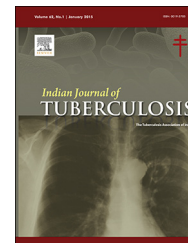


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Review Article

Standards for TB care in India: A tool for universal access to TB care

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ARTICLE INFO

Article history:

Received 10 August 2015

Accepted 20 November 2015

Available online xxx

Keywords:

Tuberculosis

Diagnosis

Treatment

Standards for TB care

India

ABSTRACT

In 2014, Government of India in collaboration with World Health Organization Country Office for India released the policy document on Standards for tuberculosis (TB) care in India after in-depth deliberation with national and international experts. The standards for TB care represent what is expected for quality TB care from the Indian healthcare system including both public and private systems. The details of each standard have been compiled in this review article. It is envisioned that the standards detailed in the manuscript are adapted by all TB care providers across the country.

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1. Introduction

The vision of India's national TB control programme is that the people suffering from TB receive the highest standards of care and support from healthcare providers of their choice.¹ India, with nearly a quarter of the world's annual incidence of TB has one of the largest TB control programmes in the world. Over 15 million patients have been treated, and 3 million additional lives have been saved by the Revised National TB Control Programme (RNTCP) over the entire last decade. Despite having a comprehensive national TB control programme 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.²

The private sector has predominance of health care service delivery in India. Nearly half of TB patients are getting treatment from private sector.³ National TB control Programme has very little information about TB patient managed in the private sector, and the quality of treatment, including treatment outcomes are largely unclear.⁴ Engaging the private sector effectively is the single most important intervention required for India to achieve the overall goal of universal access to quality TB care. From the patients' perspectives, the

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public sector and private sector are not two separate universe, and they frequently change the health care providers. Non-uniformity between public and private sector standards make it difficult to ensure continuum of care. A uniform standard for management of TB is critical for prevention of development of drug resistant TB (DR-TB). Thus, it was felt essential to develop and disseminate the standards for TB care, that is particularly relevant in Indian context, applicable to the medical fraternity in both the public and private sectors in India. The new diagnostic tools and strategies for early TB diagnosis, emerging evidences on existing regimens and newer regimens, and the need for better patient support strategies including addressing social inclusiveness have further necessitated the development of Standards for TB Care in India (STCI).⁵

In 2014, Government of India in collaboration with WHO Country Office for India released the policy document on STCI after in-depth deliberation with national and international experts.

The standards detailed in the STCI differ from existing guidelines; in that, the standards present what should be done, whereas guidelines describe how the action is to be accomplished. There are comprehensive national guidelines from the Central TB Division, GoI [www.tbcindia.gov.in] that are regularly reviewed and updated. These standards represent what is expected for quality TB care from the Indian healthcare system including both public and private systems.

2. Methods

STCI was developed through series of consultations and review of literature with special attention on data from India. Methodology for developing these standards consisted of extensive consultations based on in-depth analysis of India's programme data and review of literature including findings from various operational researches conducted with in the programme, and other recent national and international evidences available. International standards and guidelines such as International Standards for TB care 2nd edition (2009),⁶ WHO treatment of tuberculosis guidelines 4th edition (2010),⁷ Guidelines for Programmatic Management of Drug Resistant TB (2011),¹⁵ etc. were used as reference. A workshop was organised to develop these standards, and the expert groups were asked to find out the answers to the following questions:

1. What should be the standard tools and strategies for early and complete detection?
2. What should be the standards of treatment in terms of drugs and regimens for best patient outcome?
3. What should be the public health standards including regulations, strategies and systems for public health impact?
4. What should be standards for patient support systems, both in public and private sectors and for community engagement for social inclusion?

Answers to these questions formed the basis for these standards. Detailed methodology in developing these standards is described elsewhere.⁵

2.1. Standards for TB care in India

These comprise of four basic sets of standards:

- Standards for diagnosis of TB (Standard 1–Standard 6)
- Standards for treatment of TB (Standard 7–Standard 11)
- Standards for public health for TB (Standard 12–Standard 21)
- Standards for social inclusion for TB (Standard 22–Standard 26)

2.2. Standards for diagnosis of TB (Standard 1–Standard 6)

2.2.1. Standard 1: testing and screening for pulmonary TB

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 contact with pulmonary TB cases must be evaluated for TB.^{8,9,11}

People living with HIV (PLHIV), malnourished, diabetics, cancer patients, patients on immunosuppressant or maintenance steroid therapy, should be regularly screened for signs and symptoms suggestive of TB. Enhanced case finding should be undertaken in high risk populations such as health care workers, prisoners, slum dwellers and certain occupational groups such as miners.^{8,10}

2.2.2. Standard 2: diagnosis

All patients (adults, adolescents and children, who are capable of producing sputum) with presumptive pulmonary TB should undergo quality-assured sputum test for rapid diagnosis of TB for microbiological confirmation. Wherever available, chest X-ray should be used as a screening tool to increase the sensitivity of the diagnostic algorithm.^{8,12} Serological tests are banned and not recommended for diagnosing TB.¹⁴ Tuberculosis skin test (TST) and immunoglobulin G release assay (IGRA) are not recommended for the diagnosis of active TB. Standardised TST may be used as a complimentary test in children. CB-NAAT (cartridge-based nucleic-acid amplification test) (GeneXpert) is the preferred first diagnostic test in children and PLHIV.¹³

2.2.3. Standard 3: testing for extra-pulmonary TB

For all patients (adults, adolescents and children) with presumptive extra-pulmonary TB, appropriate specimens from the presumed sites of involvement must be obtained for microscopy/culture and drug sensitivity testing (DST)/CB-NAAT/molecular test/histo-pathological examination.^{15,16}

2.2.4. Standard 4: diagnosis of HIV co-infection in TB patients and drug resistant TB

All diagnosed TB patients should be offered HIV counselling and testing.

Prompt and appropriate evaluation should be undertaken for patients with presumptive MDR-TB who have failed treatment with first line drugs, paediatric nonresponders, TB patients who are contacts of MDR-TB, TB patients who are found positive on any follow-up sputum smear examination

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