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International Standard for Tuberculosis Care 2014

Standards for Diagnosis

Standard 1. To ensure early diagnosis, providers must be aware of individual and group risk factors for tuberculosis and perform prompt clinical evaluations and appropriate diagnostic testing for persons with symptoms and findings consistent with tuberculosis.

Standard 2. All patients, including children, with unexplained cough lasting two or more weeks or with unexplained findings suggestive of tuberculosis on chest radiographs should be evaluated for tuberculosis

Standard 3. All patients, including children, who are suspected of having pulmonary tuberculosis and are capable of producing sputum should have at least two sputum specimens submitted for smear microscopy or a single sputum specimen for Xpert® MTB/RIF* testing in a quality-assured laboratory.

Patients at risk for drug resistance, who have HIV risks, or who are seriously ill, should have Xpert MTB/RIF performed as the initial diagnostic test. Blood-based serologic tests and interferon-gamma release assays should not be used for diagnosis of active tuberculosis.

*As of this writing, Xpert®MTB/RIF (Cepheid Corp. Sunnyvale, California, USA) is the only rapid molecular test approved by WHO for initial use in diagnosing tuberculosis, thus, it is specifically referred to by its trade name throughout this document.

Standard 4. For all patients, including children, suspected of having extrapulmonary tuberculosis, appropriate specimens from the suspected sites of nvolvement should be obtained for microbiological and histological examination.

An Xpert MTB/RIF test is recommended as the preferred initial microbiological test for suspected tuberculous meningitis because of the need for a rapid diagnosis.

Standard 5. In patients suspected of having pulmonary tuberculosis whose sputum smears are negative, Xpert MTB/RIF and/or sputum cultures should be performed. Among smear- and Xpert MTB/RIF negative persons with clinical evidence strongly suggestive of tuberculosis, antituberculosis treatment should be initiated after collection of specimens for culture examination.

Standard 6. For 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 respiratory

secretions (expectorated sputum, induced sputum, gastric lavage) for smear microscopy, an Xpert MTB/RIF test, and/or culture.

Standards for Treatment

Standard 7. To fulfill her/his public health responsibility, as well as responsibility to the individual patient, the provider must prescribe an appropriate treatment regimen, monitor adherence to the regimen, and, when necessary, address factors leading to interruption or discontinuation of treatment. Fulfilling these responsibilities will likely require coordination with local public health services and/or other agencies.

Standard 8. All patients who have not been treated previously and do not have other risk factors for drug resistance should receive a WHO-approved first-line treatment regimen using quality assured drugs. 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 WHO recommendations. Fixed-dose combination drugs may provide a more convenient form of drug administration.
*Ethambutol may be omitted in children who are HIV-negative and who have non-cavitary tuberculosis.

Standard 9. A patient-centered approach to treatment should be developed for all patients in order to promote adherence, improve quality of life, and relieve suffering. This approach should be based on the patient’ s needs and mutual respect between the patient and the provider.

Standard 10. Response to treatment in patients with pulmonary tuberculosis (including those with tuberculosis diagnosed by a rapid molecular test) should be monitored by follow up sputum smear microscopy 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 microscopy should be performed again at 3 months and, if positive, rapid molecular drug sensitivity testing (line probe assays or Xpert MTB/RIF) or culture with drug susceptibility testing should be performed. In patients with extrapulmonary tuberculosis and in children, the response to treatment is best assessed clinically.

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 (if known), should be undertaken for all patients. Drug susceptibility testing should be performed at the start of therapy for all patients at a risk of drug resistance.
Patients who remain sputum smear-positive at completion of 3 months

of treatment, patients in whom treatment has failed, and patients who have been lost to follow up 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 an Xpert MTB/RIF test should be the initial diagnostic test. If rifampicin resistance is detected, culture and testing for susceptibility to isoniazid, fluoroquinolones, and second-line injectable drugs should be performed promptly. Patient counseling and education, as well as treatment with an empirical second-line regimen, should begin immediately to minimize the potential for transmission. Infection control measures appropriate to the setting should be applied.

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 quality-assured second-line antituberculosis drugs. The doses of antituberculosis drugs should conform to WHO recommendations.
The regimen chosen may be standardized or based on presumed or confirmed drug susceptibility patterns. At least five drugs, pyrazinamide and four drugs to which the organisms are known or presumed to be susceptible, including an injectable agent, should be used in a 6–8 month intensive phase, and at least 3 drugs to which the organisms are known or presumed to be susceptible, should be used in the continuation phase. 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 specialist experienced in treatment of patients with MDR/XDR tuberculosis should be obtained.

Standard 13. An accessible, systematically maintained record of all medications given, bacteriologic response, outcomes, and adverse reactions should be maintained for all patients.

Standards for Addressing HIV Infection and other Co-morbid Conditions

Standard 14. HIV testing and counseling should be conducted for all patients with, or suspected of having, tuberculosis unless there is a confirmed negative test within the previous two months. Because of the close relationship of tuberculosis and HIV infection, integrated approaches to prevention, diagnosis, and treatment of both tuberculosis and HIV infection are recommended in areas with high HIV prevalence. HIV 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 ofhigh risk of HIV exposure.

Standard 15. In persons with HIV infection and tuberculosis who have profound immunosuppression (CD4 counts less than 50 cells/mm3), ART should be initiated within 2 weeks of beginning treatment for tuberculosis unless tuberculous meningitis is present. For all other patients with HIV and tuberculosis, regardless of CD4 counts, antiretroviral therapy should be initiated within 8 weeks of beginning treatment for tuberculosis. Patients with tuberculosis and HIV infection should also receive cotrimoxazole as prophylaxis for other infections.

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 at least 6 months.

Standard 17. All providers should conduct a thorough assessment for co-morbid conditions and other factors that could affect tuberculosis treatment response or outcome and identify additional services that would support an optimal outcome for each patient. These services should be incorporated into an individualized plan of care that includes assessment of and referrals for treatment of other illnesses. Particular attention should be paid to diseases or conditions known to affect treatment outcome, for example, diabetes mellitus, drug and alcohol abuse, undernutrition, and tobacco smoking.
Referrals to other psychosocial support services or to such services as antenatal or well-baby care should also be provided.

Standards for Public Health and Prevention

Standard 18. All providers should ensure that persons in close contact with patients who have infectious tuberculosis are evaluated and managed in line with international recommendations. The highest priority contacts for evaluation are:
- Persons with symptoms suggestive of tuberculosis
- Children aged <5 years
- Contacts with known or suspected immunocompromised states, particularly HIV infection.
- Contacts of patients with MDR/XDR tuberculosis

Standard 19. Children <5 years of age and persons of any age with HIV infection who are close contacts of a person with infectious tuberculosis, and who, after careful evaluation, do not have active tuberculosis, should be treated for presumed latent tuberculosis infection with isoniazid for at least six months.

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 to minimize possible

transmission of M. tuberculosis to patients and health care workers.

Standard 21. All providers must report both new and re-treatment tuberculosis cases and their treatment outcomes to local public health authorities, in conformance with applicable legal requirements and policies.