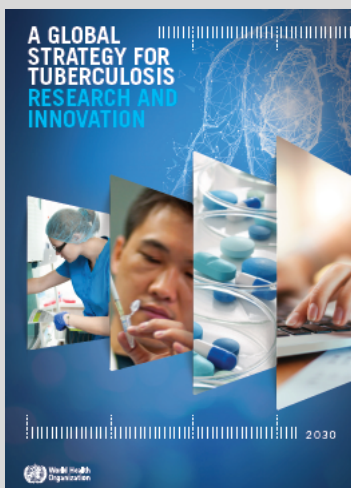


Situational Assessment Checklist

to guide implementation
of the global strategy for
tuberculosis research
and innovation



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**World Health
Organization**

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1. INTRODUCTION

Research along its full spectrum, from basic to implementation, is critical for developing new tools and strategies for better tuberculosis (TB) prevention, diagnosis, treatment and care and to provide scientific evidence for programmes, practitioners and policy-makers working to alleviate morbidity and mortality from TB. At the World Health Assembly in 2018, Member States adopted a resolution on TB that included a request to the WHO Director-General to develop a global strategy for TB research and innovation.¹ The rationale for the strategy was: “to make further progress in enhancing cooperation and coordination in respect of tuberculosis research and development”.

Under the leadership of WHO, the global strategy was developed in consultation with Member States, including managers of national TB programmes and other officials from within and beyond ministries of health, including ministries of science and technology. Also consulted were members of the WHO Strategic and Technical Advisory Group for Tuberculosis and the WHO Global TB Research Task Force, representatives of civil society and affected communities, professional associations, research funding institutions and other stakeholders in TB research and innovation. The global strategy for TB research and innovation (hereafter referred to as the global strategy)² offers an opportunity for Member States and other relevant stakeholders to translate political commitments on research and innovation made in the Moscow Declaration to End TB (November 2017) and the political declaration at the United Nations high-level meeting on TB (September 2018) into concrete actions.

Four major areas for action are addressed in the strategy: creating an enabling environment for TB research and innovation; increasing financial investment in TB research and innovation; promoting and improving approaches to data-sharing; and promoting equitable access to the benefits of research and innovation. A prerequisite for accelerating efforts to end TB is a concerted effort by all stakeholders to collaborate. Hence, the strategy also makes the case for a unified, aligned response in which national and international partners and affected communities support Member States by making the necessary investments or partnerships (or both) for accelerating innovation. The primary audiences for the strategy are Member States, particularly ministries of health, science and technology, finance and education. Member States adopted the strategy during the Seventy-third World Health Assembly in 2020.³

¹ Preparation for a high-level meeting of the General Assembly on ending tuberculosis (WHA7.13). Seventy-first World Health Assembly. Geneva: World Health Organization; 2018 (https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R3-en.pdf, accessed 1 November 2020).

² Global Strategy for TB Research and Innovation. Geneva: World Health Organization; 2020 (<https://www.who.int/teams/global-tuberculosis-programme/development-of-a-global-strategy-for-tb-research-and-innovation>, accessed 1 November 2020).

³ Global Strategy for TB Research and Innovation (WHA73.3). Geneva: Seventy-third World Health Assembly. Geneva: World Health Organization; 2020 (https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R3-en.pdf, accessed 1 November 2020).



2. PURPOSE OF THE SITUATIONAL ASSESSMENT

A situational assessment is an important step in national adaptation of a global strategy. Ideally, it is conducted as part of the planning cycle in implementation of the strategy and updated every few years. The checklist presented here is designed to support countries in planning their analyses according to their own contexts. While it sets out the key principles and recommendations to frame the situational assessment, it deliberately avoids being overly prescriptive, giving countries the space and flexibility to determine what is missing, what should be strengthened and the most feasible approaches to addressing pressing challenges. It consists of four topics aligned with the four objectives of the strategy to strengthen thematic analyses.

This tool is not designed for identifying or prioritizing research gaps but rather for improving policy and strategic decisions to enhance TB research on the four thematic areas (objectives) of the global strategy. For those interested in developing a research agenda, WHO has published a toolkit that provides guidance and allows sharing of best practices.⁴

The release of this checklist coincides with the significant impact of the COVID-19 pandemic on health

Box 1. What is the purpose of a situational assessment?

A situational assessment is valuable:

- to describe the baseline health research system, with all its strengths and weaknesses, their causes and effects, in order to reach consensus on the status of TB research and innovation in the country;
- to provide evidence for implementing the recommendations of the global strategy in a manner that is responsive to the needs of the country;
- to extend the engagement and participation of relevant stakeholders, including the private sector; and
- to support and strengthen monitoring and evaluation during implementation of the global strategy.

care systems and health research. It is expected that this tool will allow adaptation of the global strategy in such a way that TB research will be able to respond to the changing, complex environment of TB prevention and care caused or exacerbated by the pandemic, while remaining faithful to the principles of the End TB Strategy and the Sustainable Development Goals.

The checklist is designed as a reference for ministries of health

and other entities responsible for governing national health research. It presents the recommendations of the global strategy in a series of thematic questions that allow robust analysis of the current situation before any changes are made and to measure progress. The situational assessment itself should serve as an opportunity to promote meaningful dialogue among sectors, by involving academia, funding agencies, scientists, civil society (including young people), professional associations, the private sector and other relevant stakeholders.

⁴ A toolkit for developing a national TB research plan, in support of the third pillar of the End TB Strategy. Geneva: World Health Organization; 2016 (https://www.who.int/tb/publications/TB_research_toolkit/en/, accessed 21 September 2020).

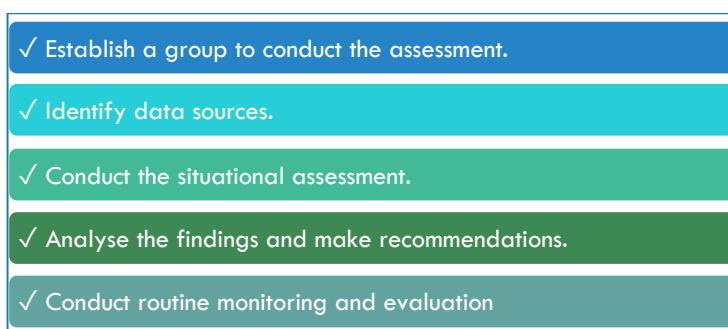
3. CONDUCTING A SITUATIONAL ASSESSMENT

Various kinds of knowledge, experience and background should be brought together to conduct a situational assessment effectively, addressing the four objectives of the global strategy:

1. Create an enabling environment for high-quality TB research and innovation.
2. Increase financial investments in TB research and innovation.
3. Promote and improve approaches to data-sharing.
4. Promote equitable access to the benefits of research and innovation.

The assessment should provide an evidence base for action, including changes in policies, programmes and interventions, that will accelerate progress towards the goals and targets of the End TB Strategy. Steps that could facilitate a situational assessment are proposed below and in Fig. 1.

Fig. 1. Steps in conducting a situational assessment



3.1 Preparation

A situation assessment with the above-mentioned objectives can be conducted by a small cross-sectoral working group or network under the Ministry of Health, which collects data and the necessary information. This will aid in understanding the country's needs, challenges and progress in implementing the strategy. This group or network could include researchers, health care providers, programme managers, policy-makers from ministries of science, technology and health, the private sector, public-private partnerships, product development partnerships and representatives of civil society and nongovernmental organizations.

The process can involve the following:

1. Establish a group with the appropriate knowledge and skills to identify the data sources and analyse findings. The ministry of health could coordinate this process.
2. Conduct the situational assessment using the present checklist as a guide.
3. Analyse the findings, and submit recommendations to relevant ministries and health committee parliamentarians, as applicable, on implementation of the global strategy in order to address national needs and challenges.

**The checklist is available in Annex 1.
A country case study on use of the checklist is available
in Annex 2**



3.2 Data sources

Several sources of data can be used for this exercise, including information collected routinely in national TB programmes, reports of other government or international research organizations, reports from funding organizations, periodic reviews of other ministries involved in health research and data (peer reviewed or “grey material”) from academia, partners, civil society, nongovernmental organizations, the private sector and others.

Insufficient national data or lack of information about certain areas included in the situation assessment may pose a challenge. While it is beyond the scope of the situation assessment to account for such gaps, it should indicate where the data gaps are and whether they are concentrated in a particular thematic area. This can lead to dialogue with relevant entities. If no data are available for certain thematic areas, other strategies should be used to inform the assessment, such as extrapolation of data or use of proxy metrics for key measures. Qualitative methods are other potential sources of information. If there is little data and information, a situation assessment can serve as a baseline to indicate where information is lacking for future monitoring and evaluation rounds.

3.3 Using the outcomes

The group conducting the situational assessment should use the findings of the evaluation to make **evidence-based recommendations** for specific (identifiable) sectors. Depending on the country context, the recommendations may be suggestions to improve current work or broader suggestions for better governance of TB research. To support implementation, the ministry of health should coordinate incorporation of the recommendations into strategic documents such as the national strategic plan for TB, the national TB research plan or other strategic documents that guide health research (e.g. the national health research strategy). The recommendations will thus be positioned for a needs-based response within national strategies throughout their implementation or in preparing the next plan.

In the absence of a well-functioning national health research system, the working group may consider recommending the development of a *national plan for TB research* to bridge the gap between research needs, country capacity, available resources, the research environment and public health impact. While this checklist provides an opportunity for high-level policy analysis and dialogue, other resources provide more detailed guidance for developing a national TB research plan step by step.^{5,6}

3.4 Dissemination of findings

If appropriate, the findings and recommendations of the situational assessment can be published, in the grey literature, in an academic journal or through other channels suitable for the country context. This can improve the quality and coherence of dialogue among policy-makers, decision-makers, advocates and other stakeholders.

⁵ A toolkit for developing a national TB research plan, in support of the third pillar of the End TB Strategy. Geneva: World Health Organization; 2016 (https://www.who.int/tb/publications/TB_research_toolkit/en/, accessed 1 November 2020).

⁶ Rudan I. Setting health research priorities using the CHNRI method: IV. Key conceptual advances. *J Glob Health*. 2016;6(1):010501.



3.5 Monitoring and evaluation

The recommendations from the initial situational assessment can serve as a baseline for monitoring progress as a component of routine national TB programme reviews. Such reviews can be important for integrating sustainable monitoring among countries, with support from WHO country and regional offices, partners and civil society.

4. WAY FORWARD

The situational assessment described in this document is only part of a continuum of efforts necessary to facilitate implementation of the global strategy. Its specific aim is to help countries meet the commitments made in the global strategy; however, success will require the concerted efforts of all stakeholders in ensuring that the recommendations of the situational assessment are implemented. To achieve maximum impact, the work should be complemented by capacity-building and institutional strengthening, dedicated leadership, domestic TB research funding and a system for monitoring and evaluation that promotes both learning and implementation.

Annex 1. Checklist for a situational analysis

GOOD PRACTICES IN CONDUCTING A SITUATIONAL ASSESSMENT

Understanding of the country context is the basis of a situational assessment. The assessment should present data, trends and insights for the four thematic areas and explore how those elements interact with one another and with other important country-specific factors and goals. Good principles of a situational analysis include:

- full participation of all relevant stakeholders, ensuring buy-in for implementation of the recommendations;
- triangulation of a wide range of quantitative and qualitative information to understand the situation fully;
- use of a causal framework to investigate the interactions of the situational assessment inputs, processes and past outputs with each other and with other country-specific factors and goals (including those stated in the national strategic plan for TB) to better understand the causes of the current situation and to make evidence-based recommendations for the future;
- setting public health impact as the main goal of the situational assessment and the recommendations; and
- acknowledging the multisectoral nature of health research, as stated in the global strategy, and considering cross-sectoral solutions to challenges.



A. Enabling environment for high-quality TB research and innovation

Potential (overall) measure: Extent of government engagement in research networks and public–private partnerships for TB research and innovation and time required for regulatory approval of clinical trial protocols and product evaluations			
Checklist			Examples of data and information to be reviewed (the list is not exhaustive)
1.1	<input type="checkbox"/>	A national TB research network or working group to guide a national research plan, including identifying research questions, capacity and financial needs and other questions on implementation and policy	<ul style="list-style-type: none"> - Mapping of networks or task forces that have (can) contribute(d) to aligning TB research with national public health needs - Availability of a TB research unit (focal person) within the ministry of health to help coordinate research
1.2	<input type="checkbox"/>	A country-specific TB research agenda and strategic plan to guide country-specific action	<ul style="list-style-type: none"> - Recent (< 5 years) national TB research agenda (plan or priorities) and wide dissemination of the document
1.3	<input type="checkbox"/>	Sufficient local researchers with the necessary profiles in TB research and incentives to retain them in employment	<ul style="list-style-type: none"> - Numbers of completed MScs and PhDs on health research (and, if known, on TB research) - Financial support (particularly long-term) to education and training institutions, including centres of excellence for TB research - Proportion of health researchers in permanent versus contractual or project-limited employment - See the WHO toolkit for developing a national TB research plan for more examples.⁷
1.4	<input type="checkbox"/>	Specialized training (on TB) for new researchers, research infrastructure and incentives to stimulate innovation and increase the capacity to use innovations	<ul style="list-style-type: none"> - Transparent policies favourable for investment in health research (education, human capital and information technology) - Numbers of completed MScs and PhDs on TB research (if known) - Initiatives for strengthening clinical trial capacity to international and national ethical standards - Special training for TB research coordinated nationally or through international partners
1.5	<input type="checkbox"/>	Availability of international collaborative research initiatives (as necessary) to advance TB research and innovation	<ul style="list-style-type: none"> - North–South or South–South collaboration in TB research, including capacity-building initiatives - Use of partnerships in the overall approach to TB research, to encourage or implement research that might not otherwise be conducted - Special governance arrangements for collaborative research (e.g. through specific institutions) - Contribution of collaborative initiatives to cost-sharing (see 2.3)

⁷ A toolkit for developing a national TB research plan, in support of the third pillar of the End TB Strategy. Geneva: World Health Organization; 2016 (https://www.who.int/tb/publications/TB_research_toolkit/en/, accessed 1 November 2020).



1.6		Predictable regulatory processes for review of clinical trials and other TB research	- Procedures and policies for reviewing clinical trial and other TB research protocols at national, sub-national and institutional levels
1.7	<input type="checkbox"/>	Incentives or public health provisions to expedite the review of TB products that have high potential health impact	- Procedures and policies for rapid evaluation of life-saving tools for TB prevention and care (products developed in-country or abroad). Refer to Table 5.1 of the global strategy to see examples.
1.8	<input type="checkbox"/>	Predictable regulatory processes for evaluation of TB products developed elsewhere	- Procedures, policies, guidelines, standards and biological reference materials for effective guidance for evaluation of health products developed in-country or elsewhere - Platforms to empower (e.g. through capacity-building) regulatory authorities to expedite registration of life-saving products, including generics
1.9	<input type="checkbox"/>	A clear, predictable pathway for transport of biological samples, study drugs, research reagents and equipment in and out of the country to advance innovation, while protecting privacy and confidentiality	- Clear policies, operating procedures, staff and infrastructure to provide guidance on this issue at national and/or sub-national levels
1.10	<input type="checkbox"/>	Public-private partnerships and product development partnerships for TB research in the country	- Numbers and types of national and foreign public-private partnerships and product development partnerships operating in TB research in the country - Numbers (%) of local and international private sector firms collaborating with local universities or research institutes in TB research and innovation - Performance (productivity) of public-private partnerships and product development partnerships in the TB field
1.11	<input type="checkbox"/>	Does the government have policy frameworks to incentivize public-private engagement in research and the private sector in general, such as pharmaceutical companies, biotechnology firms and others in research and development of vaccines, medicines, diagnostics and other health technologies, to improve TB prevention and care?	- Refer to Table 5.1 of the global strategy for examples of incentives to encourage the engagement of non-public sectors in TB research and development.
1.12	<input type="checkbox"/>	Engagement of civil society in implementation and uptake of research	- Numbers of civil society organizations engaged in TB research - Norms for inclusion of civil society in the design, implementation and dissemination of TB research

B. Financial investments in TB research and innovation

Potential (overall) measure: Nationally, proportion of gross domestic expenditure on research and development that is allocated to TB research			
Checklist			Examples of data and information to be reviewed (the list is not exhaustive)
2.1	<input type="checkbox"/>	Proportion of gross domestic expenditure on research and development that is allocated to TB research	<ul style="list-style-type: none"> - Proportion of gross domestic spending on TB research and development (review of trend over past 5 years) - TB research expenditure from other sources (e.g. partnerships, private sector, philanthropy) as proportion of total funding for TB research - Impact or consequences of TB research funding on public health
2.2	<input type="checkbox"/>	Incentives to separate the cost of investment in research and development of vaccines, medicines and diagnostic tools from the price and volume of sales (if applicable)	<ul style="list-style-type: none"> - Several “push and pull” incentives may be considered. Examples are given in Table 5.1 of the global strategy, but others may be applicable.⁸
2.3	<input type="checkbox"/>	Collaborative funding mechanisms to increase financial investment in TB research	<ul style="list-style-type: none"> - Opportunities for co-funding TB research projects by local, regional or international research actors such as universities, funding institutions or the private sector - Percentage of TB research projects in local universities or research institutes financed by local or foreign institutions, including the private sector
2.4	<input type="checkbox"/>	Sufficient funding for operational, implementation, social, economic and health system research to ensure effective, efficient delivery of research benefits, particularly to vulnerable groups	<ul style="list-style-type: none"> - Numerical disaggregation of national budgeting and funding structures for TB research by discipline (research area) in the past year - Inclusion of vulnerable groups in publicly funded TB research (as applicable in the country context)

⁸ Renwick M, Brogan DM, Mossialos E. A systematic review and critical assessment of incentive strategies for discovery and development of novel antibiotics. *J Antibiot.* 2015;69(2):73–88.

C. Approaches to data-sharing

Potential (overall) measure: Extent of government efforts to establish or strengthen a well-resourced national open data initiative for TB research in various disciplines and sectors and government contribution to timely, consistent global data-sharing to guide global policy decision-making and development of new tools for TB		
Checklist		Examples of data and information to be reviewed (the list is not exhaustive)
3.1	<input type="checkbox"/>	<p>National health information and vital registration systems for the collection of high-quality data for reliable tracking of the TB epidemic (in terms of absolute numbers and trends in incidence and deaths), in order to detect and monitor subnational, national, regional and global trends and to inform decision-making while protecting patient confidentiality</p>
3.2	<input type="checkbox"/>	<p>Policies for open access to and open data for scientific research financed by public funds to reduce duplication of work, expedite research and facilitate the translation of evidence into national and global policies for TB prevention, diagnosis, treatment and care, while maintaining patient privacy and confidentiality and protecting intellectual property</p>
3.3	<input type="checkbox"/>	<p>Policy for voluntary technology transfer to develop and diffuse knowledge and wider transfer of evidence for policy and practice</p>

D. Equitable access to the benefits of research and innovation

Possible (overall) measure: Proportion of people with TB or at risk of TB with affordable access to the best proven standard of diagnosis, treatment and prevention; and percentage of TB-affected households that experience catastrophic costs as a result of TB		
Checklist		Examples of data and information to be reviewed (the list is not exhaustive)
4.1	<input type="checkbox"/>	<p>Most recent guidelines on the prevention, diagnosis and treatment of TB at all levels of the health care system, including those for key TB populations (e.g. prisoners and migrants)</p> <p>- National and sub-national TB guidelines updated according to the latest recommendations of WHO</p>
4.2	<input type="checkbox"/>	<p>Sufficient human, infrastructural and material resources (e.g. adequate medicines and technologies) at all levels of the health care system, including those for key TB populations (e.g. prisoners and migrants)</p> <p>- Equitable distribution of screening, diagnosis, and treatment facilities and tools among regions, including in facilities for vulnerable populations</p>
4.3	<input type="checkbox"/>	<p>Inclusion of TB technologies and medicines in national essential medicine and technology lists and effective supply-chain management to facilitate procurement and use of high-quality medicines and technologies</p> <p>- Presence (absence) of TB technologies and medicines on the country's national essential medicines and technology lists and impact on the security of supply and access to TB services and tools</p> <p>- Sustainable supply chain of essential TB medicines and technologies and reliable demand forecasting</p>
4.4	<input type="checkbox"/>	<p>Policies on trade, health and intellectual property to ensure equitable access and promote innovation to meet the needs of people with TB, as highlighted in the Global strategy and plan of action on public health, innovation and intellectual property</p> <p>- Practices, incentives and barriers, including provisions related to intellectual property, that positively or negatively affect TB research and innovation</p> <p>- Policies and practices for managing intellectual property such as for maximizing health-related innovation and promoting access to health products</p> <p>- Cross-sectoral collaborative projects among the ministry of health and other relevant ministries, such as the ministry of science and innovation, to ensure equitable access to innovation</p> <p>- Policies and practices to monitor pricing and to improve the affordability of TB medicines and technologies</p> <p>- Policies and practices to encourage generic production and entry for essential TB medicines</p>
4.5	<input type="checkbox"/>	<p>Regulatory frameworks and partnerships among sectors to reduce trade and distribution mark-ups on the prices of essential TB medicines and technologies</p> <p>- Affordable, high-quality, safe, efficacious TB medicines and technologies available to health systems and patients</p> <p>- Supply and distribution chains and procurement policies (and practices) conducive to minimizing cost (e.g. trade tariffs) and to increasing access to life-saving TB medicines and technologies</p>



			- Cross-sectoral collaboration among relevant ministries, such as health, trade, science and technology, innovation
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Annex 2. Country case study: Ethiopia

In 2020, Ethiopia assessed its preparedness for implementing the Global strategy for TB research and innovation. Mekelle University, a member of Ethiopia’s national Tuberculosis Research Advisory Committee facilitated the assessment. The Advisory Committee was established in 2001 by the Ethiopian Federal Ministry of Health to better coordinate the conduct of TB research in the country to meet national priorities and needs. The Committee consists of a voluntary network of relevant departments in the Ministry, including the National TB Programme, public research institutions, major national universities, professional associations and other key TB stakeholders. Its activities range from identifying national TB research priorities to conducting research, coordinating and implementing capacity-building and organizing an annual meeting.

For the assessment, Mekelle University triangulated qualitative and quantitative information from relevant Government and nongovernmental bureaus. The assessment identified both strengths and gaps and presented contextualized recommendations for what key stakeholders could do to improve national TB research. The recommendations are an adaptation of the recommendations of the Global strategy to the country’s political, economic and social realities and its progress towards the goals and targets of the End TB Strategy. In a next step, the Ministry will facilitate implementation of the recommendations within Ethiopia’s national TB research plan (2017–2022).

Contextualized recommendations for implementation of the Global strategy for TB research and innovation in Ethiopia


A. Create an enabling environment for high-quality TB research and innovation.

1. Political and administrative leadership are key for enabling research. *For overall coordination, the Federal Ministry of Health should establish a TB research unit (or at least a research focal person) within the national TB programme.*
2. Better coordinated, more purposeful collaboration is necessary to advance research to meet national needs. *The Ministry should establish a platform or designate an institution to coordinate and facilitate North–South and South–South partnerships for TB research.*
3. Ensure meaningful engagement of the private sector in TB research. *The Ministry should work with relevant sectors in implementing the Federal Public–Private Partnership policy to strengthen the engagement of the private sector, including product development partnerships, and with research institutes in financing, implementing and capacity-building for TB research.*
4. Clear review processes are required for clinical trials to improve the overall timeline. *The Ministry of Science and Higher Education, in collaboration with the Ministry of Health should develop mechanisms for expedited review of TB research protocols.*

B. Increase financial investments in TB research and innovation.

5. Insufficient domestic funding for TB research remains a challenge. *The Federal Ministry of Health should increase expenditure for TB research and innovation.*

C. Promote and improve approaches to data-sharing.

- 
6. Better-quality programmatic data are necessary to monitor progress and learn from programmes. *The Ministry of Health should provide training and adapt the content of the District Health Information Software 2 tool to make it user friendly, thereby improving data quality.*
 7. Clinical trial data should be disclosed to strengthen learning, innovation, accountability and transparency. *The Ministry of Science and Higher Education in collaboration with the Federal Ministry of Health should consider including policies on the disclosure of results of completed clinical trials in the new guidelines for Ethiopia's National Ethics Review Committee.*

D. Promote equitable access to the benefits of research and innovation.

8. The latest guidelines on TB prevention and care should be available both nationally and sub-nationally; this is not always the case at regional level. *Regional TB programme offices should ensure the availability of all the necessary guidance documents for TB prevention and care at all levels of the health care system.*
9. Sufficient trained health care staff are essential for efficient access to TB services.
 - *The National TB Programme should identify and address the challenges associated with high turnover rates of health care staff, including laboratory personnel.*
 - *The Federal Ministry of Health should address the shortage of laboratory personnel, in collaboration with the Ministry of Education.*
 - *The Federal Ministry of Health should establish strong links with local universities for training human resources for TB.*
10. High-quality medicines must be available at all levels of the health system to ensure equitable access.
 - *The National TB Programme should facilitate introduction of new anti-TB medicines (as they become available) to accelerate their availability in facilities.*
 - *National and regional TB programmes should strengthen the capacity of facility staff to forecast TB supplies efficiently in order to avoid stock-outs.*
 - *The Federal Ministry of Health should allocate an adequate budget to ensure robust supply-chain management of TB-related drugs and technologies.*





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