

## Introduction to the International Standards for TB Care

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### INTRODUCTION

The International Standards for Tuberculosis Care have been developed by the Tuberculosis Coalition for Technical Assistance (TBCTA) with funding support from the US Agency for International Development. The partners for TBCTA are the World Health Organization, the American Thoracic Society, the Centre for Disease Control and Prevention (USA), International Union Against Tuberculosis and Lung Disease, and KNCV Tuberculosis Foundation<sup>1</sup>.

### BACKGROUND

Although there have been several approaches developed by WHO, Stop TB partnership and National TB Control programmes for the involvement of the private sector, there has been no generally agreed upon set of standards describing the essential actions that should be taken by all practitioners in providing tuberculosis services. To address this shortcoming, the International Standards for Tuberculosis Care (ISTC) were developed through a year-long inclusive process guided by a 28-member steering committee. The steering committee included individuals who represented a wide variety of relevant perspectives on tuberculosis care and control. In addition, the document was presented at various public forums with an open invitation for comments<sup>2</sup>.

### PURPOSE

The International Standards for Tuberculosis Care (ISTC) describe a widely accepted level of care that all practitioners, public and private, should seek to achieve in managing patients who have, or are suspected of

**Table 1:** International Standards for TB Care: Standards for Diagnosis

**Standard 1.** All persons with otherwise unexplained productive cough lasting two–three weeks or more should be evaluated for tuberculosis.

**Standard 2.** All patients (adults, adolescents, and children who are capable of producing sputum) suspected of having pulmonary tuberculosis should have at least two, and preferably three, sputum specimens obtained for microscopic examination. When possible, at least one early morning specimen should be obtained.

**Standard 3.** For all patients (adults, adolescents, and children) suspected of having extrapulmonary tuberculosis, appropriate specimens from the suspected sites of involvement should be obtained for microscopy and, where facilities and resources are available, for culture and histopathological examination.

**Standard 4.** All persons with chest radiographic findings suggestive of tuberculosis should have sputum specimens submitted for microbiological examination.

**Standard 5.** The diagnosis of sputum smear-negative pulmonary tuberculosis should be based on the following criteria: at least three negative sputum smears (including at least one early morning specimen); chest radiography findings consistent with tuberculosis; and lack of response to a trial of broad spectrum antimicrobial agents. (NOTE: Because the fluoroquinolones are active against *M. tuberculosis complex* and, thus, may cause transient improvement in persons with tuberculosis, they should be avoided.) For such patients, if facilities for culture are available, sputum cultures should be obtained. In persons with known or suspected HIV infection, the diagnostic evaluation should be expedited.

**Standard 6.** The diagnosis of intrathoracic (i.e. pulmonary, pleural, and mediastinal or hilar lymph node) tuberculosis in symptomatic children with negative sputum smears should be based on the finding of chest radiographic abnormalities consistent with tuberculosis and either a history of exposure to an infectious case or evidence of tuberculosis infection (positive tuberculin skin test or interferon gamma release assay). For such patients, if facilities for culture are available, sputum specimens should be obtained (by expectoration, gastric washings, or induced sputum) for culture.

having, tuberculosis. The document is intended to effectively engage all care providers in delivering high quality care for patients of all ages, including those with smear-positive, smear-negative, and extra-pulmonary tuberculosis, tuberculosis caused by drug-resistant *Mycobacterium tuberculosis* complex, and tuberculosis combined with HIV infection<sup>3</sup>.

**Table 2:** International Standards for TB Care: Standards for Treatment

**Standard 7:** Any practitioner treating a patient for tuberculosis is assuming an important public health responsibility. To fulfill this responsibility the practitioner must not only prescribe an appropriate regimen but, also, be capable of assessing the adherence of the patient to the regimen and addressing poor adherence when it occurs. By so doing, the provider will be able to ensure adherence to the regimen until treatment is completed.

**Standard 8.** All patients (including those with HIV infection) who have not been treated previously should receive an internationally accepted first-line treatment regimen using drugs of known bioavailability. The initial phase should consist of two months of isoniazid, rifampicin, pyrazinamide, and ethambutol. The preferred continuation phase consists of isoniazid and rifampicin given for four months. Isoniazid and ethambutol given for six months is an alternative continuation phase regimen that may be used when adherence cannot be assessed, but it is associated with a higher rate of failure and relapse, especially in patients with HIV infection. The doses of antituberculosis drugs used should conform to international recommendations. Fixed-dose combinations of two (isoniazid and rifampicin, three (isoniazid, rifampicin, and pyrazinamide), and four (isoniazid, rifampicin, pyrazinamide, and ethambutol) drugs are highly recommended, especially when medication ingestion is not observed.

**Standard 9.** To foster and assess 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. Supervision and support should be gender-sensitive and age-specific and should draw on the full range of recommended interventions and available support services, including patient counseling and education. A central element of the patient-centered strategy is the use of measures to assess and promote adherence to the treatment regimen and to address poor adherence when it occurs. These measures should be tailored to the individual patient's circumstances and be mutually acceptable to the patient and the provider. Such measures may include direct observation of medication ingestion (directly observed therapy—DOT) by a treatment supporter who is acceptable and accountable to the patient and to the health system.

**Standard 10.** All patients should be monitored for response to therapy, best judged in patients with pulmonary tuberculosis by follow-up sputum microscopy (two specimens) at least at the time of completion of the initial phase of treatment (two months), at five months, and at the end of treatment. Patients who have positive smears during the fifth month of treatment should be considered as treatment failures and have therapy modified appropriately. (See Standards 14 and 15.) In patients with extrapulmonary tuberculosis and in children, the response to treatment is best assessed clinically. Follow-up radiographic examinations are usually unnecessary and may be misleading.

**Standard 11.** A written record of all medications given, bacteriologic response, and adverse reactions should be maintained for all patients.

**Standard 12.** In areas with a high prevalence of HIV infection in the general population and where tuberculosis and HIV infection are likely to co-exist, HIV counseling and testing is indicated for all tuberculosis patients as part of their routine management. In areas with lower prevalence rates of HIV, HIV counseling and testing is indicated for tuberculosis patients with symptoms and/or signs of HIV-related conditions and in tuberculosis patients having a history suggestive of high risk of HIV exposure.

**Standard 13.** All patients with tuberculosis and HIV infection should be evaluated to determine if antiretroviral therapy is indicated during the course of treatment for tuberculosis. Appropriate arrangements for access to antiretroviral drugs should be made for patients who meet indications for treatment. Given the complexity of co-administration of antituberculosis treatment and antiretroviral therapy, consultation with a physician who is expert in this area is recommended before initiation of concurrent treatment for tuberculosis and HIV infection, regardless of which disease appeared first. However, initiation of treatment for tuberculosis should not be delayed. Patients with tuberculosis and HIV infection should also receive cotrimoxazole as prophylaxis for other infections.

**Standard 14.** An assessment of the likelihood of drug resistance, based on history of prior treatment, exposure to a possible source case having drug-resistant organisms, and the community prevalence of drug resistance, should be obtained for all patients. Patients who fail treatment and chronic cases should always be assessed for possible drug resistance. For patients in whom drug resistance is considered to be likely, culture and drug susceptibility testing for isoniazid, rifampicin, and ethambutol should be performed promptly.

**Standard 15.** Patients with tuberculosis caused by drug-resistant (especially multidrug resistant [MDR]) organisms should be treated with specialized regimens containing second-line antituberculosis drugs. At least four drugs to which the organisms are known or presumed to be susceptible should be used, and treatment should be given for at least 18 months. Patient - centered measures are required to ensure adherence. Consultation with a provider experienced in treatment of patients with MDR tuberculosis should be obtained.

## SUMMARY

A listing of the 17 ISTC standards is provided in the three tables in this document. The basic principles of care for persons with, or suspected of having, tuberculosis are the same worldwide: a diagnosis should be established promptly and accurately; standardized treatment regimens of proven efficacy should be used with appropriate treatment support and supervision; the response to treatment should be monitored; and the essential public health responsibilities must be carried out. Prompt, accurate diagnosis and effective treatment are not only essential for good patient care, they are also the key elements in the public health response to tuberculosis and the cornerstone of tuberculosis control. Thus, all providers who undertake evaluation and treatment of patients with tuberculosis must recognize

that, not only are they delivering care to an individual, they are also assuming an important public health function that entails a high level of responsibility to the community, as well as to the individual patient. Good care for individuals with tuberculosis is also in the best interest of the community<sup>3</sup>.

**Table 3:** International Standards for TB Care: Standards for Public Health Responsibilities

**Standard 16.** All providers of care for patients with tuberculosis should ensure that persons (especially children under 5 years of age and persons with HIV infection) who are in close contact with patients who have infectious tuberculosis are evaluated and managed in line with international recommendations. Children under 5 years of age and persons with HIV infection who have been in contact with an infectious case should be evaluated for both latent infection with *M. tuberculosis* and for active tuberculosis.

**Standard 17.** All providers must report both new and retreatment tuberculosis cases and their treatment outcomes to local public health authorities, in conformance with applicable legal requirements and policies.

### ISTC IN THE CONTEXT OF RNTCP AND THE ROAD AHEAD

India was intimately involved in the development of the ISTC, and the Revised National Tuberculosis Control Programme (RNTCP) of the Government of India conforms to all the standards prescribed in the ISTC. In India, practicing RNTCP in its entirety is the only means to ensure that the international standards are observed for the management of TB cases. It is

imperative that professional bodies endorse the ISTC and provide their commitment that all health care providers shall provide care to their TB patients as per the international standards.

The National Task Force on involvement of Medical Colleges in RNTCP (NTF) in its meeting held in November 2006, has adopted and endorsed the International Standards for TB Care, and also committed that the NTF members shall undertake advocacy for RNTCP with other professional bodies.

Therefore, the important step ahead for all health professionals in the country is to take these standards to all professional bodies, and through them to all medical practitioners, and seek their commitment to these international standards, which is also their commitment to the principles of the RNTCP. The Indian medical community has to demonstrate its commitment to provide the best possible care in managing patients with tuberculosis, in accordance with international guidelines and standards.

### REFERENCES

1. Central TB Division (CTD), Government of India. Training Module for Medical Practitioners. New Delhi: CTD, 2006.
2. Hopewell P, Pai M, et al. International Standards for Tuberculosis Care. *Lancet Infect Dis* 2006;6:710-25.
3. Tuberculosis Coalition for Technical Assistance. International Standards for Tuberculosis Care (ISTC). The Hague: Tuberculosis Coalition for Technical Assistance, 2006.