Indian J Med Res 125, April 2007, pp 491-497

Editorial

Are we providing quality care to our patients with tuberculosis ?

Tuberculosis (TB) remains a significant global health concern, despite the substantial progress made over the past decade[1-4]. Every year, nearly 9 million new cases of TB are reported, and nearly 2 million people die of this curable disease[1,2]. The number of TB cases that occur in the world each year is still growing, although the rate of increase is slowing[1,2]. The failure to fully engage and involve all health care providers in the delivery of high quality TB care is probably one reason that accounts for these worrisome global trends.

Over the past decade, there has been a slow but steadily growing recognition of the importance of the private sector in provision of health care. In many parts of the world, private health care providers are involved in the diagnosis and treatment of TB[5-8]. This is especially true in India, where the private health care sector is dominant, and, largely unregulated. In India, more than half of all TB patients seek TB care from the private health sector, although this figure may vary considerably across the country[9]. In addition, traditional healers, family physicians, chest physicians, medical college faculty, unlicensed practitioners, practitioners of alternative medicine, community health workers, and non governmental organizations (NGOs) all play important roles in provision of TB care. For a long time, the private sector was ignored by government-sponsored national disease control programmes in India. This, however, has changed in recent times, with a lot more emphasis on public-private mix (PPM) and partnerships involving multiple sectors[9]. Indeed, engagement of all providers is an essential component of the new Stop TB strategy, including the Global Plan to Stop TB (2006-2015)[10].

While it is laudable that TB care is available from a variety of sources and health care providers, are TB patients getting quality care from all types of providers? Unfortunately, available data suggest that in many instances the services are of poor and highly variable quality. In 1999, the World Health Organization (WHO) conducted a global survey of 23 countries, to study the involvement of private sector in TB care[5]. This survey, as well as other studies, show that providers who work in the private sector often deviate from standard, internationally recommended, TB care practices[5-9]. For example, these deviations include underutilization of sputum smears for diagnosis, excessive use of chest radiography, use of non recommended drug regimens, use of incorrect combinations of drugs, errors in both drug dosage and duration of treatment, and failure to assure adherence to treatment[5-9]. These findings suggest that substandard TB care is common, especially among poor and vulnerable populations that are least able to bear the consequences of suboptimal care[11]. Substandard quality of care is by no means restricted to the private sector; chronically under-funded, crowded, and poor staffed public hospitals are seldom able to deliver high quality care.

Any discussion on quality of care invariability provokes the question: what is quality TB care and how will we know if TB care is “substandard”? Defining quality of care is not easy, but one popular

definition is that of the Institute of Medicine (IOM) in the US: *"the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge"*[12]. The basic principles of care for persons with, or suspected of having, TB are the same worldwide: a diagnosis should be established promptly and accurately; standardized treatment regimens of demonstrated efficacy should be used, together with appropriate treatment supervision; the response to treatment should be monitored; and the essential public health functions must be carried out. These principles are consistent with current professional knowledge, and if not implemented, will likely result in poor patient outcomes such as relapse or death, continued transmission of *Mycobacterium tuberculosis* in the community, and development of drug resistance.

One recent effort to set standards for quality in TB care is the "International Standards for Tuberculosis Care (ISTC)", released as a report on World TB Day 2006[13], and subsequently published in the *Lancet Infectious Diseases*[14]. Since its release, the ISTC has been widely publicized through several websites (listed at the end of this article), editorials and commentaries[15-18], translated in several languages, and endorsed by more than 30 international and national agencies and organizations, including the WHO, the Stop TB Partnership, the American Thoracic Society (ATS), the US Centers for Disease Control and Prevention (CDC), and the International Union against TB and Lung Disease (IUATLD). In India, the ISTC has been endorsed by the Indian Medical Association (IMA) and has been incorporated into training materials of the Revised National Tuberculosis Control Programme (RNTCP).

The ISTC release was the end result of an year long international effort to develop and set internationally acceptable, evidence-based standards for TB care. The ISTC describes a widely endorsed level of care that all practitioners, public and private, should seek to achieve in managing individuals who have, or are suspected of having, TB and is intended to facilitate the effective engagement of all health care providers in delivering high quality care for all TB patients[13,14]. The ISTC was developed by a multi-disciplinary team by examining existing guidelines, recommendations and research evidence and, where evidence was lacking, conducting rigorous systematic reviews. The result was agreement on a group of 17 standards addressing diagnosis, treatment, and public health responsibilities (Annexure)[13,14].

With the availability of a globally applicable and widely endorsed set of international standards, the ISTC now helps us tackle the question of what is quality TB care and how we can identify care that is "substandard"? It also helps us revisit the question we began with – are we providing quality care to our patients with TB? These questions, ultimately, will have to be answered at an individual provider level. Thus, we encourage every health care provider who manages TB patients to use these standards as a checklist and find out for themselves if their practice matches up to the ISTC standards.

Using the annexure as a checklist, each provider should be able to identify areas where their practice is in compliance with the ISTC, and perhaps also identify areas where their practice falls short of the ISTC. For example, providers who do not routinely request at least two sputum smears on patients with suspected TB will fall short of Standard 2 which states that "all patients suspected of having pulmonary TB should have at least two, and preferably three, sputum specimens obtained for microscopic examination"[13,14]. Similarly, practitioners who do not maintain medical records of the care they provide will fall short of Standard 11 which states that "a written record of all medications given, bacteriological response and adverse reactions should be maintained for all patients"[13,14]. Clearly, providers who meet all 17 standards should be providing quality care, and such providers have every reason to be proud of their work

and commitment to patient welfare. Indeed, every provider who cares for TB patients should aspire to meet all 17 standards and do the best they can for their patients.

What role do patients play in their own care? Patients have to be responsible as well, and their roles, rights and responsibilities have been laid out in the newly developed *Patient's Charter for Tuberculosis Care*[19]. Developed in tandem with the ISTC, the Patient's Charter empowers people with the disease and their communities through this knowledge. Initiated and developed by patients from around the world, the Patient's Charter makes the relationship with health care providers a mutually beneficial one[19].

In 2006, the global TB community sounded alarm over a new threat — extensively drug-resistant tuberculosis (XDR-TB)[20]. XDR-TB is defined as TB resistant to at least isoniazid and rifampicin (which is the definition of MDR-TB) in addition to any fluoroquinolones, and to at least on of three injectable second-line anti-TB drugs (*i.e.*kanamycin, amikacin and capreomycin). Because XDR-TB is resistant to several first- and second-line drugs, treatment options are seriously limited, and mortality rates are extremely high. Thus, prevention of MDR and XDR-TB must receive more emphasis than treatment.

While the true extent of the XDR-TB problem is still unclear, what is evident is that had quality care been provided in the areas where XDR-TB is emerging, this major threat may not have arisen. The emergence of XDR-TB is a strong sign that proper standards of TB care are far from being universally applied[21]. Thus, as emphasized by the Global Task Force on XDR-TB, countries should attempt to prevent XDR-TB by ensuring that the work of all providers caring for people with TB is carried out according to the International Standards for TB Care[20].

In conclusion, we now live and practice medicine in the era of XDR-TB. Given this threat of virtually incurable TB, it is critical that we ask the question "are we providing quality care to our TB patients?" Without widespread provision of quality care, we may see a rapid spread of XDR-TB which will overwhelm our already stretched healthcare delivery system. Now more than ever, our TB patients need us to practice the best medicine we can.

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Annexure. International Standards for Tuberculosis Care: a checklist to verify if your practice matches up to the international standards

Standard No.	Description of the standard	Does my clinical practice match up to this standard? (Yes or No)
Standards for diagnosis		
Standard 1	All persons with otherwise unexplained productive cough lasting > 2–3 wk should be evaluated for TB.	
Standard 2	All patients (adults, adolescents and children who are capable of producing sputum) suspected of having pulmonary TB 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 TB, 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 TB should have sputum specimens submitted for microbiological examination.	
Standard 5	The diagnosis of sputum smear-negative pulmonary TB 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 TB; and lack of response to a trial of broad-spectrum antimicrobial agents. (Since fluoroquinolones are active against *M. tuberculosis* complex, and thus may cause transient improvement in persons with TB, they should be avoided). For such patients, if facilities 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) TB in symptomatic children with negative sputum smears should be based on the finding of chest radiographic abnormalities consistent with TB and either a history of exposure to an infectious case or evidence of TB 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.	
Standard for Treatment		
Standard 7	Any practitioner treating a patient for TB 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 2 months of isoniazid, rifampicin, pyrazinamide and ethambutol. The preferred continuation phase consists of isoniazid and rifampicin given for 4 months. Isoniazid and ethambutol given for 6 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 anti-TB 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 sex 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 (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 TB by follow-up sputum microscopy (two specimens) at least at the time of completion of the initial phase of treatment (2 months), at 5 months and at the end of treatment. Patients who have positive smears during the 5th month of treatment should be considered as treatment failures and have therapy modified appropriately (see standards 14 and 15). In patients with extrapulmonary TB 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, bacteriological 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 TB and HIV infection are likely to co-exist, HIV counseling and testing are indicated for all TB patients as part of their routine management. In areas with lower prevalence rates of HIV, HIV counseling and testing are indicated for TB patients with symptoms and/or signs of HIV-related conditions and in TB patients having a history suggestive of high risk of HIV exposure.

Standard 13 All patients with TB and HIV infection should be evaluated to determine if antiretroviral therapy is indicated during the course of treatment for TB. Appropriate arrangements for access to antiretroviral drugs should be made for patients who meet indications for treatment. Given the complexity of co-administration of anti-TB 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 TB should not be delayed. Patients with TB 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 TB caused by drug-resistant (especially MDR) organisms should be treated with specialized regimens containing second-line anti-TB 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 $\geq$18 months. Patient-centered measures are required to ensure adherence.

Consultation with a provider experienced in treatment of patients with MDR-TB should be obtained.

Standards for public health responsibilities

Standard 16 All providers of care for patients with TB should ensure that persons (especially children aged <5 yrs and persons with HIV infection) who are in close contact with patients who have infectious TB are evaluated and managed in line with international recommendations. Children aged <5 yrs 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 TB.

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

Source: Tuberculosis Coalition for Technical Assistance. *International Standards for Tuberculosis Care (ISTC)*. The Hague: Tuberculosis Coalition for Technical Assistance, 2006[13]

TB: tuberculosis; DOT: directly observed therapy; MDR: multidrug resistant.

Additional sources:

The International Standards for Tuberculosis Care report can be freely downloaded from several websites, including Stop. TB: *http://www.stoptb.org/resource_center/assets/documents/istc_report.pdf*, WHO: *http://www.who.int/tb/publications/2006/istc/en/index.html*. TBC India (RNTCP): *http://www.tbcindia.org / pdfs / Summary % 2of % 20ISTC.pdf*. The abbreviated publication (Hopewell *et al. Lancet Infect Dis* 2006; *6* : 710-25) can be downloaded freely from the Lancet website: *http://www.thelancet.com/journals/laninf*. The Patient's Charter for Tuberculosis Care document can be freely downloaded from: *http://www.worldcarecouncil.org/* and *http://www.nationaltbcenter.edu/international*