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EDITORIAL

# Improving the TB case management: the International Standards for Tuberculosis care

**G.B. Migliori*, P.C. Hopewell#, F. Blasi¶, A. Spanevello+ and M.C. Raviglione§**

Tuberculosis (TB) is currently the leading cause of death from a curable infectious disease [1]. The World Health Organization (WHO) estimates that 8.9 million new TB cases occurred in 2004 (of which 3.9 million were sputum smear positive), although only about half of the estimated number were reported by public health systems [1, 2].

Whilst the highest TB incidence rate is in sub-Saharan Africa (estimated to be 356 new cases per 100,000 population per yr), in most countries of the former Soviet Union the estimated incidence rate exceeds 100 new cases per 100,000 population per yr [1, 2].

Although the rate of increase in the TB incidence rate is decreasing, the global TB notification grew by 1% between 2003 and 2004, the last year for which data are available. This continued increase is largely the result of the striking increase in cases in sub-Saharan Africa and, to a lesser extent, in the former USSR. Whilst the worsening of the TB incidence in Africa is due to the HIV epidemic compounded by an insufficient health infrastructure, it is due to different causes in Eastern Europe, including economic decline, increased poverty, social disruption and sub-standard health services. In addition, as a result of these factors, >10% of new TB cases in the Baltic states and in some parts of Russia are multidrug-resistant (MDR-TB), *i.e.* resistant to at least isoniazid and rifampicin [3].

In the European region, 445,000 new TB cases and nearly 70,000 deaths were estimated to have resulted from TB in 2004. In the Eastern part of the region, the levels of directly observed treatment, short-course (DOTS) strategy coverage and case detection are the lowest among the world regions, and the overall treatment success rate is the second lowest (75%) after Africa [2].

## THE NEW STOP TB STRATEGY FOR TB CONTROL

The DOTS strategy (composed of five key elements: government commitment, bacteriological diagnosis, standardised and supervised treatment, uninterrupted drug supply, and regular programme monitoring) has greatly contributed to improved global TB control during the past decade [4, 5]. As of the end of 2004, 183 countries had adopted DOTS, and the latest performance assessments show that the global case detection rate was 53% (cases notified/estimated number of cases) in 2004, and the percentage of patients treated successfully was 82% in the 2003 cohort.

Several examples of country success stories have been reported, including China (significant reduction in the prevalence of pulmonary, smear-positive and culture-positive TB) [6], Peru (incidence of TB declining 6% per annum after DOTS introduction) [7], India (600,000 additional lives saved during the first 8 yrs of DOTS implementation), Cuba, Tanzania and Malawi among others [4].

However, for a variety of reasons, DOTS has not been sufficient to control the epidemic in sub-Saharan Africa or Eastern Europe. To address these and other challenges to TB care and control, the WHO developed a broader approach that is embodied in the new Stop TB Strategy. The new strategy, while keeping DOTS as the first and foremost of its six components [5], has made explicit five additional components that must be implemented to reach the 2015 Millennium Development Goals relevant to TB. These have the following aims: 1) to pursue high-quality DOTS expansion and enhancement; 2) to address TB/HIV, MDR-TB and other challenges; 3) to contribute to health system strengthening; 4) to engage all care providers; 5) to empower people with TB, and communities; and 6) to enable and promote research.

Within these six components, the engagement of all care providers is of utmost importance and deserves emphasis. Many patients with symptoms caused by what ultimately is proven to be TB initially seek care in the private sector and many private providers both diagnose and treat the disease. Relying solely on governmental services in many areas greatly limits TB control efforts. Since prompt, accurate diagnosis and effective treatment to cure are the core elements of TB control, it is essential that all practitioners who provide TB services do so in an effective manner in conformance with international standards.

## THE *INTERNATIONAL STANDARDS FOR TUBERCULOSIS CARE*

The *International Standards for Tuberculosis Care (ISTC)* document [8] has been developed as a tool that can be used to unify public and private sectors in providing high-quality care for TB. The *ISTC* is intended to facilitate the effective delivery of high-quality care for all patients regardless of age or sex,

*WHO Collaborating Center for Tuberculosis and Lung Diseases, Fondazione S. Maugeri, Care and Research Institute, Tradate, ¶Istituto Malattie Respiratorie, Università degli Studi di Milano, Padiglione Sacco, Ospedale Maggiore Milano, IRCCS Fondazione Policlinico-Mangiagalli-Regina Elena, Milan, and +University of Foggia, Fondazione S. Maugeri, Cassano Delle Murge, Bari, Italy. #Francis J Curry National Tuberculosis Center, University of California, San Francisco, CA, USA. §Stop TB Dept, World Health Organization, Geneva, Switzerland.

CORRESPONDENCE: G.B. Migliori, WHO Collaborating Centre for Control of Tuberculosis and Lung Diseases in Europe, Fondazione Salvatore Maugeri, Care and Research Institute, via Roncaccio 16, 21049 Tradate, Italy. Fax: 39 0331829402. E-mail: gbmigliori@fsm.it

**TABLE 1** The International Standards for Tuberculosis Care

| Standards | |
|---|---|
| **Standards for diagnosis** | |
| Standard 1 | All persons with otherwise unexplained productive cough lasting ⩾2–3 weeks 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 |
| **Standards for treatment** | |
| Standard 7 | Any practitioner treating a patient for TB is assuming an important public health responsibility. To fulfil 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 (or rifampin) 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-centred 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 counselling and education. A central element of the patient-centred 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 counselling and testing are indicated for all TB patients as part of their routine management. In areas with lower prevalence rates of HIV, HIV counselling 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 |

**TABLE 1** Continued

| Standards | |
|---|---|
| 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 specialised 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 $\geqslant$18 months. Patient-centred 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 |

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

including the ''complicated'' cases, *i.e.* those who are sputum smear negative, have extrapulmonary sites of disease, and those who are affected by MDR-TB or co-infected with HIV. They are designed to put the patient at the centre of care and the healthcare provider at the centre of TB control. As summarised in table 1, the document includes six standards for diagnosis, nine standards for treatment and two standards addressing public health responsibilities.

As accurate diagnosis and effective treatment are the core of both TB care and TB control, any clinician providing TB services to individual patients is, by definition, assuming an important public health function as well as providing individual patient care. Thus, at the centre of the *ISTC* is the notion of both individual and public health responsibility. The *ISTC* emphasises that TB diagnosis should be promptly and adequately established, based, whenever possible, on bacteriological evidence. Internationally recommended treatment regimens of proven quality should be prescribed, using the recommended doses, and for the recommended duration, with appropriate treatment support and supervision. The response to treatment should be monitored and microbiological examinations performed after the initial intensive phase of treatment, after 5 months and at the end of treatment. The essential public health responsibilities are to be fully satisfied, including evaluation and management of close contacts, as well as case notification and reporting of new cases and treatment outcomes.

The *ISTC*, in underlining the importance of these essential care operations, is fully consistent with WHO recommendations, as described in a number of guidelines published over the years, and complementary to local and national TB control policies. The *ISTC* document is also consistent with European Respiratory Society guidelines [9, 10].

Although the *ISTC* is evidence based and widely accepted, it is only a tool, not an end in itself. To achieve adherence to the *ISTC*, it is critical that it has sufficient ''weight'' to wield influence and that it is disseminated to relevant practitioners. This can best be achieved by having the broad endorsement of influential medical and nursing professional societies, both national and international, and that these societies develop educational activities based on the *ISTC*. Of key importance is the close collaboration with the national TB programme and the synergistic attempt to include the *ISTC* among the basic tools required for the proper implementation of public–private mix DOTS approaches.

Each healthcare provider in Europe (chest physicians and infectious disease specialists, in particular) should have a copy of the *ISTC* on his/her desk, hopefully translated by an appropriate national professional society or national programme in his/her native language. This will help to improve the quality of care of all TB cases and increase the proportion of cases successfully treated, while, at the same time, achieve the national programme targets for TB control.

The complete English versions of the *International Standards for Tuberculosis Care* and The Patients' Charter for Tuberculosis Care (outlining the rights and responsibilities of people with tuberculosis) are available at www.worldcarecouncil.org.

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