Legal Environment Assessments for Tuberculosis
An Operational Guide

July 2017
ACKNOWLEDGEMENTS

This guide was adopted from and based on ‘Legal Environment Assessment for HIV: An operational guide to conducting national legal, regulatory and policy assessments for HIV’ produced by UNDP in January 2014. It is recommended that this guide, the HIV guide, and the guidance for conducting gender assessments are used in tandem, where applicable, for efficiency and for further scale up of the response to the two epidemics.

The TB operational guide was developed by Marina Smelyanskaya, independent consultant, with guidance from Colleen Daniels, Human Rights, Gender, TB/HIV Advisor, Stop TB Partnership; Clifton Cortez, Team Leader, Gender, Key Populations, and LGBTI for HIV, Health and Development Group, UNDP; and Boyan Konstantinov, Policy Specialist, Key Populations and LGBTI, UNDP.

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ABBREVIATIONS AND ACRONYMS

AIDS – Acquired immunodeficiency syndrome
ART – Antiretroviral therapy
CAT – Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment
CEDAW – Convention on the Elimination of All Forms of Discrimination against Women
CERD – International Convention on the Elimination of All Forms of Racial Discrimination
CRC – Convention on the Rights of the Child
The Global Fund – The Global Fund to Fight AIDS, TB and Malaria
HCW – Health care workers
HIV – Human immunodeficiency virus
HRC – United Nations Human Rights Council
ICCPR - International Covenant on Civil and Political Rights
ICESCR – International Covenant on Economic, Social and Cultural Rights
ILO – International Labour Organization
LEA – Legal Environment Assessment
LGBTI – Lesbian, gay, bisexual, transgender, and intersex
MDR-TB – Multidrug-resistant tuberculosis
MWC – International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families
OHCHR – Office of the United Nations High Commissioner for Human Rights
PLHIV – People living with HIV
PWUD – People who use drugs
TB – Tuberculosis
UN – United Nations
UNAIDS – Joint United Nations Programme on HIV/AIDS
UNDP – United Nations Development Programme
UNFPA – United Nations Population Fund
I. INTRODUCTION

1. A human rights-based approach to TB

TB has persisted throughout history because its roots are deeply intertwined with economic and social inequalities. TB has always been a disease of poverty, and a litmus test for our commitment to social equality and health for all.

Drs. Aaron Motsoaledi & Joanne Carter, Stop TB Partnership Coordinating Board

We need a new global attitude in the fight against the disease. We need to change the way we have been thinking and working. We need to properly react against this biosocial disease of enormous and unacceptable magnitude that kills millions, unnecessarily, before our very eyes, and that impoverishes and degrades the lives of millions more. We need to break with old approaches that have failed to rationally use the most effective approaches to combating the disease, and mobilize sufficient political will and resources to prevent needless transmission, sickness and death. We can accept no less than zero new TB infections and deaths.

Political will is the driving force that enables countries with high burdens of TB to reduce deaths, infections and suffering. Commitment of other sectors of government beyond the health sector – and of society beyond government, including the private and nonprofit sectors, industry, and civil society – are instrumental in achieving these gains. We need to confront the social determinants of this disease that affects mostly the poor and marginalized, and provide the dramatically increased resources critical to achieving this.

Treatment Action Group Zero TB Declaration

Linking TB and human rights

The World Health Organization (WHO) estimates that, in 2015, 10.4 million people globally fell ill with tuberculosis (TB) and 1.4 million died of the disease. A preventable and curable condition, TB kills three people every minute. TB also continues to be the leading cause of death among people living with HIV.

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one in three HIV related deaths are due to TB. In addition, almost half a million people are estimated to have developed multidrug-resistant TB (MDR-TB) in 2015, but less than a quarter of them were started on treatment.

Defying these grim statistics, 2015 became a catalysing year for the drive to end the world’s deadliest infectious diseases. In September 2015, UN member states unanimously adopted the Sustainable Development Agenda that includes the ambitious goals of eliminating TB and HIV as public health threats by 2030. However, between 2000 and 2014, TB incidence fell by only 1.5% a year. At this rate, it would take until 2182 for the world to meet the 2030 targets for TB incidence and death – nearly 150 years behind schedule. A clear and decisive change in the status quo is needed, as only about half of those who become ill with TB have the opportunity to be cured. While scientific breakthroughs to improve TB diagnosis and treatment and price reductions to make new medicines widely available are key, policy shifts to increase access for those most affected by TB are even more crucial.

In the field of HIV prevention, treatment and care, it has long been established that discrimination and stigmatization, as well as punitive legal and policy environments that infringe rather than protect human rights can severely undermine the effectiveness of national and global HIV responses. In 2012, the report of the Global Commission on HIV and the Law brought these concerns to light. The report outlined the key legal and practical barriers that impact the success of HIV interventions and should be addressed by local, regional and global stakeholders. As a reflection of these and other efforts promoting rights-based approaches to HIV, the imperative for human rights was set forth in the 2016 Political Declaration on HIV and AIDS in which member states signed on to end the AIDS epidemic by 2030.

In refining the global TB response, human rights have not received as much attention as in the fight against HIV and AIDS; they are, however, no less important. TB affects those who are already more vulnerable or marginalized. PLHIV, people who use drugs (PWUD), mobile populations, rural and urban poor, miners, prisoners, women and children face significant challenges when accessing TB care. These challenges are rooted in the social and economic disparities faced by these communities. Moreover, these challenges are perpetuated and exacerbated by policies and practices that violate human rights, hinder the achievement of gender equality, restrict access to essential medications, and generally discourage health-seeking behaviour. In some cases, laws that aim to protect and promote human rights are in place, but not fully implemented.

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As a result of these deficiencies in law and practice, people affected by TB suffer both from the disease and from its impact on their enjoyment of other human rights. People with TB⁶ might plunge into poverty due to loss of employment as a result of the disease or the high costs associated with treatment. They may also be subjected to involuntary hospitalization, isolation and incarceration. TB-associated stigma and discrimination overlap with discrimination based on poverty, HIV status, gender or belonging to other marginalized groups. This overlap erects further barriers to accessing treatment and care. For the global TB response to succeed, these issues must be addressed immediately through human rights-based initiatives.

The leading health agencies that provide guidance on TB programme implementation recognize that policies and practices that explicitly address human rights must be an integral part of national TB responses. Both Stop TB Partnership and WHO have presented a set of targets for ending TB. They urge national stakeholders to build TB initiatives that focus on the link between the protection of human rights and the effectiveness and efficiency of national TB responses.

WHO’s post-2015 End TB Strategy includes the protection and promotion of human rights, ethics and equity as one of its key principles. WHO also advises that countries acknowledge the ethical dilemmas and inequities of TB and encourage national dialogues to help resolve these issues. Such dialogues should promote equity by identifying the risks, needs and demands of those affected by TB.

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⁶ This term encompasses people who are ill with active TB. The term “people (or person) with TB” recognizes that people with TB should not be defined solely by their condition. The term may be preferable to the word “patient” in certain contexts (e.g., non-medical and community settings).
In the Global Plan to End TB 2016–2020, Stop TB Partnership outlines recommendations for improving the reach and quality of current medical interventions for TB; provides resource investment strategies for different regions; and clearly acknowledges that TB programming will not be successful unless global and national programmes utilize approaches grounded in human rights and gender equity.

7 The targets of the Global Plan to End TB are included in the Political Declaration on HIV and AIDS: On the Fast-Track to Accelerate the Fight against HIV and to End the AIDS Epidemic by 2030 (see paragraph 60(g)). Member states have committed to reducing TB deaths among people living with HIV by 75% by 2020 through funding, achieving the Plan’s 90-90-90 targets, and other initiatives, including 100% coverage of intensified TB case finding among all persons living with HIV, with particular attention to underserved and at-risk populations.
Both WHO and Stop TB Partnership establish gender as another key concern that must be a focus of national TB programmes. In many settings, gender inequality restricts the ability of women and girls to realize their human rights, including their right to health. Epidemiology shows that TB impacts more men than women. However, while women share some of the barriers that men encounter in accessing TB diagnosis, treatment and care, they often face additional obstacles due to gender inequality. These obstacles result in poor outcomes among women and girls. Therefore, focus on gender-specific initiatives is needed in settings where gender inequalities persist. In most settings, men and women may have different needs in terms of improving access to TB diagnosis, treatment and care.
Defining a human rights framework for TB
The human rights, equality-driven, gender-based approach to TB envisioned by both WHO and Stop TB Partnership is grounded in international and regional human rights instruments and domestic laws. These laws are built around core human rights principles and recognize that all human beings have equal human rights, regardless of their nationality, ethnic origin, sex, race, religion, or any other status.

Box 1. Key principles guiding rights-based approaches to TB
The same principles that guide other human rights initiatives are applicable to TB:

- **Universality**: Human rights are for everyone, without exception, everywhere and for all time. People are entitled to these rights simply by virtue of being human.
- **Indivisibility and Interdependence**: Human rights are indivisible, interdependent and interrelated. The indivisibility principle recognizes that if a right such as the right to health is violated, it necessarily affects people’s ability to exercise other rights such as the right to life or the right to vote.
- **Equality and Non-Discrimination**: All human beings are equal. Equality must be recognized, protected and promoted under law, including through protections against discrimination of any kind. This includes not only intentional discrimination, but also policies and practices that have discriminatory effects.
- **Accountability**: Government and other actors must be held accountable for failing to uphold their obligations to realize human rights. Effective measures must be included in laws and policies to promote and facilitate accountability, and to allow for access to adequate and appropriate remedies.
- **Participation**: People have a right to participate, directly or through capable representatives, in decisions that impact their lives, including government decision-making processes that impact their health. Civil society and community group participation in decision-making processes is key to realizing this principle.
Human rights and gender equality protections are also outlined in the eight core UN international human rights treaties. All member states have ratified at least one of these treaties, and 80% of UN member states have ratified four or more, declaring their commitment to protecting the rights of their citizens.

<table>
<thead>
<tr>
<th>Treaty</th>
<th>Monitoring Body</th>
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<tbody>
<tr>
<td>International Covenant on Civil and Political Rights (ICCPR)</td>
<td>Human Rights Committee</td>
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<tr>
<td>International Covenant on Economic, Social and Cultural Rights (ICESCR)</td>
<td>Committee on Economic, Social and Cultural Rights</td>
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<tr>
<td>International Convention on the Elimination of All Forms of Racial Discrimination (CERD)</td>
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<tr>
<td>Convention on the Elimination of All Forms of Discrimination against Women (CEDAW)</td>
<td>Committee on the Elimination of Discrimination against Women</td>
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**Box 2. The right to health**

Among the rights identified in the Universal Declaration of Human Rights, the right to health is most closely linked to TB. Inequalities, discriminatory practices and unjust power relationships impact the ability of people with TB to enjoy their right to health. The right to health is also closely related to other human rights. It is important to underline the core principles of the right to health, as these principles should also guide human rights-based national approaches to TB:

- **Availability**: There should be a sufficient quantity of functioning health care facilities, goods and services for the diagnosis and treatment of TB, as well as adequately developed and updated TB programmes.
- **Accessibility**: Health facilities, goods and services for TB must be accessible to everyone. Accessibility has four overlapping dimensions:
  - non-discrimination
  - physical accessibility
  - economical accessibility (affordability)
  - information accessibility.
- **Acceptability**: Health facilities, goods and services for TB must be respectful of medical ethics and culturally appropriate, as well as sensitive to gender and life-cycle requirements, and the special needs of key populations most at risk for TB.
- **Quality**: Health facilities, goods and services for TB must be scientifically and medically appropriate and of good quality.
These treaties establish government obligations to respect, protect and fulfill human rights.

- The **obligation to respect** means that states must refrain from interfering with or curtailing the enjoyment of human rights.

- The **obligation to protect** requires states to protect individuals and groups against human rights abuses committed by non-state actors and other third parties.

- The **obligation to fulfill** means that states must take positive action to facilitate the enjoyment of human rights.

For example, in the case of the right to health, governments must respect this right by not interfering with one’s bodily integrity or autonomy; protect this right by ensuring that state or non-state actors do not violate this right; and fulfill this right by creating a national health system that will support the realization of this right.

For people with TB, this might mean:

**RESPECT**: That people with TB are not involuntarily hospitalized by the state and public health providers.

**PROTECT**: That people with TB are not discriminated against in the health care sector.

**FULFILL**: That TB medications and diagnostics are available and accessible to all people with TB.

As such, national stakeholders should consider human rights approaches to TB that align with human rights principles, fulfill state obligations outlined in key treaties, and aim to halt TB; in doing so, they should seek ways to reform those policies and practices that violate the individual’s rights, including their:

<table>
<thead>
<tr>
<th>How is this right defined in international human rights law?</th>
<th>What does this right mean for people with TB?</th>
<th>How is this right commonly violated for people with TB?</th>
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<tr>
<td>Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (CAT)</td>
<td>Committee against Torture</td>
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<tr>
<td>Convention on the Rights of the Child (CRC)</td>
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<td>International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families (MWC)</td>
<td>Committee on Migrant Workers</td>
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<tr>
<td>Convention on the Rights of People with Disabilities (CRPD)</td>
<td>Committee on the Rights of People with Disabilities</td>
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| Right to Life | ICCPR 6(1): Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life. | People with TB have the right to access life-saving diagnostics and treatment. | • Imprisoned or otherwise institutionalized individuals face a disproportionate risk for TB infection, disease and death;  
• Health workers face prolonged exposure to TB, and increased risk for MDR- and XDR-TB and death;  
• PWUD, prisoners and other marginalized communities may be denied life-saving TB treatment and face death. |
| Right to the Highest Attainable Standard of Physical and Mental Health | ICESCR 12(1): Everyone has the right to enjoyment of the highest attainable standard of physical and mental health including state obligations to:  
- improve environmental and industrial hygiene;  
- prevent, treat and control epidemic, endemic, occupational and other diseases;  
- create conditions which would assure to all medical service and medical attention in the event of sickness. | [See Box 2 above] People with TB have the right to available, accessible and acceptable good-quality diagnostics and treatment on a non-discriminatory basis. | • People with TB are denied access to quality TB treatment and care in prison;  
• People with MDR-TB are denied tailored therapies with second-line medicines;  
• Governments fail to utilize donor resources to construct isolation wards;  
• People with TB who belong to additionally marginalized groups are discriminated against in TB care, e.g., given subpar treatment or denied care. |
| Right to Enjoy the Benefits of Scientific | ICESCR 15(1)(b): Everyone has the right to enjoy the benefits of scientific  
People with TB have the right to be able to access the most effective diagnosis | • People with TB in resource-constrained settings may have limited access to high-quality |
Progress and its Applications

• diagnostic services and first- and second-line medicines for treatment;
  • Restrictive intellectual property regimes limit access to quality, affordable anti-TB medicines.

Violations of these rights have a profound impact on the spread of TB in a particular setting. To effectively address TB epidemics, national stakeholders should also ensure that policies are in place that allow people with TB to fully realize the following rights:

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<tr>
<th>Right to Non-Discrimination and Equality</th>
<th>How is this right defined by international human rights law?</th>
<th>What does this right mean for people with TB?</th>
<th>How is this right commonly violated for people with TB?</th>
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<td>ICCPR (26):</td>
<td>All persons are equal before the law and are entitled without any discrimination to the equal protection of the law. In this respect, the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination on any ground such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.</td>
<td>Legal frameworks should exist that prohibit discrimination against people with TB in both public and private settings, including, but not limited to, health care, employment, education, and access to social services.</td>
<td>• People with TB are refused medical treatment or given a lower standard of care; • People with TB are denied and fired from jobs based on their TB status or TB history.</td>
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<tr>
<td>CRPD 5(2):</td>
<td>States Parties shall prohibit all discrimination on the basis of disability and guarantee to persons</td>
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Legal frameworks should exist that prohibit discrimination against people with TB in both public and private settings, including, but not limited to, health care, employment, education, and access to social services.
| **Right to Privacy** |  **CCPR 17(1):** No one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honour and reputation. |  **Information related to an individual’s TB status and treatment must be kept private and shall not be disclosed to any party, unless approved by appropriate medical professionals under narrowly and expressly tailored circumstances enumerated in law, including to protect third parties who are at serious and imminent risk of infection and to share essential health information with medical professionals providing care to the patient. |  **• Information about a patient’s TB status is disclosed;**  
  **• Patient’s migrant, HIV, drug use, or other status is disclosed in TB diagnostic settings.** |

**With disabilities equal and effective legal protection against discrimination on all grounds.**

**ICERD 5(e)(iv):** States Parties undertake to prohibit and to eliminate racial discrimination in the right to public health, medical care, social security and social services.
<table>
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<tr>
<th>Right to be Free from Torture or Cruel, Inhuman or Degrading Treatment or Punishment</th>
<th>How is this right defined by international human rights law?</th>
<th>What does this right mean for people with TB?</th>
<th>How is this right commonly violated for people with TB?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Right to Be Free from Torture or Cruel, Inhuman or Degrading Treatment or Punishment</strong></td>
<td><strong>CAT 16(1):</strong> ...prevent ...other acts of cruel, inhuman or degrading treatment or punishment which do not amount to torture as defined in article I [of CAT], when such acts are committed by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity.</td>
<td>Prisoners with TB and those at risk of contracting the disease in prison shall be free from torture and cruel, inhuman and degrading treatment during their detention. This requires providing appropriate TB testing and treatment during detention and ensuring sanitary and hygienic prison conditions to avoid transmission of the disease. People with TB who use drugs shall have access to substitution treatment or other form of drug treatment if hospitalized for TB treatment, so as not to be forced into withdrawal.</td>
<td>• Institutional settings are overcrowded and unhygienic, making it more likely for individuals to contract TB; • Prisoners cannot access medical treatment and care for a TB diagnosis; • Prisoners are not screened or tested for TB; • In institutional settings, other medicines, such as substitution treatment, are not provided to people with TB who also use drugs; • People with TB who are detained are often kept in conditions where they lack access to basic medical services. Placing individuals who are arbitrarily arrested in such conditions could constitute cruel, inhuman or degrading treatment.</td>
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<p>| Right to Informed Consent | The right to informed consent is defined by the Special Rapporteur on the Right of everyone to the enjoyment of the highest attainable | People with TB shall have the right to informed consent prior to treatment for TB and the right to be free from | • People with TB are involuntarily tested for HIV; • Unapproved medication regimens are used to |
| Right to Freedom of Movement | ICCPR 12(1): Everyone lawfully within the territory of a State shall, within that territory, have the right to liberty of movement and freedom to choose his residence; 12(2): Everyone shall be free to leave any country, including his own; 12(4): No one shall be arbitrarily deprived of | People with TB shall be free to move within and outside the country and able to receive free treatment in the location where they reside. | • TB patients under quarantine, in isolation or in detention are unable to freely move or reside in a country, or leave and return; • People exercising freedom of movement for work are denied TB services because they lack identity documents; • In some settings, people with TB may only receive free treatment in their |</p>
<table>
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<tr>
<th>Right to Information</th>
<th>How is this right defined by international human rights law?</th>
<th>What does this right mean for people with TB?</th>
<th>How is this right commonly violated for people with TB?</th>
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<td>the right to enter his own country.</td>
<td>People with TB shall have access to information about the nature of the disease, its transmission and contagiousness, effective preventive measures, and treatment availability and options, including the duration of treatment, the names and kinds of medicines involved, the nature of side effects, and the risks of treatment non-adherence.</td>
<td>• People who are illiterate may have less knowledge of TB and its signs and symptoms; • Health care workers fail to give adequate information to patients on the importance of adhering to TB medicines and possible side effects.</td>
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<tr>
<td>ICCPR 19(2): Everyone shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other media of his choice. WHO guidance also refers to this right specifically: Individuals who undergo TB testing should receive basic information about the nature of TB and why they are being tested. Individuals who are offered TB treatment should be given information about the risks and benefits of the proposed interventions (for both the patient and others in the community), the importance of completing the full course of treatment and of infection control measures, and available support to help patients</td>
<td></td>
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<tr>
<td>Right to Freedom from Arbitrary Arrest and Detention</td>
<td>ICCPR 9(1): Everyone has the right to liberty and security of person. No one shall be subjected to arbitrary arrest or detention. No one shall be deprived of his liberty except on such grounds and in accordance with such procedure as are established by law. CAT 16(1): Each State Party shall undertake to prevent in any territory under its jurisdiction other acts of cruel, inhuman or degrading treatment or punishment which do not amount to torture as defined in article I, when such acts are committed by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity.</td>
<td>People with TB shall have the right to liberty and freedom from arbitrary detention, including involuntary detention or isolation of contagious persons, except in exceptional circumstances enumerated in law and proportional to what is strictly necessary, using the least restrictive and intrusive means available to achieve legitimate public health aims (e.g., when a person is known to be contagious and is likely to transmit the disease, but refuses treatment, and all reasonable measures to ensure adherence have been attempted and proven unsuccessful); • People diagnosed with TB, who have been declared to be noncompliant with TB treatment, are arrested; • People arrested for noncompliance with TB treatment are not provided with treatment while in detention or detained in environments that constitute non-medical settings (prisons, holding cells, etc.).</td>
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<p>| Right to Fair Trial/Due Process | ICCPR 14(1): All persons shall be equal before the courts and tribunals. In the determination of any criminal charge against him, or of his rights and obligations in a suit at law, everyone shall be entitled to a fair and public hearing by a competent, independent and impartial tribunal established by law. ICCPR 14(3): In the determination of any criminal charge against him, everyone shall be entitled to... minimum guarantees, in full equality. | People with TB who have had their right to liberty restricted through involuntary detention of isolation shall have the right to due process, including the right to be heard by an independent authority, the right to appeal the decision to detain or isolate, and the right to have counsel during the proceedings. | People with TB who have had their right to liberty restricted through involuntary detention of isolation shall have the right to due process, including the right to be heard by an independent authority, the right to appeal the decision to detain or isolate, and the right to have counsel during the proceedings. | People with TB are detained without adequate justification that it is the least restrictive alternative, strictly necessary or a measure of last resort. |
| Right to Participation | Participation is a key principle of human rights-based approaches. | People with TB and former TB patients have the right to participate in decision-making processes affecting their health, including the design, | People with TB and former TB patients have limited opportunities to have a say in the design of programmes that aim to support them; | |</p>
<table>
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<tr>
<th>Right to Access of an Adequate, Effective and Prompt Remedy</th>
<th>How is this right defined by international human rights law?</th>
<th>What does this right mean for people with TB?</th>
<th>How is this right commonly violated for people with TB?</th>
</tr>
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<tbody>
<tr>
<td>This right is instrumental in providing redress for individuals whose rights have been violated; it is an integral part of the respect, protect and fulfill obligations.</td>
<td>People with TB shall have access to an adequate, effective and prompt remedy under the law for the infringements and violations of their rights.</td>
<td>• Communities of people with TB are not seen as partners in the fight against TB; • Peer-to-peer approaches are not common in TB care programmes.</td>
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</table>

Revising policy and practice at the national level and bringing them in line with the framework outlined above can begin the process of transforming and accelerating national TB responses. Other rights related to TB prevention should also be considered. Although these are freestanding rights, they are also related to the underlying determinants of health:

- **Right to adequate housing**<sup>12</sup>
- **Right to adequate food**<sup>13</sup>
- **Right to water and sanitation**<sup>14</sup>
- **Right to a healthy environment.**

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TB prevention and treatment efforts will continue to be hindered if these rights are not realized, particularly considering the well-established links between adequate nutrition and better treatment outcomes, and adequate housing and TB risk reduction.

In addition to focusing on specific rights, human rights-based approaches to TB also imply prioritizing those who are most in need of services. This principle of **priority-setting** applies to groups or populations that may be most vulnerable to and most affected by TB; it is especially important in settings where resources are limited. Prioritizing these populations ensures that approaches address inequality and inequity, and no one is left behind. Consequently, Stop TB Partnership and other national and international organizations urge a focus on TB key populations, which are characterized according to the conditions underlying their risk for TB: increased exposure to TB, limited access to TB services, or possession of certain biological or behavioural characteristics.

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### People who have INCREASED EXPOSURE to TB due to where they live or work

**Prisoners, sex workers, miners, hospital visitors, health care workers and community health workers**

**PEOPLE WHO:**
- live in urban slums
- live in poorly ventilated or dusty conditions
- are contacts of TB patients, including children
- work in environments that are overcrowded
- work in hospitals or are health care professionals

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### People who have LIMITED ACCESS to QUALITY TB SERVICES

**Migrant workers, women in settings with gender disparity, children, refugees or internally displaced people, illegal miners, and undocumented migrants**

**PEOPLE WHO:**
- are from tribal populations or indigenous groups
- are homeless
- live in hard-to-reach areas
- live in homes for the elderly
- have mental or physical disabilities
- face legal barriers to access care
- are lesbian, gay, bisexual or transgender

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### People at INCREASED RISK of TB because of biological or behavioural factors that compromise immune function

**PEOPLE WHO:**
- live with HIV
- have diabetes or silicosis
- undergo immunosuppressive therapy
- are undernourished
- use tobacco
- suffer from alcohol-use disorders
- inject drugs

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It is also critical to consider the role of gender in accessing health services in a particular setting. Because of harmful gender norms that remain the status quo in many settings, women often face barriers in accessing health services. These barriers are exacerbated when women face stigma and discrimination associated with TB.
While risks and barriers might vary among different populations depending on the setting, special attention should be given to the following groups in national TB laws and policies and their implementation:

- Children
- Health care workers
- Indigenous populations
- Migrants and refugees\(^{15}\)
- Miners
- People living with HIV
- People who use drugs
- Prisoners
- Urban and rural poor
- Women

Translating human rights principles into effective laws and policies

Governments are responsible for protecting and promoting human rights through effective law and policymaking and execution. In most countries, national constitutions recognize a robust and broad set of human rights. In addition, by ratifying international treaties, states are obligated to respect, protect and fulfill the rights protected in those treaties, including through domestic law in the form of legislation, policy and judicial decisions.

In addition to national constitutions, protections for human rights may be established through other legislation. At the same time, however, some laws and policies may violate the human rights of people with TB by, for example, restricting their movement or discriminating against them in access to employment. Some laws criminalize certain population groups, including PWUD, sex workers, and lesbian, gay, bisexual, transgender, and intersex (LGBTI) people, and may restrict access of these groups to TB diagnostics and treatment.

\(^{15}\) Including internal and external migrants and in some settings nomadic and pastoralist populations
At the national level, the strongest form of protection for people with TB is legislation that addresses TB specifically and guarantees the rights of people with TB and those affected by TB. Such legislation is, however, lacking. In a recent review of the laws and policies in 22 TB high-burden countries, only two countries were found to have TB-specific laws. Although TB might be mentioned in some policies and regulations and other non-TB-specific legislation, such mention does not equate to the kind of clear definition of the rights of people with TB that a TB-specific law would provide.

However, the battle for the rights of people with TB does not end with the adoption of TB-specific laws. First, these laws must be truly protective and avoid language that may cause rights violations. Next, implementation of these laws must be rigorously monitored. To this end, judges, parliamentarians and other key government stakeholders should be engaged in order to foster cross-sectoral collaboration on improving access to rights-based approaches to TB, implementing TB-specific laws, and removing harmful and unproductive legislation and regulations. These approaches need to be used in combination in order to advance the rights of people with TB.

Even in the absence of TB-specific legislation, advocates have been able to utilize international, regional and national mechanisms to bring attention to the human rights of people with TB and to ensure that those whose rights have been violated are able to access justice. In addition, state reporting to international human rights bodies has helped bring to light some of the key issues faced by people with TB.

**BOX 3. Peru TB law: leading by example**

In 2014, the Republic of Peru adopted one of the most progressive, rights-based legislations on TB.

The Peruvian law defines the following rights:

**Rights of people affected by TB:**

- Right to comprehensive health care, including the right to access free treatment for those with or without health insurance
- Right to file complaints and to be free from discrimination, including in the health sector or in other public, private or mixed institutions
- Right to privacy and respect for dignity and right to receive nutrition.

People with TB are also guaranteed certain rights during treatment that are centred around informed consent and autonomy – e.g., people undergoing treatment need to be informed about their options and have access to their records. Their right to participate in research programmes, their dignity and their religious beliefs should all be respected under this law.

The law also guarantees benefits to health workers, including regular screenings and access to compensation and social security. The law outlines the conditions and provisions for continuity of treatment for incarcerated individuals, and derives opportunities for individuals with DR- and XDR-TB to be treated first in hospitals and then in the community.

The law also calls for civil society participation in all aspects of implementation and guarantees people with TB easy access to National Identification Cards in order to obtain free treatment.
TB. States comply with international human rights obligations in a number of ways, for example, through periodic reporting to human rights treaty monitoring bodies, through individual complaints, and during the Universal Periodic Review of the Human Rights Council. These country reviews provide an opportunity for civil society and other stakeholders to assess and report on states’ compliance with human rights obligations. Multiple treaty bodies have provided states with recommendations and expressed concerns that focus on TB (see Review of treaty bodies and their application to TB on p. 66). Additionally, regional human rights bodies and national courts have ruled on cases involving people with TB. For example, in recent years, the European Court of Human Rights has decided in favour of the applicants in several cases concerning the treatment of people with TB in detention; these decisions have emphasized states’ violations of the right to life and the right to be free from cruel, degrading or inhuman treatment. Along with providing redress for individuals affected, these cases set legal precedents. In some settings, such cases have attracted national attention and shed light on the rights violations affecting people with TB. Litigating such cases is important to initiate changes in policy and practice.

In several cases, national highest courts of appeal have upheld the rights of people with TB. Most notably in South Africa, the High Court permitted a class action suit by miners with TB to proceed against the mining industry, giving mine workers an opportunity to obtain remedies for violations of their rights. In another case, the Constitutional Court of South Africa recognized that the negligence of correctional services had put prisoners at increased risk for TB. Even more recently, the High Court of Kenya held that the imprisonment of two individuals with TB who had stopped taking their treatment was unconstitutional.

These proceedings in Kenya offer an example of how courts can uphold the rights of people with TB and how legislation can impact TB prevention and treatment.

It is evident that international, regional and national legal frameworks are increasingly recognizing TB as a human rights issue, and there is a growing need for countries to review their national commitments concerning people with TB. Such a review can help to devise better national policies, promote government–civil society collaboration, and improve access to life-saving health services.

2. Legal Environment and Gender Assessments

About this guide
This guide aims to build national capacity for facilitating an inclusive and participatory process through which to develop a human rights framework for TB and to bring national laws and policies in line with this framework. In the broader context of national efforts to address TB and HIV epidemics, Legal Environment Assessments (LEAs) play an important role in identifying multiple contextual issues impacting access to diagnosis, treatment and care for those who are most vulnerable to the two diseases.

**BOX 4. TB and the law: a recent victory in Kenya**

In Kenya, public health authorities were using the provisions of the Public Health Act to arrest, charge and confine to prison people with TB who had stopped their treatment. Section 26 of the Act reads as follows: “Removal to hospital of infected persons: Where, in the opinion of the medical officer of health, any person certified by a medical practitioner to be suffering from an infectious disease is not accommodated or is not being treated or nursed in such manner as adequately to guard against the spread of the disease, such person may, on the order of the medical officer of health, be removed to a hospital or temporary place which in the opinion of the medical officer of health is suitable for the reception of the infectious sick and there detained until such medical officer of health or any medical practitioner duly authorized thereto by the local authority is satisfied that he is free from infection or can be discharged without danger to the public health.”

Kenya Legal and Ethical Network on HIV and AIDS filed a case on behalf of two petitioners with TB. The petitioners had initially been sentenced to be imprisoned for a period of 8 months, but were released on court order after 46 days. While in prison, the petitioners were given medication; however, they were placed in overcrowded conditions and not supported with nutrition or other services that people with TB are entitled to in Kenya. As a result, the health of the two petitioners was further compromised, as was the health of the public in contravention of the Public Health Act. While the two petitioners had in fact defaulted on their medication intake, the Judge ruled that placing them in prison to force them to take their medication was a violation of their Constitutional rights. The Judge also ordered a revision of public health laws and regulations in order to deliver a policy that complies with the Kenyan Constitution and WHO best practice.

LEAs aim to identify and examine the important legal and human rights issues affecting all people in a country. For HIV, LEAs have served to assess the restrictive environments that hamper access to prevention, treatment and care for key populations, women, and others who are significantly marginalized. At country level, HIV LEA processes have focused on reviewing human rights violations, laws and policies that create barriers to accessing HIV services. LEAs have engaged countries in reviewing the laws, policies and practices that were detrimental to an effective HIV response. In doing so, LEAs have promoted national dialogues and resulted in amendments to harmful policies and practices. To date, 51 countries have conducted HIV LEAs and reviews to inform legislative reform, and 49 countries have engaged in national dialogues and action planning on HIV and the law.

BOX 5. HIV LEA: positive outcomes

Malawi conducted a full Legal Environment Assessment through national stakeholder consultations, a desk review and interviews with key stakeholders. The process identified multiple legal challenges faced by key populations in accessing HIV-related services. For example, one of the key barriers for men who have sex with men (MSM) to actively seek health services was the criminalization of same-sex relationships that remained in the Malawian legal framework from colonial times. As a result of the national discussions, the government made a formal commitment to suspend the prosecution of MSM. Recently, two men were attacked in their own home by members of the neighbourhood watch team, but a Malawian Justice Minister made a powerful statement against the prosecution of LGBTI couples. Consequently, the bogus charges against the couple were dropped. Malawi is currently reviewing the laws that violate the rights of the country’s LGBTI citizens.

UNDP and Stop TB Partnership believe that a similar impact can be achieved in the context of TB. As two agencies that work closely with multilateral donors, governments and civil society partners on the ground, we believe that the review of laws and policies related to TB can accelerate the global response to TB. In addition, such a review can help build multisectoral collaboration and national drive to eliminate barriers to care for those most impacted by TB. Indeed, TB LEAs can foster national dialogue and accelerate positive policy change by focusing on the laws, policies and practices that block the access of vulnerable populations to TB treatment and care, and by facilitating the meaningful involvement of affected communities.

Combining assessments to benefit national responses to TB and HIV

The Global Fund recognizes LEA as a useful tool for identifying the laws, policies and practices that pose barriers to accessing health services and to inform the planning of practical programmes that address those barriers. As part of comprehensive programming to address human rights and gender-related barriers to accessing health services, the Fund recommends that national stakeholders closely examine human rights and gender-related barriers in order to maximize the impact of national HIV and TB responses. UNAIDS, UNDP, Stop TB Partnership and the Global Fund have also developed guidance on conducting Gender Assessments to aid country-level planning and budgeting for effective gender-focused and gender-transformative TB and HIV responses, including joint applications for the Global Fund.
TB and HIV LEAs and Gender Assessments pursue the same goal of improving national responses to the two epidemics, with consideration for those most affected by the two epidemics. This goal is to be achieved through the following objectives:

- Identifying populations that are particularly impacted by TB and/or HIV;
- Reviewing laws, policies and practices that serve as barriers to access for these populations;
- Analysing where human rights violations might hamper access;
- Moving the response along the continuum from gender-blind to gender-sensitive, and ultimately to gender-transformative\(^\text{17}\);
- Engaging country stakeholders in the alignment of laws, policies and practices with human rights and gender equality frameworks; and
- Planning for the allocation of resources (human, political and financial) to implement changes.

The three operational guides providing guidance to national stakeholders on how to conduct LEAs and Gender Assessments for TB and HIV also discuss the same approaches:

- Through a participatory and inclusive process (national dialogue), establishing key populations and outlining key barriers for these populations in accessing services, as well as identifying specific challenges to access based on gender;
- Engaging a national group of experts who are deeply invested in the process, influential and representative of the interests of key affected populations to oversee the LEA or Gender Assessment process;
- Conducting a legal review and in-depth consultations with key stakeholders in order to better assess barriers and practices;
- Identifying potential solutions; and
- Continuing participatory consultations to implement these solutions.

Considering that these tools are similar in their goals and approaches to reviewing national policies and practices, and share a focus on human rights and gender-based approaches to TB and HIV, national stakeholders are encouraged to utilize these tools together. To efficiently allocate resources and efforts, national stakeholders can use country dialogues to discuss all issues relevant to the two diseases. In addition, stakeholders should create several task forces comprised of experts in particular fields in order to ensure that issues of gender equality and the legal environments affecting TB and HIV responses are included. A team of experts proficient in these different issues should be hired to conduct data collection and analysis and to deliver a combined assessment that is sufficiently comprehensive. Although we recommend that each separate guide be consulted on specific issues pertaining to TB, HIV and gender, the processes can be combined.

More about TB LEAs

This guide discusses LEAs centred around the laws, policies and practices that impact national TB responses, with the focus on TB key populations. As described, the LEA process envisions not only a legal and regulatory review, but also the extensive consultation with experts and key stakeholders, training for judges and lawyers, and other activities across sectors that focus on contributions from affected populations, as these populations can bring invaluable expertise and recommendations to the table.

The scope of an LEA may be broad or narrow. A broad LEA includes review of all legal and policy concerns related to TB, including international and human rights law; national obligations to international treaties; constitutional law; and policies and guidelines regulating treatment and care delivery. A narrow LEA on the other hand may address one or several specific issues, or the impact of TB on one or several key populations, focusing on the laws, regulations and lack of protections that impact access to TB treatment and care for these groups.

Both broad and narrow reviews require an analysis of TB disease epidemiology and mortality, and the identification of the legal and policy barriers to TB detection and treatment success among national key populations. Most importantly, the participation of key affected populations in the LEA is crucial to its success.

3. TB key populations and a focus on gender

As described earlier, both the WHO and Stop TB Partnership strategies for effectively combating TB focus on key populations and gender-sensitive approaches. Through the LEA process, national

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18 Adopted from women4gf.org/wp-content/.../5_TB_HIV-Gender-assessment-tool-Introduction.ppt
stakeholders have the opportunity to identify the groups most affected by TB and the barriers to access created by gender inequity. In 2016, Stop TB Partnership produced briefs on the populations affected by TB in most settings, describing the challenges faced and outlining recommendations and solutions. While national focus on particular groups will vary from setting to setting, country stakeholders are encouraged to familiarize themselves with these briefs for the following TB key populations:

- Children
- Health care workers
- Indigenous peoples
- Miners
- Mobile populations
- People living with HIV
- People who use drugs
- Prisoners
- Rural poor
- Urban poor

Here, summaries of issues relevant to each key population are presented. At the national level and in preparation for the LEA, country stakeholders will need to engage in discussions on epidemiology in order to identify key populations. The LEA process is largely dedicated to establishing the particular barriers faced by these groups and proposing solutions to overcome them. As discussed above, a narrow LEA can also focus on a particular group or population.

**Children:** WHO estimates that, in 2014, 1 million children (aged 15 and younger) had TB and there were 140 000 TB-related deaths among this population.\(^{19}\) However, these estimates might be faulty due to the difficulties in diagnosis and inadequacies in current surveillance systems. TB in children is an issue that is complicated by multiple challenges. Childhood TB is extremely difficult to diagnose. Missed or late diagnosis can have catastrophic health impacts for the child and increase the chance of mortality. Childhood TB also presents evidence of system failures; as children likely contracted TB from their immediate surroundings, it indicates a dearth of prevention and surveillance efforts. Moreover, children with TB often exist as a vulnerable population within already vulnerable populations (e.g., urban or rural poor, migrant or indigenous communities, etc.). Childhood TB thus needs to be addressed by tackling broader challenges in national TB responses and by catalysing all efforts to improve surveillance, prevention, diagnosis, treatment and community education.

**Health care workers (HCWs):** Regardless of economic settings and TB incidence in the population, HCWs are at an increased risk of acquiring TB compared to the general population. In low-resource, high TB-burden settings, occupationally acquired TB is depleting the very workforce (often already scarce) fighting the disease on the frontline. Failures in health systems, occupational health (OH) services and TB infection control (TBIC), staffing shortages, supply issues, lack of funding, and lack of supervision are putting the lives of HCWs, their families and those they are tasked with caring for at risk. The fear of stigma, coupled with weak labour protections and poor confidentiality measures, often means that HCWs are afraid to disclose their health status to employers for fear of being ostracized or losing their jobs. Where available, OH services and compensation schemes for HCWs are often poorly resourced and inefficient, leading HCWs to feel as though their TB is their problem alone. HCWs are perhaps the most valuable resource in

the fight against TB. This group must be consulted in the LEA process; in some countries, organizations of 
HCWs – both formal and informal – have sprung up to advocate for change in policy and practice.

**Indigenous peoples:** The world’s 370 million indigenous peoples face a plethora of issues caused by 
displacement, dispossession, loss of livelihood, systematic racism and abuse, and lack of recognition.20 
Further hindering an adequate response to these challenges, there is a pervasive lack of data on 
indigenous peoples in terms of health and other key development indicators. The data that are available 
show a prevalence of extreme poverty and severe health disparities that include TB. Data further 
indicate that indigenous peoples universally experience higher TB burdens than their non-indigenous 
counterparts; they also struggle with access to services due to remote location, severe discrimination, 
and lack of health programming that can accommodate their non-Western views of health and well-
being.21 Multiple structural barriers must be eliminated, and TB programmes should include indigenous 
peoples at all stages of design and implementation in order to be effective.

**Miners:** The confluence of biological and social conditions has led to the interaction of silicosis, HIV and 
TB in the mining industry. This interaction is best documented in the mining industry of South Africa, 
where the consequences have been devastating, causing deaths and transmission into peri-mining and 
rural communities; the response to the crisis has also been extremely slow. Evidence suggests that similar 
patterns are developing elsewhere. Mine workers, who are predominantly male, live in crowded quarters 
and informal settlements; they leave behind families and community support structures as they migrate 
from site to site in search of employment – both within the borders of one country and across a continent. 
This migration accounts for TB and HIV transmission into labour-sending communities. These communities 
are often rural and impoverished, and their health systems are unable to effectively address TB. As a 
result, TB in the mines becomes a public health crisis for communities both in the surrounding areas and 
far away from the mines. Weak government regulations are poorly monitored and do little to hold mine 
owners to account. The mining industry continues to rely on cheap labour, and a culture of negligence

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20 Hall GH, Patrinos HA. Indigenous peoples, poverty, and development. Cambridge: Cambridge University Press; 2012; Bartlett 
JG, Madariaga-Vignudo L, O’Neil JD, Kuhnlein HV. Identifying indigenous peoples for health research in a global context: a 
world’s indigenous peoples: indigenous peoples’ access to health services. New York: United Nations; 2015 

21State of the world’s indigenous peoples: indigenous peoples’ access to health services. New York: United Nations; 2015 
2nd-volume-health/, accessed 24 February 2017); Tollefson D, Bloss E, Fanning A, Redd JT, Barker K, McCray E. Burden of 
accessed 5 March 2017).
and impunity persists. Along with the government and civil society sectors, it is necessary to engage the private sector in addressing policy and practice in the mines.

Mobile populations: Migration is a phenomenon that is driven by a number of complex economic, social, political and environmental factors. In recent years, migration has been on the rise both internally (within the boundaries of a country) and externally (across borders). Migration is a determinant of ill health, and various dimensions of the migration process impact the health outcomes of migrants. Migrants often arrive at their destination with low socioeconomic status, which makes them especially vulnerable to diseases such as TB due to poor living conditions, limited access to health services, and other hardships. When accessing health care, migrants must contend with discriminatory policies and practices, poor availability of services, negative attitudes from health care workers, language barriers and stigma. Migrants and mobile populations such as nomads and pastoralists might be outside the reach of formal health systems and thus face additional risks and delays when it comes to TB diagnosis and treatment. To address TB among migrants and other mobile populations, focus must be on delivering care to these groups in a way that is most accessible to them, and policies must be negotiated both between jurisdictions within the same state (such as revising residence requirements for obtaining care) and between different countries (such as addressing the expulsion of migrants with TB after holding them in cells with no access to care).

People living with HIV: Out of the 9.8 million new cases of TB estimated in 2014, 1.2 million were among PLHIV. The risk of developing TB for PLHIV is about 30 times greater than for those who do not have HIV; latent TB infection also progresses into active TB much faster in PLHIV, especially in the absence of antiretroviral therapy (ART). Even in the presence of ART, TB is the most common condition among PLHIV; in 2014, 400 000 people died of HIV-associated TB, making TB the major cause of death among PLHIV worldwide. While PLHIV’s vulnerability to TB is largely the result of HIV-induced immunosuppression, this is compounded by forms of discrimination, stigma, the absence of precise point-of-care diagnostics, and weak TB and HIV service integration, making TB particularly deadly for this population. Along with stigma, other factors, such as gender, poverty and malnutrition promote delays in diagnosis, present barriers to treatment and impact adherence to medications. On the policy side, delays in implementing WHO recommendations, staff shortages and inefficient distribution of staff, along with poor collaboration between vertical TB and HIV systems, also hinder the timely delivery of urgent care to PLHIV with TB. PLHIV are a diverse group, and the key populations most affected by HIV in some settings are among the most marginalized groups. Criminalization and other challenges that laws, policies and human rights violations place on these groups can serve as a barrier to diagnosis and treatment for both

TB and HIV. Addressing the needs of PLHIV with TB could be best conducted through joint TB and HIV LEA processes.

People who use drugs: Globally, PWUD remain stigmatized and criminalized. This contributes to devastating health disparities, including extremely high rates of TB often combined with HIV and viral hepatitis. The range of these health issues and the prevailing lack of integrated health services capable of delivering TB, HIV and harm reduction services in one place largely contribute to the scope of the TB crisis in communities of PWUD. Irrespective of their HIV status, PWUD tend to have higher rates of TB and higher prevalence of latent TB infection. HIV increases the likelihood of TB in communities of PWUD, with HIV-positive people who inject drugs (PWID) two to six times more likely to develop TB disease than HIV-positive non-users. While the effects of the TB epidemic are most acutely felt in PWUD communities in Eastern Europe and Central Asia, evidence from South and South-East Asia and sub-Saharan Africa suggests that these issues have become universal. Stakeholders need to take immediate action in countries where HIV epidemics are concentrated among PWUD and where rates of TB and MDR-TB are high; they must work alongside global and regional networks of PWUD and local PWUD activists to devise solutions that forgo punitive approaches to drug use and instead deliver effective and efficient results. Stakeholders in other locales where TB epidemics among PWUD may be just beginning need to implement the necessary measures to engage communities of PWUD in all aspects of initiative planning, service delivery and impact evaluation. LEA processes allow for such collaboration and engagement, enabling issues of TB and HIV to be tackled through the review of harmful policies and practices.

Prisoners: More than 10.2 million people globally are held in penal institutions at any one time, with four to six times this number passing through the world’s prisons every year. Overcrowding is an issue in the majority of the world’s prisons and greatly contributes to the spread of TB. The risk of TB disease in prison is on average 23 times higher than in the general population, and the chance of prisoners having a latent TB infection is 26 times higher than for people in the general population. Since prisons are intrinsically

linked to communities, the TB and MDR-TB epidemics in prisons have impacted health outcomes, especially in countries where excessive incarceration is prevalent. Governments struggle to address the needs of large prison populations. Moreover, the lack of financial support and training for prison health staff, and various comorbidities presenting among prisoners with TB make it difficult to deliver effective TB treatment in prisons. These factors can also cause delays in diagnosis, facilitate rapid spread of infection, and trigger frequent treatment interruptions. The issue of TB and MDR-TB in prisons cannot be addressed without focusing on alternatives to incarceration, promoting the rights of prisoners and prison staff, providing adequate support to health infrastructures within prisons, and working alongside communities and prisoners to develop more effective, rights-based TB treatment and care-delivery models.

**Rural poor:** Globally, the burden of TB is more acute in urban areas; however, in countries where large portions of the population are rurally located and reside in extreme poverty, these statistics are reversed, making TB more dominant among rural dwellers. Poverty and limited access to health facilities and health workers significantly diminish the ability of people with TB who reside in rural areas to obtain timely diagnosis and treatment. Stigma and widespread lack of knowledge about TB are also more common in rural communities. In addition, the majority of the world’s indigenous populations are rurally located; for them, the intersectional discrimination and stigma of TB combined with the stigma associated with their indigenous status perpetuates policies that might hamper their rights and contributes to a high TB burden. Although solutions are being implemented through policy and practice in rural settings, these need to be scaled up. Such solutions involve engaging with informal health care providers, contributing to ‘know your rights’ programming among rural populations, reducing stigma, ensuring transparency for rural health programming, and reviewing the laws and policies that might impact rural workers and rural women.

**Urban poor:** Around 54% of the world’s population now lives in cities, with the most rapid rates of urbanization being witnessed in developing countries. Social factors, such as poverty, stigma, gender and overcrowding, contribute to the spread of TB and resistance to health seeking among the urban poor. The inability of public health care services to keep up with the massive population growth in urban centres has led to an expansion of the informal, private, for-profit health care sector. These private providers are able to meet their customers’ demands by offering services that have been overlooked by the formal health sector, such as longer opening hours, more flexible payment options and more convenient locations. However, lack of regulation in this sector has led to poor quality of care for TB, along with inadequate and inappropriate treatment regimens and management. Such practices contribute to increased drug resistance and loss to follow-up. Private providers can also exploit low consumer awareness and knowledge about the free TB services available. The informal health care sector should be recognized as a crucial stakeholder that needs to be engaged as part of any effort to combat TB in poor urban populations. Improved surveillance data, urban regeneration schemes and social protection initiatives are also important. In addition, as with other stigmatized populations affected by TB, individuals with TB residing in urban areas must be empowered to better understand their rights.

**Gender and TB**
A focus on gender is essential when designing TB programming and when analysing laws, policies and practices. TB epidemiology clearly varies by gender: In 2014, over 60% of new cases of TB occurred in men. Despite higher HIV prevalence among women in sub-Saharan Africa, TB incidence is higher in men, except in women who are 15–24 years old in areas of high HIV prevalence. Furthermore, gender dynamics in TB enrolment, treatment and cure rates vary by setting. In most low- and middle-income countries, about two thirds of reported TB cases are among men and only one third are among women; however, it is not clear whether this disparity is due to a higher risk of developing TB among men or the under-notification of TB among women. Evidence indicates that women are less likely to be diagnosed with TB and successfully treated.

Women and men have very different needs in terms of access to TB services. Male-specific risks of acquiring and becoming ill with TB include larger networks of social contacts, employment in high-risk settings, smoking, possible higher rates of alcohol consumption, and limited health-seeking behaviour. Female-specific risks include higher stigma, delayed diagnosis, less access to treatment services, and the previous WHO policy of passive case finding. High rates of extrapulmonary TB among women also mean that they are harder to screen and diagnose. Furthermore, gender harmful policies and practices make it more difficult for women to access and receive services in most settings. While TB in women is more difficult to diagnose and they might encounter challenges and delays at the various stages of seeking help for TB, men seek help at later stages of the disease.

Women often constitute an invisible segment of the key populations listed above. While programming for TB prevention and treatment might start in male prisons, it is slow or never rolled out in settings where women are incarcerated. Even though women who use drugs are at the highest risk for HIV and heightened risk for TB, programming for them is practically non-existent, especially programming that addresses their needs surrounding TB care.

These differences and challenges are best mediated through gender responsive TB services that align with the needs of both women and men, and through the review of gender harmful policies and practices that might impact women.


Gender inequalities pose barriers to access to TB services among women

TB kills more women globally than any other single infectious disease, and more women die annually of TB than of all causes of maternal mortality combined. Women with TB who are also living with HIV are significantly more likely to die of TB than men living with both conditions. Globally, more men have TB than women; however, in some countries, more women than men are detected with TB, and in countries with a high prevalence of HIV, more women than men are notified with TB.

Several factors might be responsible for the intensified impact of TB on women. These include biological differences, harmful gender norms and societal beliefs that prevent women from seeking and accessing diagnosis, treatment and care services for TB.

There is some evidence that biological differences between women and men might make it more difficult to diagnose TB in women. A number of studies have found that TB progresses more quickly in women of reproductive age than in men of the same age group. Women have a higher prevalence of extrapulmonary TB (TB infections that occur outside the lung) than men – particularly genital TB, which is difficult to diagnose and has been identified as an important cause of infertility in settings with high TB incidence.

Gender inequality persists in the majority of the world’s locales; accordingly, women’s health might not be as valued as the health of men. Due to their caretaking responsibilities for children, partners and the elderly, women might be the last to access TB services. With limited financial resources, family budgets might be distributed in such a way that resources are not allocated to address the health-seeking needs of women. In addition, in some settings, women can only obtain treatment with their husband’s approval or must be accompanied by a husband or other male relative when travelling to a health care facility.

Stigma and women’s diminished role in society also lead to extreme behaviours, such as women with TB being ostracized by their families, thrown out of their homes without possessions, relinquishing their rights to property and land, and being separated from their children. These and other violations are completely without recourse in the absence of proper protections for women. There is evidence that young women with TB face the reality of no marriage proposals even once they are cured. In societies, where opportunities for women are already limited, such a plight might be devastating.

These and other particularities of TB service access related to gender must be taken into consideration when reviewing laws and policies, and generating legal and community responses to TB.

4. What’s in this operational guide?

This guide includes

- background information on key TB, legal and human rights issues, resources, and links to resources on legal and policy frameworks that could be utilized for TB;
- information on planning for a TB LEA, including how to ensure (i) that the assessment process is consultative, participatory, and inclusive of a range of key stakeholders and populations, and (ii) that it is relevant to and focused on priority TB, legal and human rights issues within the country;
- references and links to other useful resources to inform the process of undertaking an LEA;
- details of timeline and operational considerations in conducting an LEA;
- practical steps for undertaking an assessment, including recommended methodologies for identifying and analysing national laws, regulations and policies, and information on stigma, discrimination and other human rights violations, key populations, access to justice, and law and regulation enforcement issues;
- recommendations for obtaining feedback on and finalizing the assessment in a way that accommodates the perspectives of all those involved;
- ideas for disseminating and working with the results of the LEA together with key stakeholders;
- suggestions for moving from the assessment towards action planning for strengthening the legal and policy framework for TB; and
- examples of legal reviews for TB, case studies of best laws and practice, and annexes with practical information on budgeting for LEAs and other specific issues.

Using this operational guide

This guide can be used in all countries, regardless of the type of LEA that is being conducted and the scope or stage of development and implementation of TB-related laws, regulations and policies. It is recommended that the guide be used as a reference guide when developing and planning an LEA. The suggestions for possible processes and structures may guide decision-making related to the LEA based on the country’s particular needs, resources and time constraints (e.g., what process to follow, who will be involved and how the assessment will take place). As suggested above, a TB LEA might be best conducted in tandem with an HIV LEA or Gender Assessment or both.

Because of the dearth of studies on TB and the law, this guide provides recommendations, examples and guidance grounded in the main concepts of inclusivity, participation and human rights.

The guide is divided into five main sections dealing with a recommended five-stage process to support countries in conducting a national LEA:

(1) Planning

(2) Assessment

(3) Feedback and finalization
Important points to consider in the LEA process and some limitations of the TB LEA guide:

The operational guide as a starting point for the identification of key legal and human rights issues at the national level: This guide is the first of its kind to document issues relevant to TB and human rights and to foster national dialogue around TB laws. This guide focuses on priority issues related to TB legal and human rights, as highlighted by global health and human rights stakeholders as well as by TB advocates all over the world. It provides a starting point for countries to zero in on the issues of TB and human rights, explores key human rights frameworks, identifies possible queries and presents issues to examine. The guide does not account for all possible issues and concerns that may be raised at the national level, nor does it account for every possible type of law, regulation, policy or guideline present in each country.

The LEA process does not end with the LEA report: The LEA process follows a five-stage process that does not end with the development and finalization of the LEA report. It is important to use the findings of the LEA to generate evidence with which to actively review policies, strategies and practices, as well as to review and reform laws.

Determining relevant norms and standards: While this operational guide outlines the parameters of an LEA process that may be followed and adapted in different countries, conducting a national LEA remains a decidedly local task for each country. This guide does not offer a uniform format; each country will need to identify national norms and standards depending on the legal framework in place. In some countries, there may be limited examples of current or comprehensive medical and health laws, and various relevant laws, regulations and policies will be found in other areas of the law – from health law to labour law, to laws on immigration. In other cases, the lack of health and TB-specific laws may require countries to apply general laws (such as constitutional laws) to health issues. Many countries have dual legal systems in which civil laws and other laws (e.g., customary or religious laws) and practices conflict, creating further complexity. In addition, several countries are currently reviewing and reforming health, child care, personal, family, marriage, customary and other laws to bring them in line with international and regional human rights standards. Some countries may also be reviewing their constitutions. Considering how these laws, regulations and documents might impact TB and MDR-TB treatment access may represent both an opportunity and a challenge. As a result, determining relevant norms and standards is not always a straightforward process.

Looking beyond the law: Some of the issues identified as priority TB, legal and human rights concerns are not issues generally set out in law (e.g., the need for appropriate sensitization of lawmakers, law enforcers and service providers). Protective laws and policies are also often ineffective due to weak access to justice and law enforcement practices. Accordingly, to gain a comprehensive understanding of the strengths and weaknesses of the current legal and policy framework, the assessment process may be required to look beyond the law and include a review of access to justice and law enforcement issues.
Looking beyond policy, human rights and civil society stakeholders: Involving key human rights, government and civil society stakeholders is key to conducting an effective LEA and seeing that its findings result in policy change. However, to make tangible progress in some areas of TB policy implementation and regulations, it may be necessary to consult with and secure buy-in from other stakeholders, such as private sector companies and labour organizations. Because TB is so closely linked to poverty, the expertise of organizations, investment partners and other entities working in the area of poverty elimination might be useful in advising on best initiatives. State health insurance providers could also be consulted on how to best regulate spending on TB treatment and care. Moreover, it is critical to ensure the meaningful involvement of people living with or affected by TB.

Dealing with gaps and weaknesses in the legal and policy framework: The assessment findings are likely to highlight strengths as well as gaps and weaknesses in a country’s legal and policy framework. These findings cannot create a protective legal and policy framework in and of themselves; rather, they can guide and catalyse advocacy for reform. Where the LEA identifies gaps, challenges, human rights abuses and barriers to an effective TB response, country teams and stakeholders need to follow up the assessment process with strategic recommendations and planning for the way forward. Some issues, however, are not easily remedied through the review and reform of laws; long-term strategies may be required to deal with cultural practices, attitudes, stigma and discrimination involving specific populations (e.g., gender inequality or the stigmatization of PLHIV, PWUD, and others).

Dealing with urgency and resource constraints: This guide suggests a comprehensive five-stage process for conducting an LEA. Due to time and budget constraints, some countries may need to consider shortcuts to the process. An extensive and consultative LEA could take between three and six months, whereas an abbreviated process could be finalized within three months. While it is possible to conduct an LEA without undertaking all of the proposed steps, it is important to ensure that the process is consultative and involves the active participation of key stakeholders, including key populations, throughout all stages of the process.

Documenting experiences and outcomes: This guide provides guidance on how to document the national LEA process and conduct follow-up to the LEA. Because of limited resources on TB and the law, and TB and human rights, countries are encouraged to share their experiences and outcomes of the LEA process, so that other stakeholders can more meaningfully engage in LEAs in their settings.
II. PROCESS OF THE NATIONAL LEA

Section 1. Planning a national LEA

<table>
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<tr>
<th>WHAT</th>
<th>Governing/Executive Body</th>
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| LEA PLANNING PROCESS | Technical Working Group | All Key Stakeholders | • National Dialogue  
• Inception Report/Concept Note  
• Technical Action Team | 1 month |

1. Map of the planning process

<table>
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<td>Epidemiological reports, consultations with civil society and UN partners</td>
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| Identify Key Issues for TB and the Law | • Utilize the framework for TB and human rights in the Introduction section of this operational guide  
• Review Stop TB Partnership TB key population briefs  
• 5 Whys approach  
• Submissions from civil society |
| Identify Key Issues for TB and the Law | National dialogue |
| Produce Concept Note for the LEA | |
| Recruit LEA Task Team | |

PLANNING PROCESS RESULT: LEA INCEPTION REPORT/CONCEPT NOTE

The planning stage aims to ensure that the LEA process is transparent, participatory and focused on priority TB, legal and human rights issues of national concern to all. The planning of the LEA involves extensive consultation with a range of stakeholders who are key to a successful TB response within the
country. These consultations and transparent discussions help to increase collaboration, cohesion and awareness of the LEA, and foster buy-in and support from the leadership. This ensures that the LEA process is relevant to the needs of the country and that the findings of the LEA have policy impact.

The planning stage of an LEA may involve various steps, including some or all of the following:

- identifying key stakeholders – government representatives, private sector actors, UN agencies, civil society groups and most affected populations;
- establishing a representative Technical Working Group to lead the assessment;
- holding a consultative meeting or National Dialogue to discuss national TB, legal and human rights issues, agree on the purpose, nature and scope of the LEA, and identify priority issues of national concern;
- briefing the Technical Working Group on the relevant background information on TB, the law and human rights;
- agreeing on Terms of Reference for the LEA Task Team; and
- planning for the legal and policy assessment, which includes mapping the laws, regulations and policies to review, discussing interviews and consultations to conduct with key stakeholders, and engaging in other relevant activities.

The planning stage might also require countries to reflect on the TB disease epidemiology, cross-sectoral partnerships, and overall human rights framework in their country.
Box 1. Global Fund recommendations on assessing human rights in the TB response

The Global Fund to Fight HIV, TB, and Malaria outlines the following steps applicants should take to identify human rights programmes that will promote the uptake and success of TB initiatives:

1. **Know the epidemic** – Applicants are advised to conduct an analysis of the human rights and gender-related barriers to accessing TB services, their impact on specific vulnerable populations, and overall response to the epidemic. This analysis should build on available data and reports, utilizing both quantitative and qualitative data collection methods. It may also be advisable to consult with domestic and regional experts on key vulnerable groups and on human rights, including national human rights commissions, domestic human rights organizations and scholars, regional human rights mechanisms, and experts at WHO, Stop TB Partnership, the UN Office of the High Commissioner for Human Rights (UNHCHR) and other related partners.

For instance, in a country where TB prevalence is high among a specific population, such as PWUD, applicants may opt to examine the country’s policies, laws and practices and how they affect that specific population’s access to TB services, especially in health care settings, prisons and other closed settings. Countries are encouraged to analyse the status of the human rights of those affected by TB and MDR/XDR-TB, and to develop indicators to measure the political commitment of funds devoted to TB prevention and care as a percentage of GDP or health budgets.

2. **Consult with representatives of key and vulnerable groups** – Patients and communities play an integral role in TB treatment literacy, social support, monitoring, advocacy, communication and social mobilization. TB cannot be adequately addressed without meaningfully involving those most affected in the planning and implementation of the policies and programmes that impact them. Systems of representation that are ‘owned’ by the patient community are the most effective and sustainable mechanisms of involvement. A human rights-based approach to TB places affected persons and communities at the centre, as equal partners driving health policy, and provides them with the tools to participate and claim specific rights.

In assessing potential human rights barriers to effective initiatives and designing programmes to address those barriers, applicants are encouraged to draw on the knowledge and experience of those vulnerable to and affected by TB. Countries are encouraged to create networks and communities of key and vulnerable populations. Representatives of these communities should be included in the Country Coordinating Mechanism (CCM) and involved in the development and oversight of concept notes and grants. However, if they are not currently part of the CCM or other formal consultation mechanisms, they should still be involved in the development and oversight of concept notes and grants through the country dialogue process. Such consultation also creates local ownership and channels for communication, ensuring that human rights programmes are fully implemented.

Country applicants should also consider the need to develop mechanisms for cross-border and transnational continuation of care and should address the needs of mobile and displaced populations.
2. **Know the TB epidemic**

Because of the persistent stigma associated with TB, the difficulty of treatment, and the impact of going through treatment on one’s life, people who have successfully completed TB treatment might prefer to separate themselves from TB for a variety of reasons. As a result, “communities” of people with TB may be non-existent in a country. However, such communities are beginning to appear in many settings and must be included in the LEA process. More importantly, to ensure the engagement of all key stakeholders, it is necessary to understand the TB and MDR-TB epidemics in the country. This involves identifying not only the communities most affected, but also the government, non-government, community and private sector actors who can potentially participate in changing policy and practice to expand access for those communities. Reviewing national surveillance and discussing statistics with a group of key stakeholders is crucial to LEA process planning and identifying which issues and policies might need to be investigated, changed, updated or seen through to implementation. Epidemiology and statistics, however, cannot provide sufficient insight into the severity of the barriers encountered by these groups or the solutions that might be needed to overcome these barriers. Thus, other approaches are required and extensive consultations need to take place.

3. **Link human rights programmes to other interventions** – Based on these consultations, applicants should identify programmes addressing human rights and gender-related barriers that are closely aligned with the health initiatives for which the applicant also requests support. For instance, if an applicant’s aim is to increase the number of people who present to be tested for TB, but consultations with networks of vulnerable groups reveal that many people fear that their medical information will not be kept confidential, the applicant may focus on working with health providers to raise awareness on patients’ rights, including the right to medical confidentiality; conduct ‘Know-your-Rights’ training for members of the community in order for them to better understand and demand their rights as patients; and develop a mechanism through which the breach of medical confidentiality can be reported and addressed, thereby encouraging groups in vulnerable situations to come forward, be tested and receive care free of charge.

4. **Explore potential intersectoral partnerships** – Some human rights initiatives may be developed solely within health ministries. However, most require the establishment of relationships with partners in other sectors, including legislators, civil society organizations, the justice department, economic and labour ministries, etc. Assessing the potential for productive partnerships with other sectors should be part of the consultation process. To a limited extent, Global Fund TB investments may be directed at the intersectoral level in order to address drawbacks in state functions that adversely affect multiple sectors, including health, and that consequently interfere with the effective delivery of disease control programmes.

5. **Create a plan for technical assistance** – Where necessary, applicants may build technical assistance needs into their funding request. Technical assistance on human rights can be provided by domestic and regional networks of vulnerable populations, domestic and regional human rights organizations, and through the assistance of UN agencies and Stop TB Partnership.
The 5 Whys approach
The 5 Whys inquiry technique is used to establish a cause and effect relationship between a problem and its root cause. It is frequently used for problem-solving in various industries and allows for iterative inquiry into a particular problem. By the end of the 5 Whys process, a clearer idea or action plan for tackling a particular problem should be apparent.32

Mine workers have the highest TB rates in the country. WHY?

In addition to silica exposure that increases TB risk, mine workers also have very little access to care. Furthermore, they are worried about losing their jobs if they are diagnosed with TB. Therefore, they conceal TB from their coworkers and supervisors until they are too sick to work.

While some mining companies have clinics that test and treat workers for TB, most do not. There are no regulations for mining companies to provide care to workers, and since most workers are migrants, they are not necessarily aware of their rights. It is also easier for some mining companies to lay off workers with TB and hire new ones than to provide treatment.

National labour regulations and guidelines do not include provisions on TB care for mine workers. If they do, there is no oversight over how such regulations/guidelines are executed.

It is difficult to exert pressure on employers through the usual mechanism of unions.

The government has not demonstrated enough political will in strengthening regulatory frameworks and overseeing their implementation, and civil society stakeholders have not documented violations to impact change. International stakeholders have not been slow to get involved.

PWUD have the highest TB prevalence and incidence in the country. WHY?

PWUD also constitute the population most affected by HIV in the country; they are at increased risk for TB but have limited access to TB services.

Starting early ART and initiating isoniazid preventive therapy (IPT) are key TB prevention strategies for people living with HIV and for PWUD living with HIV. IPT is also effective for HIV-negative PWUD, but PWUD have difficulty accessing both HIV and TB treatment and prevention services.

There are few “one stop shop” initiatives that address the needs of PWUD. They have to get HIV treatment in AIDS clinics and TB treatment in TB clinics. If they also want to be maintained on opiate substitution treatment, they might have to go to another treatment centre. NGOs cannot deliver TB or HIV treatment services.

Regulations allowing HIV, TB and drug treatment services are lacking, along with regulations that could allow NGOs to deliver TB and HIV treatment at drop-in and harm reduction sites. PWUD are fearful of state institutions.

Drug use is criminalized and PWUD are targeted by the police, including when they access prevention and treatment programmes.

The 5 Whys approach can help to identify some of the key stakeholders for the LEA process. In the mine worker example above, the involvement of the private sector and labour rights movement might be necessary; in the PWUD example, the participation of law enforcement and the criminal justice sector would be critical. Because of the marginalization and poverty that might silence the voices of the communities most affected by TB, such iterative and reflective exercises are necessary. Some communities, such as migrants, refugees, and others, might struggle with additional challenges such as illegal status; in such cases, ensuring that someone is representing these communities is crucial.
Key stakeholders in the LEA process include, among others:

- patients’ groups and networks of people with TB (if they exist);
- key populations and their networks/representatives (e.g., women, PWUD, formerly incarcerated individuals, migrant rights advocates, health worker collectives, miner unions, etc.);
- civil society organizations (e.g., those working on health, women’s rights, legal and human rights issues and with key populations);
- legal and human rights academics and activists;
- faith-based organizations and leaders;
- government offices (e.g., Health, Justice, Interior, Gender, Education, Correctional Services, Social Welfare, Safety and Security, Trade and Industry);
- statutory bodies (e.g., Human Rights Commission, Law Commission, Ombudsperson), traditional authorities, academia and research institutions;

**BOX 2. Commitment and leadership from all partners**

Government commitment ensures the participation of key ministries and institutions, and facilitates the integration and uptake of the recommendations emerging from the LEA into national strategies and action plans. Therefore, government commitment is crucial to the success of the LEA. Similarly, the involvement of other types of leadership at all levels of society, including traditional and religious leaders, is also vital to the LEA and the final outcomes of the process.

In order for the LEA to focus on priority human rights issues experienced by key populations in their daily lives, the LEA needs to ensure the participation of key populations, such as PWUD, formerly incarcerated individuals, TB and MDR-TB survivors, and PLHIV, at the national level, and include their voices and perspectives as individuals and through civil society organizations. This participation will ensure that the LEA’s recommendations are relevant to and supported by the key populations. The LEA process may also facilitate the creation of networks of people with TB – groups most interested in realizing the recommendations and outcomes of the LEA. Such network creation is beneficial for ensuring a rights-based approach to TB initiatives in a country and oversight over the execution of the LEA’s recommendations.

It is important to recognize that many challenges might arise in the process. Any potential challenges to the commitment and participation of the relevant stakeholders should be identified, discussed and addressed at the outset. Challenges may include a lack of government commitment and poor leadership of the LEA process; ‘jurisdictional’ disputes between government institutions or between the government and other stakeholders regarding the leadership or scope of the LEA; conflicts between the traditional or religious norms and beliefs held by leaders and communities and the human rights principles that underpin the LEA; the ‘invisibility’ of key populations within a country (particularly in countries where they are criminalized and unable to live and organize freely without fear of harassment); and the lack of capacity within government and civil society to participate effectively in the process.
• professional bodies (e.g., Medical Associations, Nurses’ Council, other Health Workers’ Unions and Associations);
• parliamentarians, members of the judiciary;
• UN agencies and international organizations; and
• the private sector.

3. Setting up a Technical Working Group

A Technical Working Group (a Steering or Advisory Committee) can guide, support and oversee the work of the LEA, as well as take up recommendations after the LEA. Ideally, the role, composition and functioning of the Technical Working Group should be discussed and deliberated on during the consultative planning stage. The Terms of Reference for the group should be agreed on by the Technical Working Group itself at its first meeting.

From the beginning, the Technical Working Group should discuss and identify the time span of its involvement and the best way to take up recommendations resulting from the LEA process.

The roles and responsibilities of the Technical Working Group are not fixed and will differ from country to country. A number of suggested roles are set out below for countries to consider when developing locally relevant Terms of Reference.

Roles and responsibilities of the Technical Working Group

The Technical Working Group has a number of possible roles that it may fulfill in guiding and supporting the national LEA:

• **Planning:** The Technical Working Group begins the planning process for the LEA and potentially oversees the National Dialogue.

• **Oversight:** The Technical Working Group needs to guide and monitor the assessment process in order to ensure that it is conducted according to the agreed-upon processes and in a way that is consultative, inclusive and committed to a rights-based response.

• **Advice:** As a multiperspectival and representative body, the Technical Working Group itself can provide various viewpoints and technical inputs on key TB, legal and human rights issues and on the various stages of the LEA process.

• **Implementation:** In some situations, particularly where resources are limited, Technical Working Group members may take on the implementation of some aspects of the LEA process.

The Technical Working Group should comprise around 10 to 15 representatives (at most) from a range of sectors, institutions and organizations that are key to the national response to TB. It should also seek representation from individuals with a range of skills, experience and competencies, as well as those with direct experience and understanding of stakeholder perspectives and key human rights issues.
Experts in the areas of human rights (health, more broadly), trade (intellectual property), governance (on procedural aspects of the law), and so on may be called on by the Technical Working Group to provide useful insights without being members of the Group. As with the LEA process itself, the composition of the Technical Working Group should be guided by principles of inclusivity, participation and diversity. Accordingly, the Technical Working Group should seek balanced representation among government, civil society and other groups, and ensure gender diversity.

There should be clarity in the roles and responsibilities of the various members of the Technical Working Group. This includes identifying institutions that will provide leadership and those that will provide administrative, financial and other support to the process. The Technical Working Group should be supported and ‘administered’ by key government ministries with technical expertise in, and responsibilities for, the uptake of the final recommendations of the LEA.

Technical Working Group membership
The Technical Working Group charged with overseeing the LEA may include representatives from the following organizations and institutions:

- relevant government ministries and entities (e.g., Health, Justice, Social Welfare, Youth, Gender, Trade and Industry, Prisons, Labour, etc.);
- national governing bodies on TB such as National TB Programme representatives;
- statutory bodies (e.g., Human Rights Commission, Law Commission, Women’s Commission);
- professional bodies (e.g., Medical Council, Nurses’ Council, Law Society);
- patients’ groups and networks of people with TB (if they exist);
- key populations and their networks (e.g., women, PWUD, formerly incarcerated individuals, migrant rights advocates, health worker collectives, miner unions, etc.);
- civil society organizations (e.g., organizations that serve people with TB, law and human rights organizations, organizations working with key populations, women’s health and rights organizations, community-based organizations, etc.), including ‘mainstream’ human rights organizations not specifically working on TB-related issues;
- faith-based organizations (e.g., organizations of religious leaders operating in communities impacted by TB);
- legal and academic institutions;
- the national parliament; and
- UN agencies (e.g., UNAIDS, UNDP, UNFPA, UNICEF, WHO, Stop TB Partnership, UNODC, OHCHR, ILO, etc.).
For the Technical Working Group to be equipped with the relevant expertise to carry out the LEA process, its members should possess a range of skills, experience and competencies in areas such as:

- public health;
- law and human rights;
- gender equality;
- trade and intellectual property; and
- working with key populations such as people with TB, women, children, PWUD, prisoners and migrants.

It is important to ensure the involvement of all key populations within the context of the particular country. This may require special effort to include less visible key populations.

*See Annex 1B for an example of a generic Terms of Reference for a Technical Working Group.*

4. **Holding a consultative planning meeting or a National Dialogue**

The Technical Working Group may convene a consultative planning workshop or a National Dialogue. This may be a useful starting point for a national LEA and a way to encourage the participation and inclusion of all partners. This may help to:

- raise awareness and understanding of TB, legal and human rights issues in the country and the importance of an LEA for strengthening an effective response to TB;
- ensure a transparent, participatory and rights-based approach to conducting the LEA;
- clearly define and agree on the purpose, nature, scope, methodology and implementation of the LEA;
- discuss and agree on oversight and reporting mechanisms for the various stages of the LEA, including the possible nature, purpose and composition of a participatory Technical Working Group to guide and oversee the process;
- identify key stakeholders to participate in consultations, focus group discussions and surveys;
- agree on preliminary focus areas for the LEA based on key TB, legal and human rights issues raised by participants; and
- brainstorm the laws, regulations, policies, research reports and other documents that need to be reviewed during the LEA.

A National Dialogue during the planning stage is particularly important in settings where leaders are unwilling to engage on particular issues, or where key populations are ‘invisible’ within a specific context or unable to participate due to lack of organization, fear of harassment, criminalization or other forms of marginalization. A National Dialogue can provide a safe space for a moderated dialogue between key
populations or the civil society organizations assigned to represent them and the government on TB, legal and human rights issues. In this way, such a dialogue raises awareness and encourages the sensitization of stakeholders; it also facilitates the identification of key issues for the LEA. The first National Dialogue may take place during the planning process. Once the LEA is finalized, another National Dialogue might be necessary in order to share and obtain consensus on the findings, as well as to devise a way forward.

In the context of HIV, multiple National Dialogues were conducted to follow up regional and country submissions to the Global Commission on HIV and the Law. These experiences are documented on the Global Commission’s website and in the UNDP-produced manual. Countries are encouraged to review these materials. Here, key steps and recommendations for conducting National Dialogues are summarized and adopted for TB.

Prior to convening the National Dialogue, the Technical Working Group can solicit written input from civil society stakeholders in order to help identify priority issues for review in the LEA. This input can be formalized in the form of reports; however, civil society stakeholders should also be given the opportunity to submit less formal case studies and reports, and to do so anonymously.

**Brief National Dialogue guidance**

**Key elements of a successful National Dialogue**

- Ownership of the National Dialogue process: Key stakeholders should commit to the dialogue as an opportunity to identify pressing legal and human rights issues that need to be tackled in the national TB response;
- Careful selection, briefing and preparation of participants: Participants should be invested not only in the LEA process, but also in the follow-up of the LEA’s recommendation; the populations most affected should be among key participants;
- A skilled, trusted and well-prepared moderator: Since some controversy is bound to arise, the moderator should be experienced in managing conflict and fostering productive conversation where power dynamics and sentiments might complicate proceedings;
- Two-day format: Day one is for constituencies to prepare, while day two is for a town hall style meeting that brings together all participants;
- A venue and seating plan that encourages interaction; and
- A well-prepared agenda for the town hall meeting that features short interventions and actively moderated discussion.

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The following additional guidelines should be kept in mind at all stages of planning a National Dialogue on TB and the law:

- **Evidence-informed National Dialogue**: Some form of background research, analysis or documentation of the national legal, regulatory and policy environment in the context of TB is necessary to help identify discussion topics for the Dialogue. The type of background research and analysis or other inputs for the Dialogue will depend upon the country context and available resources. Countries are encouraged to seek submissions from key affected populations, conduct iterative exercises described above and review TB epidemiology to prepare the evidence.

- **Participation and active engagement of all key stakeholders**: It is essential that the National Dialogue create space for constructive and frank discussions. Careful consideration should be given to the selection and appropriate involvement of key populations; people with TB and people with experience of TB\(^3\); government and elected officials involved in making laws and policies; and other people with relevant expertise in TB, human rights and the law. It is critical for follow-up purposes to involve participants with the right rank, expertise and governmental influence to make a difference.

- **Safety and confidentiality of key populations and people with TB**: One of the key objectives of the National Dialogue should be to highlight the legal and human rights issues affecting key populations and people with TB. It is important to provide a platform for these groups to voice their concerns about punitive laws, policies and practices that impact their lives, prevent their access to health services and increase their vulnerability to TB. It is particularly important for these participants to feel that their experience at the National Dialogue is a positive one that does not jeopardize their safety or confidentiality.

- **Balancing the interests and engagement of all constituencies**: Another important objective of the National Dialogue should be to provide a platform for government and elected officials involved in making laws and policies and other people with relevant expertise in TB, human rights and the law to express their concerns. The experience should be positive for all participants and should safeguard the confidentiality of the participants representing affected communities.

- **Consensus building through dialogue**: The purpose of a National Dialogue should not simply be to have a consultation meeting, or a debate on TB and the law. Rather, the dialogue should be seen as an opportunity for a constructive exchange that aims to share good practices and identify solutions. A dialogue should identify common ground and potential joint actions for advancing the national TB response in order to foster understanding between those making laws and policies and the affected communities.

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35 Please see the Global Plan to End TB for these and other definitions that recognize that people with TB or people who have had TB should not be defined solely by their condition.
• **Thorough planning and organization**: Thorough preparation is essential for the success of any National Dialogue. This includes identifying clear objectives and the scope of the issues to be discussed, managing the expectations of participants, adequately preparing those who will speak, and ensuring that the dialogue report clearly identifies who is responsible for follow-up activities and next steps.

• **Well-briefed and well-prepared moderator**: As the quality of the exchanges between stakeholder groups is key to the outcome of the National Dialogue, the selection and briefing of the moderator for the town hall meeting are also critical steps in the planning process.

**Note**: In the absence of sufficient time and resources to conduct a full National Dialogue, countries are encouraged to hold consultative workshops that invite a broad range of participants. These workshops should utilize the same principles as the National Dialogue in order to identify the priority issues for review and agree on the scope of the LEA.

**Issues to assess in requests for submissions from civil society or in consultative workshops**

Civil society stakeholders should be invited to submit formal and/or less formal reports that address such issues as:

- rights violations of people with TB, including discrimination;
- impacts of laws and policies on access to TB treatment and diagnostics among key and vulnerable populations;
- stories and case studies that pertain to individuals, but describe challenges encountered by people with TB; and
- whether established laws and regulations related to TB are actually being implemented effectively and on a non-discriminatory basis.

**Documentation**

Both the proceedings of the National Dialogue and the discussions of the consultative workshops should be adequately documented as summaries outlining the key issues discussed and the main outcomes and agreements between key stakeholders.

5. **Identifying legal and policy issues for analysis**

An LEA aims to determine the nature, extent, efficacy and impact of the legal and policy framework in protecting rights and promoting universal access to TB diagnostics, treatment, care and support. This requires the identification of the key TB, legal and human rights issues in a country and how they are addressed by laws, regulations and policies.

The following are issues common to countries across the world:

- stigma and discrimination, including in health care, education and the labour sector;
• lack of access to quality diagnostics and treatment;
• lack of access to TB diagnosis, treatment and care in prisons;
• mandatory treatment or confinement;
• inability to complete treatment;
• challenges in access to diagnosis and treatment among TB key populations; and
• gender disparities in accessing TB care.

Countries will also need to address any additional country-specific issues identified during the consultative planning stage, through stakeholder consultations, and in research and related documentation. In addition, to guide the LEA process, the Introduction section of this operational guide provides an extensive human rights framework for use in identifying issues of concern for people with TB in a particular country.

6. **LEA purpose and scope: broad vs. narrow**

In some countries, an LEA may have a very specific and narrow focus (e.g., focusing on a specific issue). For example, a narrow LEA could review the impact of laws, policies and practices that promote gender inequality and harmful gender norms in the context of TB in a country. Alternatively, a narrow LEA may focus on a specific law – for example, a systematic review of laws that address discrimination in the health or labour sector as they apply to TB.

In other countries, an LEA may be a broad-based assessment of a country’s legal and policy framework as a whole. A broad LEA would include a review of all relevant laws, regulations and policies that have an impact on TB and on key populations (e.g., health laws, criminal laws, anti-discrimination laws, children’s laws, employment laws, etc.), as well as a review of the extent to which laws are known, implemented and enforced. This may include customary and religious laws and practices, as well as the extent to which communities are able to access justice for violations of their rights. A broad review would also mean looking at issues such as the nature and extent of TB-related stigma and discrimination by institutions, service providers, communities and leaders; the extent to which people know their rights; the existence of organizations and programmes designed to reduce stigma and discrimination and provide legal literacy and legal support services; and the extent to which service providers, lawmakers and law enforcers are sensitized to TB, legal and human rights issues.

7. **Developing an inception report or concept note**

An inception report or concept note sets out a clear plan of action for conducting the national LEA, integrating all previous discussions and deliberations (such as the outcome of the consultative planning
process, National Dialogue and meetings of the Technical Working Group) into a final road map for the assessment process.

**WHAT TO INCLUDE IN AN INCEPTION REPORT/CONCEPT NOTE:**

**Purpose and scope of the LEA**

The inception report or concept note should clearly set out the purpose and scope of the LEA, including:

- a brief overview of the contextual background of TB, the law and human rights in the country; key gaps, challenges and priorities related to law and human rights in the current TB response; and the role of the LEA in strengthening an effective legal framework for TB;
- a short review and consolidation of any previous work that is relevant in a legal review of TB, such as national TB programmes, cases brought before national courts and national human rights bodies by people with TB, Universal Periodic Review recommendations, and concluding observations of UN human rights monitoring bodies that are relevant to TB;
- the scope of the LEA – i.e., whether it will be broad (examining all relevant laws and policies as they relate to TB) or narrow (focusing only on particular issues); and
- a brief overview of the nature of the LEA, how it will be carried out and what type of information it will seek to report.

**Methodology and implementation modalities**

The inception report or concept note should specify the various methodologies, activities and deliverables that will form part of the LEA process, including: (1) a desk review; (2) stakeholder consultations; and (3) national consultative forum(s) or dialogue(s) for presenting draft findings. These methodologies are described in greater detail in the following section. The inception report/concept note should also include a broad overview of the roles, responsibilities and reporting mechanisms of various partners in the process, including the lead organization(s), researchers and the national reference group set up to oversee the process. The inception report or concept note should also mention as a deliverable the final report to be completed by the LEA researchers/LEA Task Team.

**Detailed road map**

It will be useful for the inception report or concept note to include a detailed work plan that outlines:

- specific activities to be carried out during the various stages of the LEA;
- the deliverables to be achieved during the various stages of the LEA;
- the timelines attached to the specific activities and stages of the LEA;
- the specific roles and responsibilities of the various partners in each activity;
- the incorporation of reporting and feedback mechanisms during the process; and
- the support and resources required for each stage of the process.
Appendices

Other useful information that should be attached to the inception report or concept note includes:

- a list of international and regional human rights instruments, national laws, regulations, policies, strategies and plans, as well as foreign countries/laws to be reviewed;
- a list of stakeholders to be consulted or surveyed through interviews, consultsations, focus group discussions or questionnaires;
- tools to be used in the review process, including tools for analysing the legal and regulatory framework, questionnaires, surveys and interview guides;
- an outline of the LEA report;
- minutes of meetings of the LEA project teams (Technical Working Group, Task Team, etc.); and
- a report of the consultative planning workshop or National Dialogue.

8. Recruiting the LEA Task Team

The recruitment of the LEA Task Team for the research and implementation of the LEA process is an important step. It is recommended that at least two consultants (one national and one international) be recruited. These consultants will provide technical support and guidance throughout the LEA process, in close collaboration with the Technical Working Group, in order to ensure the successful implementation of the project. Due to the responsibility of the LEA Task Team and considering the contentious aspects that may surface when discussing TB and legal issues, careful attention should be paid to the selection of the Team. Selection should be based on a thorough review of the expertise of the consultants, which should be acknowledged across government officials and civil society organizations.

See Annex 1C for an example of a generic Terms of Reference for the research and implementing team (LEA Task Team).
Section 2. Conducting the Legal Environment Assessment

This section outlines some of the common methodologies that can be used to effectively conduct an LEA in various countries. Legal reviews generally include a literature or desk review, as well as a component aimed at understanding the experiences of key stakeholders and populations in accessing justice and navigating TB services, and/or in executing laws and regulations and delivering services related to TB.

<table>
<thead>
<tr>
<th>WHAT</th>
<th>Governing/Executive Body</th>
<th>Participants</th>
<th>Outcome(s)</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>DESK REVIEW*</td>
<td>Technical Working Group</td>
<td>LEA Task Team</td>
<td>• Report on the legal review</td>
<td>1 – 2 months</td>
</tr>
<tr>
<td></td>
<td>LEA Task Team</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>STAKEHOLDER CONSULTATIONS</td>
<td>Technical Working Group</td>
<td>A selection of key stakeholders identified for research purposes</td>
<td>• Results of interviews and focus groups • Final reports</td>
<td>1 – 3 months</td>
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<tr>
<td></td>
<td>LEA Task Team</td>
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<td></td>
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</tbody>
</table>

* if the LEA process ends here due to financial/time constraints, it is essential that all key stakeholders review and comment on the report.

Review of laws and consultations with stakeholders

Here and elsewhere in the document, the importance of the consultative process for the success of the LEA is underlined. Therefore, if only a desk review is anticipated due to limited resources, it is crucial that (i) the focal issues of the desk review are decided on through a consultative process – either a National Dialogue or consultative workshops as described in the previous section, (ii) multiple stakeholders are able to comment on the desk review report, and (iii) an agenda for action is developed in consultation with all stakeholders.

If resources for the LEA allow for further consultations with stakeholders, the format of the consultations at this point in the LEA process differs slightly from the planning stage. If civil society partners have an opportunity to submit reports for the National Dialogue, these consultations provide an opportunity to explore the pressing issues raised in those reports in further detail and with a focus on the priority topics identified for the LEA. Furthermore, these consultations present an opportunity to seek solutions, recommendations and commitments from civil society, government, private sector and UN stakeholders.

1. Desk review

Although legal systems differ from country to country, most countries have various sources of law as well as different branches of law. Countries also have a range of organizations, services, mechanisms
and institutions that implement laws, regulations and policies, and enable people to access justice and enforce laws when these are violated.

A desk review of laws, regulations and policies relevant to TB involves looking at many sources of law in a country. Rarely are the laws on TB codified in one form. In the majority of cases, health norms are found in various sources and branches of the law, and are complemented by a range of health regulations, policies, guidelines, plans and strategies. Some countries might have specific national TB prevention and control policies, very few will have laws that specifically address TB, and the majority will not have legislation that directly concerns TB; instead, they might have general laws and policies regarding public health. General laws related to health, disability and medical practice (e.g., laws affirming patients’ rights or regarding the safety, quality and availability of health services) will apply equally to TB. In addition, general principles of law, such as those set out in the constitution, as well as common law principles relating to privacy and autonomy, will also apply to patients’ rights.

**The constitution.** It is important to recognize a particular country’s constitution as a key, binding document that defines the rights of people within the country’s jurisdiction. Thus, the first step in the desk review process could be to review articles of the constitution and revise how they are implemented to protect the rights of people with TB.

**Why are TB-specific laws important?** National TB prevention and control policies often provide guarantees for people with TB, such as for treatment and financial and social support; however, in most cases, such policies do not establish cognizable legal rights. The provisions of a TB law should define the rights and privileges of affected populations and regulate compliance across multiple sectors (e.g., health, criminal justice). A TB law should contain realistic government commitments to rights-based initiatives for TB prevention and care, and social support for people with TB, including those who are incarcerated; in addition, the government should encourage transparency and civil society participation in matters related to TB prevention and care, and make realistic proposals in terms of financing national TB initiatives. Defining and protecting the rights of people with TB, however, does not stop with TB-specific laws. Multiple strategies should be utilized to ensure that these laws are properly implemented and that the regulations set forth within them are executed to eliminate harmful practices.

TB touches the lives of many different people and groups across a wide range of sectors; the ways in which their lives and activities are regulated may affect their exposure to TB or their vulnerability to the impact of TB. Diverse laws outside the health sector are equally important to understanding the impact of the law on access to TB diagnosis, treatment, care and support. Therefore, the desk review needs to include a range of laws affecting the country’s TB key populations, such as:

- children’s laws that set out children’s rights;
- family, marriage and inheritance laws providing information on the rights of women to own and inherit property;
• criminal laws that affect people with TB (e.g., laws that criminalize non-adherence to TB medication or call for the solitary confinement of people with TB and MDR-TB); laws that criminalize the behaviour of key populations at risk for TB including PWID;
• intellectual property laws that restrict or promote access to TB medications;
• correctional service laws that determine access to services for prisoners;
• citizenship, immigration/migration and/or refugee laws that determine access to services for non-citizens;
• employment laws that set out the rights of people with TB in the workplace, and necessitate non-discrimination and compensation; and
• disability laws that set out the rights of people with disabilities.

Finally, a country may have a ‘dual’ legal system, wherein statutory law operates alongside customary and/or religious laws and practices. In such cases, customary or religious laws may have a greater impact on people’s daily lives than the statutory laws of the land. It is important to ensure that these types of laws form part of the LEA.

States are also signatories to multiple human rights treaties that have both global and regional implications. In some regions, human rights courts may have examples of case law that are relevant to TB. Although national court decisions related to TB might be rare, they may still exist in some countries and could be useful for review in all settings. In addition, non-binding but powerful regional declarations and agreements should be reviewed in order to record national commitments to positive change.

**Documents to be reviewed**
The desk review needs to include an assessment of:

• the constitution;
• international and regional human rights instruments and declarations;
• laws, regulations and policies;
• plans, strategies and guidelines;
• case law from national courts and regional human rights courts, and UN treaty body jurisprudence;
• annual reports and research reports of civil society organizations, statutory bodies (such as a Human Rights Commission), international and regional organizations (e.g., reports submitted to Universal Periodic Review, Human Rights Watch reports, etc.) and academic publications;
• Regional agreements and high-level declarations (such as the South African Development Community Declaration on Tuberculosis in the Mining Sector, the Barcelona Declaration, etc.); and
• country reports on human rights commitments to regional bodies (e.g., the African Commission on Human and Peoples’ Rights) and international bodies (e.g., the UN).

In the process of the desk review, it is important to maintain focus on the **key issues** identified as priority issues for the LEA review. Each of the key issues may be informed by a range of laws, regulations, policies and/or guidelines. The assessment process will require all relevant laws to be identified and analysed in order to describe how they protect rights in the context of TB or act as barriers to universal access to services. The checklist below provides an indication of potentially useful laws, regulations, policies and guidelines that may apply to TB. In addition, each such law or regulation may be assessed against the **status quo** in order to identify whether or not it is actually being implemented. For example, if the national TB programme of a given country guarantees access to free medication, but the majority of people with TB have to pay for treatment and/or there are interruptions in treatment supply and stockouts, this discrepancy needs to be properly identified in the course of the desk review and in the resulting report.

**Checklist of laws relevant to TB**

Where to look: The following types of international and regional instruments and national laws, regulations, policies or guidelines may contain provisions that protect rights (or block access to services) in the context of TB:

- the constitution (particularly constitutional provisions related to rights);
- international and regional human rights covenants, charters and declarations;
- anti-discrimination laws (e.g., equality legislation);
- medical and health laws and regulations, including TB-specific laws that address prevention, care, and the criminalization of non-adherence to treatment plans, as well as those that regulate TB/HIV and drug treatment service integration, TB diagnosis, and treatment delivery;
- intellectual property laws, regulations and trade laws/agreements regulating medicines and medical supplies;
- laws on equal access to medicines;
- consumer rights laws;
- labour laws and regulations, including occupational health and safety laws, laws protecting against discrimination in the workplace, and TB-specific laws that might bar people with TB from working in certain industries despite having been treated (e.g., tourism, child care, etc.);
- civil laws with provisions affecting the personal rights of adults, minors and people with limited capacity (e.g., people with disabilities); these may include issues such as status, capacity, age of majority and guardianship;
- children’s laws;
laws affecting women’s rights (e.g., family, marriage and inheritance laws, domestic violence laws);
• criminal laws, including laws criminalizing key populations (e.g., PLHIV through criminalization of HIV transmission and exposure, PWUD, and others);
• correctional service/prison laws;
• disability laws, regulations and policies;
• education laws;
• social welfare and development laws;
• laws that regulate migration within as well as across borders and/or restrict movement (such as quarantine);
• customary and religious laws; and
• policies and ethical guidelines (e.g., health policies, codes of ethics and ethical guidelines for health practitioners).

What to look for: Provisions in laws and policies that may be relevant to the LEA include:
• the protection of basic human rights (e.g., the rights to equality, non-discrimination, dignity, autonomy, liberty, security of the person and privacy; the right to be protected from cruel, inhuman or degrading treatment or punishment; the right to reproductive health, etc.): These rights provide all people with broad human rights; as such, these rights also apply to people as patients in TB-related health care services and as populations entitled to protection;
• the specific regulations related to health (including TB) rights, responsibilities and services: Provisions within health laws may provide clear guidance on how health programmes and services are provided and establish standards for ensuring the availability, accessibility, safety and quality of diagnostics and treatment, as well as related health goods and services. Countries can also review WHO and other international best practice to ensure that national legislation aligns with this guidance, and to assess whether national laws permit access to services in the community and promote the level of integration necessary to provide quality services to people with TB who are also living with HIV or using drugs;
• laws that contain provisions related to the responsibilities of health care providers and the rights of patients with respect to health (including TB) issues, such as their rights regarding informed consent to medical treatment, medical confidentiality, access to health care services (including women’s rights to access health care), and protection from harm;
• the regulation of intellectual property and related laws, including anti-counterfeiting legislation and competition laws: This legislation will provide guidance on the extent to which a country’s laws restrict or facilitate access to affordable quality-assured treatment;
• the regulation of employment and occupational health and safety: These laws and regulations provide for the rights and responsibilities of employers and employees, and establish norms and standards for ensuring safe working conditions;

• regulations regarding the access of all children to education and access to alternative forms of education while undergoing long-term treatment;

• protection against gender inequality, harmful gender norms and gender-based violence: Provisions in family, marriage and inheritance laws may provide information on women’s rights to equality within their relationships and their rights to own and inherit property, including marital property. These laws may also provide information on the nature and extent of protection against gender-based violence (e.g., domestic violence, family violence) and harmful gender norms (e.g., early marriage, widow inheritance and women’s access to health care with or without permission of a husband);

• the criminalization of certain behaviours, such as drug use: These provisions will help to determine the climate within which key populations live and whether criminal laws exist that may pose barriers to their access to TB diagnosis, treatment, care and support;

• laws that regulate health care delivery and the delivery of social and other services in the justice system, as well as legal protections for populations that are vulnerable in the context of TB such as prisoners, refugees, migrants, workers in various industries (e.g., mining, fishing) and people with disabilities: These provisions may help to determine whether these populations have equal access to the TB prevention, treatment and care services they need;

• access to justice – for example, through the right to representation and the accessibility of legal aid.
CASE STUDY 1: DESK REVIEW OF LAWS IN INDIA

To begin developing a rights-based approach to TB in India, researchers at the University of Chicago Law School, International Human Rights Clinic and national stakeholders undertook a review of India’s domestic law and international human rights commitments. The group has conducted extensive research to date; here, the findings are significantly abridged, including only those findings in national law that provide insight into the type of analysis that might be required to identify relevant laws and protections.

Prior to undertaking this review, the group established particular challenges in the access to TB diagnostics and treatment (e.g., barriers to obtaining free, state-provided care, and cases where care was denied to particular individuals based on their social status). The legal review then addressed the particular issues to be resolved and approached the laws and regulations governing the protections of the rights of people with TB.

Domestic Law

India does not have a single, comprehensive piece of legislation aimed at combating TB. Nonetheless, three statutes entitle individuals with TB to certain legal protections: (1) the Indian Penal Code, (2) the Consumer Protection Act (COPRA), and (3) the Protection of Human Rights Act (PHRA). In addition, the National TB Control Program and the Constitution provide certain guarantees and protections.

Revised National Tuberculosis Control Program (RNTCP).

People with TB hold entitlements as a result of the Revised National Tuberculosis Control Program (RNTCP). The RNTCP provides TB care throughout the country and entitles everyone to free diagnostic services and free, quality TB medicines. More specifically, it entitles Indians to (1) sputum microscopy free of charge at designated microscopy centres; (2) treatment under direct observation at a DOTS centre near the patient’s home; and (3) enhanced supervision through a Tuberculosis Unit (TU).

Several problems with implementing the RNTCP remain. Often individuals seek care outside of the RNTCP because of: (1) poor knowledge of TB; (2) poor knowledge of the services available through the RNTCP; (3) the inconvenience of such services; (4) a desire for confidentiality; or (5) a desire for personalized care. Lack of awareness of the RNTCP disproportionally impacts illiterate, impoverished and rural communities.

Penal Code

The Indian Penal Code entitles Indians to file a criminal complaint against a physician who commits a rash or negligent act causing death. Specifically, the Code states, “Whoever causes the death of any person by doing any rash or negligent act not amounting to culpable homicide, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine, or with both.” The complainant has the burden of proof to show that the physician was grossly negligent. The Code thus entitles individuals to legal recourse against a physician who acts rashly or negligently and thereby causes the death of a patient with TB.

The Consumer Protection Act of 1986

COPRA protects consumers against (1) defective goods sold in the market and (2) deficient or negligent services provided by private physicians. As such, COPRA can be used by people with TB who have received poor treatment in the private sector. This is significant for India where many patients are unaware of free government services and so turn to private providers.
The Protection of Human Rights Act of 1993 (PHRA)

PHRA provides a domestic legal basis for individuals with TB to address violations of those rights guaranteed by domestic and international law. Specifically, PHRA creates a National Human Rights Commission (NHRC) and endows it with the power to investigate, either *sua sponte* or by petition, violations of “the rights ... to life, liberty, equality and dignity of the individual guaranteed by the Constitution or embodied in the International Covenants and enforceable by courts in India.” The Commission also has the power to “intervene in any proceeding involving any allegation of violation of human rights pending before a court with the approval of such court.” Finally, the Act gives the Commission the power to “review the safeguards provided by or under the Constitution or any law ... for the protection of human rights” and to “recommend measures for their effective implementation.”

In short, PHRA entitles people with TB whose human rights have been violated to: (1) petition the NHRC for an investigation; (2) have the NHRC intervene on their behalf in a legal proceeding; and (3) have the NHRC recommend further safeguards for protecting their human rights.

The Constitution

The Indian Constitution entitles individuals with TB to certain rights. The Constitution protects the rights to life, health, non-discrimination, privacy, informed consent, housing and food. These rights are safeguarded either explicitly or implicitly under the “Fundamental Rights” part of the Constitution (Articles 13 to 35) and are enforceable in courts. Fundamental rights are interpreted in light of the “Directive Principles of State Policy” part of the Constitution (Articles 36 to 51). While Directive Principles are not themselves directly enforceable in courts as legal rights, they do establish specific duties that the government must strive to fulfill when making laws.

One such Directive Principle in Article 46 obligates “the State [to] promote with special care the educational and economic interests of the weaker sections of the people” and to “protect them from social injustice and all forms of exploitation.” Although the phrase “weaker sections of the people” lacks a specific definition in the Constitution, individuals with TB have distinct physical vulnerabilities and are often members of other “weaker sections,” such as the extreme poor. Individuals with TB are therefore arguably included among the “weaker sections of the people” protected under Article 46.

Case Law

Multiple cases in the Indian Supreme Court and various local and regional courts have upheld the rights of Indian citizens protected by the Constitution. While there is as yet no case law that directly addresses TB, the bulk of cases that do exist can assist legal practitioners and civil society groups in bringing cases of people with TB before the Indian courts.
| Right to Health | Article 21: Protection of Life and Personal Liberty (The Right to Life) for All Persons | None | • *State of Punjab and Others v. Mohinder Singh*: The right to health is integral to the right to life, and the government has a constitutional obligation to provide health facilities.  
• *Consumer Education and Resource Centre v. Union of India*: The right to health entitles all individuals to health care services.  
• *Samiti v. State of West Bengal*: Government-run hospitals are duty bound under Article 21 to extend medical assistance for preserving human life. |
| Right to Non-Discrimination | Article 14: Equality before Law and Equal Protection of the Law for All Individuals  
Article 15: Prohibition of Discrimination on Grounds of Religion, Race, Caste, Sex or Place of Birth  
*Indian Penal Code, 1860, Arts. 153A, 153B*: Provides penal remedies in cases involving discrimination on the grounds of religion, race, place of birth or residence, language, | • *Confederation of Ex-Servicemen Associations & Orgs. v. Union of India*: Granting relief in favour of one class and denying same or similar relief in favour of another class violates Article 14.  
• *MX v. ZY (Bombay High Court)*: A person who (1) is fit and able to perform his/her job functions; (2) is otherwise qualified; and (3) poses no substantial risk to others cannot be denied employment by a public sector entity. Also, any determination of whether a person is incapable of performing in the course of employment must be made by conducting an individual inquiry.  
• *G v. New India Assurance Co. Ltd (Bombay High Court)*: An individual who is otherwise fit cannot be denied employment solely on the basis of being HIV-positive. |
| Right to Privacy | Article 21: Protection of Life and Personal Liberty (The Right to Life) | **Code of Medical Ethics:** Individuals with TB are entitled to:  
- The confidentiality of their communications with their physician; and  
- Access to their medical records upon request.  
**Right to Information Act, 2005, Chapter 2(8)(j):** Individuals living with TB have the right to the nondisclosure of personal information. | • *Singh v. State of Uttar Pradesh:* Individuals living with TB are entitled to an implied right to privacy derived from Article 21.  
• *MX v. ZY (Bombay High Court):* An individual living with HIV, or likely HIV, can litigate anonymously under an assumed name to protect against social stigma.  
• *Mr. Y and Mr. X v. Secretary to the Government (Madras High Court):* (1) The confidentiality of medical records should be maintained; (2) in medical testing for employment, only conclusions relevant to employment should be disclosed. |
| Right to Informed Consent | Article 21: Protection of Life and Personal Liberty (The Right to Life) | **Code of Medical Ethics, 2002:** Individuals with TB are entitled to the rights:  
- To be informed of the extent of their condition;  
- To provide written consent before any operation be performed upon them; and  
- To provide consent before photographs and case reports of their TB can be | • *Samira Kohli v. Prabha Manchanda:* A doctor may not remove a patient’s organs without informed consent, even if the doctor thinks it is in the patient’s best interest. For individuals with TB, treatment requires consent. |
Indian Penal Code, 1860, Arts. 96, 102, 104, 106: Protects the right to bodily integrity against invasion by another.

| Right to Housing and Food | Article 21: Protection of Life and Personal Liberty (The Right to Life) | National Food Security Act, 2013: | Francis Coralie Mullin v. Union Territory of Delhi: The right to life includes the right to live with adequate nutrition, clothing and shelter, as well as “freely moving about” and “commingling with fellow human beings.”

Shanistar Builders v. Narayan Khimalal Totame: The right to life includes the “basic needs of man,” which have traditionally been considered food, clothing and shelter.

Chameli Singh v. State of Uttar Pradesh: The right to life implies the right to food, water, a decent environment, education, medical care, and shelter. |
| Article 19(1)(e): Right to Reside and Settle in Any Part of the Territory of India | The Act provides entitlements for the following individuals with TB: |
| | - Women with TB who are either pregnant or lactating mothers are entitled to free daily meals; |
| | - Any child with TB up to the age of 14 has some form of nutritional support based on age; and |
| | - Children with TB who suffer from malnutrition are entitled to free meals through their respective State government. |
International Law

At the international level, India has ratified six treaties relevant to TB: Universal Declaration on Human Rights, ESCR, CRC, CERD, CRPD and CEDAW. Therefore, India is obligated to respect, protect and fulfill the rights protected therein. While these obligations are not self-executing, they may be judicially interpreted as domestic law. In effect, in instances where international law is consistent with domestic law, the judiciary may enforce international law by importing its obligations into domestic law. Under international law, India must take steps to progressively realize the rights to health, housing and food, and must immediately achieve the “minimum core obligations” of these rights. Minimum core obligations include the obligations: (1) to ensure access to health care facilities, goods and services on a non-discriminatory basis; (2) to make essential medicines accessible and affordable in sufficient quantity and quality at all points of distribution; and (3) to provide food in sufficient quantity and quality to protect persons from being predisposed to TB as a result of malnutrition. India must also immediately realize the full extent of the rights to non-discrimination, privacy and informed consent. India must also ensure the participation of all relevant and affected communities in all decision-making processes affecting their health during the formulation, implementation, and monitoring and evaluation of national TB policies. Obligations created by international law are further fleshed out in international guidelines. For instance, WHO’s End TB Strategy calls on member States to meet their obligations by, among other things, pursuing high-quality Directly-Observed Treatment, Short-Course (DOTS) and empowering people with TB and their communities.
Many states are signatories to the key human rights treaties, and the obligations under these treaties have implications for domestic law. Therefore, it is important to be aware of the treaties a particular state has ratified in order to analyse the possible links between the treaty, the rights of people with TB and the implementation of domestic laws. This table outlines several such links and provides examples of how treaty bodies have followed up with countries to encourage compliance. Further details can be obtained from the *Health and Human Rights Resource Guide* prepared by the FXB Center for Health and Human Rights at Harvard University. Legal experts could be consulted to shed light on the links between the rights outlined in the treaties and domestic law.

<table>
<thead>
<tr>
<th>TB and the Right to Life</th>
<th>Human Rights Standards</th>
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<tbody>
<tr>
<td><strong>ICCPR 6(1):</strong> Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.</td>
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**Treaty Body Interpretation**

**HRC:** Expressing concern to Georgia at “the still very large number of deaths of detainees in police stations and prisons, including suicides and deaths from tuberculosis” and urging the State to “ensure that every case of death in detention is promptly investigated by an independent agency.”

**CCPR/CO/74/GEO (2002)**

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<tr>
<th>TB and the Right to the Highest Attainable Standard of Physical and Mental Health</th>
<th>Human Rights Standards</th>
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<tr>
<td><strong>ICESCR 12(1):</strong> The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. 12(2): The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: ... (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases. <strong>CRC 24(1):</strong> States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such</td>
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37 These examples have been adopted from Health and human rights resource guide. Cambridge, MA: FXB Center for Health & Human Rights, Harvard University; 2014 (https://www.hhrguide.org/).
health care services.

**Treaty Body Interpretation**

**CESCR:** Expressing concern to Estonia about the high rate of cases of TB and recommending that “the State party intensify its efforts to combat the spread of tuberculosis.” E/C.12/1/ADD.85 (2002)

**CESCR:** Expressing concern to Moldova about the “rising incidence of tuberculosis in the State party,” noting “with particular concern the acuteness of this problem in prisons where the infection rate is more than 40 times higher than the national average,” and recommending that “the State party intensify its efforts under the National Programme on Tuberculosis Prophylaxis and Control to combat the spread of tuberculosis, including by ensuring the availability of medicines and adequate sanitary conditions in prisons.” E/C.12/1/ADD.91 (2003)

**CESCR:** Expressing concern to Kyrgyzstan over new health threats such as the “reemergence of communicable and vaccine-preventable diseases such as tuberculosis” and urging “the State party to continue its efforts to address the prevailing health threats, and to target progressively resources to health services.” E/C.12/1/ADD.49 (2000)

**CESCR:** Expressing concern to Russian Federation over “the spread of drug addiction, including by way of injection, which is the main factor for the growing epidemic of HIV/AIDS, hepatitis C and tuberculosis in the Russian Federation” and urging “the State party to apply a human rights based approach to drug users so that they do not forfeit their basic right to health.” E/C.12/RUS/CO/5 (2011)

**CESCR:** Expressing concern to Azerbaijan over “overcrowding and sub-standard conditions in prisons in Azerbaijan which have given rise to a disproportionately high rate of tuberculosis and other health problems among prisoners” and recommending “that the State party continue to take measures to improve the sanitary and hygienic conditions in prisons and to ensure that the right to mental and physical health of all prisoners in Azerbaijan is respected.” E/C.12/1/Add.104 (2004)

**CRC:** Expressing concern in Latvia over increasing rates of TB and recommending that the government “[offer] HIV-related care and treatment ... including for the prevention and treatment of health problems related to HIV/AIDS, such as tuberculosis and opportunistic infections.” CRC/C/LVA/CO/2 (2006)

And many other examples...

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<thead>
<tr>
<th>TB and Rights to Non-Discrimination and Equality</th>
<th>Human Rights Standards</th>
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<tr>
<td><strong>ICERD 2(1):</strong> States Parties condemn racial discrimination and undertake to pursue by all appropriate means and without delay a policy of eliminating racial discrimination in all its forms and promoting understanding among all races.</td>
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<tr>
<td><strong>ICERD 2(2):</strong> States Parties shall, when the circumstances so warrant, take, in the social, economic, cultural and other</td>
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</table>
fields, special and concrete measures to ensure the adequate development and protection of certain racial groups or individuals belonging to them, for the purpose of guaranteeing them the full and equal enjoyment of human rights and fundamental freedoms.

**ICERD 5(e)(iv):** States Parties undertake to prohibit and to eliminate racial discrimination in the right to public health, medical care, social security and social services.

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<tr>
<td><strong>CERD:</strong> Expressing concern to India over “reports that members of scheduled castes and scheduled and other tribes are disproportionately affected by ... tuberculosis ... and that health care facilities are either unavailable in tribal areas or substantially worse than in non-tribal areas” and recommending that the State ensure adequate health care facilities for members of scheduled castes and scheduled and other tribes and “increase the number of doctors and of functioning and properly equipped primary health centres and health sub-centres in tribal and rural areas.” CERD/C/IND/CO/19 (2007)</td>
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<th>TB and the Right to be Free from Torture or Cruel, Inhuman or Degrading Treatment or Punishment</th>
<th>Human Rights Standards</th>
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<tr>
<td><strong>CAT 16(1):</strong> ... prevent ... other acts of cruel, inhuman or degrading treatment or punishment which do not amount to torture as defined in article I [of CAT], when such acts are committed by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity.</td>
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<td><strong>CAT:</strong> Expressing concern to Zambia over the prevalence of TB and the high contamination rate of inmates and prison officers due to overcrowding and the lack of adequate health care, and recommending that the State speed up the establishment of health care services in prisons, including the recruitment of medical personnel, as established under the Prisons Act of 2004. CAT/C/ZMB/CO/2 (2008)</td>
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<td><strong>CAT:</strong> Urging Ethiopia to “take urgent measures to bring the conditions of detention in police stations, prisons and other places of detention into line with the Standard Minimum Rules for the Treatment of Prisoners, as well as with other relevant standards, in particular by ... Improving the quality and quantity of food and water as well as the health care provided to detainees and prisoners, including ... tuberculosis patients.” CAT/C/ETH/CO/1 (2011)</td>
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<td><strong>CAT:</strong> Expressing concern to Russia over the distressing conditions of pre-trial detention, including the prevalence of TB and other diseases, as well as the poor and unsupervised conditions of detention in IVS (temporary police detention) and SIZO (pre-trial establishment) facilities, and recommending “Urgent consideration should be given to making a medical examination compulsory for persons when they enter IVS and SIZOs.” CAT/C/CR/28/4 (2002)</td>
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<td>TB and Freedom from Arbitrary Arrest and Detention</td>
<td>Human Rights Standards</td>
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<td><strong>ICCPR 9(1):</strong> Everyone has the right to liberty and security of person. No one shall be subjected to arbitrary arrest or detention. No one shall be deprived of his liberty except on such grounds and in accordance with such procedure as are established by law.</td>
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<tr>
<td><strong>CAT 16(1):</strong> Each State Party shall undertake to prevent in any territory under its jurisdiction other acts of cruel, inhuman or degrading treatment or punishment which do not amount to torture as defined in article I, when such acts are committed by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity.</td>
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**Treaty Body Interpretation**

**HRC:** Noting that in Moldova “under a regulation promulgated in August 2009, persons with tuberculosis may be subjected to forcible detention in circumstances where he or she is deemed to have ‘avoided treatment’. In particular, the regulation is unclear as to what constitutes the avoidance of treatment and fails to provide, inter alia, for patient confidentiality or for the possibility for the judicial review of a decision to forcibly detain a patient”; recommending that the State “should urgently review this measure to bring it into line with the Covenant, ensuring that any coercive measures arising from public health concerns are duly balanced against respect for patients’ rights, guaranteeing judicial review and patient confidentiality and otherwise ensuring that persons with tuberculosis are treated humanely.” CCPR/C/MDA/CO/2 (2009)

**CAT:** Expressing concern to Moldova over legislation that provides for the forcible detention of persons with TB deemed to have “avoided treatment,” including lack of clarity “as to what constitutes the avoidance of treatment” and failure to provide adequate safeguards and procedural rights with respect to access to legal representation, “regular review of the reasons for detention or for maintaining continued detention, privacy, family and correspondence, confidentiality, data protection, non-discrimination and non-stigmatization”; recommending that the State “should urgently review the regulation on forcible detention of persons with tuberculosis and related policies, and bring them into compliance with the Convention, in particular guaranteeing independent regular review of detention measures, patient confidentiality and privacy, as well as non-discrimination in their application.” CAT/C/MDA/CO/2 (2010)
Note: If the process of documentation for the LEA ends here, it is essential that multiple stakeholders review and comment on the report produced from the desk review. See Section III for further detail.

2. Stakeholder consultations

While a legal review of domestic laws and regulations can provide an extensive body of evidence on the legal and policy environment, consultations with key stakeholders ensure that those who experience these laws and regulations in the course of their work or as populations accessing services may express their opinion. Consultations promote an inclusive and participatory LEA in which the voices of all key stakeholders are heard. They help to gain insight into issues and experiences that may not otherwise be documented, particularly in relation to the impact of laws, regulations and policies on people’s lives, their access to justice, and how laws are implemented and enforced. Stakeholder consultations also raise awareness and promote dialogue about TB, legal and human rights issues and the purpose of the LEA.

In the planning stage of the LEA, it is important to determine:

- which stakeholders will be consulted during the process;
- how stakeholders will be consulted;
- who will undertake the stakeholder consultations; and
- what stakeholders will be consulted on.

Once these parameters have been established, the work on developing interview and focus group guides can begin. For focus group discussions and qualitative interviews, some countries may require a formal ethical review and approval process to be completed beforehand (see the paragraph on ethical review and approval below).

Consultations with key stakeholders

As mentioned in the planning section of this guide, key stakeholders should include a broad range of individuals and organizations from different sectors and at different levels in the country, as well as networks of people with TB (if such exist), women, and those representing key populations. This section provides an extensive guide to selecting key stakeholders for interviews. Although this list is not exhaustive, it should be used in every country to find those stakeholders who are most likely to see that the LEA recommendations and conclusions are seen through to implementation.

It is important to look beyond TB-specific organizations and institutions to include a broader range of ‘mainstream’ organizations, such as those working on human rights, health, women’s issues, employment rights, and so on. It is also important to recognize that members of key populations and other subgroups may be diverse and do not constitute a homogeneous group. For instance, migrant workers might have issues and concerns separate from those of PWUD; women living in rural areas may have specific needs and concerns not shared by formerly incarcerated women.
Key stakeholders may include:

- leaders and technical experts from the executive branches of key government ministries, including those dealing with TB, Health, Justice, Gender, Social Development, Education, Trade and Industry, Employment/Labour, Correctional Services, Safety and Security, among others;
- parliamentarians, members of the judiciary, legal fraternity and legal aid services;
- representatives of statutory bodies such as an Ombudsperson, Public Protector, and Human Rights Commission and Law Commission officials;
- representatives of professional bodies including medical councils, nursing councils, councils of psychologists;
- service providers such as health care workers, educators, social welfare workers (who may represent both as service providers and as members of a population at risk);
- networks of people with TB (if such exist);
- representatives and networks of key populations including PWUD, PLHIV, formerly incarcerated individuals, miners, migrant workers, rural community representatives and others;
- women and women’s rights groups, groups representing children’s rights or mothers of children with TB;
- civil society organizations working on health, TB, legal and human rights issues and working with key populations;
- faith-based organizations, traditional authorities and religious leaders; and
- any other group of specific relevance to the country’s TB epidemic.

Various methodologies may be used for undertaking consultations with stakeholders and key populations. Care should be taken to ensure that these consultations are carried out in an ethical way. Ensuring the safety and confidentiality of respondents should be a priority, as well as obtaining informed consent from them prior to the group discussion/interview. The principle guiding the ethical process should be the principle of ‘do no harm’. Some examples of consultations include:

- undertaking one-on-one interviews with individual representatives of organizations;
- holding focus group discussions with groups of individuals who share common characteristics and/or have possible shared experiences and concerns, such as:
  - service providers delivering similar services (e.g., health care workers, legal aid lawyers);
  - people who share characteristics such as age, gender, disability, or social origin (e.g., women, workers of the mining industry, etc.);
  - people who share similar positions in society (e.g., traditional leaders); or
  - people who self-identify with a specific population (e.g., PLHIV, PWUD);
- conducting site visits to document first-hand the impact or implementation of relevant laws and policies, and to speak with people at different sites across the country (e.g., clinics, courts,
prisons, drug treatment and integrated TB/HIV treatment sites);
• distributing questionnaires to selected individuals and organizations from different sectors;
• conducting online surveys including through the websites of different organizations; and
• developing short ‘vignette’ questions, commonly used in survey research, which could be useful for starting discussions around TB and human rights without having to ask direct questions.

The researchers will also need to develop tools to ensure a standardized approach to the stakeholder consultations, whether they are one-on-one interviews or focus group discussions. This approach should allow for:

• the provision of background information on the law and human rights in the context of TB, and the purpose, scope and nature of the LEA process;
• questions for discussion and feedback on common issues relevant to all stakeholders; and
• questions and discussion points on key issues relevant to each particular organization or institution.

The feedback from stakeholder consultations needs to be documented in the form of a brief report on each interview, visit or focus group discussion. The information should also be collated and analysed to draw out the key issues identified by the stakeholders. If possible, the following should be described in a consolidated report on the stakeholder consultations:

• the level of awareness of TB, legal and human rights issues, and their role in an effective response to TB;
• the key HIV, legal and human rights concerns of various stakeholder groups, including:
  ▪ concerns over current laws, regulations and policies;
  ▪ concerns over the level of awareness of rights and the ability to access justice; and
  ▪ concerns over the ways in which rights are implemented and enforced;
• the impact of protective or punitive laws on people’s ability to promote or achieve universal access to TB diagnosis, treatment, care and support services; and
• recommendations for strengthening the legal and policy framework.

Examples of survey, interview and focus group questions are provided below. It is important that these questions be uniform for all stakeholders so that the information can be effectively collated and analysed. It will also be useful to separate questions thematically and prepare several questionnaires for
different stakeholders, for example, one for government stakeholders that addresses existing policies and recommendations, and one for people affected by TB and key populations that assesses whether these policies are actually implemented and analyses barriers.
Questions for surveys, questionnaires, and structured interviews:

The following questions can be asked during interviews or sent out in the form of “vignettes” or questionnaires. In the case of site visits, researchers might also want to create observation reports that address some of these questions – for example, whether consent is sought for HIV testing of people with TB or whether health workers charge patients for diagnostics that are supposed to be free. These questions and observation reports are not meant to be punitive, but rather focus on barriers to access, rights of patients, and processes and procedures that should be put in place.

Which diagnostic measures can people with TB obtain for free? (please check all that apply):

- Microscopy
- Chest X-ray
- GeneXpert
- Tuberculin skin test
- IGRA
- LED microscopy
- DST
- Other __________________

What kind of information is provided to individuals who come for TB testing? (please check all that apply):

- the nature of TB
- why they are being tested
- prevention measures
- free treatment and care for TB
- Other __________________

How many clinic visits are usually required to obtain a TB diagnosis?:

- one
- two
- more than two
Is there HIV testing among TB patients?

- Yes, at every TB clinic/any primary care provider
- Yes, at some TB clinics
- Only at HIV clinics
- They can get tested anywhere
- Other ________________

Does the patient provide informed and written consent to HIV testing?

- Yes, always
- Not if they are already diagnosed with TB
- Only at HIV clinics
- Not if they represent an at-risk population
- Other ________________

What kind of information is provided to people for whom diagnosis is confirmed?

- the risks and benefits of the proposed interventions
- the importance of completing the full course of treatment
- treatment options
- infection control measures
- available support
- Other ________________

How are people who come for diagnosis and treatment made aware of their rights?

- through an informational note that is present in the clinic
- they are informed by health workers
- there are no mechanisms to make them aware of their rights
Are there particular TB patients that are prioritized over others?

- [ ] no
- [ ] children
- [ ] pregnant women
- [ ] people living with HIV
- [ ] Other__________________

If access to MDR- and XDR-TB medications is limited, are particular MDR- and XDR-TB patients prioritized over others?

- [ ] no
- [ ] children
- [ ] pregnant women
- [ ] people living with HIV
- [ ] Other__________________
Other questions for consideration

Access to medications and treatment modalities

- Which medications can people with diagnosed TB obtain for free?
- Do people with TB have a legal right to free TB medicines, including but not limited to rifabutin, bedaquiline, delamanid and linezolid?
- Are these medicines quality-assured?
- When patients are offered drug susceptibility testing in the absence of treatment, are they informed of the risks and benefits of testing and specifically asked if they are willing to consent, even though treatment may not be available to them?
- What happens to patients who refuse to consent to TB treatment?
- Do patients have choices about the location of treatment?
- Do patients have choices about the individuals who will be observing their treatment (DOT)?
- What support is available to help patients complete the full course of treatment?
- Is it possible to refuse the initiation/continuation of treatment if it appears that a particular patient is unlikely to adhere to the prescribed regimen?
- What happens if the patient is non-adherent?

Social protection and material assistance

- Is there compensation for time lost from work?
- Is there compensation for work-related TB for health care workers/miners/workers in other professions who are at higher risk for TB?
- Is there additional compensation for health care workers working in TB? (please list all)
- What are the rights of people affected by TB in terms of adequate standard of living and social protection in the event of unemployment, sickness or disability?
- What kind of support is provided to TB patients during treatment (e.g., social accompaniment, financial motivation, food packages)?
- What barriers do people affected by TB commonly face in accessing social protection and other benefits? What measures are in place to eliminate these barriers?
- Is TB recognized as an episodic disability, and are disability benefits extended to people with TB?
- Are there disability benefits for people with TB who acquire permanent disability as a result of their TB?

Protection of privacy and confidentiality

- Do individuals have a constitutional or statutory right to privacy and confidentiality in their health status, including their TB status?
- Under what circumstances can an individual’s right to privacy and confidentiality be infringed upon?
- Who are the contacts of a TB patient, and how are they notified?
- Is contact tracing done with minimal intrusion into individuals’ privacy and autonomy?
- How are contacts notified if patients are unwilling to participate in the process of contact identification and notification?
- Is there a policy for the non-consensual disclosure of a patient’s TB status?
- How is it ensured that the non-consensual disclosure of TB status is performed in accordance with the law and human rights principles?
**Political, social and cultural life**

- What protections do people with TB have against harassment, intimidation, violence and other human rights violations?
- Is there involuntary isolation, quarantine or detention of people with TB?
  - If so, under what circumstances?
  - Is there a legal standard governing the isolation, quarantine or detention of people with TB? What law governs?
- Do people with TB have the right to due process in circumstances where they are deprived of their liberty?
- In the rare event that isolation or detention is used, does it take place in adequate settings, with appropriate infection control measures, as specified more fully in WHO guidance?
- Is reasonable social support provided to isolated patients and their dependents, taking into account the local system’s capacity?
- Is there forced treatment?

**Education, employment, work and housing**

- Do legal protections exist that prohibit discrimination in education based on TB status and ensure that children with TB are not prohibited from attending school?
- What barriers do people with TB commonly face in accessing education? What measures are in place to eliminate these barriers?
- Do legal protections exist to guarantee people with TB access to employment and non-discrimination in the workplace?
- Do state policies address the links between poor health, TB and a lack of adequate housing?
- Do legal protections exist that prohibit discrimination in housing based on TB status?
**Access to justice**

**Legal protection**

- What legal remedies are available to people with TB when their rights are violated, including their rights to free testing and treatment, privacy, etc.?
- What accountability exists under law for government or private actors that violate the rights of people with TB, including their rights to free testing and treatment, privacy, etc.?
- Do national human rights monitoring and enforcement mechanisms consider TB-related issues?
- What measures are in place to ensure that cases of TB-related discrimination and other human rights violations in the context of TB response are systematically recorded, documented, and addressed, and that remedies are made available?

**Legal awareness, assistance and representation**

- What measures are in place to educate people affected by TB and key populations about their legal rights?
- Is there support for legal awareness-raising programmes implemented by civil society and international organizations?
- Are legal literacy materials presented to people with TB and key populations in a format and style that is readily accessible?
- Are free legal services provided to people with TB who are unable to access or afford the services of paid lawyers?

**Access to a fair trial, and enforcement of remedies**

- Does the state’s infrastructure create an enabling environment for access to justice?
- Does the state ensure that the forums administering justice are easily accessible in both urban and rural communities?
- Are the costs associated with TB-related dispute resolution in the formal justice system reasonable?
Questions for focus groups and structured interviews

These questions can be asked during in-person interviews with people with TB or groups of key populations.

- How long did it take to get diagnosed (in weeks, clinic visits)?
- How were you treated at the clinic when you first received your TB diagnosis?
- How much did you pay for the tests? Were there any additional costs associated with the testing?
- How many times did you have to go to the clinic until you received your final diagnosis?
- What kind of information about TB and about treatment did you receive from your health care provider?

- For specific populations:
  - How do you feel people living with HIV/people who use drugs/women are generally treated in health care settings?
  - Are health services easy to access for people living with HIV/miners/people who use drugs/women/other key populations? If not, why?
  - What are the main barriers to TB diagnosis and treatment for people living with HIV/people who use drugs/rural women/other key populations?
  - What TB programmes would be helpful for people living with HIV/miners/people who use drugs/women/children/other key populations?

- Are there any institutions or organizations you can turn to in case of violence or abuse of your rights?

- What rights do you know you have as a person with TB?

Ethical review and approval

As with other studies that collect data from people, an LEA must observe certain standards with respect to ethical issues and data protection. Those responsible for conducting the LEA should ensure that it conforms to their country’s ethical and data protection requirements.
CASE STUDY 2: KYRGYZ REPUBLIC (KYRGYZSTAN)

A legal review (including a desk review and consultations with key stakeholders) was conducted in Kyrgyzstan between December 2015 and March 2016. For the consultations, 25 key stakeholders were identified that included government, UN agency and civil society representatives, and 57 former TB patients were surveyed through seven focus groups (including one focus group in a prison setting).

The objectives of the review were identified as follows:

- To review information on the status of the human rights of people affected by TB in Kyrgyzstan;
- To identify evidence-based recommendations for strengthening the TB legal and regulatory framework, and to outline solutions to overcome obstacles to implementation; and
- To provide recommendations for potential (civil society) initiatives.

The desk review focused on international and national legislation.

The following signed and ratified international conventions were reviewed:

- International Covenant on Civil and Political Rights (ICCPR)
- International Covenant on Economic, Social and Cultural Rights (ICESCR)
- Convention on the Elimination of All Forms of Discrimination against Women (CEDAW)
- Convention on the Rights of the Child (CRC)
- ILO Labour Inspection in Industry and Commerce Convention

The following national legal documents were reviewed:

- The Constitution
- The law to protect the population against tuberculosis
- State TB budget
- National TB Program (2013–2016)
- Den Sooluk - State Health Program
- Law on Health Protection
- Law on Social Guarantees
- Law on Medicines
- Other relevant provisions and regulations.
The desk review aimed to assess whether the following rights and entitlements were observed in quality (TB) diagnosis, treatment, care and support:

- Right to non-discrimination
- Right to privacy
- Right to informed consent
- Right to bodily integrity
- Freedom from torture and inhuman or degrading treatment
- Freedom of movement
- Right to social security
- Right to information
- Right to education
- Right to participation
- Right to access to health services and essential medicines
- Right to enjoy the benefits of scientific progress and its applications
- Right to social and economic determinants of health (food, housing, sanitation, water)
- Right to due process protection.

The following government obligations to ensure equal access to health for all were also analysed:

- respecting individual rights;
- fulfilling entitlements;
- protecting against rights violations by non-state actors, including regulating the private health sector; and
- ensuring adequate, equitable and sustainable financing.

The findings of the LEA suggested that there were no violations of the right to freedom from torture and inhuman and degrading treatment, and people with TB were free to realize their right to participation, were included in the Country Coordinating Mechanism for oversight of the Global Fund grants, and had the opportunity to join public oversight committees on Ministry of Health activities. The findings also showed that Kyrgyzstan does not promote compulsory isolation, thus adhering to the principles of freedom of movement and freedom from arbitrary detention of its citizens.

The following key issues were identified by the review: Lack of information has resulted in stigma and a lack of knowledge about TB and TB infectivity, particularly among women; there are insufficient regulations with respect to new TB drugs, which limits access to life-saving DR-, MDR-, and XDR-TB medications; laws that impact the employment of people with TB are outdated; and there is a lack of focus on the right to privacy.
Access to information

While people with TB in Kyrgyzstan are afforded multiple entitlements, such as social benefits, informed consent, free legal benefits, and others, patients with TB are poorly informed about these entitlements. No steps to proliferate this information have been taken. This lack of information and education about TB has had the most profound effect on rural women, who spoke of violence, abandonment and losing access to their children.

Access to medications

Patients also reported a lack of knowledge about which procedures and treatment are provided for free and which cost money. Focus group participants noted the practice of soliciting money for free medication as punishment for interrupting treatment, along with other examples of unjust extortion for services that should be free of cost. Kyrgyzstan currently lacks legislation that would assist the country in obtaining access to new and repurposed drugs, thereby limiting the options for patients with drug-resistant TB.

Discrimination and lack of compensation in the labour sector

Even at the advanced level, understanding of TB infectivity was found to be poor, and stakeholder consensus was that people with TB should not be able to work until officially “cured.” Currently, there are laws that prevent people who have had TB from working in client-facing services (transportation, household services, etc.), in food-related industries, and with children (which includes making children’s clothes or packing baby food). These laws need to be eliminated and clear guidelines need to be established that confirm the right of people with TB to return to work and education. Furthermore, findings showed that, in the health care sector, employees lacked compensation if they got TB and health workers with TB commonly faced stigma from coworkers and supervisors.

Right to privacy

It was noted that the right to privacy of people with TB should be more carefully observed during contact tracing, and clear guidance should be produced on how the notification process proceeds and what contacts are considered close. Instructions on stigma reduction should also be adopted by the TB service, and collaboration with patient groups and the community should be strengthened.

The review also revealed topics for further exploration, such as the impact of TB on women, TB treatment and compulsory treatment in prisons, and whether children with TB are allowed to realize their right to education and to return to school when they are no longer infectious.
CASE STUDY 3: REPUBLIC OF KENYA (KENYA)

In 2017, Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN), with support from Stop TB Partnership and technical support from University of Chicago Law School, conducted a TB LEA in Kenya in order to pilot the LEA Operational Guide.

KELIN utilized its established reputation as a prominent human rights network to reach out to partners in communities of people with TB, government stakeholders and legal experts in order to create a Technical Working Group for the LEA. KELIN and its partners utilized the Guide’s methodology to:

1. Develop a map of the LEA process with guidance from the Technical Working Group;
2. Conduct a desk review of laws, policies, guidelines and strategies;
3. Work in the field to conduct 20 key informant interviews and a focus group with populations affected by TB;
4. Conduct a country-level community dialogue with key stakeholders that addressed laws, policies and the rights of people with TB; and
5. Produce a final report on the LEA.

The report is currently being validated by the many stakeholders involved in the LEA. Here, the preliminary findings are summarized.

The Desk Review included the following documents or categories of documents relevant to TB:

- Key international and regional covenants and charters
- The Kenyan Constitution
- The Public Health Act (Cap 242 Laws of Kenya)
- Laws on prison settings
- Kenyan Health Policy
- National Patients’ Rights Charter
- Kenya’s current National Strategic Plan on Tuberculosis, Leprosy and Lung Diseases
- National Guidelines on Management of Tuberculosis in Children
- Guidelines for TB Infection Prevention and Control for Health Care Workers in Kenya
- Guidelines for Management of Tuberculosis and Leprosy in Kenya
- Ministry of Health circulars related to the imprisonment of TB patients and preventive TB therapy for PLHIV
- The Children’s Act

The Desk Review identified multiple protections for people with TB that already exist within that national legal framework; however, several documents were identified as either having a negative impact on the rights of people with TB or having inadequate protections, protections that are not being executed, or protections that are difficult to execute under current circumstances.

The Public Health Act was identified as the most problematic for people with TB, as it criminalizes TB and prescribes involuntary arrest and detention of individuals who experience treatment interruptions. In March 2016, the High Court of Kenya ruled that the provisions of the Public Health Act related to the arrest and detention of people with TB are unconstitutional. The Court ruled to issue a circular to public health officers stating that section 27 should not be used to confine TB patients in prisons. The Government was also directed to commence the process of developing a policy on the involuntary confinement of persons suffering from infectious diseases (TB included) that is in line with international standards.
This policy is currently in development. The Court’s decision served to bring together stakeholders in an attempt to resolve the issues related to treatment interruption and to ensure supportive environments for TB treatment.

The Kenyan Prisons Act and Persons Deprived of Liberty Act were also found to fall short of fully protecting the rights of people with TB, specifically in terms of their privacy, confidentiality, and access to diagnostics and treatment.

National regulations concerning the treatment and access to education for children with TB were also found to be extremely problematic.

Stakeholder interviews demonstrated that, despite Kenya’s rather advanced support for patients’ rights, a rights-based approach has yet to be realized in the management, treatment, care and support of people with TB. While TB diagnosis and treatment are free, people with TB still incur costs for related diagnostics and treatment such as x-rays, experience delays in accessing services, and suffer from discriminating attitudes of health care workers. The stigma surrounding TB still prevails in Kenya, with poor dissemination of accessible information about TB and a lack of involvement of communities of TB survivors in decision-making processes.

The lack of guidance on the isolation of patients and the non-existence of isolation units presents a loophole for possible human rights violations of people with TB. Furthermore, there is little guidance addressing TB-related discrimination and human rights violations at the facility and policy level. TB-related discrimination particularly affects those who are most vulnerable: children, migrant and seasonal workers, health workers, prisoners, and urban and rural poor.

The empowerment and education of patients about their rights and about TB is largely left to community-based civil society and partner organizations.

Preliminary findings of Kenya’s TB LEA found that the following laws and policies should be reviewed or developed to protect people with TB:

- Public Health Act;
- The Isolation Policy;
- Policies on prisons infrastructure;
- Workplace policy to address aspects of TB screening, Infection Prevention Control (IPC), confidentiality and leave for treatment;
- Policies and procedural manuals defining roles and structures for TB diagnosis and treatment; and
- Policy on treatment – for free x-ray services.

The LEA also identified the following legal and policy gaps:

- Guidance on workers rights in the transport sector;
- Non-discrimination policies for students in the education sector; and
- Guidance addressing TB-related discrimination in the workplace, including patients’ ability to access daily medication; and challenges related to health facilities, for example, delays in serving patients.

While the results of Kenya’s TB LEA are pending, the country-level dialogue has already produced commitments from several county health authorities to ensure that the patients’ bill of rights is present in every health facility and collaboration on strategies to address TB among migrant workers.
### Section 3: Feedback and finalization

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</table>

1. **Overview of the results of the LEA**

The completed LEA will have consolidated information – and potentially unearthed some new perspectives – on the role of the law and its links with TB, health and human rights in the national context.

While it may be possible to achieve consensus on recommendations and the way forward, it is also likely that some of the emergent issues will be new for some people, including members of the Technical Working Group, and some findings may elicit different opinions (for example, in relation to the discrimination experienced by some key populations in health settings or in the workforce).

The results of the LEA will provide an opportunity to generate and facilitate informed debate about the critical issues arising at the intersection of law, human rights and health in a country. In future, it may also be possible to compare the key findings of national LEAs in order to observe the similarities and differences between legal environments in different epidemic settings.

2. **Purpose of the feedback and finalization stage**

The purpose of this stage of the LEA is to:

- present draft findings and recommendations to national stakeholders;
- provide an opportunity for dialogue on key issues and feedback on draft findings and recommendations;
- disseminate the draft final report and discuss potential recommendations based on the LEA;
- seek consensus on the final findings and recommendations, and at least agree on common principles and objectives that can be endorsed by the Technical Working Group going forward;
- prioritize recommendations and key actions for moving forward to strengthen the legal framework for TB; and
• create a mechanism or forum for the ongoing monitoring and evaluation of the process.

There are a number of different options for feedback and consensus-building throughout the LEA process and the dissemination of the report findings and recommendations. Some possible processes are discussed below for consideration at country level.

**Ongoing peer review**

Various opportunities for reviewing draft findings may be built into the LEA process. These include:

• Reporting back to the Technical Working Group regularly on key issues emerging from stakeholder consultations, on draft findings of the desk review, and on draft versions of the LEA report;
• tabling the draft report at various relevant sectoral and multisectoral meetings and forums;
• meeting individually with various stakeholders with updates on the LEA; and
• disseminating the draft report to a ‘readers group’ of peers with skills, expertise and experience in TB, legal and human rights issues, for them to provide written comments.

**3. Consultative validation workshop**

Stakeholders who have participated in the process should also have an opportunity to discuss and deliberate on the outcomes and recommendations arising from the LEA process once the near-final report is available. This particular phase is likely to be more comprehensive and consolidated in nature than the ongoing review process outlined above. The report-back process should aim to:

• thank stakeholders for their participation in the LEA;
• inform stakeholders about the LEA process, including:
  • which laws, policies and documents were reviewed and which stakeholders were consulted;
  • how stakeholders’ perspectives and other findings were incorporated into the LEA;
  • how reporting was done and feedback received on preliminary findings; and
  • any limitations and challenges during the process and how these were handled;
• present key issues, draft findings and recommendations arising from the LEA;
• provide an opportunity for dialogue on key issues and feedback on the process, findings and recommendations; and
• reach consensus on the findings and recommendations, including priority recommendations for strengthening the legal and policy framework.

As recommended in Section 1, a National Dialogue could take place at the outset of the LEA to kick-start the process. Alternatively, a National Dialogue could take place at the end of the LEA process. As
resources might be limited, national stakeholders might decide to hold a wider dialogue at either the outset or the conclusion of the LEA and a smaller one at the other end. The point of the National Dialogue(s) and consultative validation workshops is to ensure that the goals of the LEA are set out correctly and that the process results in a concrete plan to implement desired changes based on the findings of the LEA.

4. Producing a final report
The report from the LEA should be finalized after feedback is received from the Technical Working Group and the consultative validation meetings. The final report should build on the foundation of the inception report/concept note and include:

- an executive summary – a summary of findings and recommendations that can be easily distributed among and utilized by all key stakeholders as an advocacy document;
- the purpose, scope and nature of the national LEA;
- the key TB, legal and human rights issues of priority national concern that were addressed during the process;
- the methodology and specific activities undertaken;
- the deliverables achieved;
- the responsibilities and involvement of various parties in the process;
- a summary of the work plan and timeframe in which the work was undertaken;
- an account of resources required, effective resources mobilized and final budget;
- any questionnaires, survey plans, discussion guides and analysis tools that were used during interviews, focus group discussions and desk reviews;
- any ethical approval sought and gained (as required) for the research process;
- laws, regulations and policies reviewed;
- key stakeholders consulted during the assessment;
- key findings from the desk review and key informants;
- discussion of the results and key findings;
- implications of the key findings;
- any challenges encountered during the LEA process, how they affected the process and LEA outcomes, and how/if they were resolved;
proposed recommendations for going forward and making an impact with the results;

references and a list of key resources; and

acknowledgements of all involved in the process and any donor support, and declarations of any conflicts of interest among the LEA Task Team.

The complete final report from the LEA is likely to be a long document, ranging from 40 to 100 pages depending on the scope and objectives set out in the inception report. While one final report might be the initial goal, it may be that specially tailored reports might better serve the needs of key stakeholders (see Section 4).

5. Summary policy briefing

To make the key results more easily accessible to those who do not have time to read the final LEA report in full, a summary policy briefing based on the final report might be a useful document. This shorter document could be 2–4 pages and include:

- a summary of the purpose, scope and nature of the national LEA and the key TB, legal and human rights issues of priority national concern that were addressed during the process;

- highlights of the methodology and specific activities undertaken, including reference to any ethical approval sought and gained (as required) for the research process;

- a summary of the process and key stakeholders involved;

- an overview of any challenges and remedies applied;

- a summary of the key results and their implications;

- proposed recommendations; and

- details of where to access the full report and further details about the LEA.

Specific thematic or issue-based briefings could also be produced, for example, presenting the narrow results of the LEA related to specific population groups (such as children, PLHIV, PWUD, migrants, rural and urban poor) or specific legal areas (such as criminal law, public health law, and constitutional law reform).

Production of final resource materials

Depending on the extent and availability of resources, the final report and policy briefing report could be produced as designed reports (for example, including logos of partners, photographs taken to document the process, pull quotations, etc.) and made available online as PDFs and/or printed for distribution at the national launch event to disseminate the results. The stages involved in the production of these materials include proofreading, designing, reviewing, a print preview, printing and distribution.
Translation

Consideration should be given to the language of publication for the final report and briefing. Issues to consider include accessibility for:

- national policymakers, legislators, law enforcers and other stakeholders;
- participants in the research process;
- the general public in the national context; and
- an international audience, as the LEA results may be a potentially useful resource for other countries.

The results and/or report of the LEA may need to be translated into one or more languages to ensure that the results are accessible and effectively communicated to a range of audiences.


Section 4: Dissemination
Throughout all the steps of this implementation phase of the LEA, it is important that the main audience for all associated activities include, at least, those who participated in the process at all levels, including the stakeholders, Technical Working Group, and people and groups who participated in the interviews and discussions.

Purpose of disseminating the results of the LEA
The purpose of this final stage of the LEA is to:

- provide the opportunity for dialogue on the final results, key issues and recommendations;
- maximize the potential impact of the findings and recommendations to national stakeholders;
- use the evidence to inform law reform processes;
- sustain momentum and generate multi-stakeholder commitment to address key issues emerging from the LEA; and
- trigger, support and/or sustain multi-stakeholder action to take the recommendations forward.

It is important to first consider the target audience for any dissemination activity, and then consider the most appropriate channel of communication and language through which to reach that specific audience. As noted above, for specific audiences, it may also be useful to consider generating thematic summary reports tailored to specific issues, key findings and/or key populations in order to highlight timely and critical issues raised in the LEA.

There are a number of different options for disseminating the results of the LEA. Some possible processes are discussed below for consideration at country level.

Dissemination workshop
All countries should plan to have at least a national dissemination workshop to launch the results of the LEA. A final national dissemination workshop may be an opportunity to:

- disseminate the final LEA report and its findings and recommendations;
- provide an opportunity for dialogue and discussion on the findings and recommendations;
- prioritize recommendations for strengthening the legal and regulatory framework for TB;
- discuss key actions to take forward, including issues for:
  - reviewing and reforming laws;
  - strengthening access to justice; and
  - sensitizing judges and criminal justice system representatives to issues of TB, human rights, and access to care and support for marginalized and key populations;
- discuss the roles and responsibilities of various partners in taking up recommendations;
• develop a road map for the future actions required to ensure the implementation of recommendations; and
• establish a process or forum for the ongoing monitoring and evaluation of the process.

Media engagement

Engaging the media and generating media coverage of the LEA process and results can be another way to promote and inform public dialogue about key issues. Depending on the resources available, a variety of approaches could be used to promote coverage of the LEA through news stories, in-depth features and more sustained investigative journalism, and/or commissioned public service announcements.

Channel of communication that could also be considered include print, television and broadcast media (such as commercial and community radio), as well as online and other social media.

Some possible activities for consideration include:

- press releases, jointly issued by all partners involved in the Technical Working Group, to trigger news coverage of the national launch event and release of the final LEA report;
- media fellowships to support and sustain in-depth investigative reporting of the key issues emerging from the LEA through feature stories. The fellowships could include short capacity development training specifically for journalists and editors on the results and recommendations of the LEA; stipends to support travel costs and provide an incentive for journalists to invest time and energy in in-depth coverage of the issues; and ongoing mentoring support from a senior ‘expert’ journalist
who can provide technical guidance on the content and style of the features while also potentially assisting journalists in placing their stories with other media houses outside their own;

- public service announcements to ensure that regular, controlled messages are disseminated consistently over a period of time; and

- online and social media coverage of the LEA process and results (depending on the reliability and coverage of internet access).

As with all dissemination and communication activities, the target audience, cost and resources will be important considerations in determining which activities may be undertaken effectively.

**Tailored summary reports on key findings**

The LEA process is likely to produce a vast amount of useful information that can be presented in numerous ways, focusing on different critical issues and/or concerns for specific stakeholders and/or priorities for different key populations.

It may be useful to consider producing focused thematic summary briefs that draw out specific aspects from the key findings, results and recommendations of the LEA. This can be a particularly useful approach if a broad focus is adopted for the LEA and that focus impacts the diverse members of the Technical Working Group and other stakeholders in different ways.

Possible ways to summarize the key findings could include a specific focus on:

- individual key population groups and how different laws specifically interact to have an impact: for example, a summary of legal and policy issues related to the integration of TB and HIV services and specific barriers to accessing HIV services for TB key populations; or a summary of legal and policy steps that need to be taken to improve access to TB services for migrant workers;

- cross-cutting themes, such as gender, stigmatization, discrimination in the workplace, or access to health services, and how different laws have a specific impact – positive or negative – in particular thematic areas;

- actors and champions to take action on specific recommendations: for example, key recommendations proposed could be broken down to develop tailored resource briefs that include a summary of the relevant findings that have informed the specific recommendation, details of the laws implicated, and strategies for action, mapping out key actors, stakeholders, risks, vulnerabilities and opportunities for taking the recommendations forward.

These summary reports could be issue- or population-based, and used to support targeted advocacy or community mobilization on specific issues. While the reports can be presented in a variety of formats, they should always be framed in the context of the wider concerns raised and addressed in the LEA (for
example, through a reference or short paragraph of introduction that contextualizes the specific report). Some possible formats for presenting specific summary reports include:

- short written reports (2–4 pages);
- webinars and/or a specific round-table discussion;
- community awareness-raising activities within key populations (for example, discussion of the LEA results and implications in mining communities or at a community gathering in a rural setting where religious and community leaders can propose activities related to stigma reduction);
- professional network meetings or capacity development activities, for example, with a national union of journalists (drawing on the findings from the LEA related to the media coverage of legal and public health issues); miners’ unions; the National Law Reform Commission; or the National Law Society.
III. NEXT STEPS

In order to develop a successful TB response, urgent and decisive action is needed. Countries have a unique opportunity to undertake TB LEAs and thereby contribute to the local, regional and global TB response by instituting rights-based, effective and efficient TB initiatives. The following steps can be implemented after an LEA is undertaken.

Small grants for tailored advocacy

Given the participatory nature of the LEA process, one of its greatest strengths will be the breadth and diversity of the partners and stakeholders involved. One way to facilitate and support partners in taking the LEA’s results and recommendations forward may be to provide small grants for key stakeholders to implement their own initiatives and activities in order to maximize the dissemination and potential impact of the LEA. This may include developing new and discrete pieces of work, as well as incorporating a focus on the LEA into existing programmes and activities. It may also include specific grants to support the tailored summary reports outlined above.

Sustaining the process

It is important to ensure that the LEA does not end with the production of the final report. In the final workshop, it may be useful to engage in a consultative process of prioritizing recommendations and identifying some key actions for strengthening the legal and regulatory framework as a way to increase ownership in future processes that build on the LEA findings. In addition, it is important to identify some further steps to sustain all stakeholders’ commitment to strengthening the legal framework after the LEA. Such steps include:

- assigning responsibilities for follow-up work to various institutions and organizations;
- designating a structure to coordinate and communicate with the various sectors and oversee follow-up work (such as the Technical Working Group or a new structure specifically established for this purpose);
- integrating LEA recommendations and follow-up activities into the existing work of organizations and into national strategies and plans (such as national development plans, national strategies on TB, and UN development assistance frameworks);
- promoting activities that empower key populations and civil society organizations to claim their rights and that build the capacity of state institutions to implement TB and human rights activities; and
- fostering linking, sharing and learning across countries and across the region in order to increase long-term national and regional knowledge and capacity in TB, the law and human rights and encourage efforts to strengthen legal and regulatory responses to TB.
Sharing country LEA results at the regional level
As unique as national challenges in a country’s TB response might be, there are notable regional patterns in how TB and MDR-TB epidemics have developed globally. Consequently, sharing LEA results with stakeholders at the regional level and raising issues related to TB and the law and TB and human rights regionally could produce faster results on a larger scale. With cross-border and in-country migrants constituting a key population affected by TB, such regional sharing could help to foster cross-regional collaboration and response. Issues related to concurrent epidemics of TB and HIV are also best discussed at the regional level. Countries can also support a regional skills exchange through the sharing of LEAs and recommendations. Moreover, looking beyond national issues can make governments and civil society more at ease with the problems they are encountering on the ground and help them to refocus on achievable results.

Addressing issues of gender
The links between harmful gender norms and lack of access to health care have been established in multiple areas of public health and are profound for TB. Accordingly, it is crucial to tackle these issues first, addressing the needs of women and girls in accessing TB services. TB LEAs can be utilized to begin eliminating harmful gender norms and bring about desired results in both TB prevention and treatment, putting countries on the path to achieving the SDGs.

Zeroing in on TB-specific laws
A rights-based, key stakeholder-driven response to TB is best guided by good legislation. As such, all countries undertaking a TB LEA should prioritize a commitment to TB-specific laws and regulations.
APPENDIX A

Sample questionnaires for various stakeholders38

KEY INFORMANT INTERVIEW GUIDE

<table>
<thead>
<tr>
<th>Interviewer Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greet the key informant. Introduce yourself if you have not had previous personal contact with him or her.</td>
</tr>
<tr>
<td>Thank the key informant for taking the time to talk with you about the legal environment for TB. Provide a brief overview of the Legal Environment Assessment and why the interview is being conducted.</td>
</tr>
<tr>
<td>Observe demographic characteristics of the key informant. Clarify information as necessary with him or her, asking only for information that cannot be determined from observation. Do not use a checklist with the informant.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interviewer’s Name:</td>
</tr>
<tr>
<td>Respondent’s Name:</td>
</tr>
<tr>
<td>Organization:</td>
</tr>
<tr>
<td>Date of the Interview:</td>
</tr>
<tr>
<td>Interview Site/Setting:</td>
</tr>
<tr>
<td>Start Time:</td>
</tr>
</tbody>
</table>

38 Adopted from the collaboration between STOP TB Partnership, KELIN, and Chicago University Law School.
## Demographic Information

<table>
<thead>
<tr>
<th>Gender</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>□ 19–24 years</td>
</tr>
<tr>
<td>Female</td>
<td>□ 25–34 years</td>
</tr>
<tr>
<td>Transgender: male to female</td>
<td>□ 35–44 years</td>
</tr>
<tr>
<td>Transgender: female to male</td>
<td>□ 45 years and over</td>
</tr>
<tr>
<td>Don’t know</td>
<td>□ Don’t know</td>
</tr>
</tbody>
</table>

### Cluster

- □ Legal Officer
- □ TB Survivor
- □ Health Care Provider
- □ KP Consortium/NGO/PBO/CSO
- □ Other (specify: ____________________________)

---

### Interviewer Instructions:

Read the following statement to the key informant, or provide the information in your own words, before asking interview questions.

Thank you again for taking the time to talk to me today. As indicated when this interview was arranged, this questionnaire seeks to solicit your honest views, knowledge and perceptions on the legal environment for TB management, prevention and treatment in [COUNTRY]. We will specifically seek to gather your knowledge, views, perceptions, attitudes and experience on the subject. Every subject matter discussed with you will be treated with all the ethical and confidentiality requirements of Good Research Practice.

The information you provide will remain confidential and will be used solely for this purpose. Participation in this discussion is purely voluntary and there is no penalty for refusing to respond to any question. If you have any questions regarding this study, please feel free to contact: [INSERT CONTACT]
Thank you.

Do I have your consent to continue with the discussion?  Yes (  )  No (  )

Do you have any questions to ask me before we begin?  Yes (  )  No (  )

[OPTIONAL] Consent to record:

As mentioned, your views/opinions are very important. We would like to write down everything you say, but we cannot write at the same pace as we are talking. For us to not lose any information, we would like to record this interview so that we can write down your views and opinions at a later time. This recording will be used for the sole purpose of getting your view right. It will not be aired anywhere or used to link you to your contribution. The interview will take approximately one hour of your time.

Do I have your consent to record this discussion?  Yes (  )  No (  )

Signature of Interviewer: ________________________________
Date:______________________________

Signature of Respondent: ________________________________
Date:______________________________

[Interview Questions Start On Next Page]
FOR ALL PARTICIPANTS

~~~~~~ General Situation and Understanding of TB ~~~~~~~

☐ What is the overall situation with regard to TB in [COUNTRY]?
☐ Do people with TB have a right to free TB drugs?
☐ Are the TB drugs quality-assured?
☐ Do patients have choices about the location of treatment?
☐ Which TB services do people diagnosed with TB receive at a cost/fee?
☐ Is there adequate and good-quality TB diagnosis and treatment capacity? If not, what are the options to address the gap?
☐ Which are the most at-risk populations for TB in [COUNTRY]? Who is at risk of getting TB? Describe whether persons are at an increased risk because of legal-related barriers.
☐ Are there specific subpopulation groups that may face increased vulnerability to TB due to access barriers?
☐ Are prevention, testing, treatment and care initiatives effectively reaching these subpopulations and groups?
☐ What is the available support to help TB patients complete the full course of treatment?
☐ Do these subpopulations have access to appropriate health education and information in relation to TB? Is such information medically and culturally appropriate?
☐ What activities are needed to reach out to these subpopulations?

USE DIFFERENT TYPES OF QUESTIONS BELOW FOR DIFFERENT TYPES OF STAKEHOLDERS

~~~~~~ Structured Interviews for Prison Officers ~~~~~~~

☐ What are some of the available TB services within prison settings in [COUNTRY]?
☐ Are TB and HIV services integrated in this prison?
☐ What measures are in place to ensure the timely diagnosis of TB in prisons?
☐ Are there any policies, guidelines or frameworks for TB prevention, treatment and care in prisons?
☐ Does the current infrastructure of prisons in [COUNTRY] hinder or support TB management? How is overcrowding addressed as a barrier to effective TB management?
☐ Do you have isolation facilities for TB patients?
☐ What rights do TB patients enjoy while in prison?
☐ Do prisons have a programme for Community-Based TB Care? How do you engage the community or community-based organizations?
☐ What measures are in place to educate or inform prisoners on TB and TB rights?
☐ Do prisons officers receive any capacity building on issues of TB and human rights for prisoners?
How do prisons link up with other arms of government in addressing TB in prisons?

Is there screening for TB in prisons? How often?

Is the screening voluntary, confidential and respectful of prisoners’ rights? What are the general guidelines on how TB patients are handled from diagnosis through treatment?

Is there HIV testing among TB patients? Are testing and counselling services voluntary, confidential, accessible, affordable and respectful? Is there informed and written consent of the patient to HIV testing?

What happens to prisoners who refuse to consent to TB treatment? What measures are in place to ensure adherence to TB treatment?

~~~~~~~~ Structured Interviews for Health Care Providers ~~~~~~~

What kinds of TB services does this health facility provide?

Are TB and HIV services integrated in this health facility? Does this facility have a programme for Community-Based TB Care?

Does this facility initiate DS-TB and DR-TB treatment?

Does this facility provide services for continuing TB patients?

Have any of this facility’s patients ever had a period of interrupted treatment? Did the patient give a reason for his/her treatment interruption?

What is the common reason for TB treatment interruption among patients?

Have you ever experienced any TB or HIV drug shortages in this facility?

Are TB drugs always readily available at the health care facility? Are the TB drugs provided free of charge?

Was the treatment of any of the facility’s TB patients interrupted because of the drug shortages?

Is there HIV testing among TB patients? Are testing and counselling services voluntary, confidential, accessible, affordable and respectful? What are the general guidelines on how TB patients are handled from diagnosis through treatment?

Is there informed and written consent of the patient to HIV testing?

Do you think HCWs have enough time to explain the TB disease to the patients?

Do all health services have laws or policies on non-discrimination on the basis of health status? Are these laws or policies enforced?

Are health providers trained in principles of non-discrimination and informed consent? Are there penalties if the laws or policies are violated?

What happens to patients who refuse to consent to TB treatment?

Is it possible to refuse to initiate/continue treatment when it appears that a particular patient is unlikely to adhere to the prescribed regimen? What happens if the patient is non-adherent?

How are people who present for diagnosis and treatment made aware of their rights?

Do you know what the [GOVERNMENT] policy on TB prevention and management is? Do you know of any County Government policy on TB prevention and management?
When patients are offered drug susceptibility testing in the absence of treatment, are they informed of the risks and benefits of testing and specifically asked if they are willing to consent even though treatment may not be available to them?

ADD QUESTIONS SPECIFIC TO LEGAL PROVISIONS FOR PEOPLE WITH TB

Structured Interviews for Institutions and Groups Working with Persons Affected by TB

Who are the main NGO and CSO stakeholders in the area that are already involved in TB?

What are the strengths, weaknesses, opportunities and threats to TB activities?

What are the best existing community-based structures for community-based TB activities?

What is the capacity of the NGO/CSO to use the structures for community-based TB activities?

What are the main barriers to better delivery of TB services? Can community-based TB activities address the barriers identified?

Have key populations been named in the national TB strategic plan? Are strategies outlined for responding to their specific needs? Have representatives of these populations participated meaningfully in the development of the national TB strategic plan?

Which diagnostic measures can people with TB obtain for free? Are there particular TB patients who are prioritized over others?

What barriers do people with TB commonly face in accessing health (TB) education? What measures are in place to eliminate these barriers?

Is there compensation for work-related TB for health care workers/miners/workers in other professions who are at higher risk for TB? Do you think there should be one in place?

Are health services affordable to all? Are there any financial barriers to accessing health services, such as user fees? Are health services of an acceptable quality?

Are health services within safe physical reach for all, including key populations? Do indigenous people, migrants and IDPs have equal access to TB services and information in their own languages?

What are the rights of people affected by TB in terms of adequate standard of living and social protection in the event of unemployment, sickness or disability?

What kind of support is provided to TB patients during treatment (e.g., social accompaniment, financial motivation, food packages)?

What barriers do persons affected by TB commonly face in accessing social protection and other benefits? What measures are in place to eliminate these barriers?

Are there disability benefits for people with TB who acquire permanent disability as a result of their TB?

Are key populations criminalized? Are there realistic opportunities to change the laws in the current environment?

Is there involuntary isolation, quarantine or detention of people with TB? If so, under what circumstances? Is there a legal standard governing the isolation, quarantine or detention of people with TB? What law governs?

Do people with TB have the right to due process in circumstances where they are deprived of liberty?
In the rare event that isolation is used, does it take place in adequate settings, with appropriate infection control measures, as specified more fully in WHO guidance?

Is reasonable social support provided to isolated patients and their dependents?