

Purpose of ISTC



The purpose of the International Standards for Tuberculosis Care (ISTC) is to 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 having, tuberculosis.

ISTC Version 2: Key Points


- 21 Standards
- Differ from existing guidelines: standards present what should be done, whereas, guidelines describe how the action is to be accomplished
- Evidence-based, living document
 - Version 1 published in 2006
 - Version 2 in 2009
- Developed in tandem with *Patients' Charter for Tuberculosis Care*
- *Handbook for using the International Standards for Tuberculosis Care*

ISTC: Key Points

- **Audience:** all health care practitioners, public and private
- **Scope:** diagnosis, treatment, and public health responsibilities; intended to complement local and national guidelines
- **Rationale:** sound tuberculosis control requires the effective engagement of all providers in providing high quality care and in collaborating with TB control programs

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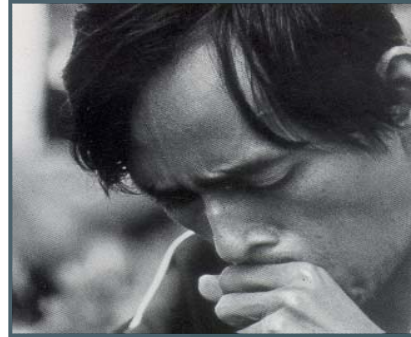
Standards for Diagnosis



Not all patients with respiratory symptoms receive an adequate evaluation for tuberculosis. These failures lead to increased disease severity for the patients and a greater likelihood of transmission of *M. tuberculosis* to family members and others in the community.

ISTC Standard 1

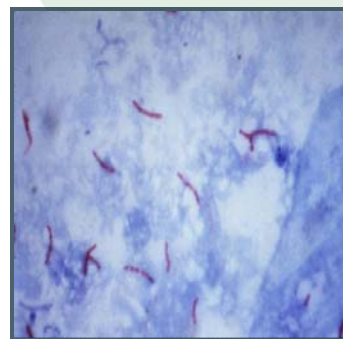
All persons with otherwise unexplained productive cough lasting two-three weeks or more should be evaluated for tuberculosis



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ISTC Standard 2

All patients (adults, adolescents, and children who are capable of producing sputum) suspected of having pulmonary tuberculosis should have at least two sputum specimens submitted for microscopic examination in a quality-assured laboratory. When possible at least one early morning specimen should be obtained



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ISTC Standard 3

For all patients (adults, adolescents, and children) suspected of having extra-pulmonary tuberculosis, appropriate specimens from the suspected sites of involvement should be obtained for microscopy, culture, and histopathological examination



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ISTC Standard 4

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



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ISTC Standard 5

The diagnosis of sputum smear-negative pulmonary tuberculosis should be based on the following criteria:

- at least two negative sputum smears (including at least one early morning specimen);
- chest radiographic 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, sputum cultures should be obtained. In persons who are seriously ill or have known or suspected HIV infection, the diagnostic evaluation should be expedited and if clinical evidence strongly suggests tuberculosis, a course of antituberculosis treatment should be initiated.

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ISTC Standard 6

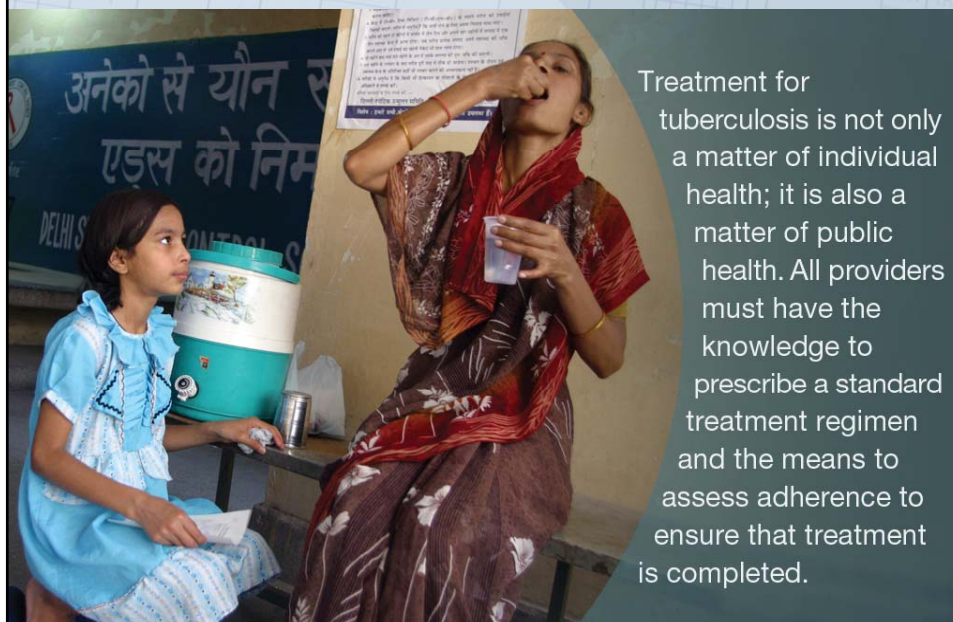
In all children suspected of having intrathoracic (i.e., pulmonary, pleural, and mediastinal or hilar lymph node) tuberculosis, bacteriological confirmation should be sought through examination of sputum (by expectoration, gastric washings, or induced sputum) for smear microscopy and culture.

In the event of negative bacteriological results, a diagnosis of tuberculosis should be based on the presence of abnormalities consistent with tuberculosis on chest radiography, a history of exposure to an infectious case, evidence of tuberculosis infection (positive tuberculin skin test or interferon gamma release assay) and clinical findings suggestive of tuberculosis.

For children suspected of having extrapulmonary tuberculosis, appropriate specimens from the suspected sites of involvement should be obtained for microscopy and for culture and histopathological examination.

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Standards for Treatment



Treatment for tuberculosis is not only a matter of individual health; it is also a matter of public health. All providers must have the knowledge to prescribe a standard treatment regimen and the means to assess adherence to ensure that treatment is completed.

ISTC Standard 7

Any practitioner treating a patient for tuberculosis is assuming an important public health responsibility to prevent ongoing transmission of the infection and the development of drug resistance.

To fulfill this responsibility the practitioner must not only prescribe an appropriate regimen, but also utilize local public health services and other agencies, when necessary, to assess the adherence of the patient and to address poor adherence when it occurs

ISTC 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.



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ISTC Standard 8

The initial phase should consist of two months of isoniazid, rifampicin, pyrazinamide and ethambutol. The continuation phase should consist of isoniazid and rifampicin given for 4 months. The doses of antituberculosis drugs used should conform to international recommendations.

Fixed dose combinations (FDCs) of two (isoniazid and rifampicin), three (isoniazid, rifampicin, and pyrazinamide) and four (isoniazid, rifampicin, pyrazinamide, and ethambutol) drugs are highly recommended.



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ISTC Standard 9

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.



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ISTC Standard 9

Supervision and support should be individualized and should draw on the full range of recommended interventions and available support services, including patient counseling and education.



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ISTC Standard 9

- 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) and identification and training of a treatment supporter (for tuberculosis and, if appropriate, for HIV) who is acceptable and accountable to the patient and to the health system.
- Appropriate incentives and enablers, including financial support may also serve to enhance treatment adherence of 3

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ISTC Standard 10

Response to therapy in patients with pulmonary tuberculosis should be monitored by follow-up sputum microscopy (two specimens) at the time of completion of the initial phase of treatment (two months).

If the sputum smear is positive at completion of the initial phase, sputum smears should be examined again at 3 months and, if positive, culture and testing for resistance to isoniazid and rifampicin should be performed.



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ISTC Standard 10

In patients with extra-pulmonary tuberculosis and in children, the response to treatment is best assessed clinically.



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ISTC Standard 11

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.

Drug susceptibility testing should be performed at the start of therapy for all previously treated patients.

Patients who remain sputum smear positive at completion of 3 months of treatment and patients who have failed, defaulted from or relapsed following one or more courses of treatment should always be assessed for drug resistance.



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ISTC Standard 11

For patients in whom drug resistance is considered to be likely, culture and testing for susceptibility/resistance to at least isoniazid and rifampicin should be performed promptly.

Patient counseling and education should begin immediately to minimize the potential for transmission.

Infection control measures appropriate to the setting should be applied.



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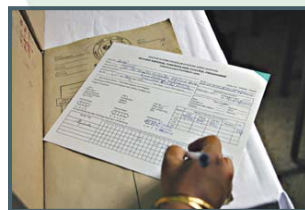
ISTC Standard 12

- Patients with or highly likely to have tuberculosis caused by drug-resistant (especially MDR/XDR) organisms should be treated with specialized regimens containing second-line anti-tuberculosis drugs. The regimen chosen may be standardized or based on suspected or confirmed drug susceptibility patterns.
- At least four drugs to which the organisms are known or presumed to be susceptible, including an injectable agent, should be used and treatment should be given for at least 18-24 months beyond culture conversion.
- Patient centered measures are required to ensure adherence. Consultation with a provider experienced in treatment of patients with MDR/XDR tuberculosis should be obtained.

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ISTC Standard 13

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



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Standards for Addressing HIV Infection and other Co-morbid Conditions



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ISTC Standard 14

- HIV testing and counseling should be recommended to all patients with, or suspected of having tuberculosis. Testing is of special importance as part of routine management of all patients in areas with a high prevalence of HIV infection in the general population, in patients with symptoms and/or signs of HIV-related conditions, and in patients having a history suggestive of high risk of HIV exposure.
- Because of the close relationship of tuberculosis and HIV infection, in areas of high HIV prevalence integrated approaches to prevention and treatment of both infections are recommended.



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ISTC Standard 15

- 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.
- However, initiation of treatment for tuberculosis should not be delayed.
- Patients with tuberculosis and HIV infection should also receive co-trimoxazole as prophylaxis for other infections.

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ISTC Standard 16

- Persons with HIV infection who, after careful evaluation, do not have active tuberculosis should be treated for presumed latent tuberculosis infection with isoniazid for 6-9 months.



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ISTC Standard 17

- All providers should conduct a thorough assessment for co-morbid conditions that could affect tuberculosis treatment response or outcome.
- At the time the treatment plan is developed, the provider should identify additional services that would support an optimal outcome for each patient and incorporate these services into an individualized plan of care.
- This plan should include assessment of and referrals for treatment of other illnesses with particular attention to those known to affect treatment outcome, for instance care for diabetes mellitus, drug and alcohol treatment programs, tobacco smoking cessation programs, and other psychosocial support services, or to such services as antenatal or well baby care.



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Standards for Public Health



The inability to conduct targeted contact investigations results in missed opportunities to prevent additional cases of TB, especially among children. Thus, more energetic efforts are necessary to overcome barriers to optimum TB control practices.

ISTC Standard 18

- All providers of care for patients with tuberculosis should ensure that persons who are in close contact with patients who have infectious tuberculosis are evaluated and managed in line with international recommendations.
- The determination of priorities for contact investigation is based on the likelihood that a contact: 1) has undiagnosed tuberculosis; 2) is at high risk of developing tuberculosis if infected; 3) is at risk of having severe tuberculosis if the disease develops; and 4) is at high risk of having been infected by the index case. The highest priority contacts for evaluation are:
 - Persons with symptoms suggestive of tuberculosis
 - Children aged <5 years
 - Contacts with known or suspected immunocompromise, particularly HIV infection
 - Contacts of patients with MDR/XDR tuberculosis
- Other close contacts are a lower priority group.

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ISTC Standard 19

Children <5 years of age and persons of any age with HIV infection who are close contacts of an infectious index patient and who, after careful evaluation, do not have active tuberculosis, should be treated for presumed latent tuberculosis infection with isoniazid.



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ISTC Standard 20

- Each health care facility caring for patients who have or are suspected of having infectious tuberculosis should develop and implement an appropriate tuberculosis infection control plan.

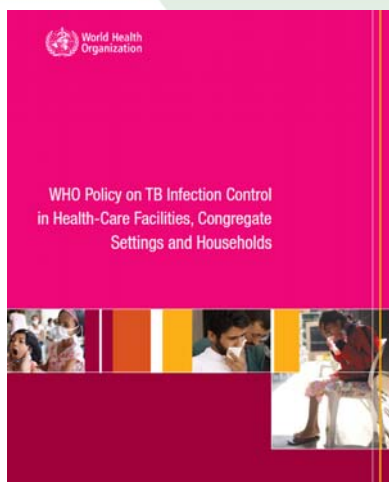


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ISTC Standard 20

- 2009 WHO policy on TB Infection Control



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ISTC Standard 21

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.



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TBCTA
 The Tuberculosis Coalition
 for Technical Assistance

Developed by the Tuberculosis Coalition
 for Technical Assistance (TBCTA)

TBCTA Partners:

- American Thoracic Society
- Centers for Disease Control and Prevention (US)
- Family Health International
- International Union Against Tuberculosis and Lung Diseases (The Union)
- Japan Antituberculosis Association
- KNCV Tuberculosis Foundation
- Management Sciences for Health
- World Health Organization



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