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Standards for Tuberculosis Care in India – A Benchmark to Private Practitioners for Quality Tuberculosis Diagnosis and Treatment

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Abstract: *In 2015, an estimated 9.0 million people developed TB, and 1.5 million died from the disease. In India, the quality of care for TB patients receive varies considerably and often is not in accordance with the international standards. In this paper, we provide an overview of the recent standards for TB care in India (STCI) and the role of qualified private practitioners. In India, a large segment of the population seeks health care services from individual or institutional private health-care providers for health care. Role of the private players on STCI in treating TB patients were also discussed in this paper. The community health care providers both private and public should work as partners with a view to improve TB care and enhance the effectiveness of the healthcare process so that the STCI is objectively implemented in the day-to-day practice of private practitioners.*

Keywords: *Tuberculosis, Standards for Tuberculosis Care in India (STCI), Diagnosis, Treatment, Public Health, Social Inclusion, Revised National TB Control Programme (RNTCP), Central TB Division, Ministry of Health and Family Welfare, World Health Organisation (WHO) and European Union Standards of TB Care.*

I. Introduction

India, the world's second most populous country, accounts for a quarter of the world's annual incidence of TB. Every year around two million people develop TB in India and 300,000 die of TB. Over 15 million patients have been treated and three million additional lives have been saved by the Revised National TB Control Programme (RNTCP) over the last decade. Cure rates have consistently been above 85% and the TB Millennium Development Goals are reachable. However, despite a comprehensive national TB control program guiding states for implementation of TB diagnosis and treatment there is still a long way to go. The decline in TB incidence has been slow, mortality remains unacceptably high and the emergence of drug-resistant TB has become a major public health concern. The private sector holds a factual predominance of health care service delivery in India. There is very little information about the TB patient from the private sector available to the programme and little is known about their quality of treatment, including treatment outcomes. Engaging the private sector effectively is the most important intervention required for India to achieve the quality TB treatment.

Studies in India have reported that patients often begin seeking care in the informal private sector, then seek care from qualified practitioners, and eventually end up in the RNTCP for free treatment. Prescription studies have shown in the past and continue to show widespread use of irrational drug regimens. Diagnostic practices in the private sector in India remain suboptimal and heavily reliant on unreliable blood tests for TB. Thus, quality of TB care in India is variable and often not aligned with international standards and one of the first steps in improving the quality of TB treatment to set standards in private sector.

II. TB Burden In India

Each year about 2.2 million people develop TB in India and an estimated 220,000 die from the disease. Some estimates calculate the deaths as being twice as high. TB can affect any age, caste or class but cases are mainly poor people. Slum dwellers, tribal populations, prisoners and people already sick with compromised immune systems are over-represented among the cases, compared to their numbers in the population. The economic burden of TB is extremely high. Between 2006 and 2014, TB cost the Indian economy a massive USD 340 billion.

TB treatment & care in India is provided by the government's RNTCP as well as through private sector health providers. In 2015 the RNTCP covered a population of 1.28 billion. A total of 9,132,306 cases of suspected TB were examined by sputum smear microscopy and 1,423,181 people were diagnosed and registered for TB treatment. There are some more TB statistics for India.

TB Case notification in India

The notification of TB cases is estimated to be only 58%. Over one third of cases are not diagnosed, or they are diagnosed but not treated, or they are diagnosed and treated but not notified to the RNTCP. This could be even higher, and the World Health Organisation (WHO) estimates that possibly as many as another 10 lakh (1,000,000) Indians with TB are not notified. One of the reasons for the low case notification is the largely unregulated and unmonitored private sector which accounts for almost half of the TB care delivered in India.

Private Sector Care for TB

The private sector in India, has unfortunately, been a source of mismanagement of TB and hence of drug resistance. This includes the use of incorrect diagnostics (e.g. blood tests), incorrect regimes and a lack of supervision to ensure all TB patients complete their TB treatment. So every effort is being made to engage the private sector in India and improve the quality of care provided by private practitioners.

The RNTCP has tried to involve non public health providers in promoting TB care, but it is believed that many patients continue to seek treatment elsewhere and currently go unreported. A number of studies and surveys of TB prevalence including self reporting of TB prevalence, have suggested that up to 46% of patients may not be currently reported.

There are many reasons why people in India seek care from the private sector. These include:

- poor knowledge about TB
- poor knowledge about services available through the national programme
- the convenience of services
- a desire for confidentiality
- a desire for personalized care.

National Strategic Plan (NSP) 2012 -2017

For the five year National Strategic Plan for 2012 – 2017, the vision of the government was for a TB free India, through achieving Universal Access by provision of quality diagnosis and treatment for all TB patients in the community. This was a major policy change. The policy change meant extending the reach of RNTCP services to all people diagnosed with TB, including those with drug resistant TB, as well as those seeking treatment in the private sector. The new policy also included improving the quality of existing RNTCP services.

Standards for Tuberculosis Care in India

The first edition of the STCI that is described here is the result of a long process that culminated in a 3-day national workshop organized by the Central TB Division at New Delhi in December 2012 with the technical assistance with technical assistance from WHO Country Office for India. About 120 experts from national and international level including various public health administrators, program managers, representatives from various professional associations, donors, technical and implementation partners, pharmaceutical companies, and pharmacists. As an output of the workshop, 26 standards with India specific evidence was developed. These standards are intended to be used to enhance quality and mutually acceptable engagement with the private and other sectors in India to enhance TB care. Thus, this is an important tool for attaining the quality treatment in TB.

III. Standards On Diagnosis: (1 – 6)

Standard – 1: Testing and Screening for Pulmonary Tuberculosis

Testing - any person with symptoms and signs suggestive of TB including cough >2 weeks, fever >2 weeks, significant weight loss, haemoptysis etc. and any abnormality in chest radiograph must be evaluated for TB. Children with persistent fever and/or cough >2 weeks, loss of weight / no weight gain, and/ or h/o contact with pulmonary TB cases must be evaluated for TB.

Standard – 2: Diagnostic Technology

Microbiological confirmation on sputum - all patients (adults, adolescents, and children who are capable of producing sputum) with presumptive pulmonary TB should undergo a quality-assured sputum test for rapid microbiological diagnosis of TB.

Chest X-ray as screening tool - where available, chest X-ray should be used as a screening tool to increase the sensitivity of the diagnostic algorithm.

Serological tests - serological tests are banned and not recommended for diagnosing tuberculosis.

Tuberculin Skin Test (TST) & Interferon Gamma Release Assay (IGRA) - TST and IGRA are not recommended for the diagnosis of active tuberculosis.

Standard – 3: Testing for Extra-pulmonary Tuberculosis
Testing for extra-pulmonary TB - for all patients (adults, adolescents and children) with presumptive extrapulmonary TB, appropriate specimens from the presumed sites of involvement must be obtained for microscopy/culture and drug sensitivity testing (DST)/CB-NAAT/molecular test/histopathological examination and DST.

Standard – 4: Diagnosis of HIV Co-infection in Tuberculosis Patients and Drug-Resistant Tuberculosis
Diagnosis of HIV in TB patients - all diagnosed TB patients should be offered HIV counselling and testing.
Diagnosis of Multi-Drug Resistant TB (MDR-TB) - Prompt and appropriate evaluation should be undertaken for patients with presumptive MDR-TB or Rifampicin (R) resistance in TB patients who have failed treatment with first line drugs, paediatric non responders, TB patients who are contacts of MDR-TB (or R resistance),
Diagnosis of Extensively Drug Resistant TB (XDR-TB) - on detection of Rifampicin and isoniazid resistance, patient must be offered sputum test for second line DST using quality assured phenotypic or genotypic methods, wherever available.

Standard – 5: Probable Tuberculosis
Probable TB - Patients with symptoms suggestive of TB without microbiological confirmation (sputum smear microscopy, culture and molecular diagnosis), but with strong clinical and other evidence (e.g. X-ray, Fine Needle Aspiration Cytology (FNAC), histopathology) may be diagnosed as "Probable TB".

Standard – 6: Pediatric Tuberculosis
Diagnosis of paediatric TB patients- in all children with presumptive intra-thoracic TB, microbiological confirmation should be sought through examination of respiratory specimens (e.g. sputum by expectoration, gastric aspirate, gastric lavage, induced sputum, broncho-alveolar lavage or other appropriate specimens) with a quality assured diagnostic test, preferably CB-NAAT, smear microscopy or culture.

IV. Standards On Treatment: (7 – 11)

Standard – 7: Treatments with first-line regimen
Treatment of New TB patients - all new patients should receive an internationally accepted first-line treatment regimen for new patients. The initial phase should consist of two months of Isoniazid (H), Rifampicin (R), Pyrazinamide (Z), and Ethambutol (E). The continuation phase should consist of three drugs (Isoniazid, Rifampicin and Ethambutol) given for at least four months.

Standard – 8: Monitoring Treatment Response
Follow-up sputum microscopy - response to therapy in patients with pulmonary tuberculosis, new as well as retreatment cases, should be monitored by follow-up sputum microscopy/culture (one specimen) at the time of completion of the intensive phase of treatment and at the end of treatment.

Standard – 9: Drug Resistant Tuberculosis Management
Treatment of M/XDR-TB(or R resistant TB) - patients with TB caused by drug-resistant organisms (especially M/XDR or only R resistance or with O or K resistance), microbiologically confirmed by an accredited laboratory, should be treated with specialized regimens containing quality assured second-line antituberculosis drugs.
Model of care for drug resistant TB - Patients with DR-TB should be treated using mainly ambulatory care rather than models of care based principally on hospitalization. If required, a short period of initial hospitalisation is recommended.

Standard – 10: Addressing Tuberculosis with HIV Infection and other Co-morbid Conditions
Treatment of HIV infected TB patients - TB patients living with HIV infection should receive the same duration of TB treatment with daily regimen as HIV-negative TB patients.
Anti-retroviral therapy and co-trimoxazole prophylactic therapy in HIV infected TB patients - Anti-retroviral therapy must be offered to all patients with HIV and TB as well as drug-resistant TB who require second-line anti-TB drugs, irrespective of CD4 cell-count, as early as possible (within the first eight weeks) following initiation of anti-TB treatment. Appropriate arrangements for access to anti-retroviral drugs should be made for

patients. However, initiation of treatment for TB should not be delayed. Patients with TB and HIV infection should also receive Cotrimoxazole as prophylaxis for other infections.

Standard – 11: Treatment Adherence
Patient-centered approach for adherence - to assess and foster adherence, a patient-centered approach to administration of drug treatment, based on the patient's needs and mutual respect between the patient and the provider, should be developed for all patients.

V. Standards On Public Health: (12 – 21)

Standard – 12: Public Health Responsibilities
Any practitioner treating a patient for TB is assuming an important public health responsibility to prevent on-going transmission of the infection and the development of drug resistance. To fulfill this responsibility, the practitioner must not only prescribe an appropriate regimen, but when necessary, also utilize local public health services/community health services, and other agencies including nongovernmental organizations to assess the adherence of the patient and to address poor adherence when it occurs.
India continues to have high TB incidence and the mortality due to TB is still unacceptably high. The challenges of TB control in India are magnified by the existence of parallel systems for TB diagnosis and treatment – the public and private.

Standard – 13: Notification of Tuberculosis Cases
All health establishments must report all TB cases and their treatment outcomes to public health authorities (District Nodal Officer for Notification). Proper feedback need to be ensured to all healthcare providers who refer cases to a public health system on the outcome of the patients which they had referred. TB is a notifiable disease in India as per the government order dated 7 May, 2012 and requires that all healthcare providers who have diagnosed a case of TB through microbiological testing or clinically diagnosed and/or started treatment for TB must report to the District Nodal Officer for Notification. Notification is a basic public health activity common to diseases of public health importance.

Standard – 14: Maintain Records for all Tuberculosis Patients
A written record of all medications given, bacteriologic response, adverse reactions, and the clinical outcome should be maintained for all patients. Patient-level recording of details of diagnosis, treatment and outcome are the foundations of any effective public health surveillance system. Use of appropriate technology such as Nikshay should improve the quality and accessibility to a primary provider initiated record that is linked at every level from a primary clinic to the State Department of Health.

Standard – 15: Contact Investigation
All providers of care for patients with TB should ensure all household contacts, and other persons who are in close contact with TB patients are screened for TB. In case of pediatric TB patients, reverse contact tracing for the search of any active TB case in the household of the child must be undertaken.

Standard – 16: Isoniazid Prophylactic Therapy
Children who are <16 years of age who are close contacts of a TB patient, after excluding active TB, should be treated with isoniazid for a minimum period of 6 months and should be closely monitored for TB symptoms. Because children are more susceptible to TB infection, more likely to develop active TB disease soon after infection, and more likely to develop severe forms of disseminated TB, it is widely recommended (The Union, WHO) that close contacts of index cases under the age of 6 who do not have active TB should receive IPT.

Standard – 17: Airborne Infection Control
Airborne infection control should be an integral part of all healthcare facility infection control strategy. Each healthcare facility caring for patients who have, or are suspected of having, TB should develop and implement an appropriate airborne infection control plan as per the national guidelines. Administrative, environmental and personal protective measures should be implemented in all health care facilities as per national airborne infection control guidelines. Protection of health care workers from airborne infection should be ensured through adequate preventive measures including training, personal protection measures in high risk situations and periodic screening at least once a year.

Standard – 18: Quality Assurance Systems for Diagnostic Tests
All healthcare providers should ensure that all diagnostic tests used for diagnosis of TB are quality assured. Quality assurance (QA) for anti-TB drugs. QA system should ensure that all anti-TB drugs used in the country are subjected to stringent QA mechanisms at all levels. Providers should ensure that all anti-TB drugs prescribed come from a QA source.

Standard – 19: Panchayat Raj Institutions
Panchayat Raj Institutions and elected representatives have an important role to share the public health responsibility for TB control with the healthcare providers, patients and the community. Health being an important responsibility of the PRIs in India, there are many opportunities for greater involvement of the PRIs for TB control. Because the diagnosis and treatment of TB is complicated and takes long, and mistreatment of TB and emergence of drug-resistant TB affects everybody in the community, the Panchayat should be involved in all aspects of TB control.

Standard – 20: Health Education
Every TB symptomatic should be properly counseled by the healthcare provider. TB patients and their family members should get proper counseling and health education at every contact with the healthcare system. Proper health education to the patient and family is very important for TB care. There should be systems for education and counselling as an integral part of TB treatment. Every visit of the patient to the healthcare provider and visit of the health worker to the patient's home should be utilised for health education.

Standard – 21: Death Audit among Tuberculosis Patients
Death among TB patients should be audited by a competent authority. Investigation into the cause of death is an important standard which needs to be followed to study the conditions that led to the death in order to initiate actions to prevent development of such conditions to other TB patients. Every TB death should be notified to the concerned authority. Competent authority at the district level should do the death audit of every TB death and provide a report to the programme to take necessary steps for preventing avoidable deaths.

VI. Standards on Social Inclusion: (22 – 26)

Standard – 22: Information on Tuberculosis Prevention and Care Seeking
All individuals especially women, children, elderly, differently abled, other vulnerable groups and those at increased risk should receive information related to TB prevention and care seeking.

Standard – 23: Free and Quality Services
All patients, especially those in vulnerable population groups, should be offered free or affordable quality assured diagnostic and treatment services, which should be provided at locations and times so as to minimize workday or school disruptions and maximize access.

Standard – 24: Respect, Confidentiality, and Sensitivity
All people seeking or receiving care for TB should be received with dignity and managed with promptness, confidentiality and gender sensitivity. Public health responsibilities including notification, contact tracing, chemoprophylaxis, fast tracking, outcome monitoring etc. should be sensitive to respect and confidentiality of patients.

Standard – 25: Care and Support through Social Welfare Programs
Healthcare providers should endeavour to derive synergies between various social welfare support systems such as RSBY, nutritional support programmes, national rural employment guarantee scheme etc. to mitigate out of pocket expenses such as transport and wage loss incurred by people affected by TB.

Standard – 26: Addressing Counseling and Other Needs
Persons affected by TB and their family members should be counselled at every opportunity, to address information gaps and to enable informed decision-making. Counseling should also address issues such as healthcare, physical, financial, psycho-social and nutritional needs.

VII. Conclusion

Private providers play an important role in providing health care services to a large proportion of patients with tuberculosis. There is a need for innovative measures to increase participation of the private sector in the national TB control program and to improve the quality of services in government facilities. One of the

critical components of the STOP TB strategy is the engagement of all health care providers to ensure access to high-quality diagnosis and patient centric care. This is especially important to follow the STCI guidelines for countries like India where a large, segmented, and unregulated private health care sector caters to the health needs of 75% of the population. In India, much of the population, across all socioeconomic strata, consult private providers at some time during their illness. These private providers outnumber public health care providers and often offer better geographical access and more personalized care than the public facilities. The involvement of the private sector has, therefore, become extremely important to improve the effectiveness and outreach of TB control efforts in India. With a large and fast growing private health care sector in India, the above STCI guidelines should be a compel planners of TB control to urgently consider more innovative ways to engage private providers so that they may willingly contribute toward the control efforts for TB disease in India.

References

[1] Achanta S, Jaju J, Kumar AM, Nagaraja SB, Shamrao SR, Bandi SK, et al. Tuberculosis management practices by private practitioners in Andhra Pradesh, India. PLoS One 2013;8:e71119.

[2] Babiarz KS, Suen SC, Goldhaber-Fiebert JD. Tuberculosis treatment discontinuation and symptom persistence: An observational study of Bihar, India's public care system covering>100,000,000 inhabitants. BMC Public Health 2014;14:418.

[3] Bharaswadkar S, Kanchar A, Thakur N, Shah S, Patnaik B, Click ES, et al. Tuberculosis management practices of private practitioners in Pune municipal corporation, India. PLoS One 2014;9:e97993.

[4] Bhargava A, Pinto LM, Pai M. Mismanagement of tuberculosis in India: Causes, consequences, and the way forward. Hypothesis 2011;9:1-13.

[5] Bhat R. Characteristics of private medical practice in India: A provider prospective. Health Policy Plan. 1999;14:26–37.

[6] Hazarika I. Role of private sector in providing tuberculosis care: Evidence from a population-based survey in India. J Glob Infect Dis 2011;3:19-24.

[7] Indrajit Hazarika., Role of Private Sector in Providing Tuberculosis Care: Evidence from a Population-based Survey in India, Journal of Global Infectious Diseases. 2011 Jan-Mar; 3(1): 19–24.

[8] Jaroslawski S, Pai M. Why are inaccurate tuberculosis serological tests widely used in the Indian private healthcare sector? A root-cause analysis. J Epidemiol Glob Health 2012;2:39-50.

[9] Kapoor SK, Raman AV, Sachdeva KS, Satyanarayana S. How did the TB patients reach DOTS services in Delhi? A study of patient treatment seeking behavior. PLoS One 2012;7:e42458.

[10] Mishra G, Mulani J. Tuberculosis Prescription practices in private and public sector in India. Natl J Integr Res Med 2013;4:71-8.

[11] Migliori GB, Zellweger JP, Abubakar I, Ibraim E, Caminero JA, De Vries G, et al. European union standards for tuberculosis care. Eur Respir J 2012;39:807-19.

[12] Pai M, DAS J. Management of tuberculosis in India: Time for a deeper dive into quality. Natl Med J India 2013;26:65-8.

[13] Pai M, Satyanarayana S, Hopewell P. Improving quality of tuberculosis care in India. Indian J Tuberc 2014;61:12-8.

[14] Pai M. Promoting affordable and quality tuberculosis testing in India. J Lab Physicians 2013;5:1-4.

[15] Pai, M "Formidable killer: drug-resistant tuberculosis", The Tribune, India, August 6, 2013 www.tribuneindia.com/2013/

[16] Purty AJ, Singh Z, Bazroy J, Chauhan RC, Murugan N. Standards for tuberculosis care in India, a road map to universal access in quality tuberculosis care. J Curr Res Sci Med [serial online] 2015 [cited 2016 Dec 2];1:6-11.

[17] Satyanarayana S, Nair SA, Chadha SS, Shivashankar R, Sharma G, Yadav S, et al. From where are tuberculosis patients accessing treatment in India? Results from a cross-sectional community based survey of 30 districts. PLoS One 2011;6:e24160.

[18] Satyanarayana, S "From where are Tuberculosis patients accessing treatment in India? Results from a cross-sectional community based survey of 30 districts", PLoS ONE www.plosone.org/article/info:doi/10.1371/journal.pone.0024160

[19] Shrivastava SR, Shrivastava PS, Ramasamy J. Standards of tuberculosis care: An India perspective. Prog Health Sci 2014;4:280-82.

[20] Sreeramareddy CT, Qin ZZ, Satyanarayana S, Subbaraman R, Pai M. Delays in diagnosis and treatment of pulmonary tuberculosis in India: A systematic review. Int J Tuberc Lung Dis 2014;18:255-66.

[21] Tamhane A, Ambe G, Vermund SH, Kohler CL, Karande A, Sathiakumar N. Pulmonary tuberculosis in Mumbai, India: Factors responsible for patient and treatment delays. Int J Prev Med 2012;3:569-80.

[22] Tuberculosis Coalition for Technical Assistance. Handbook for Using the International Standards for Tuberculosis Care. The Hague: Tuberculosis Coalition for Technical Assistance; 2007.

[23] Udwadia ZF, Pinto LM, Uplekar MW. Tuberculosis management by private practitioners in Mumbai, India: Has anything changed in two decades? PLoS One 2010;5:e12023.

[24] Uplekar MW, Shepard DS. Treatment of tuberculosis by private general practitioners in India. Tubercle 1991;72:284-90.

[25] World Health Organization. Standards of TB Care in India, WHO SEA Regional Office and Central TB Division, MOHFW, Govt. of India; 2014. Available from: http://www.tbcindia.nic.in. [Last accessed on 2015 Aug 01].