

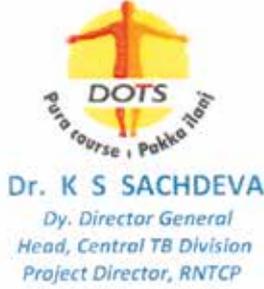
# LEGAL ENVIRONMENT ASSESSMENT FOR TB IN INDIA 2018



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FOR TB IN INDIA  
2018**

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## 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

**Authored by Vivek Divan, Veena Johari & Kajal Bhardwaj**

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## **Acknowledgements from the Authors**

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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 partner and donor 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

## List of Expert Advisory Group Members

- Mr Arun Kumar Jha, Economic Advisor, Ministry of Health & Family Welfare, Govt. of India
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- Dr Sunil Khaparde, former DDG-TB, Central TB Division, Ministry of Health & Family Welfare, Govt. of India
- Dr. Sundari Mase, WHO Country Office, India
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- Dr Beena Thomas, Department of Social and Behavioral Research, National Institute for Research in Tuberculosis
- Mr. Brian Citro, Assistant Clinical Professor of Law, Bluhm Legal Clinic, Northwestern Pritzker School of Law

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# Recommendations [at-a-glance]

## 1. COUNTERING DISCRIMINATION

### 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.
- ab) Help persons with TB access the justice system.
- ac) 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.
- ad) Provide ancillary support where there is inadequacy in the healthcare system, such as human resources and skills development for counseling services.

## **2. ISOLATION**

### **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 es-

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

#### 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.
- c) 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.
- d) 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.
- e) 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 Diu Public Health Act, 1985*. However, a national survey and reform of all such laws at the state level requires to be undertaken.)
- f) 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)

- g) 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.
- h) Notification data collected through Nikshay should be stored with stringent, foolproof confidentiality protocols to be followed.

- i) 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.
- j) 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***

- k) 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.
- l) Provide comprehensive information to the patient under the legal mandate that requires medical professionals to notify TB.
- m) 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.
- n) 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**

### **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

### 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**

### **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.

## **7. DRUG REGULATION**

### **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**

### **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**

### **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**

### **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**

### **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.

## **12. ACCESS TO TREATMENT & DIAGNOSTICS**

### **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**

### **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.

## **14. TB in the Workplace**

### **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**

**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:
  - o 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.

- o 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.
- o 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.
- ab) Help prison officials and staff in the care and treatment, to the extent required, of prisoners with TB.

## **16. MOBILE POPULATIONS**

### **Key Issues for Research**

- a) 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**

### **Key Issues for Research**

- a) 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.
- b) 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.
- c) Nutritional aspects relating to women that make them vulnerable to diseases like TB.
- d) Methods to obtain quick maintenance for women with TB and prevention of abandonment of women with TB.

## **18. People living with HIV**

### **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**

### **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



# I. BACKGROUND

## **1. Introduction**

*a. Tuberculosis and the Law*

*b. An Overview of the Legal System in India*

*c. Human Rights Framework in India*

*d. An Overview of TB in India*

## **2. TB LEA: Methodology, Limitations & Structure**



# 1. Introduction

This report presents the findings of the TB Legal Environment Assessment (LEA) conducted for India. The TB LEA was undertaken at the behest of REACH – the Resource Group for Education and Advocacy for Community Health, Chennai, 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. The purpose of this LEA is to inform this commitment by examining how the law may be deployed to foster an enabling environment that reduces vulnerability to TB in the populace, alleviates the consequences of TB for people who live with it, and more broadly to reflect on what the law and its implementation can do to impact public health so that it serves the needs of communities and society.

LEAs can play a key role in understanding the country's legal infrastructure – the laws and policies that obligate the government, state, public health agencies and the private players concerning health and helps identify how effectively disease control efforts can be undertaken by respecting the rights of people infected and affected by the disease (TB) and brings to light peoples' ability to access health services. In doing so, they can 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.

The Fundamental Right to life in the Indian Constitution provides a firm legal basis on which a variety of related and ancillary socio-economic rights have been articulated by the Indian Supreme Court, many of which are apposite in the context of TB. These include the rights to health, food, and education. All of these aspects of life have a deeply significant impact on living with and becoming vulnerable to TB. Yet, beyond the affirmation of rights by the courts, there is limited understanding of how these aspects are bolstered (or not) by legal frameworks in the context of TB. This LEA throws light on the intersections of these and other issues of human rights with TB and the policy response it has generated.

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 workplaces, private healthcare providers, regulators, NGOs etc. It is hoped that people with TB in particular find this report useful in identifying and advocating for their rights.

### **a. Tuberculosis and the Law**

The wise words from the Bhore Committee Report of 1946 are as perceptive and fundamentally true today as they were then:

*“A social disease such as tuberculosis can be combated successfully only if ameliorative measures on an extensive scale can be undertaken so as to improve the general standard of living, including housing, nutrition and the sanitation of the environment in the home, the workplace, and places of public resort.”<sup>1</sup>*

Health is a right of all persons, which most nations, including India have committed to deliver to its people in international law, and through recognition of it in the Constitutional framework. As such, 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 and commodities for prevention, care, and treatment of disease and ensuring wellbeing and the full enjoyment of a healthy life. One way in which the ownership of the duty to protect and promote the right to health manifests is in the political will demonstrated by the State to reduce mortality, incidence and prevalence of disease through various public health measures that are based on evidence, sound science and a commitment of resources.

Tuberculosis (TB) has emerged as one of the leading causes of death and ill health, globally as well as in India, and has re-emerged, in most places, with virulent multi-drug resistant bacilli. In 1993, the World Health Organization (WHO) declared TB a global emergency, recommending strengthening of national TB control programmes, and widespread adoption of the directly observed treatment, short course (DOTS).<sup>23</sup> In 2001, the WHO called for political will to adopt legislations to control communicable diseases and formulate regulations for TB control. The critical elements for a successful national response to TB were noted to be government commitment to sustained, comprehensive

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1 Chairman Sir Joseph Bhore, “Report of the Health Survey and Development Committee,” Survey, published by the Manager of Publications, Delhi, 1946, Vol.1, page 103

2 Coker, R.J. &ors. “Public health law and tuberculosis control in Europe”, Public Health (2007) 121, 266-273; doi:10.1016/j.puhe.2006.11.003

3 Pinet, G, Good Practice in Legislation and regulations for TB control: An indicator of political will, Communicable TB Cluster, Stop TB, WHO, Geneva, Switzerland, WHO/CDS/TB/2001.290, May 2001. Available at [http://apps.who.int/iris/bitstream/10665/68708/1/WHO\\_CDS\\_TB\\_2001.290.pdf](http://apps.who.int/iris/bitstream/10665/68708/1/WHO_CDS_TB_2001.290.pdf)

TB control activities, case detection of TB, standardized treatment regimes, regular uninterrupted supply of TB drugs and standardized recording and report keeping.<sup>4</sup> The role of the law is to provide parameters for these elements and regulate their appropriate implementation through legislation and policies was seen to be critical to an effective response.<sup>5</sup> It was also noted that,

*“the question of patients’ rights is central to the evolution of health legislation as the vulnerability of the sick makes them easily subject to violation of their rights and more affected by shortcomings of social and health administrations.”<sup>6</sup>*

Another critical understanding of the role of law in relation to health issues and disease control emerged in the late 20<sup>th</sup> century, through the global response to HIV. What HIV revealed was that a health condition solely dealt with through a biomedical response to provide commodities and medicines to prevent or treat it was inadequate. An effective response to control HIV requires understanding and recognition that structural factors – such as social and economic marginalization – contribute to HIV vulnerability; and that societies need to develop abilities and demonstrate the political will to mitigate the impact of these factors if HIV is to be effectively controlled. HIV is often found to reside in parts of society that are extremely marginalized and disempowered – the ‘key populations’ of sex workers, transgender people, people who use drugs and men who have sex with men. Much of this marginalization has been cemented in the social fabric over several generations. Some of it is further reinforced through legal frameworks that punish the already marginalized. It was in this context that a rights-based approach emerged, which spoke of the necessity to create an enabling legal environment for these marginalized communities to feel secure in accessing health services, seeking accurate health information, and thereby looking after their health and wellbeing. It became clear that this approach where human rights were central rather than peripheral to public health goals was the only effective way 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. Indeed, the Bhore Committee did speak to this even over 70 years ago. In relation to TB, some of the vulnerable and marginalized – people living with HIV, sex workers, prisoners – overlap with the ‘key populations’ of the HIV response. But other disempowered people’s realities and needs also require to be fully understood to tailor appropriate law and policy responses – miners, mobile populations, urban slum dwellers.

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; particularly when States seek to exercise their

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4        Ibid.

5        Ibid.

6        Ibid.

legislative authority to allow for the isolation, detention or even incarceration of those it assumes will spread or transmit the disease or even to force treatment. These archaic notions of public health law are now seeing a challenge in the context of TB as governments move 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. One framework for assessing and challenging the use of State power lies in the Siracusa Principles that have been relied on by the WHO and several legal scholars. The Siracusa Principles were developed by a group of experts and specify the manner in which rights enshrined in the International Covenant on Civil and Political Rights (ICCPR) including the right to movement, may be limited by the State.<sup>7</sup> Under these principles such limitations may occur when they are:

*“(1) provided for and carried out in accordance with the law; (2) directed towards a legitimate objective of general interest; (3) strictly necessary in a democratic society; (4) the least intrusive and restrictive in severity and duration to achieve the objective; and (5) based on scientific evidence and neither drafted nor imposed arbitrarily nor in a discriminatory manner.”<sup>8</sup>*

Even the application of these principles in the TB context is not without debate, as noted later in this report, but as some scholars argue their proper and strict application taking into account facts and evidence often shows the tension between public health and human rights to be a false one.

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. Its imprimatur can also have a salient affirmative impact in protecting the rights of the marginalized and ensuring that they have equal access to social resources, protections and opportunities, including to health, education, employment, insurance, housing, and nutrition.

Specific to TB, the law can play multiple roles: it can provide safeguards to prevent its spread in the population at large; it can 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 that comes with TB, and the marginalization that causes TB or exacerbates it.<sup>9</sup> Laws and regulations can shape these aspects in many ways. Apart from ensuring provision of housing, food, access to uninterrupted supply of medicines and testing facilities for people suspected of or having TB, they can also regulate economic and social structures in society that bring about equality (such as taxes and social security schemes), influence job creation and job

7 United Nations Commission on Human Rights, The Siracusa principles on the limitation and derogation provisions in the International Covenant on Civil and Political Rights U.N. Doc. E/CN.4/1985/4, Annex (1985) available at <http://adilet.zan.kz/eng/docs/O8500000001>

8 Mburu et al, Detention of People Lost to Follow-Up on TB Treatment in Kenya: The Need for Human Rights-Based Alternatives, Health and Human Rights Journal, June, 2016, 43–54 available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5070679/>

9 Pinet, G, *Good Practice in Legislation and regulations for TB control: An indicator of political will*, Communicable TB Cluster, Stop TB, WHO, Geneva, Switzerland, WHO/CDS/TB/2001.290, May 2001. Available at [http://apps.who.int/iris/bitstream/10665/68708/1/WHO\\_CDS\\_TB\\_2001.290.pdf](http://apps.who.int/iris/bitstream/10665/68708/1/WHO_CDS_TB_2001.290.pdf)

security, ensure minimum wages and make compassionate provisions for workers and students who are coping with TB.

Yet, as important as the law on the books in the form of legislations and regulations, is the vigour and commitment with which the law is implemented so that the right to health can be fully realized by people. 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 to ensure a competent, empathetic, transparent and accountable healthcare system, and special attention to the most vulnerable.<sup>10</sup>

Although the law cannot by itself address all the challenges that are posed to the health system generally, and the TB response in particular, it is one of many tools that can constructively contribute to public health priorities and social wellbeing. Indeed, if used humanely, it can support in achieving India's commitment within the new development agenda of Sustainable Development Goals in ensuring healthy lives and promoting wellbeing for all people, including ending TB by 2030.<sup>11</sup>

## **b. An Overview of the Legal System in India**

The Constitution of India is the highest law of the land and establishes India as a sovereign, socialist, secular democratic republic. It is a union of 29 states and 7 union territories. India is considered to have a federal structure with a unitary bias i.e. although states have their own jurisdiction to make laws, the central government enjoys greater powers. The Constitution adopts a parliamentary system of democracy.

### **Sources of Law**

There are multiple sources of law in India. *Constitutional Law* refers to the Constitution, which is written and supreme. No laws legislated either by the central or state governments can supersede or be in excess of the powers prescribed in the Constitution. Any law that goes beyond the Constitution or that violates the rights and provisions laid down in the Constitution can be struck down by courts of law. *Statutory law* refers to legislation enacted by Parliament or State Legislatures and may be substantive or procedural in content. *Personal laws* refer to laws relating to one's religion and are specifically recognized in the Constitution. Marriage, divorce, custody, maintenance, property inheritance, succession are governed by personal laws which may or may not be codified and are different for different religions. *Customary law* refers to customs that have been recognized by the courts and legalized over time, as they have been used by communities. And, finally India also follows the system of *common law*, which refers to judge-made law and is based on precedents laid down by the courts.

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10 Srinivasan, R, "Healthcare in India – Vision 2020 – Issues and Prospects". Available at [http://planningcommission.gov.in/reports/genrep/bkppap2020/26\\_bg2020.pdf](http://planningcommission.gov.in/reports/genrep/bkppap2020/26_bg2020.pdf)

11 See Sustainable Development Goal 3, available at <http://www.un.org/sustainabledevelopment/health/>

## Statutory Law Making and Health

The Union (Central) and State Lists of the Constitution establish the areas where laws can be made by Parliament and State Legislatures, which enjoy exclusive jurisdiction in the areas listed. A third Concurrent List stipulates areas that both Parliament and State Legislatures can legislate on; however, if there is a conflict then the Parliamentary law will override the state law. Health is listed as an area under the State List. However, various aspects impacting healthcare fall under the Central or Concurrent lists of the Indian Constitution 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. Both Central and State laws therefore impact TB. In addition, certain tribal areas that are declared as autonomous districts<sup>12</sup> have independent councils that have powers to make laws on any matter relating to village or town administration, including public health and sanitation.<sup>13</sup>

## The Court System

Redress of rights violations lies largely with the courts in India. The Constitution of India mandates that the State have an independent judiciary.<sup>14</sup> India has a unitary three-tier judiciary, consisting of the Supreme Court at the apex of the entire judicial system headed by the Chief Justice of India. The Supreme Court has original jurisdiction over cases involving Fundamental Rights and over disputes between the central and state governments,<sup>15</sup> and has appellate jurisdiction over High Courts.<sup>16</sup> The pronouncements of the Supreme Court are binding on all courts.<sup>17</sup> Below the Supreme Court are twenty-four High Courts in each State or group of States.<sup>18</sup> Below the High Courts, lies a hierarchy of Subordinate Courts.<sup>19</sup> In addition, there are Family Courts established to handle disputes and promote conciliation in to marriage and family affairs,<sup>20</sup> and other special tribunals established over time to decide over specific areas such as income tax, environmental issues etc.

## International Conventions and Treaties

Under the Constitution, the Executive of the Union Government has the power to enter into treaties.<sup>21</sup> As India follows a dualist system, treaties and international agreements entered into by the government are not directly enforceable unless Parliament passes a law bringing such treaties and international agreements into effect. If there are conflicts between the provisions of international treaties and domestic laws, then the domestic law prevails.<sup>22</sup> In the absence of domestic laws to the

12 For instance, tribal areas of the states of Assam, Meghalaya, Tripura and Mizoram. See Sixth Schedule, Constitution of India

13 Paragraph 3, Sixth Schedule, Constitution of India

14 Article 50, Constitution of India

15 Article 131, Constitution of India

16 Articles 132,133 & 134, Constitution of India

17 Article 141, Constitution of India

18 See <http://www.supremecourtfindia.nic.in/jurisdiction>

19 Ibid.

20 *The Family Courts Act, 1984*

21 *Union of India v. Azadi Bachao Andolan* (2004) 10 SCC 1

22 *Gramophone Company of India Ltd. v Birendra Bahadur Pandey* (1984) 2 SCC 534 and also see *Jolly George Varghese v. Bank of*

contrary, courts do refer to treaties and international agreements while interpreting the contents of domestic law.<sup>23</sup>

In terms of international human rights instruments, India is signatory to the International Covenant on Civil and Political Rights (ICCPR), the International Covenant on Economic, Social and Cultural Rights (ICESCR), the Convention on Elimination of All Form of Discrimination Against Women (CEDAW), the Convention on the Rights of the Child (CRC) and the International Convention on the Elimination of All Forms of Racial Discrimination (ICRD). In 1948, as a member of the UN, India voted in favour of the Universal Declaration of Human Rights. India has also been signatory to resolutions at the UN relating to international commitments on health such as the General Assembly Declaration of Commitment on HIV/AIDS, 2001, the World Health Assembly's Global Strategy and Targets for tuberculosis prevention, care and control after 2015 (End TB strategy) and the SDGs adopted in September 2015. These treaties and resolutions are bases for undertaking legislative reform, changes in policies or used in the reasoning of court decisions.<sup>24</sup> International trade treaties such as the World Trade Organization (WTO) also impact domestic law for instance in relation to healthcare services, insurance and intellectual property. The provisions of these treaties impact TB in different ways and while some provide the basis for a rights-based approach to TB policy and programming, others may create barriers in this regard.

### **c. Human Rights Framework In India**

The Indian Constitution follows the traditional cleave of human rights and recognizes political and civil rights as 'Fundamental Rights' while economic and social rights are recognized as 'Directive Principles of State Policy' (DPSPs). 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 equality before law or equal protection of the laws to every person within India.<sup>25</sup> The State is prohibited from discriminating against citizens on the grounds of religion, race, caste, sex or place of birth of a person.<sup>26</sup> Fundamental Rights also guarantee equality of opportunity in matters of public employment<sup>27</sup> and freedom to practice religion.<sup>28</sup> Apart from these provisions the Constitution provides special protection and affirmative action for women and children.<sup>29</sup> Part III also recognizes the freedom of speech and expression, freedom of association, peaceful assembly, to move freely within India, freedom to reside and settle anywhere in India, to carry on any trade, occupation or profession.<sup>30</sup> However, these rights

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*Cochin* (1980) 2 SCC 360: AIR 1980 SC 470

23 *Vishaka v. State of Rajasthan* (1997) 6 SCC 241

24 See for instance *Valsamma Paul v. Cochin University* AIR 1996 SC 1011 and the *HIV and AIDS (Prevention and Control) Act 2017*

25 Article 14, Constitution of India

26 Article 15, Constitution of India

27 Article 16, Constitution of India

28 Article 25, Constitution of India

29 Article 15 (3), Constitution of India

30 Article 19, Constitution of India

are not absolute and are subject to certain restrictions.<sup>31</sup> The Constitution abolishes the practice of untouchability.<sup>32</sup> It also guarantees the right to life and personal liberty.<sup>33</sup> The Constitution provides that children from ages 6 to 14 have a fundamental right to education.<sup>34</sup>

The DPSPs in Part IV of the Constitution on the other hand are meant to inform government action and are not enforceable in a court of law. These directives provide a positive covenant for the State to confer or create conditions for the exercise of rights. However, social and economic rights have attained an equal standing with civil and political rights and 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.<sup>35</sup> The Supreme Court while holding that the right to health of a worker falls within Article 21 of the Constitution of India relied on the UDHR and the ICESCR, asserting that the right does not mean the mere absence of sickness but complete physical, mental and social well-being.<sup>36</sup> The Supreme Court and the High Court have articulated various components of the right to health and the obligations of the State in providing health care including to ensure the right to safe and affordable medicines<sup>37</sup>, provide proper public health infrastructure<sup>38</sup>, ensure health safeguards in patent laws are strictly applied<sup>39</sup> and safeguarding the rights of clinical trial participants.<sup>40</sup>

The other Fundamental Rights recognized in the Constitution as they apply to TB are discussed in detail in the following sections. In case of violation of a Fundamental Right, the Constitution provides specific remedies.<sup>41</sup> These rights can be enforced in the Supreme Court as well as in High Courts through writ petitions.<sup>42</sup> A law that violates a Fundamental Right is void.<sup>43</sup> However, personal laws<sup>44</sup> cannot be challenged as violating Fundamental Rights.<sup>45</sup> An additional mechanism for redress of complaints is in the *Protection of Human Rights Act, 1993, which establishes the National Human Right Commission (NHRC)* which is empowered to conduct investigations and provide recommendations to the government to rectify violations. For example, in the case of silica TB the NHRC issued an investigative report and recommended that compensation be given to those affected.

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31 Article 19(2), (3), (4),(5) & (6), Constitution of India

32 Article 17, Constitution of India

33 Article 21, Constitution of India

34 Article 21A, Constitution of India

35 *State of Punjab and others v Ram Lubhaya Bagga* 1998 (4) SCC 117

36 *Kirloskar Brothers Ltd. v Employees' State Insurance Corporation* AIR 1996 SC 3261

37 *Vincent Panikulangara v Union of India and others* (1987) 2 SCC 165

38 *PB Khet Mazdoor Samiti v State of West Bengal* (1996) 4 SCC 37

39 *Novartis v Union of India and others* (2013) 6 SCC 1

40 *Swasthya Adhikar Manch and another v Ministry of Health and Family Welfare & others* Writ Petition (Civil) No. 33 of 2012

41 Article 32, Constitution of India

42 Articles 32 and 226, Constitution of India

43 Article 13, Constitution of India

44 Family relations in India are governed by personal laws based on their respective religion. So the personal law governs the laws in matters of marriage, divorce, succession, adoption, guardianship, maintenance and inheritance. They all share the similarity of women having less rights than men in corresponding situations.

45 *The State of Bombay v Narasu Appa Mali* AIR 1952 Bom 84

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. Right to Information (RTI) applications in the context of TB have been filed to obtain figures related to people with multi-drug resistant TB (MDR-TB) and death in one hospital in Delhi,<sup>46</sup> discrepancies in TB death information in the Brihanmumbai Municipal Corporation<sup>47</sup>, data on the number of TB cases in Telangana<sup>48</sup> and information on the agreement between the government of India and Janssen Pharmaceuticals for the supply of an MDR-TB drug.<sup>49</sup>

#### **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.<sup>50</sup> The estimates for India were revised in 2017 incorporating information from a wider range of sources including notifications from the private sector. (See table<sup>51</sup>) This followed a revision in the previous year by the WHO, which found that India had been under reporting cases for 15 years.<sup>52</sup> The figures for India are expected to undergo further revisions as the country prepares to conduct a national TB prevalence survey in 2018. India also has the world's highest burden of MDR-TB cases. The first National Drug Resistance Survey showed an overall MDR-TB rate of 6.19% with 2.84% among new and 11.60% among previously treated TB patients. Among MDR-TB patients, XDR-TB rate was 1.3%.<sup>53</sup> Treatment success for MDR-TB has been less than 50% and death rates high at 21%.<sup>54</sup> 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.<sup>55</sup>

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46 Kerry McBroom, *Litigation as a Tb rights strategy*, Health Hum Rights. 2016 Jun; 18(1): 69–84, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5070681/>

47 BMC's TB, malaria death figures inconsistent, RTI query reveals, The Hindu, 8 July 2016, available at <http://www.thehindu.com/news/cities/mumbai/news/BMC%E2%80%99s-TB-malaria-death-figures-inconsistent-RTI-query-reveals/article14476912.ece>

48 Lungs choked: Majority TB cases in Telangana from capital, Times of India, 25 February 2017, available at <https://timesofindia.indiatimes.com/city/hyderabad/lungs-choked-majority-tb-cases-in-telangana-from-capital/articleshow/57339235.cms>

49 Prashant Reddy, *RTI Replies Reveal the Deal between Janssen and the Ministry of Health on Bedaquiline*, 8 March 2018, available at <https://spicvip.com/2018/03/rti-replies-reveal-the-deal-between-janssen-and-the-ministry-of-health-on-bedaquiline-access-and-data-sharing-from-govt-run-clinical-trials.html>

50 Central TB Division, *TB India 2017: RNTCP Annual Status Report*, 2017, available at <https://tbcindia.gov.in/WriteReadData/TB%20India%202017.pdf>

51 Central TB Division, *India TB Report 2018: RNTCP Annual Status Report*, 2018, available at <https://tbcindia.gov.in/index1.php?lang=1&level=1&sublinkid=4160&lid=2807>

52 Vidya Krishnan, *India under-reported TB for 15 years: WHO*, The Hindu, 14 October 2016, available at <http://www.thehindu.com/sci-tech/health/India-under-reported-TB-for-15-years-WHO/article16070274.ece>

53 Ministry of Health and Family Welfare, *Report of the First National Anti-Tuberculosis Drug Resistance Survey India 2014-2016*, available at <https://tbcindia.gov.in/showfile.php?lid=3315>

54 Ibid.

55 WHO, *Global TB Report 2017* available at [http://www.who.int/tb/publications/global\\_report/MainText\\_13Nov2017.pdf?ua=1](http://www.who.int/tb/publications/global_report/MainText_13Nov2017.pdf?ua=1)

**Table: 2.1. Estimates of TB Burden in India and Global, 2016** (Source: *Global Tuberculosis Report 2017*)

Indicator	No.	No./Lakhs	Global Statistics
Incidence of TB (including HIV)	27, 90,000	211	1,04,00,000
Mortality due to TB (Excluding HIV)	4,23,000	32	13,00,000
Incidence of MDRTB/RR	1,47,000	11	6,01,000
Incidence of HIV-TB	87,000	6.6	10,30,000
Mortality due to HIV-TB co-morbidity	12,000	0.92	3,74,000

The Indian Government through the Ministry of Health and Family Welfare runs a vertical programme to address TB, which was originally known as the National TB Control Programme. In 1997 when the Revised National TB Control Programme (RNTCP) was launched, the government adopted WHO recommended DOTS as its main strategy. In 2006, the national programme expanded to cover the whole country and include services for HIV co-infection, MDR-TB and to cover the private sector. The previous National Strategic Plan adopted the aim of universal access to quality diagnosis and treatment including for drug-resistant TB (DR-TB). Since it started, the programme has reportedly treated more than 20 million people with TB.<sup>56</sup>

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. In 2017, the number of CBNAAT laboratories had increased to 651. MDR-TB diagnostic and treatment services, which started in 2007 are reported to have achieved complete coverage by 2013; till 2017, 1,78,170 persons with MDR-TB/ RR-TB were diagnosed of which 1,622,362 were put on treatment.<sup>57</sup> In 2016, bedaquiline was first made available at six sites and by end 2017, 900 patients had been initiated on a regimen containing this drug at 21 sites; rollout of bedaquiline is expected to increase considerably with RNTCP initiating the procurement of 10,000 courses of treatment. In 2017, the phased rollout of delamanid was also announced<sup>58</sup> and guidelines for the use of 400 courses of Delamanid through donation in 7 states have been issued. Single window delivery of HIV-TB services has been expanded to all

56 Central TB Division, TB India 2017: RNTCP Annual Status Report, 2017, available at <https://tbcindia.gov.in/WriteReadData/TB%20India%202017.pdf>

57 Central TB Division, India TB Report 2018: RNTCP Annual Status Report, 2018, available at <https://tbcindia.gov.in/index1.php?lang=1&level=1&sublinkid=4160&lid=2807>

58 New TB drug to be introduced in controlled manner: Health Min, Outlook India, 4 October 2017, available at <https://www.outlookindia.com/newscroll/new-tb-drug-to-be-introduced-in-controlled-manner-health-min/1160546>

antiretroviral therapy (ART) centres and 99DOTS (“Health for the 99%”<sup>59</sup>), an ICT-based treatment adherence system has been rolled out. In March 2016, the much-delayed daily TB treatment regimen replaced the intermittent regimen (three times a week), thanks to prodding from the judicial system; 30 October 2017 onwards, all patients diagnosed have been put on the daily regimen throughout the country.<sup>60</sup> 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.*”<sup>61</sup> 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.*” The four focus areas for the NSP are private sector engagement, plugging the leak from the TB care cascade, active TB case-finding among key populations (socially vulnerable and clinically high-risk) and specific protection for prevention from development of active TB in high-risk groups.<sup>62</sup> Detect, Treat, Prevent, Build are the four strategic pillars of the NSP. The WHO’s Global TB Report 2017 notes that India’s budget commitment on TB stood out in contrast to other countries; in 2017, the budget almost doubled from the previous year to USD 525 million. “*The budget is fully funded, including US\$387 million (74%) from domestic sources (triple the amount of US\$124 million in 2016) and the remainder (26%) from international donor sources.*”<sup>63</sup>

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59 <https://www.99dots.org/>

60 Central TB Division, India TB Report 2018: RNTCP Annual Status Report, 2018, available at <https://tbcindia.gov.in/index1.php?lang=1&level=1&sublinkid=4160&lid=2807>

61 Central TB Division, Revised National Tuberculosis Control Programme, National Strategic Plan For Tuberculosis Elimination, 2017–2025, March 2017, available at <https://www.tbfacts.org/wp-content/uploads/2018/01/NSP-Draft-2017-2025.pdf>

62 Ibid.

63 WHO, Global TB Report 2017 available at [http://www.who.int/tb/publications/global\\_report/MainText\\_13Nov2017.pdf?ua=1](http://www.who.int/tb/publications/global_report/MainText_13Nov2017.pdf?ua=1)

## 2. Methodology, Limitations & Structure

The methodology adopted for the assignment was based on the Stop TB Partnership and UNDP Legal Environment Assessment for TB: An Operational Guide<sup>64</sup> with modifications as required by constraints within which the LEA was undertaken. More specifically, limitations of the LEA included a restrictive time frame that did not permit far greater in-depth research on laws and their impact in various facets of people's lives that relate to TB. This included a limited ability to undertake key informant interviews, including of government functionaries engaged with the TB response, and members of communities understood to be vulnerable to TB. Larger consultative meetings with communities of people with TB and other stakeholders were also not possible.

Time constraints also confined the LEA to focus on a few vulnerable communities. Legal and policy issues related to people who used drugs, children, tribal populations, and miners require further research and analysis. Recommendations for areas of further research have also been made in the section on "People in Vulnerable Contexts". Some of the constraints also derive from the fact that the current impetus being given to the TB response is generating new policy and law in real time. For instance, at the time of submission of the first draft of the report, the Indian government had just issued a notification fixing criminal liability related to non-notification of TB. A subsequent update of the report was required to include an in-depth analysis of its impact. Despite these limitations, readers will find a thoroughly researched LEA on a vast majority 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, to obtain a foundational understanding and overview of the relevant legal and policy environment. This literature review and research took place throughout the period of the LEA. The review included an analysis of statutory law passed by Parliament, and relevant judgments of key courts in India that had decided on TB-related issues. Online legal databases such as 'Manupatra', 'SCCOnline', All India Reporter, and <https://indiankanoon.org/> were primarily used for the literature review of statutory and case law. As health is a state subject

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64 Available at [http://www.stoptb.org/assets/documents/communities/StopTB\\_TB%20LEA%20DRAFT\\_FINAL\\_Sept%202027.pdf](http://www.stoptb.org/assets/documents/communities/StopTB_TB%20LEA%20DRAFT_FINAL_Sept%202027.pdf)

under Schedule VII of the Indian Constitution, much health-related legislation is passed by state legislatures. As agreed with REACH, the LEA focused mainly on legislation in Maharashtra, given the limited time, TB burden on the state, and geographic convenience for the report writers. Time permitting, research and related analysis was undertaken of state laws in Tamil Nadu too.

- ii. *Interviews with key experts and stakeholders* were undertaken between December 2017 and February 2018, to gather information particularly where gaps existed, and to get better understandings of how law and policy affects ground realities in relation to TB specifically, and related healthcare more generally. This was done through individual meetings, either in person or telephonically and focus-group discussions organized through REACH or by the report authors, and based on informed consent indicated in writing in response to an information sheet and consent form, and questionnaires derived and adapted from the operational guide. 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. This analysis was informed by the literature review and research, and the interviews with key experts. The review and analysis of laws included the following:
  - Constitutional laws that establish Fundamental Rights and their protection;
  - Current legal and policy frameworks as they pertain to TB;
  - General laws related to delivery of health services relevant to TB (including prevention, care, support and treatment) provided through government and non-governmental mechanisms;
  - Laws covering and affecting key groups vulnerable to TB, including prisoners, women, mobile populations, people living with HIV, and sex workers;
  - Laws covering and affecting people with TB (including criminal laws, and civil laws, such as those impacting nutrition, alternative systems of medicine, and quackery);
  - Laws and policies related to non-discrimination, notification, isolation, informed consent and confidentiality affecting key groups and people with TB; and
  - Laws related to affordable and accessible TB treatment and diagnostics, including intellectual property laws, drug regulation, regulation of the private health sector, and insurance.
- iv. *Development of the LEA Report* as a final part of the assignment. The first draft of the report was submitted in March 2018. A final update of the report was done in June 2018 based on reviews received from experts and from a presentation of the report to the REACH team as well as to incorporate critical, contemporaneous changes in law and policy. The report follows the following structure: It begins with key legal-ethical issues comprising of sections on discrimination,

isolation, notification, consent, confidentiality, and criminal law. This is followed by key health sector issues comprising sections on the drug regulatory framework, regulation of the private sector, alternative systems of medicine, quackery, universal health coverage and insurance. Key issues of access are covered next, being access to treatment and diagnostics, and access to nutrition. Finally, the LEA covers people in vulnerable contexts, including TB in the workplace, and in prisons; issues related to people in other vulnerable contexts are only briefly raised and these require further in-depth research (mobile populations, women, people living with HIV, and sex workers). The conclusion highlights key cross-cutting issues and the way forward. Recommendations are included in every section but are also presented together at the beginning of the report for convenience. Due to the length of the report, a separate Executive Summary has also been prepared.

## II. LEGAL-ETHICAL ISSUES

1. **Countering Discrimination**
2. **Isolation**
3. **Notification**
4. **Consent**
5. **Confidentiality**
6. **Limiting Criminalisation**

# 1. Countering Discrimination

Social determinants of health are linked to the economic and social conditions people find themselves in while living and working, which in turn are shaped by the distribution of money, resources and power at macro and micro levels.<sup>65</sup> Many of these determinants are responsible for health inequities seen within and between countries.<sup>66</sup> Stigma is one such determinant, shaped by community norms, personal attitudes and institutional rules, and is directed towards a particular trait, or behaviour of an individual or a group that is labeled as undesirable and devalued.<sup>67</sup> Those who are stigmatized often internalize this undesirability and develop shame, guilt and disgust, resulting in concealing the trait, withdrawing from society or increasing the risky behaviour.<sup>68</sup> Stigma in TB has an adverse impact on the health and health seeking behaviour of people with TB. The fear of acquiring TB has been the leading cause of stigmatization of people with TB.<sup>69</sup> Lack of knowledge about transmission and prevention methods also contributes to this stigma. People with TB sometimes have self-perceptions of stigma, viewing themselves as a risk to others influenced by a number of social determinants.<sup>70</sup> TB-related stigma also includes perceived association with poverty and malnutrition. One of the direct consequences of stigma is ostracizing, abandonment and loss of employment for persons with TB. Stigma can be more devastating than the disease itself.<sup>71</sup> The social impact of TB for certain key populations, such as women, tribal, etc. prevents them from accessing health care in a timely manner, thereby having long term adverse consequences on their health.

Discrimination, also a social determinant of health, though linked to and sometimes used interchangeably with stigma, is different in the sense that discrimination actually excludes and brings about inequality. It occurs when, in comparison to other people in similar circumstances, a person is treated unfairly or unjustly for various reasons, including on grounds of their sex, race,

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65 WHO definition on social determinants of health, available at [http://www.who.int/social\\_determinants/sdh\\_definition/en/](http://www.who.int/social_determinants/sdh_definition/en/)

66 Ibid.

67 Courtwright, A and Turner, A.N, "*Tuberculosis and Stigmatization: Pathways and Interventions*", Practice Articles, Public Health Reports, 2010 Supplement 4, Volume 125, pages 34-42

68 Ibid.

69 Ibid.

70 Ibid.

71 Cousins, Sophie "*Women survivors of TB speak out against stigma in India*", News Deeply, Women and Girls, Health, March 23, 2017, available at <https://www.newsdeeply.com/womenandgirls/articles/2017/03/23/women-survivors-tb-speak-stigma-india>

gender, sexual orientation, gender identity, age, caste, religion, health status, etc.<sup>72</sup> Discrimination occurs in a direct form when people are outright rejected,<sup>73</sup> such as when people lose their jobs due to TB. Direct discrimination could occur when there are discriminatory laws and policies or there is intentional application of discriminatory practices of otherwise neutral laws and policies.<sup>74</sup> Structural discrimination is subtler,<sup>75</sup> in that, for example, the reason given for terminating the services of a person would not be stated directly as ‘due to TB’ but indirectly as ‘termination of service due to long periods of absenteeism’. Indirect discrimination may not be intentional or explicit, but has an impact that is discriminatory.<sup>76</sup> Persons with TB confront human rights violations when experiencing discrimination at work, in healthcare contexts, in education institutes, 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.<sup>77</sup>

Based on the foundational UDHR, which articulates the right to equality,<sup>78</sup> many international treaties make it incumbent on States to guarantee non-discrimination and equality. Article 26 of the ICCPR ensures all persons equality before the law and equal protection of the law without discrimination, on grounds such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status. The ICESCR states that everyone is entitled to the same rights without any discrimination.<sup>79</sup> Other international covenants also speak clearly about anti-discrimination.<sup>80</sup> As pointed out earlier, although India is signatory to these international treaties, and while constitutional courts in India occasionally do reference them in their judgments, international treaties are not recognized as law in India unless they are passed as such by an Act of Parliament.

## 1.1 The context in India – law, policy and jurisprudence

The NSP recognises that people with TB face stigma and states that TB policy will include, “non stigmatization for TB patients and families etc.” While the NSP notes the importance of stigma free interventions there is actually little programmatic attention in terms of dealing with stigma and discrimination.

The law can play a significant role in prohibiting discrimination and reducing the effect of stigma on people.<sup>81</sup> The law in India guarantees the right to equality and non-discrimination, thereby providing

72 Baral, S &ors., “Causes of stigma and discrimination associated with tuberculosis in Nepal: a qualitative study” BMC Public Health 2007, 7:211; doi:10.1186/1471-2458-7-211

73 Link, BG and Phelan, J C, “Stigma and its public health implications”, Lancet 2006: 367: 528-529, February 11, 2006.

74 Citro, Brian “Measuring structural stigma: Human rights and legal discrimination”, Chapter 6 in KNCV “TB Stigma Measurement Guidance”, December 2017

75 Link, BG and Phelan, J C, “Stigma and its public health implications”, Lancet 2006: 367: 528-529, February 11, 2006.

76 Citro, Brian “Measuring structural stigma: Human rights and legal discrimination”, Chapter 6 in KNCV “TB Stigma Measurement Guidance”, December 2017

77 *National Legal Services Authority v. Union of India* AIR 2014 SC 1863

78 See Articles 1, 2 and 7, *Universal Declaration of Human Rights*

79 Articles 2(2) and 3, *International Covenant on Civil and Political Rights*

80 See the *Convention on the Elimination of All forms of Discrimination Against Women*, the *International Convention on the Elimination of All forms of Racial Discrimination* and the *Convention on the Rights of the Child*.

81 Burriss, Scott “Stigma and the law”, Lancet 2006: 367: 529-31, February 11, 2006

protection against discrimination. However, this legal framework's ambit is inadequate and limited in preventing discrimination against people with TB.

Article 14 of the Indian Constitution guarantees the right to equality to all persons, including the equality of status and opportunity referred to in the Preamble of the Constitution. Article 15 prohibits discrimination on the basis of religion, race, caste, sex or place of birth. Further, it permits the State to make "special provision for the advancement of any socially and educationally backward classes of citizens..."<sup>82</sup> And, Article 16 guarantees equality of opportunity in matters of public employment, while Article 17 abolishes untouchability. The Constitution thus lays down provisions for both equality and affirmative action.<sup>83</sup>

The guarantee of equality also acts as a foil to arbitrariness of State action, and as an enabler of fairness.<sup>84</sup> As has been noted by the courts, non-arbitrariness is a necessary concomitant of the rule of law and an imperative component of every action of all public functionaries on behalf of the State for the public good.<sup>85</sup>

Notably too, the equality protection under Article 14 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. In the context of TB, discriminatory policies, employment rules, and arbitrary dismissal from work have been raised before Indian courts. Article 14 has protected people with TB in getting back their jobs, or in striking down arbitrary dismissal policies of State employers. But, as far as discriminatory practices of the private sector are concerned, there has been little redress.

The recent *Rights of Persons with Disabilities Act, 2016* (Disabilities Act) incorporates the principles of equality and non-discrimination and covers private sector discrimination in relation to persons with disabilities. TB does very often leave a person disabled, and to that extent this law can be seen as a step in the right direction in the context of TB. The *HIV and AIDS (Prevention and Control) Act, 2017* (HIV Act), prohibits discrimination against a person living with HIV including in employment, healthcare, education, housing, holding public office, insurance, etc. People living with HIV are susceptible to tuberculosis, and many of them are co-infected with TB. The HIV Act would come to the aid of people with TB to this extent. The relevant provisions of these two laws are highlighted below.

## Employment

People with pulmonary and extra-pulmonary TB have lost their jobs and faced discrimination from co-workers due to their health status, or due to long periods of absence from work, and have faced subtle discrimination in various forms. Most people with TB do not approach the courts to contest

82 Article 15(4), Constitution of India

83 *Andhra Pradesh Public Service Commission v Baloji Badhavath* (2009) 5 SCC 1

84 *Dr. S.K. Agarwal & ors. v The Principal and Chief Superintendent, S.N. Medical college and Hospital, Agra & ors.* AIR 1985 Allahabad 306

85 *Style (Dress Land) v Union Territory, Chandigarh* AIR 1999 SC 3678

the discrimination they face. Jurisprudence on the issue appears to be far less than the problem. The few court cases on the issue reveal the deep-rooted stigma attached to TB and the insensitivity and low level of knowledge about it that has adversely affected people with TB.

Unfortunately, the one Supreme Court decision that dealt with the question of whether a law related that provided for TB as disqualification for holding a position was arbitrary took a conservative approach to application of Article 14. Under the *Orissa Municipal Act, 1950*, persons who, inter alia, have leprosy or TB are disqualified from contesting or holding public office.<sup>86</sup> The Supreme Court noted that although these diseases could be cured with modern medicine, and that the legislature should re-think whether such a legal provision is to be retained, the classification to disqualify some people was not arbitrary and did not violate Article 14 of the Constitution, as the rationale was to prevent the spread of contagious disease.<sup>87</sup> Unfortunately, the Supreme Court did not take cognizance of the fact that TB becomes non-contagious after a few weeks of commencing treatment. It should be noted that the case dealt primarily with the situation of leprosy.

However, there have been far more progressive judgments delivered by the High Courts. For instance, the principles that should be applied to employees who may have a disease that could be transmitted, were followed in a landmark case related to HIV by the Bombay High Court. In this case, an HIV-positive employee who was found to be otherwise qualified for the job and did not pose a significant risk of transmission to others, was reinstated in the job with back wages.<sup>88</sup> The judgment relied on a US Supreme Court landmark decision where a school teacher was fired from her job solely because of relapse of TB disease. The US Supreme Court held that to allow the employer to discriminate by distinguishing between a disease's contagious effects on others and its physical effects on the patient would be unjustified, and contrary to the statute that ensures that disabled individuals are not denied jobs because of prejudice and ignorance of others.<sup>89</sup> It was held 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.<sup>90</sup> If found that there may be risk based on the above assessments, employers must then determine whether the employee can be reasonably accommodated to ensure continued employment and livelihood.<sup>91</sup> These principles have been incorporated in the HIV Act.

The high courts have also upheld equality and non-discrimination of employees with TB by invoking not just Article 14 of the Constitution but also the provisions of the *Disabilities Act*. The fitness of

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86 *Dhirendra Pandua v State of Orissa & ors.* AIR 2009 SC 163

87 *MX v ZY* AIR 1997 Bom 406

88 *Ibid.*

89 *School Board of Nassau County, Florida v Gene H. Arline* (1987 (94) Law Ed 2d 307)

90 *Ibid.*

91 *Ibid.*

a person with TB has been assessed to either continue the employment or to provide reasonable accommodation.

In a recent case, the Delhi High Court directed an airline to renew the contract of an airhostess who had Potts disease (tuberculosis in the spine) and was declared fit to work by the medical doctor.<sup>92</sup> The case brought forth issues typical of what persons with TB face at the workplace. The airhostess had taken leave as she was diagnosed with TB of the spine and required long term treatment. She informed the airline through emails requesting sick leave. However, the management, although aware of her illness, did not sanction leave, and later insisted that she was on unauthorized leave, and did not deserve renewal of contract.

The court held that the management's action was unfair and unreasonable, and the decision to deny renewal of the contract was arbitrary and revealed discrimination due to her illness.

The court relied on the US judgment of *School Board of Nassau County, Florida v. Gene H. Arline* and the *Disabilities Act*. Discrimination is defined under section 2(h) of the *Disabilities Act* as “any distinction, exclusion, restriction on the basis of disability which is the purpose or effect of impairing or nullifying the recognition, enjoyment or exercise on an equal basis with others of all human rights and fundamental freedoms in the political, economic, social, cultural, civil or any other field and includes all forms of discrimination and denial of reasonable accommodation...” Section 2(s) defines “person with disability” as someone with “long term physical, mental, intellectual or sensory impairment which, in interaction with barriers, hinders his full and effective participation in society equally with others.”

The court relied on this legislation, which applies to government and private establishments. The Delhi High Court held that even though the *Disabilities Act* came into effect after the grievance of the airhostess was raised, the airline was a government agency and therefore bound by Article 14 of the Constitution to reasonably accommodate the airhostess and ensure that her contract was renewed, without the period of illness coming in the way of consideration of her case. It noted that the refusal of the airline to renew her contract was an indirect method of getting rid of older employees, perhaps in favour of hiring younger personnel.

## Reasonable accommodation or compassionate allowance

In *Anand Bihari v Rajasthan State Road Corporation*<sup>93</sup> the court dealt with the issue of reasonable accommodation, where a large number of drivers were terminated from service due to a single medical disability, poor eyesight, which was attributable to their work. The court directed that before dispensing with the services of an employee on medical grounds an attempt must be made to find alternative employment to accommodate them, failing which additional compensation should be

<sup>92</sup> *Chitra Sharma v Airline Allied Services Lts. & anr.* MANU/DE/3475/2017

<sup>93</sup> AIR 1991 SC 1003

paid for the period of service remaining.<sup>94</sup> The principles of reasonable accommodation are well articulated in cases of HIV, wherein people living with HIV who do not pose a significant risk of transmission, can be reasonably accommodated in order to prevent economic hardship, particularly where they are unable to carry out their regular work.<sup>95</sup> This is also reflected in the HIV Act. The *Disabilities Act* also makes provision for “reasonable accommodation” as “*necessary and appropriate modifications and adjustments without imposing disproportionate or undue burden in a particular case, to ensure to persons with disabilities the enjoyment or exercise of rights equally with others*”.

Some people with TB experience debilitating effects from treatment. In such cases reasonable accommodation is an effective legal recourse for them. In Maharashtra, reasonable accommodation is provided to government employees with TB. The *Maharashtra Civil Services (Leave) Rules, 1981* makes a provision for such government employees, allowing them to resume duty on the basis of a fitness certificate, which recommends light work.<sup>96</sup>

In the past, Indian courts have not allowed challenges to implementation of government rules that were discriminatory against people with TB. For instance, in one case the government discontinued the services of an employee at 55 years of age as he had long-term TB.<sup>97</sup> A challenge to the discontinuation of his services was not entertained by the courts. In 2015, in a case of a police constable with TB who had taken intermittent leave on this account, the Supreme Court upheld the order of dismissal on the ground of misconduct in view of unauthorized absenteeism.<sup>98</sup> But in 2016, compassionate allowance was provided to people who were unable to work after getting TB. The Gujarat High Court, in a case of a constable who had worked in the state battalion for 10 years, directed he be given special consideration as he had TB and could not resume work, and held that he was entitled to compassionate allowance or pension, which was being denied to him.<sup>99</sup>

## **Leave with benefits**

There are provisions in central and state laws that provide leave and sickness benefits to people affected by TB. The *Central Civil Services Leave Rules* allow persons with TB to return to work based on a fitness certificate.<sup>100</sup> Rule 32 provides for 18 months leave to those employees who have completed one year of service, for pulmonary TB or pleurisy of tubercular origin or TB of any part of the body.

The *Employees State Insurance Act, 1948* (ESI Act) provides certain benefits to employees in case of sickness, maternity and employment injury, and ensures that an employee is not economically deprived and continues to get wages while sick. Workmen or employees covered under the *ESI Act* are paid and provided medical benefits that are extended to their families too, all of which are

94 *Anand Bihari v Rajasthan State Road Corporation* AIR 1991 SC 1003

95 *Simon Thwaites v Canadian Armed Forces* (1994) CLC 17040

96 Rule 26 (Note 1-A), *Maharashtra Civil Services (Leave) Rules, 1981*

97 *Sridhar Nigam v State* AIR 1966 All 560

98 *Rajinder Kumar v State of Haryana* AIR 2015 SC 3780

99 *Hitendrasinh Jadeja v Union of India* MANU/GJ/1162/2016

100 Rule 24, *Central Civil Services Leave Rules*

relevant in the context of TB. All employees in factories and establishments to which the *ESI Act* applies are insured, and the benefits extended to them are provided under section 46 of the Act. Sickness benefits, maternity, miscarriage, or sickness due to pregnancy benefits, and disablement benefits are provided on the certification by a duly appointed medical practitioner. Periodical payments to dependants in case of death of the employee, funeral benefits and medical benefits are also provided to family members. The *ESI Act* prohibits an employer from reducing the wages of any employee, except as provided in the regulations, or to discontinue or reduce benefits payable to an employee under the conditions of service. The employer also cannot dismiss or punish the employee during the period of sickness.

The government of Maharashtra has extended the benefits of the *ESI Act* to establishments where 20 or more persons are employed, and has included shops – departmental stores, super bazaars - financial institutions, chit fund companies, etc. where sale or service is rendered to a customer within its ambit. This also includes hotels, restaurants, cinemas, road motor transport establishments and newspaper establishments in Maharashtra.<sup>101</sup>

An example of beneficial social justice legislation that supports the health and wellbeing of government employees is the *Maharashtra Civil Services (Leave) Rules, 1981*. They provide for extraordinary leave in special circumstances to a government servant who has completed one year of continuous service, with 18 months leave where they are undergoing treatment for (i) pulmonary TB or pleurisy of tubercular origin in a recognized sanatorium or at their residence with certification by a specialist that they have a reasonable chance of recovery on the expiry of the leave recommended; (ii) TB of any part of the body certified by a qualified TB specialist or civil surgeon.

In one case, the Maharashtra Administrative Tribunal, Mumbai, District Thane, passed a judgment in favour of a woman head constable with MDR-TB by allowing a long period of leave (approximately 4.5 years) that was not sanctioned by her superiors and the Board that looks into such matters, (a period of two years leave was sanctioned earlier), and also directed that she be given all the service benefits due to her, as if there was no break in her service in the grant of her leave.<sup>102</sup>

Government employees and those working in factories and establishments covered under the Employee State Insurance Corporation (ESIC) who are affected by TB are able to get benefits under the *ESI Act*, as mentioned earlier. But employees not covered by ESIC and working in private companies are not able to avail of such benefits, becoming vulnerable to job loss, and having to fend for themselves.

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101 See [http://esicmaharashtra.gov.in/htmldocs/coverage\\_shops.htm](http://esicmaharashtra.gov.in/htmldocs/coverage_shops.htm)

102 *Mrs. Surekha Dattatraya Muluk v The State of Maharashtra & ors.*, Maharashtra Administrative Tribunal, Mumbai, at Thane, judgment dated 31.1.2017, in Original Appln No. 84 of 2016, available at [https://mat.maharashtra.gov.in/Site/Upload/Pdf/O.A.84%20of%202016%20\\_%20J%2031.1.2017.pdf](https://mat.maharashtra.gov.in/Site/Upload/Pdf/O.A.84%20of%202016%20_%20J%2031.1.2017.pdf)

## Equal pay for equal work

When a person gets TB, they may not only be deprived of benefits, promotions, and long leave, but may also be paid less, due to absence from work for health reasons. The gendered response to TB may also exacerbate discrimination at the workplace in terms of recruitment, promotions, and leave.

Discrimination has been experienced even by persons working to implement the RNTCP. For instance, the Health Visitor (TB) having the same qualifications as lab technicians and X-ray technicians were being paid a lower salary under the revised 6<sup>th</sup> Pay Commission.<sup>103</sup> The Patna High Court, and in a similar case the Jharkhand High Court, held that the pay scale fixed was discriminatory and directed the respective governments to pay the Health Visitor at par with the lab and X-ray technicians.<sup>104</sup> The Supreme Court has laid down the principle of “equal pay for equal work” in detail, wherein even temporary employees are entitled to draw wages at the minimum pay scale extended to regular employees, holding the same post.<sup>105</sup>

## Education

Every child has a right to education in India as per the Fundamental Rights guaranteed in the Constitution.<sup>106</sup> The *Right of Children to Free and Compulsory Education Act, 2009 (Right to Education Act)* also provides every child between 6 and 14 years a right to elementary school education. (Secondary and higher education is conditional upon economic capacity.) This law specifically provides that children from weaker sections and those belonging to disadvantaged groups are not to be discriminated against and prevented from pursuing elementary school on any grounds.<sup>107</sup> Yet, millions of children from disadvantaged communities are denied the right to education and are discriminated against. Sickness and disease, and consequent absenteeism is not specifically dealt with in the *Right to Education Act*, although in practice a student’s overall past performance may be considered for granting exemptions and promotions to the next class. This has a direct bearing on children with TB. Of note, persons with disabilities have a right to pursue free and compulsory education under the *Disabilities Act*. An expansive understanding of TB as being covered by the *Disabilities Act* can provide legal recourse to children experiencing discrimination due to TB. However, it is important to note that while the *Disabilities Act* mandates inclusive education for persons with disabilities, it fails to accommodate the needs of students who are unable to give examinations due to a disability, to be promoted based on their earlier performances. Some positive provision in the law and policy is required to prevent discrimination of students with TB in educational institutions.

Yet, there have been positive initiatives taken with regard to TB. For instance, in early 2016, the Maharashtra State Education Department took serious note of medical trainees and resident

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103 *Bihar Medical and Public Health v State of Bihar &ors.*, High Court of Patna, judgment dated 22.8.2014 in Civil Writ Jurisdiction Case No. 15856 of 2004; also see *Jharkhand Medical and Public Health v State of Jharkhand*, High Court of Jharkhand, judgment dated 27.7.2017, in W.P. (S). No. 3606 of 2015

104 *Ibid.*

105 *State of Punjab v Jagjit Singh*, in the Supreme Court of India, judgment passed on 26.10.2016 in Civil Appeal No. 213 of 2013

106 Article 21A, Constitution of India

107 Sections 8(c) and 9 (c), *Right to Education Act*

doctors with TB, and sanctioned 75 days leave on this basis.<sup>108</sup> In another instance, the Allahabad High Court ruled in favour of an educational institution that promoted a high performing student on humanitarian grounds as he could not appear for the final exams due to having TB.<sup>109</sup> The court held that other students who were ill and were unable appear for the final exams having to take supplementary exams to be promoted were not discriminatory nor did it display favouritism.<sup>110</sup>

There are State Children's Acts that do not allow refusals of admission based on serious illness.<sup>111</sup> In fact, some Acts list children as a vulnerable population that requires care and protection.

## Healthcare

The Constitution of India guarantees the right to life that includes the right to health and health care. The Disabilities Act makes it incumbent on all government and local authorities to provide free healthcare to such family income as maybe notified; and to provide barrier free access in government, private hospitals and other healthcare institutions and centres and to provide priority in attendance and treatment to persons with disabilities.<sup>112</sup> The HIV Act also has a redressal mechanism for complaints against discrimination. Both the Acts are newly enacted, and its case law has not yet been developed on the issue of discrimination in healthcare.

## Abandonment by family

Section 24(3)(b) of the *Disabilities Act*, which provides for social security measures for children who are disabled and have no family or abandoned or are without shelter or livelihood could provide legal recourse to some extent. However, schemes for adults and the elderly who are abandoned by their families due to a disease are lacking. Shelter homes and homes of the aged may be reluctant to take in a person with TB, due to the stigma and misinformation or ignorance about the disease and how its spread can be prevented.

Although personal laws provide people property rights, many may not have the means or the strength to claim their rightful share or to go back to their home, from where they have been removed. Others are not aware of their rights or are unaware of what action they can take in case they are abandoned or not maintained by their family.

For instance, parents, wives, and children have the right to be maintained under section 125 of the *Code of Criminal Procedure*. Personal laws such as the *Hindu Marriage Act*, the *Hindu Guardianship and Maintenance Act*, the *Special Marriage Act*, Muslim personal law, the *Muslim Women (Protection on Divorce) Act*, the *Parsi Marriage and Divorce Act*, and the *Indian Divorce Act*, entitle women to claim maintenance from their husbands for themselves and their children.<sup>113</sup> Abandoned persons can file suits to get maintenance for their sustenance by using these legal provisions.

108 See <https://medicaldialogues.in/maharashtra-doctors-entitled-to-tb-leave-now/>

109 *Deputy Shankar Rastogi v Principal S.M. College, Chandausi & anr.* AIR 1962 All 207

110 *Ibid.*

111 See *Goa Children's Act, 2003 with Rules, 2004*, available at <https://www.childlineindia.org.in/CP-CR-Downloads/Goa%20children%27s%20act%20and%20rules.pdf>

112 See section 25, *Disabilities Act* on health care

113 Discussed further in the section on Women in "People in Vulnerable Contexts"

Another law that can come to the aid of people abandoned in the context of TB is the *Maintenance and Welfare of Parents and Senior Citizens Act, 2007 (MWPSA Act)*, under which parents and senior citizens have the right to be maintained by their adult children and those senior citizens who do not have children have a right to be maintained by a relative who is in possession of their property or would inherit the property after the death of the senior citizen.<sup>114</sup> Maintenance includes provision for food, clothing, residence and medical attendance and treatment.<sup>115</sup> The *MWPSA Act* has constituted a tribunal to accept applications or complaints from parents and senior citizens abandoned by their children. In Maharashtra, the first such case was heard in 2012, where a senior citizen who was abandoned by his son sought not just maintenance but also alleged the forceful transfer of his property through a gift deed to render his will void.<sup>116</sup> There have been many such cases across the country, especially in states that have instituted the tribunal under the *MWPSA Act*. In a recent case that was appealed from the Pune Tribunal and Appellate Board, to the Bombay High Court, it was held that each of the two adult sons had to pay their parents a monthly maintenance of INR 2,000 (the tribunal can order maintenance up to an amount of INR 10,000 per month as maintenance).<sup>117</sup> The court also urged the government to spread more awareness about the *MWPSA Act*, which was not widely known to the citizenry.<sup>118</sup>

## 1.2 Experiences

Although TB related discrimination is seldom litigated, the interviews revealed that it is commonplace. Experts interviewed for this report acknowledged that discrimination at the workplace was an all too frequent occurrence: *“Discrimination takes place at the workplace for people with TB. People are afraid of getting TB, and so the one’s who have it are thrown out of their job. Many people drop out of their jobs as they are unable to work. The disease and medication drains them and they are weak. Once thrown out of the job, economic hardship issues arise.”*

This was confirmed by a TB survivor who stated that,

*“there is a lot of discrimination at the workplace and things are hushed up as people don’t want to lose their jobs. There is subtle discrimination by the co-workers, they will stop sitting next to the person with TB, they will start to mumble things, and isolate the person. At the workplace, people should not be fired, because they have TB. We need to stop being insensitive and start being sensitive towards patients with TB.”*

The private sector, unfortunately, does not consider long leaves as appropriate, and are generally quick in terminating the services of an employee with TB. As a consequence, an interviewee pointed out that, *“because people are afraid of losing their jobs, they hide their status from the employer and others at the workplace. This makes others vulnerable to the disease”*. A TB survivor conveyed their

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114 Section 4 read with Section 2(g), *Maintenance and Welfare of Parents and Senior Citizens Act, 2007*

115 Section 2(b), *Maintenance and Welfare of Parents and Senior Citizens Act, 2007*

116 Jayaraman, G, “A courtroom of (and for) grandparents”, Livemint, July 31, 2012, available at <http://www.livemint.com/Politics/zSvhxQX2OKCd8zpDluAU4L/A-courtroom-of-and-for-grandparents.html>

117 Section 9(2), *Maintenance and Welfare of Parents and Senior Citizens Act, 2007*

118 *Santosh Patil v Surendra Patil & ors.* Bombay High Court, Criminal Writ Petition No. 1791 of 2016, order dated 23.6.2017

frustration: *“In the private sector, if one has TB, they can be thrown out of the job. The person has no way to access social welfare schemes, as there are none for TB.”* An expert interviewed for this report stated emphatically that,

*“it is important that those with TB continue to get their full wages till the end of their treatment and are kept in the job, as economic support is required. They should not be given half wages, but be given their full wages.”*

Although there has been little, if any litigation on TB-related discrimination in educational settings, TB adversely affects students. They are unable to attend classes due to sickness or the stigma associated with wearing masks in school or college. As a consequence, students fail examinations, and this can adversely affect their mental health and economic prospects. A TB expert described the challenge as follows:

*“We are seeing young students of 10<sup>th</sup> to 12<sup>th</sup> standards getting TB – there is a propensity to get TB because of stress, attending classes from early morning to night in closed and not well-ventilated settings, and because of their hours, they do not take a proper diet. In air-conditioned places the transmission is higher.”*

Discrimination in healthcare settings was also reported and was a significant concern for several interviewees. Despite the existence of medication and preventive methods, rejection and discrimination against people with TB is seen even today within the healthcare system, in both the public and private sectors. As an interviewee pointed out, many private healthcare providers demonstrate their prejudice by asking patients to go elsewhere or stay away on finding out the person has TB. The TB hospital in Mumbai has many patients who have been rejected by other hospitals. There have also been instances where medical practitioners at government hospitals have treated patients with TB discriminatorily. For instance, an interviewee with experience working in hospital settings explained that discrimination occurred when a person with TB attempting to access the orthopedic department of a government hospital was told to stay away when his status became known to the staff. This was an experience repeated by other interviewees too. In some tertiary centres doctors avoid people with TB by passing on all care responsibilities to Class-IV employees. This creates an atmosphere where prejudicial behaviour infiltrates from down from the top of the healthcare hierarchy.

If stigma and discrimination in healthcare settings are not addressed urgently, their presence can discourage people from accessing healthcare services and may delay testing and treatment or interrupt it, causing drug resistance in the longer term. As one TB survivor said: *“The biggest problem is that the healthcare system is not an enabling environment. One issue is stigma, fueled by the attitude of healthcare workers. They can treat you bad, and get away with it. There is no mechanism to prevent it or for the patients to enforce their rights. There is a need to remove fear of TB.”*

While on the one hand, stigma and discrimination are fueled by healthcare workers, on the other

hand they are also at a great risk of acquiring TB. In public hospitals, with low resources and high workload, there are multiple issues that the staff face, which fuel discrimination and stigma.

An example is of the Sewri TB Hospital in Mumbai, Asia's largest TB hospital. Until 2015, the hospital was in the news for all the wrong reasons. It was reported that the hospital did not provide infection control methods, due to which as many as 65 hospital staff died between the years 2007-2011.<sup>119</sup> Overworked staff, especially Class IV workers, - cooks, sweepers, and cleaners - were acquiring TB, including MDR-TB, and some of them continued to work there even after this.<sup>120</sup> Apart from this there was acute staff shortage, and a shortage of N-95 masks. In 2015 the hospital workers went on strike, due to this dismal situation and because those who had contracted MDR-TB and extensively drug resistant TB (XDR-TB) were not given 24 months paid leave as approved by the Mumbai municipal corporation's standing committee in 2013.<sup>121</sup> With the media attention that the staff protests received, the situation radically improved - staff leave was approved, working conditions were enhanced, and an increased number of workers were hired to meet the demands placed on the hospital.

Most importantly, however, there has also been a change in the attitude and behaviour of the staff towards patients and their families, which has substantially reduced stigma and discrimination. The hospital now conducts staff sensitization, regular trainings, and provides staff support through regular check-ups and medication. A Patient Support Committee has been set up to regularly oversees patient needs, along with a grievance cell for addressing patient complaints.

Another issue that is faced with disturbing frequency at the Sewri TB hospital in Mumbai is abandonment of at least one body every week at the morgue.<sup>122</sup> Abandoned bodies of deceased persons pile up for more than a month dogged by red tape, which delays the final rites of the deceased. An acute shortage of morgue workers is fueled by people being unwilling to do such work due to the fear of contracting TB.<sup>123</sup>

The issue of abandonment is very serious in relation to TB. There is lack of awareness, little or no legal aid or knowledge of the options available for people abandoned by their families. Interviewees with extensive expertise in relation to TB affirmed that discrimination and ostracization continue to occur within families. Abandonment manifests in people with TB being dropped off at public hospitals by family members. Those familiar with public hospital settings confirm that in every ward

119 Siddique, Zeba, "Staff deaths at leading hospital put India's TB battle in spotlight", Reuters, October 12, 2015. Available at <https://in.reuters.com/article/sewrihospital-mumbai-tb-health-modi/staff-deaths-at-leading-hospital-put-indias-tb-battle-in-spotlight-id!NKCNOS603Y20151012>

120 Ibid.

121 Business Wire India, "Staff at Sewri hospital to go on strike on Thursday", Free Press Journal, October 28, 2015, available at <http://www.freepressj.co.in/mumbai/staff-at-sewri-tb-hospital-to-go-on-strike-on-thursday/693856>

122 Chakraborty, R, "Unclaimed bodies pile up at Sewri TB hospital", The Asian Age, March 18, 2016, available at <http://www.asian-age.com/mumbai/unclaimed-bodies-pile-sewri-tb-hospital-360>

123 Ibid.

there are one or two cases of such abandonment, where people have been left behind for over two years. Sometimes there is nowhere for them to go even after full recovery, because the slums they come from have been demolished and their families evicted without any trace. Non-governmental organizations (NGOs) providing shelter are also unwilling to take them due to the stigma associated with TB.

In a case from Sewri TB hospital, a 39-year-old lady was admitted by her son in 2014 for pulmonary TB. He visited her once and then abandoned her. She stopped communicating and went into depression after she realized she was abandoned, and remained bed-ridden at the hospital for three years.<sup>124</sup> An NGO, after getting her tested and ensuring that she does not have TB, took her to their shelter home. Police complaints to find the family have not succeeded in doing so. To counter abandonment, a Government Resolution in Maharashtra prevents adults who no longer require hospitalization to be discharged, without a relative present to ensure that the patient will be taken home safely.

Such abandonment also happens within marriages – a wife with TB is dumped at a public hospital, as are alcoholic husbands with TB. Sometimes women married to the latter leave the marriage. Homeless men with TB are also left at the public hospital.

The housing conditions of people, especially those living in slums and overcrowded settings are such that ventilation is poor, making it fertile ground for spread of TB. It was pointed out that discrimination within families takes place within such crowded homes, which is the living context of many urban Indians. It is often the elderly who face the brunt of exclusion by being sent away to the village or told to stay out of the house. In congested contexts,

*“the stigma of TB is so much that neighbours of people infected with TB do not treat them well, if they come to know of the TB status. Neighbours do come to know as they recognize when a person wears a mask, or is coughing constantly, or is losing weight, or when healthcare staff visits home at times – all this may add to the stigma. Patients sometimes refuse to allow people and the health visitor to come to their home.”*

### **1.3 Conclusions and Recommendations**

*“The motivating factors are where there is employer’s support, family support and good counselors; where there are not too many economic pressures and there is economic support.”*  
- from an informant interview on consequences of discrimination at the workplace

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

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<sup>124</sup> Barnagarwala, T, “NGO comes to the rescue of 39 year old TB patient abandoned by family in hospital 3 years ago” The Indian Express, September 18, 2017, available at <http://indianexpress.com/article/cities/mumbai/ngo-comes-to-rescue-of-39-year-old-tb-patient-abandoned-by-family-in-hospital-3-years-ago-4848492/>

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.<sup>125</sup>

Although there have been important decisions upholding the right to equality of persons with TB, there have also been decisions that are cause for concern. Anti-discrimination provisions are required in law to ensure that the right to equality for people with TB is applied uniformly. The difficulty with enforcement of law is that it mostly requires adjudication through an elusive, financially and otherwise draining court system, which is especially so for a person who is already unwell. The right to equality can, therefore, be just an empty promise in such an environment. A wholehearted commitment to equality may require more creative legal structures, including not just prohibitions of discriminatory behaviour but positive duties to promote equality, and systems that are easily accessible, affordable, and prompt.

Outside the legal system wholehearted efforts to inform the general public with non-stigmatizing, accurate information aimed at reducing discrimination and its far-reaching consequences on the health of people with TB is a vital concomitant.

## **Recommendations to Government (Central, State and Local bodies)**

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

- i) Identify, repeal and amend laws, policies, government resolutions, notifications that discriminate directly or indirectly against people with TB.
- j) 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.
- k) 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.
- l) Ensure that the law has provisions of reasonable accommodation and compassionate allowance.
- m) 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)***

- n) 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

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<sup>125</sup> Burris, Scott "Stigma and the law", Lancet 2006: 367: 529-31, February 11, 2006

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***

- o) 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.
- p) Build shelter homes and other facilities for people abandoned due to TB.
- q) 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.
- r) 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***

- s) 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.
- t) 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.
- u) 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.
- v) Encourage lawyers to be pro-active in giving legal advise, aid and litigation services to people affected by TB.
- w) 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.
- x) 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***

- y) Ensure that all persons with TB are provided complete and adequate treatment in a non-discriminatory manner.
- z) 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.
- aa) Ensure accountability of persons in healthcare settings who cause stigma and discrimination against persons with TB.
- ab) 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.
- ac) Ensure sufficient counselors in the healthcare setting to provide honest and complete knowledge relating to TB to patients and their relatives.
- ad) 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.
- ae) 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***

- af) Empower people with TB to eliminate TB-related stigma and discrimination. Provide complete, honest and adequate information about TB to reduce stigma and discrimination.
- ag) Provide legal literacy to people with TB, to know their rights and be able to access grievance redress mechanisms.
- ah) Liaise with government and private institutions that provide treatment or care to people with TB and provide services or information to people with TB.
- ai) Undertake projects or raise funds to provide shelter homes for people abandoned due to TB.
- aj) Help persons with TB access the justice system.
- ak) 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.
- al) Provide ancillary support where there is inadequacy in the healthcare system, such as human resources and skills development for counseling services.

## 2. Isolation

While mitigating the transmission of infectious diseases is an essential aspect of public health, law can support such aims by ensuring that powers, rights, roles and responsibilities of various stakeholders in these efforts are tailored by factoring in aspects such as the seriousness of the disease on mortality, and the ease and means of transmissibility. Sometimes legal responses to public health concerns allow interference with rights such as the freedom of movement, and the rights to autonomy and privacy. However, this interference is justifiable only if necessity requires such restrictions to be imposed for public good.<sup>126</sup>

Isolation is one such measure that is to be exercised with restraint in the case of infectious diseases, and only if alternative methods are ineffective, given the extreme manner in which it can snatch away the fundamental right to movement. Caution in exercising such a measure is also essential given that its imposition can be used abusively and discriminatorily. Courts have held that isolation should be a measure of last resort, based on the government demonstrating that it is necessary to prevent a significant risk of harm to others, and is the least restrictive choice in such cases.<sup>127</sup>

The WHO has laid down ethical principles that need to be built into legislation that restricts personal rights and freedoms in the context of public health.<sup>128</sup> In relation to isolation the WHO states that public health necessity requires coercive powers to be exercised only on the basis of a demonstrable threat to the public, and that the means used to curtail freedoms should be reasonable, effective, proportional, and transparent.

Also, in its Ethics Guidance for the implementation of the End TB Strategy, 2017, the WHO makes clear that in the context of TB, “*involuntary isolation must always be a last resort to be considered only after all else fails.*”<sup>129</sup> It adds that, “*isolation cannot be justified if other ways of protecting the public from infection exist, such as enrolment on effective treatment and use of masks.*”<sup>130</sup>

126 WHO, Advancing the right to health: the vital role of law, 2017, available at <http://apps.who.int/iris/bitstream/10665/252815/1/9789241511384-eng.pdf>

127 Parmet, Wendy E., Legal Power and Legal Rights — Isolation and Quarantine in the Case of Drug-Resistant Tuberculosis, available at <http://www.nejm.org/doi/full/10.1056/NEJMp078133>

128 WHO, Advancing the right to health: the vital role of law, 2017, available at <http://apps.who.int/iris/bitstream/10665/252815/1/9789241511384-eng.pdf>

129 WHO, Ethics Guidance for the implementation of the End TB Strategy, 2017, available at <http://apps.who.int/iris/bitstream/handle/10665/254820/9789241512114-eng.pdf;jsessionid=1EEE447A5B1A30D1B8CD6F8B5E2E85A6?sequence=1>

130 Ibid.

In this guidance on TB, the WHO goes on to state that isolation

*“is almost always voluntary. Involuntary isolation, except in narrowly defined circumstances... is unethical and infringes an individual’s rights to liberty of movement, freedom of association, and to be free from arbitrary detention.”*

Further, that

*“Isolation should never be implemented as a form of punishment. Patients who decline treatment and who pose a risk to others should be made aware in advance that their continued refusal may result in compulsory isolation.*

*Involuntary isolation should be limited to exceptional circumstances when an individual:*

- *is known to be contagious, refuses effective treatment, and all reasonable measures to ensure adherence have been attempted and proven unsuccessful; OR*
- *is known to be contagious, has agreed to ambulatory treatment, but lacks the capacity to institute infection control in the home, and refuses inpatient care; OR*
- *is highly likely to be contagious (based on laboratory evidence) but refuses to undergo assessment of his/her infectious status, while every effort is made to work with the patient to establish a treatment plan that meets his needs.”<sup>131</sup>*

As noted in the Introduction, the Siracusa Principles define the limits on government power to restrict civil rights that are largely reflected in the WHO ethics guidance. In the context of isolation, particularly in cases of MDR and XDR TB there has been some debate among scholars about the circumstances in which isolation could be justified using these principles. Some have argued that the Siracusa Principles would allow isolation as a last resort where for instance a person refuses treatment or even diagnosis.<sup>132</sup> Others have cautioned that principles that may be satisfied in theory may not be borne out by practice and that “details matter enormously.” They argue that with community-based treatment of MDR and XDR TB in several countries it is clear that “less-restrictive, proven, and internationally accepted treatment delivery alternatives” are available, begging the question of what situations would actually amount to “last resort.” Contrasting the experience in South Africa of incarcerating people with TB and the community based TB treatment in Lesotho, they find that “the so-called opposition between public health and human rights proves to be a red herring: public health goals of treating and preventing the transmission of TB and the human rights interests of individuals can be reconciled in most cases of drug-resistant TB. Only in exceptional cases, where patients resist treatment after all feasible programmatic solutions have been exhausted, should detention — with proper checks, balances, and safeguards — be considered.”<sup>133</sup>

This debate is squarely reflected in the recent decision of the Kenyan Constitutional Court striking down Kenya’s policy of incarcerating people with TB in prisons. While the Court found that there

<sup>131</sup> Ibid.

<sup>132</sup> See: <https://pdfs.semanticscholar.org/9eae/1419f1a596838dab8d444314d9dc980f9a29.pdf>

<sup>133</sup> See: <https://www.hhrjournal.org/2009/10/limitations-on-human-rights-in-the-context-of-drug-resistant-tuberculosis-a-reply-to-boggio-et-al/>

may be situations where isolation is warranted, the manner in which Kenyan authorities isolated people with TB in prisons for several months failed the constitutional guarantees of right to liberty and freedom of movement. Moreover, given the crowded conditions in Kenyan prisons the very purpose of the isolation stood defeated.<sup>134</sup>

Experience in South Africa in relation to TB in the early 2000s also suggests that isolation measures can be easily abused through methods resembling penal incarceration.<sup>135</sup> Often this is permitted by public health legislation that lacks safeguards to ensure that while some rights are curtailed while isolating people, other constitutional and human rights remain protected, through the assurance of dignity and the deployment of the least restrictive options.

## 2.1 The context in India – law, policy and jurisprudence

Article 19(1)(d) of the Indian Constitution guarantees the fundamental right of all citizens to “move freely throughout the territory of India”, while Article 19(5) permits the restriction of this right “in the interests of the general public”.<sup>136</sup> While restrictions on fundamental rights are permitted very exceptionally, public health strategies of isolation are one such instance. Yet, indicative of the approach that the Indian government has taken over the last decade, isolation finds no mention in key policy and programme documents of the RNTCP such as the NSP. However, law on the books does provide isolation as a public health strategy. The *Epidemic Diseases Act, 1897* is the national level legislation that is relevant in the context of isolation. Section 2 of the Act provides that if a state government is “*threatened with an outbreak of any dangerous epidemic disease*” which extant laws cannot adequately address, then it “*may take, or require or empower any person to take, such measures and, by public notice, prescribe such temporary regulations to be observed ... as it shall deem necessary to prevent the outbreak of such disease or the spread thereof...*” As pointed out in the section on “Notification”, the Act does not define “*dangerous epidemic disease*”. A plain reading suggests very wide powers, which could well include isolation. Other laws allowing isolation relate to travelers, such as the *Aircraft (Public Health) Rules 1954* issued under the *Aircraft Act 1934*.

The *Public Health (Prevention, Control and Management of Epidemics, Bio-Terrorism & Disasters) Bill, 2017* is the proposed legislative measure to replace the *Epidemic Diseases Act, 1897*. Yet, it fails to build in rights-based imperatives to implement public health measures in controlling spread of disease, as per international guidance such as the WHO’s *Guidance for Managing Ethical Issues in Infectious Disease Outbreaks, 2016*.<sup>137</sup> While recognizing that restrictions on movement may be required occasionally to control infectious disease, this guidance states that they should not be *implemented without several aspects being met. These include:*

- Demonstrating with the best evidence a justifiable basis for the necessity to impose restrictions
- Deploying the least restrictive means which curtail the right to movement

134 See: <http://www.kelinkenya.org/wp-content/uploads/2016/04/TB-is-not-a-Crime-Judgment-.pdf>

135 Baleta, A., Forced isolation of tuberculosis patients in South Africa, *The Lancet Infectious Diseases*, Volume 7, Issue 12, 771

136 Part III, Constitution of India

137 Available at <http://apps.who.int/iris/handle/10665/250580>.

- Ensuring that financial cost is not a justification to ignore least restrictive means
- Ensuring that humane conditions are provided when imposing restrictions
- Addressing the financial (e.g. loss of income) and social (e.g. ostracizing) consequences that can be the outcome of restrictions such as isolation
- Guaranteeing due process protections to challenge the restrictions promptly, and in any case without excessive delays
- Equitable application of the restrictions
- Communicating and acting transparently by engaging communities affected on how restrictions can be imposed with the least possible burden

State governments have specifically legislated on isolation. For instance, section 240 of the *Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965* provides for the “control and prevention of dangerous diseases”. As part of their duties to take measures for the prevention, treatment and control of disease, municipal councils are permitted to isolate persons with TB of lungs and intestines (included as a “dangerous disease”) if they believe that there is threat of an outbreak.<sup>138</sup> Although the *Mumbai Municipal Corporations Act, 1888*, does not provide strictly for isolation, section 424 states that the designated authority can remove any person “who is lodged in a building occupied by more than one family, and who is suffering from a dangerous disease, to any hospital or place at which patients suffering from the said disease are received for medical treatment.”<sup>139</sup> The Mumbai law does not define a “dangerous disease” to specifically include TB.<sup>140</sup> Contravention of the Maharashtra and Mumbai laws attract fines under section 246 and section 471 respectively.<sup>141</sup>

Section 54 of the *Tamil Nadu Public Health Act, 1939* requires municipal authorities to provide for isolation hospitals and wards for the reception and treatment of persons with infectious diseases.<sup>142</sup> Section 58 of this law is analogous to the aforementioned section 424 of the *Mumbai Municipal Corporations Act, 1888*.<sup>143</sup>

One other example to note, mainly because of the broad scope of isolation, is the *Goa, Daman and Diu Public Health Act, 1985*.<sup>144</sup> Section 49 provides for the maintenance of isolation hospitals, wards “and other places” by the local authority if so required for the reception and treatment of persons with infectious diseases, which includes pulmonary TB under section 47 of the law.

138 Section 240, *Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965*, available at <http://raigad.nic.in/PEN/pdf/mmcic.pdf>

139 Available at <http://bombayhighcourt.nic.in/libweb/acts/1888.03.pdf>

140 Under section 3(aa) of the Mumbai legislation, “dangerous disease means cholera and any endemic, epidemic, or infectious disease by which the life of man is endangered.”

141 Section 471, *Mumbai Municipal Corporations Act, 1888*

142 Available at <https://latestlaws.com/wp-content/uploads/2015/11/Tamil-Nadu-Public-Health-Act-1939.pdf>

143 The examples in this section are by way of illustration, since it was not possible to analyse all state-level public health-related legislation in India given the time constraints for this report.

144 Available at [goaprintingpress.gov.in/?media\\_dl=509](http://goaprintingpress.gov.in/?media_dl=509)

## 2.2 Experiences

What becomes clear from a reading of these municipal and public health legislations is the broad extent of limits imposed on quotidian aspects of life such as 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. This section focuses on isolation, while other sections refer to other limitations put on the fundamental rights of people (on privacy when health status notification is allowed dealt with in the sections on “Notification” and “Privacy & Confidentiality”; and on movement inability to travel, attend institutions etc. dealt with in the section on “Limiting Criminalisation”). Yet, notably these statutory provisions do not appear to have been used in the context of TB,<sup>145</sup> at least as reflected in reported judgments of the constitutional courts in India. Therefore, although such wide powers are vested with authorities under these laws how they are exercised is unclear, and suggest spare use. Many of these laws are either of the colonial era or at least half a century old. With advancements in science and medicine, and changes in urbanization and ways of habitation, it may be necessary to bring these laws up to date in order to reflect realities and be more appropriate to current times. For instance, as noted earlier per WHO guidance voluntary isolation should be the standard that is codified in law, with involuntary isolation stipulated as a last resort. And, if restrictive options such as isolation are thought to be required they should be implemented after ensuring several rights-based safeguards, as noted above.

Isolation appears not to have been used as a public health strategy, while TB is officially recognized as a public health concern. Interviewees felt that this is because it is thought not to be a fit strategy to deal with TB in India given other approaches that can enhance infection control, including early detection and treatment, occupational precautions such as masks and ultraviolet light, nutritional support, and health education on prevention including domestic hygiene measures that can be taken such as limiting contact with children, and proper air ventilation. Indeed, it was noted with some concern that wards in some hospitals are allocated for people with TB, as part of an infection control strategy. Another view was expressed that if assigning sections in a hospital for people with TB 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.

While some recognized that the idea of isolation gained currency in Mumbai when reports were published of a set of patients supposedly with TDR-TB in 2012, there was ambivalence about the use of isolation among interviewees, the broad view being that effective education and counseling on disease control and implementation of proven prevention strategies was the key to an effective TB response, while public health measures such as isolation should be available as mandated by law only as a last resort. Indeed, education measures must be painstakingly deployed at the family level, including at the patient’s house by public health workers.

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<sup>145</sup> Instructions and advisories related to quarantine and isolation of travelers have been issued by the Indian government at airports during global outbreaks of Zika and Ebola. Isolation and quarantine has been undertaken in cases of Ebola, Nipah and even HIV in the early days of the epidemic in India.

The initial reported response of government agencies to the “TDR TB” cases in Mumbai was to require isolation.<sup>146</sup> It was quickly realized that the beds in the TB hospitals in the city were full leading to a plan to shift the people with TB out of the city.<sup>147</sup> Almost immediately experts questioned this idea asking how the government would differentiate the situation from those with MDR or XDR-TB and how they would find the beds to accommodate all such patients.<sup>148</sup> Realizing that most of the people with TB were also income generators for their families, the government then said it would invest in counseling them.<sup>149</sup> Eventually the people with TB were not isolated as they were not acutely sick, chronic or bedridden and the government turned its attention to counseling, increasing the number of beds in the city’s TB hospitals and making TB notifiable.<sup>150</sup>

Interviewees also expressed that an effective TB control response also requires financial commitments such as investing in commodities like N-95 masks for people with TB, workers and family members. Practical concerns were also expressed in relation to isolation, including the logistical and financial challenges to equip the public health system with modern airborne transmission isolation facilities.

Some interviewees did opine that isolation may be justified in singular situations such as if a person with MDR-TB refuses to take their treatment. It was pointed out that in some jurisdictions, such as states in the US, 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. However, as WHO guidance instructs: *“Public health laws should authorize compulsory treatment only in circumstances where an individual is unable or unwilling to consent to treatment, and where their behaviour creates a significant risk of transmission of a serious disease. Compulsory treatment orders should restrict individual liberty only to the extent necessary to most effectively reduce risks to public health.”*<sup>151</sup> As noted above, these situations are likely to be few and far between.

## 2.3 Conclusion and Recommendations

Isolation, in a populous, high-density country where TB is endemic, will exacerbate and not arrest the spread of the disease. Therefore, it is important to use a rights-based, participatory and inclusive public health approach rather than an isolationist approach. Unlike the experience in a few other countries with a high burden of TB, it is heartening to note that the Indian government does not view the isolation of people with TB as an instrument of infection control. Still, the sheer scope of power vested in public authorities under various public health and municipal laws calls for a serious review and overhaul of these laws to reflect a modern, scientific and evidence-based State response to public health. To meet State obligations to take measures to prevent or minimize the transmission of TB, the risk factors for TB need to be identified within populations with high prevalence of TB,

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146 See <https://timesofindia.indiatimes.com/india/Drug-resistant-TB-patients-set-to-be-isolated-in-Maharashtra/article-show/11494463.cms>

147 See <https://www.pressreader.com/india/the-times-of-india-mumbai-edition/20120115/281621007206758>

148 Ibid.

149 See <https://timesofindia.indiatimes.com/city/mumbai/TDR-TB-patients-will-be-counselled-first/articleshow/11504404.cms>

150 See <https://www.hindustantimes.com/mumbai/surviving-9-patients-not-to-be-isolated/story-KgdXyXJ41F2gCYy5yVR1kK.html>

151 WHO, Advancing the right to health: the vital role of law, 2017, available at <http://apps.who.int/iris/bitstream/10665/252815/1/9789241511384-eng.pdf>

and steps need to be taken to reduce the risk factors. An example is overcrowded housing and low socio-economic status that may lead to spread of TB. The solution does not lie in isolating the person with TB, but in making structural changes to housing by providing proper ventilation, giving masks to persons in the household, and providing information on how to prevent TB within the home and as discussed in later sections, at the workplace.

## **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 healthcare providers to mandatorily report cases that they encounter to public health authorities, including details of the patient and their related information. In some countries, the burden of notification also falls on other actors such as employers. Notification is often justified on the grounds that it facilitates accurate determination of disease burden in a given geography, 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. It usually falls on treating physicians and diagnostic facilities to fulfill notification obligations by reporting cases to public health authorities. One study indicates that a majority of countries with a high incidence of TB (>70 per 100,000 population per year) where data was available had made the disease notifiable.<sup>152</sup>

In its most basic iteration notifiability of a disease entails the breach of confidentiality of a person’s health (TB) status and therefore a limitation of their fundamental right to privacy. Notification may also lead to further direct limits on rights and indirect consequences such as stigma and discrimination when notification leads to home visits from government TB workers or requirements to attend TB clinics etc. Given the curb on rights, notifying diseases must be considered and exercised with great caution. As discussed in the previous section on “Isolation” limiting fundamental rights in the context of public health cannot be done as a matter of course, but need to meet certain tests to be deemed justifiable: demonstrating necessity for the limits, using the least restrictive means, addressing economic and social consequences of the limits, assuring due process, and equitable application of restrictions. In the case of notification it means that details such as the manner of notification, the process for notification and the stated objectives be tested against these principles, including is notification provided for by law? Is it directed to a legitimate objective? Does evidence suggest that

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152 Uplekar et al, Mandatory tuberculosis case notification in high tuberculosis-incidence countries: policy and practice, European Respiratory Journal 2016, ERJ Express. Published on October 20, 2016 as doi: 10.1183/13993003.00956-2016

it is necessary? Are there less intrusive and restrictive measures? Does it satisfy the requirements of non-arbitrariness and non-discrimination?

### **3.1 The context in India – law, policy and jurisprudence**

India's NSP for TB 2017-2025 recognizes that, “[t]he overwhelming challenge facing TB control in India remains delayed diagnosis and inadequate treatment, particularly among patients seeking care from private providers, who alone are ill-equipped to sustain their patients on prolonged, costly treatment.”<sup>153</sup>

#### **Central Government Notifications**

##### **2012 Notification**

Given this reality, which was recognized by policymakers in years prior,<sup>154</sup> the MoHFW, Government of India issued an order in May 2012 mandating all healthcare providers to notify all TB cases that they treated or diagnosed to local health authorities, thereby making TB a notifiable disease. The order states:

*“TB continues to be a major public health concern accounting for substantial morbidity and mortality in the country. Early diagnosis and complete treatment of TB is the cornerstone of TB prevention and control strategy. Inappropriate diagnosis and irregular/ incomplete treatment with anti-TB drugs may contribute to complications, disease spread and emergence of Drug Resistant TB.*

*In order to ensure proper TB diagnosis and case management, reduce TB transmission and address the problems of emergence and spread of Drug-Resistant TB, it is essential to have complete information on all TB cases. Therefore, the healthcare providers shall notify every TB case to local authorities i.e. District Health Officer/ Chief Medical Officer of a district and Municipal health Officer of a Municipal Corporation/ Municipality every month in a given format (attached).”*

##### **2015 Notification**

Therefore, the intent of making TB notifiable was to obtain accurate information on its prevalence across public and private sector healthcare, and to get patients on to and keep them on treatment. An amendment to the order in 2015<sup>155</sup> stated thus:

*“Once private practitioner notifies TB patient information following actions will be taken by local public health staff of general health system of Government or local bodies and entered in Nikshay:*

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153 National Strategic Plan for Tuberculosis Elimination 2017-25, available at <https://tbcindia.gov.in/WriteReadData/NSP%20Draft%2020.02.2017%201.pdf>, at page 7.

154 Ibid.

155 Available at <https://tbcindia.gov.in/showfile.php?lid=3285>.

- Patient home visit as per convenience of patient,
- Counselling of TB patient and family members,
- Treatment adherence and follow up support ensure treatment completion,
- Contact tracing, symptoms screening, evaluation of TB symptomatic and offering INH chemo-prophylaxis to eligible contacts,
- Offering HIV testing, Drug Susceptibility Testing (DST), if eligible.”

This clarified the strategies the government felt were necessary to serve their original intent – to follow up with patients through home visits, counseling, treatment support, undertake contact tracing and offer further health checkups.

The government’s Guidance for TB Notification in India<sup>156</sup> further reveals its intent. It states that,

*“Tuberculosis is a major public health problem in India. Early diagnosis and complete treatment of TB is the cornerstone of TB prevention and control strategy...*

*...The country has a huge private sector and it is growing at enormous pace. Private sector predominates in health care and TB treatment. Extremely large quantities of anti-TB drugs are sold in the private sector. Non standardized prescribing practices among some of the private providers with inappropriate and inadequate regimens and unsupervised treatment continues without supporting patient for ensuring treatment adherence and completion... This frequently leads to treatment interruptions and subsequent drug resistance. Revised National TB Control Programme provides mechanisms to ensure treatment adherence support including Directly Observed Therapy (DOT). But a large number of patients are not benefitted with these programme services and leads to non-adherence, incomplete, inadequate treatment leading to M/XDR TB, mitigating all the efforts of the programme to prevent emergence and spread of drug resistance. If the TB patients diagnosed and treated under all sectors are reported to public health authorities, the mechanisms available under the programme can be extended to these patients to ensure treatment adherence and completion. The impending epidemic of M/XDR TB can only be prevented to a large extent by this intervention.*

*In order to ensure proper TB diagnosis and case management, reduce TB transmission and address the problems of emergence of spread of Drug Resistant-TB, it is essential to have complete information of all TB cases. Therefore, Govt of India declared Tuberculosis a notifiable disease on 7th May 2012. All public and private health providers shall notify TB cases diagnosed and/or treated by them to the nodal officers for TB notification.”*

The guidance further lays down “mechanisms for TB notification”, which include how patient information is to be transmitted – submission of a hard copy to the Nodal Officer by post, courier or hand; submission of a soft copy to the Nodal Officer by authorized email; submission to the

<sup>156</sup> Available at <https://tbcindia.gov.in/showfile.php?lid=3139>.

Nodal Officer using authorized mobile phone call, Interactive Voice Response System or SMS; or uploading information directly on the Nikshay portal <https://nikshay.gov.in>. The guidance further explains that in states, union territories or districts where there is a bilateral understanding between the health establishment and the local public health authority for convenient local TB notification, the information can be submitted to the local public health authority such as the Medical Officer of the Primary Health Centre (PHC) designated by the district nodal authority, after consultation with the concerned district Nodal Officer.

The information required to be shared while notifying a TB case includes the name, age and sex of the person, the government issued identity number (which could be a driving license or Aadhaar card), detailed address with pin code, phone number, basis of diagnosis (microbiologically/ clinically confirmed), whether the person is a new case or a recurring patient, the kind of TB, and any drug resistance the patient may have.<sup>157</sup>

Nowhere in the notifications or the guidance is any reference made to issues such as consent to testing, and methods to ensure confidentiality of health data and other personal information.

## 2018 Notification

Most recently, a related notification of the MoHFW places a duty on all healthcare providers and medical laboratories to notify the relevant public health authority of people with TB, and pharmacies, chemists and druggists dispensing anti-TB medication to do the same along with 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 so that support for complete treatment can be extended to them. It also requires that the confidentiality of the identity of the person with TB be maintained, although it is unclear how this is to be done, given the plethora of people who will be privy to such information – “...local Public Health Authority, namely, District Health Officer or Chief Medical Officer of a District and Municipal Health Officer of urban local bodies in whatever way they are known; or their designated District Tuberculosis Officers”, and “the Nodal Officer of the District or any Officer authorised by Nodal Officer”.

This notification has been issued in the context of an effort at increasing TB notification, which has not succeeded. In an effort to exert pressure on healthcare providers, diagnostic facilities and pharmacists to notify, the notification takes the unusual step of instituting potential penalties for failure to notify – Sections 269 and 270 of the Indian Penal Code (IPC) may be attracted, which impose jail terms of six months to two years for negligent or malignant acts likely to spread infection of life-threatening disease. Effectively, non-notification would tantamount to such negligent and malignant acts. This criminal liability also extends to “local public health staff of general health system of rural or urban local bodies” who do not make patient home visits, provide counseling to patients and family members, ensure treatment adherence, undertake contact tracing, offer

<sup>157</sup> Guidance for TB Notification in India, Ministry of Health & Family Welfare, available at <https://tbcindia.gov.in/showfile.php?lid=3139>.

HIV and drug susceptibility testing, and link with social welfare schemes. In effect, such public health functionaries, pharmacists, labs and physicians who do not notify TB cases or perform their expected duties are criminalized, a radical punitive approach the implications and effects of which need to be seriously considered. Apart from the efficacy of such an approach, it is worth considering whether tools already available in the law have at all been used to optimum effect in increasing TB notification by healthcare providers. These legal options – the *Clinical Establishments Act, 2010*, and the *Code of Medical Ethics Regulations 2002* are discussed later. Moreover, practical questions arise, including: what are the administrative burdens expected of pharmacies and labs to maintain and report medical records? What is the protocol by which a chemist is expected to maintain a person's prescription information in a confidential manner? How is information to be gleaned when it is not the ill patient who goes to the chemist with a prescription, but a relative? How are duplicate/triplicate notifications of the same person going to be reconciled?

In terms of the impact of law a vital question to ponder is whether such a punitive approach opens the door for a person with TB to be accused under Sections 269 or 270 of the *IPC* by a co-habiting relative or a co-worker? After all, if a doctor, lab or pharmacist can be booked under such a law, surely a person with a closer nexus to potential transmission of TB will be penalized too.<sup>158</sup> If people with TB are foisted with a criminal offence, it would hamper access to health services and would drive the disease underground, leading to an exponential spread of the disease, with no control. Indeed, how can this serve RNTCP's patient-centric public health approach to eliminate TB?

The FAQ which has been issued for the 2018 notification also reveals deeply worrying aspects to justify adoption of such an extreme, punitive approach.<sup>159</sup> For one, it suggests that the main benefit that a person with TB will gain from notification of TB status is not access to treatment but access to INR 500 for nutritional support. Moreover, notifiers (physicians and pharmacists) will benefit more than the patient – with a cash incentive of INR 1000 per patient.<sup>160</sup> Although the FAQ suffers from poor language, it appears that one of the main reasons behind the notification is to enroll people with TB in the Aadhaar scheme, which apart from being voluntary, hitherto ensures no data security system for enrollees. Indeed, the FAQ states that the “[m]ain objective of this gazettes (sic) is to ensure use of Aadhaar as identity document for delivery of services or benefits or subsidies...” The government has gone to great punitive lengths – criminalizing healthcare providers and pharmacists – in order to achieve the objectives of providing nutritional support to people with TB, financial incentives to health practitioners and pharmacists, and linkage to an identification scheme the validity of which is still under question in the Indian Supreme Court. The 2018 notification is confused in its objectives, unsound in its efficacy and overreaching in its attempt to inappropriately criminalize people involved in health delivery. As such, it fails in providing a coherent and rational basis for the public health strategy of notification, which is essential to justify interference with the fundamental right to privacy.

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158 Further discussion on the use of criminal law in addressing the spread of TB can be found in the section on Criminalization.

159 Available at <https://tbcindia.gov.in/showfile.php?lid=3323>

160 Annual India TB Report 2018, available at <https://tbcindia.gov.in/showfile.php?lid=3314>

Given that notifying a disease has serious ramifications on the exercise of the fundamental right to privacy, an assessment is necessary to determine whether it is succeeding in its avowed objective to identify people with TB and rapidly get them onto treatment and ensure effective disease management. There is little clarity on how information on TB status being collected through the notification process is being used. For instance, once a person is notified what are the mechanisms in place to ensure that treatment is offered, taken, adhered to and sustained? How is nutritional support being ensured? This information will reveal whether notification itself can be justified as a public health strategy despite encroaching on fundamental rights.

Notably also, it is 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. As mentioned below, the power to make a disease notifiable vests in the state government under the *Epidemic Diseases Act, 1897*, whereas the 2012 and pursuant notifications have been issued by the central government.

### **Public Health and Municipal Laws**

The apparent intent of the 2012 order making TB notifiable conveys that this was done in the best interests of people with TB – to enable a system that detects their TB status, and informs the public health authorities about it so that people can be provided with treatment options at the earliest. On the other hand, older legislation in India that addresses notification of disease, much of it colonial and archaic, was based on a paternalistic view of the state, which would control the subject individual and proscribe the individual's rights vis-à-vis public health. Punitive mindsets are not particularly surprising in such a view of the State's role. The national legislation that allows government to “take special measures and prescribe regulations” to deal with “dangerous epidemic diseases” is the *Epidemic Diseases Act, 1897*, just such an outdated law that needs an overhaul to meet current social realities.<sup>161</sup> Section 2 of the Act provides that if a state government is “threatened with an outbreak of any dangerous epidemic disease” which extant laws cannot adequately address, then it may take measures or prescribe regulations to be observed by the public to prevent the outbreak of the disease. Notably, this is a power vested in the state government and not the central government. Further, the Act does not define “dangerous epidemic disease”. Moreover, as it is a law that is meant to address outbreaks of disease, it is questionable whether it can at all apply to the context of an endemic disease such as TB in India.

The *Clinical Establishments Act, 2010 (CEA)* is another legislation that is relevant in the context of disease notification.<sup>162</sup> It applies in ten states and most union territories, and covers standards of care and services in public and private sector healthcare. This includes ensuring compliance with standard treatment guidelines issued by the government, including the Standards for TB Care in India.<sup>163</sup> These standards include notification of TB Cases. Non-compliance with these standards

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161 Rakesh PS, The Epidemic Diseases Act of 1897: public health relevance in the current scenario, Indian Journal of Medical Ethics Vol I No 3 July-September 2016

162 More details on this legislation are discussed in the section on “Regulation of the Private Sector”.

163 Available at <http://clinicalestablishments.gov.in/WriteReadData/93.pdf>

attracts penalties extending from INR 10,000 to INR 5,00,000.<sup>164</sup> In essence, non-compliance in notifying a case of TB by a clinical establishment already has consequences, making the 2018 notification questionable in as far as it applies to healthcare providers. Public health goals are better served in robust implementation of the CEA, instead of inappropriately ratcheting up penalties against healthcare providers under the IPC.

State and city governments have legislated in regard to notifying diseases, with some variations. For instance, section 237 of the *Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965* lists TB as a “dangerous disease”.<sup>165</sup> Section 241 places an obligation on medical practitioners, medical officers in charge of any hospital or dispensary, managers of factories, headmasters of schools, keepers of lodging houses and heads of households to inform the Chief Officer or Health Officer of the Municipal Council, if they are aware or suspect that a person has a dangerous disease. Other provisions impose a number of restrictions on persons who have a dangerous disease: section 238 empowers government authorities to prohibit the use of public transport by such persons, and section 239 prohibits them from exposing themselves to others without taking proper precautions. Section 246 penalizes contravention of all of the aforementioned provisions with a fine.<sup>166</sup> Similar provisions on notification, public transport and penal consequences are present in the *Mumbai Municipal Corporations Act, 1888*,<sup>167</sup> although this legislation does not define a “dangerous disease” to specifically include TB<sup>168</sup> and requires only a medical practitioner to inform government authorities of a case of dangerous disease.<sup>169</sup>

Section 56 of the *Madras Public Health Act, 1939* (which covers parts of the former Madras Presidency now in Kerala) foists an obligation on a medical practitioner to inform authorities of a case of TB that they have come to know of in “any private or public dwelling other than a public hospital”.<sup>170</sup> In another instance, section 56 of the *Tamil Nadu Public Health Act, 1939*<sup>171</sup> requires medical practitioners, including practitioners of traditional medicine (“hakims or vaidyas”) to report unreported incidence of TB to the respective authorities in municipal and non-municipal areas. An analogous provision (section 288) exists in the *Tamil Nadu District Municipalities Act, 1920*.<sup>172</sup> There are several such laws at the state level, some which were legislated during colonial rule, and amended to reflect post-independent reorganization of states.<sup>173</sup>

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164 Section, 40, *Clinical Establishments Act, 2010*

165 Section 237 mentions “Tuberculosis of the lungs and intestines”. Available at <http://raigad.nic.in/PEN/pdf/mmcic.pdf>

166 Available at <http://raigad.nic.in/PEN/pdf/mmcic.pdf>.

167 Sections 424, 428, 430 and 471, *Mumbai Municipal Corporations Act, 1888*, available at <http://bombayhighcourt.nic.in/libweb/acts/1888.03.pdf>

168 Under section 3(aa) of the Mumbai legislation, “dangerous disease means cholera and any endemic, epidemic, or infectious disease by which the life of man is endangered.”

169 Section 421, *Mumbai Municipal Corporations Act, 1888*

170 Available at [http://www.sanchitha.ikm.in/sites/default/files/MadrasPublicHealth\\_%20Act1939..pdf](http://www.sanchitha.ikm.in/sites/default/files/MadrasPublicHealth_%20Act1939..pdf)

171 Available at <http://latestlaws.in/wp-content/uploads/2015/11/Tamil-Nadu-Public-Health-Act-1939.pdf>

172 Available at <http://cma.tn.gov.in/cma/en-in/Downloads/The%20Tamil%20Nadu%20District%20Municipalities%20Act,%201920.pdf>.

173 The examples in this section are by way of illustration, since it was not possible to analyse all state-level public health legislation in India given the time constraints for this report.

TB notification legislation is being proposed in Maharashtra, a draft of which has gone through the law department and is expected to be tabled soon.<sup>174</sup> The draft Bill requires healthcare establishments to notify the appropriate authority within 30 days of diagnosing a person with TB or starting them on treatment. It further provides that non-compliance is punishable with fines, increased fines for recidivism, and finally recommendation of suspension to the concerned Medical Council.

The Medical Council of India is a statutory body that is meant to oversee standards of medical education and practice in India. It passed the *Code of Medical Ethics Regulations* in 2002,<sup>175</sup> which prescribe duties of physicians, including notification of “every case of communicable disease under his care” if required by law, (Regulation 5.2), maintenance of confidentiality (Regulation 2.2) of patient information “unless their revelation is required by the laws of the State”, and prohibition from disclosing “secrets of a patient” while rendering professional services unless it is to do with reporting notifiable diseases (Regulation 7.14). Moreover, the regulations prescribe that violations of these and other provisions would amount to professional misconduct, which are to be complained of before the appropriate medical council for disciplinary action, including fine, suspension or removal from practice (Regulation 8.2). Clearly, the regulations identify possible failures to notify and provide a mechanism for remedies, making the punishment meted out in the 2018 notification unnecessary, apart from being inappropriate.

### 3.2 Experiences

Since TB has become notifiable under the government order of 2012, there has been some analysis and experience about the effect of notification. The Indian government’s Annual TB Report 2018 notes that TB notification has steadily increased since the start of the RNTCP. When RNTCP reached complete geographical coverage in 2006 the annual TB notification rate increased to 130 per 100,000. In 2017, the total TB notification rate was 138 per 100,000 people. The Annual TB report 2017 notes that between notifiability in 2012 and end 2016 more than 113,961 private sector health care establishments (including private practitioners, clinics, hospitals, nursing homes and laboratories) have been registered under Nikshay, with approximately 15,000 facilities being registered every year. It adds that strategies to engage the private sector in notifying cases have been implemented in some locations (Patna, Mehsana, Mumbai and Nagpur), and have included offering ICT support, free TB drugs for notified patients, and extending treatment adherence support services for patients from the private sector. This has witnessed total TB case notification rates increasing 1.5-4 -fold.<sup>176</sup>

A study undertaken among private healthcare providers in Mysore city in 2014, two years after TB was notified, found low uptake of Nikshay – only 15.5% were registered on the portal, and of these only 29% had used it to report. Some of the reasons for not registering or notifying included suspicion of the motive behind notification, and worries of losing patients and breaching patient

174 On file with the report writers

175 Available at <https://www.mciindia.org/CMS/rules-regulations/code-of-medical-ethics-regulations-2002>

176 Annual TB Report 2017, Central TB Division, Ministry of Health & Family Welfare, available at <https://www.tbcindia.gov.in/WriteReadData/TB%20India%202017.pdf>

confidentiality. Providers felt that they would be enabled to adhere to notification requirements if they were able to provide free treatment to patients, be trained in notification objectives and processes, and penalized on failure to notify.<sup>177</sup> Some of these issues were also raised by a study in Alappuzha, Kerala.<sup>178</sup>

Some of these concerns (e.g. penalties for non-reporting, and patient information confidentiality) are envisaged by initiatives such as the Maharashtra TB Notification Bill, others (such as provider education and training, and linking private providers with free treatment) are programmatic aspects that need human resource and financial investment.

Informant interviews elicited the general view that making TB notifiable is a useful first step, but meaningless if not backed up with effective and ethical implementation. For instance, in Chhattisgarh all laboratory reports were noted in a register with the state TB programme manager, and on diagnosis or commencement of treatment the Nikshay form was filled up and submitted online to the state government authority. However, it was unclear how the state government was storing the TB test data, including whether patient information was being confidentially maintained through a systematic storage method. TB reports were being linked to the Aadhaar scheme presumably for patients to avail of benefits (e.g. direct benefit transfers, and nutritional support). Yet, how this linkage ensured patient confidentiality was unclear. It was felt that the benefits of notification should be fully realized, including linking the patient to social security schemes such as nutritional support and insurance. Private sector challenges were shared in following notification through Nikshay, including the time-consuming nature of filling up the lengthy form, the lack of human resources for sole practitioner physicians without staff support to undertake such a task, and a general resistance to being regulated as a sector. Another experience of working in HIV prevention and treatment in Maharashtra revealed that information on a person's TB status was only known to the concerned HIV intervention staff and the concerned person in the TB department to whom it is notified. Monthly coordination meetings between these personnel ensure that the staff knows its roles and responsibilities with such information, thereby mitigating the chance of confidentiality of a person's status being breached. It was also pointed out that a past challenge in the notification system of public health officials visiting patients' homes to get them into public sector treatment created fear among patients, which has now ceased to occur.

With notification from the private sector in the last three years having doubled year on year – from 40-50,000 to 100,000 and touching 400,000 in 2017-18, a view was shared that notification has been beneficial to some extent, although it could be more so if properly enforced with incentives to providers for abiding and penal consequences for not notifying.

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177 Singh Chadha et al. Mandatory TB notification in Mysore city, India: Have we heard the private practitioner's plea? *BMC Health Services Research* (2017) 17:1 DOI 10.1186/s12913-016-1943-z

178 Philip S et al. "They Know, They Agree, but They Don't Do": the paradox of tuberculosis case notification by private practitioners in Alappuzha District, Kerala, India. *PLoS One* 2015; 10: e0123286.

### 3.3 Conclusion and Recommendations

Notification of infectious diseases like TB can potentially help in strengthening the health system to reach out to those with TB who are unable to get treatment. It can prove to be useful if the data collected through notification is analysed to understand not just the prevalence, but also the combination of medicines that people with TB are taking, whether they have completed their treatment regimen, the number of people with TB co-infections, the number of children on TB treatment, and can also help in reaching out to those who have dropped out of treatment. Although notification of TB has been made compulsory, severe under-reporting remains. The reasons for this need to be reflected, backed by the government providing education, training and incentives to all those involved in the diagnosis and treatment of TB.

Further, any notification that gathers personal and private data of individuals must ensure that confidentiality and privacy norms are devised and maintained and that notification is not undertaken through the breach of these rights. The data ought to be used for the benefit of public health, and in identifying gender and other inequities in TB testing and treatment, while respecting the rights of people with TB. If the data is not being used appropriately, notification will remain only a statistics-gathering tool that would not justify rights intrusions.

#### 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.
- c) 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.
- d) 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.
- e) 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 Diu Public*

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

- f) 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)***

- g) 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.
- h) Notification data collected through Nikshay should be stored, with stringent, foolproof confidentiality protocols to be followed.
- i) 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.
- j) 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***

- k) 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.
- l) Provide comprehensive information to the patient under the legal mandate that requires medical professionals to notify TB.
- m) 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.
- n) 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. 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. Taking consent also serves to legally protect a healthcare provider from accusations of assault or battery on a person were the same to be made, although it does not protect against negligent actions. The principle of autonomy posits that a competent person has the right to all the information required for that 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. The essence of consent in relation to healthcare contexts has been expressed thus: *“Every human being of adult years and sound mind has the right to determine what should be done with his own body; and a surgeon who performs an operation without the patient's consent commits an assault.”*<sup>179</sup>

In relationships between healthcare providers and patients, the principle of consent is identified as a key factor contributing to balancing the otherwise unequal relationship between the two parties. The healthcare provider is armed with knowledge and training, and is reposed with the trust of the patient. Informed consent about a test or treatment provides patients with sufficient knowledge to make an autonomous decision of whether to undergo a test, treatment or medical procedure, or whether to refuse it. Ensuring that consent is informed is the duty of the healthcare provider. Consent must be given voluntarily i.e. without coercion, undue influence or misrepresentation. A person's ability to consent to a medical procedure is dependent on their legal capacity. For adults of sound mind, legal capacity is presumed while proxy consent from a guardian or next friend or a healthcare provider is required for persons living with mental illness, in cases of emergency (as part of the doctrine of necessity) or in the case of minors. Medical procedures, including testing and provision of treatment without the consent of a person may only be allowed in exceptional situations, such as in an emergency where necessity to save the life of the person would protect the medical professional, or if it is so required by a statute, or by an order of a court to decide issues before it, or to prevent diseases.<sup>180</sup>

179 *Schloendorff v Society of New York Hospital* (1914) 103 NE 92

180 Consent, *Legislating an Epidemic*, Lawyers Collective HIV/AIDS Unit, Universal Law Publishing Co. Pvt. Ltd., 2003

Although making a disease notifiable, as is the case with TB, places the response to it within an exceptional realm in some ways, ethics and human rights related to healthcare still remain intact 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. In its Ethics Guidance for Implementation of the End TB Strategy, the WHO states that,

*“[f]or TB testing, there is usually no need for a specific process of confirming the patient’s agreement, as the consent to go through necessary diagnostic testing is an implicit agreement to undergo a medical examination.”*

It notes an exception in cases where drug susceptibility testing is offered when DR-TB treatment is unavailable, since implicit consent to testing *“is premised on the assumption that treatment will be offered.”*<sup>181</sup>

On consent for TB treatment the guidance states that,

*“When patients are offered treatment for TB, for either latent TB infection or active disease, they should be informed about and asked for their specific consent, just as they would be for any other significant medical interventions. Unlike testing, patients’ consent to TB treatment cannot be inferred from the mere fact that they have decided to undergo a medical examination.”*<sup>182</sup>

Therefore, according to the WHO, while consent is implied for a TB test when a person seeks diagnosis, specific consent is necessary when TB treatment is offered.

In relation to empowering a person with information, the WHO, in its Guidance for Managing Ethical Issues in Infectious Disease Outbreaks, advises that those offered diagnostics or treatment for an infectious disease outbreak *“should be informed about the risks, benefits, and alternatives, just as they would be for other significant medical interventions. The presumption should be that the final decision about which medical interventions to accept, if any, belongs to the patient.”*<sup>183</sup>

Notably, this guidance adds:

*“In exceptional situations, there may be legitimate reasons to override an individual’s refusal of a diagnostic, therapeutic, or preventive measure that has proven to be safe and effective and is part of the accepted medical standard of care.”*

Decisions to override such a refusal should be based on, inter alia:

*“Public health necessity of the proposed intervention – a mentally competent individual’s refusal of diagnostic, therapeutic, or preventive measures should only be overridden when there is substantial reason to believe that accepting the refusal would pose significant risks to public*

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181 WHO, Ethics Guidance for Implementation of the End TB Strategy, 2017

182 Ibid.

183 WHO, Guidance for Managing Ethical Issues in Infectious Disease Outbreaks, 2016, available at <http://apps.who.int/iris/handle/10665/250580>

*health, that the intervention is likely to ameliorate those risks, and that no other measures to protect public health — including isolating the patient — are feasible under the circumstances.”*

The guidance also adds:

*“Assessing the importance of universal participation — Public health surveillance is typically conducted on a mandatory basis, without the possibility of individual refusal. Collecting surveillance information on a mandatory basis is ethically appropriate on the grounds of public interest if an accountable governmental authority has determined that universal participation is necessary to achieve compelling public health objectives.*

*Regardless of whether individuals are given the choice to opt out of surveillance activities, the process of surveillance should be conducted on a transparent basis. At a minimum, individuals and communities should be aware of the type of information that will be gathered about them, the purposes for which this information will be used, and any circumstances under which the information collected may be shared with third parties.”*

#### **4.1 The context in India – law, policy and jurisprudence**

Autonomy is contained within the meaning of the right to life and personal liberty under Article 21 of the Indian Constitution. “Personal liberty” is considered to be of the widest amplitude and covers a wide variety of rights.<sup>184</sup>

The Supreme Court of India has also emphasized the paramount nature of consent in healthcare contexts:

*“What is relevant and of importance is the inviolable nature of the patient’s right in regard to his body and his right to decide whether he should undergo the particular treatment or surgery or not. Therefore ...unless the unauthorized additional or further procedure is necessary in order to save the life or preserve the health of the patient and it would be unreasonable (as contrasted from being merely inconvenient) to delay the further procedure until the patient regains consciousness and takes a decision, a doctor cannot perform such procedure without the consent of the patient.”<sup>185</sup>*

The notion of consent is at the core of civil laws such as the *Indian Contract Act, 1872*, which stipulates that contracts are valid only if made with the free consent of the parties,<sup>186</sup> and consent is understood to mean when two or more persons “agree upon the same thing in the same sense.”<sup>187</sup>

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184 Maneka Gandhi v Union of India AIR 1978 SC 597

185 Samira Kohli v Dr. Prabha Manchanda & Anr (2008) 2 SCC 1

186 Section 10, *Indian Contract Act, 1872*

187 Section 13, *Indian Contract Act, 1872*

Autonomy is also reflected in health-related Indian laws, most recently in the *HIV Act*, which provides for informed consent.<sup>188</sup> Section 5 of the legislation states that an HIV test cannot be performed on any person, and no person living with HIV shall be subject to medical treatment except with that person's informed consent. Further, informed consent for an HIV test includes pre-test and post-test counseling. The *Mental Healthcare Act, 2017* also reflects the principle of autonomy. Section 86(5) states that a "*patient shall not be given treatment without his informed consent.*"<sup>189</sup> The Medical Council of India's *Code of Medical Ethics Regulations, 2002*,<sup>190</sup> prescribe that consent is required to be taken in writing before a healthcare provider performs an operation.<sup>191</sup>

The *Public Health (Prevention, Control and Management of Epidemics, Bio-Terrorism & Disasters) Bill, 2017*, has been proposed to provide "*for the prevention, control and management of epidemics, public health consequences of disasters, acts of bio terrorism or threats thereof...*" and related matters. In its non-prescription of standards of consent in public health matters it has failed to recognize the fundamental right to privacy as manifest in autonomy and bodily integrity of the individual. In failing to do so it has ignored the lessons of the HIV response, which demonstrated that informed consent was also a vital public health tool through which counseling and information could be provided and empowerment and responsibility nurtured to aid public health.

Provisions within state law do exist, which restrict the right of consent for testing in the case of infectious diseases. For instance, under the *Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965* the municipal council where an outbreak of a dangerous disease is declared, has the power to direct a medical officer to examine any person, and such is required to "*give his name and address and present himself daily for a medical examination at such times and places as may be prescribed, for a period not exceeding ten days.*"<sup>192</sup> A similar provision is contained in the *Tamil Nadu Public Health Act, 1939*.<sup>193</sup>

Testing for TB, it can be argued, may be differentiated from the aforementioned contexts of HIV, mental health or operative situations since it is an airborne infectious disease, although it does carry stigma similar to mental illnesses and HIV. Yet, the centrality of the fundamental right to privacy, which includes autonomy and bodily integrity are not diminished due to the nature of one's health condition. As mentioned above, WHO guidance advises that consent needs to be taken from those being subject to TB testing (implied) and treatment (specific) along with thorough factual information about the risks, benefits, and alternatives available to them. There are practical benefits that can accrue to public health efforts if testing for TB is accompanied with consent and comprehensive

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188 Section 5, *HIV Act, 2017* available at <http://naco.gov.in/sites/default/files/HIV%20AIDS%20Act.pdf>

189 *Mental Healthcare Act, 2017* available at <http://www.prsindia.org/uploads/media/Mental%20Health/Mental%20Health-care%20Act,%202017.pdf>.

190 Available at <https://www.mciindia.org/CMS/rules-regulations/code-of-medical-ethics-regulations-2002>

191 Regulation 7.16 available at <https://www.mciindia.org/CMS/rules-regulations/code-of-medical-ethics-regulations-2002>

192 Section 245, *Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965*, available at <http://raigad.nic.in/PEN/pdf/mmcic.pdf>

193 Section 76, *Tamil Nadu Public Health Act, 1939*, available at <https://latestlaws.com/wp-content/uploads/2015/11/Tamil-Nadu-Public-Health-Act-1939.pdf>

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.<sup>194</sup>

Consent as a legal or ethical notion finds scarce mention in the policy, planning and programmatic documents of the RNTCP. This could be attributable to the fact that apart from recognition in the *HIV Act* and the HIV response more generally, consent is not respected as an ethic or human rights issue that should be a part of the standard of care. Indeed, one interviewee pointed out that in their experience the same physician when functioning in the context of HIV will follow a consent protocol, but when not dealing with an HIV case, does not think it important to take consent. Yet, the Guidelines for Programmatic Management of Drug-resistant TB (PMDT) in India 2017<sup>195</sup> refers to the right of a patient to consent to treatment for DR-TB, due to the toxicity of the medications involved. This begs the question – can patients exercise their autonomy by refusing to take medication for pulmonary TB? And, why do protocols for pulmonary TB treatment not stipulate the need to take consent, as do the PMDT Guidelines? Indeed, as the HIV response has taught us, counseling can play a crucial role in getting people on to treatment, and choosing not to after making an informed decision.

The vital need for consent as part of a public health response to disease control is ignored in the Active Case Finding (ACF) methodology – “*a provider initiated activity with the primary objective of detecting TB cases early by active case finding in targeted groups and to initiate treatment promptly*” as prescribed in the Active TB Case Finding Guidance Document of the RNTCP.<sup>196</sup> This guidance prescribes sputum smear microscopy to be done for all symptomatic persons, who “*will be initiated on treatment within 2 days*” if they are sputum positive. Further, case finding teams are incentivized – they provide “*...Rs 500/- for every new case of TB diagnosed and put on treatment under this activity*”. This guidance suggests that consent to testing or treatment has very little, if any role to play in the ACF initiative. And, even if it does, would the aforementioned incentive have the effect of de-prioritizing it in the eyes of the case finding team or concerned healthcare provider? Issues of confidentiality in ACF are discussed in the section on “Privacy & Confidentiality”. Yet, given the paramount nature of fundamental rights many concerns are self-evident in the ACF Guidance Document. For one, in essentially ignoring the need to take consent it reveals a methodology that is disrespectful of autonomy and physical integrity of the person. It envisages a coercive approach in ‘finding cases’, without any consideration for the impact such an approach can have in fueling fear and distrust of the public health system and fueling stigma against people with TB. Instead, voluntariness and free, informed consent – for testing and treatment – should be encouraged in ACF

194 National Strategic Plan for Tuberculosis Elimination 2017-25, available at <https://tbcindia.gov.in/WriteReadData/NSP%20Draft%2020.02.2017%201.pdf>, chapter 11

195 Available at <https://tbcindia.gov.in/index1.php?lang=1&level=2&sublinkid=4780&lid=3306>

196 Available at <https://tbcindia.gov.in/index1.php?sublinkid=4754&level=3&lid=3290&lang=1>

techniques in order to instill confidence in the system and encourage health-seeking behaviour.

Indeed, the Patients' Charter for Tuberculosis Care lists the right to information as critical to an effective TB response, including:

*“- The right to information about what healthcare services are available for tuberculosis and what responsibilities, engagements, and direct or indirect costs are involved*

- *The right to receive a timely, concise, and clear description of the medical condition, with diagnosis, prognosis (an opinion as to the likely future course of the illness), and treatment proposed, with communication of common risks and appropriate alternatives*
- *The right to know the names and dosages of any medication or intervention to be prescribed, its normal actions and potential side-effects, and its possible impact on other conditions or treatments...*<sup>197</sup>

In cases where TB is notifiable, as in India, 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. And, 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. With the latest central government notification of 16 March 2018 – which puts an onus on not only healthcare providers, but also medical laboratories and pharmacists to notify – taking consent becomes even more vital, given that one's personal information can be shared with and by an increasing array of actors, which every person has a right to know the likelihood of. Presumably then, if a person refuses to undergo testing for TB or take treatment, the same cannot be undertaken unless the law specifically permits the overriding of such refusal.

## 4.2 Experiences

Informant interviews elicited a range of views on the issue of consent and related aspects. It was pointed out that in the context of TB healthcare providers were not required to explicitly take consent for testing – the consent was considered implicit in the act of the person approaching the provider or healthcare institution. When a person appears symptomatic, testing for TB is done as a matter of routine without taking consent. However, where consent forms were required to be filled up, they did not contain information that if tested positive for TB the patient's details would be notified to government authorities by law. But, in relation to treatment for DR-TB specific consent appeared to be taken as the treatment is toxic and it is administered invasively.

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.

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<sup>197</sup> Available at [http://www.who.int/tb/publications/2006/istc\\_charter.pdf](http://www.who.int/tb/publications/2006/istc_charter.pdf)

References were often made to the utility and centrality of counseling in the HIV response. Where TB treatment was linked to HIV treatment (for people living with HIV who also had TB and were accessing ART centres), it was noted that 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. This was attributed partly to the workload in high burden contexts where healthcare providers were seeing several patients with little time to dedicate for thorough information sharing. Additionally, however, and in large part it was attributed to the paucity of a cadre of trained counselors as part of the public health response to TB in most contexts.

Often, after testing, healthcare providers perceived imparting of information on nutrition, prevention of spread of TB to and testing of family members, and asking for a follow-up visit to the provider after a few months as a task that had to be fulfilled as a routine, and not as an opportunity for empathetic discussion and clarification of concerns with the patient. Dedicating financial and human resources to train nurses and physicians on counseling techniques was seen as vital to improving TB services.

Model practices on how to provide robust counseling services for TB have been demonstrated by organizations such as Medicins Sans Frontieres (MSF) in Mumbai, which began at the government Sewri TB hospital. Over time, people were trained to provide counseling, including through linkages with other institutions such as the Tata Institute for Social Sciences. MSF counselors continue to function at the TB hospital, where they educate patients through educational talks, information, education and counseling, focusing on treatment awareness and adherence and psychosocial needs. For counseling to be effective trust needs to be built with the patient, who is often skeptical of the public health system. MSF develops this over two to three rounds of counseling and tries to persuade patients to undergo testing or take treatment. Holistic counseling, it was found, did not eliminate treatment dropouts entirely, but it significantly reduced the dropout rate. Indeed, family counseling has been seen to be useful in encouraging people to undergo testing, and improve treatment adherence by sensitizing and building the competence of care givers at home on keeping the patient on treatment.

The importance of counseling is increasingly reflected in the TB response. The TB India 2017 RNTCP Annual Status Report states that counseling services have been provided to over 8000 MDR-TB patients in 30 districts resulting in a significant reduction (by 2/3) in loss to follow-up and death amongst MDR-TB patients. There is recognition that although TB treatment has been available for a long time, it has not been delivered with counseling in the TB programme. It is only with DR-TB treatment delivery that counseling has been linked for the first time, with counselors being situated in every district. The aim of the TB programme is to emulate the National AIDS Control Organization's (NACO) model of linking integrating counseling services with community involvement; the NSP for TB Elimination refers to ensuring counseling and information support to TB patients by TB survivors

who will act as DOSTs (Deliverers Of Support during Treatment).<sup>198</sup>An impetus to counseling is also being given with manuals and protocols being developed and piloted with a focus on DR-TB with the support of the Tata Institute of Social Sciences (TISS).<sup>199</sup>

### 4.3 Conclusion and Recommendations

Inherent and fundamental to the right to privacy are autonomy and bodily integrity, which implicate the principle of consent in their realization. The right to privacy, and therefore consent cannot be diluted or ignored unless the State can demonstrate a compelling necessity, and the use of a proportional means to justify curbing of the right. Absent these requirements, informed consent in the context of healthcare delivery is central to upholding the right to privacy. It is, therefore, essential that informed consent forms a part of general medical practice, including in cases of testing and treatment for TB, particularly given the notifiability of the disease in India, and the toxic effects that medicines can precipitate for a person with TB who gets on to treatment.

#### 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 undertak-

198 National Strategic Plan for Tuberculosis Elimination 2017-25, available at <https://tbcindia.gov.in/WriteReadData/NSP%20Draft%202020.02.2017%201.pdf>, at page 51

199 Annual TB Report 2017, Central TB Division, Ministry of Health & Family Welfare, available at <https://www.tbcindia.gov.in/WriteReadData/TB%20India%202017.pdf>, at page 43

ing 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* relates to information about oneself that is revealed to another person in the course of a particular professional relationship of trust, in the absence of which such information would not be revealed. Privacy and confidentiality are rights that find articulation in most legal frameworks, including in India. A key legal issue related to healthcare is that of confidentiality of health information. 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. For instance, courts have found 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.<sup>200</sup> Courts have laid down another standard to justify disclosure of health-related information – where a physician determines that the patient poses a serious danger to a foreseeable third party then the physician owes a duty to warn that party over their duty of confidentiality to the patient.<sup>201</sup> 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.

Judicial pronouncements and legislative provisions related to confidentiality of health information aim to draw a balance between two *public* interests – the importance of maintaining confidentiality and that of disclosure. Indeed, the preservation of confidentiality has itself been viewed as serving societal interests: *“In the long run, preservation of confidentiality is only way of securing public health; otherwise doctors will be discredited as a source of education, for future individual patients ‘will not come forward if doctors are going to squeal on them’.”*<sup>202</sup> Therefore, preserving confidentiality has been understood to serve not just the individual interest of the concerned patient, but also the *public* interest

200 *Hunter v Mann* [1974] 2 All ER 414 QBD

201 *Tarasoff v Regents of the University of California* 17 Cal 3d 358

202 *X v Y* [1988] All ER 648

of ensuring that society at large maintains its belief in the health system, and therefore is encouraged to access health seeking information and services, instead of shying away from them. The public interest is not served if a person knows that their health status will be revealed if they access the health system.

In the context of infectious diseases such as TB the issue of confidentiality is also linked to the issue of family notification – should people who cohabit or are potentially carers be informed of a person’s TB status in order to take prophylactic steps or provide appropriate care? And if so, what is the manner for this to be done? As discussed further below, as TB is a notifiable disease in India 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? Privacy and confidentiality are also relevant in the context of TB in non-healthcare settings such as the workplace and in educational settings. Discrimination in such settings against people with could well occur if privacy and confidentiality are not protected.

WHO, in its *Guidance for Managing Ethical Issues in Infectious Disease Outbreaks*<sup>203</sup> advises that personal information (name, address, diagnosis, family history etc.) collected during such an outbreak must be protected from unauthorized disclosure; doing this requires laws *“that safeguard the confidentiality of information generated through surveillance activities, and that strictly limit the circumstances in which such information may be used or disclosed for purposes different from those for which it was initially collected.”* In relation to disclosing such information the guidance states that, *“at a minimum, individuals and communities should be aware of the ... circumstances under which the information collected may be shared with third parties.”*

The Patients’ Charter for Tuberculosis Care states that patients have the rights to *“have personal privacy, dignity, religious beliefs, and culture respected”*, and *“have information relating to the medical condition kept confidential and released to other authorities contingent upon the patient’s consent.”* It further places responsibilities on patients, including *“to provide information to the health provider about contacts with immediate family, friends, and others who may be vulnerable to tuberculosis or may have been infected by contact.”*<sup>204</sup>

## **5.1 The context in India – law, policy and jurisprudence**

Until recently very few legislations in India articulated the right to confidentiality in India.<sup>205</sup> With parliament passing the *HIV Act* and the *Mental Healthcare Act* in 2017 medical confidentiality, at least in these contexts, has clear statutory footing. For instance, section 8 of the HIV law provides for the limited bases on which a person’s HIV status can be revealed, including shared confidentiality between healthcare providers in the interests of the person living with HIV, if required by a court

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203 WHO, *Guidance for Managing Ethical Issues in Infectious Disease Outbreaks*, 2016, available at <http://apps.who.int/iris/handle/10665/250580>

204 Available at [http://www.who.int/tb/publications/2006/istc\\_charter.pdf](http://www.who.int/tb/publications/2006/istc_charter.pdf)

205 For instance, section 129 of the *Indian Evidence Act, 1872* protects confidential information shared by a person with his legal adviser

order or in legal proceedings to decide a case, and in cases of partner notification after an assessment is made to reveal by following a protocol stipulated in section 9 of the law.<sup>206</sup> Section 23 of the *Mental Healthcare Act* similarly lays down the very limited exceptions to confidentiality of a person's health information.

The right to privacy received a significant fillip in 2017 through the Supreme Court judgment in *Justice KS Puttaswamy (Retd.) v Union of India*,<sup>207</sup> which emphatically upheld privacy as a fundamental right deriving from and intrinsic to Article 21 of the Indian Constitution, which guarantees the right to life and personal liberty. The notion of confidentiality is related to this fundamental right to privacy – that every person has the right to a sphere of activity and personal information that is exclusive to them which they have the sole right to disclose as they consider in their best interest. In *Puttaswamy* the Supreme Court made specific reference to medical information:

*“The sphere of privacy ...expresses a right to be left alone...Data such as medical information would be a category to which a reasonable expectation of privacy attaches... Apart from safeguarding privacy, data protection regimes seek to protect the autonomy of the individual.”*

The court, while recognizing that there may be legitimate state interests to curb privacy noted that this can be done exceptionally, and only after making certain that three aspects are satisfied to justify the limiting of the right. First, as expressly required in Article 21 of the Constitution there must be a law in existence to justify an encroachment on privacy. Second, the curb must be to achieve a legitimate state aim. Third, the means that are used to curb the right should be proportional to the object sought to be achieved by the law; both of the latter are required to guarantee against arbitrary state action. The court went on to note that,

*“...the state may assert a legitimate interest in analysing data borne from hospital records to understand and deal with a public health epidemic such as malaria or dengue to obviate a serious impact on the population. If the State preserves the anonymity of the individual it could legitimately assert a valid state interest in the preservation of public health to design appropriate policy interventions on the basis of the data available to it.”*

This is relevant in the context of TB, where public health concerns of its burden have made it a notifiable disease (although notification is generally applicable in cases of disease outbreaks under the *Epidemic Diseases Act*, and not in endemic contexts such as TB in India), which may be used to justify limiting the right to privacy (and thereby confidentiality). Yet, it is not clear if the TB response has met all the three requirements set out by the Supreme Court in *Puttaswamy*. For instance, has the disclosure of TB status to public health authorities through notification been mandated through law? As pointed out in the earlier section on “Notification”, the MoHFW order of 2012 making TB

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206 Sections 8 and 9, *HIV Act, 2017* available at <http://naco.gov.in/sites/default/files/HIV%20AIDS%20Act.pdf>

207 Writ Petition (Civil) No 494 of 2012, available at [http://supremecourtindia.nic.in/supremecourt/2012/35071/35071\\_2012/Judgement\\_24-Aug-2017.pdf](http://supremecourtindia.nic.in/supremecourt/2012/35071/35071_2012/Judgement_24-Aug-2017.pdf)

a notifiable disease (and subsequent order and notification) does not appear to have been issued under legislation. Further, given the primacy given to the right to privacy by the Supreme Court in *Puttaswamy*, it is necessary to ensure the right to privacy of the health status of people with TB, subject to exceptional situations, in contexts such as employment, educational settings, and housing.

As an update to the *Epidemic Diseases Act 1897*, the *Public Health (Prevention, Control and Management of Epidemics, Bio-Terrorism & Disasters) Bill, 2017*, has been proposed to provide “for the prevention, control and management of epidemics, public health consequences of disasters, acts of bio terrorism or threats thereof...” and related matters. In its vesting of untrammelled powers on the State to notify a disease, isolate people, or undertake medical procedures on them with no mention of assurances of confidentiality (and, indeed, informed consent, autonomy, and bodily integrity as mentioned in the earlier section on “Consent”), the proposed law falls foul of the Supreme Court’s *Puttaswamy* ruling.

For physicians, the Medical Council of India’s *Code of Medical Ethics Regulations, 2002* also outline their duty to maintain confidentiality. They state that a physician can disclose confidential information of a patient 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. Additionally, such disclosure should be done by the physician in a manner that they would like another to act toward one of their own family in like circumstances.<sup>208</sup>

As mentioned in the section on “Notification”, but also related to the issue of confidentiality, at the state level, section 241 of the *Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965* is illustrative of the extent to which disclosure requirements of a person with a dangerous disease are expected of a wide variety of actors. The provision places an obligation on medical practitioners, medical officers in charge of any hospital or dispensary, managers of factories, headmasters of schools, keepers of lodging houses and heads of households to inform the Chief Officer or Health Officer if they are aware or suspect that a person has a dangerous disease, which is defined to include TB.<sup>209</sup> Section 246 of the legislation makes it a crime for any person who is obliged to report to disobey this mandate, with a fine of INR 200. Worryingly, identical provisions exist in the *Mumbai Municipal Corporations Act, 1888*, which does not even specify what a ‘dangerous disease’ is.

TB notification legislation being proposed in Maharashtra, a draft of which was made available to the report writers provides that the “state shall protect the confidentiality of notifications within health system”.<sup>210</sup> However, the issue of confidentiality of health data and personal information, including TB status fails to find mention in the RNTCP’s policy and programmatic documents that have been reviewed for this report, except the Guideline for PMDT in India 2017, and the 16 March 2018

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208 Regulation 2.2, *Code of Medical Ethics Regulations, 2002* available at <https://www.mciindia.org/CMS/rules-regulations/code-of-medical-ethics-regulations-2002>

209 Section 237, *Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965*

210 On file with the report writers

notification of the MoHFW making non-notification by labs, healthcare providers and pharmacists a criminal offence.<sup>211</sup> Although this latter notification mentions that “*confidentiality of the individual identity of the tuberculosis patients shall be maintained*”, it does not provide a system by which this is to be ensured, and appears to allow for an array of actors to be made aware of a person’s TB status: “*...local Public Health Authority, namely, District Health Officer or Chief Medical Officer of a District and Municipal Health Officer of urban local bodies in whatever way they are known; or their designated District Tuberculosis Officers*”, and “*the Nodal Officer of the District or any Officer authorised by Nodal Officer*”. All of this is of concern given the other multiple ways in which TB prevalence and incidence is sought to be traced and recorded in India, some of which are described below.

For instance, there is the mechanism of notification provided in the Guidance for TB Notification in India,<sup>212</sup> which includes how patient information is to be transmitted – submission of a hard copy to the Nodal Officer by post, courier or hand; submission of a soft copy to the Nodal Officer by authorized email; submission to the Nodal Officer using authorized mobile phone call, Interactive Voice Response System or SMS; or uploading information directly on the Nikshay portal <https://nikshay.gov.in>. The guidance further explains that in states, union territories or districts where there is a bilateral understanding between the health establishment and the local public health authority for convenient local TB notification, the information can be submitted to the local public health authority such as the Medical Officer of the PHC designated by the district nodal authority, after consultation with the concerned district Nodal Officer.

In 2017 ACF was undertaken as per the Active TB Case Finding Guidance Document<sup>213</sup> in “*campaign mode*” in 3 phases as per the guidance, which also envisages electronic data reporting as cases are found. For examinations in “*high risk pockets*” the initiative envisages “*house-to-house visits by health workers to involve community leaders, panchayat members particularly the women members, religious leaders and other local influencers like medical practitioners, local moneylenders, grocery shop owners, popular teachers, prominent youth etc.*” Further, “*local community members/influencers must accompany search teams during house-to-house visits in such areas, especially during revisit to houses.*”

In relation to ACF, the NSP<sup>214</sup> states that “*Increased coverage can be achieved by focusing on clinically, socially and occupationally vulnerable populations. It must be remembered that ‘screening’ is a dynamic process and the prioritization of vulnerable groups, choice of screening approach and screening interval will be regularly reassessed by the programme. Decisions on when and how to screen for TB, which vulnerable groups to prioritize and which screening tool to use depend on the vulnerable group, the capacity of the health system, and the availability of resources.*”

211 These documents were: National Strategic Plan 2017-25, Guidance for TB Notification in India, Active TB Case Finding Guidance Document, RNTCP’s Annual TB Report 2017, and the Technical & Operational Guidelines for TB Control in India 2016, and the Guideline for PMDT in India 2017

212 Available at <https://tbcindia.gov.in/showfile.php?lid=3139>

213 Available at <https://tbcindia.gov.in/index1.php?sublinkid=4754&level=3&lid=3290&lang=1>

214 Available at <https://tbcindia.gov.in/WriteReadData/NSP%20Draft%2020.02.2017%201.pdf>

The RNTCP's Annual Status Report: TB India 2017,<sup>215</sup> describes Project Axshya as a civil society initiative with community volunteers to support the RNTCP in expanding its reach, visibility, and effectiveness. The report adds that, with Axshya's focus

*“on enhancing access to vulnerable and marginalized communities including tribals, slum-dwellers, homeless, the trained community volunteers of Axshya (called AxshyaMitras) have reached over 14 million households disseminating information on TB and simultaneously screening the family members for symptoms of TB. Over 153,000 presumptive TB patients were identified and tested and this included collection and transportation of sputum samples of nearly 130,000 presumptive TB patients. Almost 15000 TB patients were diagnosed and initiated on treatment through the active case finding intervention.”*

In relation to “case based routine surveillance” the NSP states that an

*“ICT supported systems to rapidly receive and transmit data up-down with GIS mapping of every patient, and identify hot spots will be crucial for a quick and adequate response. It will capture information on household income, high risk occupation if any, residential status: native/migrant/temporary worker/visitor, and co-morbidities. It will also capture systematic screening of close contacts.”*

The Technical and Operational Guidelines for TB Control in India 2016 – elucidates a case finding and diagnosis strategy and recording and reporting for the programme.<sup>216</sup> These describe maintenance of a special register containing detailed identity information of each individual screened, a register with similar information of all presumptive TB cases, a TB notification register, and a RNTCP PMDT register.

Chapter 11 of the NSP for TB Elimination concerns itself with “Contact Tracing”. Yet, it fails to make any reference as to how confidentiality of TB status of the primary patient will be safeguarded while tracing contacts.

The aforementioned instances reveal the many ways in which well-intentioned RNTCP efforts plan to control TB. However, they also 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. Added to this is the MoHFW's notification of June 2017 which mandates Aadhaar enrollment for “TB patients, private health care providers and treatment supporters” to avail of a conditional cash assistance scheme provided by RNTCP.<sup>217</sup> Given the concerns that have arisen around Aadhaar data leakage, protection of confidentiality for TB patients and survivors becomes an issue in relation to this scheme too.

215 Annual TB Report 2017, Central TB Division, Ministry of Health & Family Welfare, available at <https://www.tbcindia.gov.in/WriteReadData/TB%20India%202017.pdf>, at page 42

216 Available at <https://tbcindia.gov.in/index1.php?lang=1&level=2&sublinkid=4573&lid=3177>

217 Available at <http://www.livelaw.in/aadhaar-mandatory-tb-patients-get-cash-assistance-government-scheme-read-notification/>

An assessment on uptake of TB notification through Nikshay by private healthcare providers in Mysore pointed toward the public health value of ensuring confidentiality in the TB programme. It suggested that assurance of confidentiality was crucial to seeing both private practitioners and patients take up mandatory notification, and this needed to be done by expanding RNTCP awareness and educational campaigns to the general public and TB patients.<sup>218</sup>

Yet, as highlighted earlier, guarantees of confidentiality are scarcely mentioned in policy and programme documents of the TB programme. It is only the 16 March 2018 MoHFW notification and the Guidelines for PMDT in India 2017<sup>219</sup> that refer to the right of a patient to confidentiality. Emphasizing a patient-centric approach, the guidelines state that treatment efforts for DR-TB “*must ensure that the confidentiality and dignity of the patient is protected*”. Further, “*confidentiality and informed decision making process according to sound ethics standards is paramount when performing education and counselling to patients and their family members,*” and highlighting the importance of counseling it states that the same should take place “*in a confidential and supportive environment*”. It is unclear why these principles are not reflected in other policy documents.

Presumably, the Electronic Health Records Standards 2016 issued by the MoHFW<sup>220</sup> 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). These standards do enumerate data ownership, access, collection, storage, and sharing roles and responsibilities, which logically should be applied to the RNTCP. Yet, concerns remain of how non-electronic health information data that is collected as part of the TB notification processes will be stored and uphold confidentiality, and how the many strategies for screening TB that are envisaged in the programme will limit the availability of health information to only those officials who need to know TB status. 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.

## 5.2 Experiences

Informant interviewees, while acknowledging the importance that notification can play in TB control if implemented robustly, also felt that such implementation should be informed by ethical practice. While this includes collecting health data such as TB status and personal identity information, confidentiality of this information must be assured to TB patients and survivors. Such information should only be known to RNTCP personnel who are directly involved in screening, diagnosis, notification and treatment. It was also felt that in many cases in the Indian context, family involvement was crucial (in ensuring treatment adherence), and necessary (in cases of contact screening). In such cases although shared confidentiality may be advisable the same should be done after taking patients and family members into confidence with robust and non-stigmatizing counseling and information

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218 Singh Chadha et al. Mandatory TB notification in Mysore city, India: Have we heard the private practitioner’s plea? BMC Health Services Research (2017) 17:1 DOI 10.1186/s12913-016-1943-z

219 Available at <https://tbcindia.gov.in/index1.php?lang=1&level=2&sublinkid=4780&lid=3306>

220 Available at <https://mohfw.gov.in/sites/default/files/17739294021483341357.pdf>

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.

Informant interviews also revealed that there was no knowledge among stakeholders about rules to ensure confidentiality of TB status and related information. In such a context custodians of this information were unrestricted in their conduct with such information, which was undesirable. There have been instances where a patient's TB status is discussed by healthcare workers casually in health establishment canteens, in the absence of sensitization, training or consequences against such conduct. This can also happen in pharmacy contexts. Therefore, general health legislation to govern the right to privacy and confidentiality in health-related information is necessary.

Such legislation should also provide for accountability of healthcare providers who are charged with accessing and storing such information. However, any legislation in this regard will also have to account for ground realities and challenges – for instance, while the RNTCP has provided for treatment supporters at the local village level, people with TB do not want their health status revealed, and go to the extent of accessing tertiary healthcare to ensure this, thereby defeating the purpose of providing local and more immediate support.

Learning from the experience with HIV, part of a holistic response in ensuring that confidentiality is maintained as required in the RNTCP is to sensitize healthcare providers about patients' and healthcare workers' rights and responsibilities, which is insufficiently done at present. This requires financial and human resources at a sufficient scale, and also needs to be systemically built in to healthcare and medical training and education. Investing in strengthening invaluable and sensitive counseling is part of this approach and needs to be a priority in responses within health systems generally, and TB in particular given the thrust being given to the RNTCP.

### **5.3 Conclusion and Recommendations**

For stigmatized diseases like TB it is incumbent on the part of the health care providers and the TB programme howsoever it envisages the provision of services – either in healthcare institutions, within community spaces, or by going door-to-door or using other methods for follow-up of people with TB, to maintain their confidentiality as a matter of right. The challenge in doing so is posed not just by the number of actors envisaged in rolling out the RNTCP, but also the fact that TB is now a notified disease with a requirement to collect and store personal data, and without comprehensive and clear legal architecture to ensure protection of this data.

#### **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:
  - First, as expressly required in Article 21 of the Constitution there must be a law in existence to justify an encroachment on privacy.

- Second, the curb must be to achieve a legitimate state aim.
  - 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, Axshya, 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

At the outset, it needs to be stated that in the context of health, criminal law ought to be used sparingly, and should **not** be used with the aim to control a spread of a disease or be used as a deterrent for compliance of certain laws, policies or government resolutions. Experience from other countries has shown that foisting criminal liability on TB patients for non-adherence has little public health impact, and disproportionately affects individuals who are poor and have little social and economic support.<sup>221</sup> The WHO guidance states “exceptional” circumstances in which forcible detention of TB patient may be considered, and emphasizes on counseling, community based care and adherence.<sup>222</sup> The “least restrictive”, “least intrusive” and “strictly necessary” requirements in international covenants ought to be followed by governments prior to restricting rights of people with TB and of those involved directly or indirectly with their care and treatment.<sup>223</sup>

### Crime and criminal law

A crime is a legal wrong, the consequence of which is punishment by the State after prosecution of the accused, if they are found guilty.<sup>224</sup> An action or an omission is considered a crime when it is legislated as an offence. In the context of TB certain acts or omissions fall within the purview of criminal law.

Criminal law is based on the principle of *actus non facit reum, nisi mens sit rea*— an act or omission does not make a person legally guilty unless the mind is legally blameworthy.<sup>225</sup> The *actus reus* is the act 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.<sup>226</sup>

*Mens rea*, which is concerned with legal and not moral guilt, is a ‘guilty mind’ - it refers to the state of mind in respect of the offence charged.<sup>227</sup> Instances of *mens rea* include intention, recklessness and

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221 Todrys, K.W. et al, “Failing Siracusa: government’s obligations to find the least restrictive options for tuberculosis control” Public Health Action, 2013, 3 (1): 7-10; doi:[10.5588/pha.12.0094](https://doi.org/10.5588/pha.12.0094)

222 Ibid.

223 Ibid.

224 Card, Cross and Jones, *Criminal Law* 14<sup>th</sup> Edition, Butterworths London Edinburgh and Dublin, 1998, Chapter 1: Introduction; page 1

225 Ibid. at page 31

226 Ibid. at page 33

227 Ibid. at page 44

knowledge.<sup>228</sup> Most offences require proof of ‘intention’ - where the actor knows the consequences of their action or inaction.<sup>229</sup> Intention is the state of mind to cause the consequences on the aggrieved person/s and intention is also having the knowledge as to circumstances.<sup>230</sup> Given the gravity of finding a person guilty, criminal law prescribes procedures that are lengthy and complex. Evidence plays an important role in proving a fact beyond reasonable doubt, so that no innocent person is convicted wrongfully.

## 6.1 The context in India – laws, policy and jurisprudence

The issue of criminality arises in the context of TB since (i) the *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”; each of the other aspects is discussed below)

### Negligent and malignant spread of infection

Sections 269 and 270 of the *IPC* prescribe penalties for actions that unlawfully, negligently or malignantly transmit a disease dangerous to life. Section 269 states, “*Whoever unlawfully or negligently does any act which is, and which he has or has reason to believe to be, likely to spread the infection of any disease dangerous to life, shall be punished with imprisonment of either description for a term which may extend to six months, or fine, or both.*” Section 270 penalizes the malignant spread of infection that attracts a punishment of two years.

Negligence is conduct that departs from the standard to be expected of a reasonable person. Negligence is the unintentional taking of an unjustifiable risk by a person who ought to have known of the risk. It denotes culpable carelessness.<sup>231</sup> Persons who have less knowledge or capacity to see the relevant risk (known or ought to have known) can still be brought under the purview of criminal liability. Therefore, in the context of TB, people may not be aware of how to prevent the spread of the disease or may feel too stigmatized to access health care services and may inadvertently spread the infection. They could still be penalized for negligent transmission under section 269. However the few cases that have been prosecuted under this provision have placed limits on too broad an interpretation of this provision.

Very few cases have invoked section 269, and where they have done so it has been in the context of negligent transmission of various diseases such syphilis<sup>232</sup>, small pox<sup>233</sup> and plague<sup>234</sup> and most date

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228 Ibid.

229 David Ormerod, *Smith and Hogan: Criminal Law*, Chapter 5, “The elements of crime”; 12<sup>th</sup> Edition, at page 97

230 Ibid.at page 116

231 Black’s Law Dictionary; 7<sup>th</sup> Edition, Bryan A Garner, 1999

232 *The Queen Empress v Rakmakom Sadhu* 1886 Bombay Series Vol. XI 59 Criminal Reference No.103 of 1886

233 *S. Cahoon v A. Mathews* 1897 ILR Vol. XXIV 494

234 *The Empror v Nadiar Mal* 1902 Criminal Judgements No.22, 56

from over a century ago. In the case of *the Emperor v Nadiar Mal*,<sup>235</sup> the accused was convicted for negligently spreading disease by leaving a plague stricken area and travelling to other areas by rail because his wife had died and her body had to be cremated, despite orders that he should not leave that area. It was held in revision by the court that the offence requires the accused to have knowledge or reason to believe that his act is likely to spread infection. In this case, since he was warned by the medical officer it was fair to presume that he had reason to believe that the prohibition was in public interest. In going to the railway station and mingling with the crowd, he took a grave risk and there was no evidence to show that he took special precautions to avoid the spread of the plague. His conviction was confirmed by the court, though it recognized the circumstance that made him travel – the cremation of his wife - was not a wanton act.<sup>236</sup> In another case the court held that mere suspicion or doubt cannot be equated with the term “*reason to believe*” in section 269; instead, there needs to be sufficient cause to believe that there is negligent spread of a life-endangering infection.<sup>237</sup>

In a case involving TB, the Rajasthan High Court reversed the order of the Magistrate convicting a person under section 269 for unlawfully and negligently spreading TB to family members of the complainant through the operation of a flourmill.<sup>238</sup> The court held that the TB of the complainant’s family members could not be proved attributable to the running of the flourmill by the accused. The court stated that the purport of section 269 was not focused on the cause of the infection, but was about the spread of infection.<sup>239</sup>

### **The 2018 Notification invoking sections 269 & 270, IPC**

As explained earlier, the MOHFW issued a notification on 16 March 2018 stating that “*tuberculosis is a dangerous epidemic disease, threat to life and is a major public health problem accounting for substantial morbidity and mortality in the country*”, and placing a duty on all healthcare providers and medical laboratories to notify the relevant public health authority of people with TB, and pharmacies, chemists and druggists dispensing TB medication to do the same along with the list of medication of each person, and to keep a copy of the prescription. Further, it invokes sections 269 and 270, *IPC* for non-notification by these actors and extends this criminal liability also to “*local public health staff of general health system of rural or urban local bodies*” who do not make patient home visits, provide counselling to patients and family members, ensure treatment adherence, undertake contact tracing, offer HIV and drug susceptibility testing, and link with social welfare schemes.

Effectively, it makes “*failing to notify*” and “*not taking appropriate public health action*” tantamount to a crime of negligently or malignantly spreading a dangerous disease, an extreme stretching of the intent of the law. Read in another way, the notification could mean that non-notification or

235 1902 Criminal Judgements No.22, 56

236 *The Emperor v Nadiar Mal* 1902 Criminal Judgements No.22, 56

237 *Dr. Prabha Malhotra & ors. v State*, 2000 Cri.L.J. 549, Allahabad High Court

238 *Vikram Singh v State of Rajasthan*, High Court of Rajasthan, Jodhpur, *vide* order dated 3.8.2017 in S.B. Criminal Misc. (Pet.) No. 3204/ 2014

239 *Ibid.*

not taking appropriate said public health action could tantamount to abetment of the crime under sections 269/ 270, *IPC*. This, too, appears to be stretching an understanding of the law, since it cannot be assumed that a person with TB will transmit the disease (either at all or maliciously or negligently), or will not take the precaution of preventing its spread. Abetment to a crime requires that there is instigation, conspiracy or intentional aiding in the commission or omission of an act that is an offence.<sup>240</sup> There needs to be wilful misrepresentation or concealment to instigate a person or doing of an act that facilitates the commission of an offence.<sup>241</sup> Doctors who treat, laboratories who test and druggists, pharmacies or chemists who provide the medicines to people with TB ought not to be seen as abettors to a criminal offence or those causing likely spread of a dangerous disease when all they are doing is their job to test, prescribe, and provide medicines to treat an unwell person.

Moreover, sections 269 and 270 may be invoked against the person who is negligently or malignantly transmitting or doing an action likely to transmit a life-threatening disease. Intent, *mens rea*, and actual transmission are required aspects of such a crime. Non-notification or not taking appropriate public health action can at most be a civil wrong for breach of a duty by a doctor, laboratory, or pharmacist and public health official.

Further, for criminal liability to attach for non-notification or not taking of appropriate public health measures that lead to the transmission or likelihood of transmission of TB would require proof beyond reasonable doubt, a burden which would be extremely onerous to meet. Criminal prosecutions also create heavy financial and administrative burdens on the government. Cases can take years and appeals even longer. This begs the question of whether the inappropriate invocation of criminal law in the context of TB notification is the correct use of the State's resources in the TB response. It appears that the State has misused its power and has arbitrarily issued the notification threatening to prosecute under Sections 269 and 270, *IPC*.

The notification of March 2018 can only serve one purpose – to instil fear in the people in the health system and infrastructure engaged with TB. Can such fear contribute to better notification, and consequent TB elimination? Or, will criminalizing these actors have the troubling effect of creating reluctance to provide and distancing them from TB-related services? Will not an approach that incentivizes both the public and private sectors through provider education and training, and linking providers with free treatment be a more humane approach that strengthens the health system instead of punishing it? Indeed, as stated earlier strategies of engagement such as offering ICT support, free TB drugs for notified patients, and extending treatment adherence support services have been implemented in Patna, Mehsana, Mumbai and Nagpur and yielded notification rates increasing 1.5-4 -fold.<sup>242</sup> Should this tried and tested model not be scaled up instead of invoking the criminal law?

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240 Section 107, *IPC*

241 Explanation 1 and 2, Section 107, *IPC*

242 Annual TB Report 2017, Central TB Division, Ministry of Health & Family Welfare, available at <https://www.tbcindia.gov.in/WriteReadData/TB%20India%202017.pdf>

## Public Health laws<sup>243</sup>

TB has been listed as a “*dangerous disease*” in municipal council Acts in many states.<sup>244</sup> This gives power to municipal authorities to impose restrictions for preventing the spread of disease. TB of various kinds, including pulmonary TB is also listed as an infectious disease in some state public health statutes, wherein power is given to health or other officers to remove the person with TB to a hospital or other place where they can receive treatment.<sup>245</sup> The health officer can take the help of the police or the criminal justice system to implement the law. This 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.<sup>246</sup> Restrictions can be placed on sale of food articles, where there is an imminent outbreak of a dangerous disease, though it would be incumbent on the authorities to give proof that the prohibition is required to contain the spread of the disease.<sup>247</sup> The Magistrate may direct the closure of a lodging house or any place where food articles are sold or prepared or exposed for sale, etc. on account of existence or recent occurrences in such a place of a notified disease. The Magistrate also has the power to direct the immediate disposal of a body of a person who died while suffering from a notified disease.<sup>248</sup>

Of possible relevance to the context of TB was a case of a person with cholera who was convicted under section 188, *IPC* for not submitting himself to get inoculated on the ground that he had taken preventive Homeopathic medicine. The said section covers cases of disobeying orders promulgated by a public servant. The person was found guilty for contravening regulations made under the *Epidemic Diseases Act*.<sup>249</sup>

## Evidentiary value

A person’s TB status was relevant in a case of alleged murder, where the victim had TB and the accused claimed that the person died for that reason and not because of alleged injuries inflicted on them.<sup>250</sup> Though the charge against the accused was of murder caused by *lathi* charge, medical evidence revealed the direct cause of death to be TB of an advanced stage, thus bringing the case under the lesser crime of culpable homicide not amounting to murder under section 299 of the *IPC*.<sup>251</sup> Death due to TB has also been used as a defence by those accused of charges of cruelty against woman in cases of dowry death, where death has been attributable to TB and not bodily injury.<sup>252</sup>

243 The provisions illustrated here are also discussed in the sections on Notification and Isolation.

244 Section 237, *Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965; Tamil Nadu District Municipalities Act, 1920*.

245 *Goa, Daman and Diu Public Health Act, 1985 and Rules, 1987; Madras Public Health Act, 1939; Travancore-Cochin Public Health Act, 1955*

246 *Goa, Daman and Diu Public Health Act, 1985 and Rules, 1987; Madras Public Health Act, 1939; Travancore-Cochin Public Health Act, 1955*

247 *Bhagwan Dass & anr. v Municipal Corporation of Delhi* AIR 1995 Delhi 17

248 *Goa, Daman and Diu Public Health Act, 1985 and Rules, 1987*

249 *J. Choudhury v The State* 1963 Cri.L.J. 659, Orissa High Court

250 *Vijai Bahadur Singh & ors. v State of U.P.* 1998 Cri.L.J. 2358, Allahabad High Court

251 *Ibid.*

252 *Vishnu Prasad & ors. v State* 2006 Cri.L.J. 2865, Delhi High Court

## 6.2 Conclusions and Recommendations

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.

Fortunately, the RNTCP and NSP emphasize a patient-centric approach, including advocacy communication and social mobilization through various initiatives to increase awareness, impart training and increase the reach of the TB programme to be more inclusive. That the NSP promotes reduction of stigma and use of infection control measures and does not mention the use of criminal law as a prevention strategy reflects a rights-based, non-punitive approach. Unfortunately, by invoking the criminal law the MoHFW notification of 16 March 2018 is at odds with this approach, and could potentially backfire if aspects relating to criminalization are not rolled back and deleted from the notification.

### 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.



## **III. Health Sector**

**7. Drug Regulation**

**8. Regulation of the Private Sector**

**9. Alternative Systems of Medicine**

**10. Quackery**

**11. Universal Health Coverage/ Insurance**

# 7. Drug Regulation

Drug regulation refers to legal and regulatory structures that ensure the safety, efficacy and quality of drugs and diagnostics. The obligation to protect the fundamental right to health requires that the State “take all necessary measures to safeguard persons within their jurisdiction from infringements of the right to health by third parties. This category includes such omissions as the failure to regulate the activities of individuals, groups or corporations so as to prevent them from violating the right to health of others; the failure to protect consumers and workers from practices detrimental to health, e.g. by employers and manufacturers of medicines...”<sup>253</sup> In the case of TB drugs and diagnostics in India there have been several concerns regarding the availability of unreliable diagnostics, the quality of drugs and permission for marketing of newer TB drugs.

## 7.1 The context in India – Laws, Policies & Jurisprudence

India’s drug regulatory structure is provided for in the *Drugs and Cosmetics Act, 1940*(DCA) and the *Drugs and Cosmetics Rules, 1945* (DC Rules). The DCA regulates the import, manufacture, distribution and sale of drugs and cosmetics. The DC Rules contain detailed provisions covering a range of issues including licensing of manufacturing units, clinical trials and approval of drugs supplied in India. Regulatory roles are distributed between the central and state governments through statutory and non-statutory bodies. The key regulatory agencies at the Central level are the Drugs Controller (General) of India (DCGI) and the Central Drugs Standards Organization (CDSCO). One of the key areas identified by the NSP for strengthening regulatory approaches relates to the “regulation of drug sales and distribution in public and private sectors to ensure the quality of TB medication, its combinations, standardized dosages and treatment regimens.”<sup>254</sup>

### Regulation of Sales

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 exercised its power under section 26A of the DCA to ban the manufacture, sale, distribution, use and import of serological diagnostic tests for TB. Explaining the ban in Parliament, the Minister of Health at the time noted that this was in

253 Committee on Economic, Social and Cultural Rights, General Comment 14, The right to the highest attainable standard of health (Twenty-second session, 2000), U.N. Doc. E/C.12/2000/4 (2000), available at [http://www.unhcr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En](http://www.unhcr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En)

254 Central TB Division, National Strategic Plan for Tuberculosis Elimination 2017 – 2025, available at <https://tbcindia.gov.in/WriteReadData/NSP%20Draft%2020.02.2017%201.pdf>

keeping with the WHO recommendation that “commercial serological tests provide inconsistent and imprecise estimates of sensitivity and specificity and these tests should not be used for the diagnosis of pulmonary and extra-pulmonary TB.”<sup>255</sup>

In 2014, an amendment to the *DC Rules* came into force introducing Schedule H1 aimed at controlling over-the-counter dispensing of antibiotics.<sup>256</sup> The schedule accordingly lists several antibiotics including key TB medicines, which are to be sold only on prescription. These medicines are subject to several restrictions including that they can only be sold on prescription and the sale has to be recorded in a separate register giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied. The NSP hopes to leverage the implementation of Schedule H1 to identify practitioners “for prioritizing or targeting to encourage TB notification from them.”<sup>257</sup> A violation of the requirements of the *DC Rules* in relation to Schedule H1 can lead to the suspension or cancellation of the license for sale of drugs.<sup>258</sup>

### Approval of New MDR-TB Drugs

Even as new provisions have been introduced in an attempt to control the sales of current TB drugs, easing access to new MDR-TB drugs has also required action under the *DCA*. Both bedaquiline and delamanid are drugs introduced abroad and under the *DC Rules* must undergo Phase III trials before approval in India. This requirement may be waived in public interest and approval may be granted based on data available from other countries. In 2014, the Ministry of Health<sup>259</sup>, determined that such waivers could only be considered “in cases of national emergency, extreme urgency, epidemic and for orphan drugs for rare diseases and drugs indicated for conditions/diseases for which there is no therapy.”<sup>260</sup> Although an amendment to this effect has not been made to the *DC Rules*, this view was reaffirmed by the Apex Committee while considering the recommendations of the SEC and the Technical Committee on local clinical trial waivers for key drugs including bedaquiline. In the case of bedaquiline, the following recommendation of the Technical Committee for waiver of local trials and approval for conditional access was approved:

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255 Explaining the ban in Parliament, the Minister of Health at the time noted that this was in keeping with the WHO recommendation that “commercial serological tests provide inconsistent and imprecise estimates of sensitivity and specificity and these tests should not be used for the diagnosis of pulmonary and extra-pulmonary TB.” Ministry of Health and Family Welfare, Diagnosis of Tuberculosis, Press Information Bureau, Government of India, 30 November 2012 available at <http://pib.nic.in/newsite/PrintRelease.aspx?relid=89739>

256 *Drugs and Cosmetics (Fourth Amendment) Rules 2013*, Gazette Notification G.S.R. 588(E), Ministry of Health and Family Welfare, Government of India, 30 August 2013 available at <http://cdsco.nic.in/writereaddata/588E30thAug2013.pdf>

257 Central TB Division, National Strategic Plan for Tuberculosis Elimination 2017 – 2025, available at <https://tbcindia.gov.in/WriteReadData/NSP%20Draft%2020.02.2017%201.pdf>

258 Rule 66, *Drugs and Cosmetics Rules 1945*

259 Based on the recommendations of the Prof. Ranjit Roy Chaudhury Expert Committee to Formulate Policy and Guidelines for Approval of New Drugs, Clinical Trials and Banning of Drugs. See Ministry of Health and Family Welfare, “Actions On The Recommendations Of Prof. Ranjit Roy Chaudhury Expert Committee To Formulate Policy And Guidelines For Approval Of New Drugs, Clinical Trials And Banning Of Drugs,” 2013 available at [http://www.cdsco.nic.in/writereaddata/Action\\_RR\\_Choudhury\\_Committee\\_06.11.2013.pdf](http://www.cdsco.nic.in/writereaddata/Action_RR_Choudhury_Committee_06.11.2013.pdf)

260 CDSO, “Waiver of Clinical Trial in Indian population for approval of New Drugs – regarding”, File No. 12-01/14-DC Pt.47, 3 July 2014, available at <http://www.cdsco.nic.in/writereaddata/oo7.pdf>

*“The Committee observed that Bedaquiline is approved in the US, EU and other major countries. Bedaquiline is indicated for the treatment of pulmonary tuberculosis due to multi-drug resistant Mycobacterium tuberculosis (MDR-TB) for which presently no effective therapy is available in India. MDR-TB is a serious life threatening condition with high mortality and it disease of special relevance to Indian Health Scenario. Therefore, the Committee recommended waiver of local clinical trial at this stage and the approval of the drug bedaquiline with restriction that it shall be approved for use under RNTCP framework for conditional access through the PMDT program for treatment of MDR-TB patients only.”<sup>261</sup>*

In January 2015, the DCGI issued an import license to Janssen Pharmaceuticals for 100 mg tablets of bedaquiline fumarate for use only in adults (above the age of 18) and required that the packaging include a clear warning that the imported drug was only for use in the RNTCP. Janssen was also required to put in place a system for post-marketing surveillance and to report all adverse reactions to the DCGI.<sup>262</sup> In June 2017, the CDSCO gave permission to Johnson & Johnson to conduct a Phase II clinical trial to evaluate the possible use of bedaquiline in children and adolescents below the age of 18.<sup>263</sup>

Similarly, in the case of delamanid, the SEC on 14 June 2017 recommended that the requirement of local clinical trials be waived and that approval for the drug be granted only for the conditional access programme under the RNTCP.<sup>264</sup> Approval for the use of 50 mg delamanid in adult patients was accordingly given by the CDSCO in August 2017.<sup>265</sup>

## Personal Import Provisions

The RNTCP’s rollout of the new MDR-TB drugs has been slow and restrictive. For patients in the private sector who prefer not to seek care in the public sector, the personal import provisions in the *DC Rules* are their only option for getting access to the new MDR-TB drugs. Rule 36 allows for the personal import of small quantities either in a passenger’s baggage for their exclusive use or otherwise if an application (Form 12-A of the *DC Rules*) is made to and accepted by the CDSCO, for *bona fide* personal use, of a quantity that in the opinion of the CDSCO is reasonable and is covered by prescription from a registered medical practitioner. The CDSCO then grants a permit for in Form 12-B of the *DC Rules*.<sup>266</sup> The application has to be made at one of the CDSCO port offices.<sup>267</sup>

261 Minutes of the 19th Meeting of the Apex Committee held on 24-12-2014 under the chairmanship of Secretary, Health and Family Welfare for supervising clinical trials on new chemical entities in light of directions of the Hon’ble Supreme Court of India dated 03.01.2013, available at <http://www.cdsc0.nic.in/writereaddata/Apex%20Committee.pdf>

262 RNTCP, Guidelines for use of Bedaquiline in RNTCP through conditional access under Programmatic Management of Drug Resistant Tuberculosis in India, February 2016 available at <https://tbcindia.gov.in/index1.php?lang=1&level=2&sublink-id=4682&lid=3248>

263 CDSCO, Letter to Johnson&Johnson dated 27 June 2017, File No. CT/44/16-DCG (I), Clinical Trial NOC No.” GCT/17/17, available at [http://www.cdsc0.nic.in/writereaddata/Sr\\_%20No\\_%2025%20CT-44-16-Johnson%20&%20Johnson.pdf](http://www.cdsc0.nic.in/writereaddata/Sr_%20No_%2025%20CT-44-16-Johnson%20&%20Johnson.pdf)

264 Recommendations of the SEC (Antimicrobial & Antiviral) made in its 34<sup>th</sup> meeting held on 14.06.2017 at CDSCO HQ New Delhi, available at [http://www.cdsc0.nic.in/writereaddata/MOM%20of%20SEC%20Antimicrobial%20and%20Antiviral%2014\\_06\\_2017%20\(Website\)%20\(1\).pdf](http://www.cdsc0.nic.in/writereaddata/MOM%20of%20SEC%20Antimicrobial%20and%20Antiviral%2014_06_2017%20(Website)%20(1).pdf)

265 CDSCO, List of Approved New Drugs, available at <http://www.cdsc0.nic.in/forms/list.aspx?lid=2034&ld=11>

266 Under rule 34-A, government hospitals and autonomous medical institutions can also apply for licenses to import small quantities of drugs.

267 CDSCO, Procedure for permission to Import Small Quantities of Drugs For Personal Use, available at <http://www.cdsc0.nic.in/forms/list.aspx?lid=1852&ld=30>

## Oversight of Clinical Trials

A significant number of TB clinical trials are planned in India; though the post-trial access of the TB medicines, being tested on Indian population may be little or none at all, if the prices of the tested approved drugs are high and monopolistic. In June 2017, the CDSCO gave permission to Johnson & Johnson to conduct a Phase II clinical trial to evaluate the possible use of bedaquiline in children and adolescents below the age of 18.<sup>268</sup> Demonstration of safety and efficacy of a drug for use in humans is essential and must be done in accordance with Schedule Y of the DCA, the *DC Rules*<sup>269</sup> and the Good Clinical Practice guidelines of CDSCO. New drug trials require DCGI permission and approval by Ethics Committees (ECs) at the institutions where the trial and recruitment of participants takes place.

All research needs to follow the Good Clinical Practice guidelines and the provisions of Schedule Y for conducting clinical trials. ICMR also issues guidelines called the “*National Ethical guidelines for biomedical and health research involving human participants*”, which is updated at regular intervals, with the latest guidelines issued in 2017. The guidelines, though they are not necessarily enforceable through the courts, are supposed to be followed for ethical conduct of any research, as they contain safeguards and protection of trial participants. The guidelines state that “*vulnerable participants are those individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability, environmental burden, social injustice, lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so.*” The *DC Rules* also makes provision for compensation in case of injury or death during clinical trials<sup>270</sup> and provide for free medical management and financial compensation to injured trial participants.

As far as TB is concerned there is a need for new research on TB drugs, as there is an ever increasing resistant to the current drugs. Much research is in the pipeline and is ongoing, but procedures as laid down in the law should be followed. In case of waiver of Phase III trials for a new drug, the post-marketing surveillance and Phase IV trials are of importance.

## 7.2 Experiences

The enforcement of the *DCA* is an area of concern. News reports, whistleblowers and litigation related to the flouting of drug regulation in India abound. In the case of the serological TB test ban reports suggest that while the use of these tests has decreased dramatically,<sup>271</sup> the ban on over-the-counter sales of TB drugs is not being properly enforced. It has also been noted that Schedule H1 omits certain key medicines including Linezolid, which can be used as part of an MDR-TB treatment regimen.

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268 CDSCO, Letter to Johnson&Johnson dated 27 June 2017, File No. CT/44/16-DCG (I), Clinical Trial NOC No.” GCT/17/17, available at [http://www.cdsc.nic.in/writereaddata/Sr\\_%20No\\_%2025%20CT-44-16-Johnson%20&%20Johnson.pdf](http://www.cdsc.nic.in/writereaddata/Sr_%20No_%2025%20CT-44-16-Johnson%20&%20Johnson.pdf)

269 Rules 122A, 122B, 122D, 122DA, 122DAA and 122E, *DC Rules*

270 Rule 122DAB, *DC Rules*

271 Sarman Singh, Serology testing ban needs to be enforced, 23 April 2014, available at <http://www.thehindu.com/opinion/open-page/serology-testing-ban-needs-to-be-enforced/article5820021.ece>

There has also been concern over the quality of TB drugs ; in 2016, the WHO banned all TB products from Svizera’s Mumbai site due to concerns over manufacturing standards and quality management.<sup>272</sup> According to one informant, *“the quality of TB drugs in India must be ensured and the low quality, ineffective, spurious or adulterated drugs that are in the market should be weaned out.* There have also been concerns over the impact of poor storage conditions of TB drugs which can impact their effectiveness.<sup>273</sup>

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;<sup>274</sup> people with TB and their doctors have lamented this overly cumbersome process in news reports.<sup>275</sup> 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 have 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.<sup>276</sup> On the other, the “conditional access” and limited access in the private sector are resulting in considerable barriers in access to treatment for patients with no other options.

Involvement of the private sector in allowing better access to MDR-TB drugs is essential and there is no provision in the law that warrants a conditional access only through the public sector.

### 7.3 Conclusions and Recommendations

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.

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272 WHO Suspends TB Drugs From Big India Supplier On Quality Fears, Business World, 19 March 2016, available at <http://business-world.in/article/WHO-Suspends-TB-Drugs-From-Big-India-Supplier-On-Quality-Fears/19-03-2016-92130/>

273 Ekatha Ann John, Poor storage lowers quality of TB drugs, Times of India, 7 March 2014, available at <https://timesofindia.india-times.com/city/chennai/Poor-storage-lowers-quality-of-TB-drugs/articleshow/31572632.cms>

274 Battle for access to tuberculosis medicine reaches HC, Economic Times, 4 January 2017, available at <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/battle-for-access-to-tuberculosis-medicine-reaches-hc/articleshow/56321031.cms>

275 Divya Rajagopal et al, India’s dependency on charitable program for MDR TB drugs not helping, doctors say, 17 November 2017, available at [economictimes.indiatimes.com/articleshow/61682769.cms?utm\\_source=contentofinterest&utm\\_medium=text&utm\\_campaign=cppst](https://economictimes.indiatimes.com/articleshow/61682769.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst)

276 Grover, Anand, Debate: India’s TB Patients Need Bedaquiline Now, Never Mind the Critics, thewire.in, 13 June 2018, available at <https://thewire.in/health/debate-indias-tb-patients-need-bedaquiline-now-never-mind-the-critics>

## **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 previously (in the section on “Notification”), the role of the private sector is a key concern in addressing TB in India. Various studies indicate that misdiagnosis and wrong treatment for TB are common in the private sector. Studies conducted two decades apart (1991<sup>277</sup> and 2010<sup>278</sup>) in Mumbai among private practitioners in the same geographical area revealed poor results: while the 1991 study showed that 100 of the 102 private practitioners surveyed prescribed 80 different regimens, in 2010, only 6 of the 106 respondents wrote a prescription with a correct drug regimen, 63 different drug regimens were prescribed by these 106, and only 3 wrote an appropriate prescription for MDR-TB treatment. The 2010 study noted that despite the efforts of RNTCP and increased outreach to the private sector, little had changed. In this context, legal accountability and avenues to address these concerns in the private sector are important.

### 8.1 The context in India – Laws, Policies & Jurisprudence

The NSP recognises that although, “over 80% of people with TB first attend the private sector, yet substantial diagnostic delays occur, and diagnosis and treatment are of variable quality.” It proposes strengthening regulatory approaches, including regulation 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, the NSP does not however, it is of note that several laws exist on the books that cover the private healthcare sector.

#### Clinical Establishments Act

The *Clinical Establishments (Registration and Regulation) Act, 2010 (CEA)* aims to establish minimum standards of health care facilities and services across the public and the private healthcare sector so “that the mandate of article 47 of the Constitution for improvement in public health may be achieved.”<sup>279</sup> As health is a State subject, the CEA is applicable only in those States that have agreed to its application.<sup>280</sup> At present the CEA is applicable in all Union Territories (except the National Capital

277 Uplekar MW, Shepard DS (1991) Treatment of tuberculosis by private general practitioners in India. *Tubercle* 72: 284–290 available at <https://www.ncbi.nlm.nih.gov/pubmed/1811360>

278 Udawadia ZF et al, *Tuberculosis management by private practitioners in Mumbai, India: Has anything changed in two decades?* *PLoS One* 2010;5:e12023 available at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0012023>

279 Preamble, *Clinical Establishments (Registration and Regulation) Act, 2010* available at <http://clinicaestablishments.nic.in/WriteReadData/969.pdf>

280 Article 252(1), Constitution of India

Territory of Delhi) and in the States of Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim, Uttar Pradesh, Uttarakhand, Rajasthan, Bihar, Jharkhand and Assam.

The CEA requires all clinical establishment to be registered under the CEA. The *Clinical Establishments (Central Government) Rules, 2012*, further specify that such registration is contingent on ensuring “compliance of the Standard Treatment Guidelines as may be determined and issued by the Central Government or the State Government.” In 2014, the Central TB Division of the MoHFW and WHO India issued the ‘Standards for TB Care in India,’ which are available on the website dedicated to the implementation of the CEA. However, whether these standards are being enforced through the CEA. In addition, the RNTCP also issued updated Technical and Operational Guidelines for Tuberculosis Control in India in 2016 that updates the 2014 Standards for TB Care in India and reflect, for instance, the transition to daily TB treatment and updated guidance on MDR-TB drugs. These guidelines are intended for use by all personnel in the country engaged in TB. Again, it is unclear if the updated guidelines are enforceable through the CEA.

### **Indian Medical Council Act**

In terms of medical negligence related to TB, the *Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002* (MCI Regulations) issued under the *Indian Medical Council Act, 1956* govern medical practitioners in India. Under the *MCI Regulations*, a practitioner should “not wilfully commit an act of negligence that may deprive his patient or patients from necessary medical care.”<sup>281</sup> Complaints of violations of the regulations can be filed with the appropriate medical council and can lead to disciplinary action.

### **Indian Penal Code**

Criminal law has also been invoked at times against the medical profession. Section 304A of the *IPC, 1860* punishes whoever causes death by a rash or negligent act with imprisonment up to two years or with fine or both. The application of this provision to the medical profession has been a cause of concern for courts. In *Jacob Mathew v. State of Punjab and anr.*,<sup>282</sup> the Supreme Court held that “The standard to be applied for judging, whether the person charged has been negligent or not, would be that of an ordinary competent person exercising ordinary skill in that profession...the essential components of negligence are three: ‘duty’, ‘breach’ and ‘resulting damage’...A simple lack of care, an error of judgment or an accident, is not proof of negligence on the part of a medical professional.” Negligence would become actionable based on the injury.

The Supreme Court distinguished clearly the concept of negligence in civil and criminal law. “For negligence to amount to an offence, the element of mens rea must be shown to exist. For an act to amount to criminal negligence, the degree of negligence should be much higher i.e. gross or of a very high degree. Negligence which is neither gross nor of a higher degree may provide a ground for action in civil law but cannot form the basis for prosecution.” The Supreme Court then read the word

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281 Regulation 2.4, *Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002*

282 (2005) 6 SCC 1

'gross' into Section 304A,IPC stating that it is "settled that in criminal law negligence or recklessness, to be so held, must be of such a high degree as to be 'gross'." It was also held that the principle of "res ipsa loquitur" i.e. where negligence can be inferred from the very nature of the event, would be applicable only to cases in civil law and would have a limited, if any role in criminal cases. laid down guidelines restricting the prosecution of medical professionals including the requirement that a complainant produce a credible opinion given by another competent doctor and that the investigating officer also obtain an independent and competent medical opinion.

## Consumer Protection Act

Where healthcare workers or institutions are negligent in diagnosing or treating TB, cases are often filed under the *Consumer Protection Act, 1986* (COPRA) which was enacted to protect consumers from defects in products or deficiency of services. However, liability is restricted to cases where the patient has paid (including a nominal fee) for the services. Services provided free of cost at government hospitals and clinics do not fall within the scope of this legislation though there is ongoing litigation on this issue.<sup>283</sup>

In several cases under *COPRA*, courts have awarded significant amounts of compensation to aggrieved parties, foisting liability on private physicians and hospitals to pay for proven negligence or deficiency in services.<sup>284</sup>This has happened in the case of TB as well. In *B. Suvarama Phani v. Miot Hospitals*,<sup>285</sup> the complainant's husband had TB, and died after appropriate tests were not conducted and his condition was misdiagnosed. The hospital report revealed that a Laparotomy was done instead of a Laparoscopy, which was medically indicated. The Tamil Nadu State Consumer Disputes Redressal Commission found that the doctors had been negligent, and granted INR 35,00,000 as compensation, and a sum of INR 5,00,000 for mental agony. In *Ch. V. Narasimha Rao v. K. Raja Rajeswari*,<sup>286</sup> the deceased wife of the complainant was misdiagnosed with peritonitis of the intestine when she had advanced TB. The Andhra Pradesh State Consumer Disputes Redressal Commission found that due diligence had not been exercised and granted INR 1,50,000 as compensation.

However, it should be noted that apart from such cases taking several years to be resolved, even if there has been an error in cases, it may not result in liability. In *Ms. Kamani Sharma & Ors. v Dr. Anil Nadir & Ors*<sup>287</sup> the complainant's husband was diagnosed by the respondent as having TB when in fact he had cancer. In determining whether there was medical negligence, the National Consumer Disputes Redressal Forum (NCDRF) held that there was an error of judgment and then held that in such cases, the principle of "loss of chance" would be applicable. The NCDRF held that the failure to diagnose would not have mattered as the cancer was at such a stage that there was less than a 50%

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283 Choudhary, Amit Anand, "SC stays NCDRC order to bring govt hospital's free medical services under consumer law ambit", Times of India, 17 October 2017, available at <https://timesofindia.indiatimes.com/india/sc-stays-ncdrc-order-to-bring-govt-hospitals-free-medical-services-under-consumer-law-ambit/articleshow/61119601.cms>

284 *Dr. Balram Prasad v Dr. Kunal Shah and others*, Supreme Court, Civil Appeal No. 2867 of 2012, judgment dated 24.10.2013

285 IV(2012) CPJ50(RE)

286 II(2011) CPJ1(AP)

287 Consumer Case No. 351 Of 2001, National Consumer Disputes Redressal Commission New Delhi, Date Of Decision: 13 July, 2015

chance of survival. Because the patient also did not follow advice on further diagnosis the NCRDF also found there was contributory negligence.

## 8.2 Experiences

Several informants raised concerns about the laxity of regulations relating to the private sector and the contribution of misdiagnosis and wrong treatment to the development of MDR-TB in India. According to one informant, the 1991 and 2010 studies on TB prescription practices in Mumbai shows that, *“we are unable to break this cycle.”* He said, *“the government should set TB prescriptions and alternative prescriptions should be decided only by a government authority. Unfortunately, the national programme does not want to get on the wrong side of the private sector.”* Another informant felt that stern legal action could send a clear message to the private sector: *“suspend ten doctors for wrong diagnosis of TB and you will see a change. But we have not seen any healthcare worker ever held accountable.”*

On the other hand, one informant noted, *“It is important to understand that the situations are so varied that you cannot club it all under one umbrella and call it private sector. They are all in different categories – private hospitals, private GPs.”* Some informants also felt that the attitude of private doctors is often less stigmatizing than those in the public sector. Another highlighted the importance of training programmes: *“Training programs are required to be conducted with private associations like IMA in collaboration with the public sector and should include scientific and non-scientific sessions. In Maharashtra, there is compulsory accreditation and doctors are required to attend such conferences, workshops, seminars where they get updated with the knowledge on TB.”*

## 8.3 Conclusions and Recommendations

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)***

- a) 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***

- b) 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.
- c) 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***

- d) 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***

- e) 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.
- f) 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***

- g) 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 records show 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.<sup>288</sup> Though AYUSH practitioners hold degrees in alternate systems of medicine, and receive 4-5 years of formal training to obtain degrees equivalent to their counterparts in allopathy, they are perceived as ‘informal’ providers of healthcare in the country.<sup>289</sup> At PHCs and in urban pockets, AYUSH practitioners are the primary point of medical service to address the health needs of the populace. This is also the case for people seeking treatment and care for TB.

### 9.1 The context in India – law, policy and jurisprudence

The *Drugs and Cosmetics Act, 1940* (DCA), and related *DC Rules, 1945* 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.<sup>290</sup> 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.<sup>291</sup> State governments also have the power to regulate the sale of homeopathic medicines<sup>292</sup> and manufacture and sale of drugs other than homeopathic medicines.<sup>293</sup> A proposed legislation, the *National Medical Commission Bill, 2017* envisages training AYUSH practitioners to enhance the interface between traditional Indian systems of medicine and modern medicine.<sup>294</sup> The training may contemplate AYUSH practitioners as prescribers and managers of TB medication and treatment under the RNTCP.

288 McDowell, A & Pai, M, “Alternative medicine: an ethnographic study of how practitioners of Indian medical systems manage TB in Mumbai” *Trans R Soc Trop Hyg* 2016; 110: 192-198, doi:10.1093/trstmh/trw009

289 Ibid.

290 Section 3(a), *Drugs and Cosmetics Act, 1940*

291 Chapter IVA, Sections 33B to 33K, *Drugs and Cosmetics Act, 1940*

292 Part VI-A, Rules 67A to 67H, *Drugs and Cosmetics Rules, 1945*

293 Part VII, *Drugs and Cosmetics Rules, 1945*

294 Das, M “Why experts are calling Bill proposing AYUSH docs to practice modern medicine a bad idea”, *The News Minute*, Jan. 02, 2018, available at <https://www.thenewsminute.com/article/why-experts-are-calling-bill-proposing-ayush-docs-practice-modern-medicine-bad-idea-74037>, last accessed on 25.2.2018

This approach appears in the NSP as well which states that, “[t]here is still lack of clarity on roles of AYUSH in TB patient care and hence, engagement with AYUSH practitioners is currently guarded” but that mapping of such providers is essential to begin engaging with them. Further, the NSP states that “[c]onsidering the large number of AYUSH providers (3,598 hospitals and 25,723 dispensaries) in India, efficient symptom identification and referral system will be established to enable early diagnosis. Existing referral linkages will be strengthened and some new linkages will be established based on provider mapping. This will result in early and accurate diagnosis of TB and timely initiation of treatment, improved access to TB care, less number of patient drop-outs and increased patient satisfaction. They will also be involved in expanding the patient support system.”<sup>295</sup>

## 9.2 Experiences

As pointed out by TB experts, 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, it was noted, Ayurvedic experts use allopathic prescriptions mixed with Ayurvedic ingredients. One study found that AYUSH practitioners do not exclusively practice their system of training.<sup>296</sup> In fact, the average consultation fees of an AYUSH practitioner for prescribing bio-medicine/ allopathic drugs was INR 50, whereas a consultation in their own system was much higher - between INR 100 to 300.<sup>297</sup> And, the demand for such 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.<sup>298</sup> Such choices are exercised often because AYUSH practitioners’ services are cheaper than private allopathic private practitioners and they are primary care givers in many locales where allopathic doctors do not have presence. These studies also revealed that AYUSH practitioners prescribed 4-5 antibiotics, like amoxicillin or ciprofloxacin that are relatively inexpensive.

In relation to such prescription by AYUSH practitioners, one expert noted:

*“The issue is that fluoroquinolones – Ofloxacin, levofloxacin, moxifloxacin and ciprofloxacin - are prescribed a lot, even for common ailments/ infections – and therefore there is some amount of drug resistance. But, drug resistance happens also in the natural course – and people just become resistant to some antibiotics, and therefore there is a need to find new drugs, every now and then.”*

Additionally, experts in the field reiterated what was found in the aforementioned study that AYUSH practitioners felt comfortable referring patients with presumptive TB to local private clinics or laboratories and the majority of them referred a person diagnosed with TB to a chest specialist at

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295 National Strategic Plan for Tuberculosis Elimination 2017-25, available at <https://tbcindia.gov.in/WriteReadData/NSP%20Draft%2020.02.2017%201.pdf>, at pages 28-30

296 McDowell, A & Pai, M, “Alternative medicine: an ethnographic study of how practitioners of Indian medical systems manage TB in Mumbai” *Trans R Soc Trop Hyg* 2016; 110: 192-198, doi:10.1093/trstmh/trw009

297 Ibid.

298 Ibid.

the public healthcare centre.<sup>299</sup> The study also found that although the AYUSH practitioner would refer to diagnose a person with TB, it would take several visits to such a practitioner, and a course of antibiotics to be completed prior to considering the referral for a TB test.<sup>300</sup> 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 treating people with TB because they are often the first point of contact in the healthcare system for many people. It is, therefore, crucial to include AYUSH practitioners under the RNTCP and provide them systematic training for the same.

### **9.3 Conclusions and Recommendations**

In order to tackle the issue of TB in the country, it is important to gather all the professionals and practitioners, train them to reach out to people with TB, test, counsel and treat them effectively. Involvement of AYUSH practitioners in the RNTCP is therefore essential and of much importance too.

#### **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

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299 Ibid.

300 Ibid.

***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. This insufficiency is reflected in the inability of the needy to access TB services for diagnosis and treatment at PHCs and DOTS centres. People make do with what is available, convenient and affordable, due to ignorance and mistrust of the available facilities and systems of medicine. And, ineffective regulation and weak vigilance, provides an opportunity to unlicensed persons - quacks - to provide 'healthcare' services.

Generally, when there is no other treatment available, or when the side-effects of the available treatment are toxic, people get lured by quacks, who provide a promise of 'cure' and treatment, who give time to listen, and who provide some 'medicine', more often a spurious concoction, or promise to heal the person through their so-called 'powers'. The practice of quackery involves the supply of steroids, or weird combinations of drugs that may cause further harm to patients in the long run.

## 10.1 The context in India – law, policy and jurisprudence

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.<sup>301</sup> The courts have repeatedly directed State governments to prevent unqualified persons from practicing any branch of medicine,<sup>302</sup> and recently the Supreme court dismissed an appeal filed by an association of unqualified practitioners seeking regularisation as they were "paramparavaidyas" (traditional healers), stating that they could not show that they had the requisite qualifications in any of the branches of medicines.<sup>303</sup>

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301 *Rajesh Kumar Srivastava v AP Verma & anr.* AIR 2005 All 175

302 *Anubhava Allopathy v Union of India*, Madras High Court, *vide* order dated 19.8.2008, in W.P. No. 1598 of 2001, available at <https://indiankanoon.org/doc/616326/>. Also, see *DK Joshi v State of UP*, Supreme Court of India, *vide* order dated 25.4.2000 in Appeal (Civil) No. 2016 of 1996, available at <https://indiankanoon.org/doc/12564134/>

303 *Kerala Ayurveda Paramparaya Vaidya Forum v State of Kerala*, Supreme Court of India, *vide* order dated 13.4.2018, in Civil Appeal No. 897 of 2009 available at <https://indiankanoon.org/doc/2987190/>

The *DC Rules*<sup>304</sup> and the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (*DMR Act*) are the two legislations that prohibit a person from claiming a drug to purport or prevent or cure certain diseases. Diseases listed in Schedule K of the *DC Rules* do not include TB, since there is an allopathic cure and treatment for it. However, 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.<sup>305</sup>

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.

## 10.2 Experiences

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.

## 10.3 Conclusions and Recommendations

Quackery is symptomatic of a healthcare system that is poorly funded, inaccessible and not serving the needs of most people. 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

- a) 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.
- a) Strengthen primary health centres by training and sensitizing personnel to provide proper counseling and treatment to people with TB.

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304 Rule 106 read with Schedule J, *DC Rules*

305 Sections 3 and 4, *DMR Act, 1954* read with No.50 in the Schedule

## **Recommendations to Other Stakeholders**

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

- a) Must pass strict orders against persons practicing quackery and prevent them from opening their shop or starting their unauthorized practice of medicine again.
- b) 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***

- c) 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

Of the seventeen Sustainable Development Goals that have been set as targets of a global compact by the community of nations, to “ensure healthy lives and promote well-being...” is the third goal focused on health. Within it one of the targets is to “achieve universal health coverage, including financial risk protection...”<sup>306</sup> In explaining the concept of universal health coverage (UHC) the WHO states that,

*“Good health is essential to sustained economic and social development and poverty reduction. Access to needed health services is crucial for maintaining and improving health. At the same time, people need to be protected from being pushed into poverty because of the cost of health care.”*

It defines UHC as:

*“ensuring that all people have access to needed promotive, preventive, curative and rehabilitative health services, of sufficient quality to be effective, while also ensuring that people do not suffer financial hardship when paying for these services.”<sup>307</sup>*

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 (discussed in more detail in the section on “Access to Treatment and Diagnostics”). 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 by ensuring that all the essential elements of it – health financing, human resources for health, essential medicines and health products, health systems governance, health statistics and information systems, and service delivery and safety – are sufficiently provided for and efficiently run.<sup>308</sup>

306 See <http://www.un.org/sustainabledevelopment/health/>

307 See [http://www.who.int/healthsystems/universal\\_health\\_coverage/en/](http://www.who.int/healthsystems/universal_health_coverage/en/)

308 See [http://www.who.int/universal\\_health\\_coverage/en/](http://www.who.int/universal_health_coverage/en/)

Although various law and policy issues arise in relation to all of these components, this section focuses on one aspect of health financing where there has been some degree of intersection with the law in India viz. insurance. This aspect has been part of debates and discussions on public health in India for some time, but has received greater attention recently with the announcement of National Health Protection Scheme in the central government's annual budget, which aims to cover ten crore poor and vulnerable families with INR 5,00,000 coverage per family per year for secondary and tertiary care hospitalization.<sup>309</sup>

### 11.1 The context in India - Law, policy & jurisprudence

The NSP recognizes the need for financial support to effectively address the plight of those with TB and their families. Among the strategies it articulates for marginalized and economically deprived people, the need to “*consider a group life-insurance scheme for all TB patients to prevent the catastrophic consequences for the family in the event of death during TB treatment*”, and to “*explore and advocate for micro-insurance and health covers for management of complications due to TB among pregnant and lactating women...*” are two. The NSP notes that efforts should be made to mitigate out-of-pocket expenses by making “*synergies between various social welfare support systems like RSBY (Rashtriya Swasthya Bima Yojana), National Family Benefit Scheme, Group Life insurance scheme (Jan Shree Bima Yojana), national rural employment guarantee scheme...*” Further, the NSP states that the TB programme shall also make linkages with extant government health insurance schemes and “*at a later date with the Universal Health Coverage (UHC) of the Government.*”

The NSP also recognizes that there are catastrophic consequences on families and communities which have to cope with out-of-pocket expenditure and envisages the RNTCP to cover costs borne in the private sector related to TB diagnosis, treatment, nutrition, and travel through reimbursements or subsidies to patients or private providers.<sup>310</sup> (Financial support for food is an issue dealt with in the section on “Nutrition”.)

#### The unorganized sector

An overwhelmingly large majority of people – over 80 per cent – work in the unorganized sector in India.<sup>311</sup> The social security policy response to this has been the passing of the *Unorganized Workers Social Security Act* in 2008, which is aimed at providing welfare for the unorganized workforce.<sup>312</sup> This law requires the central government to formulate social security schemes for the unorganized sector worker relating to, inter alia, health benefits.<sup>313</sup> One such scheme is the RSBY, a national health insurance scheme, which was initially meant for households below the poverty line, but has been expanded over time to include those in unorganized sectors such as construction, street vending, domestic help, miners, rag pickers, rickshaw drivers, and those qualified under the national

309 See <https://mofapp.nic.in/budgetmicrosite/index.html>

310 National Strategic Plan for Tuberculosis Elimination 2017-25, available at <https://tbcindia.gov.in/WriteReadData/NSP%20Draft%2020.02.2017%201.pdf>, at page 56

311 See <http://pib.nic.in/newsite/mbErel.aspx?relid=154133>

312 Available at <http://www.ilo.org/dyn/travail/docs/686/Unorganised%20Workers%20Social%20Security%20Act%202008.pdf>

313 Section 3, *Unorganised Workers Social Security Act, 2008*

rural employment guarantee scheme.<sup>314</sup> RSBY covers hospitalization costs up to INR 30,000 per year for a family, pre-existing conditions, and a list of diseases, including “*respiratory tuberculosis, bacteriologically and histologically confirmed*” with an allowed length of hospitalization being ten days.<sup>315</sup> The cover extends to a maximum of five members of a family, including the head of the household, the spouse and up to three dependents. Additional financial support that is provided under RSBY is transportation costs of INR 100 per hospitalization (up to a maximum of INR 1000 per year per family). The contribution expected from a beneficiary is a registration fee of INR 30 per year, with central and state governments paying premiums on a cost-share basis to the insurer who is selected on the basis of a public tender. This has been a long overdue requirement for the unorganized workforce, and as of 31 March 2015 approximately 3.6 crore beneficiaries were enrolled in the RSBY (about 10 per cent of the total unorganized workforce).<sup>316</sup> Crucially, however, RSBY does not cover out-patient care and prescription costs, both of which are relevant in the context of TB, and both of which are causes for significant out-of-pocket expenditure for patients<sup>317</sup> particularly in the private sector where a vast majority of people with TB first interact with the health system.<sup>318</sup> Indeed, recent research suggests that despite government provided health schemes, those with such insurance coverage continued to be burdened by out-of-pocket expenditure, which was more in the private sector than the public sector, and that hospitalization of the insured led to catastrophic health expenditure for a large proportion of households.<sup>319</sup> In relation to TB, however, research suggests that tapping into the RSBY can reduce catastrophic expenditure from diagnosis to treatment for people with MDR-TB, in the public and private sector.<sup>320</sup>

Another government scheme that caters to the unorganized sector is the Aam Aadmi Bima Yojana, which provides life insurance for those between 18 and 59 years of age who are below or marginally above the poverty line. The premium to be paid is INR 200 per year for a cover of IN 30,000.<sup>321</sup>

## The organized sector

In linking health insurance to one’s employment, various laws in India provide for cover in the organized labour sector. Interestingly, these laws often specifically mention TB as a health condition requiring special treatment, such as in the instances below.

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314 See [http://www.rsby.gov.in/about\\_rsby.aspx](http://www.rsby.gov.in/about_rsby.aspx)

315 See Guidelines for Revamp of RSBY -Operational Manual for Phase I (Released on 16th July 2014), available at <http://www.rsby.gov.in/Documents.aspx?id=3>

316 See <http://pib.nic.in/newsite/mbErel.aspx?relid=154133>

317 Reddy, K Srinath, Health assurance: Giving shape to a slogan, Current Medicine Research and Practice, Volume 5, Issue 1, 1-9 available at [http://www.cmrp-journal.com/article/S2352-0817\(15\)00012-4/fulltext](http://www.cmrp-journal.com/article/S2352-0817(15)00012-4/fulltext)

318 National Strategic Plan for Tuberculosis Elimination 2017-25, available at <https://tbcindia.gov.in/WriteReadData/NSP%20Draft%2020.02.2017%201.pdf>, at page 25

319 Nandi S, Schneider H, Dixit P (2017), Hospital utilization and out of pocket expenditure in public and private sectors under the universal government health insurance scheme in Chhattisgarh State, India: Lessons for universal health coverage. PLoS ONE 12(11): e0187904

320 Kundu D et al. Innovative social protection mechanism for alleviating catastrophic expenses on multidrug-resistant tuberculosis patients in Chhattisgarh, India. WHO South-East Asia J Public Health 2015;4:69-77

321 See <https://www.licindia.in/Products/Aam-Aadmi-Bima-Yojana>

For instance, the *Employees' State Insurance Act, 1948* is one such law. It provides that 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.<sup>322</sup>

Under the *Employees' Provident Funds Act, 1952* a scheme has been framed under which 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.<sup>323</sup> A member of the scheme who has contracted TB after leaving employment is deemed to have been incapacitated for work, and thereby entitled to withdraw funds for their treatment.<sup>324</sup> The Supreme Court has provided an altruistic view of schemes such as those of provident funds, in the context of TB. For instance, where a widow claimed family pension from the fund to which her deceased husband was a subscriber, and was denied the same since the husband had failed to contribute due to severe ill health caused by TB, the court held that the pension should not be denied to a person in such difficult circumstances.<sup>325</sup>

A very large scheme, which comes to the aid of employees and former employees of the central government and their dependent family members residing in covered areas is the Central Government Health Scheme (CGHS), being approximately 31 lakh people and their dependents as per the last census.<sup>326</sup> The scheme is also available for present and former members of parliament, freedom fighters, sitting and former judges of the Supreme Court & High Courts, railway board employees, post and telegraph department employees, Delhi police personnel, employees and pensioners of designated autonomous organizations in Delhi, and limited coverage for journalists in Delhi accredited with the Press Information Bureau. The covered geographical areas include 35 cities, a union territory and the state of Goa,<sup>327</sup> although rules permit claims for eligible persons who fall ill elsewhere and incur treatment there.<sup>328</sup> The facilities available under the CGHS include out-patient treatment including provision of medicines, specialist consultations at polyclinics or government hospitals, in-patient treatment at government and empaneled hospitals, investigations at government and empaneled diagnostic centres, and reimbursement of expenses for emergency treatment availed in government or private hospitals.<sup>329</sup> Apart from covering treatment for TB, CGHS also allows an advance up to INR 10,000 to be given for out-patient TB treatment.<sup>330</sup>

The central government is also required to set up welfare funds and schemes for members of the Railway Protection Force to "*alleviate distress from ... prolonged illnesses*" such as TB, as provided

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322 Section 52A read with Part C, 3<sup>rd</sup> Schedule, *Employees State Insurance Act, 1948*

323 Section 68-J, Employees Provident Fund Scheme, 1952 available at [https://epfindia.gov.in/site\\_docs/PDFs/Downloads\\_PDFs/EPFScheme.pdf](https://epfindia.gov.in/site_docs/PDFs/Downloads_PDFs/EPFScheme.pdf)

324 *Ibid.*, section 69.

325 *Regional Provident Fund Commissioner v Muliben & Anr*, Civil Appeal No. 6063/1998 Supreme Court of India 2000, available at <http://supremecourtindia.nic.in/jonew/bosir/orderpdf/25020.pdf>

326 See [http://dget.nic.in/upload/uploadfiles/files/publication/CENSUS\\_REPORT\\_2011\\_.pdf](http://dget.nic.in/upload/uploadfiles/files/publication/CENSUS_REPORT_2011_.pdf)

327 See <https://cghs.gov.in/showfile.php?lid=4784>

328 See <http://www.pcdabl.gov.in/paymedicalguidelines.htm>

329 See <https://cghs.gov.in/showfile.php?lid=4784>

330 See <http://www.pcdabl.gov.in/paymedicalguidelines.htm>

for in the *Railway Protection Force Rules, 1987*.<sup>331</sup> And, the *Railway Servants (Pass) Rules, 1986* provide that employees of the Indian Railways can claim special travel passes to seek treatment for TB for themselves or their family members.<sup>332</sup>

In another instance, the *Advocates Welfare Fund Act, 2001* has set up a fund for the benefit of advocates, under which a member advocate can claim an ex gratia amount ranging from INR 1000 - 30,000 (depending on the number of years they have been a member) if they are undergoing TB treatment.<sup>333</sup>

(Notably, in relation to insurance and TB specifically, Peru passed a *sui generis* legislation in 2014 that articulates a series of rights of people affected by TB, including “*the right to comprehensive health care, including the right to access free treatment for those with or without health insurance.*”<sup>334</sup>)

For health insurance policies that can be purchased, the insurance sector is regulated by the *Insurance Regulatory and Development Authority (IRDA) Act, 1999*. The IRDA has many functions and duties, one of which is to protect the policyholder’s interests.<sup>335</sup> This has included instituting an Integrated Grievance Management System, which allows policyholders to make complaints,<sup>336</sup> if they remain unresolved in the first instance before the insurance company’s Grievance Redressal Officer.<sup>337</sup> An alternative route is also the Insurance Ombudsman.<sup>338</sup> In the past, the Insurance Ombudsman has considered TB-related claims, including related to non-disclosure of material facts (having TB) under a life insurance policy.<sup>339</sup>

In relation to health insurance and TB, many cases have also been brought under the *Consumer Protection Act, 1986*, where complainants have argued that the denial of insurance claims under life insurance policies amount to a deficiency in service, which is actionable under the statute. In some of these cases, based on the evidence before it, consumer courts have held that the deceased had not suppressed his history of TB, and denial of claim amounted to deficient services under the Act.<sup>340</sup> On the other hand, insurance companies have countered that denial of claims were justified since the deceased failed 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.<sup>341</sup> The denial of coverage due to

331 Section 262, *Railway Protection Force Rules, 1987* available at <http://www.icf.indianrailways.gov.in/uploads/files/RPF%20RULE.pdf>

332 Schedule VII, *Railway Servants (Pass) Rules, 1986* available at [http://www.ner.indianrailways.gov.in/uploads/files/1349074968630-1986%20\(1993%20edition\).pdf](http://www.ner.indianrailways.gov.in/uploads/files/1349074968630-1986%20(1993%20edition).pdf)

333 Section 19, *Advocates Welfare Fund Act, 2001* available at <http://lawmin.nic.in/Id/P-ACT/2001/The%20Advocates%E2%80%99%20Fund%20Act,%202001.pdf>

334 Legal Environment Assessments for TB - an Operational Guide, July 2017, Stop TB Partnership, available at [http://www.stoptb.org/assets/documents/communities/StopTB\\_TB%20LEA%20DRAFT\\_FINAL\\_Sept%2027.pdf](http://www.stoptb.org/assets/documents/communities/StopTB_TB%20LEA%20DRAFT_FINAL_Sept%2027.pdf)

335 Section 14(2)(b), *IRDA Act, 1999*

336 See <http://igms.irda.gov.in/> and [http://www.policyholder.gov.in/Integrated\\_Grievance\\_Management.aspx](http://www.policyholder.gov.in/Integrated_Grievance_Management.aspx)

337 See <http://www.policyholder.gov.in/Report.aspx>

338 See <http://www.policyholder.gov.in/Ombudsman.aspx>

339 See [http://www.policyholder.gov.in/Case\\_laws\\_or\\_Judgements.aspx](http://www.policyholder.gov.in/Case_laws_or_Judgements.aspx)

340 *Divisional Manager, L.I.C. of India and Ors v Pappayee III* (1998) CPJ 511 (RE)

341 *Bajaj Allianz Life Insurance v Ramkumar & Others* (2017) CPJ145 (RC), *Deputy Divisional Manager (P.L.I.) and Ors v Shiv Charanjit Puri* 2008(2) C.P.C. 400

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. As the Supreme Court has pointed out, however, 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:

*“The eligibility conditions must be conformable to the Preamble, Fundamental Rights and Directive Principles of the Constitution... The rates of premium must also be reasonable and accessible. It may be made clear that the with a view to make the policy viable and easily available to the general public, it may be open to the appellants to revise the premium... but it must not be arbitrary, unjust, excessive and oppressive.”<sup>342</sup>*

Fairness should also extend to covering pre-existing conditions, which are generally excluded by insurance companies and, as stated above, become the basis for outright denial. Given this, the IRDA should mandate that insurance companies offer schemes that cover pre-existing conditions.

## **11.2 Experiences**

Part of the challenge in fully utilizing the benefits available under social security and insurance schemes is the multiplicity of these schemes within various bureaucracies, which make reaping the support they offer inaccessible. Further, there is a lack of awareness about these schemes amongst the most needy. And, some of these schemes are not specific to TB although they cover people with TB within their general framework. Efforts such as Project Axshya, an initiative of the International Union Against Tuberculosis and Lung Disease (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 (benefiting over 200 people with TB) and require to be replicated.<sup>343</sup>

## **11.3 Conclusion and Recommendations**

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. Along with this macro issues of health systems strengthening and human resources for health also require investment. As was pointed out by many experts working in the area of TB, 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 health services, and to mitigate out-of-pocket expenditure by insuring out-patient and in-patient care, and prescription expenses. Proper urban planning, integration of health and hygiene education into curricula and regular public messaging are also part of the solution; solely focusing on a medicalised approach that prioritizes health insurance would fail to address

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342 *LIC of India v Consumer Education & Research Centre* (1995) 5 SCC 482

343 See <https://www.theunion.org/news-centre/news/axshya-links-tb-patients-with-social-welfare-schemes>

the underlying reasons that cause vulnerability to TB in the first instance. 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.

# **IV. Access**

## **12. Access to Treatment and Diagnostics**

### **13. Access to Nutrition**

## 12. Access To Treatment & Diagnostics

Treatment and diagnostics for TB have changed considerably over the past decade. Before then treatment options for TB had remained the same for nearly 40 years and the diagnostic of choice in several developing countries was over a century old. Recent advances have seen the introduction of new drugs for DR-TB and more rapid diagnostics as well as drug sensitivity testing.

For properly diagnosed, uncomplicated TB, a six-month course of treatment is prescribed with older drugs remaining effective if used correctly. These are isoniazid (INH), rifampin (RIF), ethambutol (EMB) and pyrazinamide (PZA). Resistance to two of the first-line antibiotics (rifampicin and isoniazid) means that the person is considered to have MDR-TB. Treatment in this case can last up to two years, with many side effects, making treatment completion and compliance difficult. A patient resistant to at least four of the core anti-TB drugs is considered to have extensively drug-resistant tuberculosis (XDR-TB).

It is for the treatment of MDR-TB that new drugs (bedaquiline and delamanid) have been introduced. Both drugs have been approved in several countries based only on Phase IIb data due to the urgent need for newer drugs. As a result the WHO has published and regularly updates interim guidance for the use of these drugs as results of clinical trials continue to come in.<sup>344</sup> For instance, in January 2018, the WHO published a position statement on the use of delamanid based on an expedited review of results from a phase III trial that showed, among other things, the safety of the drug but at the same time, no significant statistical difference between the delamanid and placebo arms. While WHO maintained its interim guidance on delamanid pending a comprehensive review, it added that “national TB programmes and other stakeholders are advised to **only** add delamanid to a longer MDR-TB regimen when it cannot be composed according to WHO recommendations” (emphasis added).<sup>345</sup>

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344 WHO, Frequently asked questions about the use of bedaquiline according to the WHO guidelines and evidence from its early use in selected countries, 1 March 2017 (Revised) available at [http://www.who.int/tb/publications/2017/FAQs\\_Bedaquiline.pdf](http://www.who.int/tb/publications/2017/FAQs_Bedaquiline.pdf); and WHO, WHO to review its interim guidance on the use of delamanid in the treatment of MDR-TB following the release of Phase III clinical trial results, 27 October 2017, available at [http://www.who.int/tb/features\\_archive/interim\\_guidance\\_MDR\\_TB/en/](http://www.who.int/tb/features_archive/interim_guidance_MDR_TB/en/)

345 WHO, WHO position statement on the use of delamanid for multidrug-resistant tuberculosis, January 2018, <http://www.who.int/tb/publications/2018/WHOPositionStatementDelamanidUse.pdf?ua=1>

Diagnosing pulmonary TB in many developing countries relies on the century-old smear microscopy. This test requires a person to cough up sputum, which can be difficult or otherwise requires lung fluid. Microscopy is effective in diagnosis only half the time and is not advised for diagnosis of those living with HIV or children. Chest x-rays are also commonly used to diagnose pulmonary TB. A new diagnostic test, the Cartridge-Based Nucleic Acid Amplification Test or CBNAAT (referred to often by the trademark name Genexpert or Xpert) now allows for rapid diagnosis of TB as well as resistance testing for rifampicin but not for resistance to other drugs. Diagnosing extra-pulmonary TB is even more challenging. Other tests for TB include culture (which takes weeks to get results), skin TB tests (which does not distinguish between latent and active TB) and Interferon Gamma Release Assays (only for latent TB).

Research and development (R&D) in new TB drugs and diagnostics has been historically and notoriously underfunded. Traditional R&D incentives have not worked in the case of TB. For diseases like TB, the Commission on Intellectual Property, Innovation and Public Health (CIPIH) found that, there is no evidence that the implementation of the World Trade Organization's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement in developing countries will significantly boost R&D, and that *"insufficient market incentives are the decisive factor."*<sup>346</sup> According to the WHO, *"TB accounts for nearly 2% of disability-adjusted life-years (DALYs) and 2% of deaths globally, but receives only 0.25% of the estimated US\$ 265 billion spent on medical research annually."*<sup>347</sup> The WHO has called on governments to develop country-specific TB research agendas, activate domestic financing mechanisms and streamline regulatory processes.

Access to medicines and diagnostics is an integral part of the right to health. Article 12 of the International Covenant on Economic, Social and Cultural Rights ("ICESCR"), which recognises this right provides that the State take certain steps to realise this right including "the prevention, treatment and control of epidemic, endemic, occupational and other diseases....".<sup>348</sup> General Comment 14 issued by the Committee on Economic, Social and Cultural Rights in 2000 further found that "the right to health must be understood as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health"<sup>349</sup> and among the core obligations of the State is, "the provision of essential drugs as outlined by the WHO action plan on drugs"<sup>350</sup>, which includes key TB drugs.<sup>351</sup> General Comment 14 finds that the fulfillment of this right rests on the overlapping principles of availability, accessibility, acceptability

346 Public health, Innovation and Intellectual Property Rights, Report of the Commission on Intellectual Property Rights, Innovation and Public Health, April 2006, available at <http://www.who.int/entity/intellectualproperty/report/en/index.html>

347 WHO, Global investments in Tuberculosis research and development: past, present and future. A policy paper prepared for the first WHO global ministerial conference on ending tuberculosis in the sustainable development era: a multisectoral response, 2017, available at <http://apps.who.int/iris/bitstream/10665/259412/1/9789241513326-eng.pdf?ua=1>

348 Article 12, ICESCR

349 Para 9, **Committee on Economic, Social and Cultural Rights, General Comment 14, The right to the highest attainable standard of health (Twenty-second session, 2000), U.N. Doc. E/C.12/2000/4 (2000)**, available at [http://www.unhcr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En](http://www.unhcr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En) (General Comment 14).

350 Para 43, General Comment 14

351 See List item 6.2.4: Antituberculosis medicines, WHO Model List of Essential Medicines, 20<sup>th</sup> List, March 2017, available at [http://www.who.int/medicines/publications/essentialmedicines/20th\\_EML2017.pdf?ua=1](http://www.who.int/medicines/publications/essentialmedicines/20th_EML2017.pdf?ua=1)

and quality.<sup>352</sup> ICESCR also recognizes the right to enjoy the benefits of scientific progress which it has been argued can form the basis for State obligations to spend public money on R&D for new diagnostics and treatment for MDR-TB and to ensure that all patients in need are able to benefit from newer medicines.<sup>353</sup>

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.<sup>354</sup> 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 and states that the TRIPS Agreement "does not and should not prevent Members from taking measures to protect public health" and "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines."<sup>355</sup> According to the United Nations High Level Panel on Access to Medicines, States are duty bound to use TRIPS flexibilities to protect the rights of their citizens.<sup>356</sup> 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.<sup>357</sup>

## 12.1 The context in India – Laws, Policies & Jurisprudence

The Indian government provides access to TB tests and treatment free of charge. The NSP,<sup>358</sup> adopts the goal of TB elimination by 2025, 10 years in advance of WHO's global end-TB goal.<sup>359</sup> The NSP aims to detect all those people with drug sensitive TB as well as those with DR-TB. In terms of treatment, the NSP aims to initiate and sustain all patients on appropriate TB treatment wherever they seek care. In terms of public spending on R&D, in 2017, the government announced the establishment of the "India TB Research and Development Corporation" (ITRDC), a flagship initiative by Indian Council of Medical Research's (ICMR), to develop new tools (drug, diagnostics, vaccines) for TB.<sup>360</sup> The new initiative provides hope for the continuation of some aspects of the pioneering Open Source Drug Discovery (OSDD) Project run by the Council of Scientific and Industrial Research (CSIR) from 2008

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352 Para 12, General Comment 14

353 London et al, Multidrug-Resistant TB: Implementing the Right to Health through the Right to Enjoy the Benefits of Scientific Progress, *Health and Human Rights Journal*, June 2016, Vol 18, No 1 pp 24-42

354 Goal 3 targets, United Nations, Sustainable Development Goals, 2015 available at <http://www.undp.org/content/undp/en/home/sustainable-development-goals/goal-3-good-health-and-well-being/targets/>

355 WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 14 November 2001, available at [https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.pdf](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf)

356 Report of the United Nations Secretary General's High Level Panel on Access to Medicines, September 2016, available at <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>

357 See paras 38-42, General Comment 14

358 Central TB Division, National Strategic Plan for Tuberculosis Elimination 2017 – 2025, available at <https://tbcindia.gov.in/WriteReadData/NSP%20Draft%2020.02.2017%201.pdf>

359 WHO, The End-TB Strategy, available at <http://www.who.int/tb/strategy/end-tb/en/>

360 R. Prasad, ICMR wins the 2017 Kochon Prize for TB research, *Hindu*, 13 March 2018, <http://www.thehindu.com/sci-tech/health/icmr-wins-the-2017-kochon-prize-for-tb-research/article23228652.ece>

to [2016]. The OSDD project was based on an open source research platform connecting thousands of researchers across multiple countries that identified potential drug targets for TB without patent claims to ensure that any ultimate treatments would be affordable.<sup>361</sup> ICMR has also announced its intention to commence TB related clinical trials including one to explore shortening the duration of MDR-TB treatment. The NSP specifically embraces the ICMR TB Research Consortium's activities to develop low cost diagnostics and conduct clinical trials for new TB vaccines and treatments.

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. 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.

### **The Constitution & Public Interest Litigation**

Article 21 of the Indian Constitution recognises the Fundamental Right to life and personal liberty. The Supreme Court has laid down that Article 21 includes, within its scope, the right to live with human dignity, and hence minimum requirements, such as good health, must exist in order to enable a person to live with human dignity. It has also held that that providing adequate medical facilities for the people is an essential part of the obligation undertaken by the government in a welfare State, and the State cannot deny this obligation.<sup>362</sup> In a recent case, the Delhi High Court examining the obligation of the government to provide access to an expensive medication held that providing access to essential medicines at affordable prices is a core obligation of the State while noting that the availability of an expensive medicine makes it virtually inaccessible.<sup>363</sup> Under the DPSPs in the Constitution, several Articles also require that the Indian State protect the health of the people.<sup>364</sup> In upholding the fundamental rights under the Constitution, the Supreme Court and High Courts often hear public interest litigations (PIL) filed to highlight violations of the right to health including in relation to TB, against the State.

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361 Open Source Drug Discovery: <http://www.osdd.net/home>

362 *Paschim Banga Khet Mazdoor Samity v State of W.B.*, (1996) 4 SCC 37, pp. 43-44; *State of Punjab v Ram Lubhaya Bagga* (1998) 4 SCC 117

363 *Mohd. Ahmed (Minor) v Union Of India & Ors*, Delhi High Court, W.P.(C) 7279/2013, Date of Decision: 17 April 2014, available at <https://indiankanoon.org/doc/77985236/>

364 Article 39(e) of the Constitution provides that the State shall, in particular, direct its policy towards securing, "that the health and strength of workers, men and women, and the tender age of children are not abused and that citizens are not forced by economic necessity to enter avocations unsuited to their age or strength." Article 41 provides that, "the State shall, within the limits of its economic capacity and development make effective provision for securing the right to work, to education and to public assistance in cases of unemployment, old age, sickness and disablement, and in other cases of undeserved want." Article 42 provides that the, "State shall make provision for securing just and humane conditions of work and for maternity relief." Article 47 provides that the, "State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health."

In *Dr. Raman Kakar v. Union of India and Anr*<sup>365</sup>, the petitioner filed a PIL before the Supreme Court in 2016 asking for directions that the government switch from intermittent TB treatment to daily treatment. Dr. Kakar reportedly made a list of 5,300 patients who had relapses after completing treatment, in some cases multiple times.<sup>366</sup> In response to the PIL, the MoHFW in its affidavit stated that it was preparing to procure drug formulations for implementing the daily regimen and that the transition which required not just procurement but also staff training would take 9 to 12 months. On 23 January 2017, the Supreme Court disposing Dr. Kakar's petition ordered that, "*the new FDC drugs for daily regimen ATT treatment, will be administered to all new patients, after the expiry of a period of nine months from today.*"<sup>367</sup> As noted in the Introduction, as of end October 2017, the government has rolled out the daily regimen.

Lack of access to MDR-TB drugs has also been litigated on grounds of violation of Fundamental Rights in the case of *Kaushal Kishore Tripathi v. Lal Ram Sarup TB Hospital & Ors.*<sup>368</sup> In 2016, a writ petition was filed before the Delhi High Court for urgent access to bedaquiline by the father of a young girl with XDR-TB. The girl who was a resident of Patna had approached the Lal Ram Sarup TB (LRS) Hospital in New Delhi for access to bedaquiline, which was denied on the basis that she was not a resident of Delhi.<sup>369</sup> The petitioner asked the court to direct the hospital to urgently conduct a drug sensitivity test (DST), provide bedaquiline as prescribed by her treating doctors, monitor her health at a medical facility close to her place of residence, and that the government be directed to provide bedaquiline to all eligible patients in public hospitals irrespective of domicile.

After a series of urgent hearings, the case was disposed off based on a consent order between the parties.<sup>370</sup> LRS undertook that no other patient would be denied treatment on grounds of domicile. The agreement by LRS finally to provide the treatment involved a convoluted process where the petitioner and her doctor were still required to personally import bedaquiline and re-furnish the stocks of LRS. Unfortunately, not only did the High Court make no finding regarding the violation of fundamental rights, it further held that the order would have no precedent value.

## Indian Patents Act, 1970

Access and affordability of TB diagnostics and medicines, particularly those based on newer health technologies in India is impacted by the patent regime. India's reputation and capacity as the pharmacy of the developing world was built largely on the basis of the *Patents Act, 1970* which

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365 *Dr. Raman Kakar v Union Of India And Anr.*, Writ Petition (Civil) No.604 Of 2016, Supreme Court of India, Order dated 23 January 2017

366 Utkarsh Anand, Doctor's tenacity nudges government to overhaul TB programme, Indian Express, 22 November 2016, available at <http://indianexpress.com/article/india/india-news-india/doctors-tenacity-nudges-government-to-overhaul-tb-programme-tuberculosis-4388704/>

367 *Dr. Raman Kakar v Union Of India And Anr.*, Writ Petition (Civil) No.604 Of 2016, Supreme Court of India, Order dated 23 January 2017

368 *Kaushal Kishore Tripathi v Lal Ram Sarup TB Hospital & Ors.*, Delhi High Court, W.P.(C) 11879/2016, Date of Order: 20 January 2017 available at [http://delhihighcourt.nic.in/dhcqrydisp\\_o.asp?pn=11539&yr=2017](http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=11539&yr=2017)

369 *In the matter of Kaushal Kishore Tripathi*, Writ Petition, copy on file with authors

370 *Kaushal Kishore Tripathi v Lal Ram Sarup TB Hospital & Ors.*, Delhi High Court, W.P.(C) 11879/2016, Date of Order: 20 January 2017 available at [http://delhihighcourt.nic.in/dhcqrydisp\\_o.asp?pn=11539&yr=2017](http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=11539&yr=2017)

limited patent rights on food and pharmaceuticals. Only process patents for a few years were granted meaning that the medicine itself, i.e. the product, could not be patented; manufacturers could make the same medicine using different processes or reverse engineering).<sup>371</sup> This contributed tremendously to the development of the Indian generic industry which now supplies the majority of safe, effective and affordable generic medicines to the developing world including for HIV and TB.

In 2005, however, India changed this patent regime to fully comply with its obligations under the WTO's TRIPS agreement. India's patent law now allows for the grant of 20-year product patents on medicines giving patent holders exclusive rights over the manufacture, sale, use, offer for sale and import of the patented medicine. In such cases, generic competition is possible only where the patent holder grants a voluntary license or the government takes action to use TRIPS flexibilities. India's compliance with the TRIPS agreement was the subject of considerable national and international concern and saw protests from community-based groups across the country. Parliament eventually included or strengthened several health safeguards in the amended patent law, including compulsory licences, patent oppositions, the Bolar and research exceptions, parallel imports, and restricting evergreening of patents.

Thirteen years after the change to India's patent law, thousands of patents on pharmaceutical products have been granted. Patent oppositions filed by public interest groups and generic companies have succeeded in keeping critical drugs like those for first- and second-line HIV treatment off-patent. For drugs that have been patented, high prices and restricted availability are evident. In March 2012, the Indian Patent Office issued India's first compulsory license to address price and availability concerns for a drug used in the treatment of kidney and liver cancer.<sup>372</sup> The compulsory license resulted in a price drop of the medicine from INR 2,88,000 per month to INR 8,800 per month.

Both the newer MDR-TB drugs - bedaquiline and delamanid have been patented under India's amended patent regime (See Box 1). As can be seen from the table below, not only have the main compounds for bedaquiline and delamanid been patented, evergreening or new form and new use patents have also been applied for and some have been granted. As is evident from the last column in Box 1, these patents extend the period of exclusivity that the patent holders will enjoy over these medicines and further delay generic competition that could ease both the availability and affordability of these medicines. In the case of bedaquiline, Janssen's patent application for the fumarate salt was opposed in March 2013 by the Network for Maharashtra People Living with HIV. This application is still pending and yet to be heard. The patent application claims a derivative of a quinolone, which has already been patented. The opposition argues that there is no novelty and no invention or inventive step in making a fumarate salt of a known drug and that the application is aimed at extending Janssen's exclusive control over the drug.<sup>373</sup>

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371 Section 53, *Patents Act 1970* (before it was amended in 2005)

372 *NATCO Pharma Limited v Bayer Corporation*, Compulsory Licence Application No. 1 of 2011 (Before the Controller of Patents, Mumbai; Date of Decision: 9 March 2012)

373 Information on file with the authors

### Box 1: Patent Status of Bedaquiline and Delamanid in India<sup>1</sup>

Product Name	Patent Description	Patent Status	Patent Application Number	Expected expiry (dd/mm/yyyy)
Bedaquiline 100 mg	Bedaquiline compounds family	Granted	IN220/DELNP/2005	18/07/2023
	Bedaquiline to treat MDR TB	Granted	IN6315/DELNP/2006	24/05/2025
	Bedaquiline to treat latent TB	Rejected	IN5213/DELNP/2007	
	Bedaquilinefumarate salt	Filed (opposed)	IN1220/MUMNP/2009	03/12/2027
Delamanid 50 mg	Delamanid compounds family	Granted	IN600/KOLNP/2005	10/10/2023
	Delamanid compounds family to treat TB	Filed	IN824/KOLNP/2006	29/10/2024
	Delamanid compositions	Granted	IN9790/DELNP/2007	19/07/2026
	Delamanid combined with other TB drugs	Filed	IN1255/KOLNP/2008	04/10/2026

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. 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 (discussed in the section on “Drug Regulation”). For the government programme, Janssen announced in March 2016 that it was donating 600 courses of treatment to be rolled out in six public institutions as a pilot; based on data from the pilot, RNTCP would determine if access to the drug should be expanded. Subsequently the government started accessing bedaquiline through the USAID-Janssen Bedaquiline Donation Programme<sup>374</sup> under which Janssen has donated 30,000 6-month courses of \$30 million value for use in over 100 countries. Countries can place orders through the Stop TB Partnership’s Global Drug Facility (GDF) and are advised under the programme to place their orders early which can take 4-6 months to fill depending, among other things, on “availability of stocks.”<sup>375</sup> Countries are required to meet the WHO Interim Policy Guidance on bedaquiline and the government must undertake to manage the treatment and any adverse effects as well as report serious events to the GDF within 24 hours.<sup>376</sup> As for delamanid,

374 USAID’s Bedaquiline Donation Program In Partnership With Johnson And Johnson, Undated, available at <https://www.usaid.gov/what-we-do/global-health/tuberculosis/technical-areas/bedaquiline-donation-program>

375 Stop TB Partnership, FAQs regarding procurement of Bedaquiline (BDQ) through the Global Drug Facility (GDF), Undated, available at <http://www.stoptb.org/assets/documents/gdf/drugsupply/FAQonprocurementofbedaquilinethroughGDFFINALVERSION300414.pdf>

376 Stop TB Partnership, Procurement Request Forms for Medicines, Undated, available at [http://www.stoptb.org/gdf/drugsupply/procurement\\_forms.asp](http://www.stoptb.org/gdf/drugsupply/procurement_forms.asp)

in 2016, Otsuka announced a partnership with GDF to provide delamanid to countries eligible for funding from the Global Fund for AIDS, TB and malaria<sup>377</sup> at USD 1700 for a course of treatment.<sup>378</sup> RNTCP's rollout of delamanid appears to rely solely on a donation of 400 courses by Otsuka.<sup>379</sup>

The compulsory license provisions of the *Patents Act* have recently been in focus due to the slow and limited rollout of MDR-TB drugs. A civil society letter was submitted on 12 March 2018 urging the Prime Minister to issue compulsory licenses for delamanid and bedaquiline.<sup>380</sup> A compulsory license (CL) is an authorization given by the government for generic production of a patented medicine without the permission or consent of the patent holder. Under section 92 of the *Patents Act*, one method for issuing a CL involves the Central Government making a declaration by notification in the Official Gazette that it is necessary for a compulsory license to be granted on a patent in circumstances of national emergency, extreme urgency or in case of public non-commercial use. Once such a declaration is made, the Act requires that the Patent Controller issue a CL on an application by any interested person. In such cases there is no requirement for prior negotiation with the patent holder. The Act also empowers the Controller to waive any requirements for informing the patent holder and providing an opportunity for the patentee to oppose the CL application where it is necessary in the case of national emergency, extreme urgency or public non-commercial use including “*public health crises, relating to Acquired Immuno Deficiency Syndrome, human immunodeficiency virus, tuberculosis, malaria or other epidemics (emphasis added).*”

The petition for the compulsory licenses arose in light of a study showing that the estimated generic prices of bedaquiline and delamanid would be far lower<sup>381</sup> than the prices being negotiated between the government and the patent holders. These negotiations have arisen in light of the limited treatment courses available through donations and the need to expand access to the new MDR-TB drugs while following WHO's regularly updated guidance. 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<sup>382</sup> 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.<sup>383</sup> Access to these far lower priced generics would be possible only if there is proper generic competition among several producers.

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377 <sup>378</sup> Delamanid Available To 100+ Countries Through an Innovative Partnership, 19 April 2016, available at [https://www.otsuka.co.jp/en/company/global-topics/2016/20160419\\_vol87.html](https://www.otsuka.co.jp/en/company/global-topics/2016/20160419_vol87.html)

378 MSF, Access: Developing countries hit with high price for important new tuberculosis drug, 24 February 2016, available at <http://www.msf.org/en/article/access-developing-countries-hit-high-price-important-new-tuberculosis-drug>

379 Central TB Division, India TB Report 2018: RNTCP Annual Status Report, 2018, available at <https://tbcindia.gov.in/index1.php?lang=1&level=1&sublinkid=4160&lid=2807>

380 Lawyers Collective, Indian civil society pushes for 'Government Use' compulsory license on MDR-TB Drugs, 12 March 2018, available at <http://www.lawyerscollective.org/news/indian-civil-society-pushes-government-use-compulsory-license-mdr-tb-drugs>

381 Gotham et al, Estimated generic prices for novel treatments for drug-resistant tuberculosis, *Journal of Antimicrobial Chemotherapy*, Volume 72, Issue 4, 1 April 2017, Pages 1243–1252 available at <https://academic.oup.com/jac/article/72/4/1243/2884272>

382 Prabha Raghavan, Johnson & Johnson, Mylan propose ways to cut TB drugs prices in India, *Economic Times*, 15 March 2018, available at <https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/johnson-johnson-mylan-propose-ways-to-cut-tb-drugs-prices-in-india/articleshow/63308430.cms>

383 Vidya Krishnan, Extreme TB: Centre yet to push for cheaper versions of two crucial drugs, *The Hindu*, 3 March 2018, available at <http://www.thehindu.com/sci-tech/health/extreme-tb-no-licence-to-heal/article22920634.ece>

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.

## Drug Price Control

Affordability of TB medicines is also impacted by India's drug price control regime. The 2013 *Drug Price Control Order* (DPCO) under section 3 of the *Essential Commodities Act, 1955* applies price control to all medicines on the National List of Essential Medicines (NLEM) as issued and updated by the MoHFW. Of the 376 medicines in the NLEM 2015, 14 are TB medicines. The National Pharmaceutical Pricing Authority (NPPA), which is tasked with fixing prices under DPCO 2013 has issued notifications fixing the ceiling prices of these TB medicines. However, patented medicines have not been included in the DPCO. 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.<sup>384</sup>

## 12.2 Experiences

Accessibility to TB testing and treatment depends on the place where the tests and treatment are available geographically, their availability in terms of quantity as required by the population and on affordability - costs of the tests and the treatment. These issues are dependent on various factors, such as the availability of healthcare facilities where people are located, in urban, rural, and hard-to-reach (hilly terrain, tribal) areas so that treatment can be made available in all such places. Availability also depends on the number of manufacturers in the market who can cater to the demand. Costs depend on not just the cost of manufacturing and getting marketing approval of the diagnostics and medicines for TB, but also depend on market forces - the number of manufacturers and sellers in the market, government policies to cap diagnostic and medicine prices, and other factors such as patents on diagnostics and drugs and the degree of reliance on imports.

### 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 government programme on the rollout of CBNAAT. CBNAAT machines, however, are very costly at INR 16-18,00,000 per device. While the TB programme 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.<sup>385</sup> CBNAAT costs about INR 1100 in the private sector. The fact that there is 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

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384 Sengupta A, et al 2009, *Economic Constraints to Access to Essential Medicines in India*, Society for Economic and Social Studies, New Delhi and Centre for Trade and Development, New Delhi, available at <http://www.healthpolicy.cn/rdfx/jbywzd/gjy2/yd/yjwx/201002/P020100227571385215688.pdf>

385 Rao, M, "Why India's TB control is faltering: Poor diagnostics, drug supply disruptions and no counseling", Scroll.in, July 10, 2017. Available at <https://scroll.in/pulse/843244/why-indias-tb-control-is-faltering-poor-diagnostics-drug-supply-disruptions-and-no-counseling>

from a local company.<sup>386</sup> In addition there has been criticism of the over-reliance on CBNAAT for diagnosing MDR-TB as it only tests for resistance to one drug. Although the WHO recommends that the full spectrum of tests is conducted for a person who may have MDR-TB including culture tests, it appears that RNTCP is not offering culture tests on a universal basis.<sup>387</sup>

As one informant pointed out, *“the culture test to find out drug resistance for 12 drugs – for pre-XDR and XDR, costs about INR 10,000. Initially the genome tests that find out drug resistance of 23 TB drugs would cost about INR 85,000, but now that cost has come down to INR 5,000, that makes it cheaper than the culture tests, and provides results for 23 TB drugs. If the government uses this test for drug resistant TB cases, it will bring down the costs drastically”*.

### **Availability and affordability of treatment**

The cost of treatment for TB varies depending on the stage of advancement of the disease and the type of drug resistance that the person has faced. According to one interviewee, the private sector first-line medicines costs about INR 2000 for six months along with additional expenditure on vitamins and testing; patients will continue treatment from the private sector until it becomes unaffordable and will then shift to the public sector. Notably, medicines to treat side-effects of TB drugs are not covered by the RNTCP, with patients having to purchase the drugs.

The treatment costs for MDR-TB and XDR-TB are higher than first-line treatment and include injections. In the case of bedaquiline and delamanid for MDR-TB, for patients in the private sector these are currently being imported at high costs. According to one interviewee, *“MSF imports these drugs for individual patients for compassionate use and spends about USD 900 for a 6 month course of Bedaquiline with an additional cost of USD 700 for shipment making it a total cost of USD 1600 per patient for 6 months. The cost of importing Delaminid is USD 1700 with shipping cost of USD 700, making it a total of USD 2400 per person for 6 months treatment. A lot of MDR patients require anywhere between 18 months to 24 months of treatment, thereby increasing the treatment cost per patient with MDR TB.”* These prices are in the lower tier of the pricing band of the originator companies and are, as is evident, extremely expensive for individual patients and treatment programmes.

Despite government proposals to rapidly scale up access to MDR-TB drugs, the complete reliance of the government on Janssen’s various access programmes for bedaquiline and on Otsuka’s limited donation and after that, its sole licensee Mylan, for delaminid is likely to continue to hamper their rollout. The programmes under which the government is currently accessing these medicines are limited and the price being offered for purchases, as noted above, are far in excess of potential generic prices and would be unsustainable for the programme in the long run. There is a clear recognition of TRIPS flexibilities in India’s patent law and as noted above these provisions have also

386 Global Health Education, TrueNat TB Test – Diagnosis and resistance testing, TBfacts.org, Undated, available at <https://www.tbfacts.org/truenat/>

387 Rao, M, India has a drug-resistant tuberculosis crisis but lacks the right tools to detect cases, Scroll.in, 24 March 2017, <https://scroll.in/pulse/832634/india-has-a-drug-resistant-tuberculosis-crisis-but-lacks-the-right-tools-to-detect-cases>

been used by civil society groups, the government and generic manufacturers. The OSDD project was also a clear policy statement recognizing the potential barriers that intellectual property can create and accordingly provided public funding for an open source TB research initiative. These legal and policy approaches to ensuring affordable access to TB drugs and new TB research need to be properly enforced and implemented. At the same time, the government must also ensure that its ability to use TRIPS flexibilities is not undermined or hampered in ongoing free trade agreement negotiations such as those with the European Union or in the Regional Comprehensive Economic Partnership (RCEP).<sup>388</sup> This is crucial not just for patients in India but those across the developing world that rely on Indian generic medicines and should be recognized as part of India's international obligations under the right to health.

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 bedaquiline comes with a black box warning as there have been no Phase III trials due to the urgent unmet need for MDR-TB drugs and second that it is only public sector doctors who are able to handle the side-effects of the drugs. However as described in the section on "Drug Regulation", the fact is that the private sector is accessing these drugs albeit through a far slower and more cumbersome and expensive route through the personal import mechanism. While a considerable amount of reluctance stems from the distrust of the private sector, it is also evident that a rapid scale up of access to MDR-TB drugs even within the public sector would require multiple sources of supply and far lower prices. Within the public sector there is no reason for such few doctors to have training 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 also expressed concern about the toxicity of TB medicines and the sometimes debilitating side-effects they produce. This includes treatment with injectables, which may be used by people with TB who have insufficient body mass to sustain such therapy. One TB survivor said that people with TB are often not told that their urine colour may be orange or red, due to the effects of medication, creating anxiety, and the lack of capacity to know how to respond to the side effects. This is true in the case of other side effects too.<sup>389</sup> A key informant revealed that some people stop medication and take homeopathy instead, or go to quacks because they cannot tolerate the side-effects.<sup>390</sup> Not completing the full course of treatment is one of the major contributing factors

388 Shiba Phurailatpam and Kajal Bhardwaj, RCEP and Health: This Kind of 'Progress' is Not What India and the World Need, *thewire.in*, 27 February 2017 available at <https://thewire.in/external-affairs/rcep-this-kind-of-progress-is-not-what-india-and-the-world-need>

389 Rao, M, "Why India's TB control is faltering: Poor diagnostics, drug supply disruptions and no counseling", *Scroll.in*, July 10, 2017. Available at <https://scroll.in/pulse/843244/why-indias-tb-control-is-faltering-poor-diagnostics-drug-supply-disruptions-and-no-counseling>

390 See also Sharma, S, "Here's why India is struggling and failing to control tuberculosis", *Hindustan Times*, Feb 11, 2017. Available at <https://www.hindustantimes.com/health-and-fitness/here-s-why-india-is-struggling-and-failing-to-control-tuberculosis/story-urW7VnQiHM2S38yGNTgu7O.html>

for drug resistance. Reports also suggest that several patients across India stop TB treatment as they cannot cope with side-effects, which are exacerbated by malnourishment.<sup>391</sup>

One of the most common side-effects of the second line injectables is psychiatric, suicidal tendencies, in which there is a chance of losing the patient.<sup>392</sup> At the Sewri TB hospital in Maharashtra, the number of suicides has reduced substantially, because, the staff has been trained to recognize such side effects in the patients admitted in the hospital and they are able to immediately get psychiatric and psychological help, to handle the condition of the patient. The lack of treatment and management of side-effects within the TB programme is a major gap that needs to be addressed urgently.

### Supply of drugs and stock-outs

The government system of procuring and distribution of medicines is an integral part of the health care system, and limited access, or intermittent access, not only undermines the objects of equity and efficiency,<sup>393</sup> but also exposes neglect of a system that has potential of being efficient. Drug stocks in the public health system require regular monitoring and suppliers are to be kept in the loop about future requirements.<sup>394</sup> Drug stock outs happen due to negligence, corruption, and purposeful ignoring of a well-structured system,<sup>395</sup> and also when manufacturers of the drugs or vaccines stop or reduce production due to shifting of manufacture to more profitable drugs or vaccines. Informants did indicate that stock-outs happen often and more so at health posts, and in some urban, rural and tribal areas.

In one court case on TB drug stock-outs against government officials, criminal charges under the *Prevention of Corruption Act* were framed, with corruption allegations to the extent of INR 32,00,000 for procurement of TB drugs.<sup>396</sup> The government took the stand that as there was a massive shortage of TB drugs together with various demand letters from hospitals and dispensaries for their immediate supply, they had to purchase the drugs and not wait for the distribution from the RNTCP.<sup>397</sup> Debates in the Lok Sabha have raised issues of shortages of vaccines, including TB vaccines in the country, with a shortage of about 28 crore vaccine doses in the country in 2009,<sup>398</sup> and shortage of about 1122.15 lakh vaccine doses in 2010.<sup>399</sup> This was primarily because vaccine manufacturers phased out production of the less expensive vaccines between 1998 and 2001, with 10 out of 14 manufacturers

391 Ibid.

392 Bharadwaj, et al, "*Treatment of MDR-TB: Experiences in Chattisgarh*", International Journal of Scientific Study, August 2015, Vol.3 Issue 5, DOI: 10.17354/ijss/2015/356

393 "*Draft drug stock out assessment, including recommendations for the procurement system, identification of issues arising and mitigation plan, agreed with DHFW*", Department of Health and Family Welfare, government of Odisha, Odisha Technical and Management support team: Phase II – Nov. 2014. Available at <http://www.nrhmorissa.gov.in/writereaddata/Upload/Documents/12.%20Draft%20Drug%20Stock%20Out%20Assessment.%20including%20recommendations%20for%20the%20procurement%20system.%20identification%20of%20issues%20arising%20and%20mitigation%20plan.%20agreed%20with%20DHFW.pdf>

394 Mehra, C, "*The right to medicines in a world of stock outs*", The Hindu, Comment, October 4, 2014, updated May 23, 2016. Available at <http://www.thehindu.com/opinion/op-ed/the-right-to-medicines-in-a-world-of-stockouts/article6469319.ece>

395 Ibid.

396 *Dr. Ashok Sharma v State of Madhya Pradesh*, High Court of M.P., Criminal Revision No. 1314/2013, order dated 18.12.2013. Available at <http://indiankanoon.org/doc/163610996/>

397 Ibid.

398 Lok Sabha Debates, "*Shortage of life saving vaccines in the country*", November 25, 2009. Available at <http://indiankanoon.org/doc/77668/>

399 Lok Sabha Debates, "*Need to overcome the shortage of vaccines in the country*", April 15, 2010. Available at <http://indiankanoon.org/doc/484143/>

partially or fully stopping production of vaccines, resulting in an increase in vaccine prices, with the BCG vaccine cost increasing by almost by 27%.<sup>400</sup>

Recently, the Out of Step report<sup>401</sup> released by the Stop TB Partnership and MSF, recognized three problems in India's RNTCP – not being fully equipped to diagnose and treat people, regular stock-outs and lack of counseling of TB patients.<sup>402</sup> While government officials admit that stock-outs do take place, informants noted that these are often dismissed as minor distribution-supply issues. But from 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 the stock-out of vitamin B6, which is required to be given with IPT since June 2017. This letter raised patients' 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 the patients.<sup>403</sup>

### **12.3 Conclusions and Recommendations**

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<sup>404</sup> 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.<sup>405</sup> 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. Some key recommendations that emerge from the discussion on affordability and availability are:

#### **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.

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400 Ibid.

401 MSF, Out of Step: TB policies in 29 countries, 3rd Ed., 2017 available at <https://www.msfaaccess.org/outofstep2017>

402 Rao, M, "Why India's TB control is faltering: Poor diagnostics, drug supply disruptions and no counseling", Scroll.in, July 10, 2017. Available at <https://scroll.in/pulse/843244/why-indias-tb-control-is-faltering-poor-diagnostics-drug-supply-disruptions-and-no-counseling>

403 Delhi Network of Positive People (DNP+), RE: STOCK-OUT of Vitamin B6, DOTS99, ZeneXpert TB test kits and HIV test Kit 3, Letter to AS&DG NACO, 22 September 2017, on record with authors.

404 Barik, D & Thorat, A, (2015) "Issues of Unequal Access to Public Health in India", Frontiers in Public Health 3: 245; doi: 10.3389/fpubh.2015.00245

405 Ibid.

- 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

*“Ultimately, reduction of TB burden in India and its elimination will require improving the nutritional status of the community as a whole”<sup>406</sup>*

The Guidance Document on Nutritional Care and Support for patients with Tuberculosis in India<sup>407</sup> emphatically establishes the close link between undernutrition and TB, noting that, *“there is a bidirectional interaction between nutritional status and active disease.”* While undernutrition is related to an increase in vulnerability to and fatality from TB, TB in turn leads to undernutrition. India is fertile ground for this interface to create a serious public health problem - while around 40% of Indians have latent TB infection, undernutrition affects 1/3 Indian adults. The guidance notes that, *“at the population level in India, undernutrition is the most widely prevalent risk factor for TB. An estimated 55% of TB incidence in India (or more than 1 million new cases annually) are attributable to the effect of undernutrition, which is significantly greater than those attributable to other risk factors like HIV (5%), diabetes (9%) or smoking (11%).”*

Research in both rural and urban Indian contexts has revealed much moderate to severe undernutrition in TB patients, confirmed by data on body weight in over 10,00,000 patients available through Nikshay.<sup>408</sup> Some studies have revealed an alarming picture: in Chhattisgarh of 1695 adult pulmonary TB patients, 90% were found to be undernourished.<sup>409</sup> Poverty and consequent food uncertainty among people with TB prevents them from regaining ideal weight, even though they may have access to effective TB medication. And, people with TB who are undernourished are two to four more times likely to die, five times more at risk of liver damage, and if they do not gain adequate weight after treatment are more at risk of relapse. Decreased ability to absorb drugs is also seen as an effect of undernutrition. Further, if one is undernourished and in close contact with a person with TB, one’s risk of developing TB is increases. On the other hand, providing nutrition leads to better health outcomes, including lowering mortality and improving treatment adherence.<sup>410</sup>

406 Padmapriyadarsini C et al, Undernutrition & tuberculosis in India: Situation analysis & the way forward. Indian Journal of Medical Research. 2016;144(1):11-20.

407 Available at <https://tbcindia.gov.in/index1.php?sublinkid=4731&level=3&lid=3277&lang=1>

408 Guidance Document on Nutritional Care and Support for patients with Tuberculosis in India, 2017, available at <https://tbcindia.gov.in/index1.php?sublinkid=4731&level=3&lid=3277&lang=1>

409 Bhargava A, Nutritional status of adult patients with pulmonary tuberculosis in rural central India and its association with mortality, PLoS One. 2013; 8(10):e77979

410 Ibid.

Given these multiple links that nutrition has with TB, providing it is crucial to ensure an effective TB programme in India. In the process, such a programme would succeed in also addressing poverty as a social determinant of TB. The WHO has recognized this, and advised that policymakers require to address these in the TB response, while ensuring that nutritional screening, assessment and management must be integral parts of TB care and prevention.<sup>411</sup> Indeed, 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.<sup>412</sup>

### 13.1 The context in India – law, policy and jurisprudence

*“The whole question of TB is tied up with the primary determinants of health which includes nutrition. Access to TB (care) can only be there if there is a functioning health system in that area. We cannot think of TB in isolation, so when you’re talking of a legal framework the best remedy would be for the Constitution to recognize the right to health and right to food. In India right to health care and the right to food also is kind of whatever is available in terms of the Food Security Act, which is only providing cereals, and they’re not really nutrition. It doesn’t really help the cause of prevention of TB because the key deficit in India is calories as well as proteins.”*

- An expert informant

As stated in previous sections, 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. Article 47 of the Constitution is the non-justiciable yet guiding DPSP: *“State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties...”* Reading this with the right to life, the Supreme Court has expounded on the components that make up the right to life over several pronouncements. In *Francis Coralie Mullin v Union Territory of Delhi*,<sup>413</sup> it held that,

*“The right to life includes the right to live with human dignity and all that goes along with it, namely, the bare necessities of life such as adequate nutrition, clothing and shelter and facilities for reading, writing and expressing oneself in diverse forms, freely moving about and mixing and commingling with fellow human beings.”*

In *M/sShanistar Builders v Narayan KhimalalTotame*, the Supreme Court held that the right to life *“would take within its sweep the right to food, the right to clothing, the right to decent environment and a reasonable accommodation to live in.”*<sup>414</sup>

A PIL filed by the People’s Union for Civil Liberties (Rajasthan) in 2001 brought the wastage of vast amounts of food grains in government granaries to the attention of the Supreme Court, while

411 WHO, Guideline: Nutritional care and support for patients with tuberculosis. 2013, available at [http://apps.who.int/iris/bitstream/10665/94836/1/9789241506410\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/94836/1/9789241506410_eng.pdf)

412 National Strategic Plan for Tuberculosis Elimination 2017-25, available at <https://tbcindia.gov.in/WriteReadData/NSP%20Draft%2020.02.2017%201.pdf>, at page 80.

413 1981(1) SCC 608

414 AIR 1990 SC 630

millions remained undernourished or continued to die of hunger in India. Over almost a decade the court passed directives and orders in the case against the government, to oversee the enforcement of food delivery to the needy through the public distribution system and various social security schemes.<sup>415</sup>

On the back of these articulations and claims, Parliament passed the *National Food Security Act* in 2013, “to provide for food and nutritional security in human life cycle approach, by ensuring access to adequate quantity of quality food at affordable prices to people to live a life with dignity and for matters connected therewith or incidental thereto.”<sup>416</sup> This legislation entitles 75% of the rural population and 50% of the urban population<sup>417</sup> – “every person belonging to priority households” – to 5 kg of subsidized grain per person per month.<sup>418</sup> It also assures pregnant or lactating women and children up to fourteen years to free appropriate meals.<sup>419</sup> Although this law does not explicitly mention people with TB, it would cover such persons if they fell within the stipulated categories.

Many central government schemes – those for mid-day meals,<sup>420</sup> targeted public distribution<sup>421</sup> and the Integrated Child Development Scheme<sup>422</sup> – 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. For instance, Chennai’s municipal corporation has provided free breakfast for people with TB, and Tamil Nadu provides INR 1000 per month to farmers with TB. Mumbai’s municipal corporation offered calorie-rich meals to all people with MDR- and XDR-TB under a pilot project at 36 centres of Mumbai, which was found to be beneficial to users in weight gain and improved treatment adherence, and prompted expansion plans. Non-governmental efforts at a smaller scale have also benefited nutrition recipients in Chennai and Kerala.<sup>423</sup>

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. Notably, however, the NSP states that, “to address financial & nutritional hardship the patient and family undergoes due to TB and to reduce catastrophic cost to patient due to TB, cash incentive of Rs. 2000 will be provided for every TB patient through Direct Beneficiary Transfer.”<sup>424</sup> Termed the Nikshay Poshan Yojana, the scheme is for the benefit of all notified people with TB, and stipulates that “incentives can be distributed in Cash

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415 For more on this case and the Supreme Court’s orders, see <http://www.hrln.org/hrln/right-to-food/pils-a-cases/255-pucl-vs-union-of-india-a-others-.html>

416 See the preamble to the Act, available at <http://indiacode.nic.in/acts-in-pdf/202013.pdf>

417 [http://www.ideasforindia.in/article.aspx?article\\_id=2906](http://www.ideasforindia.in/article.aspx?article_id=2906)

418 Section 3, *National Food Security Act, 2013*

419 Sections 4 and 5, *National Food Security Act, 2013*

420 See <http://mdm.nic.in/>

421 See <http://dfpd.nic.in/public-distribution.htm>

422 See <http://icds-wcd.nic.in/>

423 Padmapriyadarsini C et al, Undernutrition & tuberculosis in India: Situation analysis & the way forward, *Indian J Med Res* v.144(1); 2016 Jul, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5116882/>

424 National Strategic Plan for Tuberculosis Elimination 2017-25, available at <https://tbcindia.gov.in/WriteReadData/NSP%20Draft%2020.02.2017%201.pdf>, at page 31.

(only via DBT preferably through Aadhaar enabled bank accounts)".<sup>425</sup> According to some experts the budget 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. This also leaves out people with DR-TB and XDR-TB who require treatment for much longer than 6 months. It does not include family members who live in close proximity to people with TB, and it 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. Indeed, such a situation can return them to an undernourished state and revive vulnerability to TB.

### 13.2 Experiences

Informant interviews provided some critical insights on nutrition-related issues, including programmatic, implementation-related, and policy-related aspects. Apart from a commonly held view that nutrition support is being insufficiently provided by the government, with the non-governmental sector filling this breach, 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.

When nutritional support is provided, it is often an insignificant amount (INR 500 per person per month – this was prior to the 2018 budget allocation). Moreover, a serious and widely shared concern is that nutrition is often provided only for a time-bound period with no genuine food security, leading to a recovered person reentering a cycle of undernourishment and vulnerability to TB. It is rarely provided to family members of people with or survivors of TB who also experience poverty and are vulnerable to TB. An effective nutrition support programme would entail an assessment of the support required for a person with TB and their entire family. Indeed, it was felt essential for systemic issues like poverty to be holistically addressed for TB to be seriously controlled.

Further, 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,<sup>426</sup> which is a fundamental challenge. As stated earlier, the law requires provision of foodgrains and cereals, and meals for stipulated women and children. Apart from robust implementation, to be impactful in the urgent context of TB the law may need to expand its scope to specifically apply to people with and survivors of TB, while it will also have to be considered whether undernutrition will be effectively addressed solely through the

425 See <https://tbcindia.gov.in/showfile.php?lid=3318>

426 See <https://economictimes.indiatimes.com/news/politics-and-nation/national-food-security-act-not-implemented-as-it-should-be-supreme-court/articleshow/59702676.cms>

provision of foodgrains or whether nutrient gaps such as quality protein will also have to be provided as part of food security.<sup>427</sup>

Under-nourishment is fundamentally an issue of poverty and systemic inequality. Addressing it effectively will certainly benefit attempts to control TB. The *Food Security Act* has to be implemented with committed political will for the law to be meaningful in relation to nutrition.

### **13.3 Conclusion and Recommendations**

People with TB need to take appropriate and sufficient nutrition along with medication in order to recover from TB. They need to sustain nutritious intake to ensure that they do not relapse into TB. Thus, nutritional knowledge intake is crucial to stay healthy, requiring both information and counseling on nutrition, and assured nutritious food supply.

The government needs to lead a multi-pronged approach involving different stakeholders to improve the nutritional status of communities that are undernourished, providing them food supplements and financial assistance to maintain good nutrition. Tackling unemployment and providing jobs for the poor and marginalized are the larger systemic issues that need to be prioritized to prevent and curtail 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.

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427 Padmapriyadarsini C et al, Undernutrition & tuberculosis in India: Situation analysis & the way forward. *Indian Journal of Medical Research*. 2016;144(1):11-20.

### ***(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.



## V. PEOPLE IN VULNERABLE CONTEXTS

**14. TB in the Workplace**

**17. Women**

**15. TB in Prisons**

**18. People living with HIV**

**16. Mobile populations**

**19. Sex workers**

This part of the LEA covers legal issues related to certain people in vulnerable contexts who are susceptible to TB. Referring to them the NSP notes that,

*“Key affected populations’ is a disadvantaged group of people as compared to others, mainly on account of their reduced access to medical services and the underlying determinants of health. Vulnerable, underserved or populations at risk of TB infection and illness constitute a challenge for TB control.”*

As per the Stop TB Partnership, it lists the following: prisoners, sex workers, slum dwellers, miners, hospital visitors, healthcare workers, community health workers, migrant workers, women in settings with gender disparity, children, physically challenged, tribals and populations living in hard to reach areas, refugees or internally displaced people, illegal miners, undocumented migrant, people living with HIV, diabetics or those with silicosis, those undergoing immunosuppressive therapy, the undernourished, tobacco users, alcoholics and those who inject drugs.

## 14. TB in the Workplace

Workers have a right to a safe and healthy working environment. This right finds explicit mention in international law too – Article 7(b) of the ICESCR recognizes the right of everyone to the enjoyment of just and favourable conditions of work, which ensure safe and healthy working conditions.

As an infectious disease, the occupational risk of TB for healthcare workers is well recognized. According to the WHO,

*“in health-care facilities and congregate settings, a comprehensive set of infection control measures – comprising administrative, environmental and personal protection measures – should be implemented. Periodic assessment of TB infection control in health-care facilities is essential to ensure that appropriate measures are in place.”<sup>428</sup>*

Acquiring TB is also considered an occupational risk for workers in mining, construction, and people working in other professions that have a particular impact on lung health, particularly in the informal sector. In high incidence countries TB should be a priority workplace issue as it mostly affects people in their productive ages.

In 2010, the ILO included TB in its List of Occupational Diseases.<sup>429</sup> According to the ILO, *“the workplace is ideally suited to the prevention and control of TB, a ‘win-win’ situation for both worker and employer. While the individual receives vital information, and treatment where necessary, the employer saves costs, disruption and productivity losses.”<sup>430</sup>* Joint guidance from the WHO, ILO and UNAIDS on TB and TB/HIV prevention, diagnosis, treatment and care in the workplace, states that,

*“in the case of TB, workplaces can increase disease transmission, as people spend long periods of time in close proximity...The workplace, particularly with enclosed and poorly ventilated environments, is a potentially risky environment for TB transmission as employees have*

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428 WHO, Global Tuberculosis Report, 2017, available at <http://apps.who.int/iris/bitstream/10665/259366/1/9789241565516-eng.pdf?ua=1>

429 ILO, List of Occupational Diseases (Revised 2010), available at [http://www.ilo.org/wcmsp5/groups/public/---ed\\_protect/--protrav/---safework/documents/publication/wcms\\_150323.pdf](http://www.ilo.org/wcmsp5/groups/public/---ed_protect/--protrav/---safework/documents/publication/wcms_150323.pdf)

430 ILO, Tuberculosis: Guidelines for Workplace Control Activities, available at [http://www.ilo.org/wcmsp5/groups/public/@ed\\_protect/@protrav/@ilo\\_aids/documents/publication/wcms\\_116660.pdf](http://www.ilo.org/wcmsp5/groups/public/@ed_protect/@protrav/@ilo_aids/documents/publication/wcms_116660.pdf)

*prolonged contact with each other. Any sick worker could mean disrupted workflow, reduced productivity, absenteeism, transmission to other workers, and thus entail direct and indirect costs for the employer, such as increased medical and healthcare costs, and additional recruitment and training costs... Studies suggest that on average, an employee with TB loses 3–4 months of work per year, resulting in potential losses of 20–30% of his annual household income.”<sup>431</sup>*

The NSP 2017-2025 recognizes those at increased risk of TB due to their occupation as key affected populations. This includes miners, healthcare workers and community health workers. Stone crushers are included in a list of vulnerable groups in rural areas. People with silicosis are identified as a key affected population who are at increased risk of TB due to biological reasons and identified as a risk group for TB screening. The NSP states that screening of healthcare workers for TB is a high priority for the programme and that airborne infection control implementation (pursuant to the Guidelines for Airborne Infection Control in Healthcare and Other Settings notified by the central government in 2010)<sup>432</sup> is important for preventing TB among healthcare workers. The NSP also states that necessary health insurance schemes will be made available to healthcare workers in accordance with state policy.

According to the 2007 RNTCP Annual Report *“TB causes huge economic loss with about 17 crore workdays lost due to the disease. The annual economic cost of tuberculosis to the Indian economy is at least US\$ 3 billion (more than Rs 13,000 crore).”<sup>433</sup>*

### **14.1 The context in India - Laws, Policies and Jurisprudence**

The NSP 2012-2017 identified occupational high-risk groups for TB including workers in stone crushing mills who are exposed to silica dust, coal and other mining, tobacco (bidi rolling) and carpet weaving. It also noted that, *“significant proportion of workforce in the occupationally high-risk environment is from the unorganized sector and hence cannot access services at the work place.”<sup>434</sup>* It is unclear if a proposal under that NSP<sup>435</sup> to collaborate with the Ministry of Labour and Mining to develop guidelines to support persons with occupational risk for TB and provide access to diagnosis and treatment services from the programme was achieved. India has several laws relating to occupational health and safety.

The protection of the health and safety of workers finds recognition in the Constitution in the DPSPs, which require the State to direct its policies towards securing *“that the health and strength of workers, men and women, and the tender age of children are not abused and that citizens are*

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431 WHO, UNAIDS and ILO, Working together with businesses: guidance on TB and TB/HIV prevention, diagnosis, treatment and care in the workplace, 2012, available at [http://apps.who.int/iris/bitstream/10665/44833/1/9789241503228\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44833/1/9789241503228_eng.pdf)

432 Directorate General of Health Services, Airborne Infection Control in Healthcare and other settings, 2010, available at <https://tbcindia.gov.in/showfile.php?lid=2858>

433 Central TB Division, TB India 2007: RNTCP Status Report, 2007, p. 12, available at <https://tbcindia.gov.in/showfile.php?lid=2919>

434 Central TB Division, National Strategic Plan for Tuberculosis Elimination 2012 – 2017, available at <https://www.tbfacts.org/wp-content/uploads/2017/12/NSP-2012-2017.pdf> at page 108

435 Central TB Division, National Strategic Plan for Tuberculosis Elimination 2012 – 2017, available at <https://www.tbfacts.org/wp-content/uploads/2017/12/NSP-2012-2017.pdf> at page 111

*not forced by economic necessity to enter avocations unsuited to their age or strength.*<sup>436</sup> The State is also mandated to secure “*just and humane conditions of work*”<sup>437</sup> and to “*endeavour to secure to all workers, by suitable legislation or economic organisation or any other way to ensure decent standard of life and full enjoyment of leisure and social and cultural opportunities to the workers.*”<sup>438</sup>

These mandates of the Constitution have over time, been the subject of particular focus of the Supreme Court. The recognition that TB was an occupational hazard came in *Azad Rickshaw Pullers Union v. State of Punjab*<sup>439</sup> where the Supreme Court noted that many rickshaw pullers suffer from occupational hazards such as pulmonary TB. In *Bandhua Mukti Morcha v. Union of India*<sup>440</sup>, the Supreme Court also took note of the high rates of TB among bonded labourers as a result of working in stone quarries. In *Consumer Education and Research Centre v. Union of India*<sup>441</sup>, held that the “*right to health, medical aid to protect the health and vigour to a worker while in service or post retirement is a fundamental right under Article 21.*”

The occupational risk of silicosis has received particular attention from the Supreme Court. For the past decade, the court has issued a series of orders relating to persons at risk of or afflicted with silicosis in *People’s Rights and Social Research Centre (PRASAR) v. Union of India and others.*<sup>442</sup> These orders have included the shutdown of mines violating regulations and for the payment of compensation to silicosis patients. Even before the filing of this PIL, the National Human Rights Commission (NHRC) was examining the issue of silicosis as a human rights concern and also became a party to the PRASAR case. The NHRC conducted meticulous investigations and issued detailed *Recommendations on Preventive, Remedial, Rehabilitative and Compensation Aspect of Silicosis.*<sup>443</sup>

## **Employees Compensation Act**

The *Employees Compensation Act, 1923* (formerly the *Workmen’s Compensation Act*), provides for the payment of compensation to certain specified classes of employees for injuries. Miners are covered under this law.<sup>444</sup> In the case of miners, silicosis and silico-TB (provided that silicosis is an essential factor in causing the resultant incapacity or death) caused by sclerogenic mineral dust is identified as an occupational disease.<sup>445</sup> Although Part A of Schedule III of the Employees Compensation Act includes “*any infectious and parasitic diseases contracted in an occupation where there is a particular risk of contamination*” for compensation, the list of workplaces under the Act are extremely limited.

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436 Article 39(e), Constitution of India

437 Article 41, Constitution of India

438 Article 43, Constitution of India

439 [1981] 1 SCR 366

440 AIR 1984 SC 802

441 (1995)3 SCC 42

442 Writ Petition No. 110 of 2006, Supreme Court of India; Orders available at <http://supremecourtfindia.nic.in/daily-order>

443 Undated. Available at [http://nhrc.nic.in/Documents/recomm\\_silicosis.pdf](http://nhrc.nic.in/Documents/recomm_silicosis.pdf)

444 For miners who are considered to be at greater risk of TB, the *Mines Act, 1952* and the *Mines Rules, 1955* regulate labour and safety in mines. The *Mines Rules* specify that compensation for any industrial disease would be covered by the *Employees Compensation Act, 1923*

445 Part C, Schedule III, *Employees Compensation Act, 1923*

In *Sharbati Devi v. Haryana Roadways, Sirsa Depot*,<sup>446</sup> the dependents of a bus driver employed by Haryana Roadways Sirsa filed a petition under the *Workmen's Compensation Act, 1923* seeking compensation for the driver's death. They claimed that he died of TB acquired in the course of employment. The High Court of Punjab and Haryana accepted the plea, reasoning that TB was an occupational hazard due to overcrowded buses. It remanded the case to the Commissioner under the Act to determine the quantum of compensation.

## Factory Workers

Another key law related to occupational health 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. The Act requires that a person who has ultimate control over the affairs of the factory "shall ensure, so far as is reasonably practicable, the health, safety and welfare of all workers while they are at work in the factory." In *Mangesh G. Salodkar v Monsanto Chemicals*,<sup>447</sup> the Bombay High Court converted the complaint of ill-health of an employee in a Monsanto 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 referring to the right to health under the Constitution and the duties of the State to ensure the health of workers, passed a number of directions for the state and central government to ensure the right to health and safety of employees at factories.

## Army Act

TB has been identified as an occupational risk within the armed forces. While the armed forces provide comprehensive healthcare for personnel and their families, the issue of diseases affecting personnel and whether these are attributable or aggravated by service plays a role in determining pension awards when a person is released or invalidated from service.<sup>448</sup> The *Army Act, 1950* provides for the retirement, release or discharge of a person from the armed forces. The *Army Rules 1954* further specify the procedure for release or discharge on medical grounds. Entitlement to pensions due to disabilities attributable or aggravated by military service is covered by the *Entitlement Rules for Casualty Pensionary Awards, 1982*. These rules also provide for pensions in cases of diseases arising 10 years after discharge if they are attributable to or aggravated by military service.

There has been considerable litigation on the matter of attributability and aggravation. Popularly known as "NANA" (neither attributable nor aggravated by military service) cases, several have been litigated all the way to the High Courts and the Supreme Court. In *Bero Devi v. Union of India*<sup>449</sup> the husband of the petitioner was invalidated out of service due to pulmonary TB and his disability was assessed at 70%. However after his death, his widow was denied disability pension on the grounds

446 2010 ACJ 1706

447 2007 (2) Bom CR 883

448 Sandhu et al, A Review Of Casualty Pensionary Awards: Entitlement And Assessment, Med J Armed Forces India. 1996 Jan; 52(1): 48–52, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5530279/>

449 SWP No.743 of 2001, High Court of Jammu & Kashmir

that his disability was “neither attributable to nor aggravated by army service.” The High Court of Jammu and Kashmir disagreed, finding that the army officer’s TB, “is said to be a disease which occurred on account of stress and strain of army service.”

In 2017, after clear findings by the Supreme Court in the case of *Dharamvir Singh v Union of India and Ors*<sup>450</sup> on the proper application of the *Entitlement Rules for Casualty Pensionary Awards, 1982*, the Ministry of Defence stated that it would not challenge orders for disability pension for soldiers<sup>451</sup> and issued a notification to the chiefs of all three armed forces detailing the findings of the Supreme Court and for sanction of pension to be given except where there are appeals pending.<sup>452</sup>

## Healthcare Workers

For healthcare workers, whose occupational risk of developing TB is well recognized in government policies, laws for protection and compensation are unclear. Most healthcare workplaces do not fall under the ambit of the *Employees Compensation Act* or the *Factories Act*. Occupational health and safety do not figure in the list of standards to be applied under the *Clinical Establishments Act* (discussed in section on “Regulation of the Private Sector”). For healthcare workers at occupational risk of TB in the public sector, there is some entitlement to a Hospital Patient Care Allowance/ Patient Care Allowance (PCA) that was introduced by the government in [1998].<sup>453</sup> 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 of an occasional nature. It may be noted that the *HIV Act* creates legal obligations on both public and private sector healthcare establishments to provide a safe working environment, albeit in the context of HIV transmission.<sup>454</sup>

## 14.2 Experiences

Several informants expressed concerns over the lack of enforceable legislation or policies on TB prevention in the workplace. As noted above, one key issue that has attracted the attention of the Supreme Court and the NHRC is of silicosis. Although compensation for persons with silicosis and silico-TB has been ordered, the actual process for claiming this compensation is difficult. Moreover, the focus on prevention is lacking and the few directions that have been given on this have not been enforced. As a key informant observed, “the persons most affected or at risk of silicosis will not complain about the lack of prevention measures because they are afraid of losing their jobs.”

Anecdotal evidence from informants also suggests that several healthcare workers have contracted TB occupationally. The case of a particular TB hospital in Maharashtra was mentioned by several

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450 (2013) 7 SCC 316

451 Ministry of defence will not challenge disability pension for soldiers, Times of India, 2 July 2017, available at <https://timesofindia.indiatimes.com/city/chandigarh/ministry-of-defence-will-not-challenge-disability-pension-for-soldiers/articleshow/59407215.cms>

452 Ministry of Defence, Implementaiton of Orders of Hon’ble Courts/AFTs in Neither Attributable to Nor Aggravated (NANA) by service cases, F.No.4(17)2015/D(Pen/Legal), Dated 29 June 2017

453 Government of India, Report of the Seventh Pay Commission, November 2015 available at [https://www.finmin.nic.in/sites/default/files/7cpc\\_report\\_eng.pdf?download=1](https://www.finmin.nic.in/sites/default/files/7cpc_report_eng.pdf?download=1)

454 Section 2(y), *HIV and AIDS Act, 2017*

informants, particularly the importance of availability of universal precautions and their use. Previously the staff at this hospital had no masks and there were several cases of occupational TB being reported. However, two things appear to have made a difference. The first was the issue being taken up by the unions who demanded paid leave, transfer and rotation and other conditions to improve health and safety at the hospital. And, strikes by the unions led to improved working conditions. The second was the involvement of an international humanitarian organization that provided the staff of the hospital with N95 masks and trained them in the use of universal precautions. (See section on “Countering Discrimination”)

According to several informants the situation at the hospital has changed considerably with few cases of occupational exposure being reported now, and healthcare workers who have contracted TB being given access to treatment and paid leave for 11 months. Yet, concerns remain; these benefits are not available for casual employees or residents or students who have to *“miss a term or a year. There ought to be a provision to condone their leave in matters of promotion or completion of particular number of days or years, if they lose a term.”* Another expert pointed out that, *“there is no compensation policy for workers with TB in the public sector.”*

Another issue raised by an informant related to causality: *“If I am working in the TB hospital and I do not have access to the protective masks and in case I develop TB I have no way of proving to the world that that this TB was contracted in the hospital. So that should be obviously something that is given. If he is working in a TB environment with 400 patients, and if he develops TB he shouldn’t have to prove that.”*

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 can attract stigma, which discourages patients from using them at the workplace. Consistent counseling on the importance of the masks can have a positive impact on the decision of patients to use these masks. Informants in Delhi noted that patients are given just one mask when they are first diagnosed, which they are expected to keep safe and wear every time they visit the treatment centre to get their medicines. Moreover, doctors refuse entry for patients if they do not have masks. It was pointed out that the lack of universal precautions for healthcare workers was also probably fuelling discrimination; doctors were reported sitting at great distances from patients who were required to pick up their medicines through a wire mesh.

### **14.3 Conclusions and Recommendations**

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 the conditions in prisons are conducive to the spread of certain types of disease. These settings are often overcrowded, poorly sanitized and ventilated; provide poor nutrition to inmates and with little if any infection control measures. Health facilities for diagnostics, care and treatment are limited, weakened by prison staff lacking knowledge in management of diseases, and poor budgetary allocation for maintaining adequate standards of healthcare. Health outcomes are also compromised due to interruptions in treatment where available and incompleteness of treatment on release.<sup>455</sup> With poor access to the tools or information for harm reduction, the vulnerability of prisoners to HIV is well documented. For people living with HIV, imprisonment exacerbates their precarious health condition and increases susceptibility to other infections including TB.

International guidance in the form of the UN's *Standard Minimum Rules for Treatment of Prisoners*<sup>456</sup> has laid down principles with regard to treatment of prisoners that range from minimum floor space, proper ventilation, hygiene and sanitary conditions, food of nutritional value, specialist treatment of sick prisoners, special accommodation for women requiring pre-natal and post natal care. These rules also prescribe that medical services in prisons should be linked to general health administration, and requires the medical officer in the prison to examine every prisoner as soon as possible, to discover any physical or mental ailments, and segregate prisoners with or suspected of infectious or contagious conditions.<sup>457</sup>

Prisoners are more marginalized than most, being often from already disadvantaged sections of society, and hindered from seeking health rights as they are walled off from the world, "*their voices*

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455 "Prevention of Infection and communicable disease control in prisons and places of detention: A manual for health care workers and other staff" Department of Health, July 2011. Available at [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/329792/Prevention\\_of\\_infection\\_communicable\\_disease\\_control\\_in\\_prisons\\_and\\_places\\_of\\_detention.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/329792/Prevention_of_infection_communicable_disease_control_in_prisons_and_places_of_detention.pdf)

456 Adopted by the First United Nations Congress on the Prevention of Crime and Treatment of Offenders, held at Geneva, 1955, and approved by the Economic and Social Council by its resolutions 663 C (XXIV) of 31 July 1957 and 2076 (LXII) of 13 May 1977

457 "*Standard Minimum Rules for Treatment of Prisoners*", adopted by the First United Nations Congress on the Prevention of Crime and Treatment of Offenders, held at Geneva, 1955, and approved by the Economic and Social Council by its resolutions 663 C (XXIV) of 31 July 1957 and 2076 (LXII) of 13 May 1977

are inaudible and their injustices unheeded.”<sup>458</sup> Thus, in the context of TB treatment in prisons, the WHO highlights the importance of taking equity seriously and taking into account “the often impoverished socioeconomic backgrounds of most prisoners and the power imbalance all inmates face while in prison with regard to health care and other goods; health care workers should be aware that particular attention must be given to these factors when treating prisoners with TB.”<sup>459</sup> In particular, the WHO cautions against forced screening, diagnostics and treatment in prison settings. Isolation, if necessary, should be done with informed consent, counselling, respecting privacy and in a hospital setting, as discussed in the section on “Isolation”, any involuntary isolation should only be a last resort and where there is a particularly high risk of transmission. The WHO also notes that governments are obligated to provide continued access to treatment upon the release of a prisoner.

### 15.1 The context in India – Law, policy and jurisprudence

The challenges posed by prison settings are recognized by the NSP.<sup>460</sup> The NSP identifies prisoners as a “key population” facing increased exposure to TB because of where they live. According to the NSP, “the best strategy for preventing tuberculosis in prisons is early diagnosis combined with effective treatment.” As a result, there is considerable emphasis in the NSP on screening at entry and active case finding of TB among prisoners. Issues related to consent and confidentiality in this regard are discussed in previous sections and as noted above, forced screening, testing and treatment must be guarded against. Importantly, the NSP also includes prison staff recognising their vulnerability to TB as well (see section on “TB in the Workplace”). Strategic Interventions other than testing and treatment proposed in the NSP include infection control, counseling, support for HIV/TB treatment adherence, raising awareness, avoiding transfer, improving communications between prisons and ensuring treatment follow up for released prisoners. Recognising that there is insufficient information and data on TB in prisons in India, the NSP also proposes scientific research in this regard.

That vulnerability to TB in prisons is linked to larger issues of overcrowding and living conditions is an important rights-based recognition in the NSP; it is important to note that the Constitution of India casts an obligation on the State to preserve life. Article 21 of the Constitution has been interpreted by the Supreme Court to include the ‘right to healthcare’ and makes it incumbent on the healthcare professional whether in a government hospital or otherwise to preserve life.<sup>461</sup> Courts in India have played a pro-active role in pushing prison reform in relation to health. In a 1980 decision, the Supreme Court stated that, “the Indian Constitution cannot be held at bay by jail officials dressed in a little, brief authority,” and “prisoners must be afforded all reasonable facilities for an existence consistent with human dignity.”<sup>462</sup> More recently the court, stated that the effective utilization of funds

458 *In re – inhuman conditions in 1382 prisons*, The Supreme Court of India, Writ Petition (Civil) No. 406 / 2013, order dated 5.2.2016. Available at <https://drive.google.com/file/d/0BzXilfcxe7yudWFMcdJIS0Q1aIU/view>

459 WHO, Ethics Guidance for the implementation of the End TB Strategy, 2017, available at <http://apps.who.int/iris/bitstream/handle/10665/254820/9789241512114-eng.pdf;jsessionid=1EEE447A5B1A30D1B8CD6F8B5E2E85A6?sequence=1>

460 National Strategic Plan for Tuberculosis Elimination 2017-25, available at <https://tbcindia.gov.in/WriteReadData/NSP%20Draft%2020.02.2017%201.pdf>, at page 53

461 *Parmanand Katara v Union of India* AIR 1989 SC 2039

462 *Sunil Batra v Delhi Administration* AIR 1980 SC 1579

for prisons must be ensured so as to provide better living conditions to prisoners commensurate with human dignity.<sup>463</sup>

The Gujarat High Court has held that the right to medical treatment is a basic right and directed jail authorities to take proper care of ailing inmates, and held negligent officers personally liable.<sup>464</sup> In fact, the Gujarat High Court directed that medical facilities in some prisons should be made up-to-date so that prisoners can be treated at the jail hospital itself without having to be constantly transferred to the civil hospital, and also directed that a panel of doctors be appointed to consider admission of patients from the jail to the civil hospital.<sup>465</sup> Indeed, in cases of under-trials and persons who have completed their prison sentence, courts have held that treatment once started within the prison ought to be continued by the government on the release of the prisoner. The Delhi High Court directed the government to continue providing anti-retroviral treatment for HIV to a prisoner who had been started on the medication while in prison and thereafter been released on bail.<sup>466</sup> Recently, in *suomotu* proceedings initiated by the Rajasthan High Court for improvement of the conditions in prisons, the court directed the state to take measures aimed at securing the human rights of prisoners, including to provide regular medical care facilities to inmates and to depute doctors and para-medical staff for care and treatment related to 'psychiatry, tuberculosis, eyes and dental' health care of prisoners.<sup>467</sup>

A gamut of statutes have a bearing on prisons and prisoners, and include: (i) Indian Penal Code, 1860; (ii) Prisons Act, 1894; (iii) Prisoners Act, 1900; (iv) Identification of Prisoners Act, 1920; (v) Transfer of Prisoners Act, 1950; (vi) Representation of People's Act, 1951; (vii) Prisoners (Attendance in Courts) Act, 1955; (viii) Probation of Offenders Act, 1958; (ix) Code of Criminal Procedure, 1973; (x) Mental Healthcare Act, 2017 (xi) Juvenile Justice (Care and Protection) Act, 2000; (xii) Repatriation of Prisoners Act, 2003; (xiii) Model Prison Manual, 2003; (xiv) Indian Police Act, 1860. Jail/prison manuals of each State are also critical to the administration of prisons. Various facets of these laws as they relate to TB are highlighted below.

## Prison Administration

Prison administration is governed by List II, Schedule VII of the Indian Constitution, which enumerates the subjects that state/ union territory governments are to legislate on. Most states have a variety of incarceration settings – central jails, district jails and sub-jails, women's jails, borstal schools, open jails and special jails.<sup>468</sup> The *Prisons Act, 1894* is the primary law governing prison administration in India. With prison manuals devised by state governments, it provides the legal and policy framework

463 *In re – inhuman conditions in 1382 prisons*, The Supreme Court of India, Writ Petition (Civil) No. 406/ 2013, order dated 5.2.2016. Available at <https://drive.google.com/file/d/0BzXilfcxe7yudWFMcdJIS0Q1aIU/view>

464 *Rasikbhai Ramsingh Rana v State of Gujarat* (DB) 1997 CrLR (Guj) 442

465 *SuoMotu v The State of Gujarat* on 12<sup>th</sup> May 2005, (2005) 3 GLR 2088, available at <https://indiankanoon.org/doc/1578225/?-type=print>

466 *Lx v Union of India*, (Interim order) Delhi High Court, 2004

467 *SuoMotu v State of Rajasthan*, 2017 (3) RLW 1873 (Raj)

468 Prison Statistics India, 2015, National Crime Records Bureau, Ministry of Home Affairs, available at <http://ncrb.gov.in/StatPublications/PSI/Prison2015/Full/PSI-2015-%2018-11-2016.pdf>

for prison governance. In relation to matters of health, the Act mandates the Medical Officer to take charge of sanitary administration in prisons and to report cases where discipline may injure the physical and mental health of the prisoner.<sup>469</sup> The Medical Officer is also to record the health of the prisoner, whereas female prisoners are to be similarly examined by a matron supervised by the Medical Officer.<sup>470</sup> The legislation contains a chapter on sick prisoners and mandates physically and mentally unwell prisoners to be examined by the Medical Officer and prescribes a system of record-keeping of treatment that is rendered.<sup>471</sup> Importantly, the legislation requires that, “[i]n every prison a hospital or proper place for the reception of sick prisoners shall be provided.”<sup>472</sup>

The Model Prison Manual developed by the Indian government also requires the Medical Officer to provide treatment and contain contagious diseases, and to look after hygiene and sanitation within prisons.<sup>473</sup> Segregation and isolation of prisoners who have or are suspected to have an infectious disease is permitted and to be maintained until the Chief Medical Officer considers it safe to discontinue the same. All cases of pulmonary TB are to be segregated in a special ward and all necessary precautions are to be taken to guard against its spread. Similarly, rules have been prescribed to manage deaths of prisoners due to TB. State governments have their own prison manuals, and Maharashtra has recently amended its manual.<sup>474</sup> Although it was not possible to obtain a copy of the same for this assessment, press reports suggest that healthcare reform within prisons was being proposed for the amended manual.<sup>475</sup> These include equipping prisons with super-specialty medical facilities, advanced care that ensures prisoners are able to access treatment within, instead of having to go to outside hospitals, screening facilities to nip health issues in the bud, and availability of specialists including psychiatrists on prison premises.

## Police custody

Prior to being subject to a trial or convicted, persons are arrested and held in custody by the police, at which time a medical examination may be undertaken to obtain evidence regarding an alleged offence.<sup>476</sup> Such persons can even ask to be examined by a medical practitioner.<sup>477</sup> This provision is a safeguard against torture and violence. In such situations the law foists responsibility on the person having “*custody of an accused to take reasonable care of the health and safety of the accused.*”<sup>478</sup> This becomes relevant in the context of TB in relation to treatment continuity. An informant interviewed for this report said that treatment interruption of TB medication can take place in custodial settings,

469 Sections 13 & 14, *Prisons Act, 1894*

470 Sections 24(2) & (3), *Prisons Act, 1894*

471 Chapter VIII, Sections 37, 38, *Prisons Act, 1894*

472 Section 39, *Prisons Act, 1894*

473 Model Prison Manual 2016, Ministry of Home Affairs, Government of India, available at <http://mha1.nic.in/PrisonReforms/pdf/PrisonManual2016.pdf>

474 See <http://www.firstpost.com/mumbai/no-parole-for-rapists-murderers-in-maharashtra-state-prisons-rules-amended-2985270.html>

475 See <http://www.dnaindia.com/mumbai/interview-maharashtra-prepares-new-jail-manual-after-36-years-dr-vijay-satbir-singh-2072707>

476 Section 53, *Code of Criminal Procedure, 1973*

477 Section 54, *Code of Criminal Procedure, 1973*

478 Section 55A, *Code of Criminal Procedure, 1973*

especially in police lock-ups, where arrested persons often miss their TB medications, in breach of the aforesaid duty of the custodian.

The guidelines provided by the Supreme Court in *D.K. Basu v. State of West Bengal*<sup>479</sup> on arrest and detention, include among other things, that the arrested person may request to be examined medically at the time of arrest, in case they have major or minor injuries, and should be subjected to medical examination within 48 hours of detention, and be examined every 48 hours thereafter. These provisions are primarily for checking if the person had injuries or not at the time of arrest, and also to check if there has been torture and ill-treatment at the hands of the police while in custody. The guidelines do not cater for situations where a detainee on TB or any other medication is to be medically examined to be confirmed as such and be ensured uninterrupted treatment, or where a detainee is required to be tested for infectious diseases, like TB, so that adequate steps to prevent spread of the disease can be taken while they are in custody.

The Supreme Court has held that the fundamental right to life and health is not negated when a person is arrested or convicted.<sup>480</sup> Not providing treatment to prisoners' amounts to cruelty and unusual punishment. Given this, minimum levels of healthcare, accommodation and diet for every prisoner are aspects that should be pursued by the State for public health reasons, but also as matters of right.

## Compensation

As the health rights of prisoners often get violated despite the law providing for their protection as described above, courts have stepped in and awarded compensation where custodial deaths have taken place due to negligence of officials in not providing timely and adequate medical care for TB.

Compensation is provided for human rights violations to cover physical and mental harm, including pain, suffering and emotional distress, and includes the costs incurred for medical treatment and medical services.<sup>481</sup> However, compensation has not been given in cases where a person acquires TB or any infectious disease while incarcerated.

The Patna High Court awarded INR 2,50,000 to the family as compensation for negligence by jail authorities in failing to take the deceased detainee for regular check-ups, due to which he died within 2 weeks of being diagnosed with TB.<sup>482</sup> In another case, where an undertrial at the central jail in Guwahati died due to pulmonary TB, his son was awarded INR 3,00,000 as compensation by the High Court for negligence of the jail authorities in failing to extend all required medical assistance to

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479 AIR 1997 SC 3017

480 *Sunil Batra v Delhi Administration* AIR 1978 SC 1675

481 UN General Assembly Resolution on "Basic Principles and guidelines on the right to remedy and reparation of victims of gross violations of international human rights law and serious violations of international Humanitarian law, 2005". Also incorporated in the 41<sup>st</sup> Law Commission report (1969) on Section 545, *Code of Criminal Procedure* and 154<sup>th</sup> Law Commission Report (1996) on victimology.

482 *Premshila Devi v. State of Bihar &ors.*, In the High Court of Patna, in CWJC No. 383 of 2006, order dated 26.4.2011. Available at <http://indiankanoon.org/doc/65903599/>

the father.<sup>483</sup> The court stated that the right to live with human dignity and the right to receive proper medical treatment while in custody is guaranteed under Article 21 of the Constitution of India, and cannot be denied to a prisoner just because his movement is curtailed by being incarcerated.<sup>484</sup>

Similarly, in another case, the Orissa High Court awarded INR 3,50,000 as compensation to a widow who claimed that her husband died in police custody after he contracted TB and was not provided sufficient medical treatment.<sup>485</sup>

In the case of a 16-year-old child who died while in custody of the Observation Home under the *Juvenile Justice Act*, it was found that the authorities failed to notice that the child had TB, which was in an advanced stage. The High Court found that the provisions of the *Juvenile Justice Act* were not followed with regard to providing specialized referral and treatment of the child in their custody, which was primarily because of lack of sensitivity, of awareness of the disease, and of accountability of the persons in charge of the Observation Home. The court while directing that all juveniles in such homes should be medically examined before entering them or soon thereafter, also directed compensation of INR 1,50,000 to be paid to the child's parents for the custodial death.<sup>486</sup>

### Commutation of sentence due to TB

There have also been cases where the TB status of the accused has helped them get bail or their sentence commuted. In a case of inordinate delay of more than 5½ years in considering a mercy petition of a 70-year old man suffering from an advanced stage of TB, the Delhi High Court commuted his sentence of death to life imprisonment.<sup>487</sup> In another case, the Supreme Court allowed a person with TB who had completed several years in prison as an undertrial to be released on bail.<sup>488</sup> In yet another case, the Supreme Court commuted the sentence to the period already served since the convict was 65 years old and with TB.<sup>489</sup> In one case, flexibility was shown by the court for an accused with TB where he was not exempt from surrendering, but was given an extended time of four weeks to do so, and jail authorities were also directed to provide treatment.<sup>490</sup>

## 15.2 Experiences

India has about 1401 jails, of which the highest number are in Maharashtra (154), followed by Tamil Nadu (137).<sup>491</sup> There are only 13 prisons in India exclusively for women, and about 68 open jails, of which 29 are in Rajasthan followed by 13 in Maharashtra.<sup>492</sup> The total capacity of prisons in

483 *Bhupen Biswas v State of Assam* 2008 (3) GLT 444

484 *Ibid.*

485 *Kamala Tadingi v State of Orissa* 112 (2011) CLT 537

486 *Naisul Khatun v State of Assam &ors.*, 2011 CRI.L.J. 326, Gauhati High Court

487 *Khem Chand v The State* 1990 Cr.LJ 2314, Delhi High Court

488 *Bhole & ors v State of MP*, Supreme Court of India, CRLMP No. 22608/2013 in Criminal Appeal Nos. 889-890 of 2012, order dated 25.11.2013

489 *Ramdhan v State of Rajasthan*, Supreme Court of India, CRLMP No. 355/2014 in Criminal Appeal No. 10545/2013, order dated 24.2.2014

490 *Dineshbhai S. Chaudhri v State of Gujarat*, Supreme Court of India, SLP Appeal of 2008, CRLMP No. 19085, order dated 14.1.2009

491 Prison Statistics India, 2015, National Crime Records Bureau, Ministry of Home Affairs, available at <http://ncrb.gov.in/StatPublications/PSI/Prison2015/Full/PSI-2015-%2018-11-2016.pdf>

492 *Ibid.*

India is 3,66,781, but the number of prisoners in India is 4,19,623. The occupancy rate, defined as the number of prison inmates against the authorized capacity for 100 inmates, was the highest in most central jails (113) and district jails (131) (>100 is considered overcrowding),<sup>493</sup> with Dadra and Nagar Haveli reporting the highest overcrowding (277), Delhi (226), Maharashtra (113).<sup>494</sup> There are about 1866 medical staff in Indian jails, amounting to about 225 inmates per staff member. The total amount spent on medical needs of prisoners is INR 7767 lakh across all prisons.<sup>495</sup> The average allocated expenditure per inmate per year is about INR 31,632, of which an average of only INR 7,767 is spent, revealing vast under-expenditure.<sup>496</sup>

A 2001 report of prison conditions noted that India, among other countries like Russia and Brazil, had high rates of TB in prison - approximately one out of every ten inmates had TB, with more than 20% of sick inmates having MDR-TB.<sup>497</sup> More recent studies have confirmed that TB prevalence is much-too-high in Indian prisons - between 2% to 7.5% - and deaths due to TB are from 9% to 18% of total deaths in prisons.<sup>498</sup> The high prevalence of TB in prisons is due to low levels of nutrition and poor infection control mechanisms. A newspaper report in January 2016 pointed out the high incidence of TB in Mumbai jails, and that surprise checks in central prisons by the Maharashtra State Human Rights Commission in 2015 reported serious concerns of overcrowding and poor medical care.<sup>499</sup> Further, that while data from the RNTCP showed TB prevalence in the population being 1.67 per 1000 people, in Mumbai's Arthur Road jail in 2015 it was approximately eight times higher at 14 per 1000.<sup>500</sup> Such grave figures for TB have been ascribed to overcrowding, poor ventilation, poor nutrition, co-morbid infections such as HIV, and poor healthcare facilities and support.<sup>501</sup>

The dismal state of TB-related healthcare in Indian prisons highlighted in a study conducted by Prasad *et al* cited above, also 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.<sup>502</sup> Only half the prisons screened inmates for TB at entry, while nearly 60% practiced periodic screening of TB.<sup>503</sup> The study also found that prisons followed a practice of asking inmates to disclose their health status at the time of entry, and only 14% of prisons isolated active TB patients on treatment from other inmates.<sup>504</sup> Doctors were available in 82% of prisons and were associated with diagnosing and treating TB. A high proportion of presumptive TB cases were found which were equivalent to the rate

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493 Ibid.

494 Ibid.

495 Ibid.

496 Ibid.

497 Human Rights Watch World Report, 2001 available at <https://www.hrw.org/legacy/wr2k1/print/prisons.pdf>

498 Prasad, BN et al, "Status of Tuberculosis service in Indian Prisons" International Journal of Infectious Diseases 56 (2017) 117-121, <http://dx.doi.org/10.1016/j.ijid.2017.01.035>

499 Barnagarwala, T, "TB in Mumbai prisons a steadily growing crisis", Indian Express, 24.1.2016, available at <http://indianexpress.com/article/cities/mumbai/tb-in-mumbai-prisons-a-steadily-growing-crisis/>

500 Ibid.

501 Prasad, B.N et al, "Status of Tuberculosis service in Indian Prisons" International Journal of Infectious Diseases 56 (2017) 117-121, <http://dx.doi.org/10.1016/j.ijid.2017.01.035>

502 Ibid.

503 Ibid.

504 Ibid.

in the general community.<sup>505</sup> Only 65% of doctors in prisons were trained under the RNTCP.<sup>506</sup> These statistics display the considerable mismatch between rules and regulations governing prison settings and their implementation. Indeed, past research has noted that the challenge in prisons related to TB includes poor training of healthcare workers, chronic shortages of medicines and diagnostics, and high levels of corruption.<sup>507</sup>

Anecdotal instances have been noted where sputum of the prisoner collected for TB testing at the prison by the Medical Officer is not taken for testing by the TB officer under the RNTCP for 10-15 days after collection, compromising the veracity of the test result. Other challenges include treatment interruptions due to non-availability or stock-outs of TB medication in prisons. The Model Prison Manual recognizes the problem of stock-outs and provides details about stocks of medicines and the local purchase of medicines for sick prisoners.<sup>508</sup>

### **15.3 Conclusions and Recommendations**

Various Committees<sup>509</sup> have been set up from time to time to suggest improvements in prison conditions and administration, to make them more conducive to reformation and rehabilitation of prisoners. Their suggestions have been based on broad principles laid down by the Supreme Court in various judgments to treat prisoners as human beings, entitled to certain fundamental rights within the limitation of being incarcerated. Over time reports of the Law Commission of India have also instigated changes in the Code of Criminal Procedure to ensure health and safety of arrested persons.<sup>510</sup> Still conditions in prisons and detention centres remain dismal. In the context of TB, the NSP's proposals and approach to prisoners are welcome; however the importance of improving prison conditions should not get lost in the drive for screening and case finding. Given the marginalized and under-resourced context of prisoners, and the particular vulnerabilities that prison settings raise for TB, policy and law need to be wholeheartedly implemented to ensure that TB at such sites is effectively controlled. Solutions lie in holistic approaches to better the situation of prisoners.

#### **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

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505 Ibid.

506 Ibid.

507 Levy, M, "Tuberculosis and Prisons", Issues in Medical Ethics, VII (3), July-September 1999, pages 84-85

508 Model Prison Manual 2016, Ministry of Home Affairs, Government of India, available at <http://mha1.nic.in/PrisonReforms/pdf/PrisonManual2016.pdf>

509 Examples include the AN Mulla All India Prison Reforms Committee, and subsequent committees under RK Kapoor and Justice Krishna Iyer set up by the central and state governments.

510 Examples include the 113<sup>th</sup> Law Commission Report (1985) discussing injuries in police custody, the 177<sup>th</sup> Law Commission Report (2001) on insertion of S.55A and the health and safety of arrested persons, the 268<sup>th</sup> Law Commission Report (2017) on the insertion of S.41(1A) and amendment to section 41B in relation to police officers informing arrested persons of their rights.

- 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:
- 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.
  - 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.
  - 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.
- ab) 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 per cent of 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, although precise data on this is hard to come by.<sup>511</sup> One's ability to settle in a new part of the country is dependant on the documentation one possesses. Birth registration with which domiciliary documentation is linked, happens for only a little above 1/3 of all births. This could be influenced by the fact that in many cases people are not born in hospitals or health clinics but at home. And, where a vast number of labour migrants originate from, such as Uttar Pradesh and Bihar, registration percentages are in the single digits. When they do move, then, they do so as undocumented labour.<sup>512</sup>

Documentation is key to proving one's identity in order to avail of social services that exist in one's location. For instance, a ration card is often essential to access public facilities such as subsidized food, open bank accounts or seek admission to government hospitals or schools. Although a ration card is meant to be available to all people including migrants, in practice it is difficult for a migrant to obtain one. And, not having such identity documentation translates into an inability to access health services, including TB diagnosis, care and treatment. Migration is estimated to also cause loss to follow-up of a quarter of all TB treatment.<sup>513</sup> The NSP recognizes the challenges that migrant labour pose to developing an effective TB programme that meets their unpredictable needs. Indeed, lack of documentation exacerbates already precarious circumstances that are ripe for TB to exploit, such

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511 Abbas R, Varma D., Internal labor migration in India raises integration challenges for migrants, Migration Policy Institute, Washington, DC, 2014, available at <https://www.migrationpolicy.org/article/internal-labor-migration-india-raises-integration-challenges-migrants>

512 Ibid.

513 Stop TB Partnership, Key Populations Brief: Mobile Populations, 2016

as impoverishment due to job insecurity, and claustrophobic living conditions in urban slums. The Aadhaar scheme that is being implemented under statutory authority<sup>514</sup> by the central government 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. As has been noted, India has a long tradition of receiving refugees, with support being extended to over 200,000 people, Sri Lankan Tamils and Tibetans being the two largest refugee groups that are assisted by the government, in recent times.<sup>515</sup> According to the UN High Commissioner for Refugees (UNHCR), around 14,000 Rohingya from Myanmar have also been given refuge most recently.<sup>516</sup> India has a large population of stateless people, although accurate estimates of the number are not available.<sup>517</sup> India is not a party to the UN Refugee Convention of 1951 or its 1967 Protocol and does not have a national legal framework for refugee protection. Yet, it continues to grant asylum to a large number of refugees from neighbouring countries and respects UNHCR's mandate.<sup>518</sup>

It has been observed that most refugees take flight from, and arrive at countries with high TB burdens.<sup>519</sup> Further, *"a number of crisis-associated risk factors, such as malnutrition, overcrowding in refugee camps and other settlements, and the interruption of treatment and access to health care, can impact the spread of TB in these populations. TB treatment interruptions experienced by refugees ...can increase the risk of drug resistance and the development of MDR-TB."*<sup>520</sup>

## 16.1 The context in India – Law and Policy

For migrants, the *Inter-State Migrant Workmen (Regulation of Employment and Conditions of Service) Act, 1979* is the law that addresses their circumstances. It provides the right of migrant workers to equal wages as locals, the right to paid leave to return home, and the responsibility of employers to ensure workers rights. Importantly, 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. Although, *"it articulates ideal working conditions for interstate migrants, but lacking provisions for enforcement, it has not been used to create a better policy environment in practice."*<sup>521</sup> 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 the millions of construction labourers in India, most of whom are migrants. Although this Act is meant to provide welfare support, including

514 The *Aadhaar (Targeted Delivery of Financial and Other Subsidies, Benefits and Services) Act, 2016*

515 See [http://www.unhcr.org.in/index.php?option=com\\_content&view=article&id=18&Itemid=103](http://www.unhcr.org.in/index.php?option=com_content&view=article&id=18&Itemid=103)

516 See [http://www.unhcr.org.in/index.php?option=com\\_news&view=detail&id=50&Itemid=117](http://www.unhcr.org.in/index.php?option=com_news&view=detail&id=50&Itemid=117)

517 See <http://www.unhcr.org/4cd96e919.pdf>

518 Ibid.

519 Kimbrough W, et al, The burden of tuberculosis in crisis-affected populations: a systematic review. *Lancet Infect Dis.* 2012; 12(12):950–65.

520 Stop TB Partnership, Key Populations Brief: Mobile Populations, 2016

521 Abbas R, Varma D., Internal labor migration in India raises integration challenges for migrants, Migration Policy Institute, Washington, DC, 2014, available at <https://www.migrationpolicy.org/article/internal-labor-migration-india-raises-integration-challenges-migrants>

for health to beneficiaries, it appears that it is not implemented with any seriousness, cognizance of which the Supreme Court recently took.<sup>522</sup>

Domiciliary issues have proved hugely challenging in the ability of people with MDR-TB to access treatment. This discussed in detail in the section on “Access to treatment and diagnostics”, in relation to a girl from Patna with MDR-TB being refused bedaquiline from a Delhi hospital, which required consent terms before the Delhi High Court including an undertaking from the hospital to not deny treatment to future patients on grounds of domicile.<sup>523</sup>

For refugees, many can apply for long-term visas issued by the Indian government, and based on UNHCR documentation. This allows refugees to seek employment in the private sector and access education opportunities in India.<sup>524</sup> 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.<sup>525</sup>

*Key issues for Further Research:*

a. 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.

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522 *NCC-CL v Union of India &Ors*, Writ Petition (Civil) No. 318 of 2006, available at [http://supremecourt.gov.in/supreme-court/2006/17160/17160\\_2006\\_Judgement\\_19-Mar-2018.pdf](http://supremecourt.gov.in/supreme-court/2006/17160/17160_2006_Judgement_19-Mar-2018.pdf)

523 *Kaushal Kishore Tripathi v Lal Ram Sarup TB Hospital & Ors.*, W.P.(C) 11879/2016, Date of Order: 20 January 2017 available at [http://delhihighcourt.nic.in/dhcqrydisp\\_o.asp?pn=11539&yr=2017](http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=11539&yr=2017)

524 See [http://www.unhcr.org.in/index.php?option=com\\_content&view=article&id=18&Itemid=103](http://www.unhcr.org.in/index.php?option=com_content&view=article&id=18&Itemid=103)

525 Stop TB Partnership, Key Populations Brief: Mobile Populations, 2016

# 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.<sup>526</sup> 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 can subject women to greater violence and abandonment, raising serious issues of failing social support structures and fueling destitution.

## 17.1 The context in India – Law, Policy and Jurisprudence

While the NSP recognises that “women in settings with gender disparity” as a key population, but there is no content in this section of the NSP. The primary concern expressed around women in the NSP relates to pregnancy. In addition, the NSP calls for intensive case finding among pregnant and lactating women, women having infertility, women who smoke, women having diabetes, HIV/AIDS, malnutrition; who constitute clinically vulnerable risk groups for TB. There is also concern expressed for health seeking behavior of elderly women. The NSP also outlines concerns and interventions for women in sex work (see section on “Sex workers”). Despite these references in the NSP it is evident that the impact of TB on women is not well considered in the NSP.

The Constitution of India provides the legal basis for equality of all persons, including women. More specifically, the Constitution guarantees equality in Article 14, and protection against discrimination, inter alia, on the basis of sex in Articles 15 and 16. International covenants such as the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW) specifically require State parties to take all appropriate measures to eliminate discrimination against women, including in relation to health care.<sup>527</sup>

526 Registrar General of India & Centre for Global Health Research, “Causes of Death statistics 2010-2013”, available at <http://www.cghr.org/wordpress/wp-content/uploads/COD-India-Report-2010-2013-Dec-19-2015.pdf>

527 Article 12 of CEDAW

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.

Women (and men) in India are governed by personal laws (based on one's religion) with regard to marriage and divorce. Some of these laws have advanced over time to reflect equality between the sexes, while other laws remain discriminatory and place women in disadvantageous positions. These laws determine the legal position and status of women in the household, thereby determining their share in property, inheritance and succession, and influence their social status too.

Indeed, in the context of TB, where disempowerment is rife – having TB can affect marriage prospects of women, and when revealed within marriage has caused severe violence in and abandonment from the marital home, divorce, and in extreme cases starvation and murder<sup>528</sup> too – the law has a vital role to play as an empowering and protective instrument.

***Some of the laws affecting women which also have implications in the context of TB include:***

*(i) Child Marriage Restraint Act (ii) Hindu Marriage Act, 1955 (iii) Special Marriage Act, 1954 (iv) Parsi Marriage and Divorce Act (v) Divorce Act, 1869 (vi) Christian Marriage Act (vii) Muslim Women (Protection on Divorce) Act, 1986 (viii) Dowry Prohibition Act, 1961 (ix) Sharia law (x) Family Courts Act, 1984 (xi) Code of Criminal Procedure, 1973 (xii) Protection of Women from Domestic Violence Act, 2005 (xiii) Hindu Succession Act, 1956 (xiv) Hindu Adoption and Maintenance Act, 1956 (xv) Indian Succession Act (xvi) Indian Penal Code, 1860 (xvii) Registration of Marriage Act (xviii) Partition Act (xix) Commission of Sati (Prevention) Act, 1986 (xx) Pre-Conception and Pre-Natal Diagnostic Technique Act, 1994 (xxi) Medical Termination of Pregnancy Act, 1971 (xxii) Mental Healthcare Act, 2017, (xxiii) Hindu Women's Right to Property Act, 1937 (xxiv) Maternity Benefit Act, 1961 (xxv) Dissolution of Muslim Marriage Act, 1939 (xxvi) Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act, 2013*

## **Maintenance and Divorce**

Maintenance is financial support provided to a non-earning or insufficiently earning family member for sustenance. Questions of maintenance arise when a woman is economically dependent on her husband to provide daily means of life (food, shelter, clothing, medicines, education, etc.) to maintain her or her children, and when she does not own movable and immovable property that she can use for sustenance. Indeed, socio-economic conditions in India, which are overwhelmingly favourable to men, often breed this dependency. Such imbalance makes women vulnerable to violence, abuse and exploitation, and often poor health, including the onset of health conditions like TB, which thrive in marginalized contexts. Although women who develop TB are often abandoned because of it, in law

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528 *State of Maharashtra v Vinayak Shivajirao Pol & ors.* 1998 CRILJ 306, Bombay High Court

they have a right to reside in their matrimonial home.

Females also have a right to be maintained by their father till they are 18, and after marriage by their husbands. This is true in relation to all personal laws (see box above), based on which women can make an application for maintenance under such laws or under section 125 of the Code of Criminal Procedure. Maintenance is meant to cover aspects including food, shelter, clothing, education and health care. Under Hindu law, a widow without means to sustain herself and her children can be maintained by her father-in-law or by persons in possession of the husband's ancestral property who are earning *mesne* profits from it.

Although TB is not treated like leprosy or HIV as a sole ground for divorce under personal laws, there have been cases where men have filed for divorce from a wife with TB.<sup>529</sup> Interestingly, there have also been cases where men with TB have alleged desertion by their wives as a ground for divorce, although divorce was denied since desertion was not proved.<sup>530</sup> Women with TB, too, can use the law to seek divorce on the basis that they have been subject to cruelty from their husbands.

## Domestic Violence

An early case in the context of TB revealed the extent of violence that women are sometimes subject to and its impact on their health. In the case, the husband of a woman was convicted of attempt to murder, after it was shown that he beat her up, starved her for days, resulting in deterioration in her health and acquisition of TB.<sup>531</sup> In another case, the court was more lenient, looking at the immediate cause of death of the woman – extensive pulmonary disease – and not the factors that aggravated her condition, being the cruelty that she was subject to, thereby rejecting the charge of attempt to murder while retaining charges of cruelty and dowry harassment.<sup>532</sup>

In keeping with national aspirations for social justice, laws have been enacted in the last few decades in India that protect women from domestic violence, dowry harassment and cruelty.

One such law is the *Protection of Women against, Domestic Violence Act, 2005* (DV Act) was passed with the object of providing a remedy under civil law to protect women from being victims of domestic violence. The DV Act gives every woman in a domestic relationship<sup>533</sup> a right to reside in the shared household,<sup>534</sup> whether or not she has any right, title or beneficial interest in the same.<sup>535</sup> It extends protection to all women in a domestic relationship including women in a live-in relationship. It does not require the woman to be married to afford its protection.<sup>536</sup> A woman

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529 *Tejram Gaikwad v Sunanda Gaikwad* 1996 CRILJ 172, Bombay High Court

530 *Sanjay Kumar v Pratima Devi* AIR 2010 Patna 96; and *Rakesh v Pholan Devi* AIR 2014 Madhya Pradesh 178

531 *Om Prakash v State of Punjab* AIR 1961 SC 1782

532 *Vishnu Prasad & ors. v State* 2006 CRILJ 2865, Delhi High Court

533 S. 2(f), DV Act defines domestic relationship to mean a relationship between two persons who live or have lived together in a shared household, when they are related by consanguinity, marriage or through a relationship in the nature of marriage, adoption or are family members living together as a joint family

534 S. 2(s), DV Act defines shared household to be where the aggrieved person lives or has lived in a domestic relationship, and includes a household whether owned or tenanted, etc.

535 S. 17, DV Act lays down the right to reside in a shared household

536 *Aruna Parmod Shah v UOI* WP(Crl.) 425/2008, High Court of Delhi, (Decided on 07.04.2008)

survivor of domestic violence can file a complaint against perpetrators before the competent court or with the police or protection officer.<sup>537</sup> The woman can also seek protection orders, to stop the violence and prevent the perpetrator from entering the place of employment, from alienating his assets, and from entering the house, in case the violence does not stop.<sup>538</sup> A woman facing violence can also seek compensation for loss of earning,<sup>539</sup> and monetary relief to meet her medical expenses etc.,<sup>540</sup> and custody of her children.<sup>541</sup> Indeed, this is a legal recourse that can be used in the context of TB, where violence, abandonment and destitution has been documented.

## Healthcare

Women's delayed access to healthcare also stems from family and gendered attitudes to either provide home remedies to her or take her to cheaper options such as quacks, until she reaches a point where she has to be hospitalized. Delayed diagnosis and initiation of treatment are problematic for many reasons – they prolong the length of treatment, and are sometimes occur too late to save life. As noted in a dispute, women bear the brunt of incorrect TB diagnosis, which affects them physically on taking incorrect medication, but as importantly has severe mental and emotional implications, leading to upheaval in marital life, and rejection by family members.<sup>542</sup> Indeed, an effective response calls for increased gender sensitivity within the healthcare and public health system.

Women in institutions are also vulnerable to TB, which has required courts to intervene and direct state governments to take a range of measures to improve living conditions in institutions for women and children, including proper medical care for all residents, and particularly for those coping with conditions such as skin diseases, malnutrition, anaemia and TB.<sup>543</sup>

## 17.2 Experiences

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.<sup>544</sup> Their low nutritional status,<sup>545</sup> coupled with low economic and educational status only exacerbate women's vulnerability to diseases such as TB. Indeed, many of the aforementioned barriers such as stigma, discrimination, illiteracy, and poverty contribute substantially to psychological

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537 S. 4, *DV Act* provides for information to Protection Officers

538 S.18, *DV Act* explains protection orders

539 S.22, *DV Act* lays down compensation orders

540 S.20, *DV Act* provides for monetary orders

541 S. 21, *DV Act* refers to custody orders

542 *Kalyani General Hospital v E. Bhuvanewari* MANU/RE/0003/2005, Tamil Nadu State Consumer Disputes Redressal Commission

543 *Sanat Kumar Sinha v State of Bihar* 1990 (1) PLJR 769

544 Sarojini NB et al, "An overview of Women's health status in India," Women's Right to Health, NHRC, 2006, at page 34, available at <http://nhrc.nic.in/Documents/Publications/Womens.pdf>

545 Chandrasekhar, CP and Ghosh, Jayati, "Women in India: A status report" The Hindu Businessline Tuesday, 03 Sept 2002, available at <http://www.thehindubusinessline.com/2002/09/03/stories/2002090300080900.htm>

and emotional distress from TB.<sup>546</sup> As pointed out by an informant, another factor that causes mental and emotional strain in women with TB is their prioritization and concern for their children.

Research has been undertaken that unsurprisingly shows a co-relation between women's health and domestic violence. A disturbingly high proportion - 52% - of ever married women between 15-49 years of age who have TB have experienced violence, with about 49% experiencing physical violence, 22% dealing with emotional violence and about 16% suffering sexual violence.<sup>547</sup> Data also revealed that the majority of underweight and severely or moderately anaemic women have faced some form of violence.<sup>548</sup> Further, having a disease increased the chance of facing domestic violence by 35%, while also adversely affecting the woman's nutritional status.<sup>549</sup>

### 17.3 Conclusion

Various factors affect the empowerment of women, many of which are related with systemic inequality, and historical social inequities. The legal system, more often than not, reflects these long-standing realities, making it mostly inaccessible and unaffordable to women. A rights-based approach that has been espoused in more recent discussions 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.

The passing of the DV Act is one such manifestation, as is the more recent *Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act*. Yet, in order to be truly effective such law reform has to be coupled with efforts at legal literacy of women, including knowledge of their rights and remedies, and supportive systems of legal aid, counseling and engagement with men and boys. In the context of TB and law, this requires an intersectional approach not just on health and nutrition related information, but also communicating the centrality of empowered women to wholesome family health, and a gender-responsive public health system that caters to the health needs of people of all genders, in a non-stigmatizing, nuanced, and inclusive manner.

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546 Yang, WT et al, "Barriers and Delays in Tuberculosis Diagnosis and Treatment Services: Does Gender Matter?", Tuberculosis Research and Treatment, Hindawi Publishing Corporation, Vol 2014, at <http://dx.doi.org/10.1155/2014/461935>

547 Pandey, M et al, "Domestic Violence and Women's Health in India: Evidence from Health Survey", Institute of Economic Growth, Delhi, ASARC Working Paper 2009/13

548 Ibid.

549 Ibid.

***Key issues for Further Research:***

- a) 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.
- b) 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.
- c) Nutritional aspects relating to women that make them vulnerable to diseases like TB.
- d) 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 PLHIV. Globally, an estimated 1 million PLHIV had TB in 2016 and nearly 370,000 died from HIV-associated TB.<sup>550</sup> WHO recommends routine HIV screening for people with TB and for screening of TB symptoms among PLHIV. Anti-retroviral therapy (ART) reduces the risk of TB by approximately two-thirds; for PLHIV on TB treatment, ART should be commenced within 2-8 weeks of the commencement of TB treatment. The WHO also recommends that PLHIV have access to rapid TB diagnostics and should receive Isoniazid preventive therapy (IPT).<sup>551</sup>

## 18.1 The context in India – Policy

India has the second highest number of estimated HIV-associated TB in the world. An estimated 110,000 PLHIV developed TB in 2015 and with an estimated 37,000 deaths as a result.<sup>552</sup> Collaboration between RNTCP and NACO commenced in 2001.<sup>553</sup> NACO is the agency responsible under the MoHFW for the implementation of the National AIDS Control Programme (NACP). But it is only in the last decade that co-ordination and delivery of services for PLHIV co-infected with TB has improved considerably. The government programme is in line with the recommendations of the WHO. Now, single window delivery of HIV-TB services is available at all ART centres.<sup>554</sup> CBNAAT testing was also made available for PLHIV in the early phase of its rollout. The improved collaboration has resulted in over 88% of people with TB having been tested for HIV and 90% of PLHIV co-infected with TB having received ART and co-trimoxazole prophylaxis therapy (CPT). In 2016, 'intensified TB case finding and

550 WHO, HIV Associated Tuberculosis - Factsheet, November 2017, available at [http://www.who.int/tb/publications/tbhiv\\_factsheet.pdf](http://www.who.int/tb/publications/tbhiv_factsheet.pdf)

551 Ibid.

552 Central TB Division, TB India 2017: RNTCP Annual Status Report, 2017, available at <https://tbcindia.gov.in/WriteReadData/TB%20India%202017.pdf>

553 Central TB Division and National AIDS Control Organization, National Framework for Joint HIV/TB Collaborative Activities, November 2013, available at <http://naco.gov.in/sites/default/files/National%20Framework%20for%20Joint%20HIV%20TB%20Collaborative%20Activities%20November%202013.pdf>

554 "A package of services includes intensified TB case finding through screening by four symptom complex, rapid diagnosis of TB among PLHIV with CBNAAT, Fixed Dose Combination daily treatment for TB, INH preventive therapy for prevention of TB among PLHIV, ICT enabled adherence support through 99 DOT, Airborne Infection Control measures at ART centers and implementation of pharmacovigilance by establishing adverse drug reaction monitoring centres at ART centres." Central TB Division, TB India 2017: RNTCP Annual Status Report, 2017, available at <https://tbcindia.gov.in/WriteReadData/TB%20India%202017.pdf>

appropriate treatment’ was expanded for PLHIV through all ART centres. IPT has also been rolled out for all PLHIV who do not have active TB.<sup>555</sup>

The NSP 2017 – 2025,<sup>556</sup> proposes to follow the *National Framework for Joint HIV/TB Collaborative Activities* issued jointly by the Central TB Division and NACO in 2013, which emphasizes integration of HIV and TB services. The framework refers to patient-friendly diagnosis and adherence through NGOs. There is little reference to human rights and ethical issues; interestingly, confidentiality is referred to but only in the context of HIV status.

## 18.2 The context in India – Laws

Stigma and discrimination have been the defining features of the HIV epidemic in India. The very first litigation related to HIV in India related to a case where Dominic D’souza (who went on to become a vocal HIV activist) was incarcerated under the *Goa Public Health Act* for 64 days in a TB sanatorium in Goa after testing HIV-positive. Although the Bombay High Court upheld the provision of the Act that allowed the incarceration in 1990, subsequent cases have established clearly that discrimination based on HIV status is unconstitutional, violating Articles 14 and 16 (in cases of employment in the public sector) of the Constitution.<sup>557</sup> Over the years through case law and statutory law the rights of PLHIV have been recognized in India. The *Goa Childrens Act 2003* specifically provides that no child shall be denied admission to any school on the ground that they have HIV or AIDS.<sup>558</sup> In 2017, the *HIV and AIDS (Prevention and Control) 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.

## 18.3 Experiences

One of the most interesting observations emerging from the interviews relates to the stark difference between RNTCP and NACP in terms of 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 often TB-related stigma emerged first from RNTCP centres where patients go for the first time to get initiated on TB treatment. According to one PLHIV who also has MDR-TB,

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555 For effective implementation of IPT among PLHIV patients, all States were supplied with drug - Isoniazid 100 mg (PC-7) for pediatric patients and Isoniazid 300 mg (PC-11) for adult patients.

556 Central TB Division, National Strategic Plan for Tuberculosis Elimination 2017 – 2025, available at <https://tbcindia.gov.in/WriteReadData/NSP%20Draft%202020.02.2017%201.pdf>

557 *MX v ZY* AIR 1997 Bom 406

558 Section 4, Goa Childrens Act 2003 available at <https://www.childlineindia.org.in/CP-CR-Downloads/Goa%20children's%20act%20and%20rules.pdf>

*“the doctors at the TB centre sit at a great distance from me. If I have to pick up medicines, I have to put my hand through a wire mesh and pick them up from a table. Even once I started treatment, no one actually told me I had MDR-TB and would require treatment for nearly 2 years or what side effects I would have to deal with. When I go to my ART centre, my doctor sits with me, to discuss my treatment, inform me about side effects and reassure me about their support in dealing with the side-effects. The ART Centre does not treat me like a pariah. Because I am an activist and work on HIV treatment I knew about TB treatment and MDR-TB. If I didn’t I would have little idea of what was going on with my treatment from RNTCP or even for how long I have to take the treatment or the dangers of giving up treatment without the finishing the course.”*

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:

*“Frankly we work in Maharashtra where the public health system is a bit strong. Honestly, why we are taking people to public health system is because absolutely no stigma in public health setup and we have very good facility also. This is our experience not just in Mumbai, Pune, Nagpur but everywhere in the entire state... even in Vidarbha, Marathwada.”*

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.

*“RNTCP is not open for constructive criticism. They don’t want outsiders and want to keep to their own comfort zone. NACO much better than RNTCP. After seeing TB very much appreciate NACO now.”*

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 Further 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

According to the UN Sex Worker Implementation Tool (SWIT) which offers practical guidance on effective HIV and STI programming for sex workers,<sup>559</sup> “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.” The SWIT also notes that programmes or community outreach services for sex workers are ideally placed to support TB screening and TB prevention and treatment. “They also play a vital role in training sex workers to recognise TB symptoms and understand TB transmission, as well as the importance of infection control and cough etiquette to reduce TB transmission. In addition, they can help sex workers identify nearby health facilities for diagnosis and initiation of treatment of active or latent TB, as necessary.” It also recommends that TB clinic staff be trained on respectful approaches to sex workers.

## 19.1 The context in India – Policies

The TB programme in India identifies sex workers as a key population primarily because they are key populations in the context of HIV. According to the National Framework for Joint HIV/TB Collaborative Activities 2013, “operational research conducted in high HIV prevalent states have shown that HRG’s like female sex workers (FSW), men having sex with men (MSM), injection drug users (IDU) etc. are more likely to have tuberculosis compared to general population.” The NSP 2017 – 2025 considers sex workers to have increased exposure to TB due to where they live and/ or work. It also notes that like other key populations in HIV, “there is a clear evidence to suggest that socioeconomic and cultural factors lead to barriers in accessing health care including TB care,” for sex workers. Among the strategies to provide TB services to sex workers are “stigma free and community sensitive” TB testing and counseling. Also proposed is peer outreach and community-led detection and treatment services. The plan acknowledges that “community or peer-led measures” reach key populations better. The plan also recognizes the need for safe spaces for seeking information and referrals and to increase coverage and comprehensive services for partners, families and clients; the plan states that this is for sex workers in particular.

559 WHO, UNFPA, UNAIDS, Global Network of Sex Work Projects (NSWP), World Bank, UNDP, Implementing comprehensive HIV/STI programmes with sex workers: practical approaches from collaborative interventions, 2013, available at [http://www.who.int/hiv/pub/sti/sex\\_worker\\_implementation/en/](http://www.who.int/hiv/pub/sti/sex_worker_implementation/en/)

## 19.2 The context in India – Laws

While the NSP 2017 - 2025 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 the *IPC* or Police Acts, which penalize what are described as vagrancy, loitering, disturbing public peace, or causing public nuisance. The provisions of law with such broadly termed offences are often directed against disenfranchised, stigmatized and socially marginalized people such as sex workers. More specific legislation is also used to target sex workers. The *Immoral Traffic (Prevention) Act, 1986* (ITPA) was ostensibly enacted to address the problem of human trafficking but in fact it is also deployed to criminalize several activities surrounding sex work. While sex work itself is not criminalized, activities such as running a brothel,<sup>560</sup> living from the earnings of a sex worker,<sup>561</sup> and soliciting in public,<sup>562</sup> attract criminal penalties. ITPA arms the police with overly broad powers of search and arrest and so-called raid and rescue operations. Where raids and arrests are rampant, health services are impeded and there has been, for instance, a resultant increase in incidence and prevalence of STIs and HIV.<sup>563</sup> The risk of police action often pushes sex workers into more unsafe situations for soliciting sex work leaving them vulnerable to violence and unable to negotiate condom use. The *HIV Act* provides some protection for HIV prevention programmes by protecting “strategies for the reduction of risk of HIV transmission” from civil and criminal liability. The Act specifically includes the following example: “A supplies condoms to B who is a sex worker or to C, who is a client of B. Neither A nor B nor C can be held criminally or civilly liable for such actions or be prohibited, impeded, restricted or prevented from implementing or using the strategy.” However, the continued de-facto criminalization of sex workers in India means that their ability to access health services remains hampered.

## 19.3 Experiences

### Expanding scope and layering on TB screening services in India

TB is prevalent in India and is a common opportunistic infection among people living with HIV. In 2007, after comprehensive HIV prevention services had been scaled up over a period of three years, the Avahan India AIDS Initiative, in partnership with the country’s national TB programme, conducted intensified casefinding of sex workers through verbal screening for TB symptoms during routine outreach by community workers and regular clinic visits. Sex workers with symptoms suggesting TB were accompanied to the TB diagnostic centre and, if necessary, to a DOTS treatment centre. In order to train community outreach workers to do this, low-literate tools were developed, including visual aids, such as flash cards, posters and a video. The TB verbal screening activity was easily incorporated into the community outreach workers’ tracking tools, helping to ensure routine implementation during outreach. Over a period of three years, from April 2008 to March 2011, more than 18,000 individuals were identified as TB suspects from an estimated denominator of 300,000 and were referred to a TB diagnostic centre. Of these, 17% were diagnosed with TB.

560 Section 4, ITPA

561 Section 5, ITPA

562 Section 7 and 8, ITPA

563 Arguments presented by Surat sex workers in *Sahyog Mahila Mandal & Another v State Of Gujarat & Others*, Special Civil Application No 15195 of 2003 with Special Civil Application No 4594 of 2003

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:

*“Usha Kamble, Sangli, Maharashtra 2013. Usha a sex worker was living with HIV and had a TB coinfection. When she was very ill, she came to Sangli. She had drug resistant TB. The VAMP collective members wanted to get her admitted to the civil hospital and took all the necessary documents. After seeing her condition; civil hospital staff decided not to get admitted her in the hospital. She had water collection in her back. But the hospital refused and said, ‘Please take your patient, we cannot treat her.’ The VAMP collective was there asking the civil hospital staff to assist, but they didn’t respond. The VAMP collective took Usha back to their homes and took care of her till her death.”*

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 a strong movement of sex workers, the district TB programme has been working with sex workers for over a decade to reach their peers:

*“I have been working on HIV and TB for 25 years - we have a lot of co-infection among sex workers. Our workers have been going to the TB program of the government to do DOTS. What happens is that sex work communities that are difficult to reach, so the Council Hospital has actually trained or given training to our peer educators from the HIV targeted intervention and they are the ones who administer the medication for people known to them - they may not be sex workers, they may be families of sex workers. I’ll say that at least for the TB medication, it is available for the people who we have identified, we have given the medication.”*

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:

*“The point I think is tertiary care. We have lost a lot of people to TB and HIV co-infection, we actually have had deaths. One of the reasons of this is because of drug resistant and multi drug resistant TB because that is something that we have had a very long battle and has ended always in death. There is no medication for that at all, it somehow doesn’t reach these areas and we are not able to access these medications. We send people to Pune and we try our level best but they have not been very successful and unfortunately we lost people we have been following up and sometimes its friends, relatives, our community members who are leaders. We*

*send them to an NGO in Pune who tries to help. But prolonged stay is very expensive and these are poor people. Initially they will go they will say with all the commitment we will go, we will stay, we will complete the treatment, but it cannot last like that long.”*

*Key issues for Further 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.



## VI. CONCLUSION

## VI. Conclusion

### **A patient-centric approach is inherently rights-based**

A key lesson that has been learnt in the context of public health in the last few decades has been that the welfare of many is best served by ensuring the wellbeing of the few often most vulnerable to significant health events. Frequently, alarm about health events fuels a response to barricade those who have become unhealthy in order to protect others who are still healthy – pitting the few against the many, while polarizing attitudes and encouraging punitive, rights-limiting policies and practice. It has been argued that larger societal interests of public health are only best served by limiting the fewer who are already afflicted, framing disease control debates as apparently selfish individualist interests against apparently wider public good. The rights-based approach to public health has revealed this to be a false dichotomy. Instead this approach has shown that individual interests and protection of rights are not inimical to societal interests, but complement and advance them: by protecting and empowering those already affected or vulnerable to health setbacks, the system protects larger good. This is because 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. These have been discussed in this LEA – 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, stating that people with TB "*...must not be seen as passive recipients of care. A rights based approach to patient care must be adopted.*" While proposing TB legislation, the NSP emphasizes the need to:

*"...promote TB care as a rights issue and hasten the control of TB in the country. The various clauses of the bill will cover all aspects of TB prevention and care to protect, promote and fulfil the rights of persons with Tuberculosis during delivery of TB care and services and for matters connected therewith or incidental thereto..."*

This vital recognition of rights now needs to be actualized by being a core part of policy, programmes and implementation of the TB response. Health policy and law is being rapidly proposed and launched – for instance recent initiatives such as the March 2018 notification criminalizing non-notification by physicians and druggists, and the June 2018 announcement of making TB (and leprosy) screening mandatory for people below 30 years of age.<sup>564</sup> Whether rights guarantees, such as consent, counseling, confidentiality, non-discrimination, and access to treatment are built in to this effort is unclear, but they should be.

### **Participation of and partnership with people affected**

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, it is those most affected by contexts of marginalization and compromised by health impacts – for instance, people with disabilities, people living with HIV, and people with who have experienced mental health issues – who have been seen to stimulate, guide and enhance policy responses most effectively to address their needs.

As noted in this report, TB law and policy engages with a complex web of issues, made more so by the response being led by the central government through the RNTCP and CTD, while the response to health is often determined by virtue of it a being a state subject in the Seventh Schedule of the Constitution. This makes the ability to implement policy goals and realise health rights and norms in the context of TB a challenge.

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<sup>564</sup> See <https://indianexpress.com/article/india/india-to-start-universal-screening-for-tuberculosis-leprosy-health-minister-j-p-nadda-5213653/>

## Over-arching legal themes

A series of other over-arching issues also need to be seriously considered so that TB elimination is successful, while also provoking reform for larger efforts at wellbeing and advancing the right to health. Some of them are law related, others are policy and planning related. All are inter-connected.

From a legal perspective, for those implementing the TB response there is a multitude of guidance, much of it referring to methodologies which squarely intersect with rights issues, as described in the LEA. Yet, 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 the delivery of health. Issues such as informed consent, privacy and confidentiality, non-discrimination, equity, non-stigmatization, etc. can be best addressed and assured if their contours are ingrained in healthcare workers – physicians, nurses, para-medics etc. – and public health personnel and bureaucrats at the initial stage of developing such a 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 – for example, to cover private sector discrimination, to modernize public health laws, to ensure informed consent and confidentiality, to expand food security, to fortify social security schemes, but such ***law reform and legislative drafting 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 laws that exist.*** For instance, issuing compulsory licences for local manufacture of bedaquiline and delamanid, convincing states to legislate the *Clinical Establishments Act*, and where it exists to invest in ensuring its proper enforcement, and seeing that the Indian Medical Council enforces its regulations robustly and effectively in order to make physicians accountable. Further, for violations to be mitigated and a culture of ethics to permeate the healthcare system and the TB response ***people accessing the health system need to be informed of their rights*** through dissemination of this information and linking it with ***access to legal aid***, in tandem with ensuring that ***localized and innovative grievance redress*** is made available in healthcare settings. Further, investing significantly greater in the public health system so that the work of implementers improves and is supported – for example ***training of healthcare staff and quasi-adjudicating authorities on health law and ethics***, so that violations of legal duties are reduced as a consequence.

## Addressing underlying social determinants of health

The LEA reveals that apart from the section-wise recommendations, there are some 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 the TB response. One such issue, mentioned above 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 improving health systems

These include ***investing in strengthening health systems*** rooted in and starting with primary health, which is the basic need of the vast majority of any population. This includes many things, but in the context of TB it has revealed 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. Indeed, this should be viewed as an investment in public health that will reap benefits beyond only the strengthening of disease-specific programmes such as 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. Although it will take significant and ongoing investment in financial and human resources, 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

While highlighting the key areas of law and policy that are summoned in the TB response, this LEA report also 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***. And, 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 robust, and rigorous consultative process, particularly in engaging and involving people with or survivors of TB to properly assess the impact of existing laws and policies and their deployment on the ground. Indeed, this element could provide immense value to tailoring appropriate law and policy responses. One aspect of this consultative process, in light of the findings of the LEA, can be a national dialogue with multiple stakeholders to provide holistic rights-based inputs to the NSP to strengthen the legal and ethical dimensions of the policies, programmes and schemes to be implemented as part of it.

Finally, with regards to improving the evidence base, the following are only some of the questions that have arisen in the course of preparing this LEA, which would be worth examining in greater detail:

- 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 approaches to ensure 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?

**ANNEXURE – *Specific circumstances, conditions and justifications for isolation and involuntary isolation*** [based on the *WHO Ethics Guidance for the Implementation of the End TB Strategy 2017*]

- i. Isolation should only be employed when a person with TB is contagious and there is a clear public health benefit to the community.
- ii. Isolation should always be voluntary, except in exceptional and narrowly defined circumstances, and it should use the least restrictive means possible; e.g., if basic respiratory isolation measures are sufficient, then physical isolation is not necessary.
- iii. Involuntary isolation should never be a routine component of TB prevention, testing, treatment and care. Involuntary isolation should be limited to exceptional circumstances when an individual:
  - a. Is known to be contagious, refuses effective treatment, and all reasonable measures to ensure adherence have been attempted and proven unsuccessful; OR
  - b. Is known to be contagious, has agreed to ambulatory treatment, but lacks the capacity to institute infection control in the home, and refuses inpatient care; OR
  - c. Is highly likely to be contagious (based on laboratory evidence) but refuses to undergo assessment of his/her infectious status, while every effort is made to work with the patient to establish a treatment plan that meets his or her needs.
- iv. In addition, all of the following conditions must be met in order to justify involuntary isolation:
  - a. Isolation is necessary to prevent the spread of TB; AND
  - b. There is evidence that isolation is likely to be effective in the particular case; AND
  - c. The person with TB refuses to voluntarily remain in isolation or institute adequate infection control measures despite having been properly counseled about the benefits of treatment, the risks of refusing treatment, the meaning of being isolated, and the reasons for isolation; AND
  - d. The person with TB's refusal puts others at risk; AND
  - e. Community-based care has been considered and offered before involuntary isolation is contemplated; AND
  - f. All less restrictive measures have been attempted prior to forcing isolation; AND
  - g. All other rights and freedoms (such as basic civil liberties) besides that of movement are protected; AND

- h. Due process rights are protected and the person with TB has the right to appeal the decision to involuntarily isolate him or her before an administrative, judicial or quasi-judicial body; AND
- i. The person with TB has, at least, his or her basic needs met, including all necessary clinical and social support; AND
- j. The isolation occurs in an appropriate medical setting, never in a prison cell or in a general prison population; AND
- k. The isolation time is the minimum duration necessary to achieve its goals.





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 TB 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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