HANDBOOK FOR USING THE

International Standards for Tuberculosis Care

Developed by the Tuberculosis Coalition for Technical Assistance (TBCTA)

TBCTA
The Tuberculosis Coalition for Technical Assistance

TBCTA Partners:

American Thoracic Society
Centers for Disease Control and Prevention (US)
Family Health International
International Union Against Tuberculosis and Lung Diseases (The Union)
Japanese Antituberculosis Association
KNCV Tuberculosis Foundation
Management Sciences for Health
World Health Organization

Funded by the United States Agency for International Development (USAID)

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Additional support provided by the Stop TB Partnership

Stop TB Partnership

Development coordinated by the American Thoracic Society

AMERICAN THORACIC SOCIETY 1905 ATS

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Suggested Citation:

Tuberculosis Coalition for Technical Assistance. *Handbook for Using the International Standards for Tuberculosis Care*. Tuberculosis Coalition for Technical Assistance. The Hague, 2007.

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Cover photo: Dr. L.S. Chauhan, NTP Manager, India, releasing balloons at the World TB Day celebration, India Gate, New Delhi, March 24, 2007.

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Acknowledgments

The *International Standards for Tuberculosis Care (ISTC)* was developed by the Tuberculosis Coalition for Technical Assistance and funded by the United States Agency for International Development.

Additional support was provided by the Stop TB Partnership Advocacy, Communications, and Social Mobilization Working Group, Sub Group on ACSM at the Country Level.

Guidance for using the *ISTC* is based largely on experience gained in five countries: India, Indonesia, Kenya, Mexico and Tanzania. Directors of the national tuberculosis programs in these countries, together with private sector collaborators, agreed to use the *ISTC* to address particular situations or problems encountered in their countries and to document their experiences. Perhaps the most important lesson learned from the pilot countries is that there is no substitute for in-country experience. We are very appreciative of our collaborators and would like to acknowledge their contributions.

India
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Tanzania
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We would also like to acknowledge the national tuberculosis programs of the pilot countries, the professional societies involved, and the World Health Organization.

The Handbook was written by Elizabeth Fair, PhD, MPH and Philip Hopewell, MD, with substantial input from our country collaborators.

Development of the document was coordinated by Fran DuMelle, American Thoracic Society.

List of Abbreviations

ATS	American Thoracic Society
CME	Continuing Medical Education
DOT	Directly Observed Treatment
DOTS	The internationally recommended tuberculosis control strategy
GFATM	Global Fund to Fight AIDS, Tuberculosis, and Malaria
HIV	Human Immunodeficiency Virus
IMA	Indian Medical Association
IMPACT	Indian Medical Professional Associations Coalition against Tuberculosis
ISTC	*International Standards for Tuberculosis Care*
KAPTLD	Kenya Association for the Prevention of Tuberculosis and Lung Diseases
MDG	Millennium Development Goals
MDR-TB	Multi-drug Resistant Tuberculosis
MUCHS	Muhimbili University College of Health Sciences (Tanzania)
NGO	Nongovernmental Organization
NTP	National Tuberculosis Program
PPM DOTS	Public-Private Mix DOTS
RNTCP	Revised National Tuberculosis Control Program (India)
TB	Tuberculosis
TBTCA	Tuberculosis Coalition for Technical Assistance
TB/HIV	Tuberculosis combined with HIV infection
USAID	United States Agency for International Development
WHO	World Health Organization

International Standards for Tuberculosis Care (ISTC)

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 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 two months of isoniazid, rifampicin, pyrazinamide and ethambutol. The preferred continuation phase consists of isoniazid and rifampicin given for four months. Isoniazid and ethambutol given for six 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-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 (two months), at five months and at the end of treatment. Patients who have positive smears during the fifth 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 ≥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.

Training of private providers organized by the IMA in Kerala, India

Purpose and Development of the ISTC

The ISTC has been endorsed by more than 40 national and international organizations, both public and private, concerned with tuberculosis care and control.

The *International Standards for Tuberculosis Care (ISTC)* presents a set of widely-accepted, evidence-based standards that all practitioners, public and private, should seek to achieve. Because the purpose of the *ISTC* is to describe a widely accepted level of care that all practitioners should seek to achieve in managing all patients, the audience for the document is all healthcare practitioners, public and private. The scope of the *ISTC* is diagnosis, treatment, and public health responsibilities and it is intended to complement, not replace, local, national, and international guidelines.

A high standard of care is essential to restore the health of individuals with tuberculosis, to prevent the disease in their families and others with whom they come into contact, and to protect the health of communities.[1] Substandard care will result in poor patient outcomes, continued infectiousness with transmission of *M. tuberculosis* to family and other community members, and generation and propagation of drug resistance.

It is widely recognized that many providers are involved in the diagnosis and treatment of tuberculosis.[2-5] Traditional healers, general and specialist physicians, nurses, clinical officers, academic physicians, unlicensed practitioners, physicians in private practice, practitioners of alternative medicine, and community organizations, among others, all play roles in tuberculosis care. In addition, public providers not working in tuberculosis control programs, such as those working in prisons, army hospitals, or public hospitals and facilities, regularly evaluate persons suspected of having tuberculosis and treat patients who have the disease.

Little is known about the adequacy of care delivered by non-program providers, but evidence from studies conducted in many different parts of the world show great variability in the quality of tuberculosis care, and poor quality care continues to plague global tuberculosis control efforts.[1] A global situation assessment conducted by WHO suggested that delays in diagnosis were common.[4] The delay was more often in receiving a diagnosis

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rather than in seeking care, although both elements are important.[6] This survey and other studies also show that clinicians, in particular those who work in the private healthcare sector, often deviate from standard, internationally recommended, tuberculosis management practices.[3,4] These deviations include under-utilization of sputum microscopy for diagnosis, generally associated with over-reliance on radiography, use of non-recommended drug regimens with incorrect combinations of drugs and mistakes in both drug dosage and duration of treatment, and failure to supervise and assure adherence to treatment.[3,4,7-13] Anecdotal evidence also suggests over-reliance on poorly validated or inappropriate diagnostic tests such as serologic assays, often in preference to conventional bacteriological evaluations.

Together, these findings highlight flaws in healthcare practices that lead to substandard tuberculosis care for populations that are most vulnerable to the disease and are least able to bear the consequences of such systemic failures. Any person anywhere in the world who is unable to access quality health care should be considered vulnerable to tuberculosis and its consequences.[1] Likewise, any community with no or inadequate access to appropriate diagnostic and treatment services for tuberculosis is a vulnerable community.[1]

The adequacy of care for patients with tuberculosis is the major determinant of the effectiveness of tuberculosis control: control cannot be adequate if care is not adequate. For this reason, as well as because of concern for the welfare of individual patients, all tuberculosis control programs should be committed to ensuring that tuberculosis services in their jurisdictions are of the highest possible quality within the limits of local circumstances.

New tuberculosis guidelines, recommendations, and manuals are frequently produced, yet few if any of these focus on tuberculosis **care** rather than tuberculosis **control** and on the essential interactions between care and control. In addition, none of the existing documents is supported by a broad international consensus, and most present the imperative steps to be followed for tuberculosis control and do not present the supporting evidence base for these steps. Additionally, quite commonly, guidelines developed by tuberculosis control programs, even with private sector involvement, are viewed as government documents, and therefore, not relevant to practitioners in the private sector. Finally, no other document to date specifically focuses on a global effort to improve tuberculosis care and control through effective private sector involvement.

To provide new recommendations to meet these needs, a steering committee, consisting of 28 members from 14 different countries, developed the ISTC. Members of the steering committee were selected to provide perspectives from a variety of fields and sectors rather than to represent specific organizations. Standards for tuberculosis diagnosis, treatment, and the public health responsibilities inherent in tuberculosis care were drafted, and the scientific evidence for each standard was reviewed. Where evidence was lacking, new systematic reviews (six in total) were conducted. After extensive review by the Tuberculosis Coalition for Technical Assistance (TBCTA) organizations and substantial input by individuals, the *ISTC* and *The Patients' Charter for Tuberculosis Care* (the *Charter*) were finalized in December 2005 and launched on World TB Day 2006.

Subsequently, the *ISTC* has been endorsed by more than 40 national and international organizations, both public and private, concerned with tuberculosis care and control. A list of endorsing organizations is available on the *ISTC* website (www.istcweb.org). It is planned that the *ISTC* will be a living document that will be periodically updated as the need arises.

Dr. V. Ombeka, Deputy Head of NLTP at Riruta Health Center, Nairobi, Kenya

Purpose of the Handbook

The purpose of this Handbook is to present suggestions and guidance, based mainly on country-level experiences, for using the ISTC as a tool to foster and guide the delivery of high quality care by all practitioners providing tuberculosis services.

The purpose of the *Handbook for Using the International Standards for Tuberculosis Care* (the *Handbook*) is to present suggestions and guidance, based mainly on country-level experiences, for using the *ISTC* as a tool to foster and guide the delivery of high-quality care by all practitioners providing tuberculosis services. The *ISTC* is potentially a very powerful tool to improve the quality of tuberculosis care. The *Handbook* describes ways in which the *ISTC* may be used to achieve this purpose. It should be emphasized that what is presented in this *Handbook* does not represent all of the possible ways in which the *ISTC* could be used. We encourage all persons involved with the provision of tuberculosis services to familiarize themselves with the *ISTC* and to think about ways in which it could be used in their setting or to address particular problems they encounter.

An important intent of the *ISTC* is to unify approaches to diagnosis and treatment of tuberculosis in the private and public sectors. Thus, the *Handbook* should be viewed as a companion to the WHO publication *"Engaging All Health Care Providers in TB Control"*[14] that presents a comprehensive approach to developing public–private partnerships for delivery of tuberculosis care. Among other things, the *Handbook* presents ways in which the *ISTC* can be used as a vehicle for developing these partnerships. In a larger context, both the *Handbook* and the WHO publication are the major implements to accomplish the fourth element in WHO's "Global Strategy to Stop TB" (Table 1). The Stop TB Strategy is available online[15] and was published in *The Lancet.*[16]

TABLE 1. **Global Strategy to Stop TB**

1	**Pursue High-Quality DOTS Expansion and Enhancement** ■ Political commitment with increased and sustained financing ■ Case detection through quality-assured bacteriology ■ Standardized treatment with supervision and patient support ■ An effective drug supply and management system ■ Monitoring and evaluation system, and impact measurement
2	**Address TB/HIV, MDR-TB and Other Challenges** ■ Implement collaborative TB/HIV activities ■ Prevent and control multidrug-resistant TB ■ Address prisoners, refugees and other high-risk groups and special situations
3	**Contribute to Health System Strengthening** ■ Actively participate in efforts to improve system-wide policy, human resources, financing management, service delivery, and information systems ■ Share innovations that strengthen systems, including the Practical Approach to Long Health (PAL) ■ Adapt innovations from other fields
4	**Engage All Care Providers** ■ Public-Public, and Public-Private Mix (PPM) approaches ■ International Standards for TB Care (ISTC)
5	**Empower People with TB, and Communities** ■ Advocacy, communication and social mobilization ■ Community participation in TB care ■ Patients' Charter for Tuberculosis Care
6	**Enable and Promote Research** ■ Programme-based operational research ■ Research to develop new diagnostics, drugs and vaccines

Another important companion document for the *ISTC* that is touched on in the *Handbook* is *"The Patients' Charter for Tuberculosis Care"* (the *Charter*) (available at www.istcweb.org) that defines patients' rights and responsibilities globally. The *Charter* was developed in tandem with the *ISTC*, and the *ISTC* provides medical/technical support for the *Charter*. As can be seen in Table 1, the *Charter* also provides an element of the Global Strategy to Stop TB, in the fifth component, "Empower People with TB, and Communities."

left: Initial ISTC stakeholder meeting, Nairobi, Kenya

right: World TB Day celebration, New Delhi, India, 2007

Making Use of the ISTC

Because of the way in which the ISTC was developed and the international endorsement it has received, the document is broadly credible across categories of practitioners. This credibility is a major strength of the ISTC and should be capitalized upon in its utilization.

The *ISTC* describes the essential elements of tuberculosis care that should be available everywhere and presents the scientific evidence and rationale that are the underpinnings of these elements. As such, it is not a strategy that can be implemented, but rather requires that strategies be developed and implemented to enable the standards to be met. Given the rigorous process by which the *ISTC* was developed and its broad endorsement, the standards it contains are not to be modified. If they are modified, the resulting document cannot be called the *ISTC*. However, the uses to which the *ISTC* will be put are entirely dependent on local situations and circumstances and on identified local problems. Because of the way in which the *ISTC* was developed and the international endorsement it has received, the document is broadly credible across categories of practitioners. This credibility is a major strength of the *ISTC* and should be capitalized upon in its utilization.

Given that public health authorities are responsible for normative functions, surveillance, monitoring, evaluation and reporting, NTP directors are generally quite aware of the weak areas in their programs and of the specific problems that need to be addressed. Thus, the initiative for using the *ISTC* generally, although not always, comes from the NTP. In some settings, however, use of the *ISTC* may be prompted by private-sector providers or organizations, particularly professional societies. It is important to note that the NTP or local programs, depending on the organization of services, must either already be in compliance with the *ISTC* or willing to make the necessary changes to be in compliance. As will be described below, utilization of the *ISTC* need not always be undertaken at the national level. The document is applicable at sub-national levels, and even within a single facility.

Initial Steps in Using the ISTC

Planning

Prior to developing activities based on the *ISTC*, the NTP must have a sound understanding of the individual standards and be willing and able to be in compliance with the standards. This likely will require internal assessment of capacity, planning and development of specific strategies to address the standards. For example, if the goal is to involve the private sector more effectively, the NTP must be willing to adjust and accommodate, where necessary, to the needs of private providers.

Developing a plan is essential to clarify the roles and responsibilities of NTP staff and non-NTP healthcare providers in using the *ISTC* effectively, and for monitoring the process. For systematic and sustainable development of *ISTC*-based activities, having an *ISTC* focal person at a senior level in the NTP is valuable. This person may also be responsible for coordinating PPM activities and should be advised and guided by a steering group such as an *ISTC*/PPM task force with representatives from major provider groups and other stakeholders.

Formulation of Objectives

If the *ISTC* activity plan entails a variety of approaches in-country, the objectives should be developed based on the findings from the *ISTC* feasibility analysis exercise described below. Planned *ISTC* activities should be clearly linked with the identified gaps to be filled. Overall objectives should also be formulated in relation to national tuberculosis control objectives and targets as well as the Millennium Development Goals (MDGs). Objectives may be defined with regard to process, outcome, and impact indicators.

Translation

Not surprisingly, a critical requirement for utilization is that the *ISTC* be translated into a language the intended audience understands. This is more difficult than it seems. Seemingly subtle changes can cause a drastic change in the perceived meaning of a given standard. Ideally the document should be translated by a person who is bilingual in English and the desired language, and has knowledge of tuberculosis. Although it increases the work, there should be a back translation as well, to ensure that the true meaning is preserved. The *ISTC* has been translated from English into several languages including French, Spanish, Vietnamese, Chinese, Russian, Khmer, and Bahasa Indonesian (Figure 1). PDF files of the translated versions are available at www.istcweb.org.

FIGURE 1. **The ISTC translated into Spanish, French, and Vietnamese**

Incentives for Participation

A range of factors affect the ability and motivation of providers of all types to participate in *ISTC* activities. Incentives and enablers, if well designed, can overcome some of the motivational barriers. They are used not only to attract care providers and ensure their continued involvement, but also to enhance their performance. A common notion has been that private care providers may not be interested in collaboration without adequate and direct financial compensation. Financial compensation may be necessary for providers who manage a large number of tuberculosis suspects and cases. However, evidence shows that individual private practitioners who have few tuberculosis patients at any time, and voluntary organizations providing tuberculosis care may find in-kind, non-monetary incentives sufficient to enter into collaboration with NTP. Some examples of non-monetary incentives include: access to free tuberculosis drugs, an opportunity to serve society through free care for the poor, access to free training and continuing education, free microscopy services, opportunity to deliver high-quality services, recognition due to formal association with a government program, and the potential to expand business as a result thereof.

Obtaining endorsements by influential local organizations, including governments and professional societies, serves as a way of obtaining buy-in and commitment to the principles in the ISTC.

Seeking and Obtaining Local Endorsements

Obtaining endorsements by influential local organizations, including governments and professional societies, serves as a way of obtaining buy-in and commitment to the principles in the *ISTC*. Moreover, the influence of the *ISTC* is amplified with each endorsement received, and local endorsement paves the way for further *ISTC*-related activities, as described subsequently.

The endorsement process is usually initiated by the NTP, although professional societies or institutions, on their own initiative, may begin the process. Simply by undertaking the process of endorsement, collaboration may be established between the NTP and the pro-

posed endorser(s). The process of endorsement usually requires initial discussions between the NTP or local public health authorities and the organization considering endorsement. This is generally followed by a review of the *ISTC* by a committee appointed by the endorsing organization. A presentation by an outside authority may be useful to move the process along. It is also very helpful to have either an organization or an individual serve as a "champion" for the endorsement and to be the focal point for organizing endorsements (see Indonesia profile).

The endorsement process usually includes the following:

- A meeting or workshop with leaders and key stakeholders from each of the professional societies. Depending on the circumstances, this activity may be led by an organization (in Indonesia, the pulmonology society took the lead) or an influential individual.
- A review of the professional society's current involvement in tuberculosis care and control.
- A presentation of the background of the *ISTC*, explaining how it was developed, its intended uses, how it differs from other guidelines, and its content.
- Formal endorsement from each professional society by asking the representatives to sign a letter, often drafted in advance.

Commonly during the discussions, there is some degree of disagreement with certain elements of the standards. For this reason, it is useful to have available, as a resource person, someone who is familiar with the development of the standard in question and the evidence backing the standard.

Most of the questions that arise have arisen and been addressed in the development of the standard. It is important to make the point that in developing the *ISTC*, there was extensive discussion within the steering committee, and subsequently there was broad general input, so the *ISTC* has been thoroughly vetted by experts. As noted above, the *ISTC* cannot be changed to accommodate local circumstances or practices and still be called the *ISTC*. In writing the *ISTC*, care was taken to be sufficiently generic that most variations in practice were encompassed. However, where valid practices exist that seem to be or are at variance with the *ISTC*, an annex or annexes can be written to explain the local practice. This may be the case in areas, such as Mexico, where the standards in the *ISTC* are exceeded. In such situations, however, the basic framework for tuberculosis care described in the *ISTC* will still serve as the point of departure for the discussion and should still be endorsed.

It is useful to point out that the *ISTC* should be viewed as a platform, the floor upon which additional tuberculosis care and control measures can be built. Conversely, in situations in which one or more of the individual standards aren't being met, the approach should be to analyze the reasons and to suggest solutions to overcoming the barriers to compliance with the full *ISTC*. Ideally, at the end of the process, representatives of the professional societies present will sign a formal letter of endorsement (Figure 2). Once a society or institution signs a letter of endorsement, they are encouraged to have their logo printed on the national version of the *ISTC* in order to increase local ownership.

FIGURE 2. **Endorsement letters from professional societies in Indonesia**

Professional societies and their leaders are often important members of the private medical community, have direct access to a large number of practicing clinicians, and have influence that extends beyond their membership.

Using the ISTC to Mobilize Professional Societies

A primary application of the *ISTC* is as a tool to unify approaches to diagnosis and treatment between the public and private sectors, especially in countries in which there is a strong private sector. Professional societies and their leaders are often influential members of the private medical community, have direct access to a large number of practicing clinicians, and have influence that extends beyond their membership. Generally, organized medicine has not been especially collaborative with public health programs, and in some instances (all too commonly), societies and their members have been antagonistic to tuberculosis control programs. However, in some settings, professional societies are a powerful ally of NTPs. Generally, these societies will include the national medical association, a pulmonology society, a pediatric society, an organization of general medicine practitioners, and an infectious diseases or microbiology society. The societies often include academic physicians who are influential in their own right.

As described, the *ISTC* was developed with considerable professional society input by a group of organizations that included a respected professional and scientific society, the American Thoracic Society (ATS). Moreover, the document has been endorsed by a number of societies that were not involved in its development. For these reasons, the *ISTC* has credibility in the eyes of professional societies and can be used to open the doors to these organizations.

Societies may be national or local and many are both—national with state or local chapters. These societies can provide a convenient doorway, and sometimes the only way to access the private sector is by systematically utilizing society journals, newsletters and other communications. In some countries, professional societies serve as a regulatory body with regard to physician licensing and certification. Related to this, in some coun-

The ISTC can serve as a means to focus on common goals and objectives and can provide a framework for addressing and improving the quality of care delivered by private providers.

tries societies often organize and conduct continuing medical education courses that are required for licensing. In addition, if properly utilized, the physician members of a professional society could greatly and productively expand the clinician workforce (as described in the India profile). Thus, there are a number of areas in which collaboration between tuberculosis control programs and professional societies would be beneficial.

As noted above, endorsement by national professional societies greatly enhances the credibility of the *ISTC* and can be used as the first step in mobilization. Strategic thinking needs to be applied in determining the reasons for seeking professional society support, but the *ISTC* can serve as a means to identify and focus on common goals and objectives and can provide a framework for addressing and improving the quality of care delivered by private providers. A mechanism to accomplish the goals might be an in-country network of professional societies that will collaborate with the NTP. As an example, in India a network of six professional societies came together and formed the "Indian Medical Professional Associations Coalition against Tuberculosis" (IMPACT) under the sponsorship of the Indian Medical Association. They have received funding from the Global Fund and are hosting meetings and scaling up efforts rapidly (see India profile).

The second example is from Kenya, where the Kenya Association for the Prevention of Tuberculosis and Lung Diseases (KAPTLD) hosted a two-day professional society mobilization workshop, the outcome of which was a letter of endorsement signed by four medical professional societies, one national public institution, two international public institutions, four medical training institutions, one national hospital, and individual private healthcare providers. The Kenyan example also illustrates the fact that while professional societies are valuable allies, institutions and practitioners can also act as powerful supporters and endorsers of the *ISTC* (see Kenya profile).

Private DOTS provider with patient

Using the ISTC for Feasibility Analysis

Because each of the major components of tuberculosis care is included in the *ISTC*, the standards provide a broad framework for a systematic "feasibility analysis" of local capabilities, and can serve as a vehicle for addressing any shortcomings. Conceptually, the *ISTC* feasibility analysis is a way for programs and providers to take stock of the standards that are or are not being met in their country; practically, the feasibility analysis consists of two tools, one a general "*ISTC* Feasibility Matrix" and the other a more specific "Needs Assessment Matrix by Category of Provider" (described below).

Usually, the *ISTC* feasibility analysis will be organized by the NTP. However, a local public health department, professional society or institution may also take responsibility for developing the analysis. It may, in fact, be useful if a nongovernment institution or organization takes on the task. This both indicates and fosters a stronger sense of ownership on the part of the organizing group.

Because each of the major components of tuberculosis care is included in the ISTC, the standards provide a broad framework for a systematic "feasibility analysis" of local capabilities, and can serve as a vehicle for addressing any shortcomings.

In undertaking the analysis, it is essential that the NTP be willing to acknowledge its shortcomings as they relate to the failure to comply with a given standard and to make every effort to incorporate the changes that are identified as being necessary for compliance. Moreover, it may be necessary for the tuberculosis program to make accommodations to enable other categories of providers to be in compliance with the *ISTC*. For example, this may entail developing more user-friendly mechanisms for reporting, facilitating access to laboratories, and providing treatment supervision for private patients.

There are a number of factors that determine the location, structure and focus of the feasibility analysis. These are as follows:

Level at which the Analysis Is to Be Performed

The *ISTC* feasibility analysis can be applied at any level in the health system, national, state/provincial, district, or individual institutional level. The level at which the analysis is performed depends in part on the organization and funding of tuberculosis services. For example in Indonesia, while the national program is responsible for guidance, surveillance, and reporting, programs are implemented and funded at the provincial level. Consequently, it was decided to conduct the analysis at the provincial level. Conducting the analysis at a national level can provide an overall mapping and assessment of tuberculosis services across the country; this can be useful for general NTP planning purposes, for informing policy makers, and for advocacy efforts. Conducting the analysis at a district or local level may enable those participating to discuss more specific problems and to devise more specific solutions; for example, if the problem is limited access to laboratories, specific sharing of resources can be suggested. Within an individual institution, the *ISTC* may be used to assess the availability and quality of essential tuberculosis services provided by the institution and by the clinicians practicing within the institution.

The Epidemiologic Context

Once the level at which the analysis is to be conduct is decided, the next step is to identify and determine the priority areas to assess. This will depend somewhat on the epidemiologic context of tuberculosis in the country, the ways in which services are provided, and the strengths and weaknesses of current tuberculosis care and control. For example, one might consider areas or populations in which there is a high incidence of tuberculosis

(e.g., urban areas, slums, prisons, and specific hotspots in the country), or an area in which comorbidities, such as HIV/AIDS are common. For example, if HIV infection is prevalent in the country, considering how TB/HIV services are delivered should be taken into account in organizing the analysis.

Mix of Healthcare Providers and Facilities

Patients with symptoms of tuberculosis seek care from a broad array of healthcare providers and facilities (Table 2), depending upon availability, acceptability, costs, and other factors. This provider mix varies across and within countries. Almost every healthcare provider in any setting can potentially contribute to tuberculosis control by undertaking one or more of the several essential tasks of identifying, referring, diagnosing, managing, and notifying tuberculosis cases. In structuring the *ISTC* feasibility analysis, it is important to take the categories of providers into account, because there may be (likely *will* be) differences in approach and performance, and thus in the shortcomings and problems identified. Identification of providers and facilities is described in "Engaging All Health Care Providers in TB Control" (PPM Guidance Document)[14]. Additionally, the "National Situation Analysis Tool" (NSA) developed by WHO that is designed to examine the role of the private sector in tuberculosis care can be used to provide more detailed information about the provider mix in a given area. Both the NSA and the PPM Guidance Document are valuable resources for conducting the *ISTC* feasibility analysis.

TABLE 2. **Some categories of healthcare providers and facilities that deliver tuberculosis services**

Public healthcare providers	Private healthcare providers
■ General hospitals	■ Private hospitals and clinics
■ Specialty hospitals and academic institutions	■ Corporate health services
■ Health institutions under state insurance schemes	■ NGO hospitals and clinics
■ Health facilities under government corporations and ministries	■ Individual private physicians, nurses, midwives, clinical officers, etc.
■ Prison health facilities	■ Pharmacies and drug shops
■ Military health facilities	■ Practitioners of traditional medicine
	■ Informal, non-qualified practitioners

Conducting the *ISTC* feasibility analysis should include the following steps:

- **Identify stakeholders and convene a workshop at the national, district, or local level.**
  Stakeholders participating in the workshop should represent the tuberculosis program and various categories of healthcare providers, ideally at least one person from each of the most common settings where patients with tuberculosis seek care.

- **Review each standard to determine whether or not each category of healthcare provider is in compliance.**
  Because some of the standards have many elements, discuss each standard in detail and identify the resources and skills that must be available to meet the standard. Identify the areas where the standard is or is not being met.

- **Identify obstacles / constraints to implementation by each standard and by category of healthcare provider.**
  Identify the specific shortcomings that prevent the standard from being met, and list the barriers to being able to meet the standard.

- **Suggest achievable solutions by provider category for each standard.**
  Propose solutions. Whether there is a need for additional training, increased laboratory capacity, or a new referral network, proposing specific and achievable solutions is the key to this exercise. There will be gaps in most health systems, yet a specific discussion about ways in which each category of health provider can address and fill that gap is a vital step.

- **Synthesize the results of this analysis into a work plan for implementation of the ISTC.**
  This feasibility analysis will become the basis of a work plan with the goal of being in full compliance with the *ISTC*. This work plan can be used in conjunction with existing/complimentary planning tools (for example, the WHO/TBTCA Planning and Budgeting Tool, which is a program planning tool that details the components and costs of specific interventions and initiatives in tuberculosis control).

ISTC Feasibility Analysis Matrix

The conceptual framework for conducting the feasibility analysis is a matrix in which each of the standards occupies a row and each of the columns describes the current status of compliance with the standard. This generic tool is shown in Figure 3. The goal is to review each standard and determine if it is being complied with and if not, what the barriers and possible solutions might be to achieve compliance.

FIGURE 3: **General ISTC feasibility analysis matrix**

INTERNATIONAL STANDARDS FOR TUBERCULOSIS CARE				
	Done (yes / no)	**If no, why not?**	**Feasible?** (yes / no)	**Explain feasibility**
Standards for Diagnosis				
Standard 1: Productive cough 2-3 weeks should be evaluated.				
Standard 2: At least 2 and preferably 3 sputum specimens obtained. At least 1 early morning.				
Standard 3: For suspected extrapulmonary TB, specimens from suspected sites should be obtained for microscopy, culture, histopathology.				
Standard 4: Chest x-ray findings suggestive of TB should have sputum specimens examined.				
Standard 5: Diagnosis of sputum smear negative: at least 3 negative smears; positive chest x-ray; and lack of response to broad spectrum antibiotics.				
Standard 6: Diagnosis of intrathoracic TB in symptomatic children with negative sputum smears should be based on chest x-ray abnormalities consistent with TB and history of exposure to infectious case or evidence of TB infection.				
Standards for Treatment				
Standard 7: Practitioner must prescribe appropriate regimen and be capable of assessing adherence.				
Standard 8: All patients including HIV+ who have not been treated previously should receive accepted 1st line treatment regimen.				
Standard 9: Patient centered approach to administration of drug treatment.				
Standard 10: All patients should be monitored for response to therapy: 2 specimens at completion of initial phase, at 5 months, and at end of treatment. Extrapulmonary and child cases best assessed clinically.				
Standard 11: Written record of all meds, bacteriologic response, and adverse reactions should be maintained.				
Standard 12: In HIV prevalent areas, HIV counseling and testing is indicated for all TB patients. In areas with lower HIV prevalence, testing is indicated for TB patients with symptoms and/signs/risk factors for HIV.				
Standard 13: All patients with TB and HIV should be evaluated to determine if ARV is indicated during course of TB treatment.				
Standard 14: Assessment of likelihood of drug resistance based on history of prior treatment, exposure to drug resistant organisms, and community prevalence of drug resistance, should be obtained for all patients.				
Standard 15: Patients with drug resistant TB should be treated with specialized regiments containing 2nd line drugs. At least 4 effective drugs should be used and treatment continued for at least 18 months.				
Standards for Public Health Responsibilities				
Standard 16: All care providers for TB patients should evaluate contacts. Children and HIV+ contacts should be evaluated for latent infection and active disease.				
Standard 17: All providers must report new and retreatment TB cases and their outcomes to local public health authorities.				

* The text here is not the full Standard, rather a reminder of the content of the Standard. Please refer to *ISTC* document for exact standards.

ISTC Needs Assessment Matrix

The second step is a more in-depth *ISTC* needs assessment that involves examining each standard individually to determine whether it is being done by each category of healthcare providers, and if that standard is not being done, to propose solutions to meet the needs.

Figure 4 is a matrix presenting the conceptual framework used to examine compliance with each standard by each category of healthcare provider. In this approach, each standard has its own matrix. Electronic versions of these forms can be downloaded from www.istcweb.org and adapted to local context.

FIGURE 4. **ISTC needs assessment matrix by category of provider**

STANDARD # ____						
Status	**Category of provider**					
	Health Clinics	Public Hospitals	Teaching Hospitals	Private Hospitals	Private Clinics	Private Providers
Being done						
Not being done						
Reasons why this Standard is not being done (identification of problems or obstacles):						
Steps needed to comply with this Standard (proposed solutions):						

Quality and Performance Assessment

The individual standards within the *ISTC* can be utilized to measure the quality of tuberculosis services delivered by any provider or program. A major purpose of the *ISTC* is to improve the quality of tuberculosis care. Any or all of the standards may be used as tools for monitoring and evaluation of quality. Such assessments, just as with the feasibility analysis, can identify weaknesses in programs, institutions or individual providers. Tailored interventions can then be employed to correct the weaknesses and improve quality. Used in this manner, the standards provide an objective, standardized, reproducible metric. The information thus gained can be used, for example, to define certified DOTS providers or hospitals, to determine adequacy of care for payment purposes by insurance companies or government agencies, or to compare programs within a country (provincial programs, for example) or between/among countries, thereby creating a sense of competition and incentive to improve performance.

Indonesian workshop participant presenting results from feasibility analysis exercise

Monitoring and evaluation data derived from the standards can be collected continuously or periodically. All or only a selected number of the standards may be used. Standards that are seen as being especially important in a given setting may be evaluated repeatedly until performance is determined to be satisfactory. For some of the standards, the data necessary for evaluation can be obtained from routine data sources, such as patients' medical records. For other standards, tailored data abstraction will be necessary. A suggested approach and guides for using the *ISTC* to measure quality and performance are under development.

ISTC as an Advocacy Tool

The individual standards within the ISTC can be utilized to measure the quality of tuberculosis services delivered by any provider or program.

Political commitment is a critical component of the DOTS strategy, and its absence limits DOTS implementation. There has been considerable success in bringing high-level government attention and commitment to tuberculosis control since lack of political commitment was first identified as a constraint to global tuberculosis control in 1998. However, in most countries at all levels of government, there has been a failure to translate this high-level political commitment into effective, country-level public policies that provide a framework for sustained tuberculosis control programs and activities.

Advocacy refers to activities intended to place tuberculosis control before opinion leaders and policy makers and on the public policy and political agenda in order to build political will and increase available financial resources. Advocacy can be applied at any level of government—national, regional or local. In general, advocacy aims to ensure governments—national, regional or local—remain committed to tuberculosis control.

The *ISTC* provides a set of internationally recognized standards any government should seek to meet. In using the *ISTC* feasibility analysis tools, NTPs can identify gaps in meeting the standards, providing a powerful advocacy tool to seek improved tuberculosis care and control. There should be two objectives for mobilizing partners:

- First, resource mobilization—by defining the essential components for tuberculosis control, the results of the *ISTC* feasibility analysis can be used to provide a set of recommendations for securing broad community support for increased resources for

By defining the essential components for tuberculosis control, the results of the ISTC feasibility analysis can be used to provide a set of recommendations for securing broad community support for increased resources for tuberculosis care and control.

tuberculosis care and control. The WHO/TBCTA Budgeting and Planning Tool can be used to provide detailed budgetary analyses to determine the necessary resources to implement each recommendation.

- Second, NTPs should also consider using the results of the *ISTC* feasibility analysis to develop strategies for the development, review, and revision of guidelines, public policies, regulations or laws to address any gaps or shortcomings identified. (See the WHO publication, *Good Practice in Legislation and Regulations for TB Control: Tuberculosis Legislation and Regulation*). [17]

Engaging Patients and Communities

"Empowering patients with TB and communities" is a specific component in the Global Strategy to Stop TB. The *ISTC* relates to this component in two ways:

- First, because the *ISTC* is backed by an international consensus and it describes agreed upon elements of tuberculosis care that should be available everywhere, patients worldwide should expect that their care is in compliance with the *ISTC*. The *ISTC*, thus, provides patients with the backing they need to insist that they receive high-quality care. Similarly, communities should expect that the care provided within their boundaries meets the standards, and thus is of high quality.
- Second, the *Patients' Charter for Tuberculosis Care* was developed in tandem with the *ISTC* with the intent that they would be complimentary documents. The *Charter* relies on the *ISTC* as its technical support. The *Charter* is a revolutionary document, at least insofar as it relates to patients with tuberculosis. It describes both patients' rights, but equally important, patients' responsibilities are also described. Implicit in both the statements of patients' rights and their responsibilities is that they will receive care that is in conformance with the *ISTC*. Patients' awareness of and support for the *ISTC* and the *Charter* can be used to provide leverage in dealings with policy makers and funding agencies, empowering them to be effective advocates for high-quality tuberculosis care.

Minister of Health, Kerala State, India receiving a copy of the Patients' Charter in the local language from a patient

Training of private providers organized by the IMA in Kerala, India

Training on the ISTC

ISTC-based Training Modules

The *ISTC* is being used as the content for a variety of training materials (Table 4). The core of the materials is the series of *ISTC* training modules, based on the individual standards, to be disseminated widely for training as well as educational activities conducted by NTPs, professional societies, medical schools, and other relevant organizations. The modules are a flexible and locally adaptable series of training presentations. Delivered together, the modules can be formed into a two-and-a-half to three day, instructor-led course. Alternatively, modules can be presented separately as individual, hour-long, half-day, or day-long, instructor-led courses.

The primary group of target learners for the *ISTC* training modules is practicing physicians, but the modules may also be tailored for use with nurses and other healthcare personnel, as well as for pre-service training of nursing and medical students and clinical officers. In addition, professional societies, as one of their regular functions, commonly present continuing medical education (or continuous professional development) courses for practicing physicians. The *ISTC* training modules can be used for this kind of continuing medical education, and potentially for accreditation as well. Each training module has exam questions at the end, and therefore can be linked to certification of participants.

Country Examples of Training Activities

In *ISTC* pilot project sites, training activities utilizing the *ISTC* have been developed based on a variety of factors. In India, the *ISTC* was included in training materials developed for ongoing CME courses by the Indian Medical Association, with the goal of training accredited DOTS providers within the private sector. Twenty-eight courses for approximately 1,000 private providers were held in 2006–07. The program is being expanded to six states in 2008, with funding through a Global Fund grant. In Tanzania, the potential for us-

ISTC presentation at Hasan Sadikin Hospital in Bandung, West Java, Indonesia

ing the *ISTC* as the basis for training prompted a review and revision of tuberculosis-training curricula for medical students in all of the medical schools in the country. The review also included NTLP guidelines and manuals, to ensure consistency of the training with NTLP norms. The intent is to use the *ISTC* as the basis for a standardized approach to medical student training throughout the country. It is also planned that the *ISTC* will serve as the basis for training in nursing and clinical officers' schools.

Multiple courses based on the *ISTC* have been conducted in Indonesia. These have been organized and presented largely by the Indonesian Pulmonary Society. In addition, there have been presentations at a number of medical schools and hospitals. It is planned that the Indonesian Medical Association will use *ISTC*-based training materials in their continuing professional development courses.

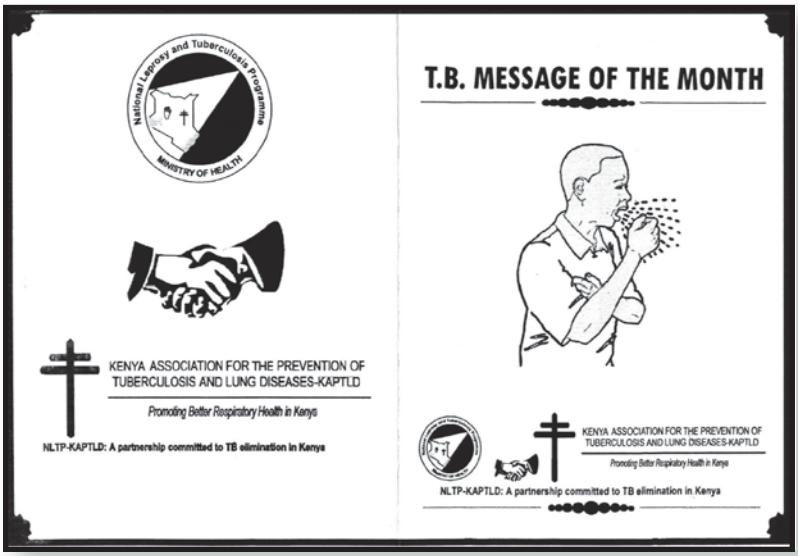
TABLE 4: **ISTC training materials**

Modules include:
▪ PowerPoint slide presentations
▪ Teaching notes
▪ Facilitators guide
▪ Case studies
▪ Testing questions and tools for evaluation

Aside from using the *ISTC* training modules for traditional, instructor-led courses, stakeholders are encouraged to be creative in their use of the *ISTC* materials and information. For example, in Kenya, the KAPTLD created "TB message of the month" cards (see Figure 5). Each card has one of the standards from the *ISTC* printed on it, along with key points related to tuberculosis care and that specific standard. The cards are put in individual healthcare providers' hospital mailboxes. Providers are, thus, introduced to the standards one at a time and, it is thought, will be more likely to focus on each standard individually due to the discrete amount of information. The project has begun and will be

scaled up to reach more healthcare providers during the next year. This is an innovative approach to increase awareness of the standards in a format that is easy to access and facilitates widespread distribution.

FIGURE 5. **"TB message of the month" card from Kenya**



Approaches to Training

Planning for *ISTC* utilization, as noted previously, should include a training plan that describes how the planned trainings are linked to or integrated with other NTP activities. Broadly, the training plan should include the following steps:

- Determine training content for different providers, including NTP staff, based on a training-needs analysis in relation to the specific standard(s).
- Adapt training methods and materials to local context and the providers' different characteristics and working conditions.
- Devise a structure for follow-up after training, which is linked to ongoing program or institutional supervision activities.
- Periodically revise training materials, course design, and plans based on evaluations.

Training materials and methods need to be suitably adapted to special needs and working conditions of different types of providers. For example, it may not be reasonable to expect a busy private practitioner to attend a training course for several days.

It is also important to identify and use suitable trainers. To illustrate, heads of large hospitals or medical colleges may be influenced most effectively through information, training, and encouragement by senior-level MOH/NTP staff. Individual qualified providers may be briefed by medical officers within the NTP, while non-physicians may be comfortable interacting with field-level staff. A common observation has been that the involvement of senior officials within the NTP and well-known local and national experts in the private sector as trainers helps considerably to improve the credibility and acceptance of the training.

Certification for Training

As described previously, the *ISTC* can be used as a metric for the quality of care. In addition to using an *ISTC*-based assessment of quality to provide certification criteria, certification can be achieved through completion of specific training courses. Thus, certification can be used as an incentive that will allow a practitioner to advertise that she or he is a certified provider of high-quality tuberculosis services.

The certification process may be informal initially and may gradually evolve into a formal, standardized procedure. Periodic evaluation of the system of certification as well as that of the criteria used for it should be undertaken. Recertification should be required at regular intervals.

International workshop with ISTC leaders from pilot countries

Early Experiences with Utilization

As stated in the acknowledgments section, guidance for using the *ISTC* is based largely on experience gained in five countries: India, Indonesia, Kenya, Mexico and Tanzania. Directors of the national tuberculosis programs in these countries, together with private sector collaborators, agreed to use the *ISTC* to address particular situations or problems encountered in their countries and to document their experiences. Perhaps the most important lesson learned from the pilot countries is that there is no substitute for in-country experience. The following section details early experience, work plans, and lessons learned from each of these countries.

Kenya

The focus of ISTC activities in Kenya is to use the document as a vehicle to unify approaches to diagnosis and treatment of tuberculosis in the private and public sectors and to improve collaboration between the two sectors.

The Context

Kenya ranks tenth in the world in the annual number of tuberculosis cases. During the last two decades, the incidence of tuberculosis has increased significantly, in large part due to the concurrent HIV epidemic. Tuberculosis case notification rates increased from 57 per 100,000 in 1987 to 329 per 100,000 in 2006. The incidence of tuberculosis increased at an average of 12–16% annually from the early 1990s until 2004, when the annual increase dramatically slowed. The annual average increase has reduced to approximately 8% in the last two years.

Despite the very large burden of tuberculosis, the World Health Organization (WHO) estimates that the notified cases represent only approximately 50% of the incident cases of tuberculosis. The estimated case detection rate (CDR) has remained static for more than a decade, although a recent review of Kenya's tuberculosis data suggests that the CDR may currently be slightly more than 60%. The treatment outcomes for notified cases have also remained static at about 80% for more than a decade. Kenya's tuberculosis control efforts have, to date, not been able to achieve the recommended tuberculosis control targets of detecting at least 70% of incident cases and treating successfully 85% of the detected cases. Unless there is a substantial intensification of efforts, Kenya may miss the Stop TB targets of halving the prevalence and deaths due to tuberculosis by 2015.

The National Leprosy and Tuberculosis Program (NLTP) in Kenya has identified the engagement of all care providers, as outlined in the new Stop TB Strategy recommended by the WHO, as a high-priority activity. Kenya has been one of the pioneering countries in implementing Public-Private Mix (PPM) initiatives. These early PPM experiences and the established infrastructure serve as a springboard for exploring ways of using the *ISTC* in Kenya.

Many healthcare provider groups in Kenya have their own professional associations, including the Kenya Medical Association, Kenya Association of Physicians, Kenya Clinical Officers' Association, and Nursing Association of Kenya. The Kenya Association for the Prevention of Tuberculosis and Lung Diseases (KAPTLD) is a nongovernmental organization active in tuberculosis control, with membership from both public and private sectors. KAPTLD has been at the forefront of initiating and scaling up both PPM DOTS implementation, and the *ISTC* implementation.

Rationale

Kenya has a significant private health sector, particularly in urban and peri-urban areas and, increasingly, in rural areas. Working together, the KAPTLD and the NLTP have been innovative in implementing Public-Private Mix (PPM) initiatives. Prior to the PPM implementation, a health systems assessment of tuberculosis care delivery in Kenya found that 61% of all health facilities in the country were dispensaries run by the public sector, and approximately one third of the health facilities were in the private sector. The assessment also showed that while 40% of individuals suspected of having tuberculosis sought care initially from a public dispensary, fewer than 15% of the dispensaries were engaged in DOTS implementation. Moreover, middle-level private practitioners were the first contact for care of a substantial proportion of the urban population. When Kenya started the PPM initiative in 2000, the goals were to standardize treatment in the private sector to prevent

emergence of drug-resistant tuberculosis, to obtain data on the burden of tuberculosis managed by the private sector, and to decongest overflowing public sector tuberculosis clinics by increasing utilization of private sector facilities.

To address these problems, the early PPM work began with the launch of a project to engage private chest physicians in tuberculosis control in 2000 under the auspices of the KAPTLD. A description of these experiences can be found in the WHO document *Engaging all Care Providers in TB Control.*[14] These early PPM initiatives are relevant because the *ISTC* pilot utilization experiences have built on these pre-existing efforts and were instigated by the same leaders of KAPTLD and the NLTP.

The focus of *ISTC* activities in Kenya is to use the document as a vehicle to unify approaches to diagnosis and treatment of tuberculosis in the private and public sectors and to improve collaboration between the two sectors. As a tool to foster effective private sector involvement in tuberculosis care, the *ISTC* has the potential to increase tuberculosis case notification and detection, to improve tuberculosis treatment outcomes, and to decrease the emergence and dissemination of drug-resistant tuberculosis, including MDR and XDR tuberculosis. In the case of Kenya, it was logical to use the *ISTC* as a mechanism for strengthening and enlarging upon the existing collaboration between the NLTP and KAPTLD and to develop a strong network of professional societies.

In addition to engaging with and working through the professional societies, the other primary use of the *ISTC* in Kenya will be to develop more standardized educational activities. The bulk of primary care in Kenya is provided by clinical officers and nurses. Pre-service training of these providers has not changed for decades and varies substantially among schools. A similar situation prevails at the medical colleges. At least in part because of their pre-service training, private healthcare providers' approaches to tuberculosis care and prevention are variable, and there is general neglect of public health tasks by these providers. Because the evidence base for the *ISTC* is compelling enough for academicians to embrace, it is being used to develop new and novel training approaches for both pre- and in-service healthcare providers.

Practical Experience in Country

Between June 2006 and July 2007, four *ISTC* planning and implementation meetings were convened in Kenya. The *ISTC* implementation initiative is being led jointly by KAPTLD and the NLTP, with primary coordination by the KAPTLD. The initial meeting was intended to introduce key stakeholders representing select medical associations and all three medical colleges in the country to the *ISTC* and to discuss ways the *ISTC* could be used to improve tuberculosis care in Kenya. This meeting consisted of didactic presentations, introducing the approach and rationale for developing the *ISTC*, and describing the content of the document. Those attending were able to ask questions about the *ISTC* and to air their concerns and disagreements with individual standards in discussions with the *ISTC* team. They also presented their ideas about how the *ISTC* could be used in the Kenyan context. It was agreed during this meeting that the *ISTC* will be used to drive existing and further expand PPM activities, as well as provide the basis for curriculum development.

In two subsequent meetings, the group of stakeholders was enlarged and plans for a larger "*ISTC* Endorsement Meeting" were developed. The two-day-long endorsement meeting was held at a conference center outside of Nairobi so that the full attention of the attendees would be on the *ISTC*. The meeting was funded by a pharmaceutical company

Participants from Professional Society Mobilization Workshop in Naivasha, Kenya

that provides some support to KAPTLD. The meeting included key stakeholders representing the following organizations and institutions:

- Ministry of Health – National Leprosy and Tuberculosis Program (MOH-NLTP)
- Kenya Medical Association (KMA)
- Kenya Pediatrics Association (KPA)
- Kenya Association of Physicians (KAP)
- Kenya Clinical Officers' Association (KCOA)
- Kenya Medical Training College (KMTC)
- Aga Khan University
- University of Nairobi
- Moi University
- Kenyatta National Hospital
- Centers for Disease Control and Prevention – Kenya
- World Health Organization – Kenya
- Kenya Medical Research Institute (KEMRI)
- Kenya Association for the Prevention of Tuberculosis and Lung Diseases (KAPTLD)

During the two day meeting, representatives from the various institutions presented data on the current state of tuberculosis care in Kenya, with a focus on the activities of the NLTP, the role of the professional societies in tuberculosis care, and the substantively challenging areas, such as the co-epidemic of tuberculosis and HIV/AIDS, and the concern with drug-resistant tuberculosis. These presentations provided a landscape of the current status and challenges of tuberculosis care in Kenya. This enabled participants to take stock of the current situation and to discuss potential areas for improvement. There were also discussions as to how the *ISTC* may best be used as a tool in Kenya. At the

conclusion of the meeting, the attendees signed a statement on behalf of their organizations and institutions that reads as follows:

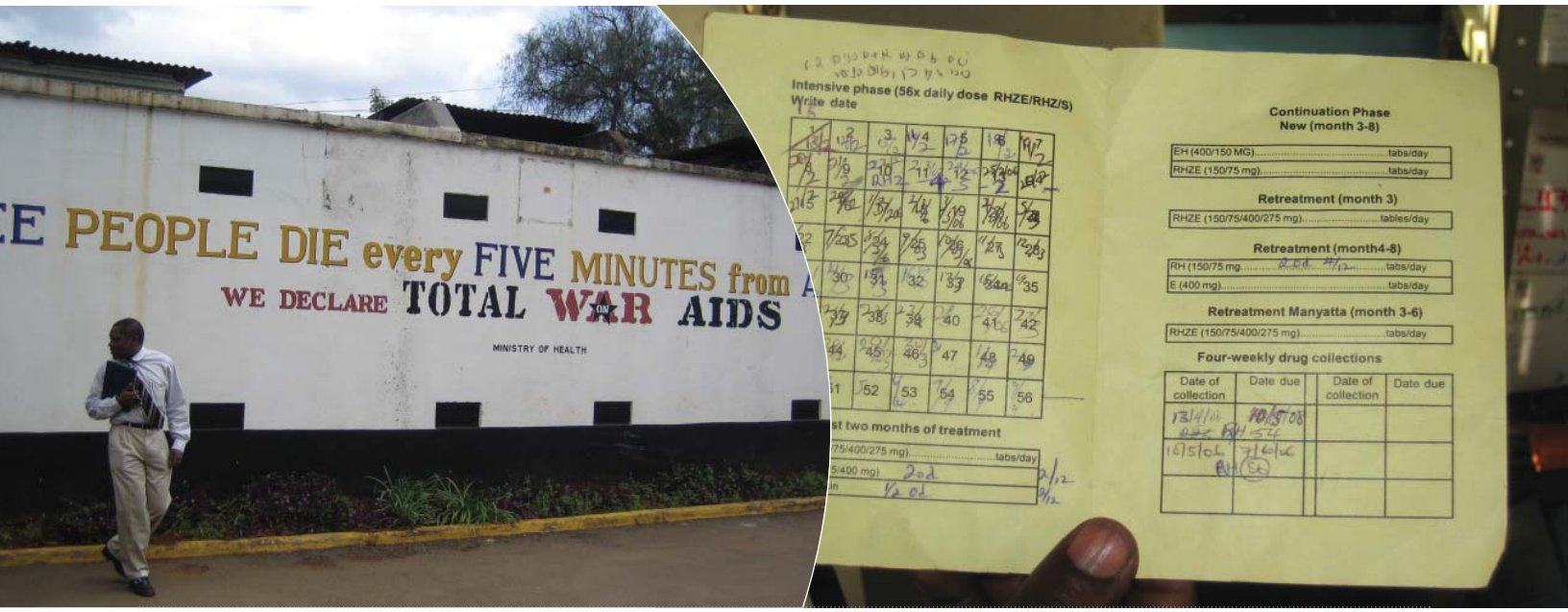
> "On Tuesday, 3rd July 2007, we the undersigned, having attended a sensitization workshop in which the International Standards for Tuberculosis Care (*ISTC*) were presented and extensively discussed; in recognition of the strategic role that the *ISTC* can play in the care and prevention of tuberculosis in Kenya, do hereby endorse the *ISTC* for implementation in Kenya."

This document now can serve as a powerful tool in Kenya. At least in principle, the represented organizations and institutions are now committed to utilization of the *ISTC* within their settings to improve tuberculosis care. The second outcome of this endorsement meeting was the development of a work plan consisting of five primary activities for utilization of the *ISTC*.

The Kenya Work Plan

- **Develop a "Kenyanized" version of the ISTC**
  A group will review the *ISTC* and modify the presentation to be representative of the Kenyan context. Specifically, the photographs will be changed so they reflect tuberculosis care and patients in Kenya, and the logos of all the Kenyan endorsing agencies will be added to foster local and national support and ownership of this international document. It was agreed that the phrasing of the individual standards would not be changed, as they were rigorously developed and have been endorsed by a broad international consensus. The country-specific version may include annexes that refer to specific topics, such as the TB-HIV co-epidemic or drug resistance that may be more relevant or need additional explanation in the country context. The goal in the first year is to print and distribute approximately 40,000 copies of the Kenya version of the document.

- **Media campaign and ISTC accreditation**
  A media campaign for the purpose of establishing accreditation on the *ISTC* will be developed. Billboards displaying the Kenyanized *ISTC* will be placed at clinics to advertise the fact that these clinics have received training and are in conformance with



Dr. J. Chakaya leaving ISTC meeting at the NLTP, Nairobi, Kenya

the *ISTC*. These clinics would then be routinely checked to ensure that they continue practicing in line with the *ISTC* and serve as pilot sites for the monitoring and evaluation of *ISTC* implementation.

- **Print and distribute ISTC standards in the form of "TB Message of the Month" cards**
  This is an innovative approach to increase the "readability" of the *ISTC* and to facilitate widespread distribution. Each card has one of the 17 standards from the *ISTC* printed on it along with key points related to tuberculosis care and to that specific standard. The cards will be distributed at regular intervals to individual healthcare providers. They are, thus, introduced to the standards one at a time and it is thought, will be more likely to focus on the specific message. The project has begun and will be scaled up to reach more healthcare providers during the next year.

- **Conduct continuous professional development meetings to promote the ISTC**
  These meetings will be convened to present the *ISTC* and promote understanding of its contents and uses throughout the country. The planned approach includes having one full-day meeting in each province (11 in total) every year. In addition, dissemination of the *ISTC* will be facilitated by having symposia at the annual scientific conferences of the Kenya Association of Physicians, the Kenya Pediatric Association, the Nursing Association of Kenya, and the Kenya Clinical Officers Association. These meetings provide a conduit for introducing the *ISTC* to broader audiences in Kenya as well as for fostering the engagement of professional societies in taking up endorsement of the *ISTC*.

- **Develop a monitoring and evaluation strategy to assess the impact of implementing the ISTC**
  Assessing the impact of these activities specifically, and *ISTC* implementation in Kenya in general, is imperative. The findings will guide future projects, and ideally can be used to lobby for additional funding for successful initiatives.

Lessons Learned

- Active support, promotion, and guidance by the NLTP is crucial.
- There needs to be a preliminary idea of the problems that can potentially be addressed by using the *ISTC* and the approaches to be taken to generate the necessary commitment.
- Having individual and organizational "champions" is critical.
- Knowledge of the potential local stakeholders and of local politics is essential.
- Persistence and consistency is required.
- Although the individual standards in the *ISTC* were developed by a rigorous process, it is important to hear and answer questions from potential stakeholders and to take the local context into account in the answers.
- For the above reasons, it is important that there be a resource person who is familiar with the *ISTC* and its evidence base present when the *ISTC* is discussed by groups.
- Formal endorsement of the *ISTC* by relevant groups is an important early step, but may require considerable discussion.
- As a way of generating support, a sequential approach to organizations and institutions after developing a core of influential supporters is useful.
- A work plan with specific activities is the goal of the first phase of the *ISTC* project.

Tanzania

The Context

The United Republic of Tanzania ranks fourteenth in the world in the annual number of tuberculosis cases. During the last two decades, the incidence of tuberculosis has increased more than four-fold. Treatment success has slowly increased toward the World Health Organization (WHO) global target of 85 percent through improved quality of services. Of the 64,200 new tuberculosis cases notified in 2005, 25,264 were sputum smear-positive (SS+). However, the detection rate for new SS+ tuberculosis cases remains low at 45 percent, well below the WHO global target of 70 percent.

Because the ISTC was recently developed and includes an evidence base making it acceptable to academicians, it presents a mechanism for both modernizing and standardizing tuberculosis training.

The HIV/AIDS epidemic is a major factor contributing to the increase of tuberculosis in Tanzania. It has been estimated that HIV/AIDS accounts for a 60% increase in tuberculosis incidence. Approximately 60% of tuberculosis patients are co-infected with HIV; the prevalence of HIV infection in the population aged 15-49 years is estimated to be 7.9%.

Rationale

Tanzania has had a head start in the process of utilizing the *ISTC* as the NTLP program manager, Dr. S. Egwaga, was a member of the committee that developed the *ISTC*. The Ministry of Health and Social Welfare has already adopted the *ISTC* by incorporating it into the National Tuberculosis Control Guidelines. Moreover, the *ISTC* came at an opportune time when the delivery of services for tuberculosis was evolving beyond the public sector.

Traditionally, health services in Tanzania have been provided mainly by the public sector. More recently, however, there is an increasing private sector involvement. With this shift, there is increasing involvement of private practitioners in providing diagnostic and treatment services for tuberculosis. It has been estimated that 10% of all tuberculosis cases are notified by the private sector. The government has expressed a willingness to support private providers in the control of tuberculosis through Global Fund for AIDS, Tuberculosis, and Malaria (GFATM) funding. Explicitly stated in the GFATM proposal were new initiatives to involve all healthcare providers, especially in the private sector. An important concern with this approach, however, is that the preparation of medical students and other allied healthcare workers such as clinical officers, nurses and others for an increased role in tuberculosis care once they graduate was insufficient. Consequently, it was the wish of the Program Manager of the NTLP that the *ISTC* be used to begin a process for standardizing tuberculosis training in the medical schools in Tanzania as well as in the training of allied healthcare personnel. It was felt that by addressing pre-service training in medical schools and allied healthcare training programs, clinicians working in the private sector as well as those in the public sector would be better equipped to take on an increased role in providing tuberculosis services in an effective collaboration with the NTLP. In addition, the standardization of training in tuberculosis in the country's five medical schools could serve as a platform for a similar unification of approach within the nursing schools and the schools in which clinical officers are trained.

Given the strength of the training institutions in Tanzania, it was decided the best approach would be to work with the medical schools and focus on updating and improving the pre-service training in tuberculosis. The rationale was simple: medical schools in Tanzania are training the future decision makers, policy makers, and many of the private care providers in the country; therefore, making the information in the *ISTC* accessible and fa-

Dr. S. Egwaga, NTLP Program Manager addressing members of ISTC consensus meeting, Dar es Salaam, Tanzania

miliar to them will have long-term impact. In these discussions, it was also recognized that the tuberculosis content in current pre-service training, in large part, is neither standardized among the schools nor is it in conformance with the *ISTC*. Because the *ISTC* was recently developed and includes an evidence base making it acceptable to academicians, it presents a mechanism for both modernizing and standardizing tuberculosis training. The intent is that this approach will have a more sustained impact than other training approaches such as in-service training. In addition, in-service trainings take significant time and resources to organize, as compared to pre-service training.

Practical Experience in Country

In the one-year period between June 2006 and July 2007, four *ISTC* planning and implementation meetings were convened in Tanzania. An initial meeting to discuss strategy with the NTLP Program Manager was held in June 2006. Possible uses of the *ISTC* and general goals of implementation were discussed.

Four approaches to dissemination of the *ISTC* were suggested:

1. To develop a curriculum, drawing on the *ISTC*, for medical doctors in training based initially at Muhimbili University College of Health Sciences (MUCHS) in Dar es Salaam. The intent was to utilize the strengths and influence of Muhimbili to lead the development of a unified approach to training among the country's medical schools.
2. To develop a curriculum, drawing on the *ISTC*, for clinical officers, nurses, and the paramedical workers (the workforce that sees 80-90% of the tuberculosis cases).
3. To use the *ISTC* to enhance the TB/HIV activities in the private sector, working with current efforts led by the Centers for Disease Control and Prevention (CDC).
4. To work with professional organizations, using the *ISTC* as a tool for advocacy.

The idea of using the *ISTC* to engage the private sector was discussed; however, the general consensus was that in Tanzania, the professional societies do not influence doctors very much. Therefore, they would not be the best target for these initial *ISTC* activities. An adapted version of the *ISTC* tailored to the Tanzanian context, however, could be presented at meetings to raise awareness in this cadre of providers and for advocacy purposes.

The NTLP Manager discussed this idea with academic leaders at MUCHS. They agreed that a curriculum revision was desirable and that they would take the lead. They agreed with the NTLP Manager that "ownership" by the academic institutions was highly desirable. As the premiere medical school in the country, MUCHS, was tasked to take the lead. A core working group was formed and representatives were selected from the departments of internal medicine, pediatrics, and continuing medical education to assess current tuberculosis training, revise and develop a curriculum, pilot test, and devise ways of evaluating the intervention.

On September 11, 2006, a consensus meeting involving all but one of the medical schools in Tanzania, as well as representatives from other schools and institutions, was held. Participating institutions included:

Medical Training Institutions:

- Muhimbili University College of Health Sciences (MUCHS), Dar es Salaam
- Hubert Kairuki Memorial University, Dar es Salaam
- Bugando University College of Health Sciences (BUCHS), Mwanza
- Kilimanjaro Christian Medical College (KCM-College) a constituent College of Tumaini University, Moshi
- International Medical and Technology University (IMTU), Dar es Salaam
- Mbeya Referral Hospital (MRH), Mbeya

Medical Association of Tanzania (MAT)

Associations of Private Health Facilities (APHTA)

National Institute of Medical Research (NIMR)

National Tuberculosis and Leprosy Program (NTLP)

World Health Organization (WHO)

Centers for Disease Control and Prevention (CDC)

Program for Appropriate Technology in Health (PATH)

United States Agency for International Development (USAID)

Allied Health Science Unit of Ministry of Health and Social Welfare targeting:

- Assistant Medical Officers Training Institutions
- Clinical Officers Training Institutions
- Nursing Training Institutions

This was the first meeting ever held in Tanzania where the medical schools came together to discuss ways of reforming and standardizing medical education for any single topic. The primary agenda of the meeting was a discussion of approaches to updating tuberculosis curriculum nationally. After preliminary background presentations, discussion focused on the structure of tuberculosis training and utilization of the *ISTC*. There was an active exchange of ideas and sharing of how each school approaches curriculum development.

Some concern about curricular restructuring was raised and the fact that changing the curriculum is a massive job as well as adding hours into an existing curriculum. Yet there was an overarching agreement that curricula should not be static, and there is an obligation and need to prioritize what is being taught based on medical breadth and given the context of health and disease in the country. There was also agreement that the *ISTC* would serve as the foundation for the curriculum improvement.

The participants agreed that the goal of this task will not be an entirely new curriculum on tuberculosis, but rather an updating of pieces that already exist in the curriculum and filling the gaps in what is being taught—i.e., to focus on the course content of tuberculosis

subject matter, and to incorporate into the tuberculosis course contents. The first steps were to conduct basic needs assessment focused on:

- The tuberculosis curricula, with focus on the course content of all the different schools
- The existing NTLP guidelines
- The *ISTC* in light of the Tanzanian context
- The HIV/AIDS curricula

On July 6, 2007, a follow-up meeting was convened at MUCHS that again brought together academic representatives from the four medical schools and other healthcare providers from NTLP and Allied Health Sciences (MOHSW), Muhimbili National Hospital, National Institute for Medical Research, Kibon'goto National Tuberculosis Hospital, International Training and Education Center on HIV/AIDS (I-TECH) Tanzania, Program for Appropriate Technology in Health (PATH), as well as colleagues from the University of California San Francisco (UCSF) and the American Thoracic Society (ATS). During deliberations at this meeting, all members once again agreed unanimously that improving the tuberculosis course content and incorporating *ISTC* is very important and would go a long way for upgrading the quality of care offered to patients in the country.

A Core Working Group to develop a Generic TB Training Module for Tanzania was formed, and based on the needs assessment, a draft document of the proposed revised course content for tuberculosis subject matter (i.e., the Generic TB Training Module for Tanzania) would be developed by September 2007. Drafts of the generic *ISTC* training materials being developed at USCF were provided to the group for their review. It was also agreed that there would be processes for updating the pre-service medical curricula and the allied health services training materials.

In addition to using the *ISTC* as a focus for medical school and allied health schools curricula development, other *ISTC* implementation activities have been taking place simultaneously throughout Tanzania under the supervision of NTLP. These include:

- Regional and district tuberculosis coordinators were oriented to the contents of the *ISTC*.
- The NTLP conducted several in-service training workshops for healthcare providers where the *ISTC* was included in the curriculum.
- The *ISTC* document was printed and distributed to all tuberculosis coordinators in the country, and they are using the *ISTC* in in-service training workshops.

The Tanzania Work Plan

The following is a list of activities proposed to be undertaken to facilitate the process of incorporation of the *ISTC* into the teaching agenda of medical schools and allied health sciences in Tanzania and the subsequent implementation.

	ACTIVITY	DATES	OUTCOME / GOAL
1	First consensus building one-day workshop held at MUCHS	Held September 11, 2006	**Outcome:** Consensus was that *ISTC* should be incorporated into the teaching agenda of medical and allied health sciences schools
2	Follow-up one-day workshop to review progress	July 6, 2007	**Outcome:** Consolidated consensus position and broadened scope of attendees –NIMR, Kibong'oto
3	A 6-day workshop of Core Group and I-TECH	September 10 –15, 2007	**Outcome:** Development and adaptation of the *ISTC* into a generic TB course contents module
4	Draft and disseminate a workshop report and generic TB course contents to all stakeholders	October 2007	**Goal:** To cultivate understanding and broader acceptance of developed TB course contents by CEO's of medical institutions
5	One-day sensitization and dissemination workshop to a broad audience – administrators of medical schools	End of November 2007	**Goal:** To develop broader acceptance and have input from decision makers of medical institutions
6	Refine generic TB course contents module and print	End of December 2007	**Goal:** To finalize the generic TB course content module and make available
7	Implementation, Monitoring and Evaluation	January – December, 2008	**Goal:** To review lessons learned, constraints and provide feed-back every 3 months

The Core Working Group (composed of representatives of the main medical schools, NTLP and Allied Health Unit Ministry of Health and Social Welfare, and I-TECH Tanzania) had a workshop in Kibaha, Tanzania from September 10–15, 2007. During the workshop, it was decided that the *Generic TB Training Module for Tanzania* should consist of the following distinct parts:

- **A Facilitator Guide** that would be used by the medical schools as standardized course content of the *Generic Modules* that would incorporate the *ISTC*, harmonized with the most recent NTLP Guidelines and TB/HIV collaborative activities.

  A draft of the Facilitator Guide was developed during the Kibaha workshop.

  The Facilitator Guide clearly outlines the aims of the *Generic TB Training Module for Tanzania*, the objectives to be attained by the students after undertaking the sessions, and a concise course outline as well as PowerPoint presentations. The contents of the *ISTC*, the NTLP Guidelines, and the TB/HIV Collaborative activities have been incorporated into the Facilitator Guide.

  A draft Generic Facilitator Guide would be presented to a much larger audience of stakeholders drawn from the decision makers of the different medical schools and key Ministry of Health and Social Welfare representatives, as well as development partners such as WHO, toward the end of 2007. The presentation of the draft Generic Facilita-

tor Guide to the stakeholders would provide an opportunity to have further input and critical appraisal, which should enhance refinement of the document and also should help to foster wider acceptance and ownership.

- **A Learner's Guide** that would be developed at a later date will be used by the students when the tuberculosis course contents are taught.
- Detailed **Course Contents** for the *Generic TB Training Module for Tanzania* will also be developed.

The NTLP, in collaboration with I-TECH Tanzania, some members of the Core Working Group and PATH, will continue to pursue the work of refining the **Facilitator Guide** and also to initiate work on the development of the **Learner's Guide** and detailed **Course Contents** that are part of the complete *Generic TB Training Module for Tanzania*.

During the next year, the work of adapting and standardizing the set of training materials for tuberculosis care and control based on *ISTC* will be finalized for all medical schools in Tanzania. The standardized training set of materials will also be adapted to the training of other cadres of healthcare providers, especially the allied healthcare providers.

Lessons Learned

- Leadership from the NTLP is essential to identify the needs that could be addressed by the *ISTC* and to define the approach using the document.
- In using the *ISTC* for medical student training, "ownership" by the medical school faculty is highly desirable.
- Concerns and questions about the individual standards must be aired and addressed with those who will be using the *ISTC*. In-country experts should be created.
- The development process for the *ISTC* and the evidence base it presents make it acceptable and appealing to academicians, and thus, an appropriate focus for training.
- Prior to beginning, it is important to identify and collaborate with other curriculum development efforts in country.
- The efforts should effectively engage the HIV community and to work with HIV/AIDS personnel to ensure that the TB-HIV educational modules are consistent and complimentary with HIV training materials.

Mexico

The Context

According to the WHO Global Tuberculosis Report 2007, Mexico had 24,255 tuberculosis cases in 2005, with an estimated incidence rate of 23 cases per 100,000 people. The National Tuberculosis Control Program (NTP) began implementing DOTS in selected demonstration areas in 1996, and according to WHO estimates, DOTS population coverage has reached 100 percent.

Unlike other *ISTC* pilot countries, Mexico is not one of the 22 identified high-burden countries with tuberculosis. The NTP has successfully kept the incidence rates of tuberculosis relatively low. Despite these successes, however, tuberculosis is a public health problem in Mexico and remains of great interest to the United States, given the shared borders and immigration flow between the two countries. In fact, according to the 2006 United States tuberculosis data from the National Tuberculosis Surveillance System, the tuberculosis rate among foreign-born persons in the US was 9.5 times that of US-born persons, and Mexico was reported as the most frequent country of origin of foreign-born tuberculosis cases in the United States.[18]

Once the ISTC has been adapted and disseminated through the NTP, ongoing assessment of use and practices related to ISTC will take place as part of routine program supervision.

Rationale

The Mexican Health System is decentralized; the federal level dictates the regulations as national health regulations (Normas de Salud) that are formulated and reviewed in collaboration with a wide range of academics and stakeholders. However, each state is relatively independent in the management, priority setting and allocation of resources.

The majority of formal workers are affiliated with public provider institutions. The private sector provides services to a small minority of the population and is difficult to quantify. Services are usually paid at the point of delivery and only approximately 4% of the population has a private health insurance.

The NTP is a department of the Centro Nacional de Vigilancia Epidemiologica (CENAVE) of the Secretaria de Salud (SSA). It consists of a central office at federal level providing stewardship, leadership, planning, training, supervision, monitoring and evaluation functions cascaded to state level through state TB coordinators (Responsable del Programa de TB del Estado) in each state and epidemiological monitoring by state epidemiologists.

Collaboration with multiple stakeholders is deeply ingrained in the NTP. Since its development, the NTP has been working closely with other public and semi-public organizations; more recently there has been a movement towards involving academic departments, private associations and other stakeholders. The launch of Stop TB Mexico in 2004 identified the potential of collaboration with another broader variety of stakeholders; to date up to 20 states have developed their own Stop TB partnerships with local tuberculosis ambassadors from many different backgrounds.

All tuberculosis services, including laboratory services, are provided free of charge. All public sector providers collaborate with the tuberculosis program of the SSA in virtually all tuberculosis control activities except for extramural activities (defaulters and contacts tracing).

The participation of the different stakeholders and the academic departments in the de-

ISTC stakeholders meeting, Mexico City, Mexico

velopment and actualization of the tuberculosis control regulations (Normas Nacionales) ensures that all these entities will cooperate in the implementation of the guidelines. Once agreed, National Norms are legal requirements and the different stakeholders must obey them. Although there are contractual arrangements or written agreements with some of the public providers outside the SSA, the majority of collaborative activities are understood as the normal development of the program and lack such agreements. As a result, many collaborative activities between the Tuberculosis Program and public and semi-public organizations are not formalized through any kind of agreement (memorandum of understanding—MOU, or contractual arrangements).

The majority of private providers are subscribed to professional colleges or medical associations. This is now more relevant since doctors need to be recertified every five years and a way to do so is through the demonstration of continuous professional development through their attendance in courses and colleges activities. The NTP collaborates with certain medical colleges and associations, although on an *ad hoc* basis.

Practical Experience in Country

In November 2006, a stakeholders meeting was convened in Mexico City. Participants included physicians and nurses from public and private sectors, radiologists, pediatricians, and infectious disease specialists. There was considerable discussion and debate about the differences between the *ISTC* and the Mexican Normas. In order to solve this issue, the discussion was directed to determine which standards are already covered by the Mexican Normas, and which standards should be considered in the future revision of the Mexican Normas. There was also interest in producing a *Mexican Standards for Tuberculosis Care* based on the *ISTC*.

Mexico, compared with the other countries where the *ISTC* has been piloted, is unique in that the burden of tuberculosis is much lower, and the national program already has very detailed “Normas” for tuberculosis care and control. The challenge in pilot testing the *ISTC* in Mexico was determining how best to implement and endorse the *ISTC* alongside the current set of Normas without providing too many materials or any contradictory information. It was noted that many of the standards outlined in the *ISTC* document are already included in the official Mexican Norms for the Prevention and Control of Tuberculosis, with slight differences. The proposed solution was to adapt the *ISTC* to the Mexican context by developing *Mexican Standards* that will be endorsed by both public and private sectors and will serve as the core material for tuberculosis trainings. This adaptation included changes in the general aspect of the document: (i.e., using photos that reflect the Mexican culture, environment and language). There was also interest in creating a document with standards of care for special situations such as management of pediatric tuberculosis, extrapulmonary tuberculosis or tuberculosis in pregnant women. Also, there were comments regarding the inclusion of standards to increase and guarantee compliance to treatment. Once the *Mexican Standards* are produced, they are planning to have a pocket-sized book.

In order to start using the *ISTC* in Mexico, a committee of experts from different public and private institutions (including academic Institutions) was formed. During three meetings (from January to August 2007), they discussed the adaptation of the *ISTC* to Mexico. A fourth meeting held on September 19, 2007 was dedicated to reviewing the final document of the Mexican version of the *ISTC*, which was endorsed by all the institutions involved in the committee. This group has also planned pilot studies for the use of the *ISTC* in private and public institutions to be used for tuberculosis patient care, as well as in nursing and medical schools for the use of the *ISTC* as teaching material. They have also discussed adapting the generic educational materials to disseminate the content of the *ISTC* in Mexico.

The Mexico Work Plan

The first stage of *ISTC* implementation in Mexico will be adapting the standards to the Mexican context and disseminating the materials for local adoption. The following steps have been proposed:

- **Create a review committee composed of the NTP and identified partners**
  This committee will be tasked with reviewing the contents of the *ISTC* and comparing them with the Mexican Normas. Areas for further clarification will be identified and raised for discussion with a larger committee. The committee will also identify areas where the *ISTC* can be expanded upon in order to be more relevant to the Mexican context.

- **Develop an annex to the ISTC in accordance with committee recommendations**
  This annex will describe how the *ISTC* can be adapted to the Mexican context. Using the *ISTC* as the platform and template, a separate document, the *Mexican Standards for Tuberculosis Care*, will be developed.

- **Pilot the Mexican Standards for Tuberculosis Care with public, private and academic institutions**
  The piloting of the *Mexican Standards* will be conducted in the public sector in two Mexican states at the jurisdiction level, including all local health units. Piloting will be conducted in the private sector through hospital and professional associations. The specific associations are yet to be determined. Finally, the *Mexican Standards* will be piloted in the academic setting at two national level and four state level universities or academic institutions. Piloting will include disseminating the new materials and conducting trainings based on the *Mexican Standards*.

- **Train NTP network of health practitioners and coordinators, as well as other public and private sector partners in adapted standards**
  Training sessions will be held as part of the pilot testing phase (in the public, private, and academic setting). The generic *ISTC* training modules will also be adapted to the Mexican context and used for these training sessions. Specific sessions to train trainers will be held initially. All materials will be translated into Spanish.

- **Disseminate Mexican Standards for Tuberculosis Care**
  The goal of disseminating the *Mexican Standards* will be to reach all care providers in all states over the next year. Five thousand copies will be reprinted in Mexico.

Once the *ISTC* have been adapted and disseminated through the NTP, ongoing assessment of use and practices related to *ISTC* will take place as part of routine program supervision. Future evaluations may be appropriate to determine the impact of the *ISTC* on field practice.

Lessons Learned

- Active support, promotion, and guidance by the NTP is crucial.
- Knowledge of the potential local stakeholders and of local politics is essential.
- Persistence and consistency is required.
- Although the individual standards in the *ISTC* were developed by a rigorous process, it is important to hear and answer questions from potential stakeholders and to take the local context into account in the answers.
- Formal endorsement of the *ISTC* by relevant groups is an important early step, but may require considerable discussion.
- As a way of generating support, a sequential approach to organizations and institutions after developing a core of influential supporters is useful.
- A work plan with specific activities is the goal of the first phase of the *ISTC* project.

India

The Context

India has the highest global burden of tuberculosis in the world, with approximately 2.2 million new cases per year. The country also has the largest documented private medical sector. The private health providers are a heterogeneous, largely independent group and include those qualified in the Western and indigenous systems of medicine as well as non-qualified practitioners. Several studies have documented inappropriate tuberculosis management practices in the private sector. Anti-tuberculosis drugs are available on prescription in the private retail market and it is not difficult to obtain anti-tuberculosis drugs without a prescription. Unlike the situation in many sub-Saharan African countries, at present, approximately 5% of new tuberculosis cases in India occur in people with HIV co-infection.

Since 1993, the Revised National Tuberculosis Control Program (RNTCP) has been implementing a well-functioning DOTS program that currently covers almost all parts of the country through its extensive public health sector network. Beside the private sector, there are other public sector healthcare institutions in the country that manage significant numbers of tuberculosis cases.

Both the IMA and RNTCP readily endorsed the ISTC and are strong advocates across the country. The full text of the ISTC is printed in the RNTCP Training Module for Medical Practitioners, and both the IMA and RNTCP have put their logos on the ISTC that is being reproduced and distributed through trainings.

Rationale

India has been a pioneer in Public-Private Mix (PPM) initiatives. During the past ten years, several projects have been launched in different parts of India implemented by NGOs, local medical associations, academic institutions and the local RNTCP. There are many examples cited in the PPM Guidance Document. Drawing upon initial experience of productive collaborations with diverse types of providers, the RNTCP has developed national guidelines to involve NGOs and private practitioners in DOTS implementation.

The Indian Medical Association (IMA) is the largest professional association in India and represents the general and specialist practitioners trained in Western medicine. The IMA is the largest NGO in the health sector. Its membership includes approximately 1,650,000 medical practitioners. IMA has a three-tier structure. IMA Headquarters is situated in the national capital of Delhi. There are 27 state branches, six territorial branches and 1,600 local branches. There is IMA outreach even in remote areas. Membership in the IMA is voluntary, and despite its breadth, less than half of the eligible private practitioners are members of IMA. Nongovernmental organizations providing primary health services also have a large presence in India. The RNTCP and the IMA both have well-organized tuberculosis programs; therefore collaborating with both organizations in implementing the *ISTC* was a logical step.

An article from the *Indian Express* on Aug 12, 2007, highlights the collaborative efforts between the RNTCP and the IMA:

> *Private practitioners are all set to give a push to the Revised National Tuberculosis Control Programme (RNTCP) across the country. The Indian Medical Association (IMA) has tied up with the Central TB Division in its endeavor to eradicate tuberculosis, which remains one of the leading causes of death of nearly two million people every year across the globe. The TB division will receive a grant of Rs 18 crore from the Global Fund for AIDS, Tuberculosis and Malaria.*

left: Indian families, Agra, India

right: Map of Kerala State, India, initial site of PPM/ISTC pilot projects

Dr L S Chauhan, Deputy Director General of Central TB Division, said that a (MoU) was signed between the Government and the private practitioners for a period of five years. During these 5 years, 50,000 doctors are expected to offer Directly Observed Treatment, Short-course (DOTS) across five states and a Union territory. These are Uttar Pradesh, Punjab, Haryana, Maharashtra, Andhra Pradesh and Chandigarh.

Dr Asokan, IMA's National Coordinator for TB, said the project aims to bring public and private providers, who would work together in combating the scourge of tuberculosis, under one "umbrella". The IMA has a wide base and a network of private medical practitioners (PPs) has the potential to penetrate NGOs, the corporate sector, medical colleges etc. Recognizing the role played by the NGOs and the private practitioners in spreading awareness within the community and realizing that many patients seek treatment from them, the Ministry of Health and Family Welfare brought out guidelines to involve NGOs and private practitioners under various schemes in 1999 and 2002. Sadly, there were not many takers. However, there seems to be a renewed vigor this time around as the IMA has decided to carry out intensified activities in the chosen areas to promote RNTCP.

Working with the IMA and the RNTCP and well-established private and public organizations to disseminate the *ISTC* made the most sense in a country as populous as India. As stated in the newspaper article, the IMA acts as an umbrella organization, capturing both public and private care providers. The IMA's National Coordinator for tuberculosis is a dedicated leader who was on the Steering Committee that developed the *ISTC*, a champion of the *ISTC* process, and works in tandem with the program director of the RNTCP, who is also a valuable member of the *ISTC* Steering Committee.

Practical Experiences in Country

Both the IMA and RNTCP readily endorsed the *ISTC* and are strong advocates across the country. The full text of the *ISTC* is printed in the RNTCP Training Module for Medical Practitioners, and both the IMA and RNTCP have put their logos on the *ISTC* that is being reproduced and distributed through trainings.

ISTC presentation at IMA meeting, Kerala, India

The *ISTC* has been successfully integrated into routine and widely distributed training materials. The activities and trainings that are being planned and held include: national level workshops, state level workshops, and district level training programs. Once these training programs reach the local level, the goal is that the private practitioners adopt RNTCP and declare themselves DOTS centers and the IMA facilitates monitoring and supervision of private providers.

The southern state of Kerala has led the way in implementing *ISTC*. The Kerala Phase II Project has the objective of consolidating the partnership of the IMA and the Kerala state government in the RNTCP, and to achieve a synergistic relationship with the public health sector in all districts in the state. The overall goal is to reduce the morbidity and mortality of tuberculosis and to cut the chain of transmission of infection in Kerala. The expected outcomes of the project are: 1) to improved access to RNTCP-DOTS in general; 2) to increase the number of patients put on DOTS, especially those from the poorer urban and rural communities; and 3) to document a sustainable model of public-private mix in the RNTCP which can be replicated in other sector collaborations, as well as for other health programs of state and national importance. The project has the following components: a) reorientation of already trained doctors in every district; b) training of a new batch of doctors in every district; c) coordination with district and state authorities; and d) documentation of the process. Stakeholders include the government, WHO, IMA, healthcare providers (especially those from the private sector), and patient communities, family and the general population. Overall, this project has served as an excellent model of bringing together a variety of stakeholders and engaging tuberculosis care providers at the local level. The *ISTC* document is a central piece of the training sessions.

Thus far, the Phase II of the project has hosted 14 training sessions and 28 CME sessions in 2006-07. 1,139 private doctors have been trained in Kerala Phase I and II (2007). The Kerala Government also endorses the *Patients' Charter.*

There has been substantial progress in *ISTC* implementation in India. Training based on the *ISTC* has been developed and the standards have been widely disseminated. A number of editorials and articles have been published in Indian journals and by Indian authors discussing the role and uses of the *ISTC*.[19–21] This kind of distribution is a valuable way to spread the word to other healthcare providers and academics who may not have had the opportunity or impetus to attend a training where the *ISTC* is explicitly taught. In addition, 25,000 copies of a *Lancet Infectious Disease* paper on the *ISTC*[1] were purchased and distributed by a pharmaceutical company in India.

There has also been significant mobilization of professional societies and private healthcare providers. A meeting was held in New Delhi on World TB Day 2007, bringing together representatives from a number of private and public medical associations. The outcome of this meeting was the genesis of a new network, referred to as the Indian Medical Professional Associations Coalition against Tuberculosis (IMPACT). Organizations in IMPACT included: Indian Medical Association, Association of Physicians of India, Indian Chest Society, National College of Chest Physicians (India), Indian Academy of Pediatrics, and Federation of Family Physicians Associations of India. A second meeting of IMPACT has also been held in Delhi. All the constituents have agreed in principle to work together for tuberculosis control and endorse *ISTC*.

The India Work Plan

The *ISTC* is poised to be used in six states under a Global Fund project. The IMA plan of action at the state level includes the following activities:

- **State workshop for IMA leaders on the ISTC**
  There is a need to sensitize the IMA leaders in each state regarding the dimension of the tuberculosis menace and the need for private sector participation. The state workshop brings together state level and district level IMA leaders with state level and district level RNTCP officials. This is an important step, bringing both together so that the ownership of the effort is shared equally.

- **Sensitization of district leaders**
  Motivated state/district IMA leaders go back to their districts to hold district-level sensitization meetings for IMA leaders from local branches in the district (from individual towns). A single district may have as many as eight-nine IMA branches.

- **Peer sensitization**
  Peer sensitization is the most crucial step. Motivated local branch IMA leaders act as RNTCP ambassadors and sensitize private doctors one-to-one (peer sensitization).

- **District modular training**
  Sensitized private doctors are encouraged to attend the district-level training based on the tuberculosis module approved by RNTCP (six hours). Private doctors are awarded certificates. General practitioners, physicians, chest physicians, pediatricians and orthopedicians are the priority groups.

- **DOTS center recognition**
  Trained private doctors undertake to practice DOTs strategy and comply with the *ISTC*. In India, the easiest way to comply with the *ISTC* is to join RNTCP. The clinics of the private doctors are recognized as DOTs centers by the district RNTCP office.

- **Coordination with RNTCP**
  IMA plays a facilitating role in all the above steps and will continue to be a catalyst for monitoring and supervision.

Lessons Learned

- A strong public sector is mandatory for successful PPM. PPM can be sustained only as a part of government initiative.
- The barrier between public and private sectors can be bridged by a facilitating professional society.
- The private sector is more than willing to participate in national health programs, given mutual trust and equal respect.
- Approaching the issue of tuberculosis control through the perspective of medical professions cuts across the public-private divide, the general practitioner-specialist divide, and the division amongst the heterogeneous providers within provider sectors.
- The *ISTC* is a powerful tool to reach out to medical professionals.

Indonesia

The Context

Efforts in Indonesia have been successful in rapidly disseminating the ISTC, sensitizing care providers to the materials, and seeking and receiving endorsements from professional societies.

Indonesia has the third highest burden of tuberculosis in the world. With a population of close to 230 million, there were 532,871 new cases of tuberculosis reported in 2005. The annual incidence of all forms of tuberculosis was 239 per 100,000 and the prevalence was 262 per 100,000 in a 2004 prevalence survey. The prevalence of HIV remains relatively low; approximately 0.8% of tuberculosis cases are infected with HIV. It is estimated that 1.6% of tuberculosis cases are multi-drug resistant.

In 1992, DOTS was first piloted in Sulawesi and, according to WHO, had expanded to cover 98 percent of the country by 2005. Indonesia has met the 85 percent target for DOTS treatment success. Detection of infectious tuberculosis cases has increased from 38 percent in 2003 to 53 percent in 2004. Preliminary data (not published) for 2005 shows a significant increase to 67 percent.

Despite the successes of DOTS implementation, the practice of tuberculosis care among physicians in Indonesia is variable. There is both over and under diagnosis, and over and under treatment. A lingering challenge is the reliance on chest radiography and the widespread belief that it is the most important diagnostic tool. The use of sputum smear microscopy is often neglected, and non-standard diagnostic tests are gaining popularity (serology, PCR etc). An additional threat to basic tuberculosis control is the incorrect prescribing and use of anti-tuberculosis drugs.

Rationale

To be fully effective, tuberculosis care and control in Indonesia must involve health care providers who have no connections to the National Tuberculosis Program (NTP). This involvement is essential because of the structure of health care in the country and the position of the NTP within the system. The NTP operates under the Directorate of Communicable Disease Control (CDC) and provides surveillance and normative functions: it has no direct responsibility for clinical activities. Government-operated primary health centers (puskesmas), under the Directorate of Community Services, provide the core of tuberculosis patient care activities and do so largely based on NTP guidance. Government hospitals and associated clinics, under the Directorate of Medical Services, also provide a substantial amount of tuberculosis patient management but are largely independent of the NTP and of the puskesmas. Private facilities are completely independent. Health care, including care for tuberculosis, is also provided by prisons, the military and corporate entities, again with no connection to the NTP. As a consequence of this organizational structure, and because of the influence of "private" consultants working in both government and private hospitals and clinics, the NTP has little au-

Prof. Hadiarto, Dr. Nyoman, and Dr. Basri at first ISTC presentation to National TB Congress, Jakarta, Indonesia

thority or influence over diagnosis, treatment, reporting, and monitoring in the public and private hospitals, in clinics attached to these hospitals or in private clinics and offices.

It is thought that a substantial amount of tuberculosis care is provided outside of the puskesmas and, consequently, outside of the sphere of influence of the NTP. However, there has been no comprehensive quantification of the numbers of patients who have tuberculosis diagnosed and treated in the private sector and in government hospitals and clinics, except as a part of the tuberculosis prevalence survey conducted in 2004.

As shown in the table below, the majority of patients being treated for tuberculosis in two of three large provinces had treatment initiated in facilities other than primary health centers. Of particular note, nearly 30% of prevalent patients in Java had treatment initiated by private physicians.

INITIATION OF TREATMENT			
PROVINCES	**HOSPITAL & CLINICS**	**PRIMARY HEALTH CARE**	**PRIVATE PRACTITIONERS**
SUMATRA	44%	43%	12%
KTI	31%	53%	16%
JAVA	49%	21%	29%

Although general practitioners constitute the largest number of providers, there are a large number of specialist and sub-specialist physicians as well. Of particular note, pulmonologists general internists, and pediatricians are quite influential in the care of patients with tuberculosis. A number of the sub-specialists, also have faculty appointments in the country's medical schools and teaching hospitals and, consequently are in a position to influence the attitudes and practices of future physicians.

Medical Professional Societies are large, active and influential in tuberculosis care and control in Indonesia. As the professional society that is most relevant to tuberculosis care and control, the Indonesian Society of Respirology (PDPI) has been involved in supporting the NTP since the DOTS Strategy was introduced in Indonesia by promoting the program with other professional organizations, developing tuberculosis guidelines with the NTP, developing tuberculosis curricula for medical schools, and conducting trainings for doctors, medical students on hospital DOTS linkage, MDR tuberculosis and the *ISTC*. Additionally, because of the size of its membership, the Indonesian Medical Association wields considerable influence.

Despite the successes of DOTS implementation, a wide gap exists between the structure and quality of tuberculosis services provided in the country's primary care clinics (puskesmas) that adhere to NTP guidelines and other providers. Although there is a very active hospital-DOTS linkage program in several regions of the country, services provided by both government and private hospitals and private practitioners in most of the country do not follow national guidelines and the quality of service in not known. Recognizing there is an urgent need to bridge the gap between the NTP-guided services and those delivered by other providers, the first priority for using the *ISTC* in Indonesia was to endorse and distribute the *ISTC* among private physicians and government and private hospitals.

Practical Experience in Country

Efforts in Indonesia have been successful in rapidly disseminating the *ISTC*, sensitizing care providers to the materials, and seeking and receiving endorsements from professional societies. The *ISTC* was first introduced at a preliminary meeting with the NTP, WHO Indonesia and members of the PDPI in July 2005. A follow-up meeting with professional societies was held later that month. Early in 2006, two meetings with the Indonesian Medical Association (IDI) were held, the outcomes of which were endorsement from IDI, endorsement from six professional societies, and endorsements from the medical faculty of the University of Indonesia and the Indonesian Nurses Association.

Following the initial endorsement meetings, activities to disseminate the *ISTC* materials and acquaint practitioners with the contents were carried out at local PDPI branches and at national conferences. Continuing Medical Education (CME) credits were offered to the medical faculties of more than six universities and at least four referral hospitals in different cities.

The achievements from the preliminary sets of meetings for the *ISTC* implementation efforts include:

1. The *ISTC* has been translated into Bahasa Indonesia and is ready to be published.
2. A pocket-sized version with just the standards has been prepared and distributed.
3. Formal letters of endorsement have been signed by:
   - Indonesian Medical Association
   - Indonesian Society of Respirology
   - Indonesian Society of Internal Medicine
   - Indonesian Society of Pediatricians
   - Indonesian Society for Microbiology
   - Indonesian Society of Obstetrics and Gynecology
   - Indonesian Nurses Association
   - Medical Faculty, University of Indonesia
4. The *ISTC* has been included as an attachment in: the Guidelines for National TB Control Programs, the Hospital DOTS Guidelines, the Guidelines for Diagnosis and Treatment of TB in Hospitals, the TB Guidelines of Indonesian Society of Respirology, and the Hospital Journal.

Taking the implementation process a step further, in March 2007 an *ISTC* Implementation Workshop was held in Jakarta. The workshop was attended by IDI branch members, pulmonologists, internists, general practitioners, and provincial health officers from eight selected provinces. The primary goals of this workshop were to: 1) present a draft of the *ISTC* feasibility analysis tools (the *ISTC* feasibility analysis matrix and the *ISTC* needs assessment matrix) and secure input on their design and format for field testing, and 2) to develop revised drafts of the tools that could be used in the field to assess constraints to full implementation of the *ISTC* at the provincial level.

TB rounds at Persahabatan Hospital, Jakarta, Indonesia

This was the initial testing of the *ISTC* feasibility analysis tools, and the experience at this workshop informed their further development and refinement. In small groups the workshop participants used the *ISTC* needs assessment matrix to review each standard and assess the gaps in tuberculosis services and to suggest possible solutions to the identified problems. At the end of this day-long process, a representative from each small group presented the group's findings to the larger group for further discussion and comments. To give a sense of the outcomes of the workshop, some of the common shortcomings identified through the feasibility analysis workshop were:

- Diagnosis of tuberculosis in children and drug therapy for children
- Limited facilities for microbiology and histopathology examination, especially in the private sector
- Limited knowledge about HIV diagnosis and management
- No regulations or rules for reporting tuberculosis cases in the private sectors to the government
- Over-reliance on chest radiography for diagnosis

The Indonesia Work Plan

- **Mass dissemination of the full translated version of the ISTC**
  The *ISTC* has been translated into Bahasa Indonesian, and the logos of all the Indonesian endorsing organizations and agencies will be added to this version of the document to foster local support and ownership. The goal is to print and distribute copies of the *ISTC* across all the provinces of Indonesia and to have the Indonesian version of the *ISTC* available at tuberculosis trainings nationally.

- **Form a national professional society working group**
  Many of the medical professional societies in Indonesia have officially endorsed the *ISTC*. The next stage is to further harness and coordinate the efforts of these groups. The IDI has agreed to lead this process. The first step is to develop terms of reference for the working group. Activities to be carried out by the professional society working group include disseminating the *ISTC* via professional journals; publishing editorials about the *ISTC* and tuberculosis care in these journals; coordinating and developing continuing education programs based on the *ISTC*; including the *ISTC* in scientific meetings; and in collaboration with NTP, providing oversight to provincial assessment and implementation of the *ISTC*.

  In addition, the professional societies are often responsible for providing trainings for continuing medical education (CME) certificates. Under the new Medical Practice Act every doctor must renew his/her Practice Certificate every five years through CMEs conducted by each Professional Collegium. The Indonesian Society of Respirology will use the *ISTC* for these CME courses and the IDI and other professional organization will use the *ISTC* to standardize their tuberculosis care and training.

- **Develop provincial ISTC working groups**
  Provincial working groups will be formed in collaboration with the national professional society working group and will include members from these professional societies as well as public health care providers from regional and local hospitals, clinics, and NGOs. A core function of these provincial working groups will be to pilot test the *ISTC* training materials and facilitator guides. It is envisioned that these provincial working groups will also provide additional training and technical assistance to provincial facilitators, and take the lead on conducting the *ISTC* feasibility and needs assessment analysis at the provincial level. The findings from the provincial feasibility analyses will be used to develop more targeted provincial work plans and budgets to address the identified gaps.

Lessons Learned

- Active support, promotion, and guidance by the NTP is crucial.
- Using the *ISTC* as a framework for conducting a situation analysis is useful to identify gaps in and barriers to effective tuberculosis care and to identify possible ways of improving care.
- Although the individual standards in the *ISTC* were developed by a rigorous process, it is important to hear and answer questions from potential stakeholders and to take the local context into account in the answers.
- Formal endorsement of the *ISTC* by relevant groups is an important early step, but may require considerable discussion.
- A work plan with specific activities at both national and provincial levels is the goal of the first phase of the *ISTC* project.

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The Francis J. Curry National Tuberculosis Center is a joint project of the San Francisco Department of Public Health and the University of California, San Francisco, funded by the Centers for Disease Control and Prevention