GUIDING PRINCIPLES AND PRACTICAL STEPS

FOR ENGAGING HOSPITALS IN TB CARE AND CONTROL

USAID
FROM THE AMERICAN PEOPLE

TBCTA
The Tuberculosis Coalition for Technical Assistance

ACKNOWLEDGMENTS

Overall Coordination

Jan Voskens, KNCV Tuberculosis Foundation

Preparation

Akihiro Ohkado, Japan Anti-Tuberculosis Association; Mukund Uplekar, World Health Organization; Mayra Arias, Gorgas, University of Alabama and Jan Voskens, KNCV Tuberculosis Foundation.

The writing committee thanks all individuals and organizations who supported this project and gave their time and efforts to develop this material, particularly the participants of the workshop on hospital DOTS linkage from the following national tuberculosis programs including their technical partners:

China (Wang Lixia, Wan Lyia, Li Qing, and Lv Qing), Indonesia (Ekasari, Muhktar, Yemfy Naswil, Siti Nadia, Franky Loprang, Atiek S. Anartati, Sri Retno Irawati, Adi Utarini, Yodi Mahendradhata, Endang Nuraini, and Triya Dinihari), Nigeria (Osakwe Chijoke, Odume Berthrand, and Ben Chukwuemeka Nwobi), Bangladesh (Khurshid Alam Hyder, A Faiz, M.Kamal Siddiqui, and Begum Vikarunnessa), Philippines (Ernesto Bontoyan and Susan Coseria), and Pakistan (Baseer Abdul Khan, Muh Amir Khan, Badar Darakshan, John Walley, and COMDIS).

Special thanks go to experts from partner organizations who assisted in development of the document, especially to Knut Lonnroth, Mukund Uplekar, and Karin Bergstrom (World Health Organization), Sven Gudmund Hinderaker (International Union Against Tuberculosis and Lung Disease), Pedro G. Suarez (Management Sciences for Health), Michael Kimerling (University of Alabama), Max Meis and Yared Kebede (KNCV Tuberculosis Foundation), Rasmus Malmborg (LHL), and members of the Public-Private Mix Subgroup who commented on the draft document during a Public-Private Mix Subgroup meeting in Cairo (2008).

GUIDING PRINCIPLES AND PRACTICAL STEPS FOR ENGAGING HOSPITALS IN TB CARE AND CONTROL

The Global Health Bureau of the Office of Health, Infectious Disease, and Nutrition, U.S. Agency for International Development (USAID), financially supports this document through the Tuberculosis Control Assistance Program (TB CAP) under the terms of Agreement No. GHS-A-00-05-00019-00.

This document is made possible by the generous support of the American people through USAID. The contents are the responsibility of TB CAP and do not necessarily reflect the views of USAID or the United States Government.

RIT/JATA

CONTENTS

AIDS	acquired immunodeficiency syndrome
DOT	directly observed treatment
DOTS	WHO internationally recognized recommended strategy for tuberculosis control
DR-TB	drug-resistant tuberculosis
EQA	external quality assurance
HBC	high-burden country
HDL	hospital-DOTS linkage
HIV	human immunodeficiency virus
IC	infection control
IEC	information, education, and communication
IRIS	immune reconstitution syndrome
IPT	isoniazid preventive therapy
ISTC	International Standards for Tuberculosis Care
IUATLD	International Union Against Tuberculosis and Lung Disease (the Union)
JATA	Japan Anti-Tuberculosis Association
KNCV	KNCV Tuberculosis Foundation
MDG	millennium development goals
MDR-TB	multidrug-resistant tuberculosis
MoH	Ministry of Health
MOU	memorandum of understanding
NGO	nongovernmental organization
NTP	national tuberculosis program
OR	operational research
PPM	Public-Private Mix
SOP	standard operational procedure
TB	tuberculosis
TB CAP	Tuberculosis Control Assistance Program
TB-HIV	tuberculosis-HIV co-infection
TBTCA	Tuberculosis Coalition for Technical Assistance
USAID	U.S. Agency for International Development
VCT	voluntary counseling and testing (for HIV)
WHO	World Health Organization
XDR-TB	Extensively drug-resistant tuberculosis

To achieve the millennium development goals (MDG) and targets for 2015,[1] the DOTS strategy was expanded in 2006, and labeled the *Stop TB Strategy*, with the purpose of addressing the pressing challenges posed by limited access to high-quality tuberculosis (TB) diagnosis and treatment, HIV/AIDS co-infection, and increasing TB drug resistance.[2,3] Among the important interventions required to reach these goals is a systematic involvement of all relevant health care providers in delivering effective and quality TB services.

Several national TB programs (NTPs) have successfully integrated public and private hospitals in the DOTS program. This integration has been particularly common in African countries, where hospitals were involved from the start of DOTS expansion or where DOTS implementation started in the hospital sector and later decentralized to the community network. Many high-burdened countries (HBCs), mainly Asian, however, have a large public and private hospital sector that has never been fully engaged in DOTS expansion, despite the fact that large numbers of TB patients seek care at hospitals. These countries share a similar set of challenges related to involvement of hospitals in TB control.

This document describes the strategies, steps, and tools that facilitate involvement and linking of hospitals into the national DOTS program.

Experiences from many countries show that, although large numbers of TB patients are being diagnosed in hospitals, often the NTP is not notified of these cases. Providers in these hospitals often do not follow the national guidelines for diagnosis and treatment of TB patients. This failure results in both under- and over-diagnosis of TB. More important, inadequate treatment supervision, resulting in poor treatment outcomes, is the norm rather than the exception in these facilities. The high drop-out rate of TB patients treated in hospitals is a significant risk factor for increased mortality and the development and amplification of drug resistance.

In most countries, hospitals also play a central role in the diagnosis and management of multidrug-resistant TB (MDR-TB). The often suboptimal management of MDR-TB, however, contributes to high failure and death rates as well as to the creation of extensively drug-resistant TB (XDR-TB). As a result, relevant public and private hospitals must be engaged in programmatic management of drug-resistant TB. Several Green Light Committee–supported programs have demonstrated that hospitals play a crucial role in programmatic management of drug-resistant TB, provided they follow the International Standards for Tuberculosis Care (ISTC).

1. WHO. 2007. *Report 2007 Global TB Control*. Geneva: WHO, p.10.

2. WHO. 2006. *The Stop TB Strategy: Building on and enhancing DOTS to meet the TB-related Millennium Development Goals*. Geneva: WHO. (WHO/HTM/TB/2006.368)

3. WHO. 2006. *The Global Plan to Stop TB 2006-2015*. Geneva: WHO. (WHO/HTM/STB/2006.35, http:/who.int/publications/2006/en/

Involvement of hospitals in NTP is thus extremely important. The DOTS Expansion Working Group, established under the Stop TB Partnership, has recognized this importance and strongly promotes public-private mix (PPM) initiatives including the expansion of quality TB diagnosis, treatment, and care among providers in hospitals.

The establishment and maintenance of effective networks between hospitals and the services of the NTP—including the implementation of standardized and evidence-based TB services by all departments and clinicians in hospitals and the linkage of these hospitals with the national TB program—are important parts of PPM interventions. This effort encompasses the hospital-DOTS linkage (HDL), which may be defined as the engagement and linkage of all public and private clinical care facilities, including primary, secondary, and tertiary hospitals, academic hospitals, private-for-profit and not-for-profit (i.e., charity or nongovernmental organization [NGO]) hospitals into the national TB control framework where DOTS forms the basis for case management.

Hospital engagement is part and parcel of PPM. The available evidence and field experiences on hospital involvement in six HBCs that have large hospital sectors, were collected during an international workshop in June 2007 in Tuban, Indonesia, and reveal a distinct commonality in problems, solutions, and interventions regarding management of TB patients in hospitals. The evidence base is still being expanded and updated including the comprehensive set of interventions and tools described in this document.

All interventions should be integrated under the umbrella of PPM activities and not implemented in parallel or isolation. An iterative approach or "learning by doing" and stepwise expansion is often required, following basic principles of case management and program integration described in the document *International Standards for Tuberculosis Care*.[4,5]

4. Tuberculosis Coalition for Technical Assistance. 2007. *Handbook for Using the International Standards for Tuberculosis Care*. The Hague: Tuberculosis Coalition for Technical Assistance. http://www.tbcta.org/TB_CAP_Toolbox/_
5. Tuberculosis Coalition for Technical Assistance. 2006. *International Standards for Tuberculosis Care (ISTC)*. The Hague: Tuberculosis Coalition for Technical Assistance. http://www.tbcta.org/TB_CAP_Toolbox/

This document provides a set of guiding principles and practical steps for planning and implementation of HDL. It is intended for use by NTP staff involved in the planning, development, and management of TB control; staff of local health services; and hospital managers and care providers working in public and private hospitals.

The document addresses (a) linkages among multiple services available within a given hospital (i.e., interdepartmental and internal linkages) and (b) the interface between hospitals and local or regional primary health facilities under NTP (i.e., external linkages) for optimal case management and follow-up.

This document is based on and complementary to the World Health Organization (WHO) guidance on implementing PPM approaches, *Engaging All Health Care Providers in TB Control*, which encompasses all PPM approaches, including those targeting hospitals.[6]

Figure 1. TB ward in a hospital in central Java, Indonesia

6. WHO. 2006. *Engaging All Health Care Providers in TB Control, Guidance on Implementing Public Private Mix Approaches*. Geneva: WHO. (WHO/HTM/2006.360)

3.1 The Benefits of Hospital Involvement

Hospitals often cater to larger volumes of patients compared to primary health services and, therefore, have a greater potential to increase TB case detection and notification. Their main advantages include availability of infrastructure, specialized health personnel, and good-quality diagnostic equipment such as laboratories, X–ray equipment, and other more advanced diagnostic tools. Major referral hospitals in large urban areas are the ones most likely to have these advantages, so they are potentially valuable for diagnosis and management of TB patients and MDR-TB.

TB patients often prefer seeking care in hospitals because the perceived quality of care is higher, compared to community health centers, and the variety of available clinical services is wider. This perception of higher quality of care is shared by providers in hospitals despite the fact that health professionals in many hospitals neither follow the DOTS strategy nor apply ISTC. Engaging hospitals in NTP assures proper case management for TB patients visiting hospital facilities. Another benefit of hospital linkage is the spillover effect to private sector providers, because most hospital doctors and specialists are also active in private practice.

Various NTPs, mainly in African and Latin American countries, have successfully integrated the public and private hospital in the DOTS program, generally because these hospitals were included from the start of DOTS expansion or because DOTS was initiated in the hospital sector and decentralized to the community health center network in a later phase. Several HBCs, however, mainly, but not exclusively, in Asian countries that have a large public and private hospital sector, share a similar set of challenges related to the fact that the hospital sector was partially or completely left out during the phase of rapid DOTS expansion. Nevertheless, these hospitals are catering to large and yet unknown numbers of TB patients.

3.2 Challenges for TB Control in Hospitals

3.2.1 TB Case Management Challenges

TB management practices in hospitals are often not in line with national guidelines and international standards. Specialists, in particular, may be reluctant to adopt internationally standardized protocols for diagnosis and treatment of TB. Practitioners often rely only on chest radiology for diagnosis. Sputum smear examination is not routinely applied and is often totally omitted. Microscopic services in hospital laboratories are often not quality assured. Frequently suboptimal or even inadequate treatment regimens are prescribed. Default rates among TB patients are often high due to poor case holding, lack of treatment supervision, and limited patient follow-up. These factors often result in higher mortality of TB for patients diagnosed and treated in hospitals compared to community health centers.

Prevalence of HIV and TB-HIV co-infection is usually concentrated in urban areas. Patients receive medical care in hospitals where services for HIV and TB are often not properly coordinated, resulting in under-diagnosis and under-treatment of TB in HIV patients and HIV in TB patients.

Because hospitals often have large catchment areas, referral linkages among hospitals and health centers, community-based workers, and NGOs are generally weak. Many patients live far from the hospital, and hospital staff is generally not allowed to operate outside the facility or may not have the resources (e.g., transportation) to trace defaulters.

3.2.2 MDR-TB Challenges

In general, TB patients diagnosed in hospitals have a higher likelihood of MDR-TB than those diagnosed in primary health care facilities, partly because treatment (i.e., directly observed treatment [DOT]) and case holding in hospitals is often more difficult compared to community health centers and results in higher numbers of failures and defaulters from treatment.

Moreover, hospitals usually receive referrals of complicated cases from both the public and the private sectors and often cater to chronic cases who have a greater chance of drug resistance.

Outpatient departments, and in particular hospital wards, may offer an optimal environment for TB transmission and amplification of drug resistance when chronic TB cases are mixed with HIV-positive patients without appropriate infection control (IC) measures.

Hospitals do play a crucial role in the programmatic management of drug-resistant TB (DR-TB) under the Stop TB Strategy. MDR patients are usually hospitalized during the first phase of treatment or when complications occur. Such hospitalizations can be realized only when hospitals provide quality DOTS services and are optimally linked to the DOTS program.

Figure 2. Young woman with MDR-TB and destroyed lungs in a hospital in Indonesia

3.2.3 Challenges Related to the Complexity of Services

Particularly within larger hospitals, services are organized in a more complex manner compared to smaller public health facilities. Suspected TB cases are usually identified at different entry points (i.e., in outpatient clinics, the emergency room, or inpatient wards), and patients are managed by practitioners with various backgrounds and training (e.g., general practitioners and specialists including internists, infectious disease specialists, and other specialists dealing with extra pulmonary TB patients and other similar cases). Overlap of TB services, the absence of standardized treatment protocols, deficiencies in coordination and communication among providers, and the absence of a centralized unit where treatment of TB patients (regardless of where they are diagnosed) is monitored and followed-up all contribute to poor case holding and deficiencies in recording and reporting of cases.

Hospitals focus primarily on curative care for individual patients with an emphasis on patient satisfaction and privacy, whereas the public health perspective of care is often neglected. This disconnect results in delayed diagnosis of TB, a high proportion of diagnoses without bacteriological confirmation, and frequent defaults and failures of treatment.

3.2.4 Challenges Related to Patient Fees and Hospital Income

In both private and public hospitals, providers may have to compromise measures that are important from public health perspective, to ensure that the TB services they provide generate sufficient revenue for the hospital. Because of fear of losing income, hospitals are reluctant to collaborate with the NTP or to refer patients. In some specialist hospitals, TB patients constitute a significant source of income, and fees for diagnostic services and treatment may be substantial. When hospital revenue is related to the frequency of patient contacts, practitioners are reluctant to refer patients, particularly in private for-profit hospitals but also in public and not-for-profit hospitals. To increase a provider's income, TB patients may undergo unnecessary or unreliable diagnostic tests. At the same time, procedures to obtain fee exemptions for poor TB patients are often cumbersome, resulting in poor patients not availing themselves of the fee exemptions they are entitled to.

3.2.5 Challenges Related to Governance

Generally, hospitals fall under a diversity of departments or sectors including federal, state, and local government departments, as well as different ministries other than the Ministry of Health (MoH), such as the Ministry of Justice or the Interior (prison health services), the Ministry of Defense (facilities of the armed forces), the Ministry of Education (university hospitals), or the Ministry of Labor (special institutions affiliated with health insurance providers) to name a few. Other hospitals belong to nongovernment, for-profit and nonprofit sectors such as private corporations, university teaching hospitals, and charity hospitals.

The wide variety of stakeholders poses a major challenge to planning, implementation, and coordination of HDL.

NTPs often have neither the technical authority and resources required to provide logistic support to hospitals nor the resources to monitor and evaluate the program operations in hospitals. As a consequence, implementation of basic TB control activities in these health facilities is limited or weak, and the quality is poor.

3.3 The Importance of the Patient Perspective

The patient-centered approach is paramount to hospital engagement in TB care and control. Rights and responsibilities of the TB patient are described in *The Patients' Charter for Tuberculosis Care*[7] and are based on a mutually beneficial relationship between providers and patients with the objective of enhancing the effectiveness of TB care. The patient perspective must be assured in all aspects of service provision including quality of services, equity, affordability, accessibility, and accountability.

Every TB patient diagnosed and treated in hospitals has the right to receive the highest possible level of care according to the ISTC. Disseminating the patient charter is, therefore, important so that all health care personnel are aware of patients' rights and responsibilities.

Many settings successfully involve cured patients in activities related to case management. This involvement may vary from participation in the planning process to accommodate patient perceptions on quality care (e.g., through focus group discussions with TB patients) to active involvement in monitoring of treatment (e.g., assistance in the DOTS unit) or participation in case audits (e.g., to obtain client feedback on the quality of services).

Figure 3. Patient receiving treatment

7. WHO. 2006. *The Patients' Charter for Tuberculosis Care*. Geneva: WHO. www.who.int/tb/publications/2006/istc/en/index.html

Objectives

The objectives of hospital engagement or HDL are in line with the objectives described in the document *Engaging All Care Providers in TB Care and Control—Guidance on Implementing Public-Private Mix Approaches.*

Specific objectives are as follows:

1. To ensure that all TB patients seeking care in the hospital sector have access to quality TB diagnosis and treatment services, in line with the ISTC
2. To ensure that all hospitals (public and private) providing care to TB patients are effectively linked to the services of the NTP, including notification, surveillance, and referral functions

Expected outcomes of successful HDL are as follows:

1. Improved early TB case detection and increased TB notification through improved quality of diagnosis and improved notification and referral routines
2. Increased treatment success rate through improved case management and improved referral systems
3. Improved access to quality care and reduced risk of catastrophic health care expenditures for the poor through the provision of free or subsidized services and reduced indirect costs
4. Reduced generation and transmission of TB drug resistance
5. Improved coordination of TB-HIV services and integrated TB-HIV care

Figure 4. Boy admitted with relapse of TB in a lung hospital in Indonesia

The steps in hospital engagement are in principle in line with those described in the document *Engaging All Care Providers in TB Care and Control—Guidance on Implementing Public-Private Mix Approaches*. This section highlights the steps and considerations that are particularly important for hospital engagement. A strategic approach to hospital engagement should involve the following steps, each outlined in detail in this section:

1. Planning and preparation
2. Building the internal network
3. Building the external network

Internal coordination within hospitals is required to ensure that every suspected case of TB in all hospital departments is screened for TB and that all TB patients are diagnosed and treated according to international standards and national guidelines and are registered with the NTP and also notified. Each hospital establishes its internal network. Likewise, optimal external coordination between hospital DOTS units and the network of local health services is needed under guidance of the NTP. This relationship is described as the external network. The external and internal networks are complementary, and their activities may overlap. The shared purpose of the networks is to shorten delays in diagnosis and treatment, avoid patient default, and ultimately prevent the generation of drug resistance.

5.1 Planning and Preparation

5.1.1 Conducting a Situation Assessment

The purpose of the assessment is twofold. First, it creates awareness among and provides feedback to the hospital administration and clinical staffs about the TB situation, the performance of TB case management in the hospital, and the existing deficiencies. Second, it creates awareness among professionals, and it contributes to increased commitment among managers. The baseline data will help set priorities and constitute the basis for measuring change and subsequent progress.

The baseline situation assessment follows the steps outlined in *PPM National Situational Assessment*.[8] It includes, among other steps, mapping of hospitals and their catchment areas, determining TB case loads in hospitals, performing case management, and analyzing the epidemiological situation, including treatment results, the HIV situation, and data on drug resistance.

8. WHO. 2007. *PPM National Situational Assessment*. Geneva: WHO/HTM/TB/2007.391 http://whqlibdoc.who.int/hq/2007/WHO_HTM_TB_2007.391_eng.pdf

5.1.1.1 Stakeholder Analysis

One of the first steps is analysis of stakeholders to identify potential partners whose involvement is critical in the participatory planning process (e.g., professional organizations, hospital associations, and NGOs). Other topics for analysis include the capacity of the local health services, resource needs, and last but not least, the regulatory environment. In hospitals where DOTS has already been introduced, the analysis should measure its current performance.

5.1.1.2 Baseline Assessment of Existing Hospital Practices

An initial priority is to assess existing practices and capacities of different departments and their staff members involved in the management of TB patients in hospitals. The NTP can participate in this process and provide materials to ensure that this activity is done in a structured way using an adapted baseline assessment form. The assessment should examine all aspects of TB case management including, for example, patient flow, suspect identification, diagnostic and treatment services for drug-susceptible and drug-resistant cases, surveillance, IC, and link with HIV/AIDS services. Information obtained during this assessment, including review of outputs and DOTS performance (e.g., cohort analysis of conversion and treatment results), should be fed back directly to hospital administration and medical staff.

5.1.1.3 Prioritization of Hospitals

In the process of hospital selection, several factors must be considered. These factors include size of the facilities and health service area, number of TB patients being serviced, and willingness or commitment of administrative and clinical staff to participate in the DOTS program. Because a primary goal is to increase access of patients to quality care, incorporating and prioritizing the facilities that provide services to marginalized and at-risk populations (e.g., HIV) where TB rates are expected to be high is an important step. Large hospitals, medical college hospitals, and facilities linked to training institutes should also be prioritized.

Based on the assessment, the plan for implementation can be developed. This process requires defining (a) objectives, (b) responsible parties or actors, (c) tasks, (d) tools, (e) indicators, (f) targets, and (g) resources (i.e., logistics and funding). The next step is to define funding gaps. The planning process should be participatory and should involve the various partners.

5.1.2 Prerequisites

A prerequisite for the initiation and sustainability of effective hospital engagement is a well-functioning DOTS program in the area where the hospitals are located. Local public health services should be ready and committed to involving the hospitals. Additional capacity at local health services or the NTP may be necessary to support the establishment and maintenance of networks. Successful hospital involvement results from consistent commitment and support of central and midlevel managers

for guidance, planning, implementation, and monitoring. These elements are especially crucial for surveillance, effective management of referrals, and prevention of treatment default.

As mentioned above, hospitals are usually administered by a variety of departments, ministries, or NGOs. Therefore, planning and implementation requires close collaboration and organization of stakeholders as well as coordination of activities at different service levels. Continuous coordination is needed to maintain commitment, mobilize resources, develop human capacity, and monitor and evaluate implementation.

5.1.3 Assessing the Policy Environment and Regulatory Framework

The chief role of the MoH and the central level of NTP is to determine overall policy direction (i.e., the formulation of national guidelines and standards) and to formulate the regulatory frameworks (e.g., promoting adherence to NTP guidelines and universal access to service, minimal service standards, certification and accreditation); the role also focuses on effective coordination between the national and subnational or regional units of the NTP and the various stakeholders.

A review of existing laws, decrees, and regulations that may affect notification and management of communicable diseases in hospitals, in particular for TB and HIV, is essential at this stage. Likewise, regulations regarding provision of TB drugs should be critically reviewed. Analyzing whether existing laws, decrees, and regulations pertaining to management of TB either facilitate or restrict implementation of DOTS in hospitals and analyzing whether official regulatory agencies exist and function well are also essential. These analyses require interaction with such entities as the legal department, the drug regulatory authorities, and others.

5.1.4 Building Partnerships

The involvement of existing central, provincial, as well as local level organizations, departments, associations, and institutions that have the potential to mobilize hospitals or to assist in multiple ways is vital. The department in the MoH that has the main responsibility for governing hospitals (e.g., the Department of Medical Services, the Department of Curative Services, or the equivalent) is an essential stakeholder with whom to liaise for policy and guideline development, planning, and resource mobilization. Professional organizations are also key partners in mobilizing health professionals for support of implementation of HDL[9] and may also function as an advocacy interface between the public health and hospital sectors (i.e., medical and hospital organizations). Teaching hospitals and academic

9. Irawati, S. R., C. Basri, M. S. Arias, et al. 2007. Hospital DOTS Linkage in Indonesia: A Model for DOTS Expansion into Government and Private Hospitals. *International Journal of Tuberculosis and Lung Disease.*11:33–39.

institutions, as centers of excellence, should be prioritized because of their important role in human resource development. Representatives of these teaching hospitals should be engaged as members of the HDL task force (see 5.1.6) and should be involved in training, monitoring and supervision, and implementing operations research.

Private hospital associations have the potential to improve coordination with the private sector, and their involvement is instrumental in planning and implementation. Community organizations could assist in sensitizing the community, referring suspected cases, providing DOT, educating patients on issues related to access, performing diagnosis and treatment, and tracing defaulters. In several countries, social security health programs, specific health insurance schemes, and NGOs help to finance the diagnosis and treatment of TB within different services, including hospitals. They may also have their own hospital networks.

Collaboration and partnership should also expand to other public health programs operating within hospitals, specifically the national AIDS program, for management of co-infected individuals. This expansion should be done in an integrated way and should be consistent with national policies.

5.1.5 Planning Coordination

To assure proper coordination of activities a hospital DOTS coordinator at the regional level (i.e., provincial or region) needs to be appointed. He or she does not necessarily need to be a new staff person to be appointed but may well be staff of the local health services or a supervisor of the local NTP. The coordinator assists with the establishment of DOTS teams in hospitals, facilitates functioning of the internal networks, supports the dissemination and implementation of the ISTC, assures that hospitals are linked to the NTP surveillance system (i.e., the recording and reporting system), assists the hospital DOTS teams in defaulter tracing, and assists in linking the hospital laboratory to the laboratory quality assurance system. He or she also facilitates the building of an effective referral system.

The coordinator is preferably supported by an HDL task force as part of the PPM basic management unit. Establishment of this task force provides an effective approach to linking key players, sharing common goals, and convening various key stakeholders such as representatives from the hospital sector, from professional societies, from NTP at local level, and from other relevant organizations. Actively involving health professionals and representatives from professional associations in the HDL task force (e.g., through activities related to the ISTC endorsement process) is an important step in the process of HDL.

Arrangements for interagency collaboration are preferably formulated in specific terms of reference agreed upon by all stakeholders. The HDL task force functions as a coordinating body that assists the coordinator by facilitating operations and monitoring activities and outputs.

The tasks of the HDL task force include the following among others:

- Advocacy
- Training
- Supervision
- Evaluation
- Policy and guidelines formulation

For further explanation, see section 5.3 "Building the External Network."

5.1.6 Advocating and Mobilizing Resources

Advocacy is an essential, initial step in the process of involving public and private hospitals.

The purpose of conducting advocacy is to gain commitment from the hospital administration and clinical staffs of the facility. Advocacy and orientation meetings can be effective to engage the hospital directors and professional staff members and to obtain effective support for initiation and sustaining implementation of DOTS in hospitals and establishing networks with local health services. The support from the various key players, such as hospital managers, administration, health professionals, and NTP, is crucial, especially in the starting phase. Continuous advocacy is needed to maintain commitment and support. Special efforts may be needed to advocate to all these different target groups. During advocacy meetings, the outcomes and results of baseline assessment done in hospitals can be shared with the audience, which may help them understand the need and rationale for implementation of DOTS.

Advocacy efforts are best undertaken in full collaboration with members of professional societies, in particular specialists who are supportive of the DOTS strategy and ISTC. The HDL task force may also be instrumental in leveraging institutional commitment and mobilizing resources.

Tools for Advocacy

A memorandum of understanding (MOU) or letter of agreement between NTP and local hospitals aims to clarify roles and responsibilities of the various stakeholders. For example, the MOU may describe the responsibilities of NTP (e.g., to provide free anti-TB medicines, other resources such as laboratory supplies and equipment, and funds), whereas the responsibilities of hospitals include expressions of commitment to follow national guidelines and provision of free (i.e., exempted from user fees) diagnostic and treatment services and active participation in TB surveillance. In some instances, the approval of a ministerial order or decree is required to provide a legal basis and assure accountability.

Other important advocacy tools include the ISTC (in particular, endorsements by local professional associations), recent reviews of the NTP, a national situational assessment on PPM, and regulatory and policy documents. These tools may help to facilitate dissemination of the concept and understanding of the purposes and benefits of hospital engagement. The messages must be clear, relevant, and consistent.

5.1.7 Developing Implementation Tools

This section provides an overview of tools available for hospital engagement. The tools are based on, and are complementary to, the document *PPM: Practical Tools to Help Implementation.*[10] Table 1 lists some helpful tools.

Figure 5. TB Patient with her child, Bangladesh

10. WHO. 2003. "Practical Tools to Help Implementation of Public Private Mix for DOTS." In *PPM: Practical Tools to Help Implementation*. Geneva: WHO/CDS/TB.

Table 1. Tools for Implementing HDL

Components	Tools
Advocacy	• NTP policy document • ISTC • MOU or letter of agreement • Official directives and decrees from the Department of Medical Services (or equivalent department)
Planning and preparation	• Baseline hospital assessment form[a] • Hospital implementation plan • Referral forms and registries • Directories of all health facilities including addresses and telephone numbers
Training the people	• Standard operating procedures (SOPs) for HDL • Job description for the hospital DOTS coordinator • Training curricula (SOP, TB/HIV coordination, and laboratory external quality assurance [EQA]) • Adapted training modules
Monitoring and evaluation[b]	• NTP data recording and reporting forms for case finding, treatment, and laboratory EQA • Modified patient treatment card (including information on place of diagnosis (i.e., referral data such as "referred from…") • Referral registries and defaulter tracing registries • Supervision checklist • Accreditation and certification documents

[a]The baseline hospital assessment form contains an inventory of all components described in this document. The assessment facilitates comprehensive and standardized qualitative and quantitative measurement of hospital engagement and all essential components related to DOTS implementation in a hospital (i.e., stakeholder commitment, performance of TB diagnosis, and treatment practices including laboratory quality assurance, surveillance, operation of internal and external networks). It not only provides the basis for planning, but also is a useful tool for monitoring of implementation and for development of certification standards.

[b]Standard records and registers for NTP surveillance are normally sufficient but some essential data entries need to be added:

> To be able to measure the contribution of hospitals in the diagnosis of TB, referral information should be recorded on patient treatment cards, patient registers, and other forms for TB case management, including quarterly reports. The inclusion of referral information (*'referred from…,'* *'referred to….'*) is particularly important when hospitals diagnose large numbers of TB patients but refer these patients to peripheral units before the start of treatment. Without this information, the contribution of hospitals in case finding cannot be measured because patients are registered and notified at the receiving peripheral unit. The forms are not included in these guidelines; they are available from NTP program and in WHO manuals, and should be introduced to hospital staff during DOTS training.

5.1.8 Developing Certification and Accreditation

Certification is an important tool to assure that hospitals and other institutions meet appropriate standards to provide the services being certified. Certification requires compliance with a uniform set of standard criteria and procedures essential for proper delivery of standardized quality TB care. Criteria for certification and accreditation should be related to the specific tasks allocated to providers, and these criteria should be similar for public and private sectors. To achieve acceptance of criteria for certification and assure optimal compliance, the standards for certification need to be set by involving all major stakeholders from various departments, sectors, and professional associations. Supply of quality-assured anti-TB medicines and laboratory supplies free of charge to non-NTP providers may be linked to a system of certification to ensure their proper use. The process to develop certification and accreditation schemes may take years and implementation may not be easy. All other ways to facilitate enforcement of existing regulations that are beneficial for implementation of HDL should be explored.

5.1.9 Involving Professional Societies for Hospital Engagement

Heads of large hospitals or medical colleges may be more effectively influenced through information, training, and encouragement by their peer group or opinion leaders within professional societies than by representatives of the NTP. Professional organizations whose members are dealing with TB patients should be fully involved from the start. Several national programs have succeeded in mobilizing opinion leaders and champions in these professional organizations to support implementation of the ISTC. This success paved the way for implementation of HDL.

Figure 6. Young girl with TB-HIV at the outpatient department of a hospital in Lagos, Nigeria

A common observation has been that involvement of well-known local and national experts in the professional societies as trainers helped considerably to improve credibility and acceptance of DOTS. Another option is to include ISTC and HDL in the continuous medical education program of the professional societies. Using these organizations and existing mechanisms will help to reach larger audiences with less effort and fewer resources.

5.2 Building the Internal Network

The internal network (figure 7) consists of a package of coordinated activities with the objective of assuring that all suspected TB cases entering the hospital through the various outpatient clinics, the emergency department, and inpatient departments (e.g., internal medicine, pulmonary medicine, infectious disease, and pediatrics) are diagnosed and treated according to the ISTC. To achieve this goal, the following interventions are needed:

- Build a coordination team within hospital (i.e., a hospital DOTS team)
- Train medical staff, nurses, laboratory staff, and other personnel necessary to the task
- Establish a DOTS unit (DOTS room) in each hospital
- Introduce standard NTP recording and reporting formats

A challenge for hospital engagement is to ensure quality of DOTS services in all hospital departments including the laboratory.

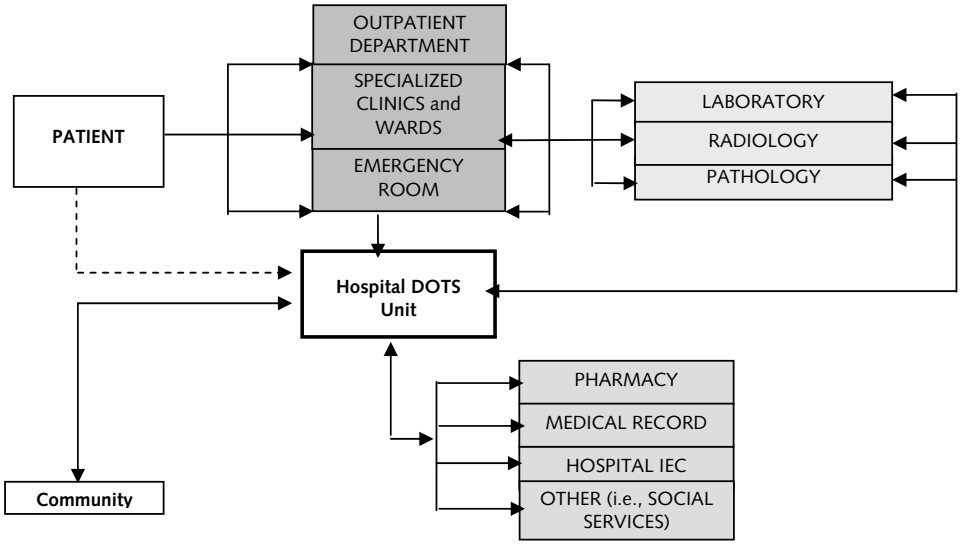

Figure 7. Internal network

5.2.1 Deciding on the Task Mix

The baseline assessment described in the section 5.1.1 should also be used to determine which clinical and public health functions can be adequately and efficiently delivered by the hospital facility to ensure optimal case management. It will also help determine the level of involvement of a given facility in implementing DOTS. The task-mix options (table 2) are selected sets of clinical AND public health responsibilities that are ALL essential steps in the process of successful TB case management.

Table 2. Suggested Basic HDL Task-Mix Options

Tasks	Option 1	Option 2	Option 3[a]	Option 4[a]
Clinical functions				
Identify suspected cases of TB	■	■	■	■
Conduct smear microscopy and (if indicated) culture and chest X-ray per NTP guidelines	■	■	■	■
Diagnose TB	■	■	■	■
Diagnose co-infection with HIV	■	■	■	■
Prescribe treatment for TB and TB-HIV	■	■	■	■
Refer diagnosed patient to health center	■	■	■	■
Supervise treatment or assign treatment observer		■	■	■
Perform clinical follow-up			■	■
Public health functions				
Record and report cases		■	■	■
Follow up on defaulters			■	■
Train hospital staff			■	■
Supervise networks			■	■
Perform laboratory EQA				■
Monitor and evaluate				■
Provide supplies and medicines				

[a]The public health functions of options 3 and 4 are variable and are normally context specific.

Each hospital facility should consider the various options and select one. The selected option should match the capacity and potential of the facility to deliver the range of functions and services according to set quality criteria. Ideally, a hospital that is unable to achieve the target for sputum smear conversion of 80 percent or a treatment completion rate of 85 percent should select option 1 and not be allowed to adopt option 2, 3, or 4.

5.2.2 Making the Work Plan for Hospital DOTS Implementation

Once the baseline assessment is conducted and the hospital's task mix has been agreed upon, the next step is to develop an implementation plan. Preferably, the NTP and other local partners should be involved in the planning phase. The purpose of the plan is to guide the process of hospital DOTS implementation by providing a comprehensive framework and by describing the overall process—including monitoring and evaluation—and the responsibilities of the various stakeholders. The plan should stipulate clear, realistic objectives and outlined activities based on the selected option, required inputs, indicators, responsible persons/parties, and a timeline for implementation. The hospital implementation plan must be supported by all key stakeholders involved.

5.2.3 Addressing Resistance to Change

Medical staff and health professionals commonly tend to resist changes in clinical practices and hospital procedures. Nonetheless, efforts to initiate and expand DOTS implementation in hospitals should be continued. Improvements are obtained only over time and sometimes are based on trial and error. Implementation of HDL activities can be initiated with only a few doctors and departments participating, but such limited participation is not ideal. If progress is well documented, results can be disseminated and used for promotion to providers that are not yet participating. These providers may then be persuaded and motivated to participate. ISTC have proven to be a powerful tool to convince medical professionals of the benefits of DOTS. Therefore ISTC dissemination activities should run parallel to HDL, and professional associations should be maximally involved from the start.

5.2.4 Forming the Hospital DOTS Team

This team functions as both an internal coordinating team and an interface between hospital service departments and the local and regional levels of the NTP. Members of the hospital DOTS team may include representatives from hospital administration, key specialists, and staff from selected departments (e.g., internal medicine, pulmonary, pediatrics, HIV and voluntary counseling and testing [VCT] units, laboratory, and pharmacy). Responsibilities of the hospital DOTS team include (a) overseeing the proper and systematic implementation of DOTS including surveillance and (b) assuring coordination between the relevant units. It should also be actively engaged in advocacy, training, development of guidelines of SOPs, monitoring and evaluation, and problem-solving.

Establishment of the team should be endorsed by hospital authorities (i.e., by hospital decree, MOU) and preferably be based on a formalized structure such as specific terms of reference. It could be backed by an official directive from a higher level, such as policy from the MoH. To smooth the initial process, the NTP could make available NTP guidelines, an advocacy package (e.g., ISTC; PPM; advocacy, communication, and social mobilization [ACSM] including information, education, and communication [IEC] materials), and sample templates (e.g., samples of an MOU or a template of a hospital implementation plan).

Figure 8. A hospital DOTS team

5.2.5 Establishing the Hospital DOTS Unit

The DOTS unit (or DOTS clinic, DOTS center) is a physical space in the hospital designated for the daily management of TB patients. Establishing this DOTS unit is important to mainstream the flow of all TB patients diagnosed in the various departments of the facility. The objective is for all suspected TB cases and TB patients entering or exiting the hospital to receive standardized care under DOTS. The unit should be centrally and strategically located to facilitate access from all departments. Adequate human, logistical, and space resources need to be allocated. Patients diagnosed at different locations within a hospital should be directed to this unit early, where case management will be initiated according to the option selected (see table 2). The DOTS unit may be located within one of the medical departments, usually the internal medicine or pulmonary department. Location should be close to the laboratory and the HIV/VCT unit. Ensuring proper patient flow is essential to reduce the risk of TB transmission and to minimize the waiting time when patients are referred to the DOTS unit, laboratory, X-ray, or VCT.

5.2.6 Ensuring Infection Control (IC)

The conditions for IC must be assessed in each facility, and an IC plan with the objective of minimizing transmission in the facility must be developed. This plan concerns specific measures and practices that reduce the likelihood of transmission of *M. tuberculosis* within the facility. Transmission control is even more important in facilities that diagnose and treat HIV and drug- resistant TB, in particular MDR or XDR patients. In general, the likelihood of multiple-drug resistance is high in hospitals because they receive referrals from peripheral health units including many chronic cases.

Interventions include the following administrative and environmental measures and respiratory protection for health staff: early screening, safe sputum collection, creating awareness through education on transmission and cough etiquette, and fast-track separation of infectious cases. Likewise important are rapid diagnosis and initiation of treatment; proper ventilation in waiting rooms, clinics, and in-patient wards; measures to protect health care workers including capacity building on IC; and regular monitoring and periodic evaluation of IC practices. For detailed information on specific measures, please refer to the guidelines on IC.[11]

5.2.7 Preparing Human Resources

The hospital administration should allocate designated staff to be responsible for running the DOTS unit. This staff member, either a physician or a nurse, is part of the hospital DOTS team and directly responsible for the daily management of TB cases under supervision of the NTP. Former patients could be involved as treatment observers or in patient education. To assure continuity, staff rotation should be kept to a minimum. Staff stability not only benefits the quality of case management and surveillance but also improves the rapport between the provider and the patient, thus reducing the risk for treatment default.

Figure 9. Patient Education is an important part of infection control

A key step in building a sustainable internal network is the training of hospital staff in TB case management according to ISTC and the Stop TB Strategy. Training for the different categories of hospital staff involved in the management of TB patients (i.e., medical, paramedical including laboratory, surveillance, and health education) should be done in close collaboration with the local NTP. The training curriculum should be based on the task mix selected. Training material can be developed from existing NTP training modules with slight adaptations for specific hospital-related issues (e.g., internal networking, standard operational procedures for patient referral, TB-IC, etc.)

Organization of training will depend on the local setting. One approach is to start with formation and training of a trainers group, who work with NTP to adapt the materials and train other hospital staff. The program must keep track of changes or turnover of trained staff in hospitals and ensure that incoming personnel receive training to prevent gaps.

11. WHO. 2009. *WHO Policy on TB Infection Control in Health Care Settings, Congregate Settings and Households*. Geneva: WHO.

Another approach is to establish centers of excellence in selected teaching hospitals. Medical students, residents, and also medical personnel from other hospitals can receive in-service training at the DOTS unit of the teaching hospital. In-depth seminars for hospital specialists on, for example, ISTC, HIV-TB co-management, TB-IC, and MDR-TB management, are important to gain their commitment and support. As noted above, all training activity must have clear objectives and should be evaluated.

A common constraint is the high turnover or reassignment of trained staff to other hospital departments, disrupting the continuity of HDL implementation. Hospital authorities in collaboration with the HDL team should take measures to address high turnover rates.

Although hospital managers may be reluctant to establish a DOTS unit because of insufficient human resources, staff members at the unit do not need to be full-time, since most of the activities can be carried out within given shifts.

5.2.8 Assuring Proper Treatment Support

A patient-centered approach is paramount, with a treatment observer appointed to each TB patient. The treatment observer may be a member of the DOTS team (i.e., either a physician or nurse), an ex-patient, or a community member (e.g., outreach health worker, or NGO worker). The treatment observer must be educated and motivated continuously to ensure compliance and prevent patient default. In an effort to improve treatment compliance, the NTP may provide food supplements in the form of, for example, food baskets or food stamps for patients treated in hospitals, if such a program exists in the community for TB patients managed by health centers. In principle, diagnosis and treatment of TB patients in hospitals should be waived from any user fee.

NTP records and surveillance forms need slight adaptations for use in hospitals. Updating of patient recording and reporting forms or registers is the responsibility of the staff of the DOTS unit. Though patient records and registers are usually kept in the DOTS unit, patient records may also be kept at other service points such as the VCT unit or hospital wards. If the records are kept elsewhere, these staff members also need to receive training in data management.

Proper surveillance based on complete records and registries is essential to monitor performance of the hospital DOTS linkages and to assess progress and outcomes. Additional forms should be kept to a minimum. The hospital DOTS team has overall responsibility for oversight of the internal network. As such, they should conduct regular and systematic supervision and monitoring, including case audits. Specifically, they should ensure that the goals and objectives contained in the hospital plan are being met. If objectives are not being met, the DOTS team should promptly assess ways to remedy the problems. Regular internal monitoring meetings should be held for this purpose.

5.2.9 Referring Patients to Local TB Treatment Facilities

TB patients seeking care in hospitals often come from far away, even from outside the regular catchment area of the facility. Mobility of TB patients in urban areas may also be high. These factors often result in irregularity of treatment or defaulting at the hospital. Limited human resources constrain the tracing of defaulters. Referral systems are often weak, and referral feedback mechanisms between facilities are usually lacking. Box 1 provides an important reminder.

Box 1. Where To Treat

As a rule of thumb, all TB patients who are in reasonable condition and without complications should be treated in the health facility closest to the home of the patient. The staff at the DOTS unit in the hospital should therefore ensure that all conditions for proper referral of patients are fulfilled to prevent patients from being lost in the process.

Furthermore, the specialized hospital services should serve as reference centers for differential diagnosis of pulmonary patients with negative bacteriological examinations and TB patients with severe complications, treatment side effects, or both. They should also serve as laboratory support for culture and drug-susceptibility testing (after achieving quality assurance) and management of treatment failures and chronic cases.

5.3 Building the External Network

The external network (figure 10) is a comprehensive framework linking the hospital to existing peripheral DOTS clinics and other health facilities that are part of NTP. The purpose of the external network is to assure optimal management of TB patients from the moment of first patient contact until cure or completion of treatment, that is, to employ the concept of a patient-centered approach to care. The basic components and steps to build an external network are discussed in this section.

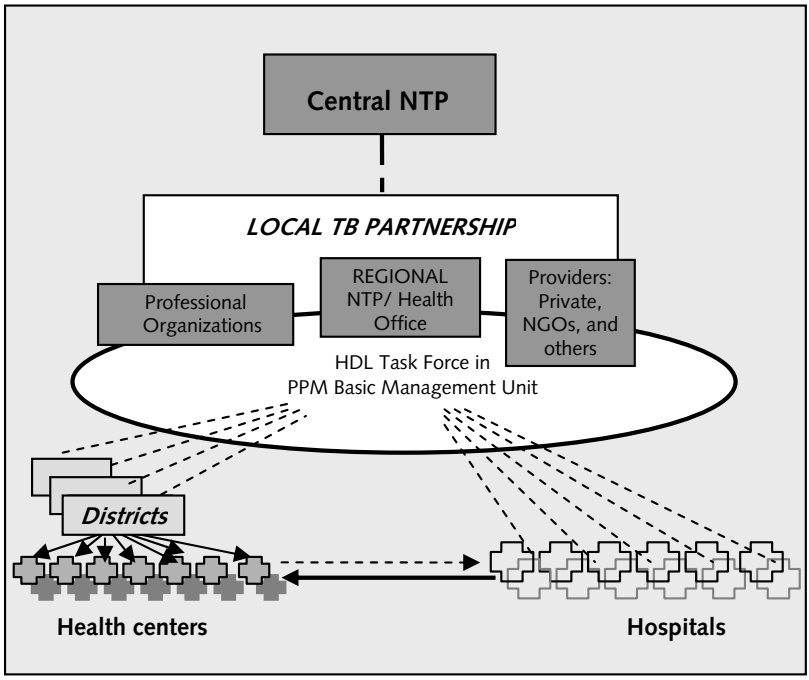

Figure 10. External network[12]

5.3.1 Human Resource Development and Training

The NTP, in close coordination with the local HDL task force, should lead human resource development activities to establish external networks for HDL. The implementation steps are outlined below.

The success of HDL initiatives depends not only on the willingness of hospitals to participate in the DOTS program, but also on the receptiveness of NTP staffs to involve hospitals and on how well hospital staffs are sensitized and trained. Thus training NTP staff on the tasks and processes related to implementation of hospital engagement is important.

Given that resistance to change among doctors and specialists providing TB care in hospitals has been identified as a major barrier, direct involvement of recognized and respected medical authorities opinion leaders in the field may facilitate behavior change among practitioners. Moreover, current innovations in medical diagnostics and information technology and new supportive global TB control initiatives (e.g.,

12. Adapted from S. R. Irawati, C. Basri, M. S. Arias, et al. 2007. Hospital DOTS Linkage in Indonesia: A Model for DOTS Expansion into Government and Private Hospitals. International Journal of Tuberculosis and Lung Disease 11:33–39.

MDG, Stop TB Partnership activities, and ISTC) can be catalysts for change. ISTC is considered to be a powerful tool to convince skeptical health professionals of the importance of DOTS implementation in hospitals.

In an effort to develop an external network, a comprehensive training curriculum should be developed and integrated with other NTP training activities. The following steps should be considered in planning and implementation of training:

- Determine the task mix, and based on that mix, develop job descriptions for staff.
- Ensure continuity, and ensure that enough trained personnel are available to run the DOTS unit in the hospital.
- Limit rotation and turnover of trained staff in the DOTS units.
- Perform a task analysis of the staff, and assess the competencies and skills. The skill gaps will define training needs and training objectives.
- Decide on training curriculum for the various categories of staff, including NTP staff, based on a training needs assessment.
- Adapt training methods to local needs, staff characteristics, and working conditions.
- Develop training materials, using or adapting available TB training modules (including topics on development of internal and external networking in hospitals). Training materials and methods need to be suitably adapted to specific needs and working conditions of different types of all categories of staff.
- Devise the training plan including a structure for follow-up and evaluation after training, preferably linked to ongoing program supervision activities. Training may also be arranged on the job, combined with supervision.

Existing NTP and international training materials and methods should be used as a basis for the training.

5.3.2 Integrating the Hospital Laboratories into the EQA Network

A major objective is to assure integration of each hospital laboratory into the NTP network. This integration should be contained in the hospital implementation plan. Activities related to this objective include (a) training of hospital laboratory technicians; (b) assuring laboratory supplies; (c) EQA through panel testing, or routine transportation of slides for cross-checking to the designated reference laboratory including feedback to the hospital laboratory of EQA results; and (d) on-site supervision visits by staff from the reference laboratory for problem solving and technical support. These activities need to be monitored and evaluated internally by the DOTS team.

Figure 11. Every hospital laboratory should be quality assured for TB diagnosis

Integrating all participating hospital laboratories into the EQA network of the NTP is quite important. Where feasible, hospitals with well-established quality assurance standards can become reference laboratories for other hospitals (e.g., performing "peer cross-checking"). Planning should include outlining the steps for routine collection, transportation, and analysis of slides from hospitals in the designated reference laboratory. Reference laboratories must provide feedback to hospitals on performance and ensure proper follow-up action if problems are identified. Additional steps can include on-site evaluation of hospital laboratories by reference laboratory personnel to ensure that standards and procedures are being followed.

Local NTP officers play a pivotal role in supporting the hospital EQA plan, assisting in collecting slides from hospitals and delivering feedback during routine visits. Their support is especially required during the early stages of development. The NTP should provide training materials and EQA guidelines to all hospitals.

5.3.3 Ensuring Supplies and Logistical Support

Regional and local NTP are responsible for adequately supplying hospitals, especially those with limited budgets, with the necessary anti-TB medicines and other essential supplies (e.g., reagents, laboratory materials, microscopes, reporting, and recording materials) to expedite diagnosis and treatment initiation, prevent default, record and report TB data, and deliver IEC materials.

5.3.4 Referring Patients Diagnosed in Hospitals

Special attention must be devoted to developing an effective referral system for patients who, after diagnosis in a hospital, choose either to initiate or continue and complete therapy at community health centers or other health facilities.

5.3.4.1 SOPs for Referral of TB Patients

The referral mechanism and steps must be clearly described in the national guideline SOPs and must include a detailed outline of the roles and responsibilities in the referral process including default tracing. These referral guidelines should be clarified to TB workers in all facilities and be included in the national training curriculum.

Active follow-up of every referral is essential to ensure that referred TB patients actually arrive at the receiving facility and continue their treatment there. The importance of appointing a referral coordinator to be responsible for hospital referrals at the regional, provincial, or district level cannot be underestimated. Preferably this person would be a member of the HDL task force or staff of the local basic management unit. If the coverage area is not too large and the workload is not too heavy, this function could be fulfilled by provincial or district NTP coordinator or supervisor. The responsibility of the referral coordinator is to oversee and monitor the registration and recording of referrals and the outcomes of referral. Through continuous communication with the hospital DOTS unit and provincial and district NTP managers, information will flow so that patients referred are registered and not lost to follow-up.

If a patient does not turn up at the local DOTS center, and no feedback is received at the referring facility, the designated staff at the hospital DOTS unit should check with the provincial or district referral coordinator who is responsible for follow-up actions. These actions include informing the receiving facility of relevant patient information essential for tracing (e.g., patient identity, address, and telephone number) through direct communication such as telephone, instant messaging, or e-mail. For this purpose, the referral coordinator compiles a directory of facilities (i.e., a list of addresses including telephone numbers and e-mail addresses) of all existing health facilities in the area, distributes this list to all facilities that are part of the network, and keeps these directories updated.

Depending on the situation, either the health staff of the receiving DOTS facility, or the referral coordinator has the responsibility to trace the defaulting patient and to verify treatment status. Local NGOs or other organizations can be involved to assist in patient tracing. Funds must be allocated for this activity in the work plan and budget.

5.3.4.2 Tools for Referral

The referral mechanism, which is outlined in figure 12, includes the following tools:

- *Patient referral form* (WHO format): completed by staff of the DOTS unit in the hospital and given to the patient, with copies sent to the health center and the provincial referral coordinator (i.e., the province and district NTP coordinator).

- *Referral feedback forms*: completed by health center staff and sent to hospital, with a copy sent to the referral coordinator (i.e., regional or district NTP coordinator). The receiving health center is required to send feedback to the hospital on the status of the referral in a timely manner. Establish the maximal timeline (e.g., one week) in the SOPs.

- *Patient referral register or log*: filled in and kept by the provincial referral coordinator (i.e., regional or district NTP coordinator). The referral register is continuously updated with information from the referral and referral feedback forms and is used for proper monitoring of the referral system (e.g., to calculate the referral success ratio). This register contains the complete data of every referral: name, age, sex, address, telephone number (if available), contact person, treatment facility, diagnosis and classification, treatment status and regimen at time of referral, date of referral, and date of arrival in receiving facility. The register is important for monitoring and evaluating the referral system and for determining actions needed to improve patient referral.

- *Default tracing form*: completed by health center staff and sent to hospital, with a copy to the referral coordinator (i.e., regional or district NTP coordinator). This form should include complete patient information: name, age and sex, telephone number (if available), name of treatment facility, contact person, diagnosis and classification, date of treatment interruption, treatment status at time of default (including treatment regimen), and the outcome (i.e., result) of tracing—for example, resumed treatment, re-started treatment, not found, died, refused treatment, referred for evaluation, or other outcome. The form should be sent to the hospital after completion of the tracing activities (i.e., within two weeks) with a copy to the referral coordinator.

- *Default tracing register or log:* filled in and kept updated by the provincial referral coordinator (i.e., province or district NTP coordinator), based on information from the default tracing forms. This register contains the complete data of every patient who defaulted (see default tracing form immediately above), the facility or person responsible for tracing, and the outcome of the tracing activities. The register is important for monitoring and evaluating the defaulter tracing system and for determining actions needed to improve patient follow-up.

- *Telephone directory of health facilities:* includes the names of all diagnostic and treatment facilities in the province or state, including address, telephone number, and contact person. The directories should be made available to all diagnostic and treatment centers and the information should be regularly updated (i.e., at least annually).

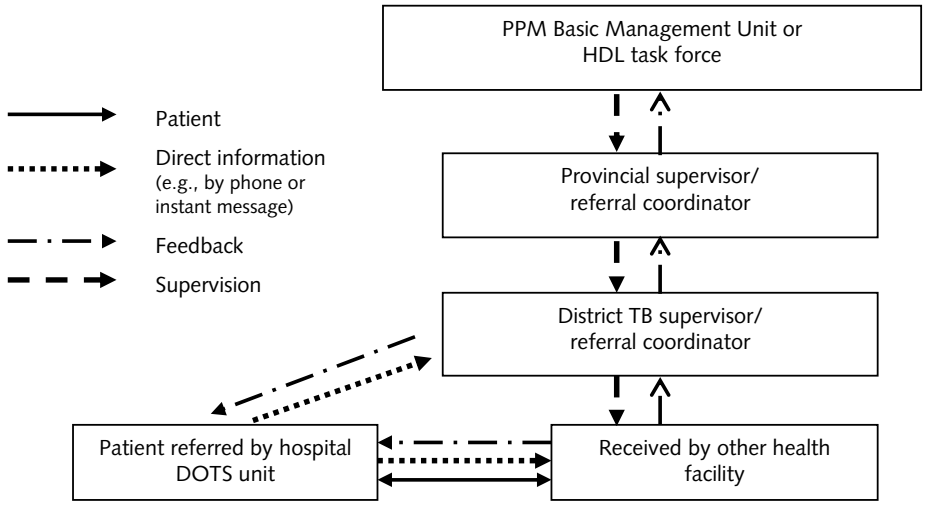

Figure 12. Generic referral mechanism

Implementation and scaling up of standardized TB diagnosis and treatment services into hospitals requires close monitoring and evaluation of case detection and treatment outcomes for all TB patients. Frequent data analysis using standardized indicators will facilitate timely identification and problem-solving. Provincial and district NTP managers must include hospitals in their supervision and evaluation plans, including the laboratory EQA and the patient referral system.

Existing NTP data-collection instruments should be adapted to facilitate proper monitoring and evaluation of hospital engagement. The data system must allow for disaggregation of hospital data so that these data can be analyzed separately. The local HDL task force plays a major role in supervision, monitoring, and evaluation through regular meetings and, as much as possible, directly through site visits.

To ensure quality of care, regular patient audits should be conducted by ascertaining the real cause of death among patients admitted in general and TB wards and in emergency rooms. Improving disease classification, recording and reporting of TB deaths, and emphasizing nursing and clinical care of admitted TB patients can significantly reduce the number of reported TB deaths.

6.1 Reporting and Information Flow

PPM faces a major challenge in creating a uniform surveillance system that incorporates all other (i.e., non-NTP) providers, but still enables performance assessment of various provider types.

To evaluate the contribution of hospitals to case detection and cure rates, the program should strive to build and sustain an information system that tracks the notification of TB cases and the treatment outcomes of hospitals in a given area. This surveillance is essential to guide corrective action and to adjust policies and resource allocation.

Another responsibility of the HDL task force is to ensure that a comprehensive information system is in place. To achieve this, the NTP must build the competencies of hospital staff to correctly fill out the TB forms and monitor and analyze the data. In addition, it must assure that data will flow from hospitals up through the different levels of the NTP. The NTP must make every effort to ensure that information from individual hospitals is collected, summarized, and analyzed routinely. Potential pitfalls are duplication (i.e., overreporting) or underreporting of cases, both of which can be averted if data are validated and matched within hospital services (i.e., matching between DOTS unit, laboratory, and pharmacy) and between the hospital and local NTP registers in health centers or district level depending on the context.

The indicators to measure case management and laboratory performance in hospitals are similar to the ones used by the NTP and will not be described in this document.

Figure 13. Data analysis essential for monitoring of HDL

Box 2. The Importance of the Conversion Rate for Monitoring of HDL

The conversion rate constitutes an early warning system and provides good and early information on the quality of case management, in particular during scaling up of hospital engagement. Most TB cases default in the intensive phase of treatment or soon after diagnosis. Low conversion rates enable early problem detection and remedial action.

6.2 Monitoring and Evaluation of the Referral System

Patient referral should be monitored closely and systematically. It should allow the tracking of patient movements from the time of diagnosis in a hospital until cure or treatment completion in a community-based health facility or clinic. Data on referral should be summarized and analyzed systematically during supervision and monitoring meetings. Remedial steps should be taken promptly if problems are detected. The provincial, district, and local health services should plan and budget for tracing of defaulters treated at, or referred from, hospitals according to the default tracing procedures.

Indicators to assess the quality of internal and external networking in HDL include the following:

- Confirmed sputum diagnosis ratio, defined as:
  $$\frac{\text{Number of patients diagnosed in hospital with bacteriological confirmation}}{\text{Number of patients diagnosed by hospital (total)}}$$

- Successful referral ratio, defined as:
  $$\frac{\text{Number of patients received at the receiving DOTS center}}{\text{Number of patients referred by hospitals}}$$

- Successful referral tracing ratio, defined as:
  $$\frac{\text{Number of patients retrieved for treatment}}{\text{Number of patients who dropped out after referral}}$$

- Proportion of TB patients tested for HIV, defined as:
  $$\frac{\text{Number of TB patients tested for HIV}}{\text{Total number of TB patients diagnosed in the hospital}}$$

Other indicators that may be used include the following:

- Treatment outcomes of referred patients compared to those that are not referred
- Proportion of HIV patients diagnosed in the VCT unit who are tested for TB
- Proportion of TB-HIV patients put on antiretroviral therapy
- Referral coordinator appointed and in place
- Percentage of hospitals implementing the SOP for referral
- Percentage of hospitals with telephone directory of facilities in cluster area (i.e., province or district)

Indicators of a successful laboratory network or EQA plan may be measured by the following:

- EQA coverage, defined as:
  $$\frac{\text{Number of hospitals routinely covered by EQA}}{\text{Number of hospitals that are engaged}}$$

- EQA feedback, defined as—
  $$\frac{\text{Number of hospitals receiving EQA report from reference laboratory}}{\text{Number of hospitals that are part of the hospital engagement}}$$

- Error rate, defined as—

  $$\frac{\text{Number of smear slides with discrepant results}}{\text{Number of smear slides examined by reference laboratory}}$$

- Availability of EQA guidelines, defined as:

  $$\frac{\text{Number of hospitals with guidelines}}{\text{Number of hospitals that are engaged}}$$

- EQA training, defined as:

  $$\frac{\text{Number of hospital laboratories with staff trained in smear microscopy}}{\text{Number of hospitals that are engaged}}$$

7.1 Incentives and Enablers

Several factors affect the ability and motivation of providers in hospitals to engage with NTP. Incentives and enablers, if well designed, can overcome some of the motivational barriers. In some programs, creating and maintaining a system of incentives and enablers may be a key factor for success, not only by attracting hospital management and health professionals and ensuring their continued support and involvement, but also by enhancing performance.

Financial compensation, under formal contractual arrangements, may be necessary for institutions that manage large numbers of TB cases and suspected cases. In particular, clear financial agreements will have to be considered when bringing hospital engagement to scale or when negotiating collaborative arrangements with hospital associations, departments of medical services, or professional associations. Such support can be in the form of externally funded or employed staffs, for example, in the DOTS unit or in the laboratory or other resources.

Evidence shows, however, that hospitals, both public and private, treating large numbers of TB patients may find in-kind, nonmonetary incentives sufficient to enter into collaboration with NTP. Many hospital administrators see it as their corporate responsibility or as an opportunity to increase credibility by serving society in providing free care to poor TB patients. Effective nonmonetary incentives include access to free anti-TB medicines and laboratory supplies, access to free training and continuing education, and an opportunity to improve the quality of services according to the ISTC. Formal recognition through association with the national TB program and official accreditation or certification may result in potential to expand business.

The types of incentives and enablers, which may vary from setting to setting, include the following:

- Free anti-TB medications supplied to hospitals
- Training and in-service updates for all participating hospital staff members
- Placement of additional staff members in the DOTS unit or laboratory or both
- Commodities supplied, such as recording and reporting forms, training and IEC materials, and diagnostic supplies and equipment (i.e., reagents, sputum collection cups, smear supplies, microscopes)
- Logistical support for laboratory EQA network
- Participation in regional HDL meetings
- Certification and accreditation

7.2 Certification and Accreditation

Accreditation and certification are possible mechanisms to assure quality TB care by selected TB care providers or facilities based on a set of closely monitored quality standards. These standards can be used to determine which institutions should be granted the right to access free anti-TB medicines and program supplies and to receive other support in cash or in kind. They can also serve as a basis for allowing access to public health insurance schemes and can help hospitals generate additional income. In the Philippines, for example, a third party (a TB coalition in collaboration with NTP) issues certification, and a national health insurance organization issues accreditation, which allows an institution to be reimbursed for TB diagnosis and treatment services, but only if they follow NTP guidelines and use NTP quality-assured medicines. This mechanism is working as a positive incentive for public and private hospitals to commit to DOTS expansion in the country.

An important reason for stakeholder involvement in HDL is to assure adequate resource allocation for hospital engagement within existing budgets of provincial, district, and local public health offices. HDL should be incorporated into grant applications to bilateral and global funding mechanisms such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, so that funding gaps hampering implementation can be filled. To the extent possible, both public and private hospitals should have equitable access to resources for different activities (e.g., diagnosis, treatment, and IEC), depending on needs, similar to those available for primary care facilities implementing DOTS.

7.3 Exemption of Fees

Patient fees for TB services in hospitals, whenever possible, should be subsidized or waived for patients unable to pay user fees. The NTP or local authorities should support the waiving of fees by providing hospitals with diagnostic supplies (i.e., slides, laboratory reagents, microscopes, and X-ray films), training, and other enablers. Ideally, diagnostic tests such as microscopy and culture for anyone undergoing evaluation for TB should be free of charge.

Operations research projects should be promoted and designed to address operational problems that are identified during HDL initiation and scaling up. Results can be used to enhance implementation and formulate relevant, evidence-based solutions and policies. These efforts should include other institutions (i.e., universities and research centers) to assist in protocol development, financing, data collection, data analysis, and report writing. The potential contribution of these institutions should be valued and utilized. Understanding the factors associated with diagnostic and treatment delays from the provider and patient perspectives, diagnostic practices of providers, incentives and enablers for providers and patients, stigma, interventions to implement or improve TB/HIV collaborations, and risk factors for MDR-TB are all topics for operations research that can assist decision-makers and program managers in adopting and strengthening sound and evidence-based policies for TB control.

Once HDL has been successfully introduced, it should be expanded in a phased manner according to the locally developed work plan, assessment of the situation, and progress. Lessons learned in the initial implementing, or pilot, areas should be applied to the expansion areas. To do so, the pilot performance should be carefully monitored. The hospital DOTS focal person from the hospital that has implemented DOTS successfully may be utilized for planning of further HDL expansion.

Routine NTP monitoring and surveillance systems should include the hospital DOTS linkages as do other PPM components. Components related to MDR-TB management and HIV co-infected TB management should also be incorporated accordingly. These latter components may require enormous inputs in addition to those for the basic DOTS components; therefore, stepwise, careful, and well-coordinated expansion is required in the process of expansion.

In the process of scaling up, initial enthusiasm on both public and non-public sides may wane for a variety of reasons. The NTP staff may view the extra efforts to engage hospitals as an additional burden. Supervision may suffer if additional staff is withdrawn. High turnover of public sector staff may set back the process of ongoing implementation, requiring orientation and training of the new staff.

Therefore, sufficient long-term financial and human resources for HDL must be assured, and training for hospital engagement must be made a part of human resource development plans in NTP. Equally important, HDL must be integrated into routine surveillance and monitoring. If the results of collaboration in terms of increasing participation of other providers, increased case notification, improved program performance, enhanced image of the program in the eyes of the community, and above all, increased patient satisfaction become apparent to all partners involved, they are likely to remain enthusiastic and continue productive collaboration.