A PEOPLE-CENTRED MODEL OF TB CARE

Blueprint for EECA countries, first edition
This document builds on the framework of the TB-REP Project to support Member States in the Eastern Europe and Central Asia region to: adopt policy options and implement effective and efficient TB service delivery systems; shift towards out-patient, people centred models of care with sustainable financing and well-aligned payment mechanisms; and achieve better health outcomes in TB prevention and care.
A people-centred model of tuberculosis care

A blueprint for eastern European and central Asian countries, first edition
ABSTRACT

This blueprint builds on the framework of the Tuberculosis Regional Eastern Europe and Central Asia Project (TB-REP) on Strengthening Health Systems for Effective Tuberculosis and Drug-Resistant Tuberculosis Control, financed by the Global Fund to Fight AIDS, Tuberculosis and Malaria. It aims to support countries in the region in adopting policy options and implementing effective and efficient tuberculosis service delivery systems; shifting towards outpatient, people-centred models of care with sustainable financing and well aligned payment mechanisms; and achieving better health outcomes in tuberculosis prevention and care.
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ACKNOWLEDGEMENTS

This blueprint of a people-centred model of tuberculosis (TB) care for countries in eastern Europe and central Asia was produced by technical partners of the TB Regional Eastern Europe and Central Asia Project (TB-REP) on Strengthening Health Systems for Effective TB and Drug-Resistant TB Control, financed by the Global Fund to Fight AIDS, Tuberculosis and Malaria. These include the London School of Hygiene and Tropical Medicine, London School of Economics and Political Science and European Respiratory Society, in collaboration with the WHO Regional Office for Europe, the Center for Health Policies and Studies and the Global Fund to Fight AIDS, Tuberculosis and Malaria, as well as the Alliance for Public Health, Stop TB Partnership and TB Europe Coalition.

The activity was made possible with funding provided by the Global Fund to Fight AIDS, Tuberculosis and Malaria through the TB-REP grant on Strengthening Health Systems for Effective TB and Drug-resistant TB Control. The authors’ views expressed in this publication do not necessarily reflect the views of the Global Fund, TB-REP or other partners of the TB-REP project.

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Disclaimer: despite all efforts, this publication may include inaccuracies and incompleteness. Statements are not meant to deal with an individual patient’s clinical management but provide policy options to improve a people-centred model of tuberculosis care. Comments and suggestions for improvements may be addressed to eurotbrep@who.int.

ABBREVIATIONS

ALOS average length of stay
BOR bed occupancy rate
DOT directly observed therapy
DR-TB drug-resistant tuberculosis
DST drug-susceptibility testing
EECA eastern Europe and central Asia
FLD first-line drug
FQ fluoroquinolones
FTE full-time equivalent
INJ injectables
MDR-TB multidrug-resistant tuberculosis
PDR polydrug-resistant tuberculosis
R rifampicin
RR-TB rifampicin-resistant tuberculosis
SLD second-line drugs
TB tuberculosis
TB-REP Tuberculosis Regional Eastern Europe and Central Asia Project [on Strengthening Health Systems for Effective Tuberculosis and Drug-Resistant Tuberculosis Control, financed by the Global Fund to Fight AIDS, Tuberculosis and Malaria]
VOT video-observed therapy
XDR-TB extensively drug-resistant tuberculosis
Xpert MTB/RIF automated real-time nucleic acid amplification technology for rapid and simultaneous detection of TB and rifampicin resistance
SUMMARY AND PRINCIPLES

This blueprint has been developed to support policy-makers and stakeholders responsible for developing and implementing health policy in countries in eastern Europe and central Asia (EECA). It aims to inform discussion and support an initial effort to shift the prevention, treatment and management of tuberculosis (TB) to outpatient settings, using a people-centred approach.

In an effort to inform as many stakeholders as possible, this publication avoids an overly technical perspective and instead takes a broader view. It is organized into a series of chapters that set out the background and context of the blueprint, including the emergence and persistence of drug-resistant TB (DR-TB) in the WHO European Region; the rationale for and importance of people-centred TB care; the design of a TB patient’s care pathway; the suggested model of TB care to achieve this; changes suggested to align this model with other health-system building blocks – health financing mechanisms, models of service delivery and human resources for health planning – to initiate reform of the overall model of TB care; and how to lead change and innovation.

The guidance in this blueprint and the planned development of subsequent technical documents aim to provide improved treatment outcomes that take into account not only epidemiological perspectives but also the possible contribution of social support, sustainable payment mechanisms, human resources for health and equity of access to high-quality medicines and technologies.

In addition, to create supportive and enabling environment for change, initiation of the policy options listed below is recommended.

For populations and individuals, suggested policies include:

- mapping the support needed from the community level and patients’ organizations as service providers to overcome sectoral boundaries and enable a people-centred approach;
- supporting the development of community health, including motivating and engaging people to organize themselves and work together to identify their own health needs and aspirations;
- supporting patient self-management and shared decision-making.

For service delivery processes, suggested policies include:

- conducting a rapid assessment or situation analysis of the current status of the model of TB care (TB service delivery in ambulatory and hospital care, including current national treatment guidance and policies) to inform development of a new model or improvement of the existing one, using the detailed guidance in this blueprint;
- revising the basic terms and definitions of the settings and facilities for TB service delivery to ensure consistency with national and international standards;
- defining and developing appropriate technical documents (clinical guidelines, hospitalization criteria and similar) for TB-related services;
- setting competencies, tasks and standards of care for the health workforce and standardizing practice using instruments such as clinical guidelines and protocols;
introducing new and/or reprofiling current settings of service delivery to correspond to the people-centred model of TB care and designing care pathways – including transitions, referrals and counter-referrals – to map optimal routes for patients according to their individual needs to maximize coordination and avoid duplication.

For **health system processes** suggested policies include:

- developing and including the new model of TB care concept in the overall health system reform agenda to tap into synergies and avoid conflicting messages and outcomes;
- linking provider payment mechanisms to performance improvements based on the model of TB care, including quality and integration;
- ensuring that clinical practice guidelines promote optimal provision of high-quality and affordable medicines;
- moving defined TB services from inpatient to outpatient care and ambulatory settings;
- adopting a framework of task shifting, which could be part of patient care pathway protocols;
- creating a system of lifelong learning to ensure that the workforce is equipped with the skills necessary for a people-centred model of TB care;
- transforming medical education to merge the TB specialty in pre-service and graduate institutions with the pulmonology/infectious disease specialty to allow a strategic shift from narrow disease-minded education to broader integrated people-oriented education.

For **change management processes**, suggested policies include:

- developing a planned approach to promote system-wide changes and to unify actions within a common vision and direction for the future, aiming for early wins to ensure sustainability;
- implementing pilots or demonstration cases to test ideas and establish transformations, using a bottom-up approach to ensure context-specific solutions.

To meet the diverse country contexts across the EECA region, adaptations of the guidance and suggested policy options in this blueprint may be needed. These can be facilitated by WHO and its network of partners through regulatory impact assessments, roadmaps and guidance development, and through advocacy for change at all levels, based on defined priority areas for action to build integrated health services delivery.
BACKGROUND AND CONTEXT OF THE BLUEPRINT

Despite notable progress in the past decade, TB is still a public health concern in the WHO European Region, which bears the brunt of multidrug-resistant TB (MDR-TB), with rates more than twice as high as those in any other WHO region in both new and previously treated patient cohorts. Of the 30 countries considered to have a high burden of MDR-TB globally, nine are in the WHO European Region (1).

The emergence and persistence of DR-TB is a direct consequence of failings in the health care system. In particular, it is the result of gaps between different parts of the system – notably between the health and prison sectors – and of a lack of adequate infrastructure such as laboratory facilities and challenges in ensuring continued access to appropriate, high-quality anti-TB medicines. These challenges, when further complicated by weak psychosocial support systems result in the delivery of inappropriate or interrupted treatment, especially for those who are most vulnerable.

Many EECA countries are changing health systems from vertical models – where interventions were largely delivered by hospitals – to more coordinated models, with strengthened primary health care. This transition, however, requires mechanisms to overcome the legacy of fragmented governance structures, finance systems that often create a set of perverse incentives, outdated service delivery approaches, weak infrastructure and inequitable distribution of staff, notably in rural areas. Additional factors contributing to challenges in service delivery include low motivation among health workers and relatively few incentives to encourage skills development (2–19).

The emergence of MDR-TB and extensively DR-TB (XDR-TB) imposes a burden on health systems. The management of MDR- and XDR-TB is complex, lengthy and costly. Moving towards models of care that can treat these strains of TB effectively requires mechanisms that support multidisciplinary models of care, acceptance of people-centred practices, cooperation between different care providers, enhanced clinical skills and high levels of staff motivation, none of which have traditionally characterized health systems in the EECA region.

Psychosocial support is often needed in order for patients to adhere to treatment. It includes both psychological support such as counselling sessions or peer-group support and material support that addresses indirect costs incurred by patients in accessing health services. This might be in the form of financial assistance such as bonuses, transport subsidies, housing incentives or living allowances, or food assistance such as meals, food baskets, food supplements or food vouchers.
Psychosocial support is of the utmost importance in addressing the many inextricably linked complexities of the social disease TB. Such support will ultimately contribute to improving TB treatment outcomes, as it helps to keep the patient on adequate treatment through improved adherence. Family members, civil society and nongovernmental organizations and community members are key conductors of psychosocial support.

The WHO Regional Office for Europe actively supports a comprehensive multicomponent approach to strengthening health systems that aims to bring significant and rapid improvements to TB prevention and care. This approach is aligned with United Nations Sustainable Development Goal 3, which includes targets to move towards universal health coverage and end the TB epidemic (20). It is further aligned with a number of key frameworks and strategies in the European Region, including Health 2020, the European policy for health and well-being (21), the Tuberculosis action plan for the WHO European Region 2016–2020 (22), and WHO’s priorities for health system strengthening in the WHO European Region 2015–2020 (23).

In efforts to promote this approach and respond to the regional challenges described above, the TB Regional Eastern Europe and Central Asia Project (TB-REP) on Strengthening Health Systems for Effective TB and DR-TB Control, financed by the Global Fund to Fight AIDS, Tuberculosis and Malaria, has been implemented in 11 EECA countries (Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan). The overall goal of TB-REP is to reduce the burden of TB and halt the spread of drug resistance by increasing political commitment and translating evidence into implementation of a people-centred model of TB care.

This blueprint, developed within the TB-REP framework, proposes a set of policy options to support countries in implementing this model. It aims to shift treatment to outpatient settings, supported by sustainable financing and payment mechanisms designed to achieve better health outcomes in TB prevention and care (24). To make sustainable and meaningful changes with better health outcomes, countries implementing this blueprint need to consider how to transform care to be more people-centred. The blueprint and the model of care it describes have been informed by:

- countries’ experiences and examples of good practice;
- lessons learnt by partners;
- national and international guidelines;
- available evidence;
- expert opinion, including input from the TB-REP Scientific Working Group and relevant civil society organizations.
THE RATIONALE FOR AND IMPORTANCE OF PEOPLE-CENTRED TB CARE

Member States in the WHO European Region share a commitment to strengthen health systems for health and development and recognize the importance of moving towards people-centred health systems (21; 25–37).

People-centred care is focused on and organized around the health needs and expectations of people and communities rather than on patients or diseases (25).

The European Framework for Action on Integrated Health Services Delivery (38) is structured around four domains (Fig. 1), each of which contains a number of actions to transform health service delivery towards people-centrness:

- **populations and individuals** – to work in partnership with populations and individuals, including patients, family members, caregivers and members of communities, civil society and special interest groups; to identify health needs; to support health-promoting behaviours; and to strengthen skills and resources that will allow people to take control of their own health, while also working to tackle the determinants of health and improve health across the life-course;
- **services delivery processes** – to ensure that new models of care are matched by the ability to implement them and are aligned with the needs of those populations and individuals they aim to serve;
- **system enablers** – to align the contributions of other health system functions, including governing, financing and generating resources, to support improved service delivery;
- **change management** – to manage the process of change, setting a clear direction, developing and engaging partners and piloting innovations to ensure transformations are tailored to the needs of the population and sustained over time.
This approach is complemented by the concept of people-centred models of care, which focuses on meeting the health needs and expectations of people throughout the life-course. It aims to balance the rights and needs of patients with their responsibilities and capacity as stakeholders in the health system (23).

The natural history of TB (a social disease requiring many months of treatment), including its risk factors and underlying determinants, make it appropriate for an approach based on people-centred programmes and policies. The journey taken by a patient – from diagnosis to treatment and ultimately to cure – can benefit significantly from a people-centred approach (37).

For this to happen, the management of TB needs to shift from a hospital-dominated model, where management takes place largely in isolation from the primary care system and the wider community, to one embedded within communities and led by the primary care system (39–46). In this way care is nearer and more accessible to the people it serves, meaning that it is more likely to be used and to benefit patients. This requires the preventive, ambulatory, community and home care sectors to enhance their capacity to plan, implement and monitor integrated models of care. Further, hospitals need to be reconsidered as one of many links in a health service delivery network, where patients move seamlessly between different settings based on their needs. Within this network, the role of hospitals is limited to delivering specialized care for those with particularly complex cases.

Nevertheless, reorienting TB care is only possible by strengthening care in the community, developing appropriate outreach services for hard-to-reach populations and, where appropriate, providing care through mobile facilities and in patients’ homes.
Community and ambulatory management of TB care and prevention is associated with non-inferior health outcomes compared to hospital and inpatient management (in terms of diagnostic delay, treatment compliance and outcomes), reduced risk of infection transmission and reduced costs of care both for TB and MDR-TB (39–42). The accumulated evidence supports WHO’s recommendations to provide TB care mainly in the ambulatory and community settings, conditional on infection control measures, patients’ clinical conditions, availability of treatment support to facilitate adherence to treatment and provisions for a back-up facility to manage patients who need inpatient treatment care (39, 47, 48). Decentralizing care and redirecting resources from hospital-based care to ambulatory-based services may enable health services to reduce costs, expand capacity and provide high-quality patient-centred care (40). Countries are advised to reinvest savings from reduced hospitalization in TB control within national TB programmes – for instance, in material, nutritional and social support for TB patients (40). In addition to non-inferior health outcomes and efficiencies, a people-centered model of TB care aims to ensure quality of clinical services, improve patient and provider satisfaction and strengthen airborne infection control, which leads to improved treatment adherence, timely and full cures and more efficient use of resources.
The appropriate model of care is one that ensures that TB patients get the right care, at the right time, by the right team and in the right place, taking account of the prevailing conditions in each setting (49). A people-centred model of TB care was defined by the TB-REP Scientific Working Group as “an efficient and integrated set of affordable, accessible and acceptable health services, provided in a supportive environment to prevent, diagnose and treat TB”.

In most EECA countries the current model of TB care was inherited from health systems that were heavily reliant on inpatient care, in which patients with TB were isolated from the community, allowing the passage of time to enable them to recover. These models were developed and implemented at a time when effective anti-TB drug regimens were not available and MDR-TB did not exist. Care was therefore provided in specialized facilities and delivered by TB specialists. Many of these hospitals remain in poor condition, with inadequate mechanisms for infection control, thereby increasing the risk of nosocomial transmission and thus transmission of TB and M/XDR-TB (25, 49–50).

A model of care must be tailored to the particular circumstances of each country. Furthermore, it is critical to take into consideration the “journey” of the patient with TB through a series of interlinked settings and facilities (50). In this context, development of a people-centred model of TB care redefines TB as a condition best managed in ambulatory care, where case managers work through specialized units in the community to coordinate the activities of all providers, in both primary and secondary care.

A people-centred model of TB care should be designed to ensure that:

- services meet patients’ and their families’ needs and expectations;
- social determinants of health are taken into consideration;
- services, tasks and responsibilities are defined for each setting and within different facilities, while recognizing the need for flexibility to respond to the needs of individual patients;
- well functioning systems for referral are in place across various settings and facilities;
- the model of care is acceptable to service users;
- a robust data-reporting system is in place to monitor performance, including diagnostic delay and loss to follow-up;
- patients and their families are protected from catastrophic financial expenses.
Although these principles have been established for many years, they have been difficult to implement due to a number of misconceptions held by several stakeholder groups. These include the myths that:

- all TB patients are infectious irrespective of their treatment stage;
- patients with TB cannot contribute to the community (i.e. they are unable to work);
- hospitalization of patients with TB is necessary to ensure adherence to treatment and infection control.

Despite these notions having been proven false time and again, many communities have sustained resistance to the shift towards outpatient treatment (51). In fact, it should be noted that hospitalization constitutes a barrier to treatment by limiting patients’ freedom to engage with their regular activities. It also increases the risk of reinfection, should the patient be exposed to newly admitted or late sputum converters.

Any delay in treatment initiation increases the possibility of transmission and of losing patients to follow-up. Consequently, a high level of awareness of TB among the population and health care professionals is essential if patients with symptoms suggestive of TB are to be identified and referred rapidly to specialized outpatient services. All patients with such symptoms should be referred to a specialized team that can perform a clinical evaluation, including collection of relevant samples for laboratory testing, as well as drug sensitivity testing. In some cases, when health workers may not have access to adequate laboratory facilities, an efficient logistics system for sample transportation and result communication should be in place. Patients should not be required to travel long distances to access services.

Early diagnosis, contact tracing and continuous uninterrupted treatment to completion, supported by patient-assistive and -supportive treatment observation (to reduce the risk of developing drug resistance) are all important and inextricably linked programmatic elements required to achieve satisfactory treatment outcomes. Patients with TB should receive daily patient-assistive and -supportive treatment observation, such as through directly observed therapy (DOT)\(^1\) or video-observed therapy (VOT), whether at home or in another adequate ambulatory facility (53). This should be accompanied by appropriate infection control measures, including prophylaxis for cohabitants when delivered in the home. Following the intensive phase, treatment observation can be implemented according to the patient’s circumstances (such as at the workplace, school, health post, primary care centre, drug/alcohol addiction treatment centre or outreach programme). It is critical to fostering treatment adherence and success that whenever possible patients are fully integrated into the community and their routine lives, enabling them to engage normally with the environment they are accustomed to. To encourage this, the regulatory and legislative framework in the countries should allow for the attendance of individuals on efficient TB treatment of school, work or pre-school institutions. Further, staff working with individuals with TB – notably those from civil society organizations – should do their best to campaign against social stigma within the community to further this integration.

Initiation of treatment based on a presumptive diagnosis may be considered in rare cases, when accompanied by an appropriate clinical evaluation. In all cases, however, the diagnosis should be confirmed subsequently by a laboratory. The clinical diagnosis will frequently be correct, and the infecting pathogen will be susceptible to first-line drugs. This will avoid any delay in initiation of patient-assistive and -supportive treatment observation, psychosocial support and contact tracing. If the initial diagnosis is not confirmed, treatment and other related measures should be stopped immediately. Where the pathogen is found to be resistant to

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1 With DOT, a carer meets a TB patient regularly. The patient takes the anti-TB drugs while the health care worker watches. The carer additionally asks the patient about any potential side effects or problems with anti-TB drugs and or TB treatment. It should be carried out at a time and place convenient for the patient (52).
first-line medicines, there is a need for reassessment, with modification of treatment and other supporting measures.

Hospitalization should be considered when the condition of the patient aligns with suggested guidance on hospitalization criteria (see Annex 1). It should last for as short period as possible, limited to the time needed to stabilize the patient and optimize treatment.

Fig. 2 sets out an illustration of a possible patient pathway.

**Fig. 2. Graphical illustration of a possible patient pathway**

Civil society organizations play an important role in ensuring that TB care is people-centred. They can support patients in continuing their treatment, thus improving treatment adherence and outcomes, and play a vital role in other important areas such as creating and maintaining public awareness of TB, destigmatizing patients and strengthening community involvement in treatment and care. They also play an important role in providing psychosocial support to patients and their families. One model, which has been found to foster civil society organization involvement, is social contracting. This helps civil society organizations to be more sustainably involved in providing some TB services, using state or other funding sources, with their advantage of generally being “nearer” to the people and their families suffering from TB. Such organizations have contributed to TB prevention and care in the WHO European Region in several different countries and settings. They thus constitute a beneficial and integral component of the TB continuum of care.
A PEOPLE-CENTRED MODEL OF TB CARE FOR THE EECA REGION

A people-centred model (see the section on design of a TB patient’s care pathway for the a definition) seeks to support patients as they progress through the care pathway. It is based on the best available evidence and knowledge of good practices in the delivery of prevention, detection and diagnosis, treatment and support services. Due to the complexity of TB care, the model outlined in this blueprint also considers integration and coordination with other sectors, and across services and settings of care, such as prisons.

Application of the people-centred model of TB care for each of these services, as well as its role in integrating and coordinating care, is detailed below. It is important to consider, however, that the model can and should be adjusted to suit the individual needs and capacity of each country.

Table 1 sets out the various components of a model of TB care; the following text is structured to provide details of the services provided in various settings and facilities and by which health workforce.
### Table 1. Components of a model of TB care

<table>
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<th>Setting</th>
<th>Facilities</th>
<th>Type of care</th>
<th>Services</th>
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<tr>
<td>Ambulatory</td>
<td>Health post&lt;br&gt;Primary care centre (rural)&lt;br&gt;Primary care centre (urban, district, oblast/region)&lt;br&gt;Specialized outpatient unit&lt;br&gt;Day care centre&lt;br&gt;Mobile units&lt;br&gt;Co-located facilities&lt;sup&gt;a&lt;/sup&gt;&lt;br&gt;Diagnostic centre</td>
<td>Prevention (promotion and protection)</td>
<td>Health promotion and education&lt;br&gt;Immunization&lt;br&gt;Latent TB infection screening&lt;br&gt;Latent TB infection prescription&lt;br&gt;Latent TB infection administration</td>
</tr>
<tr>
<td>Community</td>
<td>Community sites (nongovernmental organization, community-based organization etc.)&lt;br&gt;Mobile units</td>
<td>Detection and diagnosis</td>
<td>Active case finding&lt;br&gt;Passive case finding&lt;br&gt;Referral&lt;br&gt;Clinical evaluation TB&lt;br&gt;Lab, X-ray and others as needed</td>
</tr>
<tr>
<td>Home</td>
<td>Home</td>
<td>Treatment and support</td>
<td>Treatment initiation&lt;br&gt;Treatment administration and observation&lt;br&gt;Monitoring treatment progress and response&lt;br&gt;Prevention and detection of adverse events and comorbidities&lt;br&gt;Diagnosis and treatment of adverse events and comorbidities&lt;br&gt;Treatment lab monitoring&lt;br&gt;Counselling and psychological support&lt;br&gt;Social support</td>
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<tr>
<td>Inpatient</td>
<td>TB hospital&lt;br&gt;General hospital with TB beds&lt;br&gt;Tertiary hospital&lt;br&gt;Prison hospital</td>
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### Health workforce

| Medical doctors: generalists and specialists | Mid-level health professionals: nurses, feldshers, doctors' assistants and laboratory staff | Non-medical professionals: psychosocial workers, psychologists, nutritionists, etc. | Patient supporters: community health workers, volunteers, treatment supporters, and family members | Health management and support: administrative staff, management accountants, lawyers, drivers and cleaners |

<sup>a</sup> Co-located facilities are those where multiple providers, often specialists, are housed in one location to deliver health services – for example, an endocrinology service in a TB clinic or treatment for TB and HIV.
PREVENTION
Prevention services for TB include immunization, health promotion, patient education and latent TB infection management. Immunizations are delivered at birth in neonatal facilities and primary care centres by mid-level health professionals, generalists and specialists, as per current WHO recommendations (58).

Health promotion and primary prevention services include (but are not limited to) awareness-raisings and social mobilization activities. They can be delivered in different facilities, such as public health or primary care centres and civil society or community-based organizations. Health promotion and disease prevention services can be delivered by various different actors, such as mid-level medical professionals, non-health professionals and patient supporters.

Education on TB is delivered in all settings across the health system by appropriately trained workers, informing people about the relevant elements of TB in a way that can be understood by the specific audience (patients, their families and so on). Patient education can be provided in community and home care settings, where medical and non-medical professionals can help to reduce the stigma surrounding TB treatment and in doing so contribute to improved patient adherence. In addition, community-based organizations – if mandated by the national TB programme and appropriate authorities – can provide complementary patient education.

Screening and management of latent TB infection constitute an important element of disease prevention, depending on the level of the TB epidemic. It is generally not deemed a priority measure for high-incidence countries, and should be considered on a case-by-case basis. Appropriately trained people can also undertake activities such as screening for latent TB in ambulatory settings, as well as managing it and, importantly, offering support to individuals undergoing active TB treatment (59).

DETECTION AND DIAGNOSIS
TB detection, namely active and passive case-finding, normally takes place in ambulatory settings (58–63). Primary care providers – including medical generalists in primary care centres in both rural and urban settings, medical specialists in specialized outpatient units and generalists in mobile units and co-located facilities – are responsible for most passive case finding and for carrying out TB symptom screening and initial clinical evaluation.

A high level of awareness, as well as the capacity to detect TB, should exist in any setting where the disease burden is high, such as centres for narcology and endocrinology (regarding diabetes care), HIV centres and others.

Active case finding includes systematic screening of high-risk and vulnerable populations with limited or no access to health services (such as people who inject drugs, homeless people, people living with HIV, migrants, people in detention, displaced populations, refugees and children, as outlined in the WHO global End TB strategy and the regional TB action plan for 2016–2020 (54, 64) and determined by countries) and contact investigation (as well as investigation of source cases, potentially). It should be undertaken in ambulatory, community and home settings or in primary care facilities, specialized outpatient units, public health centres, mobile units and co-located facilities by generalists, medical mid-level health professionals, public health professionals and patients’ supporters (community workers, volunteers, treatment supporters, peers and family members).
TB diagnosis, including clinical evaluation, X-ray and drug-susceptibility testing (DST) through microscopy and molecular methods (65–66), is performed in ambulatory settings in specialized outpatient units by specialist physicians or by primary care physicians and generalists, provided they are certified and appropriately trained, in primary care facilities. Inpatient–based specialists are not supposed to conduct diagnosis but rather to receive patients who have already received a TB diagnosis.

TB diagnosis should be the moment to conduct a thorough assessment of the most prevalent comorbidities (including liver diseases, HIV, diabetes, mental health disorders and alcohol and drug use) and to consider potential social determinants and vulnerabilities (such as diabetes, drug and alcohol abuse, undernutrition and tobacco smoking) (67–68). Taking account of these conditions and determinants known to affect treatment outcomes allows providers to identify the best setting of care (according to criteria defined in Annex 1) and any additional services that can support an optimal outcome for every patient.

**TREATMENT AND SUPPORT**

In the people-centred model of TB care, specialized outpatient units (as part of general or TB hospitals, primary care or standalone facilities) may coordinate TB treatment and support; carry out monitoring of responses to treatment and treatment compliance; and plan, implement and evaluate adherence support interventions (46, 69).

It is advised that treatment initiation be carried out in identified ambulatory facilities of urban and rural primary care centres, specialized outpatient units, mobile units and co-located facilities by specialists and generalists (provided they have received appropriate training and national certification) in accordance with WHO policy guidance. The focus should be that the facility and provider are able to start treatment as soon as possible, as any delay in initiating treatment increases the chances of further transmission and loss to follow-up.

Any patients with complex forms of TB who meet criteria for hospitalization should be admitted and treated by specialists in general hospitals, using TB beds, TB hospitals and tertiary hospitals (see Annex 1). A bed forecasting tool exercise for planning inpatient care capacities based on disease resistance profile hospitalization criteria is presented in Annex 2.

Treatment regimens should follow national and international guidelines. Countries are advised to develop a people-centred approach to treatment for all TB and M/XDR-TB patients to promote adherence, improve quality of life and relieve suffering (46, 70–71). Countries are advised to incorporate these services into an individualized and people-centred plan of clinical care that includes assessment of and referral to treatment of other illnesses, as well as ongoing case management and coordination with appropriate non-medical services (as needed by the patient).

Treatment support and management include patient-assisting and -supportive treatment observation, such as through DOT or VOT, and interventions to increase adherence and limit loss to follow-up. These may include:

- social support to TB patients and their households;
- psychological support, counselling and health education;
- ensuring trusting relationships between the health workforce, patients and families;
- complying with professional ethics, deontology and confidentiality;
- material support (such as food, financial incentives and transport fees);
- so-called “tracers”, such as home visits, digital health communications (for example, text messages or telephone calls);
- digital medication monitors (72–73).

VOT can be an alternative to DOT when the video communication technology is available and can be appropriately organized and operated by health care providers and patients, including in a decentralized way (69).

Of crucial importance under the ambulatory-oriented and people-centred model of TB care is case management of patients and systematic coordination with other ambulatory, community and home facilities and their associated workforces. This allows patients – based on their specific assessed needs – the flexibility to travel from home and receive medicines under direct observation at specialized outpatient units, or for some patients to receive care from non-clinical non-professionals’ action in community or home-based settings. In determining where patients should receive care, their risk of non-compliance and any ongoing clinical or social concerns (such as homelessness, substance use or mental health and addiction issues) should be taken into consideration. This process of considering social determinants of health and their impact on patients can significantly improve the probability of successful treatment adherences (74–75) and, as a result, improved outcomes and reduced patient suffering. While some of this can be accomplished by non-medical professionals and mid-level health professionals, civil society organizations are well positioned to support this additional perspective and should therefore be closely involved in the provision of care for patients (73).

Monitoring treatment progress and response includes periodic clinical evaluation and lab monitoring (including sputum conversion monitoring, blood tests, X-ray and other tests), as defined by national clinical protocols. It is usually a specialist’s responsibility, in the ambulatory setting in specialized outpatient units, day care centres and mobile units. If the country has a certification process for generalists for this clinical competence, they can also perform this function. As before, monitoring treatment progress and response is carried out at the inpatient setting for hospitalized TB patients.

It is advisable that prevention and detection of adverse events and comorbidities are delivered by medical doctors (generalists and specialists), mid-level medical professionals and patients’ supporters in all ambulatory, home and community settings (and in inpatient settings for hospitalized TB patients). In outpatient settings, this service can be shifted from specialists to mid-level medical professionals in specialized outpatient units.

Management of adverse events and treatment of comorbidities can be performed in all settings, including ambulatory, inpatient, community and home settings. Generalists are mainly responsible for the clinically oriented management of adverse events and the treatment of comorbidities and, when needed, can refer to the specialized laboratory and imaging services needed to complement clinical treatment monitoring (located in diagnostic centres in ambulatory and inpatient settings and primary care centres in some countries, depending on available equipment and skills).

Some treatment accompanying monitoring tests, such as audiometry, general and biochemical blood analysis tests are generally widely accessible outside TB hospitals and diagnostic centres, and could be conducted as close to the patient as possible. Some tests are conducted and managed by mid-level professionals (including laboratory specialists and technicians), others by radiologists and other invasive diagnostic specialists (i.e. biopsies when indicated, for instance with regard to non-pulmonary TB).
For monitoring and evaluation purposes, at minimum, an accessible, systematically maintained and ideally digitalized record system of all medications given, bacteriologic response, outcomes and adverse reactions should be kept for all patients at the facility level. In the long run, an electronic TB patient management programme (such as E-TBManager) would be integrated with the national patient registry and be accessible to support integration of care across all settings, facilities and providers, following patients throughout their care pathways.

INTEGRATION WITH OTHER SERVICES
Countries are advised to design and implement the people-centred model of TB care in the context of the broader health and social systems, with special attention to service integration with other programmes including, but not limited to, HIV/AIDS, diabetes and other noncommunicable diseases, maternal and child health and mental health and addiction services. Some key vulnerable groups defined by WHO are homeless people, people who inject drugs, people co-infected with TB and HIV, migrants, displaced populations and refugees.

The rationale for fostering service integration in TB care takes into consideration the setting-specific burden of TB comorbidities, its shared risk factors and vulnerable groups. It also presents an opportunity to optimize health services delivery and health outcomes with different programmes. For instance, with the final aims of increasing the TB detection rate in the EECA region and of reducing diagnosis delay, TB symptom screening and referral to TB diagnosis should be further integrated with primary and paediatric care so that these services are consistently carried out by family doctors/general practitioners, as well as by others in the medical and non-medical workforce. In addition, it is advisable that TB screening and diagnosis referral are implemented in relevant disease programmes, following national and international guidelines, adapted to the context of the EECA region (76–77). For integration with diabetes care, in line with the most up-to-date guidance documents and evidence from the literature, it is advisable that regional and country efforts are devoted to:

- establishing mechanisms for collaboration;
- detecting and managing TB in patients with diabetes;
- detecting and managing diabetes in patients with TB (21).

With regard to collaborative TB/HIV activities, is advisable that regional and country efforts are devoted to:

- establishing and strengthening mechanisms for delivering integrated TB and HIV services;
- reducing the burden of TB in people living with HIV and initiating early antiretroviral therapy;
- reducing the burden of HIV in patients with presumptive and diagnosed TB (78).

In the EECA region integration also has to include collaborative TB service integration with programmes for people who inject drugs and those with mental health and addiction services more broadly, including harm reduction and drug treatment services and hepatitis-relevant services (76, 79).

Last but not least, integrating TB care with health promotion and education services provides an opportunity to promote health behaviour and include, among others, nutritional assessment and appropriate counselling on different health aspects including reproductive and maternal, neonatal, child and adolescent care and mental health (67, 79).
PRISONS

Prison settings should be engaged in the national effort to reorient TB care towards a people-centred model. This needs to be planned following the 2009 guidelines for control of tuberculosis in prisons, implemented to the greatest possible extent considering the available resources and adapted according to each specific country’s context (79, 80, 81).

Services for TB care in prisons have to include:

- prompt case detection through passive and active case-finding;
- screening at various points during incarceration, including medical screening on entry and contact investigation;
- DST;
- prompt initiation of adequate TB treatment and management of comorbidities, including TB/HIV coinfection.

Other key components of the people-centred model of TB care in prisons include infection control at the levels of personal, administrative, managerial and environmental protection control measures and implementation of effective discharge and referral plans. Further, development of specific actions for soon-to-be-released prisoners has been identified as an essential component to ensure continuity of TB care at the community level (70). In these circumstances, prison health staff, as case managers, are to coordinate the follow-up of released prisoners with the health system (district TB coordinators) regarding where prisoners live following release and coordinating any available social support and post-release assistance, considering factors such as housing, employment, continuation of treatment and psychological support.
ALIGNING THE PEOPLE-CENTRED MODEL OF TB CARE AND OTHER HEALTH SYSTEM BUILDING BLOCKS

FINANCIAL INCENTIVES

In the EECA region financial arrangements have historically been designed to encourage the delivery of services in hospital settings rather than providing incentives for professionals to manage patients across the entire continuum of care (see Fig 3). Hospitals are incentivized to maximize admissions and keep patients for the maximum length of stay. While some reforms have been applied across EECA countries in efforts to further align provider and organization remuneration with the goals of the TB-REP framework and patient-centred care more broadly, these have been implemented to different degrees and with varying levels of success.

Fig. 3. The pattern of financial arrangements in TB-REP countries

Source: adapted from Imre et al. (82) by S Szigeti and A Lourenco.
Despite these efforts, financial arrangements continue to support hospital-based care and lengthy hospital stays. This is a result in particular of using line-item budgets, which specify a detailed amount provided to hospitals and other organizations for labour, equipment, medicines and maintenance of capital. This payment method is quite rigid and is often based primarily on the previous year’s expenditure, thus incentivizing hospitals to use as much of the budget provided as possible.

Primary care and outpatient TB services in most EECA countries are remunerated through capitation or a blended capitation and pay-for-performance model. The blended model encourages the prevention of TB in primary care and outpatient settings, as well as adherence to any key indicators defined in the pay-for-performance scheme. A few countries continue to remunerate primary care through a line-item budget (see Annex 3).

In addition, it should be noted that the transformation from input-based budgeting to purchasing of services from a provider by a purchasing function or institution (purchaser–provider split) is one of the major keys to the success of strategic purchasing. Unlike input-based purchasing, the contract of care by purchasers in the purchaser–provider split model is organized separately from service providers. Nonetheless, this path is not mandatory for readjusting financial incentives towards the people-centred model of TB care.

**ALIGNING FINANCIAL INCENTIVES WITH THE PEOPLE-CENTRED MODEL OF TB CARE**

Alignment of payment methods influences the configuration of the service delivery model and, consequently, the key performance indicators, such as early diagnosis, access and adherence to treatment, length of hospital stay and admissions (see Fig 4).

Patient engagement in the management of disease is crucial for treatment completion. In most TB-REP countries patients accept hospitalization, where food and accommodation are provided, as the norm. During the transitional phase and for the new model of TB care, psychosocial support products or programmes (such as food vouchers) should be considered for patients undergoing treatment in ambulatory settings to motivate treatment adherence. This approach can also have a great impact on reducing impoverishment caused by the disease and contributing to family support of treatment completion. Such support may be organized through national social and/or health services, with direct benefits for patients.

Community services can be provided by civil society and community-based organizations or other non-health professional-based organizations to provide psychosocial support, active case-finding and treatment administration. These organizations are usually funded by grants or social contracting (contracts to provide a set of services though public funding), maintaining their management autonomy from the funder. Pay-for-performance or fee-for-service programmes are tools that can be applied – such as bonus payments for treatment completion or for confirmed diagnosis.
Primary health care adopts different configurations across the EECA region. Regarding ownership, primary health care providers can be part of the public sector, mostly funded by a line-item budget, or part of the private sector, funded based on a contractual relationship. Salaries usually remunerate public sector health professionals without a clear incentive for quality and efficiency.

During the transitional phase from inpatient to ambulatory care in countries where different contractual arrangements are in place, mixed payment methods can be introduced to improve the quality and efficiency of care delivery. Countries are advised to adopt fee-for-service programmes for screening, diagnosis and provision of treatment at ambulatory care, as these can provide financial incentives to reduce delays in diagnosis and treatment access. A pay-for-performance programme, such as rewarding completion of TB treatment, should also be implemented to enhance the incentive to reduce TB-related hospitalization and, as a result, total treatment costs (according to Imre et al. (82)). All countries could use non-financial incentives, such as presenting awards to the best performing providers and publishing performance data on each provider.

Outpatient specialized services could be organizationally part of a general or TB hospital, in decentralized units or part of primary care services. Hence, to reduce hospitalization to the facilities with outpatient services, financial incentives applied to hospitals need to be increased to promote reduced admissions and length of stay and increased use of outpatient services.
In countries where the financing framework is based on a line-item budget defined by inputs and it is not possible to move to a purchaser–provider split, two possibilities are suggested: revise the input criteria or evolve from a restrictive line-item budget to a more flexible global budget. Revision of input criteria allows incentives for hospitalization (such as number of beds, ratio of personnel to beds) to be eliminated and introduce incentives for outpatient care (such as personnel working in outpatient settings, outpatient facilities).

Countries that have introduced the purchaser–provider split are advised to exclude per diem payments totally, since these can lead to over-hospitalization (83). To promote the progressive development of an ambulatory coordination of care, hospitals can be funded by a capitation payment that bundles ambulatory and hospital care (case-bundled payment), combined with a pay-for-performance programme that rewards treatment completion (84). This payment method consists of a single tariff per TB patient, independent of where care is provided. Such a bundled payment method can improve coordination of care and provide the financial incentive to move services from inpatient (more expensive and inadequate care) to an outpatient setting (less costly and more people-centred), leading to better quality and efficiency of TB care. This model also has the advantage of maximizing existing resources without creating a disruption in the health workforce.

TB patients presenting with more complex forms of disease that demand tertiary inpatient services can be considered for a combination of case-mixed and diagnosis-related group-based payments that incentivize satisfactory lengths of stay. Other incentives can be applied to hospitals, such as rewards for achieving the target of infection control and TB sputum/cure conversion.

Outpatient services that operate independently of hospitals can be considered for the bundled payment combined with payment for performance proposed for hospitals. In this case, the financial responsibility for hospitalized patients can be attributed to outpatient services. Accordingly, if the patient is hospitalized, the hospital claims the cost from the outpatient provider.

THE HEALTH WORKFORCE

Service can be delivered at its highest quality if the right workforce is present at the right time and place, with the right skills. To transform current TB services, countries need the right number of health workers, but also need to address issues of quality, relevance, motivation and retention to meet population health needs. Political commitment is required for better collaboration between the education and health sector, other national authorities and the private sector, to improve the relationship between health professionals’ education and the realities and needs of health services delivery.
The people-centred model of TB care acknowledges roles, responsibilities and tasks across the health workforce involved in TB and DR-TB service delivery. The new model of TB care recognizes the value and experience of the current health workforce in TB prevention, detection and diagnosis, treatment and care as well as management and aims to maximize their impact on patient outcomes by transitioning towards a more people-centred approach.

Five groups can be considered to make up the health workforce in TB service delivery (see Table 2):

- specialist medical doctors;
- generalist medical doctors;
- mid-level health professionals;
- non-medical professionals;
- patients’ supporters who are actively involved in disease prevention and patient care and support.

Table 2. The health workforce for TB service delivery

<table>
<thead>
<tr>
<th>Health service providers</th>
<th>Clinical practice</th>
<th>Non-clinical practice</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical doctors:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>specialists</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulmonologists, TB specialists, other disease specialists, etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Medical doctors:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>generalists</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family doctors, general practitioners, as well as complementary and alternative medicine practitioners</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mid-level health professionals</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses, feldshers, doctors’ assistants, laboratory staffs, laboratory technicians, radiologists, etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Non-medical professionals</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychosocial workers, psychologists, nutritionists, etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Patients’ supporters</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Community health workers, volunteers, treatment supporters, peers, family members, etc.</td>
<td></td>
<td></td>
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</tbody>
</table>

*Source:* WHO (85).

Large numbers of workers with different backgrounds and levels of training are found in the health sector: far more than the health service providers themselves. These include professionals such as statisticians, computer programmers, accountants, managers and administrators, as well as various types of support staff including drivers, cleaners and craft and trade staff such as electricians. For further details for definitions and descriptions, see Annex 4.

**Task shifting**

Moving the delivery of TB services from inpatient to outpatient care requires task shifting across the health workforce and should be reflected in the patient’s care pathway. This strategy includes, where appropriate, redistributing select tasks from specialist and generalist physicians to mid-level health professionals and, in turn, from mid-level professionals to non-medical professionals, patients and patients’ supporters. In the case of TB management, task shifting may support both covering health workforce shortages by providing a better balance of providers and strengthening outpatient care, further aligning the health system with people-
centred approaches (86). In making these adjustments, however, it is crucial to consider the need for ongoing coordination among health and non-health providers, as well as across outpatient and inpatient settings of care. The “decision-making tree” tool (Fig. 5) shows the process for defining tasks for each category of the health workforce.

The competency levels for existing and newly created cadres need to be decided and updated so that:

- medical doctors are involved in purely clinical tasks for advanced consultations with patients with complex TB and those with comorbidities;
- mid-level professionals assume the tasks previously undertaken by more senior cadres (such as physicians);
- patients’ supporters assume some tasks previously undertaken by mid-level professionals and in select cases by medical doctors;
- patients in self–management assume some tasks related to their own care that would previously have been undertaken by health and non–health providers (87–88).
Health education can be provided by any member of the health workforce with an adequate level of training and possessing the relevant knowledge and skills. To be as effective as possible, it is critical that whoever delivers the service has been in early contact with the person with presumptive TB.

Non-medical professionals, mid-level medical professionals and patients’ supporters can safely and effectively undertake a large number of tasks that until recently had been performed exclusively by physicians. This includes individual screening, counselling, provision of psychosocial support and coordination of services. To ensure a smooth transition of responsibilities, sufficient levels of training, education and skills development should be in place to support mid-level professionals, patients and patient supports’ in developing these competencies (89).

Patient profile assessments can be completed by non-medical professionals. Only in situations when this is not possible should the task be assigned to mid-level medical professionals or patients’ supporters with proper training, using standardized tools. Counselling should be undertaken by non-medical professionals or mid-level medical professionals with targeted training. If there is a need for medical intervention such as psychiatric treatment, diagnosis and treatment should be performed by a specialist.

In addition to these examples, a full list of tasks and their standards should be defined in national guidelines to ensure clear responsibilities and quality of the services provided.

**Capacity-building and education**

Shifting towards a people-centred model of care requires the transformation of medical education to train both current and future health professionals. The TB specialty in pre-service training institutions can be merged strategically with the pulmonology/infectious disease specialty to support a shift away from a narrow disease-minded understanding to a broader, integrated, people-oriented education (90).

This integration should be pursued further for graduate students through a residency specialization combining the existing curricula for TB doctors with those of pulmonologists or infectious disease specialists. The residency programme should be devoted to respiratory disease (including TB) in children and adults; this will support a more comprehensive, integrated approach to pulmonary illnesses. Merging these programmes will develop providers with a new specialty and complementary skills, so new competencies for the health workforce will need to be established and clearly defined.

In efforts to institutionalize this approach, as well as to ensure that the health workforce is delivering high-quality services, EECA countries should move away from outdated systems of compulsory refresher courses towards a flexible model of continuous professional development, through which providers can collect credits for development activities and undertake short courses on a five-year cycle. Training programmes should be accredited and all activities undertaken should be tied to certification and licensing (91–93).

A key implementation challenge, however, is that it is very difficult to standardize continuous professional development, so countries will need to decide the number of credits, duration of courses and type of activities that can be included in an accreditation system (92).
Identifying skills and planning

To calculate health workforce needs, comprehensive insight is required into the organization of services, patient flow in TB control and staff workload.

Health workforce and skills planning for TB care should be based on demand for services, responsibilities of various providers, tasks to be performed and the capacity of educational institutions. Regular workload assessments based on the incidence and prevalence of the disease should be performed, taking into account the latest developments in medicines and technologies, including new diagnostic tools, tests, drugs and short regimens that may serve to increase or reduce a provider’s workload.

Experience has shown that rational planning of the health workforce for TB control based on generic staffing norms is difficult. In part, this is a result of the significant variation in the number and productivity of staff within and among countries. These are influenced by a number of additional factors including training, infrastructure and availability of needed medicines and technologies (94).

Responsibility for calculating workforce requirements falls largely to managers of health care organizations. Acknowledging that this can be particularly difficult, WHO is developing a tool to give an approximate overview of staffing needs; this will be offered to countries by the end of 2017, following an initial round of piloting in the WHO European Region.

Health workforce quality assessment

The health workforce and the demand for services are in constant flux, so it is important to reassess task lists and competencies regularly. Supervision visits should be an essential tool to observe and assess the performance of individuals against clearly defined competency levels and performance standards. Minimum benchmarks and indicators for health workforce management and means to evaluate them should be set (95–98).
LEADING CHANGE AND INNOVATION

Policy-makers, professionals and citizens are increasingly recognizing that the current models of care and vertical orientation of health systems are no longer sustainable, from cost, quality and patient satisfaction perspectives. Instead, taking steps towards implementing people-centred health systems and services is becoming a high priority. While the framework and elements included in a people-centred approach to care are well defined, less literature is available on how best to enable and lead this change. To address this gap, the WHO Regional Office for Europe has made concerted efforts to provide policy-makers, professionals and citizens across the Region with examples and lessons learned, providing a platform from which leaders at all health system levels may exchange their experiences and derive insights from the challenges and successes of others.

To help health system leaders address the question of how to create people-centred TB care, the Regional Office has embarked on a work stream entitled “Health system transformation: making it happen” (99). These efforts include convening high-level meetings of policy-makers and experts to understand and capture how system leaders have planned, moved forward and adopted new governance, financial and delivery arrangements for TB care. The preliminary results of this work stream identified some of the main barriers to and enablers of securing transformational change. Based on the experiences of these policy-makers and experts, some of the critical enablers of change are the following.

- With changing political cycles and fluctuating funding environments it is important to **articulate a long-term vision** that can unite stakeholders through the day-to-day challenges that will inevitably occur during implementation. Importantly, this vision should be technically feasible and aligned with shared values that can inspire health system actors along the continuum of care to do things differently.
- Initiatives often ignore the value of a system-wide approach due to short windows of opportunity. Using a **systems perspective** is critical to an initiative’s long-term success, combined with ensuring that, wherever possible, change is aligned with health system building blocks (governance, financial and delivery arrangements) and any values or beliefs that could otherwise undermine the initiative.
- In any system, stakeholders possess varying levels of political power afforded to them by governance structures. **Stakeholder mapping** can help to identify resources, opportunities and obstacles that may inhibit or enable the active engagement of key influencers.
- Clearly communicating a **strategic vision and inspirational narrative** can be an important part of bringing stakeholders together, especially when engaging in broad-reaching institutional change.
- The integration of **high-quality evidence in the development of health policies and management** to identify and understand issues is critical to ensure that policies are best situated to deliver the desired outcomes, with a reduced risk of unintended consequences.
- Successful reform is a product of many stakeholders across health system levels working together to effect change, rather than the heroic work of one individual. Change agents can act as an important tool, as they are able to **engage a critical mass** of stakeholders early and often by advocating and promoting the transformation agenda.
- Keeping stakeholders informed and energized by **communicating and disseminating** early successes can help to engage others and persuade those who may otherwise be sceptical about the change process. Early strategic policy and planning should recognize and measure performance against short-term achievable targets that are broadly aligned with the more complex long-term vision for change.
Balancing centralized planning and coordination with local-level implementation autonomy, **combining top-down with bottom-up implementation**, is important to generate innovation and sustainable investment.

Complex problems demand complex solutions, **balancing big bang and incremental change**. It is easy to advocate large-scale transformations that throw out current conventions, but a smooth change management strategy often requires the benefits of new approaches to be balanced with the history, culture, organizational mindsets and institutional legacies prevailing within countries from previous reforms.

Complex large-scale shifts in health policy must spread across many stakeholders and sectors, **institutionalizing change**. Professional and governmental silos need to be broken by nurturing and supporting “boundary spanners” and through investment in developing leaders who are prepared to challenge the status quo bias of many key players.

Creating change in a system takes time, notably to gain sufficient buy-in and generate excitement among stakeholders. Change agents will **need to take time and space** to think through the right vision and narrative for change, to develop trust between partners and to answer questions to reassure stakeholders.
REFERENCES


ANNEX 1. HOSPITALIZATION CRITERIA

According to current WHO policy guidance (1), patients with tuberculosis (TB), including isoniazid-resistant, rifampicin-resistant and multidrug-resistant TB (RR/MDR-TB), should be treated using mainly ambulatory care rather than models of care based principally on hospitalization. This recommendation is based on a systematic review and cost–effectiveness analysis comparing programmatic management of drug-resistant TB (DR-TB) using mainly inpatient models of care versus mainly outpatient models of care (2). The evidence shows that the overall cost–effectiveness of care for a patient receiving treatment for MDR-TB could be improved with an ambulatory model.

A systematic review conducted after the production of the WHO 2011 guidelines (3) indicates that, despite limitations in the data available, there is no significant difference in treatment outcomes between inpatient and outpatient models of care. Given the current evidence, unless there is a clear clinical or public health need, people with presumably infectious TB or confirmed pulmonary TB are not to be admitted to hospital for diagnostic tests or care.

KEY CRITERIA FOR ADMITTING TB PATIENTS TO HOSPITAL

Suggested key criteria for hospital admissions include:

- complicated forms of TB that require hospitalization (4) – conditions related directly to TB disease that require hospital treatment (i.e. respiratory failure and conditions requiring surgical interventions such as haemorrhage, pneumothorax and pleuritis);
- severe forms of diseases including disease with severe clinical manifestations of comorbidities that require hospitalization – conditions related to pre-existing comorbidities that have been exacerbated by TB and cannot be managed in outpatient settings (liver disease, renal disease and uncontrolled diabetes);
- life–threatening and serious medical events resulting from adverse effects of TB drugs (such as life–threatening arrhythmias, psychosis, renal failure and hearing loss).

Additional considerations include:

- cases where effective and safe treatment cannot be ensured in outpatient, community and home settings (i.e. in severe cases of homelessness, overcrowding, exposure of children aged under 5 years and pregnant women in households) and/or that have issues of geographical accessibility (such as a long distance to an outpatient facility);
- as last resort measure only, involuntary isolation of non–adherent patients once all other care options have been used/applied exhaustively (5).

Note these additional considerations should be applied only in very rare and extreme exceptional cases. All providers should strive at maximum for ambulatory treatment.

Those admitted should be cared for in single rooms. In hospital settings, people with presumed infectious TB or confirmed pulmonary TB should be assessed quickly for MDR-TB, following which:

- people deemed to be at low risk for RR/MDR-TB should be placed in single rooms;
people deemed to be at high risk for RR/MDR-TB should ideally be placed in a negative-pressure room, and rapid diagnostic tests, such as nucleic acid amplification tests, should be performed immediately.

**BASIC CONDITIONS FOR HOSPITALS ADMITTING TB PATIENTS**

Minimum requirements/basic conditions for hospitals admitting patients with pulmonary TB include the following (6).

- Appropriate infection control guidance should be adhered to and requirements met and monitored.
- Respiratory isolation rooms should be available for patients with TB who remain smear/culture-positive.
- All staff should be trained and adequately supervised, and adhere to administrative protocols for TB infection control.
- Sufficient trained staff should be available to guarantee patient-assisting and supportive treatment observation, such as through directly observed therapy (DOT) or video-observed therapy (VOT) for all patients.
- Open and safe space should be available for patients to socialize according to infectiousness status and resistance patterns: it is important not to mix DR-TB with drug-susceptible TB patients.
- “Friendly” administrative procedures should be in place to facilitate regular access of relatives visiting patients.
- Clearly defined protocols should be in place for effective communication and coordination, detailing terms of reference for involved staff including accountabilities and responsibilities, for laboratories providing services during treatment and for peripheral units receiving patients after discharge from hospital.
- The facility should have the capacity to develop a clinical and psychosocial care plan covering specific and individual needs identified through patient assessment, including relevant psychosocial support.

**HOSPITAL DISCHARGE CRITERIA**

A TB patient should be discharged from hospital if:

- there is no continuing clinical need for inpatient treatment (i.e. the key criteria for admission are not met) and clinical improvement is observed after administration of effective therapy, including:
  - improvement of symptoms (i.e. normal body temperature, improvement of overall health status translated by stabilization of body weight or weight gain);
  - reduction of respiratory symptoms (cough, sputum production);
  - reduction of clinical manifestations of comorbidities;
  - reduction of severity of adverse effects of TB drugs, if previously observed or reported by a health care worker and/or the patient;
- effective treatment has been ensured (treatment regimen is based on credible drug-susceptibility testing (DST) result and well tolerated) and continuity of care and DOT have been ensured in outpatient, home or community settings.

For people with confirmed TB whose overall symptoms have improved and who are unable to produce sputum, any discharge decisions should be taken by a multidisciplinary team based on the best available data and evidence, in a mutually agreed fashion. Earlier discharge for people with confirmed MDR-TB should be
A people-centred model of TB care

A people-centred model of TB care

considered if suitable mechanisms are in place for home care and if the patient can adhere to the defined TB care plan. Before deciding to discharge a patient with presumed or confirmed MDR-TB from hospital, agreement should be made with the patient and care providers, and secure arrangements for uninterrupted medical and psychosocial care and DOT in an outpatient setting should be ensured (7).

POSITIVE SMEARS AND MANAGEMENT IN OUTPATIENT SETTINGS

In line with current WHO guidance, treatment of TB – regardless of smear and DST status – can be performed in ambulatory settings from day one, including for sputum smear-positive cases, to reduce the risk of nosocomial transmission of strains in inpatient facilities and improve patient adherence to treatment. Outpatient care should be set up if the patient lives in proximity to the facility where he or she can be treated (within walking distance or with available transportation). Furthermore, if the inpatient TB facility does not meet the international standards of adequate infection control measures, treatment of smear-positive patients can also be organized at the ambulatory level. Each outpatient facility should meet certain minimum criteria to perform treatment of TB and DR-TB patients. There should be evidence of strict DOT, high-quality clinical monitoring and side-effect management during the whole duration of treatment, including the intensive phase.

Effective treatment of drug-susceptible TB can rapidly render patients noninfectious, long before conversion of sputum acid-fast smear or culture to negative occurs (8), so a positive smear is not a contraindication for hospital discharge. Nevertheless, transmission is ongoing if an ineffective regimen is used – for example, when a first-line regimen is used in a case of RR/MDR-TB, or when a first-line or RR/MDR-TB regimen is used in a case of extensively DR-TB) (6). Thus, a clear DST result to determine the drug-resistance pattern should be a prerequisite for hospital discharge.

Note: most TB patients have infected those they could infect prior to TB diagnosis and admission to hospital. The focus should therefore be on proper investigation of contacts (both household contacts and other close contacts), instead of efforts to put and keep people in hospital. Contact tracing, active case-finding according to relevant risk groups and prevention need to be further strengthened and maintained, particularly taking account of recent developments in diagnostic technologies, new drugs and shorter RR/MDR-TB treatment regimens, which are not stand-alone “silver bullets” and need to be applied in carefully tailored and chosen combinations.

SUGGESTED CRITERIA FOR PRIMARY HEALTH CARE SERVICES PROVIDING AMBULATORY TREATMENT OF TB PATIENTS

The facility should be assessed by the national TB programme and meet the minimum criteria to provide ambulatory treatment of TB and DR-TB patients. It should be ensured that:

- facility personnel are trained to perform TB and DR-TB treatment – including handling injectable agents – diagnose and manage side-effects;
- ancillary medicines (basic list) are available to manage side-effects;
- it is possible to perform regular laboratory and bacteriological examinations, as well as chest radiography, as required by national protocols (or that a strong system of referrals is in place);
- a system of loss-to-follow-up tracing is available (including home patronage with transportation);
- a system of improving adherence to treatment is in place (with incentives and enablers).
OPTIMUM COMMUNITY AND HOME SETTINGS FOR TB CARE

For optimum outpatient care for TB and MDR-TB, settings should have:

- clear policies and protocols in place on the roles, competencies and minimum requirements for community-based organizations providing support to TB patients;
- a public health legal framework allowing community members to deliver some health care functions;
- sufficient community TB supporters to guarantee DOT to all patients at least six days a week, with an extended timetable to allow the delivery of treatment twice a day when needed;
- adequately trained non-medical personnel, in line with national protocols for services to be provided by community actors;
- checks in place that a patient’s household infrastructure is compliant with respiratory infection control policy guidance;
- community-based TB and RR/MDR-TB supporters trained in patient confidentiality issues and in methods to decrease stigma.

Note: if any of these factors are not met, it does not mean that patients should be excluded from care in community, home or outpatient settings.

REFERENCES

ANNEX 2. BED FORECASTING TOOL

Note: an electronic calculation tool is available online at: http://www.pas.md/en/TBRep.

KEY ISSUES TO BE CONSIDERED FOR TUBERCULOSIS (TB) HOSPITAL CAPACITY PLANNING AND MANAGEMENT

- It should be emphasized that TB hospitals are acute care medical facilities, not institutions for long-term health or social care.
- Bed planning should be aligned with the goals of the national TB strategic plan and be based on contemporary evidence, not merely on historical setup and established practices. Importantly, this means that decisions on admission of a TB patient to hospital, as well as decisions to discharge from hospital, need to be based on the patient’s clinical status (advancement of TB disease and/or comorbid conditions) and not on other factors that may include social needs or issues in providing care in ambulatory settings.
- The overarching principle for planning inpatient care capacities is to administer treatment according to the patient’s resistance profile, which prevails over other criteria such as epidemiological status (infectious or noninfectious cases), patient history (new or previously treated cases), disease location (pulmonary or extrapulmonary), age group (adults or children) and so on.
- Appropriate planning of TB beds requires that other conditions are in place as mandated by WHO, including:
  - availability of rapid molecular tests (i.e. an automated real-time nucleic acid amplification technology for rapid and simultaneous detection of TB and rifampicin resistance (Xpert MTB/RIF)) as initial tests for TB and isoniazid-resistant, rifampicin-resistant TB (RR-TB) diagnosis;
  - full coverage with (rapid) drug-susceptibility testing (DST) and administration of correct treatment according to the patient’s resistance profile;
  - provision of appropriate treatment to all TB patients, including multidrug and extremely drug-resistant TB (M/XDR-TB) cases;
  - introduction and scale up of shorter MDR-TB treatment regimens and new and repurposed anti-TB drugs;
  - implementation of mainly outpatient TB treatment model and other patient-centred TB care approaches.
- The exercise should be conducted in a participatory manner involving key stakeholders and WHO, and, wherever possible, other international development assistance partner agencies active in the field.

METHODOLOGY FOR ESTIMATING TB HOSPITAL BED NEEDS

The forecasting tool contains 18 steps, divided into two stages. The sections below set out the instructions for following these suggested actions and example results. These are based on a fictional medium-sized country in the eastern Europe and central Asia region with a population of about 7.5 million and TB incidence at about 85/100,000 in 2015. TB case notifications (in the online electronic calculation tool, insert values only in cells highlighted in blue – as below). A number of brief explanatory notes are also included.

Note: starting with a countrywide exercise is advised. Thereafter (especially for larger countries), estimates using the same approach should be applied for administrative territories with a defined health system structure (for example, oblasts in Belarus, Kazakhstan, Ukraine and Uzbekistan) and for populations groups (adults/children, civilian sector/
penitentiary sector). Countries can also undertake a low/medium/high scenario exercise, especially for longer-term estimates (a template is included in the online electronic calculation tool).

**Stage 1 (steps A–H) involves estimating the TB epidemic profile.**
- Start with patient data for the last available year (and/or project for 3–5–10 years).
- Use the latest WHO definitions for TB notifications.
- Estimate the (current and planned) DST coverage (for first-line drugs (FLDs) and second-line drugs (SLDs)).
- Estimate the (current and expected) prevalence of drug resistance.

**Stage 2 (steps I–R) reflects treatment strategies and hospitalization practices.**
- Estimate the enrolment rates by treatment category.
- For MDR-TB cases, estimate the proportion of cases to be treated with standard and shorter treatment regimens.
- Estimate the proportion of TB cases to be hospitalized, by treatment category.
- Estimate the average length of stay in hospital, by treatment category.

**STEP A. NUMBER OF TB CASES REGISTERED (ANNUAL)**
TB case notifications are presented using common WHO case notification categories (from the latest version of the WHO data collection form).¹

<table>
<thead>
<tr>
<th></th>
<th>NEW CASES</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>New pulmonary laboratory confirmed</td>
<td>3390</td>
</tr>
<tr>
<td></td>
<td>New pulmonary clinically diagnosed</td>
<td>630</td>
</tr>
<tr>
<td></td>
<td>New extrapulmonary</td>
<td>1230</td>
</tr>
<tr>
<td>2</td>
<td>PREVIOUSLY TREATED CASE</td>
<td>1990</td>
</tr>
<tr>
<td></td>
<td>Relapses pulmonary laboratory confirmed</td>
<td>760</td>
</tr>
<tr>
<td></td>
<td>Relapses pulmonary clinically diagnosed</td>
<td>200</td>
</tr>
<tr>
<td></td>
<td>Relapses extrapulmonary</td>
<td>110</td>
</tr>
<tr>
<td></td>
<td>Previously treated other than relapse (laboratory confirmed and clinically diagnosed)</td>
<td>920</td>
</tr>
<tr>
<td>3</td>
<td>TOTAL</td>
<td>7240</td>
</tr>
</tbody>
</table>

**Note:** the WHO definition of laboratory-confirmed cases includes DST, an automated real-time nucleic acid amplification technology for rapid and simultaneous detection of TB and rifampicin resistance (Xpert MTB/RIF) and culture testing.

## STEP B. FLD DST COVERAGE: PROPORTION OF CASES WITH DST RESULTS TO FLDs (AT LEAST TO RIFAMPICIN (R))

Based on current coverage with DST to FLDs, the proportion of cases with DST results is estimated for each of the above notification categories.

<table>
<thead>
<tr>
<th></th>
<th>NEW CASES</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>New pulmonary laboratory confirmed</td>
<td>90</td>
</tr>
<tr>
<td>1</td>
<td>New pulmonary clinically diagnosed</td>
<td>5</td>
</tr>
<tr>
<td>1</td>
<td>New extrapulmonary</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>PREVIOUSLY TREATED CASES</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Relapses pulmonary laboratory confirmed</td>
<td>90</td>
</tr>
<tr>
<td>2</td>
<td>Relapses pulmonary clinically diagnosed</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>Relapses extrapulmonary</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>Previously treated other than relapse (laboratory confirmed and clinically diagnosed)</td>
<td>50</td>
</tr>
<tr>
<td>3</td>
<td>TOTAL</td>
<td>X</td>
</tr>
</tbody>
</table>

### Notes:
- “DST results to FLDs” means that at minimum a DST result to R is available (i.e. by Xpert). Further, the methodology applies the same approach to RR-TB and MDR-TB cases.
- Countries using older sputum smear-positive/smear-negative classification instead of laboratory-confirmed/clinically diagnosed classification should estimate the proportion of pulmonary sputum smear-negative cases that will be later confirmed by other laboratory methods (i.e. culture) and will have FLD DST results. These should be included as laboratory-confirmed cases (1.1 and 2.1).
- Among pulmonary clinically diagnosed cases (1.2 and 2.2), during further steps, allocate some proportion of them for RR/MDR-TB treatment as close contacts of laboratory-confirmed RR/MDR-TB cases (this proportion may vary depending on current practices and planned future steps).
- The estimates for extrapulmonary cases (1.3 and 2.3), as well as for “other retreatment cases” (2.4, which combines laboratory-confirmed and clinically diagnosed cases), should be based on the current situation and on short- to medium-term forecasts.
STEP C. NUMBER OF CASES WITH DST RESULTS TO FLDS (AT LEAST TO R)
The number of patients by category is estimated by multiplying the values in the tables above: \( C = A \times B \).

Illustration: 2.1) Relapses pulmonary laboratory confirmed: 760 notified cases \((A) \times 90\%\) DST coverage \((B) = 684\) cases with DST results \((C)\).

<table>
<thead>
<tr>
<th>1</th>
<th>NEW CASES</th>
<th>3206</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>New pulmonary laboratory confirmed</td>
<td>3051</td>
</tr>
<tr>
<td>1.2</td>
<td>New pulmonary clinically diagnosed</td>
<td>32</td>
</tr>
<tr>
<td>1.3</td>
<td>New extrapulmonary</td>
<td>123</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2</th>
<th>PREVIOUSLY TREATED CASES</th>
<th>1165</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Relapses pulmonary laboratory confirmed</td>
<td>684</td>
</tr>
<tr>
<td>2.2</td>
<td>Relapses pulmonary clinically diagnosed</td>
<td>10</td>
</tr>
<tr>
<td>2.3</td>
<td>Relapses extrapulmonary</td>
<td>11</td>
</tr>
<tr>
<td>2.4</td>
<td>Previously treated other than relapse (laboratory confirmed and clinically diagnosed)</td>
<td>460</td>
</tr>
</tbody>
</table>

| 3         | TOTAL         | 4371 |

STEP D. FLD RESISTANCE PROFILE, CASES WITH DST RESULTS TO FLDS
Based on the current resistance profile, estimates for FLD drug-resistance prevalence are applied for new and previously treated cases.

<table>
<thead>
<tr>
<th>1</th>
<th>Sensitive to all FLDs among new cases</th>
<th>70%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Polydrug-resistant TB (PDR-TB) among new cases</td>
<td>12%</td>
</tr>
<tr>
<td>3</td>
<td>RR/MDR-TB among new cases</td>
<td>18%</td>
</tr>
<tr>
<td>4</td>
<td>Sensitive to all FLDs among previously treated cases</td>
<td>41%</td>
</tr>
<tr>
<td>5</td>
<td>PDR-TB among previously treated cases</td>
<td>14%</td>
</tr>
<tr>
<td>6</td>
<td>RR/MDR-TB among previously treated cases</td>
<td>45%</td>
</tr>
</tbody>
</table>

Note: countries that do not have full FLD DST coverage should undertake an additional exercise to estimate PDR-TB and RR/MDR-TB prevalence, based on the actual coverage but taking into account the planned pace of extending this coverage over the shorter- and mid-term periods.
STEP E. NUMBER OF CASES BY FLD RESISTANCE PROFILE

The estimated number of patients by resistance profile is calculated by multiplying the values in tables C and D above: \( E = C \times D \).

**Illustration:**
4) RR/MDR-TB cases: 3206 new cases with DST results (C) \( \times \) 18% RR/MDR-TB prevalence among new cases (D) \( \times \) 1165 (C) \( \times \) 45% (D) (for previously treated cases) = 577 + 524 = 1101 estimated RR/MDR-TB cases (E).

<table>
<thead>
<tr>
<th></th>
<th>No DST results to FLDs</th>
<th>Sensitive to all FLDs</th>
<th>PDR-TB</th>
<th>RR/MDR-TB</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2870</td>
<td>2722</td>
<td>548</td>
<td>1101</td>
</tr>
</tbody>
</table>

STEP F. SLD DST COVERAGE: PROPORTION AND NUMBER OF RR/MDR-TB CASES WITH DST RESULTS TO SLDs (FLUOROQUINOLONES (FQ) AND INJECTABLES (INJ))

For RR/MDR-TB cases, the current (and/or planned) SLD DST coverage (1) is used to estimate the number of patients with DST results to SLDs (FQ and INJ): \( F(2) = F(1) \times E(4) \).

**Illustration:**
2) 1101 estimated RR/MDR-TB cases (E) \( \times \) 85% SLD DST coverage in RR/MDR-TB cases = 936 estimated RR/MDR-TB cases with DST results to SLDs (F).

<table>
<thead>
<tr>
<th></th>
<th>Proportion of RR/MDR-TB cases with DST results to SLDs</th>
<th>Number of RR/MDR-TB cases with DST results to SLDs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>85%</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>936</td>
</tr>
</tbody>
</table>

**Notes:**
- DST results to SLDs mean that DST results to FQ and injectable drugs are available (e.g. by SLD line probe assay). Currently, WHO suggests that DST to other SLDs, by any method, is not reliable and should not be used for treatment decisions.
- Similar to the note for step D above, countries that do not have full SLD DST coverage among RR/MDR-TB cases should undertake an additional exercise to estimate FQ and INJ resistance, based on actual coverage but taking into account the planned pace of extending this coverage over the shorter- and mid-term periods.
**STEP G. SLD RESISTANCE PROFILE, MDR-TB CASES WITH DST RESULTS TO SLDS**

Using the current (and/or planned) data the SLD DST resistance profile among MDR-TB cases is estimated.

<table>
<thead>
<tr>
<th></th>
<th>Resistance Profile</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No resistance to SLDs</td>
<td>55%</td>
</tr>
<tr>
<td>2</td>
<td>“Pre-XDR” TB</td>
<td>30%</td>
</tr>
<tr>
<td>3</td>
<td>XDR-TB</td>
<td>15%</td>
</tr>
</tbody>
</table>

**Notes:**
- For appropriate bed planning for the medium and longer term, countries that currently have limited SLD DST coverage among RR/MDR-TB cases, should undertake an additional exercise for estimating SLD (FQ and INJ) resistance. For this purpose, regional profile/data from other (neighbouring, as applicable) countries in the region may be used as indicative levels.
- For bed-planning purposes, “pre-XDR” and “XDR” definitions and their use in calculations should be used with appropriate caution, taking into account that kanamycin resistance levels in the region are very high but capreomycin can still be used in building the SLD regimens in a significant proportion of patients with kanamycin resistance (when full/nearly full SLD DST coverage is assured).

**STEP H. NUMBER OF CASES BY RESISTANCE PROFILE (FLD AND SLD)**

Based on the estimates and calculations in the previous steps (A–G), the annual number of patients to be treated is calculated, by resistance profile: $H = F \times G$.

**Illustration:** 6) 936 estimated RR/MDR-TB cases with DST results to SLDs ($F \times (30\% + 15\%)$) estimated “pre-XDR” and XDR-TB prevalence ($G$) = 936 $\times$ 45% = 421 estimated “pre-XDR” and XDR-TB cases ($H$).

<table>
<thead>
<tr>
<th></th>
<th>Resistance Profile</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No DST results to FLDs</td>
<td>2870</td>
</tr>
<tr>
<td>2</td>
<td>Sensitive to all FLDs</td>
<td>2722</td>
</tr>
<tr>
<td>3</td>
<td>PDR-TB</td>
<td>548</td>
</tr>
<tr>
<td>4</td>
<td>RR/MDR-TB without DST results to SLDs</td>
<td>165</td>
</tr>
<tr>
<td>5</td>
<td>RR/MDR-TB without resistance to SLDs</td>
<td>515</td>
</tr>
<tr>
<td>6</td>
<td>‘Pre-XDR’ and XDR-TB</td>
<td>421</td>
</tr>
<tr>
<td>7</td>
<td><strong>TOTAL</strong></td>
<td>7240</td>
</tr>
</tbody>
</table>

**Note:** make sure that the “Total” value in this table equates to the totals in steps A and E above.
STEP I. PROPORTION OF PATIENTS TO BE ENROLLED IN TB TREATMENT

The proportion of patients to be enrolled in treatment against active TB disease is estimated (should be close to 100%).

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No FLD DST results and sensitive to all FLDs</td>
<td>100%</td>
</tr>
<tr>
<td>2</td>
<td>PDR-TB</td>
<td>100%</td>
</tr>
<tr>
<td>3</td>
<td>MDR-TB without SLD DST results and without resistance to SLDs</td>
<td>98%</td>
</tr>
<tr>
<td>4</td>
<td>“Pre-XDR” and XDR-TB</td>
<td>95%</td>
</tr>
</tbody>
</table>

Note: recognize that not all patients (especially M/XDR-TB cases) will be included in anti-TB treatment due to extensive resistance and/or advanced clinical condition or patient refusal. The programmes, however, should aim at minimizing this proportion.

STEP J. PROPORTION OF MDR-TB PATIENTS WITHOUT SLD RESISTANCE TO BE ENROLLED IN STANDARD AND SHORTER TREATMENT REGIMEN

Based on the current (and/or planned) situation, the proportion of RR/MDR-TB cases without SLD resistance (and those without SLD DST results) that will be enrolled in treatment using shorter MDR-TB regimens is estimated.

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>MDR-TB treatment, standard regimen (20 months)</td>
<td>40%</td>
</tr>
<tr>
<td>2</td>
<td>MDR-TB treatment, shorter regimen (9–12 months)</td>
<td>60%</td>
</tr>
</tbody>
</table>

Note: at early stages of introducing shorter MDR-TB regimens countries should plan properly for the pace of rollout, taking into account the current SLD DST profile and its future forecast, prevalence of comorbidities, etc.
STEP K. NUMBER OF PATIENTS TO BE TREATED, BY TREATMENT CATEGORY

Based on the estimates and calculations in steps H–J above, the annual number of patients to be treated by treatment category: \( K = H \times I \times J \) for MDR-TB treatment) is estimated.

**Illustration:**

3) 515 estimated RR/MDR-TB cases without resistance to SLDs (H) \times 98% estimated enrolment rate for this category (I) \times 60% estimated proportion of shorter MDR-TB regimens in this group (J) = 303 cases to be enrolled in shorter MDR-TB treatment regimens (K).

<table>
<thead>
<tr>
<th></th>
<th>First-line treatment</th>
<th>5591</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>PDR treatment</td>
<td>548</td>
</tr>
<tr>
<td>3</td>
<td>MDR-TB treatment, shorter regimen (9–12 months)</td>
<td>303</td>
</tr>
<tr>
<td>4</td>
<td>MDR-TB treatment, standard regimen (20 months)</td>
<td>364</td>
</tr>
<tr>
<td>5</td>
<td>MDR-TB treatment, &quot;pre-XDR&quot; and XDR-TB regimens</td>
<td>400</td>
</tr>
<tr>
<td>6</td>
<td>Symptomatic treatment</td>
<td>35</td>
</tr>
<tr>
<td><strong>7 TOTAL</strong></td>
<td></td>
<td><strong>7240</strong></td>
</tr>
</tbody>
</table>

**Note:** the number of patients that will/will need to be enrolled in symptomatic treatment is derived from the estimated enrolment proportions, see step I above.

STEP L. HOSPITAL ADMISSION RATES, BY TREATMENT CATEGORY

Based on the current (and/or planned) practices, the proportion of TB cases that will be hospitalized is estimated, by treatment category.

<table>
<thead>
<tr>
<th></th>
<th>First-line treatment</th>
<th>50%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>PDR treatment</td>
<td>65%</td>
</tr>
<tr>
<td>3</td>
<td>MDR-TB treatment, shorter regimen (9–12 months)</td>
<td>60%</td>
</tr>
<tr>
<td>4</td>
<td>MDR-TB treatment, standard regimen (20 months)</td>
<td>70%</td>
</tr>
<tr>
<td>5</td>
<td>MDR-TB treatment, 'pre-XDR' and XDR-TB regimens</td>
<td>100%</td>
</tr>
<tr>
<td>6</td>
<td>Symptomatic treatment</td>
<td>100%</td>
</tr>
</tbody>
</table>

**Note:** according to the WHO–recommended approach, programmes should aim to reduce admission rates for TB treatment, including those for M/XDR-TB cases, notwithstanding the likely excessive existing TB bed capacities in relation to the decreasing overall annual numbers of TB patients.
STEP M. EXPECTED NUMBER OF ADMISSIONS, BY TREATMENT CATEGORY

The annual number of hospital admissions is estimated, by treatment category: \( M = K \times L \).

**Illustration:** 4) 364 estimated RR/MDR-TB cases to be enrolled in standard MDR-TB treatment regimen \((K) \times 70\%\) estimated hospitalization rate for this category \((L) = 255\) cases to be hospitalized for MDR-TB treatment, standard regimen \((M)\).

| 1   | First-line treatment | 2796 |
| 2   | PDR treatment        | 356  |
| 3   | MDR-TB treatment, shorter regimen (9–12 months) | 182 |
| 4   | MDR-TB treatment, standard regimen (20 months) | 255 |
| 5   | MDR-TB treatment, “pre-XDR” and XDR-TB regimens | 400 |
| 6   | Symptomatic treatment | 35   |

STEP N. AVERAGE LENGTH OF STAY, MONTHS

Based on current (and/or planned) practices, the average length of stay in hospital (in months) is estimated, by treatment category.

| 1   | First-line treatment | 1.0  |
| 2   | PDR treatment        | 1.5  |
| 3   | MDR-TB treatment, shorter regimen (9–12 months) | 2.0 |
| 4   | MDR-TB treatment, standard regimen (20 months) | 3.0 |
| 5   | MDR-TB treatment, “pre-XDR” and XDR-TB regimens | 6.0 |
| 6   | Symptomatic treatment | 6.0  |

**Notes:**
- Average length of stay = total number of patient-days (bed-days)/total number of admissions.
- As with the note on step L, programmes should aim at reducing the duration of hospital stays, including those for M/XDR-TB cases, notwithstanding the likely excessive existing TB bed capacities in relation to the decreasing overall annual numbers of TB patients.
STEP O. NUMBER OF HOSPITAL PATIENT-DAYS (BED-DAYS) NEEDED, BY TREATMENT CATEGORY

Based on the estimates in steps M and N, the number of hospital patient-days (bed-days) needed is estimated, by treatment category: \( O = M \times N \times 30 \) [days].

Illustration: 5) \((400 \text{ estimated } \text{“pre-XDR” and XDR-TB cases to be hospitalized (} M) \times 6\text{-month estimated average length of stay for this category (} N) \times 30 \text{ days per month}) = 72 \, 029 \text{ patient-days in hospital (} O)\) (with a rounding factor in this table and elsewhere in the calculations).

<table>
<thead>
<tr>
<th></th>
<th>First-line treatment</th>
<th>83,865</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>PDR treatment</td>
<td>16,022</td>
</tr>
<tr>
<td>2</td>
<td>MDR-TB treatment, shorter regimen (9–12 months)</td>
<td>10,898</td>
</tr>
<tr>
<td>3</td>
<td>MDR-TB treatment, standard regimen (20 months)</td>
<td>22,913</td>
</tr>
<tr>
<td>4</td>
<td>MDR-TB treatment, “pre-XDR” and XDR-TB regimens</td>
<td>72,029</td>
</tr>
<tr>
<td>5</td>
<td>Symptomatic treatment</td>
<td>6,239</td>
</tr>
</tbody>
</table>

Note: patient-days (bed-days) = number of admissions \times average length of stay [months] \times 30 [days].

STEP P. NUMBER OF BEDS NEEDED (ADJUSTED FOR 85% BED OCCUPANCY RATE), BY TREATMENT CATEGORY

Based on estimated patient-days in step O, the number of TB hospital beds needed, adjusted for the optimal bed occupancy rate (BOR) of 85% is estimated, by treatment category: \( P = \frac{O}{365 \text{ [days]}} / 85\% \).

Illustration: 1) \((83,865 \text{ patient-days needed for TB cases on first-line treatment (} O) / 365 \text{ days}) / 85\% = 270 \text{ beds needed for this category (} P)\).

<table>
<thead>
<tr>
<th></th>
<th>First-line treatment</th>
<th>270</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>PDR treatment</td>
<td>52</td>
</tr>
<tr>
<td>2</td>
<td>MDR-TB treatment, shorter regimen (9–12 months)</td>
<td>35</td>
</tr>
<tr>
<td>3</td>
<td>MDR-TB treatment, standard regimen (20 months)</td>
<td>74</td>
</tr>
<tr>
<td>4</td>
<td>MDR treatment, “pre-XDR” and XDR-TB regimens</td>
<td>232</td>
</tr>
<tr>
<td>5</td>
<td>Symptomatic treatment</td>
<td>20</td>
</tr>
<tr>
<td>6</td>
<td><strong>TOTAL</strong></td>
<td><strong>683</strong></td>
</tr>
</tbody>
</table>
Notes:
- BOR = actual patient-days/maximal patient-days [number of beds × 365 days].
- BOR is influenced by a variety of factors, including differences in clinical status and separation requirements (in TB hospitals – especially according to resistance profile), gender separation requirements, seasonal fluctuations, holiday admission and discharge patterns.
- BOR of about 85% is commonly considered optimal; this is fully applicable for TB inpatient facilities. Programmes should aim at hospital activity levels providing for optimal BOR.
- Regarding symptomatic treatment programmes should not overestimate such needs: the goal must be to provide appropriate treatment to all TB patients. Coercive isolation should be considered as a last resort, after all reasonable measures to ensure adherence have been attempted and proven unsuccessful.

STEP Q. BREAKDOWN OF BEDS BY PATIENT CATEGORY
For practical planning reasons, the number of beds needed is aggregated for three categories: patients with drug-sensitive TB, patients with DR-TB and patients requiring symptomatic treatment.

**Illustration:** 2) \((52 + 35 + 74 + 232)\) beds for PDR and M/XDR-TB treatment \((P)\) = 393 beds for DR-TB patients \((Q)\).

<table>
<thead>
<tr>
<th></th>
<th>Beds for patients with drug-sensitive TB</th>
<th>270</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Beds for DR-TB patients</td>
<td>393</td>
</tr>
<tr>
<td>3</td>
<td>Beds for symptomatic treatment</td>
<td>20</td>
</tr>
<tr>
<td>4</td>
<td>Total</td>
<td>683</td>
</tr>
</tbody>
</table>

STEP R. TOTAL NUMBER OF TB BEDS, PER 100 000 POPULATION
The total number of TB hospital beds is calculated per 100 000 population: \(R = Q \times 100\ 000\) population.

**Illustration:** 1) For the example country with a 2015 mid-year population of 7.5 million: 683 total TB beds required × 100 000/7 500 000 population = 9.1 TB beds per 100 000 population \((R)\).

<table>
<thead>
<tr>
<th></th>
<th>Total number of TB beds, per 100 000 population</th>
<th>9.1</th>
</tr>
</thead>
</table>
## ANNEX 3. CURRENT PROVIDER PAYMENT MECHANISMS IN 11 TB-REP COUNTRIES

This table presents the applied combination of payment methods for TB control and care for selected countries. The first three columns show what payment methods the countries use for the different type of care. The fourth column presents the impact of the payment methods, using two indicators describing the hospitalization: admission rate and average length of stay (ALOS). The fifth shows whether there is a separate agency for purchasing health services.

<table>
<thead>
<tr>
<th>Country</th>
<th>Primary health care</th>
<th>Outpatient specialized TB services</th>
<th>Hospitals</th>
<th>Impact on hospitalization pattern of patients in first-line treatment (admission rate; ALOS) in 2015</th>
<th>Separate agency for strategic purchasing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Armenia</td>
<td>Capitation (pay-for-performance pilot)</td>
<td>Mixed: global budget/case payment</td>
<td>High admission rate High ALOS</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Azerbaijan</td>
<td>Line-item budget</td>
<td>Line-item budget</td>
<td>Relatively high admission rate Relatively high ALOS</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Belarus</td>
<td>Capitation</td>
<td>Line-item budget</td>
<td>High admission rate High ALOS</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Georgia</td>
<td>Capitation</td>
<td>Case payment</td>
<td>Low admission rate High ALOS</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Kazakhstan</td>
<td>Capitation (pay-for-performance pilot)</td>
<td>Case based (TB in transition)</td>
<td>High admission rate High ALOS</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Kyrgyzstan</td>
<td>Capitation</td>
<td>Case based (TB in transition)</td>
<td>High admission rate High ALOS</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Republic of Moldova</td>
<td>Capitation, pay-for-performance model</td>
<td>Mixed: Capitation/case payment</td>
<td>High admission rate High ALOS</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Tajikistan</td>
<td>Capitation (pay-for-performance pilot)</td>
<td>Line-item budget</td>
<td>High admission rate High ALOS</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Turkmenistan</td>
<td>Line-item budget</td>
<td>Line-item budget</td>
<td>High admission rate High ALOS</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Ukraine</td>
<td>Line-item budget (per capita pilot)</td>
<td>Line-item budget (global budget pilot)</td>
<td>High admission rate High ALOS</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Uzbekistan</td>
<td>Line-item budget</td>
<td>Line-item budget</td>
<td>High admission rate High ALOS</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
Note: the countries listed are those involved in the Tuberculosis Regional Eastern Europe and Central Asia Project (TB-REP) on Strengthening Health Systems for Effective Tuberculosis and Drug-Resistant Tuberculosis Control, financed by the Global Fund to Fight AIDS, Tuberculosis and Malaria.

## ANNEX 4. GLOSSARY OF TERMS: HEALTH WORKFORCE

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accreditation</td>
<td>A particular form of quality assurance which leads to the formal approval of an institution or programme that has been found by a legitimate body to meet predetermined and agreed-upon standards, eventually resulting in an accredited status granted to that provider or programme by responsible authorities. Accreditation can be awarded by an external quality assurance agency or can also be given by the institution itself, which is then “self-accrediting” (1).</td>
</tr>
</tbody>
</table>
| Capacity-building | Much more than training, this includes the following at three different levels:  
  - human resource development – the process of equipping individuals with the understanding, skills and access to information, knowledge and training that enables them to perform effectively;  
  - organizational development – the elaboration of management structures, processes and procedures, not only within organizations but also the management of relationships between the different organizations and sectors (public, non-state sector and community);  
  - institutional and legal framework development – making legal and regulatory changes to enable organizations and institutions at all levels and in all sectors to enhance their capacities (2). |
<p>| Certification   | Evaluation and recognition of an individual by an authorized body, which may be either a governmental or nongovernmental organization, implying that the individual received additional education and training, and demonstrated competence against predetermined requirements or criteria (3). |
| Competencies    | A combination of the essential knowledge, abilities, skills and values necessary for the practice of health promotion. “Core” competencies are the minimum set of competencies that constitute a common baseline for all health promotion roles (i.e. what all health promotion practitioners are expected to be capable of doing to work efficiently, effectively and appropriately in the field) (1). |</p>
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
</table>
| Continuing professional development (CPD)                    | Training that is beyond clinical update and includes wide-ranging competencies like research and scientific writing, multidisciplinary context of patient care, professionalism and ethical practice, communication, leadership, management and behavioural skills, team building, information technology, auditing, and appropriate attitudinal change to ensure improved patient service and research outcomes and attainment of the highest degree of satisfaction by stakeholders.  

CPD includes education methods beyond the didactic, embodies concepts of self-directed learning and personal development, and considers organizational and systemic factors. Types of CPD may include courses and lectures, training days, peer review, clinical audit, self-learning (reading journals, books), attending conferences and eLearning activities.  

CPD may be included in national standards of conduct, performance and ethics that govern health workers. National systems for CPD may be voluntary or mandatory. Mandatory systems may include the requirement for both verifiable and general non-verifiable CPD. Verifiable CPD is activity that meets an agreed definition of CPD and for which there is documentary evidence that the health worker has undertaken the CPD and that the CPD has concise educational aims and objectives, clear anticipated outcomes and quality controls (1). |
| Full-time equivalent (FTE)                                   | Total hours worked divided by average annual hours worked in full-time jobs. Depending on data availability on working hours, FTE level may also be calculated in the following way:  

- a worker with a FTE contract should be counted as 1 FTE. Concerning workers who do not have a full-time employment contract, full-time equivalent should be measured by the number of hours of work mentioned in each contract divided by the normal number of hours worked in full-time jobs (4). |
| Health workforce                                            | All people engaged in actions whose primary intent is to enhance health (5). |
| Health workforce planning                                   | Strategies that address the adequacy of the supply and distribution of the health workforce according to policy objectives and the consequential demand for health labour (6).  

Ensuring the right number and type of health human resources are available to deliver the right services to the right people at the right time (7). |
| In-service training                                         | Training received while one is fully employed in the health sector. The aim is to equip health workers or the trainers of health workers with the skills to deliver specific interventions (8).  

Training which is aimed at maintaining core competencies and developing new competencies in response to consumer demand and evolving public health needs (9). |
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical doctors: generalists (including family and primary care doctors: ISCO 2008-2211)</td>
<td>These diagnose, treat and prevent illness, disease, injury and other physical and mental impairments and maintain general health in humans through application of the principles and procedures of modern medicine. They plan, supervise and evaluate the implementation of care and treatment plans by other health-care providers. They do not limit their practice to certain disease categories or methods of treatment, and may assume responsibility for the provision of continuing and comprehensive medical care to individuals, families and communities.</td>
</tr>
<tr>
<td>Medical doctors: specialists (ISCO 2008-2212)</td>
<td>These diagnose, treat and prevent illness, disease, injury and other physical and mental impairments using specialized testing, diagnostic, medical, surgical, physical and psychiatric techniques, through application of the principles and procedures of modern medicine. They plan, supervise and evaluate the implementation of care and treatment plans by other health care providers. They specialize in certain disease categories, types of patient or methods of treatment, and may conduct medical education and research activities in their chosen areas of specialization.</td>
</tr>
<tr>
<td>Mid-level health professionals</td>
<td>These are health service providers who have successfully completed professional/vocational medical training, have a specific scope of work/practice, have been certified or registered through licensing/registration bodies, continue to meet their performance standards and are required to maintain and update their skills and knowledge by undertaking regular and specified CPD.</td>
</tr>
<tr>
<td>Non-clinical professionals</td>
<td>These include social workers, psychologists, physiotherapists, pharmacists, nutritionists and similar. They are fully qualified (often at degree level) and registered by a professional organization.</td>
</tr>
<tr>
<td>Patients’ supporters</td>
<td>Community health workers and treatment supporters with no formal professional or tertiary education. They can be involved in either paid or voluntary work and are usually provided with informal job-related training.</td>
</tr>
</tbody>
</table>
| Task shifting | The rational redistribution of tasks among health workforce teams. Specific tasks are moved, where appropriate, from highly qualified health workers to health workers with less training and fewer qualifications, to make more efficient use of the available human resources for health. The evidence supports a broad categorization of task-shifting practices. For example:  
  - extension of the scope of practice of medical paraprofessionals to enable them to assume some tasks previously undertaken by more senior cadres (e.g. medical doctors);  
  - extension of the scope of practice of patients’ supporters to enable them to assume some tasks previously undertaken by medical paraprofessionals and medical doctors;  
  - training patients in self-management to enable them to assume some tasks related to their own care that would previously have been undertaken by health workers. Task shifting can also be extended to other cadres that do not traditionally have a clinical function, such as pharmacists, laboratory technicians, administrators and records managers. The cadre that assumes the new task, not the cadre that is relieved of the task, is the defining factor for task shifting types. For example, any extension of the scope of practice of paraprofessionals is defined as task shifting type I. |
| Workload | Total time required to perform a certain task. |
A people-centred model of TB care

Note: unless otherwise indicated, definitions were developed for the TB Regional Eastern Europe and Central Asia Project (TB-REP) on Strengthening Health Systems for Effective TB and Drug-Resistant TB Control.

REFERENCES

The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

Member States

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Armenia
Austria
Azerbaijan
Belarus
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Bosnia and Herzegovina
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Croatia
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Denmark
Estonia
Finland
France
Georgia
Germany
Greece
Hungary
Iceland
Ireland
Israel
Italy
Kazakhstan
Kyrgyzstan
Latvia
Lithuania
Luxembourg
Malta
Monaco
Montenegro
Netherlands
Norway
Poland
Portugal
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San Marino
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Slovakia
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