the country context. Besides child contacts and people living with HIV, systematic testing and treatment of LTBI may be performed in older child and adult TB contacts, patients initiating anti-tumour necrosis factor treatment, patients receiving dialysis, patients preparing for organ or haematologic transplantation, and patients with silicosis.
2. Systematic testing and treatment of LTBI may be considered for prisoners, health-care workers, immigrants from countries with a high burden of TB, homeless people and illicit drug users.

### *Key document*

- Guidelines on the management of latent tuberculosis infection. Geneva: WHO; 2015.



## PILLAR 2

### Bold policies and supportive systems

Tuberculosis is a social disease, and presents problems that transcend the conventional medical approach... It is the consequence of gross defects in social organization, and of errors in individual behaviour.

—René and Jean Dubos, *The White Plague*, 1952

Historically known as a social disease, TB control requires coordinated, whole-of-society actions that go beyond the realm of TB control and the health sector. Pillar 2 of the *End TB Strategy* appeals for strengthened and coherent health and social sector policies, and empowering and mobilizing civil society, to form a bold societal response to the TB epidemic. All Pillar Two actions support the realization of people-centred TB services envisioned in Pillar 1.

Going forward, the ministry of health, particularly the NTP, should continue coordinating and stewarding the overall national TB response, as elaborated in a national TB strategic plan (NSP) (Section 2.1.1). Under this government stewardship, more regulatory approaches should be employed to support TB control efforts including mandatory disease notification (Section 2.1.4), strong and harmonized drug regulatory policies (Section 2.1.3), and standards of care including infection control. Building on the conventional public–private mix approaches, new tactics are needed to effectively engage all care providers by balancing regulatory and partnership methods, and focusing on the quality and continuum of care (Section 2.2.2). Engaging patients, families and communities in programme planning and service delivery will not only increase community awareness, but also nurture an enabling environment for patients and families, and potentially lead to a bold community-based response (Section 2.2.1).

The *End TB Strategy* set a target of “no affected families facing catastrophic costs due to TB”. This can only be achieved by ensuring sufficient financial risk protection for people to access quality TB services in the context of UHC (Section 2.1.2). As TB disproportionately affects vulnerable populations, minimizing direct medical expenses may not be sufficient to prevent households from falling into poverty. Continued advocacy and negotiation are needed to improve and expand social protection coverage that favours TB patients (Section 2.3.1). Many TB risks stem from various social determinants, and addressing them requires a multisectoral approach, or the HiAP approach, in collaboration with a wide range of governmental and nongovernmental entities (Section 2.3.2).

As elaborated in Pillar 2 of the *End TB Strategy*, the work of TB control in the next decade requires both technical and systems approaches. By advocating and contributing to all these system-wide responses such as people-centred care, UHC, social protection and HiAP, TB programmes can set an example for how a disease control programme interacts within the health system and with institutions in other sectors.

## 2.1 Governance and stewardship

### 2.1.1 Robust national TB strategic plans supported by strong political commitment and adequate resources

#### Strategy

Scaling up and sustaining interventions for TB care and prevention requires high-level political commitment indicated by good planning and adequate financial and human resources.

An NSP, embedded in a national health sector plan, is a key instrument for managing TB control programmes. The NSP highlights the aim of the national policy to control TB and defines goals and operational objectives to be achieved through TB control efforts. A sound NSP describes a clear process and specifies the appropriate strategic interventions to reach the objectives and goal. It guides decision-making for allocating resources and for actions to pursue strategies and set priorities. It is crucial that stakeholders and partners be fully engaged in the development of the NSP and support national efforts, ensuring assistance is in harmony with global agreements and guidelines.

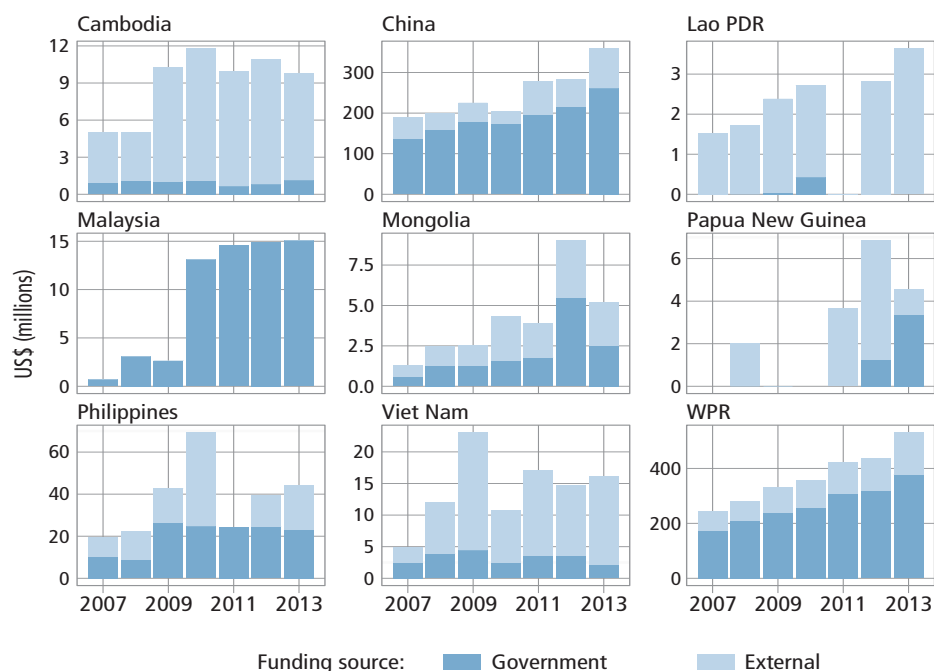
With the *End TB Strategy*, the modalities of TB control will change with the expansion of strategies across and beyond the health sector, and with the introduction of innovative tools. The ambitious plan for TB care and prevention will be possible only if adequate funding is secured. An NSP should be properly budgeted with clear identification of financial gaps, which facilitate resource mobilization from international and national sources. Coordinated efforts are required to mobilize resources to fund truly ambitious NSPs with a progressive increase in domestic funding.

#### Regional situation

All countries in the Region with a high burden of TB have developed, or updated, their NSPs. In-depth epidemiological analysis, internal field monitoring and evaluation, external NTP reviews, and stakeholder consultations significantly helped countries to assess the epidemiological and programmatic situation, determine gaps, identify new goals and objectives, and define strategic directions and interventions.

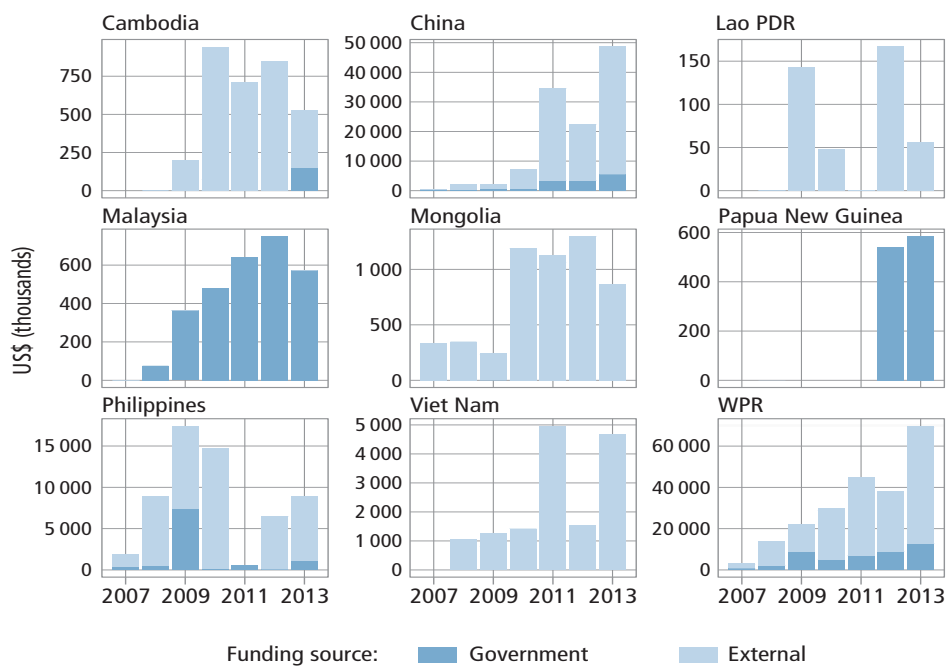
Although domestic investment in TB control is trending upwards, the level of dependency on external funds is still high in many countries (Fig. 6). Most countries with a high burden of MDR-TB rely on external funding for MDR-TB control and care (Fig. 7).

**FIGURE 6. Annual funding for TB control by source in selected countries in the Western Pacific Region (WPR), 2007–2013**



Source: Global tuberculosis database (accessed 6 October 2014).

**FIGURE 7. Annual funding for MDR-TB control by source in selected countries in the Western Pacific Region (WPR), 2007–2013**



Source: Global tuberculosis database (accessed 6 October 2014).

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## PROPOSED ACTIONS

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### ■ Proposed actions for all settings

1. Review and update NSPs periodically through: (a) sound epidemiological reviews; (b) maximum use of regular internal monitoring and evaluation; (c) joint external reviews; and (d) wide stakeholder consultations including key affected communities.
2. Aim for maximum efficiency gains through: (a) alignment of TB programme planning with the overall health sector planning framework; (b) collaboration across public health programmes to promote joint planning and share programmatic policies and strategies; and (c) improve coordination of external technical assistance.
3. Secure adequate funds through resource mobilization from diverse international and national sources by using a well-budgeted ambitious plan.

#### *Key documents*

- Toolkit to develop a national strategic plan for TB prevention, care and control. Geneva: WHO; 2015.
- Contributing to health system strengthening: Guiding principles for national tuberculosis programmes. Geneva: WHO; 2008.

## 2.1.2 Sustainable TB care delivery and financing mechanisms in the context of universal health coverage

### Strategy

The global thrust towards UHC presents great opportunities to advance TB control. UHC envisions all people having access to quality health services without financial hardship. UHC can only be achieved through adequate, fair and sustainable financing for quality-assured health services with progressive and equitable population coverage. Specifically for TB, the *End TB Strategy* has set an ambitious target of “no affected families facing catastrophic costs due to TB”, which not only is in line with the goal of UHC but also can be a good tracer indicator to monitor progress towards UHC.

TB control programmes have been contributing to the goal of UHC through the provision of essential TB services from the central referral level to the most peripheral level through the primary health care network. The packages of TB services are well defined and composed of scientifically proven, cost-effective and high-impact interventions. With often earmarked vertical funding and a results-based monitoring and evaluation framework supported by a strong surveillance system, TB programmes have demonstrated tangible public health impacts that further attracted donor investments.

However, with epidemiological, socioeconomic and health system transitions, it is becoming imperative for TB control programmes to improve efficiency and sustainability in the context of health sector reforms towards UHC, while protecting the gains achieved in the past decades.

## Regional situation

The structure of TB control and the financing situation are rapidly changing, especially in the Western Pacific Region. Economic advances and significant progress in communicable disease control in recent decades have led to a substantial reduction in funding, including from the Global Fund to Fight AIDS, Tuberculosis and Malaria. At the same time, public health priorities have diversified to include, for example, NCDs, emerging diseases, injury prevention and promotion of healthy lifestyles. These changing priorities highlight the necessity of a systems approach rather than vertical disease control approaches. In addition, many countries are undergoing major health sector reforms to improve efficiency and responsiveness. These reforms often consider restructuring and integrating disease control programmes.

While external funding is decreasing, TB control programmes in the Region are scaling up services because the range of required services is continuously expanding. Some interventions are inevitably complex and resource intensive such as PMDT, TB/HIV collaborative activities, TB screening among high-risk populations and LTBI management.

Challenges are both structural and financial. NTPs require continuous reviews of their structure according to the epidemiological situation, service needs and resource availability including human resources and TB specific expertise. While the integration of TB services into the general health system may improve efficiency, it may also cause deterioration of service quality. Effective service structure should be accompanied by effective financing mechanisms. Many countries have begun reviewing conventional vertical funding flows for TB control, and there is a general move towards more streamlined and integrated funding.

## PROPOSED ACTIONS

### ■ Proposed actions for all settings

1. Analyse the current national TB control structure and systems in terms of functions for TB control, service providers, funding flows and payment mechanisms in order to identify policy options for sustainable financing for TB control and care (this process is elaborated in Box 7).
2. Identify core essential functions for TB control that should be retained in the public sector as “non-negotiable” NTP functions to secure TB control as a public good for health. Although similar across countries, detailed composition of these functions may differ depending on national and health system contexts.
3. Continue to advocate for minimizing and eliminating patient costs associated with TB care. Increases in patient costs almost always adversely affect early diagnosis, treatment uptake and adherence, treatment outcomes, and the general TB control situation, regardless of the economic level or TB endemicity of the country. NTPs may need to make persistent efforts to progressively bring down the financial burden for TB patients (Box 8).
4. Identify nationally appropriate methodologies and periodically measure patient financial burden due to TB by adapting WHO’s generic protocol. This measurement will be used to assess the progress against one of the global targets: “no affected families facing catastrophic costs due to TB”.

### ■ Proposed actions towards elimination

1. Maintain central coordination of TB care and prevention under the stewardship of the government in order to plan and implement NSPs for TB elimination.<sup>20</sup> This will become more and more challenging as a country moves towards TB elimination.

#### BOX 7. Steps for analysis and development of financing options for TB control<sup>21</sup>

**STEP 1.** Clarify essential functions (public health and clinical) required for effective TB control according to the national context. The following are typically regarded as essential functions for TB control:

- policy formulation and stewardship functions including multisectoral coordination;
- human resources management including training;
- patient-centred clinical consultation, treatment and care, including patient support;
- diagnostic services;

20. Framework towards TB elimination in low-incidence countries. Geneva: WHO; 2014.

21. Framework for policy development: improving efficiency and sustainability of priority public health programmes. Manila: WHO Regional Office for the Western Pacific; (in press).

- TB reference laboratory function;
- disease notification and TB surveillance (registration) systems;
- epidemiological assessment, including cohort analysis and risk-group identification, at national and subnational levels;
- uninterrupted supply of quality-assured TB drugs and diagnostics;
- drug regulatory policies including the rational use of drugs;
- TB contact investigation including outbreak management;
- TB screening among specific high-risk populations; and
- advocacy, public awareness raising and health communication.

Thoughtfully discuss and determine which essential functions should be retained by the NTP as “non-negotiable” core functions.

**STEP 2.** *Identify and map key service providers and clarify the division of responsibilities for the above functions for TB control and care. Typically key service providers include the following:*

- NTPs;
- subnational health authorities, e.g. provincial and district health bureaus;
- public health centres, with or without clinical functions;
- public and private hospitals;
- public and private clinics;
- public and private laboratories;
- nongovernmental and civil society organizations; and
- non-health sector entities (e.g. prisons, military, immigration, schools, occupational health service providers).

**STEP 3.** *Explore and identify a range of funding sources to finance TB control and care. These may include the following:*

- national government line-item budget for TB control and care;
- subnational government budgets;
- public and private health insurance;
- external funds;
- innovative financing, e.g. levy on foreign exchange transactions, taxes on tobacco and alcohol;
- non-health sector government budget; and
- patient out-of-pocket payments.

**STEP 4.** *Map functions of service providers and clarify funding options for each provider and function.*

**STEP 5.** *Review the payment modality and funding flow.*

- Choose a payment modality that can ensure the quality of services and evaluate quality-assurance mechanisms for specific payment mechanisms. For example, where clinical services are funded by a health insurance scheme, modalities such as fee-for-services, capitation, case-based payment or results-based payment may significantly affect the quality of care and clinical outcome. Appropriate safeguards, quality-assurance mechanisms and the best modality in a given context should be discussed together.
- The risk of significant patient cost must be thoroughly examined and systematically monitored. Appropriate safeguards may be explored to avoid catastrophic patient cost.

### **BOX 8. Efforts to progressively minimize patient financial burden in the Republic of Korea**

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The Republic of Korea established a National Health Insurance System (NHIS) for every citizen to use in 1989. TB services were included in its coverage. In the early years, patient out-of-pocket expenses averaged around 50% of the total cost. In 2007, in order to protect MDR-TB and XDR-TB patients from catastrophic financial burden, insurance coverage was raised to 90% (leaving 10% to be borne by patients). The policy was later extended to all TB patients in 2010.

To further minimize financial burden to patients, an additional 5% subsidy from the Government has been put in place since 2011, leaving patient out-of-pocket payment at 5%. Patients can be supported by this policy up to two years for an episode of drug-susceptible TB and up to five years for M/XDR-TB. In late 2016, this policy is intended to increase coverage to 100% of medical expenses as part of the enhanced UHC policy of the Ministry of Health and Welfare.

In addition, as part of efforts to intensify contact investigation and manage LTBI, the Republic of Korea started to provide LTBI treatment free of charge in 2015. All these efforts illustrate the continuous effort of the Government to progressively minimize patient financial burden in order to achieve universal access to quality TB care for all people affected by TB.

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## **2.1.3 Drug regulatory and management systems to support TB control**

### **Strategy**

An uninterrupted and sustained supply of quality-assured TB drugs is one of the fundamental pillars of WHO's recommended approach to TB control. The quality of drugs is paramount for better treatment outcomes and for preventing drug resistance. The *End TB Strategy* emphasizes strengthening the national regulatory framework to ensure a sustained supply of quality-assured drugs.

National policy and regulatory frameworks for production or procurement and use of quality-assured medicines and diagnostics are powerful levers essential for effective TB control. In countries with a high burden of TB, these frameworks need to be urgently strengthened and enforced. Regulations and their enforcement are required for the registration, importation and manufacturing of medical products. Moreover, regulations should stipulate which types of health professionals are authorized to prescribe or dispense TB medicines.



The regulation of medicines is an essential function of public health. A functioning national medicine regulatory authority (NMRA) is critical to ensure the existence and enforcement of strict regulations for the manufacture, sale and distribution of effective, safe and quality-assured medicines in order to protect public health. Intensification of international commerce and increasing technological complexity of manufacturing and product specifications have created additional challenges for NMRAs. This requires that national regulatory capacity be regularly assessed, areas of weakness identified and, where appropriate, necessary corrective measures taken. Coordination between the NTP and NMRA needs strengthening in many countries.

TB patients frequently suffer from adverse drug reactions. Pharmacovigilance, which is an essential element of patient-centred care, minimizes risk and harm to patients, and instils public confidence in health systems. Pharmacovigilance is becoming more and more important in TB control programmes with the introduction of new drugs.

Access to quality-assured TB drugs is fundamental to TB control and can only be ensured when supply chains in both the public and private sectors are consistently performing to ensure availability of and access to effective, safe medicines and diagnostics.

## Regional situation

The Region has made good progress in drug procurement, supply and management. Regular monitoring missions were instrumental in improving drug management capacity at the country level and avoiding stock-outs.

The capacity of NMRAs to enforce national quality standards varies from country to country. Some countries procure TB medicines through international mechanisms such as the Global Drug Facility (GDF), which facilitates the procurement of quality-assured TB medicines according to stringent international quality standards. However, some countries procure drugs locally following national standards that are not aligned with internationally accepted quality standards.

Regulation of the appropriate trade and use of medicine is an important component of national medicine policy, i.e. a public policy that restricts private-sector activities in order to attain social goals set by the country. Several countries have challenges maintaining a consistently performing supply chain in both the public and private sectors to ensure the availability and consistency of effective quality-assured medicines. Shortages, lack of access and unaffordability often drive irrational use, increasing the risk of treatment failure and development of resistance.

In 2014, WHO organized a consultation workshop on strengthening and harmonizing the regulation of medicine in the Region,<sup>22</sup> using the TB programme as an example

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22. Report of the meeting on quality-assured drugs for better public health: strengthening and harmonizing the regulation of TB medicines in the Western Pacific Region. Manila: WHO Regional Office for the Western Pacific; 2014.

for other disease-specific programmes to strengthen collaboration with NMRAs. The workshop also highlighted the TB programme as an entry point for overall strengthening and harmonization of regulations for all medicines in the Region.

### **BOX 9. Regulation of the importation and sale of TB drugs in Cambodia**

Cambodia provides a good example of government action to regulate the drug market. The country banned the sale of TB drugs in the private sector to restrict the distribution of quality-assured TB medicines to the public sector in order to achieve better treatment outcomes and reduce risks from the use of poor-quality products or irrational use of drugs in the private sector.

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## **PROPOSED ACTIONS**

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### **■ Proposed actions for all settings**

- 1. Coordinate with NMRA to strengthen medical product registration systems.**
  - Assess national regulatory capacity and function using the harmonized WHO national regulatory assessment tool and implement an institutional development plan.
  - Fast-track registration through different potential mechanisms including collaborative registration and harmonization of technical dossier requirements.
  - Establish a legal framework for compassionate use of drugs.
  - Build capacity of product evaluators.
  - Build capacity of NMRA for using active pharmacovigilance methods, such as cohort event monitoring for post-marketing surveillance linked to timely registration of new TB drugs to monitor safety.
- 2. Coordinate with NMRA for quality assurance and control.**
  - Regularly monitor the quality of TB drugs.
  - Review national quality criteria/specifications of TB medicines.
  - Liaise with potential manufacturers for prequalification of TB medicines.
  - Build capacity on good manufacturing practices, e.g. inspectors to inspect manufacturers.
  - Strengthen laboratory capacity and increase availability of reference standard for second-line drugs.

### **3. Collaborate with NMRA to strengthen pharmacovigilance.**

- Strengthen the pharmacovigilance system as a component of health system strengthening (reporting, engaging all providers, inclusion of active surveillance and analytical capacity).
- Strengthen capacity of analysis of data and informing policy changes.
- Raise awareness among patients and providers.
- Create regional pharmacovigilance centres of excellence.

### **4. Promote rational use of TB medicines.**

- Establish and strengthen effective interventions to reduce the irrational use of TB medicines.
- Include indicators of quality of service in facility licensing and insurance schemes.
- Strengthen pharmacy inspection programme to monitor irrational dispensing and sale of TB medicines in collaboration with other programme, e.g. malaria control programme.
- Raise awareness among the general population, using the antimicrobial resistance platform.

### **5. Improve efficiency of procurement and supply chain management.**

- Strengthen quality-assurance processes during procurement to ensure purchasing of only quality-assured medicines and medical products.
- Improve and, where possible, integrate logistic management procedures and information systems to ensure accurate forecasting, distribution and inventory management for uninterrupted supplies.

## **■ Proposed actions towards elimination**

### **1. Identify a strategy to ensure an uninterrupted supply of quality-assured TB drugs particularly in the context of decreasing demand.**

- As the number of TB cases decreases in the country, securing quality-assured TB drugs will become a challenge due to the relatively small market size and lack of incentives.
- GDF is a potential source of procurement, but legislative requirements can be a hurdle to overcome depending on the flexibility of the national regulatory system.

## **■ Proposed actions for setting-specific considerations**

- 1. In the Pacific, identify a sustainable strategy to ensure an uninterrupted supply of quality-assured TB drugs taking into account the specific challenges faced by Pacific island countries.**

### Key documents

- Report of the meeting on quality-assured drugs for better public health: strengthening and harmonizing the regulation of TB medicines in the Western Pacific Region. Manila: WHO Regional Office for the Western Pacific; 2014.
- A practical handbook on the pharmacovigilance of medicines used in the treatment of tuberculosis. Geneva: WHO; 2012.

## 2.1.4 Disease notification and surveillance systems

### Strategy

Mandatory notification, vital registration with cause of death, and monitoring and evaluation systems are essential to assess the status and trends of TB along with the effectiveness of interventions. Complete and reliable systems allow for strong surveillance, effective contact investigation and outbreak management, and assessment of infection control measures. NTPs have historically held data recording and reporting as a core component of the programme, critical to ensuring operations run smoothly and objectives are achieved. With reliable data, in-depth epidemiological assessment can inform policy decisions and estimate programme impact.<sup>23</sup>

In 2014, WHO produced the *Standards and benchmarks for tuberculosis surveillance and vital registration systems*. This checklist and user guide provides a structure to gauge whether the data produced by these systems can adequately serve as a proxy for measuring TB incidence and mortality. The approach also highlights deficiencies in order to guide strengthening efforts. Electronic case-based surveillance systems can provide many advantages to traditional paper-based aggregate systems including increased data quality, lightened workload, more extensive and timely data access, flexibility in system updates, enhanced analysis and reporting, and easier management of complex data. Surveillance data collected but not analysed present a missed opportunity and misuse of resources. Analysis of surveillance data at national and subnational levels can give insight into TB epidemiology and provide valuable information for programmatic decision-making. Important indicators include measurement of disease burden, detection of potential outbreaks, definition of high-risk groups, and monitoring and evaluation of programme performance.<sup>24</sup>

23. TB impact measurement policy and recommendations for how to assess the epidemiological burden of TB and the impact of TB control. Geneva: WHO; 2009.

24. Nishikiori N, Morishita F. Using tuberculosis surveillance data for informed programmatic decision-making. *Western Pac Surveill Response J*. 2013;4(1):1–3.

## Regional situation

The *Regional Strategy to Stop Tuberculosis in the Western Pacific 2011–2015* called for in-depth analysis of surveillance data and the implementation of case-based electronic recording and reporting systems. Many countries in the Region produce annual TB reports that include analyses at the national and subnational levels, and several high-burden countries have published in-depth epidemiological assessments.<sup>25,26,27</sup> Six out of seven high-burden countries have conducted at least one prevalence survey; in 2013, out of 37 countries and areas, 26 reported nationwide case-based electronic recording and reporting systems and two countries had systems for MDR-TB patients only. Using WHO's *Standards and benchmarks for tuberculosis surveillance and vital registration systems*, assessments have been conducted in several countries.

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## PROPOSED ACTIONS

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### ■ Proposed actions for all settings

1. Ensure mandatory notification for TB is in place, as part of national notifiable diseases, and enforced in practice.
2. Conduct an assessment of the TB surveillance system using WHO's *Standards and benchmarks for tuberculosis surveillance and vital registration systems* and progressively improve the surveillance system.
3. Assess the completeness and reliability of the TB surveillance system. Where applicable, link to relevant information systems including the national health information system and intercountry notification systems.
4. Introduce or expand an electronic, case-based recording and reporting system. Assess the utility of existing systems and address gaps identified.
5. Conduct and promote regular in-depth analyses of surveillance data at the national and subnational levels.
6. Assess the coverage and quality of the vital registration system and address the gaps identified.

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25. Morishita F, Furphy VB, Kobayashi M, Nishikiori N, Eang MT, Yadav RP. Tuberculosis case-finding in Cambodia: analysis of case notification data, 2000 to 2013. *Western Pac Surveill Response J.* 2015;6(1).

26. Vianzon R, Garfin AMC, Lagos A, Belen R. The tuberculosis profile of the Philippines, 2003–2011: advancing DOTS and beyond. *Western Pac Surveill Response J.* 2013;4(2):11–6.

27. Nguyen NV, Nguyen HB, Pham KH, Hennig C. Tuberculosis case notification data in Viet Nam, 2007 to 2012. *Western Pac Surveill Response J.* 2015;6(1).

## ■ Proposed actions towards elimination

1. As fewer patients may make it more feasible, collect data on more variables including co-morbidities, risk factors and socioeconomic conditions. Using the information collected, study risk factors and disease determinants that could be a good source of information for risk-group mapping (Section 1.1.3).
2. Systematically link epidemiological data with molecular information (genotyping),<sup>28</sup> which will become more feasible and useful as the number of TB cases decreases and the relative importance of outbreak investigations increases.

### *Key documents*

- Standards and benchmarks for tuberculosis surveillance and vital registration systems: checklist and user guide. Geneva: WHO; 2014.
- Understanding and using tuberculosis data. Geneva: WHO; 2014.
- Electronic recording and reporting for tuberculosis care and control. Geneva: WHO; 2012.
- Definitions and reporting framework for tuberculosis – 2013 revision. Geneva: WHO; 2013.

## 2.2 Engagement and partnerships

### 2.2.1 Engaging patients, families, communities and civil society organizations

#### Strategy

A robust response to end the TB epidemic will require establishing lasting partnerships across the health and social sectors and between the health sector and communities. Informed community members can identify people with suspected TB, refer them for diagnosis, provide support during treatment, and help alleviate stigma and discrimination. Civil society organizations have specific capacities from which TB programmes can benefit. Their competencies include reaching out to vulnerable and underserved groups, mobilizing communities, channelling information, helping create demand for care, framing effective service delivery models, and addressing determinants of the TB epidemic.

28. Methods of genotyping include restriction fragment length polymorphism (RFLP) and variable number tandem repeats (VNTR).

## Regional situation

In the Region, community-based TB activities cover a wide range of activities contributing to prevention, early diagnosis and improved treatment outcomes. Efforts to engage nongovernmental organizations, civil society organizations, patients and patient organizations have been successfully initiated. Partnering with people who have personally experienced TB ensures that people affected by TB will be the central focus of the programme. It will have profound implications for the way that services are planned, delivered and evaluated.

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## PROPOSED ACTIONS

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### ■ Proposed actions for all settings

1. Engage civil society organizations, community representatives, patients and families in TB programme planning, service delivery and monitoring, as well as in information and education activities, support to peer patients and their families, research and advocacy.
2. Reach out to unengaged civil society organizations (including patient organizations), encouraging them to integrate community-based TB care into their work. Widen the network of facilities engaged in TB care and prevention.
3. Integrate community-based TB activities into other community-based activities supporting primary health-care services, such as HIV, maternal and child health and noncommunicable diseases, as well as those outside of the health sector.
4. Further develop capacity of community-based organizations for planning and management through self-help groups, empowerment workshops and the creation of networks.
5. Ensure that affected populations are meaningfully represented in venues to discuss national TB response and relevant bodies at national and local levels.

### *Key documents*

- ENGAGE-TB: Operational guidance. Geneva: WHO; 2012.
- ENGAGE-TB: Implementation manual. Geneva: WHO; 2013.
- ENGAGE-TB: Training manual. Geneva: WHO; 2014.
- ENGAGE-TB: Training for community health workers and community volunteers. Geneva: WHO; 2015.

## 2.2.2 Engaging all public and private care providers

### Strategy

In many countries, TB care is delivered by diverse public and private care providers. These providers include formal and informal practitioners, pharmacists, and nongovernmental and faith-based organizations, as well as corporate health facilities. Several public sector providers outside the purview of NTPs also provide TB care such as large public hospitals, prison health services and military health services. Leaving a large proportion of care providers out of the organized response to TB control has contributed to many TB cases left undiagnosed or not notified, inappropriate TB management and the irrational use of TB drugs leading to the spread of drug resistance. Under-notification of cases hampers disease surveillance, contact investigation, outbreak management and infection control.

Treatment of TB by non-NTP health providers presents major challenges: (a) providers may lack sufficient knowledge to provide quality TB diagnosis and treatments; (b) fee structures may encourage incomplete therapy as patients may not be able to finance the later months of their treatment; (c) lack of mechanisms and enforcement for mandatory notification hampers surveillance; (d) providers may lack the capacity to support patients throughout the entire treatment course; and (e) TB-associated stigma further deters many from seeking care and adhering to treatment in the public sector.

While building on experiences of successful initiatives, new approaches are also needed to ensure quality TB care by all health-care providers in a sustainable way. New tactics are needed to effectively engage all care providers by balancing regulatory and partnership methods, effectively using information technologies, and focusing on the quality of care including the use of standards, accreditation and other mechanisms.

### Regional situation

In the Region, regardless of their socioeconomic status, people seek health care in the growing private health sector. TB prevalence surveys in many countries also confirmed that the majority of people with TB symptoms first seek care from private and non-NTP public health providers. The magnitude of the TB caseload managed outside the network of NTPs is reflected in the large quantities of TB medicines of questionable quality available in the private market; these quantities sometimes exceed the quantities of quality-assured medicines that are procured by NTPs.<sup>29</sup> Many countries in the Region have established and expanded public–private mix approaches involving key partners and employing diverse modalities of collaboration

29. Wells WA, Ge CF, Patel N, Oh T, Gardiner E, Kimerling ME. Size and usage patterns of private TB drug markets in the high burden countries. *PLoS One*, 2011;6(5):e18964.



that reflect the country health system context. Such partners include pharmacies, private cabinets and clinics, large private and public hospitals, and health facilities in other sectors. As a result, substantial contributions from non-NTP providers have been seen in various countries. Strengthening the notification system together with close collaboration with the public health sector has resulted in a substantial increase in case notification. Engagement of large public and private hospitals particularly in metropolitan areas has resulted in considerable improvement in the diagnosis and care of TB patients.

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## PROPOSED ACTIONS

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### ■ Proposed actions for all settings

1. Enforce an infectious disease law, or equivalent, that includes mandatory notification of TB cases by all health-care providers (Section 2.1.4) and regulation of TB medicines (Section 2.1.3).
2. Scale up public–private mix approaches that are working well in specific country settings.
3. Ensure quality of care by promoting ISTC, accreditation and other mechanisms.
4. Consider accreditation and reimbursement schemes, e.g. when TB is covered by a national health insurance scheme, or by demanding certain outputs under results-based financing (Section 2.1.2).
5. Use modern information and communication technology platforms effectively to engage all care providers.

### **BOX 10. Working with the business sector to strengthen TB services in the context of occupational health services<sup>30</sup>**

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People working in certain occupational sectors (e.g. mining, construction, health care, prisons) or working and living in poor conditions in the informal sector are particularly at high risk of TB and HIV. In the case of TB, workplaces can increase disease transmission if people spend long periods of time in close proximity. Also, a number of barriers to accessing TB services are linked to work-related concerns such as loss of wages, health facilities not accessible outside working hours, stigma and discrimination, mobility, etc.

A workplace programme that comprehensively addresses TB prevention, diagnosis, treatment and care in high-burden settings can effectively mitigate the impact of the disease on the workforce and thus on productivity. The workplace is a win-win setting for TB management strategies. There are opportunities in which NTPs can provide busi-

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30. Working together with businesses: guidance on TB and TB/HIV prevention, diagnosis, treatment and care in the workplace. Geneva: WHO 2012.

nesses with strong technical skills, access to TB drugs and diagnostics, and broader health infrastructure.

Workplace programmes can be consistently monitored in line with national standards. The effectiveness of TB prevention, diagnosis and treatment should be measured against clear goals. Where successful, results and the methods used to achieve them should be disseminated widely to other businesses and to public sector and nongovernmental agencies working in the TB arena. Strengthening stakeholders' responses to TB makes good business sense.

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#### **Key document**

- Public-private mix for TB care and control, a toolkit. Geneva: WHO; 2010.

## **2.3 Addressing social determinants and social protection**

### **2.3.1 Social protection mechanisms to support patients and families affected by TB**

#### **Strategy**

Despite rapid, unprecedented economic growth in the last few decades, poverty and vulnerability continue to affect the health and well-being of millions of people. Unexpected life events – including contracting infectious diseases – further deprive people the ability to work, negatively impact household financial capacity and pull families deeper into chronic poverty. Social protection, while widely recognized as a fundamental right, remains insufficient in many countries to safeguard the most vulnerable populations from falling into poverty due to health events.

TB disproportionately affects poor individuals and families who have the least capacity to cope. As such it is critical to extend the social protection scope and expand its population coverage to reduce the patient financial burden due to TB. The *End TB Strategy* expresses three main areas for expanding social protection:

1. 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;

2. legislation to protect people with TB from discrimination such as expulsion from workplaces, educational or health institutions, transport systems or housing; and
3. instruments to protect and promote human rights, including addressing stigma and discrimination, with special attention to gender, ethnicity and protection of vulnerable groups.

The first area, which can be regarded as the social protection floor, includes various national and subnational schemes to fulfil the right to social security. In 2012, the International Labour Conference almost unanimously adopted the Social Protection Floors Recommendation, 2012 (Box 11). The recommendation, together with key international instruments, has the potential to expand social protection in favour of patients and families affected by TB. The recommendation clearly states the need to ensure access to essential health care and basic income security for people who are unable to earn sufficient income, in particular in cases of sickness. NTPs might wish to use this recommendation to advance national dialogues with relevant ministries. The second and third areas also require effective policy dialogue and negotiations with national entities such as those in charge of labour, education and civil affairs policy (Section 2.3.2). Persistent, constant and long-term advocacy is fundamental to strengthening social protection. Empowerment and capacity-building of claim-holders – particularly patients and families affected by TB – and forming a wider societal coalition to fight the disease are critical to advocate sustainable social protection for patients and families in need.

**BOX 11. Social security for all: International Labour Organization’s Social Protection Floors Recommendation<sup>31</sup>**

In 2012, the International Labour Conference adopted a new international labour standard that provides guidance in building comprehensive social security systems and extending social security coverage by establishing national floors of social protection accessible to all in need. The standard aims to ensure that all members of society enjoy at least a basic level of social security throughout their lives by covering the unprotected, the poor and the most vulnerable, including workers in the informal economy and their families.

To ensure effective access to essential health care and basic income security throughout the life course, national social protection floors should comprise at least the following social security guarantees, as defined at the national level:

- access to essential health care, including maternity care;
- basic income security for children, providing access to nutrition, education, care and any other necessary goods and services;
- basic income security for people in economically active age groups who are unable to earn sufficient income, in particular in cases of sickness, unemployment, maternity and disability; and
- basic income security for older people.

31. Social Security for All: The ILO Social Protection Floors Recommendation. Briefing Note. Geneva: International Labour Organization; 2012.

Such guarantees should be provided through the most effective and efficient combination of benefits and schemes in the national context. Benefits may include child and family benefits, sickness and health-care benefits, maternity benefits, disability benefits, old-age benefits, survivor's benefits, unemployment benefits and employment guarantees, and employment injury benefits, as well as any other social benefits in cash or in kind. Schemes providing such benefits may include universal benefit schemes, social insurance schemes, social assistance schemes, negative income tax schemes, public employment schemes and employment support schemes.

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## Regional situation

NTPs have attempted to support TB patients through transportation subsidies, food packets or vouchers, and living subsidies with varying degrees of success. However, these were often project-based and relied on external funds especially under grants from the Global Fund to Fight AIDS, Tuberculosis and Malaria. While experiences in different support schemes for different target groups provide a good foundation to identify viable policy options, translating them into sustainable, scalable public policies is a challenge, especially with decreasing donor funding.

In this context, besides project-based approaches, it is important to explore ways to effectively link existing social protection schemes. The presence of social security schemes varies country by country and does not necessarily correspond with a country's income status. NTPs can be successful in negotiating with national authorities (e.g. welfare or labour ministries) to implement a scheme in a way that TB patients can benefit most.

### **BOX 12. Preferential inclusion of TB patients under a social assistance scheme in Fiji**

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In an effort to increase social protection for TB patients, Fiji's NTP successfully negotiated with the Ministry of Women, Children and Poverty Alleviation for preferential inclusion of needy or vulnerable TB patients in a generic social protection scheme.

To determine eligibility, a welfare worker conducts a needs assessment of the TB patient upon notification by the treating physician. The eligibility criteria include household income level and other vulnerability criteria such as single-parent status, homelessness and disabilities. Families with a child with TB have also been added as additional criteria to be considered. Support for TB patients consists of food vouchers and a monthly stipend for the duration of treatment. The level of support is largely determined by the assessment of the welfare officer, but recommendations by the NTP are also taken into account.

There are many examples of enabler schemes for TB patients in the Region, but this example is unique and valuable in the sense that the NTP successfully negotiated with a non-health ministry to expand the scope of a generic social protection scheme to include TB patients.

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## PROPOSED ACTIONS

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### ■ Proposed actions for all settings

1. Review country experiences in strategies to reduce patient financial burden – e.g. enabler schemes such as transportation subsidies, food packets or vouchers, conditional cash transfers and access to microfinance opportunities – in terms of effectiveness, efficiency and sustainability.
2. Define critical and effective intervention packages (enablers) for specific target groups that could be continuously implemented or expanded. For each intervention package, determine the implementing entity (e.g. NTP, subnational governments, nongovernmental organizations and partners), funding sources and funding mechanisms (this process can be included in the steps in Section 2.1.2).
3. Explore and review social protection schemes that could be utilized to support TB patients. Consider practical arrangements for the smooth application of such schemes for TB patients such as a referral system between health and welfare offices, integrated (one-stop) service delivery points and inclusion of TB in criteria for the welfare scheme assessment (Box 12).
4. Where possible, NTPs can engage in discussions on the enhancement of national social protection floors (e.g. development, social welfare and labour ministries).

#### *Key document*

- Recommendations concerning national floors of social protection. 101st International Labour Conference session. Geneva: International Labour Organization; 2012.

## 2.3.2 Addressing poverty and social determinants by promoting the HiAP approach

### Strategy

Poverty is the greatest impediment to human development and is also one of the most powerful determinants of TB. Poverty, as well as low socioeconomic status in general, catalyses a number of risk factors for TB infection and disease development at the individual, group and community levels. Direct, downstream risk factors include

overcrowding, a high prevalence of tobacco exposure including second-hand smoke, abuse of drugs and alcohol, malnutrition, HIV, diabetes and other co-morbidities. Poor communities often share a number of indirect, upstream determinants, such as inequitable social structure, a low level of education, inadequate housing, high population mobility, high incidence of abuse and violence, poor availability and access to social and health services.<sup>32</sup>

The WHO guidelines, *Addressing poverty in TB control*, propose six actions: (a) identify the poor and vulnerable groups; (b) determine barriers to access TB services; (c) develop possible actions to overcome barriers; (d) consider actions to address special needs of specific populations; (e) explore additional resources; and (f) evaluate the impact of pro-poor measures.<sup>33</sup> Since this process has been further developed and embedded within the proposed actions for TB high-risk and vulnerable populations, it is sensible to develop pro-poor priority actions as part of a comprehensive national strategy for TB high-risk populations (Section 1.1.3).

HiAP is an approach to public policies across sectors that systematically takes into account the health implications of decisions, seeks synergies, and avoids harmful health impacts in order to improve population health and health equity.<sup>34</sup> Table 3 elaborates examples of social determinants and potential stakeholders to be engaged using the HiAP approach in the context of TB control.

The HiAP approach can be very powerful and effectively implemented when applied at the subnational level. The approach can also be applied to address TB in large urban settings that may require specific approaches (Box 13).

## Regional situation

Along with economic development, most countries in the Region have achieved the first MDG target of halving extreme poverty.<sup>35</sup> However, considering increased living costs and food prices, and vulnerability due to unexpected events, the number of poor and near-poor people has not been significantly reduced. In addition, income inequality has been increasing despite general economic growth.<sup>36</sup> In parallel with inequitable economic development leading to increasing social disparity, rapid urbanization is reinforcing the link between poverty and TB.

HiAP has been promoted within the Region with various degrees of penetration. NTPs are effectively employing multisectoral approaches to TB control according to

32. Lönnroth K, Jaramillo E, Williams B, Dye C, Raviglione M. Tuberculosis: the role of risk factors and social determinants. In: Equity, social determinants and public health programmes. Geneva: WHO; 2010.

33. Addressing poverty in TB control options for national TB control programmes. Geneva: WHO; 2005.

34. The 8th Global Conference on Health Promotion. The Helsinki Statement on Health in All Policies. 2012.

35. Extreme poverty is defined as earning less than US\$ 1.25 per day.

36. In most countries in Asia, income inequity, expressed as Gini coefficient, has increased compared to the 1995 level (Key indicators for Asia and Pacific 2014. Manila: Asian Development Bank; 2015).

the priorities guided by local TB epidemiology and context. In almost all countries in the Region, NTPs have been implementing several components included in Table 3. However, there may be a scope to systematically expand the HiAP approach to a wider range of stakeholders both at national and subnational levels.

**TABLE 3.** Examples of social determinants of TB and potential collaborative actions in different government sectors

Sector	Social determinants to be addressed and potential collaborative areas
• Social welfare	Pursuing overarching poverty reduction strategies and expanding social protection floors
• Development	Improving housing and living conditions while addressing health needs of families living under poor conditions
• Urban planning	Mapping risk factors, local social determinants and risk groups
• Local governments	Institutions for older people TB among homeless population
• Labour	Occupational risk-group management (screening, workplace-based services) Improving working conditions, employment protection and income compensation
• Agriculture, food and nutrition	Food insecurity and malnutrition
• Various departments within the health sector	Preventing direct risk factors for TB, including smoking and harmful use of alcohol and drugs Proper clinical care for co-morbidities that increase the risk of TB, such as diabetes
• Penitentiary (prison)	TB control in correctional and detention facilities
• Police	Illicit drug use
• Immigration	Addressing TB risk and specific needs of migrants Health education
• Education	Risk-group management Prevention and management of outbreaks

## PROPOSED ACTIONS

### ■ Proposed actions for all settings

1. Develop or update a strategy to address TB among the poor population as part of a comprehensive strategy to address TB among high-risk and vulnerable populations (Section 1.1.3).
2. Sensitize national and subnational TB control staff on the concept of HiAP, including purpose, rationale, principles and relevance, in the context of improving TB control and care.

3. **Employ the HiAP approach and proactively engage relevant stakeholders, including health authorities and policy-makers, at national and subnational levels.**
4. **Document and disseminate best practices aimed at TB control that promote HiAP and contribute to health equity as per resolution WHA67.12, Contributing to social and economic development: sustainable action across sectors to improve health and health equity.**

### ■ Proposed actions for setting-specific considerations

1. **Consider establishing a special approach to address TB in large cities where TB poses a significant challenge.**

#### **BOX 13. TB control in large cities – viable entry point for urban health**

TB incidence rates are often higher in urban areas than in rural areas especially in low-incidence settings. This is partly due to higher population density as well as the congregation of certain vulnerable groups. The rates of homelessness and drug and alcohol abuse are often highest in large cities. Migrants, both domestic and international, tend to settle in metropolitan areas and often live in crowded conditions. Health services may be more fragmented in urban areas, and real access, especially for vulnerable groups, may be worse than in rural areas. Urbanization may come along with widening social disparity and inequitable access to health services.

Despite these unfavourable factors, large cities can serve as an example of a robust, multisectoral response for mitigating health risks and promoting health, especially through the HiAP approach. Compared to the national government structure, city governments often have less complex governance and decision-making systems, resource allocation can be more flexible, and a less rigid vertical structure allows smoother multisectoral collaboration.

Consciously recognizing these opportunities, NTPs might explore the possibility of establishing a special approach to address urban TB in large cities where TB poses a significant challenge.<sup>37</sup> This can help NTPs mobilize additional resources and form a multisectoral partnership for TB control with strong ownership by local authorities. In addition, successful TB control in urban areas often contributes greatly to national-level progress as large cities often carry the highest disease burden. The benefit could be extended beyond TB. Success in TB control through the HiAP approach would persuade local authorities to increase political commitment for more comprehensive efforts towards better public health. TB control can be a viable entry point for promoting urban health through the HiAP approach.

37. Ohkado A, Williams G, Ishikawa N, Shimouchi A, Simon C. The management for tuberculosis control in Greater London in comparison with that in Osaka City: lessons for improvement of TB control management in Osaka City urban setting. *Health Policy*. 2005;73(1):104–23.



#### **BOX 14. Addressing TB control among homeless people in Osaka<sup>38,39</sup>**

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Osaka City, the third-largest city in Japan, has a consistently high TB case notification rate compared to the national average. The high notification rate has been partly attributable to the homeless population. In one district of the city, there are an estimated 15 000–20 000 homeless people with very low medical insurance coverage, accounting for about 80% of the district population. They are mostly daily-paid labourers living in small hostels, shelters and parks or on the streets. In the early 2000s, TB prevalence in the district was estimated at around 1000 per 100 000 population, which is substantially higher than some high-burden countries, with a high proportion of re-treatment cases.

Against this backdrop, Osaka City has strengthened TB control by mobilizing all relevant social sectors, bringing organizational change, policy enhancement, strengthened human resources and service delivery. Osaka City employed a centralized approach by building strong commitment from the local government. Through integration of the 24 ward-level TB programmes, the Osaka City Public Health Office was established in 1999 and took responsibility for the integrated TB programme for TB patients among homeless people within the city. A 10-year TB strategic plan with clear targets was launched in 2001. The main strategies included ensuring the standard treatment delivered through directly observed treatment (DOT) and regular monitoring of individual case management. During the same period, additional public health nurses were recruited and their roles were expanded to promote DOT and coordinate comprehensive services for TB patients including psychosocial and welfare support. The public health nurses were requested to interview patients within two weeks of notification to establish rapport. In addition to facility-based TB screening programmes, mobile TB screening was conducted monthly from 1973 to 2005, and weekly since 2006, by the Osaka City government.

As a result, all TB indicators in Osaka City have substantially improved. The number of TB cases dropped by 50% between 2000 and 2008, and the DOT implementation rate among homeless cases increased from 0% in 2001 to 61% in 2008. TB prevalence in the district declined from 1400 per 100 000 in 2000 to 653 per 100 000 in 2007. The proportion of re-treatment cases among homeless TB cases declined from 42.9% in 1997 to 27.4% in 2001, and to 15.1% in 2008, which further led to a successful reduction of MDR-TB.

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#### **Key document**

- Health in All Policies training manual. Geneva: WHO; 2015.

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38. Shimouchi A, Ohkado A, Matsumoto K, Komukai J, Yoshida H, Ishikawa N. Strengthened tuberculosis control programme and trend of multidrug-resistant tuberculosis rate in Osaka City, Japan. *West Pacific Surveill Response J.* 2013;4(1):4–10.

39. Tabuchi T, Takatorige T, Hirayama Y, Nakata N, Harihara S, Shimouchi A, et al. Tuberculosis infection among homeless persons and caregivers in a high-tuberculosis-prevalence area in Japan: a cross-sectional study. *BMC Infect Dis.* 2011;11:22.

## **PILLAR 3**

### **Intensified research and innovations**

#### **3.1 Enhancing TB research capacity for development, rapid uptake and optimum use of new interventions**

##### **Strategy**

Pillar 3 of the *End TB Strategy* calls for intensifying research and innovation. To reach the ambitious targets of the *End TB Strategy*, intensified research and development is required to better detect, treat and control TB. The strategy emphasizes the development of a point-of-care rapid diagnostic test, new drugs and regimens for the treatment of all forms of TB, better detection of and treatment for LTBI, and an effective vaccine against TB, including a post-exposure vaccine that prevents disease progression from LTBI.

Intensification of research needs to occur across the continuum that extends from basic research (to drive innovations for improved diagnostics, drugs and vaccines) to operational and health systems research (to improve programmatic performance and introduce novel strategies and interventions based on new tools).

To realize the massive increase in TB research activities and funding globally, it is critical to significantly increase research capacity in low- and middle-income countries that carry substantial TB burdens. Many middle-income countries are at a crossroads with research capacity rapidly increasing and the TB burden decreasing. Those countries have an opportunity now to increase their leadership in TB research and advance the TB research agenda with significant domestic investment and enhanced international collaboration.

The *Global Action Framework for Research Towards TB Elimination* proposes priority actions to promote and intensify research and innovation over the next 10 years. Specifically, the following actions are critical for countries to start operationalizing Pillar 3 of the *End TB Strategy*: (1) establishing mechanisms for collaboration such as a national TB research network; (2) developing an overarching multi-stakeholder plan such as a national TB research strategic plan; (3) establishing national TB research priorities; (4) building capacity of TB and health research human resources; and (5) increasing TB research funding through diversified funding sources.

As an initial step, countries can establish a national TB research network comprising stakeholders including researchers, public health officials and institutions, academic institutions, national and international technical partners and funders, and relevant

government entities. Such a network is critical for NTPs to promote TB research – from basic scientific research to programmatic operational research. An open collaborative venue would further attract external funders and technical partners.

A national TB research strategic plan can be developed as a stand-alone, multi-stakeholder plan, or as an integral part of the NSP. In either case, a clear monitoring framework with measurable indicators and targets would be an important component to facilitate effective implementation.

Setting national TB research priorities (national TB research agenda) is important to align all partners' efforts, avoid duplication and mobilize resources for TB research. The national TB research priorities should be developed in collaboration with all partners in the national research network, while maintaining the appropriate balance between types and broad topics of research. They should be periodically updated as a living document and fed into the update of the national TB research strategic plan.

Although long-term efforts have been made in capacity-building for TB research capacity, few NTPs have sufficient human resource capacity for TB research in both quality and quantity. More strategic planning and investment should be aimed at building a critical mass from highly qualified research/surveillance officers at the central level to TB control staff with good operational research capabilities at subnational levels. A plan for developing human resources for research should be an integral part of the national TB research strategic plan. Links with other opportunities should also be explored and incorporated, such as field epidemiology training programmes and postgraduate training programmes.

Health research is often underfunded, which poses a significant bottleneck in increasing health research activities and strengthening capacity. All of the aforementioned actions, especially with a comprehensive research strategic plan, including an effective collaborative mechanism, unified research priorities and a strategic capacity-building plan, would attract funding from both domestic and international sources. While allocating an appropriate proportion of NTP funding to operational research continues to be important, the focus should be on mobilizing more resources for TB research activities.

## Regional situation

There has been a substantial increase in TB research capacity among NTPs in the Region in the past several years especially in programmatic operational research. WHO established a TB operational research grant scheme in 2011 and since then has supported a number of critical operational research studies in many countries in the Region. Other partners are also actively engaged in TB research activities and strengthening in-country capacity to design and implement study projects, as well as to analyse and publish findings. As a result, outcomes are visible: the number of

published TB research studies from the Region has significantly increased; many NTPs are periodically conducting in-depth analysis of surveillance data; country-based evidence from operational research studies were translated into national TB control policies and also used as supporting evidence for the NSPs and applications to the Global Fund to Fight AIDS, Tuberculosis and Malaria; and many NTPs include capable epidemiologists and/or statisticians. These NTP staff members are key in analysing critical programmatic and survey data, for example from national prevalence surveys.

However, national TB research capacity is still insufficient. The number of researchers and availability of expertise have not reached a “critical mass” in most countries. The continuous development, availability and introduction of new tools and technologies in the coming decade are likely to increase the demand on TB research. As such, efforts to strengthen national research capacity must be enhanced with a much wider engagement of domestic and international partners.

The *End TB Strategy* proposes a paradigm shift in TB research. NTPs are encouraged to progressively promote TB research in countries beyond programmatic operational research and contribute to the global evidence base for research and development. A radical boost in global TB research will only be possible when all countries – including low- and middle-income countries with substantial TB burdens – form national movements in TB research promotion.

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## PROPOSED ACTIONS

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### ■ Proposed actions for all settings

1. Establish or expand mechanisms for collaboration, such as a national TB research network with the public health sector, academia, nongovernmental organizations, advocacy groups, technical partners and donors.
2. Develop an overarching multi-stakeholder plan, such as a national TB research strategic plan.
3. Establish national TB research priorities (national research agenda).
4. Plan and implement strategic capacity-building activities to increase human resources for TB and health research.
5. Increase TB research funding through diversified funding sources.

## ■ Proposed actions towards elimination

1. Increase international collaboration for TB research, particularly strengthening technical and financial support to low- and middle-income countries with a higher TB burden.

### *Key documents*

- Priorities in operational research to improve tuberculosis care and control. Geneva: WHO; 2011.
- Global Action Framework for Research Towards TB Elimination. Geneva: WHO; 2015.

### **BOX 15. VICTORY centre: spearheading lung disease research in Viet Nam**

The National Lung Hospital in Viet Nam has an impressive portfolio of basic, epidemiological, operational and clinical research in lung cancer, TB, ART, chronic obstructive pulmonary disease and other lung diseases. The number of research staff has increased over the years with strong support from the management board. The quality of research continues to improve and the number of network collaborators from civil society and national and international partners continues to increase.

Building on this foundation, the Ministry of Health decided to establish the Viet Nam Integrated Centre for TB and Lung Disease Research (VICTORY) to take the lead in implementing and coordinating TB and lung disease research under the management and orientation of the National Lung Hospital and the NTP. The centre aims to respond to the research aspirations set forth in Pillar 3 of the *End TB Strategy* and also to fulfil the Government's development-oriented science priorities. Research is a key component of the NSP up to 2020 and the vision for TB control up to 2030.

The mission of VICTORY is to implement science and technology activities, develop a network of researchers working on TB and lung disease, enhance the capacity of researchers and optimize science and technology applications into practice, optimize international mobilization, and contribute to international collaboration and cooperation. Additional responsibilities include maintaining an online database for researchers to access research results and inform the development of the research strategy, implementing research projects on lung diseases and providing training to strengthen capacity of researchers within the network.

While the centre is part of the National Lung Hospital and reports to the hospital director, it is designated as a non-profit organization and has independent financial management. In this way, the centre can mobilize resources and utilize them with a greater degree of autonomy.

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