

LEGAL ENVIRONMENT ASSESSMENT FOR TB IN INDIA 2018

EXECUTIVE SUMMARY

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This report is, in part, made possible by the support of the American People through the United States Agency for International Development (USAID).

Foreword

2018 has been a milestone year for the TB response in India. In March this year, the Honourable Prime Minister reiterated India's commitment to eliminate TB by 2025. The new National Strategic Plan for 2017-25 reflects this commitment and lays out an ambitious road-map for the country to implement a comprehensive response to TB.

I am pleased that India is one of the first countries to utilize the Communities, Rights and Gender Tools developed by the Stop TB Partnership. This is in keeping with our efforts to engage civil society and affected communities in the TB response through the creation of National, State and District TB Forums and involving TB Champions or Kshay Veers at various levels. An increased focus on the areas addressed by the CRG tools has the potential to not just increase case detection and treatment outcomes but also improve the overall quality of care.

The Legal Environmental Assessment for TB is the first exercise of its kind and recognizes that law can be an enabling factor in the TB response. Through a thorough mapping and analysis of various issues related to law and human rights, the authors draw our attention to legal frameworks in India that exist in relation to TB along with recommendations on how law and its implementation need to be adapted to best serve the TB response and advance the priorities of those with TB, those vulnerable to TB, and public health goals more generally.

On behalf of the Central TB Division, I congratulate REACH on the publication of this document and look forward to continuing our work with the TB community for a comprehensive, rights-based TB response.



Message from Stop TB Partnership

The tuberculosis (TB) response needs a paradigm shift – to become people and community centered, gender sensitive and human rights based. There is a need for country specific data and strategic information on key, vulnerable and marginalized populations. There is a need to facilitate an enabling environment to effective prevention, diagnosis, treatment and care – which requires legal and gender related barriers to be analyzed, articulated and alleviated.

The Stop TB Partnership CRG Assessments are the tool for National TB Programmes to better understand and reach their epidemics. With TB being the leading cause of infectious disease deaths globally, and with over 10 million people developing TB each year, this disease continues to be a public health threat and a real major problem in the world. The Stop TB Partnership's Global Plan to End TB and the World Health Organization (WHO) End TB Strategy link targets to the Sustainable Development Goals (SDGs) and serve as blueprints for countries to reduce the number of TB deaths by 95% by 2030 and cut new cases by 90% between 2015 and 2035 with a focus on reaching key and vulnerable populations. The Strategy and the Plan outline areas for meeting the targets in which addressing gender and human rights barriers and ensuring community and people centered approaches are central.

Ending the TB epidemic requires advocacy to achieve highly-committed leadership and well-coordinated and innovative collaborations between the government sector (inclusive of Community Health Worker programs), people affected by TB and civil society. Elevated commitment to ending TB begins with understanding human rights and gender-related barriers to accessing TB services, including TB-related stigma and discrimination. It has been widely proven that TB disproportionately affects the most economically disadvantaged communities. Equally, rights issues that affect TB prevention, treatment and care TB are deeply rooted in poverty. Poverty and low socioeconomic status as well as legal, structural and social barriers prevent universal access to quality TB prevention, diagnosis, treatment and care.

In order to advance a rights-based approach to TB prevention, care and support, the Stop TB Partnership developed tools to assess legal environments, gender and key population data, which have been rolled-out in thirteen countries. The findings and implications from these assessments will help governments make more effective TB responses and policy decisions as they gain new insights into their TB epidemic and draw out policy and program implications. This provides a strong basis for tailoring national TB responses carefully to the country's epidemic – the starting point for ending discriminatory practices and improving respect for fundamental human rights for all to access quality TB prevention, treatment, care and support services. The development of these tools could not be more timely, and the implementation of these tools must be a priority of all TB programmes.



RESOURCE GROUP FOR EDUCATION AND ADVOCACY FOR COMMUNITY HEALTH

Preface

The TB response is continually evolving. In the last few years, we've seen new diagnostic tools, new algorithms to reduce delays in diagnosis, breakthrough research on latent TB and TB infection, new social welfare schemes to support those affected by TB and even two new drugs to treat TB. We've also seen, for the first time, the language of rights and equity enter the TB discourse.

Today, I am delighted to see that globally and in India, we are talking about adopting a rights-based approach to TB. Since REACH's inception almost two decades ago, we have tried to adopt a patient-centric approach in our response to TB. Over the last 19 years, working closely with those affected by TB and their families, we have witnessed and tried to address the many vulnerabilities that impact their health. We have been part of nascent discussions on issues affecting treatment literacy and the rights of affected communities.

I am grateful that REACH has had the opportunity to be part of this important conversation in India, by undertaking the Communities, Rights and Gender Assessments. The CRG assessments has given us an opportunity to study these vulnerabilities through a more structured framework and to contribute to the discussions on data collection and measurement. It has been a steep learning curve for us and allowed us to reflect on our own work, challenge ourselves and push ourselves to do better. I am thankful to the Stop TB Partnership for giving us this opportunity and for the leadership at the Central TB Division and the Ministry of Health and Family Welfare for welcoming these conversations.

I hope that the TB community in India will find the findings of these assessments useful and interesting, and that we can work together to translate the recommendations into concrete actions that will strengthen the TB response in this country. We look forward to your feedback and continued partnership.

Nalini Krishnan

Dr. Nalini Krishnan

Director, REACH

Acknowledgements

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Acknowledgements from the Authors

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Public sector personnel: Dr. Raghuram Rao, Dr. Nishant Kumar, Dr. Amita Athavale, Dr. Kiran Keny and senior officials at Sewri TB Hospital.

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TB Champions and activists: Blessina Kumar, Dean Lewis, Ketho Angami, Lorraine Misquith, Manoj Pardesi, Meena Seshu, Mona Balani, Rhea Lobo, Vijay Bhende, Zakir Thomas, Chinmay Modi and Paul Lungdim and the entire Delhi Network of Positive People (DNP+) team.

Glossary

AIDS	Acquired Immune Deficiency Syndrome
ART	Anti-retroviral Therapy
ARV	Anti-retrovirals
CBNAAT	Cartridge-based nucleic acid amplification test
DOTS	Directly Observed Therapy Strategy
DPSP	Directive Principles of State Policy
DR-TB	Drug-resistant Tuberculosis
HIV	Human Immunodeficiency Virus
ICMR	Indian Council for Medical Research
ICT	Information and Communication Technology
IP	Intellectual Property
LEA	Legal Environment Assessment
MDR-TB	Multi-Drug Resistant Tuberculosis
MoHFW	Ministry of Health & Family Welfare
NACO	National AIDS Control Organization
NGO	Non-governmental Organization
NHRC	National Human Rights Commission
NSP	National Strategic Plan
R&D	Research and development
RNTCP	Revised National Tuberculosis Control Programme
RTI	Right to Information
SDGs	Sustainable Development Goals
STI	Sexually Transmitted Infection
TB	Tuberculosis
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNDP	United Nations Development Programme
WHO	World Health Organization
WTO	World Trade Organization
XDR-TB	Extensively drug-resistant tuberculosis

Communities, Rights and Gender Tools

The Communities, Rights and Gender (CRG) Tools were developed by the Stop TB Partnership in consultation with various donor and partner organisations. The CRG tools provide a guiding framework for undertaking rapid assessments of three different dimensions of our response to TB – gender; key and priority populations; and law and human rights. An increased focus on these aspects has the potential to not just increase case detection and improve treatment outcomes but also improve the overall quality of care available to those affected by TB.

The three tools that form part of the CRG initiative are:

1. Data for Action Framework for Key Populations, which focuses on measuring the burden of TB among key, vulnerable and priority populations in the country
2. Gender Assessment tool for national TB response, which applies a gender lens to TB in the country and assess ways in which gender affects and interacts with TB
3. Legal Environment Assessment Tool that looks to understand and examine the legal environment for TB through a rights-based framework

In 2017, the Stop TB Partnership hosted a workshop for partners from six countries including India, which would be the first to utilize the CRG tools.

India's National Strategic Plan (NSP) for 2017-25, recently formulated by the Ministry of Health and Family Welfare, Government of India, lays out an ambitious road-map for the country to achieve TB elimination by 2025. The new NSP is a sign of renewed political commitment to the fight against TB in India and this is therefore an opportune time to introduce the Communities, Rights and Gender Tools. Each of these three tools provide an opportunity to reflect on a person-centred and rights based approach to TB.

CRG Assessments Timeline in India

July 2017:	REACH Participation in CRG Workshop in Thailand
Sep – Oct 2017:	Preparatory discussions for rollout of CRG tools in India
October 2017:	Constitution of Expert Advisory Group
November 2017:	Consultative Meeting of Expert Advisory Group
December – March 2018:	Assessments underway
April – August 2018:	Feedback and revision of assessment reports
September 2018:	Final consultative meeting and publication of assessment reports

Expert Advisory Group Members

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Background

1. Introduction

This report presents the findings of the TB Legal Environment Assessment (LEA) conducted for India. The TB LEA was undertaken in the context of a renewed commitment to end TB in India by 2025 as reflected in the National Strategic Plan of the Ministry of Health and Family Welfare (MoHFW), Government of India. This LEA report presents legal frameworks in India that exist in relation to TB along with recommendations on how law and its implementation need to be adapted to best serve the TB response and advance the priorities of those with TB, those vulnerable to TB, and public health goals more generally. As there is limited information on some law-related aspects related to TB, such as a fuller understanding of contexts in which people's vulnerability to TB may be enhanced, or how the law on the books actually gets implemented, the LEA also suggests some key areas that may require further research in order to tailor more appropriate public health policy and legal responses. While this report is aimed primarily at law and policy makers in the hope that its findings can inform the design and implementation of TB policies in India from a rights-based perspective, it is also aimed at other stakeholders who play a vital role in relation to TB; for instance, employers, private healthcare providers, regulators, NGOs etc. It is hoped that people affected by TB in particular find this report useful in identifying and advocating for their rights.

a. Tuberculosis and the Law

Health is a right of all persons, and it is the duty of the State to guarantee this right through policies, programmes and actions aimed at providing equal and universal access to health services, for the full enjoyment of a healthy life. TB is a global emergency requiring a committed response to sustained, comprehensive TB control activities including case detection of TB, standardized treatment regimes, regular uninterrupted supply of TB drugs and standardized recording and report keeping. The role of the law is to provide parameters for these elements and regulate their appropriate implementation through legislation. The question of patients' rights is considered central to the evolution of health legislation as the vulnerability of those with TB makes them easily subject to violation of their rights and more affected by shortcomings of social and health systems. The rights-based approach that emerged from the response to the HIV epidemic spoke of the necessity to create an enabling legal environment for these marginalized communities to access health services and information and

thereby looking after their health and wellbeing, while attaining public health goals of securing the larger community's health. Although such an approach is still to be fully developed in the context of TB, the time has come to view the law as an enabling, empowering tool that tackles the marginalization, inequity and structural disempowerment that people who are most vulnerable to TB and those who live with it face.

One of the primary notions in relation to law and an infectious disease like TB relates to the apparent tension between human rights and public health goals; however today governments are moving away from isolationist models of public health interventions to community driven integrationist models. These approaches do not do away entirely with the notion that States may sometimes legitimately restrict individual rights; rather they demand the evidence for the use of such power and place restrictions on it as provided, for instance in the Siracusa Principles. But it is important to note that it is not only the law's punitive role that defines the relationship between TB and the law; law can and must play a vital role in driving positive and inclusive social change and attitudes, by reflecting evidence- and rights-based principles, ensuring equal access to social resources, protections and opportunities, including to health, education, employment, insurance, housing, and nutrition. The law can also provide guidelines to ensure that authorities implement appropriate disease control and treatment measures; and it can safeguard the rights of people with TB so that they don't also suffer the ostracizing and marginalization that comes with TB. These aspects are necessary in attaining equitable healthcare systems and a TB response that promote universal access, fair distribution of financial resources, good governance, adequate training for competence, empathy, transparency and accountability and special attention to the most vulnerable.

b. An Overview of the Legal System in India

The Constitution of India is the highest law of the land and adopts a parliamentary system of democracy. The Constitution lists health within the jurisdiction of States for law making; however, various aspects impacting healthcare fall under the Central or Concurrent lists resulting in laws relating to health, including the social determinants of health, being legislated at both the Central and State levels and covering a whole gamut of topics that directly and indirectly impact health services. There are multiple sources of law in India: constitutional law, statutory law, personal laws, customary law and common law (judge-made law). India's legal system is also impacted by various international conventions like the human rights covenants and international trade treaties; however, Parliament must pass a law to bring these into effect in India. Redressal of rights violations lies largely with the courts in India which have the following hierarchy: The Supreme Court followed by twenty-four High Courts in each State or group of States and below them lies a hierarchy of Subordinate Courts. There are also Family Courts and special tribunals.

c. Human Rights Framework in India

The Fundamental Rights found in Part III of the Constitution are enforceable against the State in a

court of law and pose a negative covenant on the State not to infringe these rights. They guarantee certain civil liberties - some of them are available to all persons and some are only for citizens. The Constitution guarantees the right to life and personal liberty, equality before law or equal protection of the laws, right to education, freedom of speech and expression, freedom of movement, and guarantees. The DPSPs in Part IV of the Constitution are meant to inform government action and are not enforceable in a court of law and refer primarily to social and economic rights; the Supreme Court has attempted to bridge the gap between the two sets of rights by reading components of the latter into the former. Thus, the right to life, a fundamental right, now includes the right to health. In case of violation of a Fundamental Right, the Constitution provides specific remedies and these rights can be enforced in the Supreme Court as well as in High Courts through writ petitions. In addition, the *Protection of Human Rights Act, 1993* establishes the National Human Right Commission (NHRC) which is empowered to conduct investigations and provide recommendations to the government to rectify violations. Indian courts have also pioneered the system of public interest litigations (PIL), which are petitions filed before a High Court or the Supreme Court where there has been a breach of a right of a class or group of people. It is also important to note that legal aid is a right in India. Legal aid authorities have been set up under the *Legal Services Authorities Act, 1987*. Finally, the *Right to Information Act, 2005* sets out a system for citizens to secure access to information under the control of public authorities.

d. An Overview of TB in India

The largest number of people with TB are in India, which accounts for one-fourth of the global TB burden. India also has the world's highest burden of MDR-TB cases. Treatment success for MDR-TB has been less than 50% and death rates are high at 21%. According to the WHO, India accounts for 33% of global TB deaths among HIV-negative people, and for 26% of the combined total of TB deaths in HIV-negative and HIV-positive people. The Indian Government through the Ministry of Health and Family Welfare runs a vertical programme to address TB: the Revised National TB Control Programme (RNTCP). The programme reports a massive scale-up in recent years including the increased availability of cartridge-based nucleic acid amplification test (CBNAAT) across the country. MDR-TB diagnostic and treatment services are reported to have achieved complete coverage. Newer MDR-TB drugs, bedaquiline and delamanid, are also being rolled out. Single window delivery of HIV-TB services has been expanded to all antiretroviral therapy (ART) centres and 99 DOTS ("Health for the 99%"), an ICT-based treatment adherence system, has been rolled out. As of 30 October 2017 onwards, all patients diagnosed have been put on the daily regimen throughout the country. New technical and operational guidelines intended to be applicable across the country have also been issued. On 13 March 2018, the National Strategic Plan for TB Elimination 2017-2025 (NSP) was launched with the vision of a "*TB free India with zero deaths, disease and poverty due to tuberculosis.*" The goal is "*to achieve a rapid decline in the burden of TB, mortality and morbidity, while working towards the elimination of TB in India by 2025.*" Detect, Treat, Prevent, Build are the four strategic pillars of the NSP.

2. Methodology, Limitations & Structure

The methodology for this assessment was based on the Stop TB Partnership and UNDP Legal Environment Assessment for TB: An Operational Guide with modifications as required by constraints within which the LEA was undertaken, in India including a limited time frame for in-depth research on laws and their impact in various facets of people's lives vis-à-vis TB, and for key informant interviews, including of government functionaries within the TB response, and members of communities understood to be vulnerable to TB. As the LEA looked at only a few vulnerable communities, legal and policy issues related to people who used drugs, children, tribal populations, and miners require further research and analysis. Some of the constraints were due to the current impetus being given to the TB response generating new policy and law in real time. Despite this, the report is thoroughly researched and covers most of the legal issues that intersect with TB. The methodology included the following key elements:

- i. *Literature review and research* on TB and health epidemiology in India, and laws, policies and their enforcement vis-à-vis TB, including relevant statutory law passed by legislatures, and judgments of key Indian courts. As agreed with REACH, the LEA focused on legislation in Maharashtra, given time limitations, TB burden on the state, and geographic convenience for the report writers. Limited research and related analysis was undertaken of state laws in Tamil Nadu too.
- ii. *Interviews with key experts and stakeholders* after obtaining informed consent, through individual meetings, either in person or telephonically and focus-group discussions to gather information, and to get better understandings of how law and policy affects ground realities in relation to TB specifically, and healthcare more generally. Interviewees have not been named in the LEA out of abundant caution or because specific permission to use their names was not given in many cases.
- iii. *An analysis of the laws and policies* that pointed to strengths and weaknesses was undertaken using the analytical framework contained in the operational guide, including Constitutional law, general laws related to delivery of health services and connected issues, and those affecting people with TB and key groups vulnerable to TB, and relevant policy frameworks.

iv. *Development of the LEA Report* included a first draft that was submitted in March 2018, and an updated version in June 2018 based on reviews received from experts and from a presentation of the report to REACH as well to include critical contemporaneous changes in law and policy. The report follows the following structure: Key legal-ethical issues (discrimination, isolation, notification, consent, confidentiality, and criminal law), key health sector issues (drug regulatory framework, regulation of the private sector, alternative systems of medicine, quackery, universal health coverage/ insurance), key issues of access (to treatment and diagnostics, and to nutrition), and people in vulnerable contexts (in the workplace, in prisons, and briefly mobile populations, women, people living with HIV, and sex workers). Recommendations are provided in each section. The conclusion highlights key cross-cutting issues and the way forward. This shorter version of the report summarises the key points in each section.

Legal-Ethical Issues

1. Countering Discrimination

Stigma has an adverse impact on the health and health seeking behaviour of people with TB. Its contagiousness is one reason for the stigma that surrounds TB. Discrimination, a social determinant of health, though linked to and sometimes used interchangeably with stigma, is different in the sense that discrimination excludes and brings about inequality. Discrimination occurs in a direct form when people are outright rejected, such as when people lose their jobs due to TB. Persons with TB confront human rights violations in experiencing discrimination at work, in healthcare contexts, within families, and in communities; their families, people they associate with or those at higher risk of infection due to social determinants of health also encounter discrimination.

The law can play a significant role in prohibiting discrimination and reducing the effect of stigma on people. The Constitution of India guarantees the right to equality under Article 14, 15 and 16, thereby providing protection against discrimination. The equality protection is against the State only and not against private players. Unlawful discrimination in the private sector is provided with little or no redress in law for people adversely affected by it.

There is much discrimination in workplaces due to TB. A guidance on determination of discrimination at the workplace was shown by the court in a case holding that in order to determine whether a qualified person handicapped by a contagious disease is able to continue in the job, an individualized inquiry needs to be made based on reasonable medical judgment, given the state of medical knowledge, about (a) nature of the risk (how the disease is transmitted), (b) duration of the risk (how long is the carrier infectious), (c) the severity of the risk (what is the potential harm to third parties), and (d) the probabilities that disease will be transmitted and cause varying degrees of harm.

There are laws that can come to the aid of TB patients such as Rights of Persons with Disabilities Act, 2016 that covers private sector discrimination in relation to persons with disabilities. Some employment related laws provide certain benefits, paid leave, reasonable accommodation and compassionate allowance to employees in case of sickness including TB. The HIV and AIDS (Prevention and Control) Act, 2017 also prohibits discrimination against people living with HIV in employment, education, healthcare, housing, insurance, etc. People with HIV are susceptible to TB.

Education discrimination due to TB is subtly seen in schools and colleges, as students tend to lose an academic year due to absenteeism, inability to appear for exams and face stigma if they wear a mask

to attend lectures. Positive initiatives to provide sanctioned leave to TB students, and promotion on the basis of past performances would help students with TB.

Discrimination due to TB in healthcare is seen in public and private health sector. Stigma and discrimination are fueled by healthcare workers, though they are also at a great risk of acquiring TB. Making adequate provisions for safety of health care workers and providing training to healthcare workers can bring about a change in their attitude towards TB patients and reduce stigma and discrimination.

Abandonment by family is a very serious issue in TB. Abandonment manifests in people with TB being dropped off at public hospitals by family members. Discrimination within families takes place within crowded homes, which is the living context of many urban Indians. There are laws on maintenance and The Maintenance of Welfare of Parents and Senior Citizens Act, 2007 that can be used by patients with TB to obtain maintenance from certain family members, but, due to unawareness of their rights, the law and legal procedures, they often are left abandoned to fend for themselves, or languish in hospitals for months and years.

Equality law is a vital tool to correct injustice in society, and come to the aid of the marginalized. If used effectively, it demonstrates the role of law in changing entrenched attitudes, behavior and institutional functioning in order to secure fundamental rights. Deploying it poses a challenge, since this requires high levels of motivation, novel procedures, a deep understanding of law and an appreciation of the social significance of equality. The law can be used to blunt the effect of stigma and also to mitigate harmful, unfair conduct and secure the rights of the disempowered.

Recommendations to Government (Central, State and Local bodies)

(I) Law Reform (develop, repeal, amend, review)

- a) Identify, repeal and amend laws, policies, government resolutions, notifications that discriminate directly or indirectly against people with TB.
- b) Prohibit discrimination based on TB status. Implement the fundamental rights guaranteed under the Constitution of India (to life, health, equality, non-discrimination, education, freedom of movement, right to employment, etc.), in all public sector organizations and undertakings.
- c) Legislate a broad anti-discrimination law to cover discrimination and unfair treatment in the ever-expanding private sector in India that should cover the employment, health, education, insurance and unorganized sectors. Such a law should not be disease-specific, but should be applicable to all health situations where stigma and discrimination are manifest. Legislation should be formulated with participation of all key stakeholders and be evidence-based.
- d) Ensure that the law has provisions of reasonable accommodation and compassionate allowance.
- e) Make provisions for an alternative disputes resolution system where people who have faced discrimination due to their TB status or health status are able to obtain justice quickly and in an affordable manner.

(II) Policy Reform (develop, repeal, amend, review)

- f) Develop guidelines and protocols to be followed by the management and co-workers in workplace situations, by healthcare providers in healthcare institutions, by the administration and staff in educational institutions, such that people with TB are not discriminated, do not face hardship or unfair conduct, and are able to sustain themselves and their families while on treatment or continue their employment or education.

(III) Implementation and Enforcement

- g) Ensure that all persons with TB, whether in urban, rural, tribal or remote areas receive complete treatment in a non-discriminatory manner through the public health system, and provide for persons with TB to approach the private healthcare sector, to access non-discriminatory treatment.
- h) Build shelter homes and other facilities for people abandoned due to TB.
- i) Ensure that legal aid is provided to persons who have been discriminated due to their TB status, and who also wish to seek redress in judicial fora.
- j) Ensure strict accountability in all public sector institutions to eliminate discrimination against people with TB.

Recommendations to Other Stakeholders

Role of Judges, Lawyers and others involved in the justice system

- k) Implement existing laws creatively, to ensure that people with TB are not discriminated against and are able to access the justice system to redress their grievances.
- l) Expansive and creative use of the Disabilities Act, HIV Act, Maintenance and Welfare of Parents and Seniors Act, fundamental rights and other laws relevant to persons with TB, to protect persons with TB against discrimination and unfair treatment.
- m) Introduce judicial sensitization in lower courts, and higher courts, especially those in criminal courts and district, family, labour, and industrial courts, and education tribunals to understand the issues faced by people with TB, those who are in prison or in conflict with the law, or those who have been discriminated in various contexts due to their association with TB.
- n) Encourage lawyers to be pro-active in giving legal advice, aid and litigation services to people affected by TB.
- o) Make provisions for a fully functional legal aid system. This includes ensuring provision of quality legal services, and speedy redress of grievances of people with TB approaching the justice system, and enhancing the accessibility of the system to indigent persons, and those living in remote areas.
- p) Make optimum use of provisions of arbitration, mediation and alternate dispute resolutions for quick and fair redress of issues faced by persons with TB.

Role of Doctors, Healthcare workers, Medical institutions and others involved in the health system

- q) Ensure that all persons with TB are provided complete and adequate treatment in a non-discriminatory manner.
- r) Ensure that all healthcare providers and staff are trained and sensitized on issues faced by persons with TB, and to treat them in an effective and non-discriminatory manner.
- s) Ensure accountability of persons in healthcare settings who cause stigma and discrimination against persons with TB.
- t) Ensure that all healthcare providers and staff are provided adequate protection against acquiring TB occupationally, and that all measures are actually taken by healthcare providers to follow protocols required to prevent spread of TB.
- u) Ensure sufficient counselors in the healthcare setting to provide honest and complete knowledge relating to TB to patients and their relatives.
- v) Provide a prompt and effective grievance redress mechanism in the healthcare institution in relation to discrimination faced by a person with TB while accessing healthcare.
- w) Develop a referral system to non-governmental organizations working on TB, and to legal aid centres for persons with TB who face discrimination.

Role of Civil society, activists, Non-governmental organizations, Community-based organizations and others involved in the TB response

- x) Empower people with TB to eliminate TB-related stigma and discrimination. Provide complete, honest and adequate information about TB to reduce stigma and discrimination.
- y) Provide legal literacy to people with TB, to know their rights and be able to access grievance redress mechanisms.
- z) Liaise with government and private institutions that provide treatment or care to people with TB and provide services or information to people with TB.
- aa) Undertake projects or raise funds to provide shelter homes for people abandoned due to TB.
- bb) Help persons with TB access the justice system.
- cc) Intervene to provide immediate support in cases where healthcare or educational institutions or workplaces discriminate against people with TB, and to provide longer-term sensitization in such contexts.
- dd) Provide ancillary support where there is inadequacy in the healthcare system, such as human resources and skills development for counseling services.

2. Isolation

It is only in very exceptional circumstances that the encroachment of fundamental rights is justifiable, which are otherwise of primacy in a free society. These include measures such as isolation in response to public health needs, which is to be exercised with the greatest of restraint in the case of infectious diseases, and only if alternative methods are ineffective. Well-established ethical principles of the WHO for public health laws that restrict personal rights and freedoms include justifications to curtail freedom based on reasonableness, effectiveness, proportionality, and transparency. In the context of TB, guidance provides that isolation is very exceptionally involuntary and should always be a last resort, after all other strategies, such as treatment and use of masks fail.

Isolation finds no mention in RNTCP policy and programme documents. However, statutes like the *Epidemic Diseases Act, 1897* vest wide powers with state governments to take measures in cases of outbreak of dangerous diseases, which could well include isolation. Other central laws relate to travel, including rules under the *Aircraft Act 1934*. The *Public Health (Prevention, Control and Management of Epidemics, Bio-Terrorism & Disasters) Bill, 2017* has been proposed to replace the *Epidemic Diseases Act, 1897*, but it fails to build in rights-based imperatives as per international standards such as the WHO's *Guidance for Managing Ethical Issues in Infectious Disease Outbreaks, 2016*. State municipal and public health laws specifically provide wide powers, including for isolation, for example the *Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965* (specifically for TB), *Mumbai Municipal Corporations Act, 1888*, (does not specifically include TB), and the *Tamil Nadu Public Health Act, 1939*. These laws reveal the broad extent of limits imposed on quotidian aspects of life such as movement, habitation, and human interaction in situations where authorities assess outbreak of diseases to be threatening to society at large, and are empowered to impose restrictions. These laws do not appear to have been used in relation to TB, as per reported cases Indian constitutional courts. Many of them are either of the colonial era or at least half a century old. With advancements in science and medicine, changes in urbanization and ways of habitation, and now robust understanding of the vitality of rights-based approaches in public health, it is necessary to update these laws in order to reflect realities and be more appropriate to current times.

Expert felt that isolation is not a fit strategy to deal with TB in India given other approaches that can enhance infection control: early detection and treatment, occupational precautions (N-95 masks and ultraviolet light), nutritional support, health education on prevention including taking domestic hygiene measures such as limiting contact with children, and proper air ventilation. Concern was expressed that wards in some hospitals are allocated for people with TB, as part of an infection control strategy. If this was done in a non-stigmatizing and non-discriminatory manner it could yield the desired public health goals of TB prevention, care and support while also respecting the patient-centric approach articulated in the NSP. Some felt that isolation is justified only in singular situations such as if a person with MDR-TB refuses to take treatment. In some jurisdictions, a court order is required to isolate the person in such a case, and even then this is used as an option of last resort.

Recommendations to Government (Central, State and Local bodies)

(I) Law Reform (repeal, amend, review)

- a) Repeal or amend laws that give arbitrary power to health officials to isolate people and breach their fundamental rights. In the case of TB, central and state legislation and policy must align with the WHO Ethics Guidance for the Implementation of the End TB Strategy 2017, which establishes the specific circumstances, conditions and justifications for isolation and involuntary isolation (see *Annexure* for further details).
- b) Update public health laws that allow isolation of people with TB to reflect scientific advances and rights-based understandings of public health, such as voluntariness, with involuntary isolation allowed only in specified exceptional circumstances. Examples mentioned in this report include the *Epidemic Diseases Act, 1897*, the *Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965*, the *Mumbai Municipal Corporations Act, 1888*, the *Tamil Nadu Public Health Act, 1939* and the *Goa, Daman and Diu Public Health Act, 1985*. However, a national survey and reform of all such laws at the state level requires to be undertaken.
- c) Proposed legislation such as the *Public Health (Prevention, Control and Management of Epidemics, Bio-Terrorism & Disasters) Bill, 2017* to replace the *Epidemic Diseases Act, 1897*, must include global standards for rights-based safeguards while using restrictive means such as isolation. These include demonstrating necessity, using least restrictive means, ensuring humane conditions, addressing economic and social consequences of isolation, involving affected communities in mitigating burdens imposed through isolation, assuring due process, and equitable application of isolation restrictions.

(II) Policy Reform (repeal, amend, review)

- d) Provide guidance to adhere to the protection of fundamental rights of people with TB, and use of the least restrictive methods for containing the spread of disease.

- e) Sparingly use the strategy of isolation as a public health measure for infection control, including in such rare cases informing people with TB of the consequences of isolation and the reasons for the same, before obtaining their consent.
- f) Develop a protocol for an effective public health strategy to contain the spread of TB that is rights-based, involves the participation of all stakeholders and is least restrictive.

(III) Implementation and Enforcement

- g) Provide information, masks, treatment and all other protections to persons with TB thereby empowering them to mitigate infection.
- h) While some public health laws do permit for special wards for infectious diseases, their deployment must be in a rights-based manner, ensuring non-stigmatization and confidentiality, empathy, and dignity of the patient, backed with robust infection control measures. Laws may need to be updated to reflect this. Further, this should be the standard across all congregate settings, including prisons.

Recommendations to Other Stakeholders

Role of Doctors, Healthcare workers, Medical institutions and others involved in the healthcare system

- i) Ensure provision of infection control measures throughout every healthcare facility, including in wards, waiting areas and out-patient areas.
- j) Ensure that people with TB are not isolated, and if kept in a separate ward, they are not discriminated. In the rarest of circumstances when isolation is deemed necessary, this should be based on informed consent and healthcare workers must provide complete and detailed information to patients on the reasons, consequences and duration of isolation. Any mandatory isolation must take place only under the authority of law.
- k) Confidentiality of people with TB should be maintained, in every context, including in situations where there are separate wards.
- l) Healthcare workers must not resort to isolation. Instead, they must use universal precautions, and provide complete and honest information to people with TB on how to prevent the spread of infection.
- m) All healthcare staff, and all persons involved in the care of people with TB should be sensitized and trained not to resort to isolation, where this is not permitted or indicated.
- n) If people with TB are to be isolated, they should be informed of the consequences of isolation and the reasons for the same, before their consent is obtained.

Role of civil society, activists, Non-governmental organizations, Community-based organizations and others involved in the TB response

- o) Civil society should engage in advocating for non-isolationist approaches and attitudes within healthcare settings and families through education initiatives.
- p) People with TB should be empowered with information on the nature of their disease, their rights, how they can prevent the spread of TB, and the treatment that is available. They should be empowered to seek proper information, knowledge and become partners in and not just subjects of treatment.
- q) People with TB should be empowered with knowledge and tools to prevent transmission and receive proper counseling and support to take infection control measures.
- r) Civil society, NGOs and CBOs must play a complementary role in providing information about TB, support for those undergoing treatment and the consequences of acquiring it. These stakeholders must receive the necessary financial and other support for carrying out this work.
- s) Ensure that people with TB are not subject to involuntary isolation and provide support including in accessing redress mechanisms if isolated wrongly.

3. Notification

Diseases of an infectious nature that are considered of concern to public health are often given the status of ‘notifiable’ or ‘reportable’ by governments. This requires mandatory reporting of cases to public health authorities, including details of the patient and their related information. Such notification is justified on the grounds that it facilitates accurate determination of disease burden, provides basis to design appropriate and prompt diagnosis and treatment, and plan effective prevention control measures. In the case of TB where there is efficacious treatment, notification is meant to be dually beneficent – for larger social good by enabling public health authorities to receive vital information to track infectious disease, and to use that information to get patients onto treatment and recovery thereby also ensuring the prevention of further infection.

Notification entails breach of confidentiality of a person’s health (TB) status and therefore a limitation of their fundamental right to privacy. As such, it needs to be deployed with great caution, and not as a matter of course. To be justifiable the restriction needs to meet certain tests including those laid down in international guidance and by the courts. This includes ensuring that the restrictive measure is provided through law, is directed to a legitimate objective, suggests through evidence that it is necessary, that it is the least intrusive and restrictive means, and is not an arbitrary or discriminatory action.

The NSP notes that TB control in India is challenged by delayed diagnosis and inadequate treatment of patients accessing private healthcare. Due to this the MoHFW issued an order in May 2012 mandating all healthcare providers to notify all TB cases that they treated or diagnosed to local health authorities, the intent being to obtain accurate information on prevalence across public and private sector healthcare, and to get patients on to and keep them on treatment. A following amendment in 2015 required public health staff to make home visits, counsel patients, ensure treatment adherence, undertake contact tracing, and offer HIV testing to a notified person. A 2018 notification places a duty on all healthcare providers, medical laboratories and pharmacies to notify the relevant public health authority, and the latter to also send the list of medications of each person, and to keep a copy of the prescription. The notification also encourages people with TB to self-notify, and requires that the confidentiality of the identity of the person with TB be

maintained in the process of notification, without stipulating a protocol for confidentiality. Criminal law is invoked for failure to notify by attaching sections 269 and 270, Indian Penal Code (IPC), which impose jail terms up to 2 years for negligent or malignant acts likely to spread infection of life-threatening disease. This criminality also extends to “*local public health staff of general health system of rural or urban local bodies*” who fail to undertake a variety of follow-up including patient home visits, counseling, treatment adherence, and contact tracing. Apart from the efficacy of such an approach or the appropriateness of the provisions being invoked practical issues, including the administrative burdens expected of pharmacies and labs to maintain and report medical records, protocol for chemists to maintain a person’s prescription information confidentially, reconciliation of duplication/ triplication of notifications of the same person also arise. Further, it is not clear whether available laws have been used to increase TB notification. The *Clinical Establishments Act, 2010* requires compliance of standard treatment guidelines, including for notification of TB cases with non-compliance with attracting fines. The *Code of Medical Ethics Regulations* of the Medical Council of India prescribes duties of physicians, including to notify if required as per law, with violations amounting to professional misconduct, which could attract disciplinary action – fines, suspension or removal from practice.

Worryingly, this punitive approach can open the door for a person with TB to be accused under the same IPC sections by a co-habiting relative or a co-worker, given that if a doctor, lab or pharmacist can be booked under such a law, a person with a closer nexus to potential transmission of TB will be penalized too. If so, the implications for a patient-centric approach that instills confidence in the health system are worrying. The FAQ related to the 2018 order also reveals worrying justifications for criminalization explaining that the main benefit would be INR 500 per month as nutritional support for the TB patient, and enrollment in the Aadhaar scheme. It thereby fails to provide a coherent and rational basis for the public health strategy of notification, which is essential to justify interference with the fundamental right to privacy.

Notably, it is also unclear under which law the order of 2012, its amendment of 2015, and the notification of 16 March 2018 have been issued by the central government.

Outdated legislation such as the *Epidemic Diseases Act, 1897*, provides wider powers (including notification) based on a paternalistic view of the state as an agent of human behaviour control with a punitive mindset. Notification here is envisaged to address outbreaks of disease, and therefore may not be applicable to the context of an endemic disease such as TB in India. The *Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965* penalizes medical practitioners, medical officers, factory managers, headmasters, lodging houses and heads of households who do not inform public health authorities if they are aware or suspect a person to have a dangerous disease, including TB. Similar provisions with minor variations exist in the *Mumbai Municipal Corporations Act, 1888*, *Madras Public Health Act, 1939* etc. TB notification legislation proposed in Maharashtra requires healthcare establishments to notify within 30 days of diagnosing

a person with TB or starting them on treatment, with non-compliance punishable through fines, and recommendations of suspension to the concerned Medical Council.

Data and experience indicates annual TB notification having increased from 130 to 134 per 100,000 between 2006 and 2016. Since notifiability in 2012 and end-2016, 113,961 private sector healthcare establishments have been registered under Nikshay. Where strategies to engage the private sector in notification have been implemented by offering ICT support, free TB drugs for notified patients, and extending treatment adherence support services to the private sector, TB notification rates have increased 1.5-4-fold. Low uptake of registration on Nikshay has been ascribed to many reasons, including worries of losing patients, the lengthy form, and breaching patient confidentiality. Although informants felt that making TB notifiable was a useful first step, it was meaningless if not backed up with effective and ethical implementation, including confidential storage of Nikshay data, and proper linking of the patient to treatment and social security schemes such as nutritional support and insurance.

Recommendations to Government (Central, State and Local bodies)

(I) Law Reform (repeal, amend, review)

- a) The notification of March 2018, invoking criminal liability under the Indian Penal Code against healthcare workers, laboratories and pharmacists should be withdrawn immediately.
- b) Disease-specific notification laws (such as legislation under consideration for TB in Maharashtra) have the potential to increase stigma, often where stigma is already rife, as in the case of TB. Instead, general notification legislation that reflects modern scientific and rights-based understandings of public health should be developed.
- a) The *Epidemic Diseases Act* is outdated and must be updated to reflect modern public health responses to disease outbreak, including rights-based protections that need to inform such responses instead of the paternalistic emphasis it has on isolation and notification.
- b) New public health legislation that governs aspects such as notification of disease should recognize only exceptional use of rights-limiting public health strategies informed by the principles of necessity, proportionality, appropriateness, due process, and equity. Specifically, proposed legislation such as the *Public Health (Prevention, Control and Management of Epidemics, Bio-Terrorism & Disasters) Bill, 2017* to replace the *Epidemic Diseases Act, 1897*, must be informed by these standards for rights-based safeguards in public health law.
- c) Amendments are also required in outdated state public health and municipal legislations that are overly broad in scope, and need to reflect scientific advances and rights-based understandings of public health. (Examples mentioned in this report include the *Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965*, the *Mumbai Municipal Corporations Act, 1888*, the *Tamil Nadu Public Health Act, 1939* and the *Goa, Daman*

and Dii Public Health Act, 1985. However, a national survey and reform of all such laws at the state level requires to be undertaken.)

- d) The authority of law under which the government has passed the 2012 order making TB notifiable needs to be provided. The order does not stipulate the same, and this is necessary for justifiable basis and clarity in the law.

(II) Policy Reform (repeal, amend, review)

- e) Policy on TB should be devised and implemented in line with suggested approaches in the NSP to incentivize notification from the private healthcare sector by providing free treatment to notified patients, and extending treatment adherence support services for patients from the private sector.
- f) Notification data collected through Nikshay should be stored with stringent, foolproof confidentiality protocols to be followed.
- g) Further, people being tested have the right to know how their personal data is being collected and used to improve the TB response. RNTCP should periodically share information on the way in which TB notification is being implemented and benefiting public health goals.
- h) An exercise to review public health strategies and policy approaches should be undertaken to hone effective efforts in controlling TB, including determining the impact of making TB notifiable, examining how data gathered is being used, whether there are limitations to such an approach, if other less coercive means of reporting can be encouraged, and whether the intended positive impact of such an initiative – of getting people onto and keeping them on treatment – is being achieved.

Recommendations to Other Stakeholders

Role of Doctors, Health care workers, Medical institutions and others involved in the healthcare system

- i) Take informed consent from people being tested for TB, including informing them of the need to notify in case they are found to have TB, and that notifying would entail sharing their confidential information with the concerned government authorities.
- j) Provide comprehensive information to the patient under the legal mandate that requires medical professionals to notify TB.
- k) Ensure that people with TB take prescribed medicines and adhere to the same throughout the required duration, failing which take steps to follow up with patients for compliance.
- l) People with TB should not be denied care or referred out due to the reluctance of healthcare workers to undertake the obligation of notification.

4. Consent

The fundamental reason for obtaining consent from a person before making a medical intervention on them (including providing testing or treatment services) is to uphold the person's autonomy and bodily integrity, which is part of the right to privacy as articulated by the Supreme Court. Autonomy envisages the right to receive all information required for a person to give or refuse consent to a particular test or treatment. This informed consent includes being told of the implications of the tests to be undertaken and the risks and benefits of the course of treatment being offered. Taking consent also engenders a sense of ownership, confidence and cooperation from the patient in the medical intervention, and in the case of treatment can play a part in ensuring that it is adhered to.

Even though TB is a notifiable disease, ethics and human rights related to healthcare remain applicable in this context, particularly in relation to the exercise of autonomy of the patient to decide whether to be tested for the disease or receive treatment for it. Guidance states that for TB testing specific consent is not required, since it is implicit in the person seeking to undergo a medical examination (except where drug susceptibility testing is offered when DR-TB treatment is unavailable). However, consent for TB treatment requires specific consent given the toxicity and side-effects associated with treatment. In India, where TB is notifiable, specific consent for testing should be required, since a person has a right to know that on testing positive for TB their personal information will be shared with public health authorities – and based on this information, decline or agree to be tested. A patient-centric approach to ensure that there is uptake in testing should augment and strengthen quality counseling services to convince people that testing is beneficial to them.

Guidance also advises that a healthcare provider's decision to override refusal to be tested or take treatment can be exercised exceptionally – only when such refusal would pose significant risks to public health. Yet, even where law severely restricts rights for public health exigencies, such as denying the right to consent to testing, information must be imparted to the patient that his health information is going to be shared with the concerned authorities.

The notion of consent is at the core of civil laws such as the *Indian Contract Act, 1872*. Autonomy is also reflected in health-related laws, most recently in the *HIV Act*, which provides for informed

consent for testing and treatment in detail, and the *Mental Healthcare Act, 2017*. The *Medical Ethics Regulations, 2002* prescribe that consent is required to be taken in writing before a healthcare provider performs an operation. The Supreme Court of India has also emphasized the paramount nature of consent in healthcare contexts. Provisions in state public health and municipal laws do restrict the right of consent for testing in the case of infectious diseases: the *Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965* or the *Tamil Nadu Public Health Act, 1939*.

A proposed *Public Health (Prevention, Control and Management of Epidemics, Bio-Terrorism & Disasters) Bill, 2017* for prevention, control and management of epidemics, regrettably fails to prescribe standards of consent in public health matters, and thereby uphold the fundamental right to privacy as manifest in autonomy and bodily integrity.

Practical benefits accrue to public health efforts if testing for TB is accompanied with consent and comprehensive imparting of information in the form of counseling. Investing in information sharing and recognizing the patient's autonomy in this manner becomes even more important in the context of the present NSP, which intends to make contact tracing more rigorous, expansive and accountable in order to ensure that most people with TB have their contacts screened, so that secondary cases are detected and treated. Yet, consent as a legal or ethical notion finds scarce mention in the policy, planning and programmatic documents of the RNTCP, although the Guidelines for Programmatic Management of Drug-resistant TB (PMDT) in India 2017 refer to the right of a patient to consent to treatment for DR-TB. The right to consent needs to be reflected across RNTCP implementation, including in aspects such Active Case Finding (ACF) methodology, which ignores the need to take consent and is thereby disrespectful of autonomy and physical integrity of the person. Instead, voluntariness and free, informed consent – for testing and treatment – should be encouraged in ACF techniques in order to instill confidence in the system and encourage health-seeking behaviour.

Counseling was repeatedly highlighted as a critical component of the continuum of health services related to TB, especially to foster a confidence in the health system on the part of the patient, to alleviate stigma around TB, and to support compliance in taking TB treatment and nutrition. Where TB treatment was linked to HIV treatment (for people living with HIV who also had TB and were accessing ART centres), counseling services were robust due to the longstanding attention paid to it in the context of HIV treatment. TB counseling was also well-provided where TB survivors and patients groups (including networks of people living with HIV) were rendering it as peer counselors. Yet, counseling was inadequately addressed for the most part in the TB response, attributed partly to the workload in high burden contexts where healthcare providers see several patients with little time to dedicate for thorough information sharing. In large part it was also attributed to the paucity of a cadre of trained counselors as part of the public health response to TB in most contexts. Model practices on how to provide robust counseling services for TB have been demonstrated by organizations such as Medicine Sans Frontieres (MSF) in Mumbai. Holistic counseling did not eliminate treatment dropouts entirely, but it significantly reduced the dropout rate.

Recommendations to Government (Central, State and Local bodies)

(I) Law Reform (repeal, amend, review)

- a) Consistent with recent health-related law reform in India, all legislation proposed in relation to public health including (but not confined to) the Public Health (Prevention, Control and Management of Epidemics, Bio-Terrorism & Disasters) Bill, 2017 must reflect the need for informed consent to be taken before undertaking a medical procedure or intervention on any person, related to TB or more generally.
- b) The ability and limits of minors to give consent, related to TB and more generally should also be included, recognizing the legal principle of 'mature minors'.

(II) Policy Reform (repeal, amend, review)

- c) Explicit mention of the requirement to take consent for TB testing and treatment must be made in RNTCP policies, guidance and practice, pursuant to respecting the right to autonomy and bodily integrity of the person being tested or treated as a central human right that signifies the need for permission to interfere with another person's body. Health policy should be founded on the understanding that such respect for autonomy can pay public health dividends by empowering a patient to decide for themselves, developing ownership in their health and augmenting their information on the ramifications of testing and treatment.
- d) In the context of certain strategies where there is a potential for deprioritizing consent, such as incentivized active case finding, policy and law should be clearly formulated to ensure that free and informed consent is central to any testing and treatment protocol. This includes encouraging voluntary testing of people who have been in contact with people with TB, while undertaking active case finding, and collaborating with NGOs and CBOs by training and sensitizing their staff to undertake outreach and provide information on TB, testing and treatment to contacts.
- e) Counseling should become a crucial aspect of the RNTCP, reflected in policy guidance and practice. Counseling and imparting information in the context of health delivery, is one method through which the right to autonomy can be realized. If done well, it can prove crucial to health-seeking behaviour and treatment adherence.

(III) Implementation and Enforcement

- f) Financial resources should be dedicated for systemic and ongoing training of nurses and physicians on counseling techniques in order to ensure improved prevention knowledge and treatment adherence. The government should consider emulating and scaling up successful counseling models such as those of MSF and the collaboration with TISS for people with DR-TB.
- g) Peer counseling, which has also been effective in the HIV context, should be supported as a public health strategy by RNTCP, as in the form of DOSTs.

Recommendations to Other Stakeholders

Role of Doctors, Health care workers, Medical institutions and others involved in the health care system

- h) Counseling should be prioritized, invested in heavily, and incentivized by the RNTCP, and part of public and private sector health delivery in all cases of TB incidence, not just for those with DR-TB. Where counseling has been implemented effectively, such as in HIV, it has yielded immense public health and patient-centric gains.
- i) Informed consent of all persons should be taken in relation to testing and treatment, irrespective of their contexts of vulnerability, particularly ensuring that those who are vulnerable or disempowered, such as prisoners or women are enabled to exercise their right to consent.

Role of civil society, activists, Non-governmental organizations, Community Based Organizations and others involved in the area of TB

- j) Involve social workers, and counselors in the roll out of the TB response, to not only provide counseling and follow-up on treatment, but also to explain the contents of the informed consent form to people accessing testing and treatment facilities in the language they understand, and to provide social support, referrals, and information and other services to people with TB.

5. Privacy & Confidentiality

Privacy and confidentiality are based on notions of autonomy and trust. Privacy relates to the ability of a person to control information about oneself from others thereby protecting autonomy. Confidentiality of information arises in fiduciary relationships i.e. relationships of trust, which are inherently unequal and imbalanced, where one person is privy to information that they would not have but for the particular skill that they possess – such as doctors in relation to patients, or lawyers in relation to clients. As a legal principle, confidentiality has been recognized in several judgments and in various contexts of healthcare delivery. Courts have held that a physician is duty-bound not to disclose information obtained in their professional capacity, without the consent of the patient unless required to do so by law. Courts have also laid down that disclosure of health-related information is justified only when a physician determines that the patient poses a serious danger to a foreseeable third party. Notably, these are exceptions that the courts have carved out from the fundamental general rule that patients have the right to confidentiality in the usual course of events. Judgments and laws related to confidentiality of health information aim to draw a balance between two *public* interests – the importance of maintaining confidentiality and that of disclosure; the preservation of confidentiality has itself been viewed as serving societal interests – to build trust among the public in the health system. Guidance advises that personal information collected during infectious disease outbreaks must be protected from unauthorized disclosure.

In the context of TB confidentiality is linked to the issue of family notification – should people who cohabit or those are potentially care-givers be informed of a person’s TB status in order to take prophylactic steps? And if so, what is the manner for this to be done? Further, how does the Nikshay information system ensure that data collected through it is stored and protected in a manner by which it is shared only with people who need to know a person’s status for purposes of prevention, treatment and recovery follow-up?

The *HIV Act* and the *Mental Healthcare Act* place medical confidentiality on clear statutory footing. The right to privacy, in which confidentiality is rooted, was also upheld emphatically in *Puttaswamy v Union of India* by the Supreme Court in 2017, which held that curbs can only be placed exceptionally, and only if permitted explicitly by law, to achieve a legitimate state aim, and the means used should be

proportional to the object sought to be achieved by the curb. This is relevant in the context of TB, where public health concerns have made it a notifiable disease. Yet, it is not clear if the TB response has met all the three requirements set out by the Supreme Court in *Puttaswamy*. For one, it is not clear whether the disclosure of TB status to public health authorities through notification has been mandated through law – the MoHFW order of 2012 making TB a notifiable disease (and subsequent orders and notification) does not appear to have been issued under legislation (the power to notify a disease vests in state governments under the *Epidemic Diseases Act, 1897*, whereas the 2012 and pursuant notifications have been issued by the central government).

The proposed *Public Health (Prevention, Control and Management of Epidemics, Bio-Terrorism & Disasters) Bill, 2017*, to replace the *Epidemic Diseases Act 1897*, vests vast powers on the State to notify a disease, isolate people, or undertake medical procedures on them with no mention of assurances of confidentiality, and as such falls foul of the *Puttaswamy* ruling.

For physicians, the *Code of Medical Ethics Regulations, 2002* also outline the duty to maintain confidentiality, and exceptions only if required by a court, in cases of notifiable disease or when there is a serious and identified risk to specific person or community. At the state level, the *Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965* illustrates the wide ambit given in state laws to disclosure of a person's disease status expected of a wide variety of actors – medical practitioners, medical officers, factory managers, headmasters, keepers of lodging houses and heads of households, with breach attracting a penalty. TB notification legislation being proposed in Maharashtra provides for the protection of confidentiality of notified data.

Yet, confidentiality only finds mention in two of RNTCP's policy documents - the Guideline for PMDT in India 2017, and the 2018 MoHFW notification making non-notification by labs, healthcare providers and pharmacists a criminal offence. This is done without providing any protocols and allowing a wide array of actors to be made aware of a person's TB status. The guidelines state that treatment efforts for DR-TB must ensure that the confidentiality and dignity of the patient is protected, and confidentiality is crucial when performing counselling to patients and family members. It is unclear why these principles are not reflected in other policy documents.

This assumes greater concern given the other multiple ways in which TB prevalence and incidence is sought to be traced and recorded in India: by multiple means through Nikshay, through Active Case Finding invoking participation of a wide section of society, through contact tracing, through Project Aashya, linking with Aadhaar for availing social benefits. etc., which reveal the vast number of actors who will be in positions to know, receive, record, and keep private health and related information of patients without any clarity on safeguards that are required to maintain confidentiality of such data, or the necessity for so many actors to be in the know. Presumably, the Electronic Health Records Standards 2016 issued by the MoHFW will govern confidentiality of health-related information collected by the RNTCP (including as part of the first national TB prevalence study to be undertaken shortly). Yet, how non-electronic health information data that is collected as part of

the TB notification processes will be stored and uphold confidentiality remains unclear. A *Digital Information Security in Health Care Act* is being drafted by the MoHFW, which needs to be examined to ensure that concerns raised in relation to TB are reflected therein.

Informant interviewees expressed that health data such as TB status and personal identity information must be maintained confidentially, and only with RNTCP personnel who are directly involved in screening, diagnosis, notification and treatment. In the Indian context, where family involvement was crucial, shared confidentiality may be advisable but should be done after taking patients and family members into confidence with robust and non-stigmatizing counseling and information sharing. If not done, serious consequences such as abandonment and destitution (often of women) can occur. If done effectively, the family can play a crucial role in the patient's treatment completion, recovery and wellbeing. Often, knowledge is lacking among stakeholders about rules to ensure confidentiality of TB status and related information, leading to a patient's TB status being discussed openly by healthcare workers. General health legislation to govern the confidentiality of health-related information was necessary, based on experiences learned in the HIV context.

Recommendations to Government (Central, State and Local bodies)

(I) Law Reform (develop, repeal, amend, review)

- a) Review and amend existing public health laws that impose obligations to inform authorities of TB cases on multiple actors, to bring them in line with current understandings of the right to privacy and confidentiality. (Examples mentioned in this report include the Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965, the Mumbai Municipal Corporations Act, 1888, the Tamil Nadu Public Health Act, 1939 and the Goa, Daman and Diu Public Health Act, 1985. However, a national survey and reform of all such laws at the state level requires to be undertaken.)
- b) General health legislation (which will cover TB) is required to stipulate standards and protocols for confidentiality of health and related information and privacy of health information in all contexts, including healthcare, employment, and educational settings. The Public Health (Prevention, Control and Management of Epidemics, Bio-Terrorism & Disasters) Bill, 2017 fails to provide these standards, and should either be amended or redrafted to ensure the right to privacy and confidentiality in healthcare contexts.
- c) Legislation stipulating confidentiality should clearly lay down the rule for maintaining confidentiality in all cases and specify the limited circumstances when and how and by whom confidentiality may be breached. As per statutory standards, and best practice norms, this would be in cases of shared confidentiality between healthcare workers if it is in the best interests of the patient, with a family carer after taking the patient's consent to share, if required under orders of a court, or in cases of partner notification after following a strict protocol. Such legislation should also prescribe the need to reconsider disclosure of confidential information

to a family member or partner if it is apprehended that violence or abandonment against the person with TB may be a consequence of such disclosure.

- d) A Digital Information Security in Health Care Act is currently being drafted by the MoHFW, which must ensure that the right to privacy and confidentiality are robustly protected in the context of healthcare. This will require rigorous legal provisions that prescribe data protection measures while storing health and other information records, and clear guidance on contact tracing that is designed to empower and encourage individuals to undertake TB testing, with full guarantee of confidentiality.
- e) Legislation protecting the rights to privacy and confidentiality, including those of people with TB and TB survivors, should establish mechanisms by which people whose rights have been breached can access justice to seek redress and be able do so after obtaining court orders for suppression of identity (similar to provisions in the HIV Act).

(II) Policy Reform (repeal, amend, review)

- f) All RNTCP policies and TB-related legislation should comply with the Supreme Court's decision in Justice KS Puttaswamy (Retd.) v Union of India on the Fundamental Right to privacy. In particular, this shall require satisfaction of the following criteria:
 - o First, as expressly required in Article 21 of the Constitution there must be a law in existence to justify an encroachment on privacy.
 - o Second, the curb must be to achieve a legitimate state aim.
 - o Third, the means used to curb the right to privacy should be proportional to the object sought to be achieved by the law.
- g) Stringent regulations and protocols are required to be issued that govern how the health and personal information relayed to public health authorities (electronically or otherwise) in the notification process will be stored and protected from revelation to anyone beyond those who are in charge of the notification programme.
- h) Guidance on active case finding, ICT for case-based surveillance, and Aadhaar linkage needs to be amended to give due recognition to the right of confidentiality, and detail how it is to be protected, while also ensuring that procedural or identity requirements do not lead to exclusion of persons from benefits under the RNTCP.
- i) Specific provisions need to categorically stipulate who is responsible for maintaining confidential information, how it is to be maintained, and the consequences for breaches that take place.

Recommendations to Other Stakeholders

Role of Doctors, Healthcare workers, Medical institutions and others involved in the healthcare system

- j) Healthcare workers need to be regularly trained on rights, responsibilities and methods in relation to privacy and confidentiality as part of their academic and on-job training in order to build a cadre that is familiar with the value, requirement, and systems for such protections vis-à-vis a patient. This is required in the context of RNTCP's strategies for TB elimination, and as part of health delivery generally.
- k) Those who are privy to health-related and private information of patients should be made accountable for breaches of confidentiality that may occur in the multiple processes envisaged in the RNTCP for collection and storage of such information.
- l) Explicit mention of the requirement to maintain confidentiality of health and personal information in the notification process, and between healthcare worker and patient needs to be made and implemented in RNTCP policies, and the many strategy documents that envisage case finding, contact tracing, and use of ICT to maintain programme and patient data.
- m) RNTCP staff and healthcare workers involved in data collection and storage should be provided training on legal and ethical obligations related to privacy and confidentiality to ensure proper implementation.
- n) Sharing TB status with family carers should occur only after following a protocol and taking consent of the patient, who will specify the family member to be informed.

6. Limiting Criminalization

Criminal law is based on principles of acts or omissions of doing something (or the omission of not doing it), along with the circumstances, leading to consequences that are defined, to render the act a criminal offence. The issue of criminality arises in the context of TB since (i) the Indian Penal Code (IPC) contains provisions that make spread of a life-threatening disease a punishable offence, (ii) the IPC makes it an offence to disobey the order of a public servant (like a health officer), (iii) where TB status is used as evidence in a criminal proceeding, (iv) where there is gross negligence in the diagnosis and treatment of TB (dealt with in the section on access to treatment and diagnostics).

Under S.269/270 unlawful, negligent and malignant transmission or likely spread of disease dangerous to life is a punishable offence. Though very few cases have been filed invoking these sections, the recent notification by the MOHFW on 16th March 2018, invokes these sections to include within its gamut healthcare providers, laboratories, pharmacies, chemists and druggists and the local public health staff who do not notify patients with TB or who do not take appropriate public health action as required under the Notification. There are several problems in using the criminal law for public health goals, and such a notification could only hamper the public health program, as criminalization can only instill fear and make the stakeholders distance themselves away from the TB program. Instead incentives, training and a humane approach to the program could help achieve the public health goals.

Public health laws list TB as a “dangerous disease” in various Municipal Council Acts, giving power to municipal authorities to impose restrictions for preventing spread of the disease. The health officer can take the help of the police or the criminal justice system to implement the law. A person can be prohibited from exposing others to TB and can also be prevented from engaging in certain trades and occupations, or using public transportation under these laws.

As diseases like TB are easily preventable and curable, the injudicious use of criminal law to contain it may backfire and push the disease ‘underground’, thereby hampering public health goals of prevention, control and eradication. The deployment of criminal law can exacerbate stigma and increase discrimination and ought not to be used to contain the spread of the disease.

Recommendations to Government (Central, State and Local bodies)

(I) Law Reform (repeal, amend, review)

- a) Repeal or amend laws that criminalise people with TB or others who are in contact with people with TB, such as doctors, healthcare providers and pharmacists.
- b) Amend or withdraw the notification issued in March 2018, specifically the threat to invoke Sections 269 and 270 of the Indian Penal Code.
- c) Instead of punishment and criminalization, offer incentives to healthcare providers and pharmacists to adhere to notification duties.
- d) Remove TB from the list of dangerous diseases under various public health and municipal laws, as TB can be treated and cured if detected in time and if the person with TB is provided adequate treatment.

(II) Policy Reform (repeal, amend, review)

- e) Rather than invoking the criminal law, an evidenced-based protocol should be developed with the participation of all stakeholders to help health officers contain the spread of TB by providing adequate knowledge to persons with TB, to test and treat people, and to prevent spread of the disease by sensitizing the person with TB and their family to take adequate measures to prevent spread of the infection.
- f) Criminal prosecution should not to be viewed as an element of public health strategy to control TB. It should be used judiciously to criminalize only exceptional cases where there is a malignant and willful transmission or spread of disease.
- g) Issues of knowledge and intent need to be proved beyond reasonable doubt to consider the spread of TB in a particular case an offence. Very often, people with TB are unaware of prevention methods and lack knowledge, due to which unintentional exposure to TB occurs. These instances should not attract criminal punishment.
- h) Limited resources are better used for implementing effective infection control measures and raising awareness on TB, rather than on deploying criminal law.

Recommendations to Other Stakeholders

Role of Judges, Lawyers and others involved in the justice system

- i) Allow the use of criminal law for prosecution of patients with TB and other stakeholders, in very limited and specific circumstances – in cases of intentional transmission. Discourage prosecution and imposing criminal liability as a public health measure.
- j) Apply the law based on proof of evidence, in case of criminal prosecution.

- k) Issue warnings, or provide penalties for those in conflict with the law and with TB, ensuring that they do not spread the infection.
- l) Ensure that people with TB and other stakeholders on whom criminal charges are foisted are provided quality legal aid services.

Role of civil society, activists, Non-governmental organizations, Community-based organizations and others involved in the area of TB

- m) Disseminate information relating to TB in the community and among other stakeholders, and help health officers counsel members of the community and their families with TB.
- n) Sensitize health officers, prosecutors, judges, lawyers on issues relating to TB, including why criminal law ought not to be invoked as a public health measure.

Health Sector

7. Drug Regulation

India's drug regulatory structure is governed under the *Drugs and Cosmetics Act, 1940* (DCA) and *Drugs and Cosmetics Rules, 1945* (DC Rules). Regulatory roles are distributed between the central and state governments. Given the large number of TB clinical trials taking place and planned (e.g. by ICMR), legal provisions related to their approval and oversight are important to take note of. In the past few years, several notifications and amendments have been made under the DCA and DC Rules in relation to TB. In 2012, the central government banned manufacture, sale, distribution, use and import of serological diagnostic tests for TB under section 26A of the DCA. In 2014, Schedule H1 was introduced in the DC Rules aimed at controlling over-the-counter dispensing of antibiotics. Medicines in the schedule are subject to many restrictions, including sale only on prescription.

Even as new provisions have been introduced to control sale of current TB drugs, easing access to new MDR-TB drugs has required action under the DCA. Though only phase II trial data is available for bedaquiline and delamanid, given the urgent need for MDR-TB drugs, local Phase III trials have been waived and both drugs granted "conditional access" for use only under the RNTCP programme. Patients in the private sector are using cumbersome personal import provisions as provided in the DC Rules to access these drugs.

The enforcement of the DCA is an area of concern. Both the serological TB test ban and over-the-counter sales of TB drugs ban need better enforcement. In the case of access to the new MDR-TB drugs, in the short term, the use of the personal import mechanism under the DCA requires simplification and ease of use; people with TB and their doctors have lamented this overly cumbersome process. However, these issues largely relate to the grant of "conditional access" approval, which limits access to these drugs to the public sector. The clinical trial waiver and conditional access approval has become the cause of some concern and controversy. On the one hand, a key concern across the board is what conditions should be attached to the introduction of drugs where clinical trials have been waived, the lack of transparency over agreements between the government and the companies regarding the availability of the drugs and post marketing surveillance and the rights of patients receiving drugs where phase III trials have been waived including to compensation and other benefits in case of adverse events. On the other, the "conditional access" and limited access

in the private sector is resulting in considerable barriers in access to treatment for patients with no other options.

India's drug regulatory framework comprises a complex web of laws, rules and guidelines and is populated by numerous authorities. Transparency in the working of the drug regulation machinery is vital to ensuring public trust in the manner in which drug approval, quality assurance in manufacturing and oversight of clinical trials takes place. These issues arising in the context of TB are in fact reflective of the overall problems with the drug regulatory system, which requires a proper overhaul.

Recommendations to Government (Central, State and Local bodies)

(I) Law Reform (repeal, amend, review)

- a) Instead of criminalizing pharmacists for failure to notify, greater resources should be invested in the strict enforcement of the ban on over-the-counter and non-prescription sales of TB drugs
- b) In the short term, the personal import mechanism for drugs that are approved by the DCGI for supply in India should be simplified in co-ordination with the customs authorities to remove barriers in access to timely treatment for MDR-TB patients in the private sector.
- c) The CDSCO should ensure that drugs that are approved in India are made available in the Indian market at affordable rates.

(II) Policy Reform (repeal, amend, review)

- d) Access to new MDR-TB drugs should be allowed for patients in the private sector; this would be possible even within the current conditional access approval for bedaquiline and delamanid to be provided through RNTCP, if RNTCP includes access for private sector patients within its scope.

(III) Implementation and Enforcement

- e) The CDSCO must ensure strict enforcement of the ban on serological tests and on the over the counter sale of TB medicines.
- f) The CDSCO must strengthen its oversight on the manufacture, supply and storage of TB drugs to ensure quality; regular audits of TB drugs stocked with RNTCP and with pharmacies should be conducted to check the quality of TB drugs.
- g) Decisions taken on drug approvals and clinical trial waivers should be done in a transparent manner to ensure public trust in the drug regulatory procedures; in particular correspondence between the Ministry of Health and Family Welfare or the CDSCO and pharmaceutical companies must be available in the public domain.

- h) Phase III trial waiver for new drugs requires rigorous Phase IV and post marketing surveillance by the company making the drug; all rights of clinical trial participants including for compensation for adverse events must extend to patients receiving the drugs in such a situation.
- i) The increasing number of TB trials in the country warrants close oversight from the CDSCO with particular attention to the protection of rights of trial participants in such trials.

Recommendations to Other Stakeholders

Role of civil society, activists, Non-governmental organizations, Community-based organizations and others involved in the area of TB

- j) Treatment literacy programmes related to TB should be implemented through methods of mass communication in campaign mode to empower current and future patients with sufficient knowledge to understand their own treatment and care and safeguard themselves from misdiagnosis and incorrect treatment.
- k) People with MDR-TB must have full information on the approval status of the drugs that are being prescribed to them and their rights, if the drugs have been approved based on clinical trial waivers.
- l) People with TB, their representatives and NGOs working with them should be made aware of their rights if they participate in TB trials.

8. Regulation of The Private Sector

As noted in the NSP, the role of the private sector is a key concern in addressing TB in India. The NSP proposes strengthening regulation, including of drug sales and distribution in public and private sectors to ensure the quality of TB medication, its combinations, standardized dosages and treatment regimens. In terms of regulatory approaches, it is of note that several laws exist on the books that cover the private healthcare sector.

The *Clinical Establishments (Registration and Regulation) Act, 2010* (CEA) aims to establish minimum standards of healthcare facilities and services across the public and the private sector. As health is a state subject, the CEA is applicable only in those states that have agreed to its application. Under the CEA and its rules, all clinical establishments must be registered and must implement standard treatment guidelines. In 2014, the 'Standards for TB Care in India,' (STCI) were issued, although the extent to which their enforcement is taking place through the CEA is unclear. The RNTCP has issued updated Technical and Operational Guidelines for TB Control in India in 2016 that updates the STCI; they reflect, for instance, the transition to daily TB treatment and updated guidance on MDR-TB drugs. It is unclear if the updated guidelines are enforceable through the CEA.

Criminal law has been invoked against the medical profession in cases of medical negligence. Section 304A, *IPC* punishes death caused by a rash or negligent act with imprisonment up to two years or with fine or both. The Supreme Court has laid down strict restrictions for prosecuting a medical professional for criminal negligence. Another legal framework relevant to medical negligence related to TB is The *Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002* (MCI Regulations), which govern medical practitioners. Where healthcare workers or institutions are negligent in diagnosing or treating TB, cases are filed under the *Consumer Protection Act, 1986* if the patient has paid for services. Consumer forums have awarded significant compensation to aggrieved parties in cases related to TB. In determining such cases, forums distinguish negligence or deficiency in services from "error of judgment" and more recently have started applying a "loss of chance" analysis. In relation to grievance redress, the provision in the *HIV Act* for an Ombudsman to inquire into and resolve complaints related to provision of health services may provide an interesting alternative.

Several informants raised concerns about the laxity of regulations relating to the private sector. Some informants also felt that in some respects the attitude of private doctors is often less stigmatizing than those in the public sector. One interviewee cautioned against blaming the private sector based on different prescribing practices alone, stating that at times when a patient is not doing well, the prescription does have to be changed. Another highlighted the importance of training programmes. The regulation of the private sector, particularly the imposition of consequences presents a conundrum for policy makers. The discomfort of the Supreme Court is evident, for instance in cases of criminal proceedings against doctors. It should also be noted that attempts to regulate private medical practice is usually met with protests. However, it is evident that there is a serious requirement for regulating the private sector and providing patients with mechanisms to hold the medical profession accountable. In a TB-endemic country it is difficult to accept continuing justifications for the misdiagnosis and incorrect treatment prescription by private doctors and hospitals. However, the laws and mechanism described above are difficult, time consuming and expensive for patients to use in holding the private sector accountable. In light of this, it may be worthwhile to consider a mechanism similar to the Ombudsman under the *HIV Act* to inquire into and resolve complaints related to the provision of health services in a timely manner as an interesting alternative to the court system.

Recommendations to Government (Central, State and Local bodies)

I) Law Reform (repeal, amend, review)

- a) Grievance redress mechanisms such as the Ombudsman under the HIV Act should be considered for dealing quickly with TB healthcare related complaints to provide a quick resolution of disputes. This mechanism could supplement the online TB grievance redressal system already in place within the TB programme.

(II) Policy Reform (repeal, amend, review)

- b) Instead of criminalizing healthcare workers who do not notify TB patients, greater resources should be invested in the application of the Standards of TB Care in India and updates of these standards.

(III) Implementation and Enforcement

- c) The National Council for Clinical Establishments must ensure the proper enforcement of the Clinical Establishments Act or state specific laws as the case may be and the Standards for TB Care in India; the standards must be regularly updated to reflect changing guidance from RNTCP.
- d) Strict regulation of the private sector should be balanced with government funded trainings to bring the knowledge and skills of private TB practitioners up to date; the trainings should be held in collaboration with associations of medical practitioners.

Recommendations to Other Stakeholders

Role of Judges, Lawyers and others involved in the justice system

- e) People with TB or their representatives should be provided with legal aid to be able to use existing legal mechanisms to hold the private sector accountable in cases of negligence

Role of Doctors, Healthcare workers, Medical institutions and others involved in the healthcare system

- f) Healthcare providers should ensure that their knowledge on the diagnosis and treatment of TB is up to date and where they are dealing with complicated cases should seek the assistance of RNTCP or ensure effective referrals to the public sector.
- g) The Medical Council of India and Healthcare institutions should prioritise the application of the Standards of TB Care in India among their members and staff as the case may be.

Role of civil society, activists, Non-governmental organizations, Community-based organizations and others involved in the area of TB

- h) Treatment literacy programmes related to TB should be implemented through methods of mass communication to empower current and future patients with sufficient knowledge to understand their own treatment and care and safeguard themselves from misdiagnosis and incorrect treatment.

9. Alternative Systems of Medicine

India has a diverse system of healthcare providers, comprising allopathic practitioners, and Ayurvedic, Yoga & naturopathic, Unani, Siddha and Homoeopathic (AYUSH) practitioners. The 2015 National Health Profile shows that 44% of all medical degree holders in India have a degree in AYUSH systems, and they are important providers in both rural and urban areas. TB experts interviewed informed that Ayurvedic texts do not have prescriptions for TB, although herbal medicines are used, *sans* efficacy studies. Often it is immunity boosters that are given by Ayurvedic and Homoeopathic practitioners, despite there being no effective treatments for TB in Ayurveda or Homoeopathy. Sometimes, Ayurvedic experts use allopathic prescriptions mixed with Ayurvedic ingredients for treatment of TB.

The *Drugs and Cosmetics Act (DCA)* and *DC Rules* recognize Ayurveda, Siddha and Unani medicines for use in prevention, diagnosis, treatment, and mitigation of disease when manufactured in accordance with the formulae described in their authoritative systems of medicine. The manufacture and sale of these medicines is regulated by the *DCA* and gives power to state governments to prohibit manufacture and sale of misbranded, adulterated or spurious drugs, and prohibit manufacture of Ayurvedic, Siddha and Unani drugs in public interest, where the drug is likely to cause risk to human beings or animals. State governments also have the power to regulate sale of homeopathic medicines and manufacture and sale of drugs other than homeopathic medicines.

The demand for AYUSH practitioners is significant: studies showing patients' pathways to health care in urban slums revealed that a majority of people later diagnosed with TB, first sought care from an AYUSH practitioner, before moving to an allopathic practitioner. Delayed diagnosis and treatment, or receiving incorrect treatment has an adverse impact on people with TB. It is therefore essential for AYUSH practitioners to receive adequate and regular training in diagnosing and referring people with TB because they are often the first point of contact in the healthcare system for many people.

Recommendations to Government (Central, State and Local bodies)

(I) Implementation and Enforcement

- a) Involve AYUSH practitioners in the roll-out of RNTCP only after providing them appropriate and adequate training.

- b) Hold AYUSH practitioners who delay the diagnosis and treatment of TB patients, accountable, and provide them continuous and sustained training in recognizing symptoms of TB and in management of TB.

Recommendations to Other Stakeholders

Role of Judges, Lawyers and others involved in the justice system

- c) Courts should continue to maintain a strict position on cross-practicing and requiring the registration of AYUSH practitioners with the relevant medical councils; only RNTCP trained AYUSH practitioners should be allowed to counsel TB patients and acting as part of the patient support system.

Role of Doctors, Healthcare workers, Medical institutions and others involved in the healthcare system

- d) The respective medical councils and associations of the AYUSH practitioners must ensure sufficient training is provided to them for early diagnosis and referrals for treatment of TB.
- e) AYUSH practitioners must prevent delays in diagnosing patients with TB, and must make immediate referral to the health centres for adequate testing and treatment of TB.
- f) AYUSH practitioners must get involved in the RNTCP program after obtaining adequate training and should not provide medicine to patients with TB

Role of civil society, activists, Non-governmental organizations, Community- based organizations and others involved in the area of TB

- g) Treatment literacy related to TB must include information on the inappropriateness of taking non-allopathic treatment for TB
- H) Civil society must include AYUSH practitioners in their work with healthcare providers as AYUSH practitioners are often the first point of contact for someone with TB or who they will turn to if their TB is not getting cured.

10. Quackery

The Indian public health system is insufficiently equipped to serve the needs of the populace, due to a lack of health financing for many decades, and a shortage of human resources for health. An ineffective regulation and weak vigilance, provides an opportunity to unlicensed persons - quacks - to provide 'healthcare' services. The current laws are insufficient to prevent the practice of quackery. Courts have recognized such bogus practices as violating the right to life, as guaranteed by Article 21 of the Indian Constitution. For instance, the Allahabad High Court held 'faith healing' based on a religious practice, in public, for a consideration as such. The courts have repeatedly directed State governments to prevent unqualified persons from practicing any branch of medicine, and recently the Supreme Court dismissed an appeal filed by an association of unqualified practitioners seeking regularization as they were "parampara vaidyas" (traditional healers), stating that they could not show that they had the requisite qualifications in any of the branches of medicines.

The *DC Rules* and the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (*DMR Act*) prohibit a person from claiming a drug to purport or prevent or cure certain diseases. The schedule under the *DMR Act* includes TB as one of the diseases for which there is a prohibition on advertisement making false claims or giving false impressions regarding the true character of the drug. The *DMR Act* only prohibits advertisements. It does not prohibit practice, which would come under the purview of the *IPC* - for offences of cheating and causing harm - and the respective Medical Councils of the systems of medicine that can invoke the legal machinery against those found to be practicing with false degrees or under false pretexts and who are not registered with the councils as qualified persons in their respective fields of medical practice.

Healthcare practitioners providing TB-related services shared concerns that quackery is occurring unchecked. Quacks either prescribe inappropriate allopathic medication or certain things to suppress the disease (known as "*thekha*" treatment) for prices going as high as INR 20,000. This delays a person from obtaining efficacious treatment, complicates their health, and delays their recovery from TB. There is a clear lacuna in the law, and there are no effective legal measures to curb the proliferation of quacks in the country.

Recommendations to Government (Central, State and Local bodies)

(I) Law Reform (develop, repeal, amend, review)

- a) A comprehensive legislation is required to prevent the proliferation of quacks in India and prohibit them from practicing any form of medicine.
- b) Lacunae in the law that fails to cover all forms of publication of false advertisements must be addressed, and prohibition of such spurious claims should be strictly enforced.

(II) Implementation and Enforcement

- c) Provide for sustained and regular investigation, inspection of areas, places where there is the practice of quackery by untrained, non-professional persons, and to strict action against them.
- d) Strengthen primary health centres by training and sensitizing personnel to provide proper counseling and treatment to people with TB.

Recommendations to Other Stakeholders

Role of Judges, Lawyers and others involved in the justice system

- e) Must pass strict orders against persons practicing quackery and prevent them from opening their shop or starting their unauthorized practice of medicine again.
- f) Must ensure that there is accountability of all medical practitioners, even in the alternate system of medicine, for improving the health of TB patients.

Role of civil society, activists, Non-governmental organizations, Community Based Organizations and others involved in the area of TB

- g) Must keep vigilance on the proliferation of quacks in their area of operation and must report it to the authorities to take action.

11. Universal Health Coverage/ Insurance

The UN's Sustainable Development Goals include ensuring healthy communities and individuals, which entails achieving universal health coverage (UHC), including financial risk protection. Financial setbacks are one of the serious consequences of coping with TB, which impoverishes families by afflicting those of employable age, due to loss of jobs and wages. Diagnostics, treatment, side-effects medication all take a heavy financial toll on a person with TB. This impoverishment is exacerbated in contexts such as India where most health expenditure is out-of-pocket, and eats into the savings of many families. Indeed, TB is also caused by impoverishment, which makes people more vulnerable to it, thereby creating a vicious cycle of ill health and poverty. Ensuring UHC can address impoverishment due to TB and reduce vulnerability to it. One aspect of this is insurance, which received attention recently with the announcement of National Health Protection Scheme in the central government's annual budget.

The NSP recognizes the need for financial support to effectively address the plight of those with TB and their families, including group life-insurance for people with TB to protect families from catastrophic consequences of death, and synergizing extant welfare support systems such as Rashtriya Swasthya Bima Yojana (RSBY) and Jan Shree Bima Yojana with TB efforts, culminating in links with UHC at a later date.

The unorganized sector

For a majority of people who work in the unorganized sector in India, the social security policy response has been the *Unorganized Workers Social Security Act*, aimed at providing welfare for the unorganized workforce, and requiring the central government to formulate social security schemes, including health benefits. One such scheme is the RSBY, initially meant for households below the poverty line, but expanded over time to include those in unorganized sectors such as construction, street vending, domestic help, miners, rickshaw drivers, and those qualified under the national rural employment guarantee scheme. RSBY covers hospitalization of maximum 10 days up to INR 30,000 per year for five members of a family, including pre-existing conditions and TB, and financial support includes transportation costs up to INR 1000. Yet, RSBY does not cover out-patient care and prescription costs, both of which are relevant in the context of TB, and cause significant out-

of-pocket expenditure particularly in the private sector where a majority of people with TB visit. As of March 2015 only about 10% of the total unorganized workforce had availed of RSBY. Research suggests that tapping into the RSBY for TB-related expenses can reduce catastrophic expenditure from diagnosis to treatment for people with MDR-TB, in the public and private sector.

The organized sector

In linking health insurance to one's employment, various laws in India provide for cover in the organized workforce. Laws like the *Employees' State Insurance Act, 1948* often specifically mention TB as a health condition requiring special treatment: if an employee contracts silico-tuberculosis as part of the job, it would be deemed to be an employment injury arising out of and in the course of employment and entitled to insurance protection. The *Employees' Provident Funds Act, 1952* has framed a scheme whereby an employee with TB or with a family member who has TB is entitled to claim a non-refundable advance from their account for treatment purposes. The Supreme Court has provided an altruistic view of schemes such as those of provident funds, in the context of TB. A very large scheme, which comes to the aid of employees and former employees of the central government and their dependant family members residing in covered areas is the Central Government Health Scheme (CGHS), which covers out-patient treatment including medicines, specialist consultations, investigations and in-patient treatment at government and empanelled hospitals, reimbursement for emergency treatment availed in government or private hospitals. Other instances of laws and rules include the *Railway Protection Force Rules, 1987*, the *Railway Servants (Pass) Rules, 1986*, and the *Advocates Welfare Fund Act, 2001*.

The insurance sector is regulated by the *Insurance Regulatory and Development Authority (IRDA) Act, 1999* for health insurance policies that can be purchased. One of the functions of the IRDA is to provide a grievance redress system for policyholders to make complaints, including an ombudsman, who has considered TB-related claims. Litigation related to health insurance and TB have taken place the *Consumer Protection Act, 1986*; claimants of life insurance policies have argued that the denial of claims amount to a deficiency in service under the law, which has been upheld in some cases. In other cases, insurance companies have justified denial of claims due to the deceased failing to declare TB as a pre-existing condition while taking out the policy, which amounted to suppression of material facts or misrepresentation. Consumer courts have upheld the right of insurance companies to deny claims in some of these cases. The denial of coverage due to pre-existing conditions is a significant concern for people with TB, who can be denied coverage or be charged a hefty premium for declaring they have TB. This often discourages self-revelation of their status, and denial of claims for this non-revelation in the future. Yet, as per the Supreme Court, insurance companies have a public duty to create terms and conditions in policies that are just and fair in order to ensure access to all members of society. This must include coverage of pre-existing conditions, which should be mandated by the IRDA.

There is a lack of awareness about insurance schemes amongst the most needy, leading to low uptake. Efforts such as Project Axshya, by the Union to link people with TB to social welfare schemes, which catered to economic and nutritional requirements, have been successfully undertaken at a relatively small scale but should be replicated.

While UHC has often focused largely on the provision of insurance schemes, it has paid less attention to the essential element of ensuring that all people have access to needed primary health services irrespective of paying ability. Structural determinants of health have to be addressed for TB control efforts to be effective. This includes addressing poverty, which influences living conditions, housing, nutrition, job security, and overall health. Two ways of addressing issues of poverty in relation to health are to guarantee universality of primary health services, and to mitigate out-of-pocket expenditure by insuring out-patient and in-patient care, and prescription expenses, both of which are required in India. Part of the solution is undoubtedly increasing investments in health infrastructure and human resources from the supply side. Yet, the demand side requires a commitment to reducing vulnerability through education, empowerment, and financial and nutritional support, and universal access to primary healthcare.

Recommendations to Government (Central, State and Local bodies)

(I) Law Reform (develop, repeal, amend, review)

- a) The MoHFW should foster law reform for the healthcare sector generally, in lines with the HIV Act, which stipulates a right to non-discrimination in relation to obtaining insurance. Such law reform should include TB.
- b) Legislation should require insurance companies to fulfill their public duty to offer equitable coverage in terms of health and life insurance coverage benefiting people and families with TB. Such law should ensure that pre-existing conditions cannot be used to exclude or deny coverage, and that out-patient care and prescription costs are covered to minimize debilitating out-of-pocket expenditure.

(II) Policy Reform (develop, repeal, amend, review)

- c) The National Health Protection Scheme should ensure equity in access to health services by offering comprehensive insurance coverage from primary to tertiary healthcare, covering all diseases, medication and procedures, irrespective of ability to pay, and hospitalization or out-patient care.
- d) For people to access essential health services, increased state investment that strengthens the public health system at the primary level is required. This has to be promoted in tandem with provision of health insurance, which is useful in assuring partial cost coverage for health expenditure.

- e) The MoHFW and RNTCP should educate communities and raise awareness about insurance schemes, and linking individuals with social welfare schemes, as done by the Union's Axshya initiative, which should be scaled up so that those in need fully utilize the welfare protection opportunities that exist and are under-utilized.

(II) Implementation and Enforcement

- f) Insurance coverage for TB offered by companies under the IRDA's mandate must cover 1st, 2nd and 3rd line treatment regimens, including vitamin supplements, and side-effects medication, and out-patient and hospitalization expenses. This should apply to individual schemes and group insurance taken by employers.

Recommendations to other stakeholders

Role of Doctors, Healthcare workers, Medical institutions and others involved in the healthcare system

- g) Ensure that the lack of insurance coverage does not result in denial of care and treatment for persons with TB. Any referrals to the public health system must be effective and followed up.
- H) Private hospitals should be mandated to provide subsidized treatment to patients with TB.

Access

12. Access to Treatment & Diagnostics

Treatment and diagnostics for TB have changed considerably in the past decade. The government provides TB tests and treatment free of charge. Access to medicines and diagnostics is an integral part of the right to health; the State is obligated to take certain steps including “the prevention, treatment and control of epidemic, endemic, occupational and other diseases...” and among the core obligations of the State is, “the provision of essential drugs as outlined by the WHO action plan on drugs”, which includes key TB drugs. The right to enjoy the benefits of scientific progress also forms the basis for increased public spending on TB R&D and of access to newer MDR TB medicines. The importance of using flexibilities in the WTO’s TRIPS Agreement to ensure access, availability and affordability of health technologies has been recognized in Goal 3b of the Sustainable Development Goals. The right to use these flexibilities is clearly recognized in the WTO’s Doha Declaration on TRIPS and Public Health which specifically recognized the gravity of public health problems like tuberculosis and HIV in developing countries. In light of India’s role as the pharmacy of the developing world, it should be noted that States also have international obligations under the right to health through international assistance and cooperation, and in particular, to facilitate access to essential health goods in other countries.

The Fundamental Right to life under Article 21 of the Constitution has been read to include the right to health through judgments of the Supreme Court. Under the Directive Principles of State Policy, several Articles also require that the State protect the health of the people. Despite the long-standing commitment of the government to provide access to TB treatment and diagnostics, there have been barriers faced by patients who have resorted to legal remedies. In a recent case the Supreme Court ordered that the new FDC drugs for daily regimen tuberculosis treatment be administered to all new patients. In another key case, the Delhi High Court was approached over the denial of access to bedaquiline to a young girl with XDR-TB by LRS Hospital on domiciliary grounds. While the High Court heard the case with some urgency, it failed to record a violation of fundamental rights, and noted that the final consent order between the parties had no precedent value. In addition, the agreement by the hospital to provide treatment involved an unnecessarily convoluted process.

Access, both in terms of the government’s ability to provide treatment and for patients in the private sector to access treatment and diagnostics, are also impacted by key laws that may affect the cost

of these tests and medicines. Since 2005, India has been granting 20-year product patents on medicines. Both bedaquiline and delamanid have been patented in India giving the patent holders exclusive rights to use, manufacture, sell, offer to sell and import these medicines. While the supply of bedaquiline remains solely in the hands of Janssen, for delamanid, Otsuka Pharmaceuticals announced a licensing arrangement with only one Indian generic company, Mylan, which applied for regulatory approval from the DCGI. In addition, evergreening patents on both drugs have also been applied for and granted. Janssen's patent application for the fumarate salt of bedaquiline was opposed in March 2013 by the Network for Maharashtra People Living with HIV. With both drugs under patent, access to them has been dependent on the compassionate use programmes, the donation programmes or the tiered prices set by the patent holders. As these various donations and access programmes come to an end, the government now needs to purchase the drugs from the patent holders.

A civil society letter was submitted on 12 March 2018 urging the Prime Minister to issue compulsory licenses for delamanid and bedaquiline given that estimated generic prices for both drugs are far lower than the prices being negotiated by the government with the patent holders. Janssen has reportedly proposed that one course of treatment will be free for every four courses purchased at the price of USD 900 per treatment course while generic prices could range from USD 54 - 96 for a 6-month course. Otsuka/ Mylan have reportedly offered a price of USD 1700 per 6-month course of delamanid while generic prices could range from USD 24 - 54 for a 6-month course. Access to these far lower priced generics would be possible only if there is proper generic competition among several producers. In light of the patents on these medicines possibly continuing till 2025 and 2026, by when India plans to eliminate TB, urgent government action in issuing compulsory licenses would be critical in opening up the pathway to generic competition.

Affordability of TB medicines is also impacted by India's drug price control regime. The *Drug Price Control Order (DPCO) 2013* extends price control to all medicines on the National List of Essential Medicines (NLEM). Of the 376 medicines in the NLEM 2015, 14 are TB medicines. The National Pharmaceutical Pricing Authority, tasked with fixing prices under DPCO 2013, has issued notifications fixing ceiling prices of the TB medicines. The methodology for fixing prices in the DPCO 2013 is presently under challenge by the All India Drug Action Network (AIDAN) in the Supreme Court. It is important to note that the DPCO does not cover patented medicines.

Availability and Affordability of testing: The unreliability and time taken for older TB tests to provide results has led to a keen focus in the RNTCP on the rollout of CBNAAT. However, CBNAAT machines are very costly at INR 16-18,00,000 per device. While the RNTCP reports having one CBNAAT in every district, this is unlikely to dramatically improve the reach of the test as district headquarters are usually too far for most patients and transportation of samples continues to be a significant problem. CBNAAT costs about INR 1,100 in the private sector. The presence of only a single supplier of CBNAAT also contributes to the high cost of the test. It is only recently that a new test (Trunat) has

emerged from a local company. It is evident that early technology diffusion could have contributed to lower costs and better adapted tests for Indian conditions. Also, although the WHO recommends that the full spectrum of tests be conducted for a person who may have MDR-TB it appears that RNTCP is not offering culture tests on a universal basis.

Availability and affordability of treatment: In the private sector, first-line medicines cost about INR 2000 for six months along with additional expenditure on vitamins and testing. Medicines for side-effects of TB drugs are not covered by RNTCP. Treatment costs for MDR-TB in the private sector and for NGOs include import related costs. Despite government proposals to rapidly scale up access to MDR-TB drugs, complete reliance on Janssen's various access programmes for bedaquiline and on Otsuka's sole licensee Mylan for delamanid is likely to continue to hamper their rollout. Legal and policy approaches including the use of TRIPS flexibilities are needed to ensure generic access to these drugs. The government should also safeguard the TRIPS flexibilities in the patent law in any free trade agreement negotiations.

In addition, although the government is now providing both the MDR-TB drugs free under the conditional access programme, the drugs are not available to the private sector where most people access healthcare. There are two explanations commonly put forward for this: first, that they come with a black box warning as there have been no Phase III trials; and second, that only public sector doctors are able to handle the side-effects of the drugs. However, the fact is that the private sector is accessing these drugs albeit through a far slower and more cumbersome personal import route. There is no reason for such few doctors in the public sector be trained to manage MDR-TB treatment with the new drugs. The clear lesson from HIV has been that treatment management can be decentralized and efficiently handled within the public sector.

Side-effects of TB medication: Key informants expressed concern about toxicity of TB medicines and debilitating side-effects they can produce. One survivor said that people with TB are often not told that their urine colour may change. Reports suggest that several patients across India stop TB treatment as they cannot cope with side-effects, which are exacerbated by malnourishment. Side-effects may also lead to loss of work, no income in the family, no energy to cook, no money to buy food, pushing the entire family into a circle of ill-health and indebtedness. A common side-effect of second line injectables is psychiatric, suicidal tendencies. In such cases, it is imperative for not only the patient to be counseled but also for the family to be equipped to handle the situation. Counseling, therefore, becomes an important component of diagnosing and treating people with TB. There is a shortage of counselors and many of these posts lie vacant. The lack of treatment and management of side-effects within the RNTCP needs to be addressed urgently.

Supply of drugs and stock-outs: Debates in the Lok Sabha have raised issues of shortages of vaccines, including TB vaccines, with a shortage of about 28 crore vaccine doses in 2009, and shortage of about 1122.15 lakh vaccine doses in 2010. A report by the Stop TB Partnership and MSF recognized three problems in the RNTCP – not being fully equipped to diagnose and treat people, regular stock-

outs and lack of counseling of TB patients. While government officials admit that stock-outs do take place, these are often dismissed as minor distribution-supply issues. Based on the perspective of patients, the disruption can be very serious. In September 2017, the Delhi Network of Positive People wrote to NACO highlighting TB-related stock-outs including of vitamin B6, which is required to be given with IPT. It also raised concerns on coping with side effects due to the stock-outs, and the stock-out of DOTS99 at ART centres forcing out-of-pocket expenditure of patients.

The high prevalence and incidence of TB and high mortality due to TB in India demonstrates a failure of the health system to address the ever-increasing challenges TB presents. While the government programme hopes to test and treat its way to the TB elimination target, India's complex healthcare system is wrought with vast differences between rural and urban healthcare, between private and public healthcare, and between costs of healthcare in different health set-ups. Urban areas have many more healthcare facilities than rural areas leading to unequal access to healthcare. Studies have shown that due to unavailability of diagnostic services in rural areas a sizeable number of major diseases remain untreated. Paradoxically, although India is one of the biggest suppliers of cheap medicines to the world, people in India do not have access to affordable treatment and medicines. And it is evident that the patent regime is impacting the availability of generic versions of newer TB health technologies.

Recommendations to Government (Central, State and Local bodies)

(I) Policy Reform (develop, amend, review)

- a) The government must provide the entire range of diagnostics, in particular culture tests for ascertaining exactly which drugs a person may be resistant to ensure provision of the proper combination of treatment.
- b) There should be continued investment of public funds in TB research and the OSDD TB project should be revived and properly funded. Public funded TB research should be based on the principles of open source research and affordable access free of intellectual property barriers.

(II) Implementation and Enforcement

- c) The government must ensure supply side availability and affordability of treatment for the public and private sector.
- d) Issue compulsory licenses on newer MDR-TB drugs to ensure multiple suppliers and low prices.
- e) Review the patents granted on the new MDR-TB drugs to ensure they meet India's strict patentability criteria and consider revocation in public interest if this is not the case.
- f) Require technology transfer of CBNAAT technology to local firms while also encouraging the development of local technology for rapid testing and point of care testing adapted to Indian conditions.

- g) The government must provide the entire package of treatments including supplements and side effect treatment as part of the TB treatment programme free of cost.
- h) RNTCP must ensure access to nutrition and put counseling protocols, including peer counseling in place.
- i) Systemic problems of delays, planning, forecasting requirement and monitoring drug and vaccine stocks need to be addressed and manufacture and distribution of drugs and vaccines needs to be streamlined.

Recommendations to Other Stakeholders

Role of Judges, Lawyers and others involved in the justice system

- j) Courts must exercise oversight of government accountability for violations of the right to access TB medicines in urgent hearings and ensure that all persons have equal access to TB and MDR TB medicines.

Role of Doctors, Healthcare workers, Medical institutions and others involved in the healthcare system

- k) The government must rapidly scale up the training of all physicians and healthcare providers within RNTCP and within congregate settings for MDR-TB management with new drugs and extend such training to the private sector as well.

Role of civil society, activists, Non-governmental organizations, Community-based organizations and others involved in the area of TB

- l) Civil society organisations must continue their watchdog function of tracking and reporting stock-outs of TB drugs and diagnostics on an urgent basis.
- m) Reviews of patents granted and patent oppositions on TB drugs should be filed on an urgent basis to prevent unwarranted patents that result in exclusive rights on these crucial drugs.

13. Access To Nutrition

Government guidance clearly establishes the close link between undernutrition and TB – while undernutrition is related to an increase in vulnerability to and fatality from TB, TB in turn leads to undernutrition. In India, while around 40% of the population has latent TB, undernutrition affects 1/3 of adults. Undernutrition is the most widely prevalent risk factor for TB, with about 55% of TB incidence in India attributable to undernutrition. Research in rural and urban contexts bears out this grave situation. Decreased ability to absorb drugs is also seen as an effect of undernutrition. On the other hand, providing nutrition leads to better health outcomes, including lowering mortality and improving treatment adherence. Given these multiple links that nutrition has with TB, providing it is crucial to ensure an effective TB programme in India. The NSP squarely recognizes and envisages the need to provide nutritional support as part of the response to TB control, and to address the social determinants of health.

The Indian Constitution enshrines the right to life in Article 21, which has been interpreted by the Supreme Court to include a gamut of aspects that make the right meaningful, including the right to food. Parliament passed the *National Food Security Act* in 2013, *for food security by access to affordable and adequate quality food*. It entitles persons belonging to “priority households” to 5 kg of subsidized grain per person per month and also assures pregnant or lactating women and children up to fourteen years to free appropriate meals.

Without explicitly mentioning people with TB, it would cover such persons if they fell within stipulated categories. Many central government schemes – those for mid-day meals, targeted public distribution, and the Integrated Child Development Scheme – can also be availed of by people with TB if they qualify as per beneficiary qualifications. Some states and municipalities have developed nutrition schemes that are TB-focused.

The recent Union budget has allocated INR 600 crores for TB-related nutrition support, from which INR 500 per month will be transferred to bank accounts of people with TB for the duration of their treatment through the direct benefit transfer scheme, termed the Nikshay Poshan Yojana. Some experts feel that this allocation is inadequate to meet TB-related nutritional needs effectively unless State governments supplement the allocation substantially. Critics point out that it would amount

to nutrition worth INR 500 per month for 6 months for approximately 20,00,000 people of the more than 25,00,000 people who are diagnosed annually, family members who live in close proximity to people with TB, and fails to cover nutrition expenses after recovery, of people who are not gainfully employed due to the debilitating effect of TB, and have no other source of income. Such a situation can return them to an undernourished state and revive vulnerability to TB. Apart from this, a key concern expressed was the absence of counseling and information being given on nutrition at the time people with or having survived TB access healthcare providers.

Since supply of nutrition does not fall within the health bureaucracy, recipients are put through hardship of having to seek nutrition and treatment at different sites due to lack of coordination between ministries. Nutrition related to TB requires to be prioritized by linking it to the *Food Security Act* in order to get effectively implemented and have legal standing. This is the legislative basis for people to actualize their right to food as part of their constitutional right to life. However, concern was expressed about the poor implementation of the Act and the fact that it requires provision of foodgrains and cereals, and meals for stipulated women and children, but not nutrient gaps like quality proteins, which are vital in the context of TB. The law may need to expand its scope to specifically apply to people with and survivors of TB.

Recommendations to Government (Central, State and Local bodies)

(I) Law Reform (develop, amend, review)

- a) Specifically in relation to TB, nutritional needs must be prioritized by linking them to the Food Security Act in order to derive legal standing and have an implementation framework.
- b) The Food Security Act requires provision of foodgrains and cereals. However, to be impactful in the urgent context of TB it may need to expand its scope to specifically apply to people with and survivors of TB, and include nutritional items beyond foodgrains such as quality protein as part of nutritional supply.

(II) Policy Reform (develop, amend, review)

- c) Fiscal and economic policy needs to ensure that the cost of foodgrains, remains affordable. Increasing employment opportunities for the poor and marginalized should be a priority (as is being undertaken through the Mahatma Gandhi National Rural Employment Guarantee Scheme - MGNREGA) so as to increase household income, and buying capacity that ensures well-nourished households and reduced vulnerability to TB.
- d) Financial allocations in government budgets should be sufficient in order to cover the nutritional needs of the entire family affected by TB, with state governments being required to supplement the allocation substantially through contributions.

(III) Implementation and Enforcement

- e) Consideration should be given for linking TB-related nutritional support with the public distribution, or ration system so that nutrition is provided not just for the time one has TB but for long-term.

Recommendations to Other Stakeholders

Role of civil society, activists, Non-governmental organizations, Community-based organizations and others involved in the area of TB

- f) NGOs and CBOs working with communities should maintain vigilance on the nutrition needs of these communities and provide referral services to government nutrition programmes.
- g) Provide subsidized nutritional food supplements to person with TB and their families.
- H) Provide counseling and accessible information to people with TB and their families on the importance of nutrition in tackling TB and preventing relapse.

People in Vulnerable Contexts

14. TB in the Workplace

The right to a safe and healthy working environment is recognized in international law. In 2010, ILO included TB in its List of Occupational Diseases. Actual data on TB as an occupational disease in India is scant. The NSP recognizes those at increased risk of TB due to their occupation as key affected populations. It prioritizes screening of healthcare workers for TB, implementation of airborne infection control and provision of health insurance schemes for healthcare workers.

The protection of the health and safety of workers finds recognition in the Directive Principles of State Policy of the Constitution and has been considered by the Supreme Court, particularly occupational risk of silicosis. As part of its monitoring role, the court has issued a series of orders relating to persons at risk of or afflicted with silicosis in a case filed before it in 2006. Orders have directed shutdown of mines violating regulations and payment of compensation. The NHRC has also conducted investigations and issued *Recommendations on Preventive, Remedial, Rehabilitative and Compensation Aspect of Silicosis*.

For miners, the *Mines Act, 1952* and related rules read with the *Employees Compensation Act, 1923* (ECA) identify silicosis and silico-TB caused by sclerogenic mineral dust as an occupational disease. Under the ECA, an employee who contracts an occupational disease under certain conditions can claim an injury for which compensation is due. In one 2010 case the Punjab & Haryana High Court found TB to be an occupational hazard for a bus driver due to overcrowded buses.

Another key law is the *Factories Act, 1948*, applicable to factories of 10 persons or more that manufacture with the aid of power and of 20 persons or more that manufacture without the aid of power. In one case the Bombay High Court converted the complaint of ill health of an employee in a factory engaged in manufacture of insecticides into a PIL. While the petitioner suffered a brain haemorrhage, several employees at the factory were found to be with TB. The court passed a number of directions for the state and central government to ensure the right to health and safety of employees at factories.

TB has been identified as an occupational risk within the armed forces. According to the *Guide to Medical Officers* issued by the Ministry of Defence for assessment of disabilities and their causal relationship to service, a case of pulmonary TB found within 6 months of enrolment would be considered one of “aggravation” due to service and not “attributable” as the disease likely had its

inception prior to service. The same considerations apply in the case of extra-pulmonary TB. There has been considerable litigation on the matter of attribution and aggravation. Popularly known as “NANA” (neither attributable nor aggravated by military service) cases, several have been litigated in High Courts and the Supreme Court. In one case the High Court of Jammu and Kashmir found that there was a direct relation between the stress and strain of army service and pulmonary TB. In 2017, based on a judgment of the Supreme Court, the Ministry of Defence stated that it would not challenge orders for pension for soldiers.

Most healthcare workplaces do not fall under the ambit of the *ECA* or the *Factories Act*. Occupational health and safety do not figure in the list of standards to be applied under the *Clinical Establishments Act*. For public sector healthcare workers, there is some entitlement to a Hospital Patient Care Allowance/ Patient Care Allowance (PCA). It is not available to nursing personnel who are given a separate allowance. PCA does not cover employees whose contact with patients or exposure to infected materials is occasional. The *HIV Act* creates legal obligations on public and private sector healthcare establishments to provide a safe working environment, including access to universal precautions.

Several informants expressed concerns over the lack of enforceable legislation or policies on TB prevention in the workplace. Despite the attention of the Supreme Court and the NHRC, the actual process of claiming compensation for persons with silicosis and silico-TB is difficult. Anecdotal evidence from informants also suggests that several healthcare workers have contracted TB occupationally; benefits provided are often not available for casual employees, residents or students. There is no compensation policy for workers with TB in the public sector and causality remains a key barrier. Discussions with informants on masks brought up issues related not only to universal precautions, but also stigma and discrimination. One informant noted that while masks are critical for TB prevention, they attract stigma and discourage patients from using them at the workplace. Consistent counseling can have a positive impact on the decision of patients to use these masks. Informants noted that patients are given just one mask when first diagnosed, which they are expected to keep safe and wear every time they visit the treatment centre. Doctors refuse entry for patients without masks. Doctors were reported sitting at great distances from patients who were required to pick up their medicines through a wire mesh.

The high importance placed on the health of workers in the Constitution and by the Supreme Court has yet to translate on the ground. The lack of recognition of TB as a workplace issue means that workers have to establish occupational risk of TB on a case-by-case basis in courts. The patchwork of occupational health and safety laws in India leaves out a crucial set of workers - those in the healthcare sector. Lack of access to universal precautions not only endangers the health of workers in this sector, it is also considered a critical factor in fueling stigma and discrimination against patients with TB.

Recommendations to Government (Central, State and Local bodies)

(I) Law Reform (develop, amend, review)

- a) The right to a safe working environment needs to find clear recognition in law, including the right to universal precautions in settings where there is a significant risk of TB transmission. This recognition should include training on infection control and use of universal precautions, access to treatment and compensation in case of occupational exposure.
- b) Work-related aspects of reasonable accommodation and compensation, including where appropriate, paid leave, early retirement benefits and death benefits in the event of occupationally-acquired disease need to be recognised in law. This would be over and above the reasonable accommodation proposed for all settings generally (in the section on “Countering Discrimination”).
- c) TB requires to be specifically recognized as an occupational disease in existing occupational health and safety laws and to be included in infection control measures as part of health and safety requirements under such laws.
- d) Healthcare settings to be specifically covered under existing occupational health and safety laws.
- e) In workplace settings where there is a high risk of acquiring TB, there should be no requirement for the worker to prove that TB was in fact acquired at the workplace.
- f) All establishments should be required by law to put workplace policies related to TB in place, by modifying already required HIV workplace policies or including TB as part of overall health workplace policies.

(II) Policy Reform (repeal, amendment, review)

- g) Ensure implementation of TB occupational health and safety requirements in the unorganized sector and that the government provides compensation for exposure as well as for days of work lost for persons in the unorganized sector.

15. TB in Prisons

Prisoners are vulnerable to TB because prisons are overcrowded, poorly sanitized and ventilated, with a large turnover of people who often are unable to maintain adequate levels of personal hygiene. Prisons are sites where HIV and TB co-infection can be found. Sex workers and people who use drugs are targeted by criminal law, and often arrested and imprisoned. They often have poor access to health care and nutrition, and being imprisoned only exacerbates their precarious health condition, and increases susceptibility to infections.

Article 21 of the Constitution of India casts an obligation on the State to preserve life. The Supreme Court has interpreted the right to life to include the 'right to healthcare' and makes it incumbent on the healthcare professional whether in a government hospital or otherwise to preserve life. Courts have stated that the effective utilization of funds for prisons must be ensured so as to provide better living conditions to prisoners commensurate with human dignity. The dismal state of TB-related healthcare in Indian prisons has been highlighted in a study that revealed that diagnostic services for TB were available in only 18% of prisons and treatment services for TB were available in only 54% of prisons.

People in congregate settings, be it in police custody or juvenile homes find it difficult to get treatment for TB. Mishaps have occurred and people with TB have died while in custody due to lack of care. Compensation has been provided by the courts to people with TB or their relatives where there has been negligence on the part of prison officials. In certain cases, patients with TB in prisons have also got bail or their sentences have been commuted.

Recommendations to Government (Central, State and Local bodies)

(I) Law Reform (develop, amend, review)

- a) Make prison officials and the police accountable for custodial deaths due to TB, where sick prisoners or persons detained in police custody are neglected, and where no infection control measures have been taken, leading to infection of TB to other detainees or prisoners
- b) Make provisions for compensation for prisoners who have been treated in an undignified manner by the prison officials and whose right to health has been violated by prison authorities.

(II) Policy Reform (repeal, amendment, review)

- c) Make provision within prisons for prisoners to make complaints or where prisoners can submit their grievances in relation to TB treatment.
- d) Draft a protocol for providing testing and treatment to prisoners, with the requirement for isolation as the last resort, following ethical and human rights principles.
- e) Provide for and expand the network of open prisons, which foster an environment of trust, rehabilitation and good health.

(III) Implementation and Enforcement

- f) Implement the right to health and dignity of all prisoners by ensuring access to quality health services within prisons and timely and complete treatment of TB to all prisoners who need it including:
 - 1. Provision for early diagnosis, ensure proper testing facilities for TB are available in all prisons in the country and that there are no delays in collection and testing of samples meant for TB testing.
 - 2. Free treatment for prisoners and continuum of care and treatment for prisoners who are already on treatment and also for those who are released from prisons and are on TB treatment. Ensure regular and uninterrupted supply of appropriate TB medicines for prisoners.
 - 3. Provision of counselors in prisons who are able to counsel prisoners on TB infection.
- g) Ensure that all prisons are equipped with infection control measures and ensure their use by the prisoners and prison officials. Ensure that there is adequate ventilation and masks to prisoners, prison staff and medical professionals within prisons.
- h) Ensure that prisoners with TB are provided proper nutrition and care within prisons
- i) Training and sensitization of prison officials regularly and in a sustained manner on issues relating to the health of prisoners, including those relating to TB.
- j) Make full and proper use of the medical budget meant for prisoners and increase the budget on a regular basis so as to provide complete, proper and state of the art medical facilities to prisoners in the country.
- k) Take the help of NGOs and social workers to reach out to prisoners with TB and to help them in whatever manner they can with regard to their TB condition.

Recommendations to Other Stakeholders

Role of Judges, Lawyers and others involved in the justice system

- l) Regular monitoring of the health of prisoners should be undertaken by magistrates and

judges before whom cases of sick prisoners are taken up, to ensure that prisoners and persons detained in police custody are being provided adequate health facilities and services, including TB medications.

- m) Training and sensitization of judges, lawyers, para legal professionals that handle criminal cases of persons detained in prisons or in police custody.
- n) Ensure that bail is provided to prisoners who require medical treatment on grounds of health.
- o) Ensure that prisoners or persons detained in police custody, including those with TB, obtain legal aid and are given bail are released on a personal bond, where they are unable to provide the surety or the bail amount.
- p) Investigate into cases of violation of rights of prisoners, penalize and make officials accountable for such violations and provide adequate compensation to the prisoners or their family.
- q) Provide commutation of sentence or early release of convicts who are sick with TB.

Role of Doctors, Healthcare workers, Medical institutions and others involved in the healthcare system

- r) Ensure that proper testing and treatment for TB is provided to prisoner and persons detained in police custody.
- s) Ensure that those already on treatment for TB, prior to their arrest and being detained in police custody or in prisons are provided continued treatment, even if, their sputum tests negative for TB (as it would if they are already on treatment for more than a few weeks).
- t) Provide adequate and complete information to the prisoners about TB and the course of treatment, side effects, etc.
- u) Ensure that voluntary informed consent is taken from prisoners and persons detained in police custody for testing and treatment of TB.
- v) Ensure that confidentiality is maintained in prison set-ups and only those officials who require to be informed of the health status of a prisoner should be provided the information, with consent from the prisoner.
- w) Ensure that there is regular follow up with prisoners and persons detained in police custody with regard to their treatment of TB, and the side effects, if any, are managed in a timely and appropriate manner.
- x) Adequate training of medical officers in prisons for TB testing, treatment and management of the disease, including treatment with first line, second line, third line medicines and XDR and MDR medication, must be undertaken on an urgent basis.

Role of civil society, activists, Non-governmental organizations, Community Based Organizations and others involved in the area of TB

- y) Ensure that all sick prisoners are taken to the medical officer and are given adequate health services in prisons or in hospitals attached to the prisons.
- z) Provide counseling to prisoners with TB and provide information about TB to the prisoners.
- aa) Ensure that prisoners with TB are being provided adequate nutrition, and if not, then report the same to the authorities.
- bb) Help prison officials and staff in the care and treatment, to the extent required, of prisoners with TB.

16. Mobile Populations

People moving, either internally within India or from abroad to India for work – referred here as migrants, or from abroad to India due to strife-torn conditions in the country of nationality – referred here as refugees, can cause upheaval in many aspects of their lives, including the disintegration of family structures, struggles in finding acceptance within new environments, obtaining secure livelihoods and ensuring access to education, housing and food, and access to health services.

Almost 20% Indians migrate internally, between states or districts – for reasons of marriage mostly for women, and to seek gainful work for both women and men. This movement can be permanent, semi-permanent, or seasonal, people involved in the latter facing the greatest challenges in integrating with social services and systems. One's ability to settle in a new part of the country is dependent on the documentation one possesses. Birth registration with which domiciliary documentation is linked, happens for only a little above 1/3 of all births, with these percentages being in single digits in places from where labour migrants mostly originate, leading to undocumented labour. Documentation is key to proving one's identity in order to avail of social services that exist in one's location: ration cards for subsidized food, to open bank accounts or seek admission to government hospitals or schools. Not having such identity documentation creates an inability to access health services, including for TB. Migration is estimated to also cause loss to follow-up of a quarter of all TB treatment. Domiciliary issues have proved hugely challenging in the ability of people with MDR-TB to access treatment. The NSP recognizes the challenges that migrant labour flows pose to developing an effective TB programme that meets their unpredictable needs. Lack of documentation exacerbates already precarious circumstances that are ripe for TB to exploit, such as impoverishment due to job insecurity, and claustrophobic living conditions in urban slums. The Aadhaar scheme is an attempt to bring uniformity of identity across the country to make it easier for residents to avail of social benefits and schemes. Privacy concerns have been raised in relation to data protection of Aadhaar enrollees, as have concerns on the coercive nature of the scheme.

Refugees are on far shakier footing in seeking social benefits than migrants. India has a long tradition of receiving refugees, with support being extended to over 2,00,000 people. India has a large

population of stateless people, although accurate estimates of the number are not available. It has been observed that most refugees take flight from, and arrive at countries with high TB burdens. Malnutrition, overcrowding, and interruption of treatment and access to health care, can impact the spread of TB among refugees, and increase risk of drug resistance and MDR-TB.

For migrants, the *Inter-State Migrant Workmen (Regulation of Employment and Conditions of Service) Act, 1979* provides the right to equal wages as locals, to paid leave to return home, and the responsibility of employers to ensure workers rights. In the context of TB, it stipulates the worker's right to medical care and housing at the site of employment. However, in practice the law is not implemented. Laws such as the *Building and Other Construction Workers (Regulation of Employment and Conditions of Service) Act, 1996* also exist that ostensibly cater to the needs of millions of migrant construction labourers. Its provisions for welfare and health support to beneficiaries are not implemented with any seriousness. Refugees can apply for long-term visas issued by the Indian government, based on UNHCR documentation. This allows refugees to seek employment in the private sector and access education opportunities in India. Such a status also allows access to public and private sector healthcare services. Otherwise, refugees often have to exist in a legal limbo where health services have to be brought to their confines; mobile clinics can be used in such situations, including mobile TB diagnostic stations that reduce the time between diagnosis and treatment.

Key Issues for Research

1. Analysis of impact of extant laws and welfare schemes on mobile people, particularly in relation to TB, and exploring how other rights may be impacted due to their mobile status, which affect their health outcomes.

17. Women

Women and girls constitute about a third, i.e. 1 million of the estimated 2.8 million TB cases in India each year. TB is the fifth leading cause of death among women in the country, with women between 30 and 69 years of age accounting for nearly 5% of fatalities.

Economic and social inequities, traditional structures of patriarchy, and factors such as poverty, caste and class foster inequality against women. This environment fuels disempowerment and violence and hinders women's ability to prioritize their health, and exacerbates their vulnerability to TB and other diseases. Like most people with TB, women with TB are also stigmatized, having to deal with ostracization, discrimination, and delayed or limited access to needed healthcare services.

Indeed, having TB subject women to greater violence and abandonment, raising serious issues of failing social support structures and fueling destitution. Women's health is neglected because of their low status in the family, the lack of gender-sensitive healthcare facilities, and financial limitations that manifest in low expenditure on healthcare for and by women.

Laws relating to marriage, divorce, maintenance, custody, property, inheritance and succession affect women's social and economic status. Laws relating to violence and crime, and health laws can enable women's ability to protect and empower themselves, and improve and promote their health outcomes.

A rights-based approach on women's empowerment fundamentally seeks to bring justice closer to women, among other marginalized people, through empowerment in substantive and procedural law, and recognition of their various rights, including their right to health, both mental and physical.

Key Issues for Research

1. Analysis of the factors that impede access to health systems for women, and the law and policy measures that need to be taken to overcome these hurdles.
2. Effective use of the laws relating to women, for their empowerment, protection, and easy and early access to health care, including diagnosis and treatment of TB.
3. Nutritional aspects relating to women that make them vulnerable to diseases like TB.
4. Methods to obtain quick maintenance for women with TB and prevention of abandonment of women with TB.

18. People Living With HIV

People living with HIV (PLHIV) are at particular risk of TB, and it remains the leading cause of death among them. India has the second highest number of estimated HIV-associated TB in the world. An estimated 1,10,000 PLHIV developed TB in 2015 with an estimated 37,000 deaths as a result. Collaboration between RNTCP and the NACO commenced in 2001, and the NSP proposes to follow the *National Framework for Joint HIV/TB Collaborative Activities* issued jointly by the Central TB Division and NACO in 2013. The framework refers to patient-friendly diagnosis and adherence through NGOs. There is little reference to human rights and ethical issues; confidentiality is referred to but only in the context of HIV status.

Stigma and discrimination have been the defining features of the HIV epidemic in India. In 2017, the *HIV Act* was passed as a comprehensive legislation addressing multiple legal issues relating to HIV. This Act, which is yet to be notified, prohibits discrimination and unfair treatment based on HIV, requires informed consent for HIV testing, treatment and research, prohibits disclosure of HIV-related information without informed consent and provides for a safe working environment. It also requires the government to provide “*as far as possible*” ART and opportunistic infection management. The inclusion of the phrase “*as far as possible*” has raised serious concerns among PLHIV networks regarding the extent of the obligation on the government to provide treatment. The Act also protects risk reduction strategies from criminal liability.

Observations in the interviews revealed the stark difference between RNTCP and the National AIDS Control Programme in their approach and treatment of patients in some parts of the country. PLHIV who have TB or are providing services to people with TB in Delhi noted that TB-related stigma often emerged first from RNTCP centres where patients went for the first time to begin TB treatment. By contrast, PLHIV in Maharashtra reported dealing with a far stronger public health system that had a better track record on the legal-ethical front. In terms of the responsiveness of the programmes to community groups, several respondents compared the effectiveness, involvement and mobilization of PLHIV in holding the government accountable as compared to the TB programme. According to respondents, while the HIV programme actively consults PLHIV in all aspects of programming and implementation, the TB programme is often reluctant to do the same.

Key Issues for Research

- a) Analysis of Impact of HIV and AIDS Act 2017 for PLHIV co-infected with TB
- b) Analysis of different approaches of NACO and RNTCP in particular in relation to community consultation and participation and the extent to which human rights concerns are reflected in the two programmes

19. Sex Workers

UN analysis notes that “sex workers living with HIV, sex workers who inject drugs, and sex workers exposed to poor, cramped working and living conditions, including brothels or prisons, are at increased risk of developing TB, including multidrug-resistant TB”, and that programmes or community outreach services for sex workers are ideally placed to support TB screening, prevention and treatment. It also recommends that TB clinic staff be trained on respect towards sex workers.

The TB programme in India also recognizes the heightened vulnerability of sex workers to TB, in the National Framework for Joint HIV/TB Collaborative Activities 2013 and the NSP. Although the NSP does not mention this, it is well recognized that one of the factors that makes sex workers a ‘key population’ in relation to HIV is an increased vulnerability caused by their criminalization in law. Criminalization happens through general laws like Police Acts, the *IPC* and the *Immoral Traffic (Prevention) Act, 1986* (ITPA), which criminalizes several activities surrounding sex work.

In 2016, a submission by sex workers groups for the Universal Periodic Review of the UN Human Rights Council detailed human rights violations faced by sex workers. One case study detailing a ‘raid and rescue’ operation by police in Mumbai revealed that during the raid the police detained and took away even older women who were sick and being treated for TB at the clinic of an NGO in the building where the raid took place. The submission further detailed cases where sex workers were denied medical services including TB treatment in civil hospitals. According to informants, mobilization and collective action by sex workers in some areas has led to a decrease in discrimination against them in health settings. Interestingly, sex workers seldom resort to legal remedies in such cases. In one area in Maharashtra where there is strong collectivization of sex workers, the district TB programme has been working with sex workers for over a decade to reach their peers. While sex workers who are on treatment in the district are well supported by their peers, when they have to leave for accessing MDR-TB drugs is when the lack of support has tragic results.

Key Issues for Research

- a) How are sex workers vulnerable to and impacted by TB?
- b) Analysis of Impact of ITPA and other laws on access to health services generally and TB services in particular for sex workers

Conclusion

VI. Conclusion

A key lesson derived from recent policy and law experiences in public health has been that the welfare of many is best served by ensuring the wellbeing of the few who are often most vulnerable to significant health events. This despite alarm about health events prompting responses to barricade those who have become unhealthy in order to protect others who are still healthy, which pit the few against the many, and polarize attitudes while encouraging punitive, rights-limiting policies and practice. It has been argued that larger societal interests of public health can only be best served by such limits to curb apparently selfish individualist interests for apparently wider public good. The rights-based approach has revealed this to be a false dichotomy, showing instead that ***individual interests and protection of rights complement and advance and are not inimical to societal interests of public health***. Empowerment and rights guarantees nurture a confidence in the health system, a keenness to engage with it, and better health information and health-seeking behaviour, thereby improving the health of the few, and safeguarding the health of the many. This understanding is now consistently reflected in international best practice guidance on TB control. Indeed, TB has revealed that susceptibility to it is highly influenced by structural determinants of health, including nutrition, housing, and environmental issues that are often linked to economics and poverty. These larger structural issues can only be effectively addressed through the recognition of rights and inclusive approaches. While these aspects will see results in the longer term they must be addressed with immediacy. There are also shorter term ways in which a rights-based approach can foster engagement with the health system to effectively meet India's aspirations of being TB-free – ensuring consent, confidentiality, and non-discrimination, discarding the punitive use of criminal law to address issues, advancing the right to health by enhancing accessibility to quality, affordable diagnostics and treatment, making the private sector accountable, and empowering the most vulnerable through social security benefits and ensuring a fully developed right to life in all its dimensions. An understanding and recognition that ***rights-based approaches should underpin the TB response*** is vital to making it more effective. Indeed, the NSP for TB Elimination 2017-25 also recognizes this as part of the government's vision to effectively address TB, acknowledging people with TB as active participants in the response, and deserving of a rights-based approach to patient care. This vital recognition of rights needs to be actualized as a core part of policy, programmes and

implementation of the TB response, especially in initiatives being rapidly launched by the RNTCP including recent orders and announcements foisting criminal law on physicians and druggists, and making TB screening mandatory for those below 30 years of age.

As crucially as infusing the TB response with rights-based perspectives is the need to **empower affected communities** to seek health services and commodities as part of their right to health, **listen to their voices** while tailoring the response, and **involve them as partners and participants** in the development of the most socially appropriate rights-based strategies to address TB effectively. Indeed, experience reveals that it is those most affected by contexts of marginalization and compromised by health impacts who stimulate, guide and enhance policy responses most effectively.

A series of **over-arching legal themes** also need to be considered so that TB elimination is successful, while also provoking reform for larger law, policy and planning efforts at advancing health and wellbeing. For implementers, there is much guidance referring to methodologies that intersect with rights issues. Robust ethics standards and protocols need to be developed for implementation to abide by constitutional and rights-based principles. For this, **ethics training should be at the core of public health, and medical education curricula and teaching, and in training bureaucracies engaged in health delivery**. Hitherto, such training is treated as incidental to health delivery. Issues of informed consent, privacy and confidentiality, non-discrimination, equity, and non-stigmatization, can be best addressed and assured if their contours are ingrained in healthcare workers and public health personnel and bureaucrats at formative stages of developing the healthcare workforce and professionals.

Existing laws in India can be used to address many of the challenges that TB throws up. Indeed, India has a surfeit of laws with little invested to ensure their effective implementation. **Instead of creating new legislation, use extant laws in most situations**. Some areas may require law reform (to cover private sector discrimination, modernize public health laws, ensure informed consent and confidentiality, expand food security) but such **law reform efforts should be reflected in an omnibus health law**, which anticipates and covers an array of health contexts, not just TB. Many areas do not need new legislation. Investment needs to be made in **better implementation of existing laws** (issuing compulsory licenses for local manufacture of crucial TB medication, convincing states to legislate the *Clinical Establishments Act*, and to ensure its proper enforcement, and seeing that the Indian Medical Council enforces its regulations effectively in order to make physicians accountable). To mitigate violations and for ethics to permeate the healthcare system and the TB response **people accessing the health system need to be informed of their rights** and be linked with **access to legal aid** and **localized and innovative grievance redress**. This can be aided by investing wholeheartedly in the public health system so that the work of implementers improves and is supported by **training of healthcare staff and quasi-adjudicating authorities on health law and ethics**.

There are key aspects of a cross-cutting nature that need to be focused on in order to ensure that people with TB and those vulnerable to it reap maximum benefit through the TB response, while also ensuring efficiency to it. One such issue is the need to pay ***committed attention to the structural determinants of health*** – dealing with the challenges of under-nutrition, abject housing and hygiene conditions brought on by unplanned urban planning, dangerous working conditions in the unorganized and organized labour sector, and an inadequate social net that fails to assist those in need when insecure livelihoods and poor health sink them into poverty.

Investing in strengthening health systems starts with primary health, which is the basic need of the vast majority of any population. In the context of TB this includes the need to improve accessibility to health services and products through pricing and distribution, and to improve competence of the health staff to render health services with empathy and skilled communication. This should be viewed as an investment in public health that will reap benefits beyond only the strengthening of the RNTCP. Strengthening health systems can also be aided by the government encouraging open-source research and development to develop more affordable TB treatment regimens for access in India and in other developing countries, unencumbered by intellectual property. Crucial to an empathetic and trusted health system is a committed focus on ***enhancing counseling skills, facilities and infrastructure, and human resources for counseling***. Competent counseling can play a vital role in educating those who are uninformed, reducing stigma, fostering responsibility and encouraging health-seeking behavior including self-disclosure and treatment adherence. Training a cadre of counselors on disease management, TB, science, empathy, ethics and rights for the purpose of transmitting accurate, accessible quality information while also responding to patient's concerns can be hugely significant in enhancing the effectiveness of the TB response.

VII. Ways Forward – Improving The Evidence Base

The report points to areas that require further evidence to inform appropriate and rational rights-based law and policy. The availability and accuracy of evidence is crucial in tailoring appropriate and effective public health responses. The TB response has invested in making significant efforts in gathering the best epidemiology related to TB. The ***most appropriate policy and law responses should also be based on the best evidence and practice***. Consequently, public health policy should be formulated based on the substance of what is seen to work. This report can be a springboard in that direction, by fostering a rigorous consultative process, particularly engaging and involving people with or survivors of TB to assess the impact of existing laws and policies and their deployment on the ground. This could provide immense value to tailoring appropriate law and policy responses. One manifestation of this can be in the form of a national dialogue with multiple stakeholders to provide holistic rights-based inputs to the NSP to strengthen the legal and ethical dimensions of policies, programmes and schemes to be implemented as part of it.

Specifically, with regards to improving the evidence base, some questions that have arisen in the course of preparing this report worth examining in greater detail include:

- i. Stigma and discrimination related to TB is under-reported. What sort of stigma and discrimination do people with TB face?
- ii. What are the inter-sectoral efforts that need to be made to reduce systemic vulnerability to TB, including in relation to urban planning and housing, safe working environments and welfare, and food security and nutrition?
- iii. Further research on people in vulnerable contexts, particularly the solutions in law and policy that could reduce their vulnerability, including some of the groups discussed briefly in the LEA, and others referred to as ‘key affected populations’ as per the Stop TB Partnership.
- iv. Is there evidence to show that notification is public health best approach in revealing an endemic disease like TB, and getting people onto treatment?
- v. Analyse existing data collected by Nikshay to hone better policies and approach to ensuring proper treatment

- vi. Pilot studies using best practices and rights based approaches to TB testing and treatment
- vii. What evidence supports the approach that threatening criminal law sanction on doctors and pharmacists will ensure notification of TB cases?
- viii. How can the skills developed at ICTC centres for HIV be transferred to complement the TB response?
- ix. What evidence shows that extant budgetary allocations for nutrition during the course of treatment are sufficient to effectively tackle the issue of under-nutrition, and the cycle of vulnerability to TB?
- x. Can evidence be improved to support the needs of a variety of people in potentially vulnerable contexts? If so, what data is required to tailor the most appropriate response for these vulnerable persons?
- xi. How will costs of newer TB medicines impact the sustainability of the RNTCP programme?

The Legal Environment Assessment (LEA) is one of three tools that forms part of the Communities, Rights and Gender Assessments. This report presents the findings of the Tuberculosis LEA conducted in India in 2017-18. An in-depth assessment of how TB interacts with the law and with human rights, the LEA report examines how the law may be deployed to foster an enabling environment that reduces vulnerability to TB and alleviates the consequences of TB for people affected by the disease. The LEA report identifies how effective disease control efforts can be undertaken by respecting the rights of people infected and affected by the disease and is intended to prompt reflection and dialogue among policymakers, affected communities, health sector actors and other key stakeholders on law reform and the appropriate and effective implementation of the law.

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