Tuberculosis, COVID-19, and the End Tuberculosis strategy in India

The COVID-19 pandemic caused by the novel corona virus, Severe Acute Respiratory Syndrome corona virus 2 (SARS-CoV-2), has affected 188 countries of the world with 10,450,628 reported cases and 510,632 deaths as of July 1, 2020, and the same figure for India, which has the 4th highest number of cases, are 568,092 and 17,400, respectively.^[1] Many countries and societies are impacted by the disease in an unprecedented scale. Many countries implemented lockdowns and quarantines to curtail the spread of the virus, and a large number of global populations are still under these restrictions. These restrictive measures, such as physical distancing, and restrictions on gatherings, and travel, have led to many adverse impacts on societies, economies, and health-care delivery systems. All countries of the world are struggling to maintain their health care systems to cope under such extraordinary conditions.

In addition to affecting medical care of various diseases, whether therapeutic or preventive, COVID-19 has bad prognosis if associated with certain disease conditions such as cardiovascular disease, chronic respiratory diseases (COPD and bronchial asthma), diabetes mellitus, hypertension, chronic kidney diseases, and cancer. However, the association and effect of COVID-19 vis-a-vis tuberculosis (TB) on each other is not clearly understood and experience on COVID-19 in TB patients is limited. There are many similarities and differences between the two diseases. Some limited and preliminary observations suggest that TB infection is likely to increases susceptibility to SARS-CoV-2, and increases COVID-19 severity, but this requires validation in larger studies.^[2,3] If it is so it will have a major impact in India as one third of its population is infected with TB. There are striking similarities between the two. Both cause major infection-related morbidity and mortality. While COVID-19 had caused over 0.5 million deaths so far over a period of 6 months, TB was the leading cause of mortality from an infectious disease worldwide in 2018, causing 1.2 million deaths.^[4] The number of new cases of TB globally was nearly 10 million but COVID-19 cases have already crossed that figure within 6 months of its origin. In India, COVID-19 mortality is above 17,000 over a period of 3 months out of the over 5.6 lakh infections over this period. On the other hand, in India in 2019, 24.1 lakh TB cases were reported and there was a mortality of nearly 79,000 in that year.^[5] The other similarities are that both COVID-19 and TB present with respiratory symptoms with small differences. Diagnosis and treatment of TB, or TB and COVID-19 co-infection, are likely to be compromised during the COVID-19 pandemic. Older age and associated co-morbidities are at increased risk of severe disease and adverse outcomes in both diseases. Both diseases have considerable social impact such as stigma, discrimination, and isolation in addition to the economic impact because of loss of productivity and catastrophic costs to individuals and households. There are some important differences between the two also. While TB is a slow pandemic and has affected mankind for over 7000 years the coronavirus (SARS-CoV-2) causing COVID-19 is just new and has occurred only recently with rapid spread worldwide causing a pandemic. TB has been labeled as a pandemic many times over the past three centuries, whereas this is the first COVID-19 pandemic. Children are often less severely affected by COVID-19, whereas 1.1 million children had TB disease in 2018, of whom 200,000 died^[4] and in India about 342,000 incident cases of pediatric TB are estimated to occur every year accounting for 31% of the global burden and 13% of the overall TB burden in the country.^[5] The association between poverty and COVID-19 is unclear. TB will be associated with the poverty, in which poorer people have a higher likelihood of infection, disease, and adverse outcomes. Moreover, unemployed populations including contract workers will experience increases risk of TB. While most of the cases and deaths from TB occur in low- and middle-income countries (LMICs), COVID-19 occurred more in the developed countries following China and most deaths occurred in the USA.^[1] COVID-19 has mobilized more global and human resources in a few months than TB has in decades. However, the number of COVID-19 cases and mortality might increase in future as now India is the fourth highest number country in the world with Brazil having the second highest number. ^[1] Even with these similarities and dissimilarities, there are many unknown relationships. The clinical and epidemiological interactions of COVID-19 with TB (with or without HIV) will be highly complex. The transmission of TB might rise because of increased respiratory symptoms associated with COVID-19, or it may even decline due to COVID-19-related self-isolation, use of masks and quarantine. Millions of people treated for TB that have residual, long-term lung damage who are likely to be at a higher risk of severe disease and death from COVID-19. Because of extreme pressures on health systems, exacerbated by COVID-19, people with TB are likely to face decreased access to diagnostic and treatment services, which might also result in adverse outcomes.^[6] Both TB and COVID-19 spread by close contact between people, although the exact mode of transmission differs, explaining some differences in infection control measures to mitigate the two conditions. TB bacilli remain suspended in the air in droplet nuclei for several hours after a TB patient coughs, sneezes, shouts, or sings, and people who inhale them; the size of these droplet nuclei is a key factor determining their infectiousness. Their concentration decreases with ventilation and exposure to direct sunlight. On the other hand, COVID-19 transmission has primarily been attributed to the direct breathing of droplets expelled by someone with the disease (people may be infectious before clinical features become apparent). Droplets produced by coughing, sneezing, exhaling and speaking may land on objects and surfaces, and contacts can get infected with covid-19 by touching them and then touching their eyes, nose or mouth. Handwashing is thus important in the control of COVID-19. Hospital procedures that generate aerosols predispose to infection of both conditions and should only be conducted within recommended safeguards. While the reproduction number (R_0) is 2.2 for COVID-19; the same for TB is (R_0) higher for TB like it was 4.3 in China (2012); and 3.55 in Southern India (2004-2006).^[7]

Although clinical course and outcome of COVID-19 is well reported from different parts of the world,[8-19] including commentaries, perspectives and reviews, information is scanty about the clinical course of such co-infections. Global and national experience with concomitant TB and COVID-19 is extremely limited. Mycobacterium tuberculosis was not detected in a recent analysis of 1217 consecutive respiratory specimens collected from COVID-19 patients.^[20] It is possible that synergistic co-infection of viral respiratory infections and TB will impede the host's immune responses; and therefore, their harmful synergism may contribute to more severe clinical evolution although COVID-19 pandemic is likely to affect TB in many ways in many countries. One recent study of 49 cases claimed to be the first-ever global cohort of current or former TB patients (post-TB treatment sequel) with COVID-19, was recruited by the Global Tuberculosis Network (GTN) from 8 countries and 3 continents.[21] Analysis on the outcome was not done. Most patients (53.0%) had TB before COVID-19, 28.5% had COVID-19 first and 18.3% had both diseases diagnosed within the same week. Forty-two (85.7%) patients had active TB with a median age of 45.5 years (28.0-63.0) and 7 (14.3%) had post-TB treatment sequel; the patients with TB sequel were cured 8.2 (2.7-44.3) years earlier. Overall, 26/49 (53.1%) patients were migrants, 15/48 (31.3%) unemployed, and 2/48 (4.1%) health-care workers (medical doctor and radiology technician). Forty-six (93.9%) patients had confirmed SARS-CoV-2 infection and 3 other patients (6.1%) had chest high resolution computerized tomography (HRCT) highly suggestive of COVID-19 related pneumonia (bilateral ground glass opacities). Forty-eight patients had pulmonary TB (one caused by Mycobacterium bovis). From this preliminary analysis the authors concluded that in about 40% of cases COVID-19 appeared during anti-TB treatment and limited or no protection against COVID-19 might have favored SARS-CoV-2 infection (which affected two health-care workers); since diagnosis of TB and COVID-19 was done simultaneously or within 7 days in some patients, differential diagnosis challenges will be there, which suggested that clinical assessments to investigate COVID-19 (e.g., clinical picture and HRCT) facilitated the identification of (a probably preexisting) TB. Any contribution of COVID-19 to TB pathogenesis cannot be excluded or confirmed. Although the diagnosis of COVID-19 preceded that of TB in 14 patients, larger studies are needed to understand any role played by SARS-CoV-2 in the progression of TB infection to disease. Given that up to a quarter of the population in some regions of the work is latently infected, SARS-CoV-2 infection might boost the development of active TB in the coming months. As individuals with latent TB infection followed up over time were not included in the study, it was not possible to report on the potential contribution of COVID-19 toward the development of active disease. Probably, an overlap of signs/symptoms of COVID-19 and TB occurred and COVID-19 was diagnosed earlier because of a higher index of suspicion while TB may have been there since before. Or, differently, COVID brought to clinical valuation/diagnostic assessment TB patients at an earlier stage of disease before the occurrence of TB-related symptoms. In some cases, COVID-19 occurred in patients with TB sequelae. They were older than patients under anti-TB treatment and presented higher (although not statistically significant) mortality. The presence of comorbidities was present in these cases (4 Chronic Obstructive Pulmonary Disease; 1 HIV co-infection plus liver and kidney diseases, hypertension, and cancer present in different combinations). Studies with larger numbers are necessary to further understand the role played by TB sequel. The impact on the health-care system (e.g., days of admission and intensive care unit beds) was relevant in this study. The information on BCG (Bacillus Calmette-Guérin) vaccination was modest (30 patients with information, 19 previously vaccinated in all 8 countries) and no significant elements can be provided to the ongoing debate on its protective role. At present, there was no data on drug-drug interactions.^[21] Another study data from 49 consecutive cases in 8 countries and 20 hospitalized patients with TB and COVID-19 showed that 8 out of 69 (11.6%) patients died. Most of them were young migrants. It was noted that mortality was more in elderly patients with comorbidities; TB was not a major determinant of mortality and migrants had lower mortality due to younger age and lower number of comorbidities. However, the authors postulated that in settings where advanced forms of TB frequently occur and are caused by drug-resistant (DR) strains of M. tuberculosis, higher mortality rates can be expected in young individuals.^[22] Another small series of 20 TB patients^[23] diagnosed with COVID-19 co-infection from North Italy, 12 (60%) were males and the median age was 39 (27-47) years: Foreign-born (85%) individuals were

younger than Italian nationals. Overall, 50% of patients had a body mass index BMI <18.5 kg/m² at admission and eight had comorbidities but none had HIV co-infection. Three patients reported having been vaccinated with Bacillus Calmette–Guérin (BCG).

Even if there is scarcity of data about the interaction and coexistence of both the diseases, one can draw conclusions or may expect similar outcomes from experience gained from other viral diseases occurring in the pat and their impact on TB. Recently, the issue was examined by Crisan-Dabija et al.^[24] and the on the effect of the three human coronaviruses known to cause fatal respiratory diseases like the SARS-CoV (now known as SARS-CoV-1) that led to a global epidemic in 2002; the middle-east respiratory syndrome CoV which was discovered in 2012 and still affects people from 27 countries, and most recently, the novel CoV (SARS-CoV-2) and the influenza pandemic of 1918–1919. The authors noted that these epidemics have a negative impact on TB patients; transmission prevention was crucial for containing the epidemics and in order to decrease the opportunity of SARS-CoV-2 spreading amongst TB cases, hospital treatment for TB patients should be limited to severe cases. Immunopathogenesis of these viral illnesses also will affect course of TB;^[24] diagnostic confusions. Similar observations are also made by the A consensus by the World Association for Infectious Diseases and Immunological Disorders (WAidid), GTN and members of ESCMID Study Group for Mycobacterial Infections (ESGMYC)^[19] and others.^[25] Similarly, Ebola virus disease in 2013–2015 in Liberia, West Africa had major negative effects in the form of significant decreases in diagnoses of smear-positive pulmonary TB, the declines in HIV testing and antiretroviral therapy (ART) uptake and poor treatment success.^[26]

COVID-19 had upset the major public health care system throughout the world. Prevention and treatment services for noncommunicable diseases (NCDs) are affected severely since the pandemic began. According to a WHO completed by 155 countries during a 3-week period in May, confirmed that the impact is global, but that low-income countries are most affected. There have been partial or complete disrupted in many countries. More than half (53%) of the countries surveyed have partially or completely disrupted services for hypertension treatment; 49% for treatment for diabetes and diabetes-related complications; 42% for cancer treatment: and 31% for cardiovascular emergencies. Rehabilitation services have been disrupted in almost two-thirds (63%) of countries, even though rehabilitation is key to a healthy recovery following severe illness from COVID-19. In almost, all (94%) health staff working in the area of NCDs are reassigned and diverted to support COVID-19. The postponement of public screening programs (cancer) was also widespread, in more than 50% of countries. The most common reasons for discontinuing or reducing services were cancellations of planned treatments, a decrease in public transport available and a lack of staff because health workers had been reassigned to support COVID19 services. One of the main reasons for discontinuing services was a shortage of medicines, diagnostics, and other technologies in about 20% of countries. Many countries had devised alternative strategies for continuing care which may or may not be the ideal.^[27,28]

TB is the world's biggest killer among infectious diseases, taking away more than 4000 lives each day. Interaction of TB and COVID-19 is a matter of great debate-how one influences the other. There are many similarities and some differences between the two as discussed earlier.

As the COVID-19 pandemic has overtaken many other health issues, there are numerous ways in which this will impact existing and well-performing public health programs.^[27,29-32] In the same way, the COVID-19 will interact and interfere with TB control programs, and it is important as TB is still the leading cause of death due to a single infectious disease globally. There is likely to be grave consequences for the existing and yet to be diagnosed TB patients, more so in LMICs where TB is endemic and health services are not well equipped. TB control programs will be under severe strain due to diversion of resources, loss of focus with increased attention of COVID-19 care, constraints due to overutilization of laboratories meant for TB work, issues related to availability of TB care workers, restriction of movements of patients and contacts etc., with DR-TB centers being diverted for COVID related work because of change in the priorities of health-care delivery. This is going to lead to a reduction in quality of TB care and poor outcomes.

This is an enormous challenge for the governments and societies for ensuring that the pandemic has the least possible impact on key health programs that will need continued close monitoring. According to a report released in June 2020, there has been a significant decline in the claims made under the Ayush Bharat - Pradhan Mantri Jan Arogya Yojana during the lockdown period in India. There was a steep decline of 64% (as compared to 2 weeks earlier) in the claims made under the health scheme in the 1st week since the lockdown was announced. The report confirms the concerns about reduced access to healthcare due to the sudden imposition of the nationwide lockdown to contain the COVID-19 pandemic.^[33]

India reported 2.87 million cases in 2019 accounting for 27% of the total burden according to the Annual report 2020 of the Central TB Division.^[5] Revised National Tuberculosis Control Program (RNTCP) of India is the largest public health program in the world to contain the TB problem in the country. India has declared and had an ambitious goal of Ending TB by 2025, 5 years ahead of the Global target. The strategy aimed to end the TB epidemic, with targets to reduce TB deaths by 95% and to cut new cases by 90% compared to that was in 2015; and to ensure that no family is burdened with catastrophic expenses due to TB.^[34] To achieve these goals, the RNTCP, India,

developed the National Strategic Plan (NSP) 2017–2025 to achieve these goals. Since there are many challenges and issues involved to achieve these goals and to put thrust on such strategies, in January 2020 RNTCP, was renamed as the RNTCP as the National Tuberculosis Elimination Program (NTEP). A revised draft NSP 2020–2025 is under preparation to enhance these activities so that the goals could be achieved by the committed date. However, the COVID 19 pandemic disturbed the balance jeopardizing various TB control activities those were in full swing as it disturbed many other areas of health-care delivery in many countries including India despite political commitments at the highest level – the Prime Minister.

TB case notification through Nikshay, an online case notification system through the e-platform, is a key to the NTEP. Case detection, treatment, and compliance are the key factors in the End TB strategy. COVID-19 pandemic in India has adversely affected the TB case notification. Table 1 shows the grave situation.

Thus, there is a huge gap in the case detection although the case notification was steadily increasing. This happened as a result of repeated lockdowns.

In response to the ongoing pandemic the Government of India reassigned the health personnel and equipment like use of CBNAAT machines for COVID testing were made. These arrangements led to important consequences on the performance of the TB program. Weekly counts of reported cases dropped by 75% in the 3 weeks following 22 March (average 11,367 weekly cases), when a strict nationwide lockdown was imposed, compared to an average of 45,875 weekly cases during the previous weeks of 2020. This drop was attributable to a combination of factors including delays in entering the data onto the real-time national online TB surveillance system Nikshay, reduced attendance to health services, reassignment of health personal and a reduction in TB testing and detection. National TB case detection in February 2020 dropped by 20% in comparison with the number of cases detected in February 2019. Similarly, case reporting dropped recently by 68% in January-March in Indonesia although the national TB program in Brazil reported no recent change in weekly case counts at the national level.^[34] According to estimates, the global TB case detection was decreased by an average of 25% over a period of 3 months (as compared to the level of detection before the pandemic). This will lead to a predicted additional 190,000 (56,000-406,000) TB deaths (a 13% increase), bringing the total to 1.66 (1.3-2.1) million TB deaths in 2020, near the global level of TB mortality of the year 2015.^[34]

Stop TB Partnership in collaboration with Imperial College, Avenir Health, Johns Hopkins University and USAID project carried out a modeling analysis to examine the potential impact of the Covid-19 response on TB in High-burden countries that included India, Kenya, and Ukraine. According to the modeling, if there is a 2-month lockdown with 2 months recovery, then for India, there will be an excess of 514,370 cases detected between 2020 and 2025 which is an increase of about 3.55% and an excess of TB related deaths of 151,120 during 5 years which is an excess of 5.70%. There will be similar increase in number of cases and deaths in Kenya, Ukraine, and also globally.^[35] If there is a 3-month lockdown and a protracted 10-month restoration of services, the world could see an additional 6.3 million cases of TB between 2020 and 2025 and an additional 1.4 million TB deaths during that same period. India will get an additional 1788,100 new cases (increase of 12.32%) and 511,930 excess deaths (19.31%) during this period. The modeling also found that the global response to the COVID-19 pandemic is having unintended yet drastic consequences on TB services, with lockdowns and limitations on diagnosis, treatment, and prevention services expected to increase the annual number of TB cases and deaths over the next 5 years leading to loss of gains obtained during the past years.

To minimize the impact of the COVID-19 pandemic on TB, and to save lives of TB patients and to get the country back on track in achieving the targets, all national governments including India need to take immediate measures that ensure the continuity of TB diagnostic, notification, treatment, and prevention services during the lockdown period and undertake a massive catch-up effort to actively diagnose, trace, treat and prevent. Stop TB Partnership and partners has called on the leadership of all countries - particularly those with high TB burdens - to ensure the continuity of the TB response in the time of COVID-19, to take proactive measures that include those who are most vulnerable and to provide protection against economic hardship, isolation, stigma, and discrimination. Further, the NTEP need to secure the human and financial resources needed for seamless continuation of TB services amid the COVID-19 response. Recognizing that this is an unprecedented situation, the Stop TB Partnership and the WHO are continuing support for national TB programs and partners through their multiple technical, innovative, and people-centered platforms. The Union also is providing technical help in the form of guidance during this time.

Some specific issues need special attention in India regarding TB and COVID as many migrant workers returned to their homes following lockdown. This has

| Table 1: Niksha | y Dash-board | showing ' | TΒ | notification |
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| Year | Public Sector | Private Sector | Total reported | Target (Both sectors) | Percentage reported | |
| 2017 | 14,10,579 (99%) | 3,24,386 (36%) | 17,35,262 | 23,25,312 | 75% | |
| 2018 | 15,98,105 (110%) | 5,02,823 (35%) | 21,00,928 | 21,00,928 | 73% | |
| 2019 | 17,26,656 (92%) | 6,82,068 (69%) | 24,08,724 | 28,71,755 | 84% | |
| 2020 (22nd September) | 8,88,105 (46%) | 3,59,785 (33%) | 12,47,890 | 29,99,030 | 42% | |

led to interruption of TB treatment. Loss of earnings for these migrants and other workers, will lead to malnutrition making them more susceptible to develop TB. Twenty-four percent of the urban population in India live in slums. This crowded environment and self-isolation in poorly ventilated dwellings will pose risk for both TB and COVID. Roughly 5%–10% of all COVID-19 patients will require critical care including ventilator support. As the number of COVID cases is rising steadily in India, many co-infected cases with TB will be an issue both for the availability of number of ventilators, and more importantly how to handle sputum positive TB cases on ventilators.^[36]

To contain the spread of COVID-19 (and TB), we need to educate people on infection control practices for vulnerable populations and how to care for the sick. This will benefit both the diseases. Protection of health-care workers is an important issue and by all means they should be protected to continue providing TB care as front-line warriors. It will require a coordinated approach from all sectors, from state and national governments through to the private sector and health care providers. One of the important positive effects of COVID-19 is about the awareness of infection control practices, including use of face masks, cough etiquettes, and social distancing which are to be and practiced after the COVID-19 pandemic that will help TB control also. TB treatment should not be stopped. TB preventive treatment, treatment for drug-susceptible or DR-TB and TB-HIV need special attention. Support for uninterrupted TB preventive treatment and treatment of TB disease should be ensured alongside the COVID-19 response. It is critical that TB services are not disrupted during the COVID19 response. The Stop TB Strategy, the Union, and WHO, as well as our NTEP has published guidelines for the programs how to work during the COVID-19 pandemic.^[37] Measures to be taken by people with TB to reduce their risk for COVID-19 include social distancing with "reverse-quarantine," i.e., to remain at home and avoid contact with people as much as possible including other common precautions for COVID-19. People with TB should make far fewer visits to TB clinics and health-care facilities, and instead be provided with enough medication to ensure they can complete their treatment at home. Staff at health-care facilities must receive urgent training on the importance of universal safety precautions, appropriate use of personal protective equipment and criteria for self-isolation to reduce the spread of COVID-19 in TB clinics. All people with TB should receive and wear a surgical mask while attending a TB clinic and be screened for COVID-19 through an appropriate triage system. Clinicians should recall by telephone all those with results that require urgent attention. People with TB on treatment should have a number that they can contact if they have any concerns about their treatment or other issues that could compromise their TB care. The move to all-oral regimens for DR-TB needs to be accelerated. People with TB who also have HIV and who are not on ART should be started on ART on the same day as TB treatment, with ART and TB prescriptions aligned. The program needs to ensure TB patients to receive necessary psycho-social, nutritional, and economic support. It is also necessary that TB care providers are well briefed and use essential personal protection equipment. The physician should switch to treatment for drug-resistant TB which is injection free. Ensure systems are in place for remotely monitoring of side effects and minimizing hospital visits. It is of vital importance to maintain uninterrupted TB drugs supply by planning early procurement and careful planning of local distribution and transportation in lock down situations. The national and sub-national governments should support special vulnerable population group because these populations are at greater risk of TB, because of living conditions, working environment or because of other socioeconomic factors that result in barriers to accessing health services. Despite the emergency nature of the COVID-19 pandemic, health approaches, as well as social policies, should consider rights and gender equity. Social, legal, and economic protections are to be ensured to maintain good mental health and to act against stigma and discrimination.

Although India aims to End TB by 2025, the present COVID-19 crisis and its consequential direct and indirect effects on TB along with political and economic focus on the new pandemic could result in a shift in priority. However, if the programs continue to focus on remedial measures as mentioned above to reverse this trend, which seems unlikely, the situation could be saved. Thus, if the NTEP does not take remedial measures, the country may have to revise its end TB target of 2025.

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Submitted: 01-Jul-2020

Accepted: 01-Sep-2020 Published: 30-Oct-2020

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| Quick Response Code: | Website: www.lungindia.com | | | |
| | DOI: 10.4103/lungindia.lungindia_544_20 | | | |

How to cite this article: Behera D. Tuberculosis, COVID-19, and the End Tuberculosis strategy in India. Lung India 2020;37:467-72.