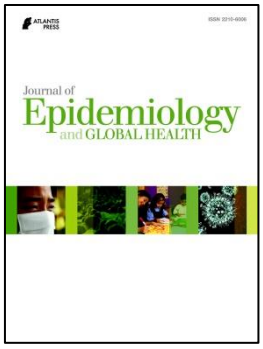

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EDITORIAL

Improving the quality of tuberculosis care: We need standards and strategies to translate them into practice

In 2012, an estimated 8.6 million people developed tuberculosis (TB), and 1.3 million died because of TB [1]. In their most recent Global TB Report, the World Health Organization (WHO) raised two major concerns for TB control. First, of the estimated 8.6 million cases, nearly 3 million cases were deemed 'missing' either because they were not diagnosed or not notified to health systems. Secondly, the alarming rise of multidrug-resistant TB (MDR-TB), where a majority of cases with MDR-TB are still not being detected [1].

Undiagnosed cases and mismanaged patients are powerful drivers of the global TB epidemic, and are strongly associated with risk of mortality and drug-resistance. The WHO report also raised concern over too many TB patients not getting the high quality TB care that they deserve. This is especially true in the private sector, which is a dominant provider of medical care in many countries [2,3].

All patients with TB, regardless of where they live or who they seek care from, should receive the same quality of care, backed by sound evidence. And patients with TB need an early and accurate diagnosis, including screening for drug-resistance; rapid initiation on an internationally-recommended drug combination with quality-assured drugs; adequate counseling about issues such as medication adherence, side effects of drugs, and diet; and a customized package of measures that can support the patient during 6 months of treatment.

First published in 2006, the International Standards of TB Care (ISTC) outlined the standards for quality TB care [4]. ISTC was envisioned to be a living document, and would stay abreast of new advances and policies. The 2nd Edition of ISTC was published in 2009, and the 3rd Edition was published on World TB Day 2014 [5].

The standards in the ISTC are all supported by existing WHO guidelines, backed by evidence from systematic reviews. The 3rd Edition of ISTC has been endorsed by organizations that include the WHO, the American Thoracic Society, FHI 360, Japan Anti-tuberculosis Association, KNCV Tuberculosis Foundation, Management Sciences for Health, and the International Union against Tuberculosis and Lung Disease [5].

The ISTC standards describe a widely accepted level of care that all practitioners, public or private, should seek to achieve in managing patients who have TB, or are suspected of having TB. The 21 Standards included in the 3rd Edition of ISTC are as follows.

1. Standards for diagnosis

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

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

Standard 3. All patients, including children, who are suspected of having pulmonary TB 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 (Cepheid Inc., California) testing in a

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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 TB.

Standard 4. For all patients, including children, suspected of having extrapulmonary TB, appropriate specimens from the suspected sites of involvement 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 TB 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 TB, anti-tuberculosis 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) TB, 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.

2. 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 the 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 who 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 anti-tuberculosis drugs used should conform to WHO recommendations. Fixed dose combination drugs may provide a more convenient form of drug administration.

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 TB (including those with TB 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 (2 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 TB and in children, the response to treatment is best assessed clinically.

Standard 11. An assessment of the likelihood of drug-resistance, based on a 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 the 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 TB caused by drug-resistant (especially MDR/XDR) organisms should be treated with specialized regimens containing quality-assured second-line anti-tuberculosis drugs. The doses of anti-tuberculosis 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 are 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 are 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 the treatment of patients with MDR/XDR TB 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.

3. 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, TB unless there is a confirmed negative test within the previous two months. Because of the close relationship of TB and HIV infection, integrated approaches to prevention, diagnosis and treatment of both TB 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 of high risk of HIV exposure.

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

Standard 16. Persons with HIV infection who, after careful evaluation, do not have active TB should be treated for presumed latent TB 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 TB 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.

4. Standards for public health and prevention

Standard 18. All providers should ensure that persons in close contact with patients who have infectious TB are evaluated and managed in line with international recommendations. The highest priority contacts for evaluation are: (1) Persons with symptoms suggestive of TB; (2) Children aged <5 years; (3) Contacts with known or suspected immunocompromised states, particularly HIV infection; and (4) Contacts of patients with MDR/XDR TB.

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

Standard 20. Each healthcare facility caring for patients who have or are suspected of having infectious TB should develop and implement an appropriate TB infection control plan to minimize possible transmission of *M. tuberculosis* to patients and healthcare workers.

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

5. Translation of standards into practice

While the updated, 3rd edition of ISTC is a welcome development, its impact will depend on adequate dissemination, implementation, and evaluation. To begin with, national or regional adaptations of the ISTC can help, such as the European Union Standards for TB Care [6], and Standards of TB Care in India [7]. Engagement of and endorsement by chest societies and private sector physician associations may also help local uptake. Indeed, the ISTC has been endorsed by many national and regional professional societies.

ISTC training sessions have been organized in several countries, and training materials and modules are freely available (www.istcweb.org), but to reach general physicians and care providers at the

lowest level (e.g., informal providers, non-allopathic practitioners), simplification of the ISTC document is necessary to make the standards less academic and more practical. Mobile phone versions of the most critical elements of ISTC might help expand the reach, and this is now available.

Since chest physicians and pulmonologists are often key opinion makers in their local medical communities and social networks, their active involvement in training (e.g., as master trainers) might have a positive influence on general practitioners who look up to them for continuing education. Managed care organizations and health insurance programs could consider reimbursing physicians who explicitly document TB care that is in line with ISTC.

In unregulated private markers, where private practitioners are rarely engaged with the TB control program, there is a need for intermediary agencies or social enterprises that can liaise between the private sector and the national TB programs. In India, a ''Private Provider Interface Agency'' (PPIA) model is now being tried out on a pilot basis [8]. PPIAs are agencies that aggregate healthcare providers, educate them on standards for TB care, incentivize them to diagnose and treat TB as per established standards, monitor adherence to the standards, and use information and communication technologies to notify cases, improve treatment adherence, and make performance-based payments.

Lastly, there is a need to develop systems to assess quality of TB care as a key indicator in global TB control [9]. Recently, standardized patients (mystery clients) were used in India to examine quality of care for angina, asthma and dysentery [10]. In this study, correct diagnoses were rare, and incorrect treatments were widely prescribed, in the private, informal and public sectors. Unlike prescription audits and hypothetical vignettes, which measure clinical knowledge and competence, the standardized patient approach has been shown to accurately assess provider practice (i.e., what physicians actually do). Efforts are now under way to evaluate the standardized patient approach to assessment of quality of TB care in India, and will, hopefully, pave the way for such work in other countries.

Overall, there is much work to be done to improve the quality of TB care. Initiatives like the ISTC need to be combined with good dissemination and translational work at the country level (e.g., PPIA model in India), coupled with sound measurement approaches (e.g., standardized patients) to see whether standards can actually change practice and improve patient outcomes.

6. Disclosure

The author was involved in the development of all three editions of the International Standards of TB Care. He has no financial or industry conflicts.

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