GUIDELINES

International Standards For Tuberculosis Care Diagnosis, Treatment and Public Health

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Nearly one third of the global population is infected with Mycobacterium tuberculosis and at risk of developing the disease. Annually more than eight million people develop active Tuberculosis (TB).Co-infection with human immunodeficiency virus (HIV) significantly increases the risk of developing TB.

In 2005 and 2006, the International Standards of Tuberculosis Care (ISTC) was developed in response to the need to unify approaches to tuberculosis care between private and public providers on an international level. In 2009 these Standards updated. A high standard of care is essential to restore the health of individuals with TB, and to prevent the disease in their families and others with whom they come into contact.

The purpose of the 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, TB. Standards differ from existing guidelines in that standards present what should be done, whereas, guidelines describe how the action is to be accomplished.

Twenty-one standards developed , standards 1 – 6 are standards for diagnosis , standards 7 – 13 are standards for treatment , standards 14 – 17 are standards for HIV and comorbid conditions ,and standards 18 – 21 are standards for public health

These ISTC are the following :

ISTC Standard 1; All persons with otherwise unexplained productive cough lasting two-three weeks or more should be evaluated for tuberculosis

ISTC Standard 2; All patients (adults, adolescents, and children who are capable of producing sputum) suspected of having pulmonary TB should have at least two sputum specimens obtained microscopic examination in a quality-assured laboratory. When possible, at least one early morning specimen should be obtained

ISTC Standard 3; For all patients (adults, adolescents, and children) suspected of having extrapulmonary TB, appropriate specimens from the suspected sites of involvement should be obtained for microscopy, culture, and histopathological examination.

ISTC Standard 4; All persons with chest radiographic findingssuggestive of tuberculosis should have sputum specimens submitted for microbiological examination.

ISTC Standard 5; The diagnosis of sputum smear-negative pulmonarytuberculosis should be based on the following criteria:

- At least two negative sputum smears (including at least one early morning specimen)
- Chest radiography findings consistent with tuberculosis
- 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 TB, a course of antituberculosis treatment should be initiated.

ISTC Standard 6; In all children suspected of having intrathoracic (i.e., pulmonary, pleural, and mediastinal or hilar lymph node) TB, 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 TB should be based on:

- The presence of abnormalities consistent with TB on chest radiography
- A history of exposure to an infectious case, evidence of TB infection (positive tuberculin skin test or interferon gamma-release assay), and
- Clinical findings suggestive of TB

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

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. The initial phase should consist of two months of isoniazid (INH), rifampicin (RIF), pyrazinamide (PZA), and ethambutol (EMB).

- The continuation phase should consist of isoniazid and rifampicin given for four months
- The doses of antituberculosis drugs used should conform to international recommendations
- Fixed-dose combinations (FDCs) of two (INH and RIF), three (INH, RIF, and PZA), and four (INH, RIF, PZA, and EMB) drugs are highly recommended

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 provider, should be developed for all patients.

Supervision and support should be individualized and 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 treatment or DOT) and identification and training of a treatment supporter (for TB 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

ISTC Standard 10; Response to therapy in patients with pulmonary tuberculosis should be monitored by follow-up sputum smear microscopy (2 specimens) at the time of completion of the initial phase of treatment (2 months).

If the sputum smear is positive at completion of the initial phase, sputum smears should be examined again at 3 months and, if possible, culture and drug susceptibility testing should be performed.

In patients with extrapulmonary TB and in children, the response to treatment is best assessed clinically.

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
- 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

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 antituberculosis 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, including observation of treatment, are required to ensure adherence
- Consultation with a provider experienced in treatment of patients with MDR/XDR tuberculosis should be obtained

ISTC Standard 13; A written record of all medications given, bacteriologic response, and adverse reactions should be maintained for all patients.

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 infections 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 TB and HIV infection, in areas of high HIV prevalence integrated approaches to prevention and treatment of both infections are recommended.

- 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 TB should not be delayed
- Patients with TB and HIV infection should also receive cotrimoxazole as prophylaxis for other infections

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

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

ISTC Standard 18; All providers of care for patients with TB should ensure that persons who are in close contact with patients who have infectious TB 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 TB

2) Is at high risk of developing TB if infected

3) Is at risk of having severe TB if the disease develops

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

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.

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.

References

1) International Standards of Tuberculosis Care ,2nd edition, 2009.

2) Facilitator's guide ,2nd edition, 2009.

3) Global tuberculosis report 2013 /WHO 2013.