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Sunitha C Srinivas Sreeprarani Rath
Analytics India Private Ltd.,
Anna Salai, Chennai, India, 600002
Email – sunitha.chandrasekhar@3analytics.com

NATIONAL TUBERCULOSIS ELIMINATION PROGRAM: INDIA'S GOALS AND CHALLENGES

Sunitha C Srinivas[1,4], Gokul Dharani[2], Mahesh PA[3], Seeprarani Rath[1], Raj Vaidya[4], Rohit O Agarwal[1,5], Krishna Kumar[6]

[1] 3 Analytics India Private Limited, Anna Salai, Chennai 600002, India.
[2] 3 Analytics, Cupertino 95014, California, United States of America
[3] Department of Respiratory Medicine, JSS Hospital Mysuru 570015, Karnataka, India
[4] Antimicrobial Resistance Stewardship initiative, Indian Pharmaceutical Association- Community Pharmacy Division, Kalina, Santacruz (East), Mumbai 400 098, India.
[5] Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education and Research, Mysuru 570015, Karnataka, India
[6] Independent Public Health Consultant, Coimbatore 641001, Tamil Nadu, India

Introduction

Tuberculosis (TB), an airborne infection caused by *Mycobacterium tuberculosis,* has remained the leading cause of morbidity and mortality due to a single infectious agent until recently, when the coronavirus outbreak started.[1,2] While TB is preventable and curable, around 25% of the global population is infected with *M. tuberculosis*, of which, 5-10% develop the disease in their lifetime. In 2020, about 10 million people developed TB and 1.4 million died. Owing to the impact of the coronavirus disease (COVID-19) pandemic, TB incidence could increase globally in 2022 and 2023.[2–4] The main aim of the WHO Global Tuberculosis Program has been to build a world free of TB, with zero TB related deaths, disease and/or suffering through universal access to people-centered prevention and care, multisectoral action and innovation. Although the success of the *End TB Strategy* depends on adaptation for diverse country settings, WHO's post-2015 *End TB Strategy* serves as a blueprint for countries to reduce TB incidence by 80%, TB deaths by 90%, and to eliminate catastrophic costs for TB-affected households by 2030.[5]

Although anyone can get infected with TB, some people are at greater risk of TB than others because some population groups have higher rates of TB disease in their communities, thus raising the risk of becoming infected with the bacteria. Additionally, a range of social, economic, and demographic factors affect a person's risk to contract TB. The probability of developing TB is much higher among people living with HIV, and among people affected by risk factors such as undernutrition, diabetes, smoking and alcohol consumption. TB can affect anyone anywhere, but 90% of the total cases are adults and there are more cases among men than women. Persons with latent TB do not show any symptoms of the disease and are not infectious even though they are infected with the TB bacteria. However, about 5 to 10% of infected persons who do not receive treatment for latent TB infection eventually develop TB disease at some time in their lives.[6]

This article highlights the situation of TB in India and how the National TB program has evolved, while providing a snapshot of the current strategic focal points under the National TB Elimination Program. Additionally, the

current digitalization of the program is highlighted to show the advantages it offers in health system strengthening. The article culminates by highlighting the importance of how community engagement and community champions can contribute to the intended elimination because it addresses a crucial missing element. The role of pharmacy practice professionals is highlighted in enhancing TB prevention and in supporting those who are treated, to complete their therapy successfully, so that pathways are created in achieving the intended National TB Elimination in India.

Situation of TB in India

India accounts for over 25% of the global TB notifications and has the highest TB burden with 188 cases of TB per 100,000 population reported in the year 2020. Among them, 2% cases occurred in HIV-positive patients with a mortality rate of 20.5% while the mortality rate for the HIV-negative TB patients was 19.5%. India accounted for 38% of global TB deaths among HIV-negative people, and for 34% of the combined total number of TB deaths in HIV-negative and HIV-positive people. There is considerable national variation in the TB mortality rate and the case fatality rate (CFR).[3,7] A significant variation in TB mortality rates was observed between all Indian states from 2000 through 2019. The number of deaths per 100,000 individuals was noticeably higher and concentrated majorly in six out of the 28 Indian states, warranting special attention to these areas.[8] It is estimated that about 40% of the Indian population is infected with TB bacteria, a vast majority of whom have latent TB. In 2021, the state of Uttar Pradesh saw the highest number of TB notifications (453,712), followed by Maharashtra with 199,976 notifications. The north-eastern state, Sikkim, had the lowest number of TB notifications (1373) within the states, whereas amongst union territories Lakshadweep, had the lowest notifications with 12 cases.[9]

The role of gender in the diagnosis and treatment of pulmonary TB is highlighted by the higher rates of transmission and reactivation of the disease and poorer treatment outcomes among men.[10] Tuberculosis disproportionately affects men and boys resulting in men having a higher prevalence of TB and, in many settings, remain infectious in the community for a longer period than women. Therefore, men are likely to generate a greater number of secondary infections than women, and social mixing patterns have suggested that, as a result, men are responsible for the majority of infections in men, women, and children. Addressing men's burden of disease and disadvantage in seeking TB care is therefore an issue not only for men's health but for broader TB prevention and care.[11,12] Additionally, the risk factors are also higher among men. In those above 15 years, 22% men smoke, in comparison to 1.4% female. Among those 18 years and above, 9.1% males are diabetic when compared to 8.3% females. Additionally, among those 15 years and above, 9.1% males have alcohol use disorders, while only 0.5% females also do.[3] Hence, smoking, alcohol abuse and diabetes as higher prevalence of risk factors in men, could also be contributing factors to their predisposition to TB.[13] One of the risk factors higher in females is due to indoor air pollution from cookstoves.[14]

TB control faces daunting challenges in India. Decades of unrestrained transmission has left hundreds of millions of Indians with latent TB infection, which may reactivate at any time. A significant proportion of the population is undernourished, which weakens immunity and drives TB reactivation. Tens of millions with previous, inadequately treated TB may recur at any time. The dense, growing urban environment facilitates the transmission of the disease cutting across all economic strata.

People with active infection spread the disease to their family and community, perpetuating the age-old cycle of transmission and risk. Despite these odds, evidence demonstrates that TB can be controlled in the modern era, if TB is diagnosed early, treated adequately and transmission is thus interrupted. The overwhelming challenge facing TB control in India remains delayed diagnosis and inadequate treatment, particularly among patients seeking care from private providers, who are ill-equipped to sustain their patients on prolonged, costly treatment. Patients seeking care in the public sector have a better chance of treatment but still 1/3rd are lost between care-seeking and successful cure. India also has a large burden of multi-drug resistant (MDR-)TB and extensively drug resistant (XDR-)TB, most of whom are undetected and continue to transmit disease; even those who are detected endure prolonged, toxic and costly treatments only to have poor odds of treatment success, along with a high loss to follow up.[15]

In India, our lack of adequate systematic reviews on the quality of TB care remains largely unaddressed. While addressing suboptimal quality of TB care, particularly in the private sector,[16] one way of improving the quality of care of TB patients is to start creating pathways to incorporate pharmacy practice personnel in TB programs in the public and private sectors. The yet to be effectively used pharmacy practice personnel can contribute immensely in addressing the gaps in the National Tuberculosis Elimination Program (NTEP), by becoming the bridge between the clinicians and patients.[17] It is to be noted that the lack of pharmacy-specific global guidelines and the regulatory environment have remained inadequately addressed topics.[18]

Timelines of India's TB program

Although six decades have passed since the Government of India launched the National TB Program (NTP) in 1962, TB still poses a major public health challenge that needs to be overcome. This was launched in the form of the District TB Centre model which involved BCG vaccination and TB treatment. In 1978, BCG vaccination was shifted under the Expanded Program on Immunisation.[19]

A joint review of NTP by Government of India, World Health Organization (WHO) and the Swedish International Development Agency (SIDA) in 1992, highlighted some programmatic shortcomings such as managerial weaknesses, inadequate funding, over-reliance on X-ray, non-standard treatment regimens, low rates of treatment completion, and lack of systematic information on treatment outcomes. Thereafter, the national strategy was revised based on these findings, to work towards the goals of 85% cure rate through administration of short-course (6-8 months) chemotherapy and to detect 70% of estimated cases.[15,19–21]

In 1993, the WHO declared TB as a global emergency, devised the directly observed treatment – short course (DOTS), and recommended it to be followed by all countries.[22] The Government of India revitalized NTP as Revised National TB Control Program (RNTCP) in the same year. The RNTCP, based on the internationally recommended DOTS strategy, was launched in 1997, and expanded across the country in a phased manner with support from World Bank and other development partners. Full nation-wide coverage was achieved in March 2006.[19] In terms of treatment of patients, RNTCP has been recognized as the largest and the fastest expanding TB control program in the world. Under the program, diagnosis and treatment facilities were provided free of cost to all TB patients. For quality diagnosis, designated

microscopy centers were established for every one lakh population in the general areas and for every 50,000 population in the tribal, hilly and difficult areas. During this period, more than 13000 microscopy centers were established in the country. DOTS centers have been established near the residences of patients to the extent possible, to provide free treatment. All public health facilities, sub-centres, Community Volunteers, ASHA, Women Self Groups etc. also were initiated to function as DOTS Providers/DOTS Centers.[23]

During 2006–11, in its second phase, RNTCP improved the quality and reach of services. Despite some achievements, undiagnosed and mistreated cases continued to drive the TB epidemic. TB was the leading cause of illness and death among persons living with HIV/AIDS and a large number of multidrug resistant TB (MDR-TB) cases were reported every year. During this period, to achieve the long-term vision of a *TB free India*, the National Strategic Plan (NSP) for Tuberculosis Control 2012-2017 was formulated with the goal of 'universal access to quality TB diagnosis and treatment for all TB patients in the community'. Significant interventions and initiatives were undertaken during NSP 2012-2017, in terms of mandatory notification of all TB cases, integration of the programme with the general health services (National Health Mission), expansion of diagnostics services, programmatic management of drug resistant TB (PMDT) service expansion, single window service for TB-HIV cases, national drug resistance surveillance and revision of partnership guidelines. Rapid communication remains important to inform NTPs and other stakeholders about the key implications for the treatment of DR-TB, to allow for rapid transition and planning at country level.[2,24]

Currently, the National Strategic Plan for Tuberculosis Elimination 2017-2025 guides the efforts to eliminate TB in India by 2025, five years ahead of the global target. This Plan provides the direction for the NTEP, to achieve TB-free India. This program is strengthening four strategic pillars 'Detect–Treat–Prevent–Build' (DTPB).[15] Although the "E" in NTEP stands for '*elimination*', we have a long path to tread to achieve this goal because many Indian states such as Uttar Pradesh, Gujarat, Odisha, Chhattisgarh, Rajasthan and Uttarakhand still experience more than 40 deaths per 100,000 individuals.[8]

Noticeably, a nationwide TB survey was never repeated after 1956. Hence, to closely monitor the progress towards TB control with the aim to '*End TB*' as per Sustainable Development Goals (SDGs), the National TB Prevalence survey in India was conducted from 2019 to 2021. One of the salient aspects of concern identified in the survey was that 64% of the symptomatic population did not seek health care services. The survey also identified the reasons as: ignoring the symptoms (68%), not recognizing the symptoms as TB (18%), self-treatment (12%) and unaffordability to seek care (2%).[25] Additionally, some of the crucial challenges identified with NTEP are: continued lack of awareness regarding airborne infections like tuberculosis (TB) and its prevention; prevalence of stigma leading to presumptive patients not seeking treatment; and need for tracking the missing cases. Also, it is evident that communication strategies are not responsive to the needs of the communities and patients. Additionally, lack of coordination between various urban sectors to address unique urban issues such as migration, access to care, familiarization with public health facilities, social safety net for patients, among others, continue to remain. Furthermore, inadequate capacities of community-level functionaries and structures to generate awareness and mobilize utilization of services, affect the program. Meager understanding of the effectiveness of active case finding;

inadequate mapping of vulnerabilities to reach "missing" cases, continues. Hence, evidence demonstrates the need for additional capacities for decentralized management of patients, especially the side effects. The need to implement airborne infection control measures, especially in health care facilities and common congregating work, educational, religious and social spaces have been identified as crucial. Evidence shows that there are delays in payment of financial support to patients for supplementing nutrition, which are intended to ensure adherence needs attention. Additionally, the need for focus on quality of care of TB patients by private providers, including ensuring management of co-morbidities and use of standardized treatment guidelines, have been highlighted as crucial. A special aspect that has been recommended is the focus on reaching the migrants adequately.[26]

Although India has managed to scale up basic TB services in the public health system, treating more than 10 million TB patients under RNTCP, the rate of decline is too slow to meet the 2030 Sustainable Development Goals (SDG) and 2035 *End TB* targets. Although sufficient insight and expertise exists to inform TB program decision-making, these resources have often been underutilized in terms of meeting the needs of policy makers for quantitative analysis and improvements in TB control policy and implementation. Continuation of prior efforts have yielded inadequate declines and will not accelerate the progress towards ending TB. Hence, new, comprehensively-deployed interventions are required to hasten the rate of decline of incidence of TB many fold, to more than 10-15% annually.[15]

An order issued by the Government of India in May 2012 mandates all health-care providers to notify every TB case diagnosed and/or treated to local authorities. RNTCP also rolled out an innovative and visionary electronic recording and reporting system - Nikshay, across the country in 2012, with 98% of reporting units sending in case-based reporting of TB patients, including notifications from private providers. Innovative approaches, including interface agencies and e-voucher systems for free medicines, have been successfully deployed as pilots to engage more private providers and improve quality of care. Modern media are being creatively used for TB control.[15]

Health care system strengthening to ensure prophylactic treatment for patients on antiretroviral treatment (ART) and children below 6 years of age, and contact screening are recommended as important. Proactive outreach to ensure migrants as part of a responsive strategy has been identified as crucial. Reaching the unreached and ensuring prevention of TB remains a cornerstone, are strategic ways to address an elimination program.[27]

TB and COVID-19

Highly complex interactions between TB and COVID-19 exist, where either TB transmission might rise because of increased respiratory symptoms associated with COVID-19, or result in decline owing to COVID-19-related self-isolation, quarantine and regular use of masks, is also a possibility. The health system infrastructure, from diagnostic tools to the workforce, has been diverted towards COVID-19 and away from other illnesses such as TB. This along with transport disruptions, restricted movement, reduced opening hours of health facilities, depleted staffing levels, fear, and stigma have resulted in constrained access to healthcare. These drivers have led to late, disseminated presentations of TB, associated with adverse treatment outcomes and death. TB

mortality was more severely impacted by the COVID-19 pandemic in 2020 than HIV/AIDS. The top nine high TB burden countries that contribute to 60% of the global cases saw a 23% decrease in diagnosis and treatment of TB, resulting in approximately 1 million missed cases. Furthermore, it is anticipated that the pandemic will contribute to a 20% increase in TB deaths globally over the next 5 years. Therefore, it is recommended that the knowledge gained thus far about COVID-19 be used to integrate it with TB strategies for prevention, case-detection, and care of these diseases along with other illnesses.[12,28–32]

Digitalization in TB patient management and care

Based on the context and feasibility, lessons from other programs that digitalised aspects of the TB program, can be adopted in the Indian context. PredictTB, a 66-month project financed by a variety of international funders and implemented worldwide, was initiated to shorten the treatment times of tuberculosis (TB) in drug-sensitive patients through individualized therapy.[33] Medication Event Reminder-Monitor (MERM), is an ongoing sub-study of PredicTB that aims to aid patient treatment adherence by giving each participant a MERM box, a device with an alarm that is linked to the participants' pills and reminds them to take their medication on time.[34]

99DOTS is a low-cost approach for monitoring and improving TB medication adherence by wrapping each anti-TB blister pack in a custom envelope, which includes hidden phone numbers that are visible only when doses are dispensed. After taking daily medication, patients make a free call to the hidden phone number, yielding high confidence that the dose was "in-hand" and has been possibly taken.[35]

Nikshay, an integrated information and communications technology (ICT) system was launched in June 2012 by the Government of India. It enables the grassroots-level healthcare providers to track every TB patient at the TB Unit level.[36] Such a TB patient database is being used at the district, state, and national levels for monitoring purposes. Following various improvements since then, Nikshay Version 2 was launched in September 2018. It provides a unified interface for public and private sector health care providers with different types of login options for all stakeholders. It integrates all adherence technologies such as 99DOTS and MERM and contains unified Drug Sensitive TB (DSTB) and Drug Resistant TB (DRTB) data entry forms. It has a mobile friendly website with a mobile app.[36]

Whenever a new patient is registered on Nikshay, an SMS is sent to the patient with registration ID and details of the DOTS Operator along with an advisory note to take the regular medicine. Daily short messaging service or text messages are sent to all monitoring authorities in the Central TB Division, to state TB Officers, and to district TB officers, giving the number of patients and peripheral health institutions registered. The Health Management Information System of NHM currently captures one element of TB, which is the number of patients on DOTS.[36]

Catastrophic costs from TB

Pharmacy practice professionals have a key role to play in the NTEP so that among several key performance indicators of the program that they can influence positively, one of them is in reducing the Household Out-of-pocket Expenditure (OOPE) of TB patients, by focusing on pharmaceutical care principles and following through adherence to treatment of TB patients. According to the World Health Organization's Global Health Expenditure database, healthcare spending in India for 2019 was 3.01% of its GDP. While about 33% of this

was Government Health Expenditure (GHE), a larger share of healthcare expenditure, approximately 55%, was OOPE.[37] This OOPE leads to impoverishment of households and may turn catastrophic (more than 20% of their family income) impacting adherence and leading to poor treatment outcomes.[38] One of the three main targets of the *End TB Strategy* (2016-2035) is that no TB-affected household suffers catastrophic costs due to TB.[39] According to the available estimates 17.3% of the population in India face catastrophic health expenditures and about 55 million people are pushed into poverty due to healthcare expenditures.[40]

Despite free diagnostic and treatment services provided, the patient cost of tuberculosis care is high. A study estimated that the mean direct cost was 45.5% of the total cost. Catastrophic cost (total cost ≥ 20% of the total annual household income) was experienced by 7% to 32.4% of drug-sensitive TB patients and by 68% of drug-resistant TB patients.[41] Indian patients incur substantial direct costs (mean: INR 3,694), while mean indirect costs (INR 52,612) constitute 93.4% of the net costs. Direct costs include OOPE for travel related to medical care, consultation fees, expenditure on TB medicines, fees for diagnostic tests, inpatient hospital bills, and food supplements. Indirect costs refer to lost wages for the TB patients and their caregivers and include costs incurred due to decreased ability to perform daily chores. Mean direct costs before diagnosis can be up to four-fold that of costs during treatment. Treatment in the private sector can result in costs up to six-fold higher than in government facilities. As many as one in three TB patients in India experience catastrophic costs.[42]

While 7% of TB patients registered under RNTCP in Delhi experienced catastrophic expenditure,[39] a mixed methods study from Puducherry, India reported that more than a third incurred catastrophic costs towards TB care and the incidences were significantly higher in patients with multidrug-resistant TB, HIV coinfection and hospitalization.[38] Risk protection mechanisms such as additional financial protection and health insurance schemes and other social protection interventions for patients with TB have been suggested to overcome this issue.

Appropriate policies need to be implemented to decrease direct and indirect TB patient costs to prevent poverty due to TB treatment and care.[43] Priority interventions to realize India's goal of eliminating catastrophic costs from TB include decreasing diagnostic delays through active case finding, reducing the need for travel, improving awareness and perception of NTEP services, and ensuring sufficient reimbursement for inpatient TB care.[42] Hence, in order to measure the country's progress in achieving zero catastrophic costs, it is recommended that monitoring and evaluation of the cost is included into the programme.[41]

TB elimination will require an optimal mix of enhanced biomedical and social interventions. Evidence highlights that TB elimination strategy in India needs a pro-poor model of patient - centered care inclusive of nutritional, psycho-social and financial support, universal health coverage, and social protection; and convergence with multi-sectoral efforts to address poverty, undernutrition, unsafe housing, and indoor pollution.[27,41,44–46]

Additionally, mobilization of funding for research for the development of improved diagnostic techniques, vaccines, novel therapeutics, equitable access to healthcare, and innovative social protection interventions for TB affected households, are crucial. It is imperative to drastically increase and sustain investment in health systems that cater to the needs of the poor and are able to withstand the threat of air-borne infections that require

isolation facilities.[47] Efficient management of the predictors of catastrophic costs by the global health system will subsequently improve the community, clinical, and financial outcomes and help achieve the goal of zero catastrophic costs for TB by 2030.[48]

Community engagement and community champions

In order to achieve the national TB elimination goals, it is imperative to engage diverse stakeholders and establish intersectoral coordination.[49] Civil society organizations (CSOs) include non-profit bodies such as nongovernmental, faith-based, community-based and patient-based organizations as well as professional associations. The reach and spread of CSOs, their understanding of the local context and ability to engage marginalized or remote groups that cannot be easily reached by national programmes have the potential to facilitate prevention, early detection, treatment and control of TB.[50,51] Collaboration between CSOs and local and national governments could greatly enhance development outcomes[51] and there is sufficient scope for these outreach activities to be initiated by pharmacy practice personnel.

India's National Strategic Plan has outlined a wide range of community-based TB activities to improve identification of people with symptoms, to support adherence to treatment, and to strengthen grievance redressal mechanisms that positively influence the outcomes of the disease.[52,53] Community mobilization to promote effective communication and participation among community members for TB prevention, diagnosis, treatment and care services is vital. These activities are usually carried out in community-based structures and homesteads outside the premises of formal health facilities. Integration of community-based TB activities with other community-based healthcare activities is necessary to improve synergy and impact.[53]

Community health workers are individuals possessing formal education who are trained to contribute to community-based health services.[54] Whereas community members who have been systematically sensitized about TB prevention and care, through training schemes or regular contact sessions with professional health workers are called community volunteers. They engage primarily within the homes and community structures and help in linking community-based activities with facility-based services.[54] TB champions are those who have effectively completed their TB treatment and recovered completely, who then volunteer to support newly diagnosed TB patients to support their treatment completion. Pharmacy practice professionals can play a key role in capacity building of TB champions as one of the ways to contribute to the NTEP.

Through the TB Call to Action project, REACH and USAID engaged TB survivors through capacity-building interventions to actively support India's TB response by providing emotional support to people with TB, sensitizing communities, and working towards reducing the stigma.[52] *From TB Survivors to TB Champions* is an important strategy to engage with TB affected communities. It is a training curriculum, developed with inputs from several key stakeholders to train TB survivors to become effective advocates.[55] In 2020, more than 30,000 people received screening, counselling, and awareness from the TB Champions working with the USAID-supported ALLIES project.[56] Since a *one-size-fits-all* approach is not always appropriate, it is necessary to devise patient-centric solutions that involve innovations such as social enterprise and telemedicine, tailored to a region's specific situation, driven by community champions.[57]

Challenges Tailored to TB in India

TB is estimated to claim more than 480,000 Indian lives every year in India. Additionally, India is believed to have over a million "missing" cases each year that are not reported. Most of these "missing" cases either go undiagnosed or are inaccurately and illegally being diagnosed and treated in the private sector.[58] NTEP's goal of reducing India's TB prevalence down from its baseline of 217 per 100,000 people was hampered by the ongoing COVID-19 pandemic. Furthermore, the prevalence-to-notification ratio in India was 2.84 indicating that merely 35.21% of the TB cases were reported to the national monitoring system. The remaining 64.79% cases were "missed".[25,59] Pharmacy practice professionals have an enhanced scope of practice in supporting NTEP and working with TB patients to monitor their adherence and pharmacovigilance, among other aspects.

However, the number of cases vary across various classes of population in the country, including the tribal community, one of the most severely affected groups. Due to lack of data from the tribal communities available while formulating National Tuberculosis Elimination Program's (NTEP) policies and methods, implementation of such programs becomes tedious, particularly in tribal regions where each community has their own approach to deal with health concerns.[60] Health beliefs of people affected with TB is one of the key aspects that influences their health seeking behavior and continued adherence until they are cured. Pharmacy practice professionals with focused training in health seeking behavior can influence these outcomes with community outreach programs focused on schools or women-centered projects.

Conclusion

Based on tracing the challenges and goals of India's National TB Elimination program, it is evident that India has to adopt multisectoral responses to address the complex and layered nuances. From active case finding to managing TB comorbidities, India has set the course to find innovative ways to achieve the expected results by 2025. Engaging with the private sector and enhancing the ICT tools to monitor adherence and well-being of TB patients calls for focused action in enhancing community engagement, is a crucial aspect where pharmacy practice professionals have a major role. Patient-centric care that reduces their OOPE needs to be prioritized by pharmacy practice professionals by ensuring that the various gaps between patient diagnosis to treatment completion are followed through, by digitalization. Addressing workplace prevention and care of TB patients supported by innovative funding from corporate social responsibility approaches could also pave the path in addressing challenges. Strategies that support health system strengthening and managing drug resistant TB are urgently required in India.[61] Additionally, it is necessary to draw inspiration and learn from experiences of other elimination and eradication programmes whilst formulating and revising policies for the ambitious TB elimination program in the context of managing the COVID pandemic.

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