The International Hospital Federation

Training Manual

on
Tuberculosis & Multidrug-resistant TB Control, Treatment & Prevention for Hospital/Clinic/Health Facility Managers
# List of contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preface</td>
<td>3</td>
</tr>
<tr>
<td>Introduction</td>
<td>4</td>
</tr>
<tr>
<td>Course Design</td>
<td>5</td>
</tr>
<tr>
<td>Workshop schedule</td>
<td>6</td>
</tr>
<tr>
<td><strong>Sessions 1 – 3: The Global Burden of TB – Introduction</strong></td>
<td>7</td>
</tr>
<tr>
<td><em>(Prepared by: New Jersey Medical School (NJMS) Global Tuberculosis Institute (GTBI))</em></td>
<td></td>
</tr>
<tr>
<td>Abbreviations</td>
<td>8</td>
</tr>
<tr>
<td><strong>Session 1: The Global Burden of TB</strong></td>
<td>9</td>
</tr>
<tr>
<td><em>Topic 1: Epidemiologic Measures and Regional Profiles</em></td>
<td>9</td>
</tr>
<tr>
<td><em>Topic 2: TB Control on a Global Scale: The Stop TB Strategy and the International Standards for TB Care</em></td>
<td>13</td>
</tr>
<tr>
<td><em>Topic 3: The Role of the National TB Control Programme and the Community in TB Control Activities</em></td>
<td>18</td>
</tr>
<tr>
<td><strong>Session 2: TB Basics: Transmission, Pathogenesis, Diagnosis and Treatment</strong></td>
<td>21</td>
</tr>
<tr>
<td><strong>Session 3: The Role of Health Facility Care Managers in Programmatic TB Control</strong></td>
<td>31</td>
</tr>
<tr>
<td><em>Topic 1: The Impact of HIV on the TB Epidemic</em></td>
<td>31</td>
</tr>
<tr>
<td><em>Topic 2: Multidrug-Resistant TB and Extensively Drug-Resistant TB</em></td>
<td>35</td>
</tr>
<tr>
<td><em>Topic 3: TB Infection Control</em></td>
<td>44</td>
</tr>
<tr>
<td><em>Topic 4: Monitoring, Evaluation and Surveillance of TB Activities</em></td>
<td>48</td>
</tr>
<tr>
<td><em>Topic 5: Laboratory Services for TB Control</em></td>
<td>50</td>
</tr>
<tr>
<td><em>Topic 6: Management of Anti-TB Drugs</em></td>
<td>55</td>
</tr>
<tr>
<td><em>Topic 7: Budgeting and Planning for TB Services</em></td>
<td>58</td>
</tr>
<tr>
<td><em>Topic 8: Human Resource Development for TB Control</em></td>
<td>61</td>
</tr>
<tr>
<td><strong>Effective Hospital Management Workbook</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Session 4: The Four Tasks of Management</strong></td>
<td>66</td>
</tr>
<tr>
<td><em>(Prepared by: Health Development International (HDI))</em></td>
<td></td>
</tr>
<tr>
<td><strong>Session 4: The Four Tasks of Management: Introduction</strong></td>
<td>67</td>
</tr>
<tr>
<td><em>Orientation</em></td>
<td>67</td>
</tr>
<tr>
<td><em>Management Tasks and Activities</em></td>
<td>69</td>
</tr>
<tr>
<td><em>The Profession of Management</em></td>
<td>70</td>
</tr>
<tr>
<td><strong>The Four Tasks of Management:</strong></td>
<td>74</td>
</tr>
<tr>
<td><em>Topic 1: Planning</em></td>
<td>74</td>
</tr>
<tr>
<td><em>Topic 2: Organising</em></td>
<td>91</td>
</tr>
<tr>
<td><em>Topic 3: Leading</em></td>
<td>101</td>
</tr>
<tr>
<td><em>Topic 4: Checking</em></td>
<td>112</td>
</tr>
<tr>
<td>Questions and answers</td>
<td>119</td>
</tr>
<tr>
<td>References</td>
<td>123</td>
</tr>
<tr>
<td>Annexes</td>
<td>129</td>
</tr>
</tbody>
</table>

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Preface

It is with great pleasure that the International Hospital Federation in collaboration with the New Jersey Medical School Global Tuberculosis Institute (GTBI) and the Health Development International (HDI), releases its updated learning material – Training Manual for TB and MDR-TB Control for Hospital/Clinic/Health Facility Managers. This updated manual has been further developed and made generic enough with information emphasizing current global strategies utilized by National TB Control Programmes, accepted infection control principles and recommendations for management of TB/HIV in a hospital setting, for managers, with and without clinical or TB experience, of general (urban, rural, public and private) hospitals, clinics and health service facilities. The revision process involved conduct of a survey to identify the needs of managers in health facilities regarding TB control and services.

The objective of the manual is to prepare its target audience to take decisions in support of action in terms of therapies and drugs to treat TB and MDR-TB. The first draft was released in 2006 and piloted in Pretoria, South Africa. This updated version has been piloted in Beijing (China – November 2008), and will be in Mumbai (India) in October 2009, with further revisions envisaged to allow for its adaptation to local circumstances. It has been translated into Chinese (2008). French and Spanish language manuals and an interactive on-line (www.ihf-fih.org) and CD-ROM versions will be available by end of 2009.

We would like to thank our collaborators at the New Jersey Medical School Global Tuberculosis Institute, namely Professor Lee B. Reichman, Amy Piatek, Nisha Ahamed and Eileen Napolitano, for contributing their time, effort and experience.

We thank and acknowledge the contributions of Dr. Rufi Macagba (Health Development International – Annex 14) and Dr. Hernan Reyes in the first draft on the management workbook and on TB management in the prison environment (Annex 15), respectively. We also thank the TB Strategy and Operations (TBS) Stop TB Department, HIV/AIDS, TB and Malaria cluster at the World Health Organization (WHO) and the peer-reviewers who have contributed their views on the first drafts of the learning material.

We thank The Lilly MDR-TB Partnership for the sponsorship grant which has made this on-going project possible.

April 2009

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Programme Development & Knowledge Manager

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Introduction

Tuberculosis (TB) presents a serious challenge to public health worldwide. In 2006, there were 9.2 million new cases of TB and 1.7 million deaths from TB. While many countries already experience a tremendous TB burden, they are also now being confronted with the additional challenges of managing TB in patients that are also co-infected with HIV or harbouring drug-resistant strains of *Mycobacterium tuberculosis*. And in some areas, health care workers are struggling to deal with the deadliest form of TB imaginable – extensively drug resistant TB (XDR-TB).

National health care systems and TB control programmes are stressed in coping with the epidemic of TB and must rely on the cornerstone of its workforce to help control TB – general health care and hospital workers in both the public and private sectors. The successful control of TB will largely depend upon the strength of TB control activities at these important levels. Strong management of health care facility and hospital staff is imperative for the implementation of appropriate and adequate TB control activities.

TB is a biomedical and social phenomenon that can only be controlled through collaborative efforts of all health-related institutions in a country, including general health care facilities and hospitals in the private and public sectors. The Stop TB Strategy is a compendium of TB control strategies that have been tried and proven in all different settings throughout the world. No other infectious disease has control strategies that are as internationally recognized and accepted as TB. Not only are these strategies beneficial to the management of TB patients, but they also help to improve the management of general health care in a community and country. TB is the logical disease model approach to developing the foundation of knowledge and skill for health care facility and hospital managers worldwide. Additionally TB programmes at all level – national, regional, and district – define a role for health care facilities in the control of TB.

From a public health perspective, poorly supervised or incomplete treatment of TB is worse than no treatment at all. The problem, however, can not be attributed to the lack of an effective treatment, but to a lack of organisation. The shortage of trained staff has consistently been cited as the main constraint facing TB control. Effective and expert leadership is therefore crucial among the managers of the treatment delivery settings and network.

Multiple strategies exist for the delivery of TB and MDR-TB treatment, including hospitalization, clinic-based treatment and community-based care. In countries where the phenomenon of drug resistance has been identified, specific measures need to be taken within TB control programmes to address the problem through appropriate management of patients and adoption of strategies to prevent the propagation and dissemination of drug-resistant TB, including MDR-TB.

Regardless of the mode of delivery, management of TB and MDR-TB depends on the assurance of a steady supply of medicines provided to patients through a reliable network of educated and effectively trained providers. The history of TB and MDR-TB treatment confirms strict hospitalization of patients as the accepted strategy, although depending on the geographical, economic and social settings, home-based care provided by trained lay and community health workers could achieve comparable results and, in theory, result in decreased rates of nosocomial spread of the disease. The answer thus to a well managed TB control programme can only be found within a framework of collaboration among all those healthcare professionals, in such vital fields as medicine, nursing and hospital management, bringing together knowledge and expertise involved in the treatment and care of sufferers of the disease.
The International Hospital Federation (IHF), as a leading global representative body for hospitals and healthcare management professionals, through this training tool seeks to provide health care facility and hospital managers with an overview of the basics of TB control together with the appropriate expertise and necessary resources to make informed decisions about the management of TB patients in their facilities.

Managers have to understand the need for continuous and strong support for MDR-TB and TB control programmes. Financial support for TB treatment drugs has to be continuous as interruption to the drug therapy process increases the potential and likelihood of resistance to all major anti-TB drugs. Managers in charge of financing and organisation of health services have the responsibility of ensuring that such lapses in drug therapy do not occur.

The role of managers would therefore be that of facilitators for doctors and nurses to enable them to provide treatment without interruption and to apply actions for monitoring the control programmes, in the absence of which costs and human suffering increase significantly, particularly as a trend in resistance to major anti-TB drugs emerges.

COURSE DESIGN

Hospitals and health programs in many countries face problems related to poor management. In developing countries they generally serve poor populations, operate with low budgets, staff shortages, and insufficiently trained staff. As a result, they have poorly maintained equipment and facilities, shortages of medicines and supplies, and an unending parade of new medical technology that they could hardly afford. Hospitals in different countries also face problems unique to their country.

Management has become a profession with skills that can take a lifetime to learn and master. This course provides a solid introduction to a lifetime of learning how management skills can help a hospital or health organisation to continually improve its ability to meet the needs of the people it serves.

The design elements of the course have remained focused around the tasks and skills managers use in their work: planning, organising, leading and checking. It has also retained an interactive teaching method that enables participants to apply the knowledge to their own culture through group exercises and discussions. The course is continually improving based on contemporary thought, feedback from participants, and a growing awareness of the challenges in each culture. A growing library of resources, examples and best-practice case studies for developing sustainable hospitals in developing countries can be found online at [http://sites.google.com/site/hdi/Home](http://sites.google.com/site/hdi/Home).
<table>
<thead>
<tr>
<th>Day</th>
<th>Time</th>
<th>Module</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>One</td>
<td>1</td>
<td>Introduction</td>
<td>Workshop Overview</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>The Profession of Management</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Planning</td>
<td>Needs Assessment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Identify internal and external needs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mission, vision and values</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Writing your own statements</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Case study</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Planning</td>
<td>Strategic planning</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Writing goals and plans</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Financial planning</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Budgets and sustainability</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Planning review</td>
</tr>
<tr>
<td>Two</td>
<td>4</td>
<td>Organising</td>
<td>Organisational Structure</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Evaluate your organisational structure</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Selecting People</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Interviewing skills exercise</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Organising</td>
<td>Delegating</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Developing Teams</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Set Standards of Good Work</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Policies, Systems and Procedures</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Case study</td>
</tr>
<tr>
<td>Three</td>
<td>6</td>
<td>Leading</td>
<td>Blind man’s game</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Leadership Styles</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Personal Self-Development</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Motivation</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>Leading</td>
<td>Creativity and Innovation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Problem-solving exercise</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Brainstorming exercise</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Interpersonal Relationships</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Case study</td>
</tr>
<tr>
<td>Four</td>
<td>8</td>
<td>Follow-up</td>
<td>Checking Work and Following Up</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Designing report forms</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Continuous Improvement</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Stellar performance model</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Conclusion</td>
<td>Open Discussion about the Workshop</td>
</tr>
</tbody>
</table>

(See Annex13 for a Daily Workshop Evaluation Form)
Session 1: The Global Burden of TB - Introduction

(Prepared by the New Jersey Medical School Global Tuberculosis Institute)

This session provides the global and regional context for the specific information for health care facility managers presented later in the document. In order to effectively play their part in TB control, it is necessary for hospital and health care facility managers to be familiar with the basic epidemiology of TB, as well as the internationally accepted strategies to control TB and the relationship of the health care facility with the national TB control programme and larger network of community workers.

- **Topic 1:** Epidemiologic Measures and Regional Profiles
- **Topic 2:** TB Control on a Global Scale: The Stop TB Strategy and the International Standards for TB Care
- **Topic 3:** The Role of the National TB Control Programme and the Community in TB Control Activities

Session 2: TB Basics: Transmission, Pathogenesis, Diagnosis and Treatment

This session provides the hospital and health care facility manager with the fundamental knowledge of the key principles of TB transmission, pathogenesis, diagnosis and treatment. It is important for the manager to have a basic understanding of TB so as to ensure that sound control policies and practices are implemented in their facility.

Session 3: The Role of Health Care Facility Managers in Programmatic TB Control

This session consists of 8 topics that provide specific information and guidance for the hospital and health care facility manager on TB control issues including TB/HIV, drug resistance, infection control, monitoring and evaluation, laboratory services, management of anti-TB drugs, budgeting and planning, and human resource development.

- **Topic 1:** The Impact of HIV on the TB Epidemic
- **Topic 2:** Multidrug-Resistant TB and Extensively Drug-Resistant TB
- **Topic 3:** TB Infection Control
- **Topic 4:** Monitoring, Evaluation and Surveillance of TB Activities
- **Topic 5:** Laboratory Services for TB Control
- **Topic 6:** Management of Anti-TB Drugs
- **Topic 7:** Budgeting and Planning for TB Services
- **Topic 8:** Human Resource Development for TB Control
# Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFB</td>
<td>Acid-fast bacilli</td>
</tr>
<tr>
<td>ART</td>
<td>Antiretroviral therapy</td>
</tr>
<tr>
<td>BCG</td>
<td><em>Bacille Calmette-Guérin</em> vaccine</td>
</tr>
<tr>
<td>DOT</td>
<td>Directly observed treatment</td>
</tr>
<tr>
<td>DOTS</td>
<td>The internationally recommended strategy for TB control</td>
</tr>
<tr>
<td>DST</td>
<td>Drug susceptibility testing</td>
</tr>
<tr>
<td>EQA</td>
<td>External quality assurance</td>
</tr>
<tr>
<td>FDC</td>
<td>Fixed-dose combination</td>
</tr>
<tr>
<td>GLC</td>
<td>Green Light Committee</td>
</tr>
<tr>
<td>HRD</td>
<td>Human resource development</td>
</tr>
<tr>
<td>ISTC</td>
<td>International Standards for Tuberculosis Care</td>
</tr>
<tr>
<td>LTBI</td>
<td>Latent tuberculosis infection</td>
</tr>
<tr>
<td>MDG</td>
<td>Millennium Development Goal</td>
</tr>
<tr>
<td>MDR</td>
<td>Multidrug resistance (resistance to isoniazid and rifampicin)</td>
</tr>
<tr>
<td>MDR-TB</td>
<td>Multidrug-resistant tuberculosis</td>
</tr>
<tr>
<td>NRL</td>
<td>National reference laboratory</td>
</tr>
<tr>
<td>NTP</td>
<td>National tuberculosis control programme</td>
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<tr>
<td>PAL</td>
<td>Practical Approach to Lung Health</td>
</tr>
<tr>
<td>PPM</td>
<td>Public-private or public-public mix</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>Union</td>
<td>The International Union Against Tuberculosis and Lung Disease</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>XDR</td>
<td>Extensive drug resistance</td>
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<tr>
<td>XDR-TB</td>
<td>Extensively drug-resistant tuberculosis (MDR strains that are also resistant to a fluoroquinolone and at least one second-line injectable agent)</td>
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Session 1: The Global Burden of TB  
(Prepared by the New Jersey Medical School Global Tuberculosis Institute)

Topic 1: Epidemiologic Measures and Regional Profiles

This session provides the global and regional context for the specific information for hospital and health care facility managers presented later in the document. In order to effectively play their part in TB control, it is necessary for hospital and health care facility managers to be familiar with the basic epidemiology of TB, as well as the internationally accepted strategies to control TB and the relationship of the health care facility with the national TB control programme and larger network of community workers.

Every year, more than 8 million people across the globe become sick from tuberculosis (TB). Most new cases of TB occur in countries in the South-East Asian, African, and the Western Pacific regions; however, TB affects people in every part of the world (Figure 1). It is estimated that 2 billion people – or one-third of the world’s total population—are infected with Mycobacterium tuberculosis. In 2005, 1.6 million people died from TB, making it one of the major causes of death from an infectious disease in the world. TB is the 8th leading cause of death in low-income countries worldwide [1] and is responsible for nearly 4% of all deaths in these countries.

Figure 1. Percentage of new TB cases by Region, 2005

Table 1 provides the absolute numbers of new TB cases (all forms and smear-positive), and deaths from TB in all regions of the world. High TB incidence and mortality rates are found in many countries throughout all regions; however, the highest rates can be found in Africa and South-East Asia. TB incidence rates are either stable of falling in each region, yet, the total number of TB cases is still rising in the African, Eastern Mediterranean and South-East Asian regions.
Table 1. TB incidence (all forms and smear-positive) and mortality (all forms) by Region, 2005 [2]

<table>
<thead>
<tr>
<th>Region</th>
<th>TB Incidence, 2005</th>
<th>Mortality, 2005</th>
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<tbody>
<tr>
<td></td>
<td>All forms</td>
<td>Smear-positive</td>
</tr>
<tr>
<td></td>
<td>Number per 100,000</td>
<td>Number per 100,000</td>
</tr>
<tr>
<td>Africa</td>
<td>2,528,915</td>
<td>343</td>
</tr>
<tr>
<td>Americas</td>
<td>351,697</td>
<td>39</td>
</tr>
<tr>
<td>Eastern Mediterranean</td>
<td>564,552</td>
<td>104</td>
</tr>
<tr>
<td>Europe</td>
<td>441,705</td>
<td>50</td>
</tr>
<tr>
<td>South-East Asia</td>
<td>2,993,251</td>
<td>181</td>
</tr>
<tr>
<td>Western Pacific</td>
<td>1,921,945</td>
<td>110</td>
</tr>
<tr>
<td><strong>GLOBAL</strong></td>
<td><strong>8,802,065</strong></td>
<td><strong>136</strong></td>
</tr>
</tbody>
</table>

TB affects both men and women of all ages. Globally, 43% of TB patients in 2005 were between the ages of 25 and 44 years old– typically the most economically productive years of a person’s life (Figure 2). By region, the percentage of TB patients between the ages of 25 and 44 year old varies from a low of 34% in the Western Pacific region to a high of 54% in Africa. TB is usually more commonly diagnosed in men (the male/female ratio varies from 1.3 in Africa to 2.2 in the Western Pacific Region; data not shown [2]); however, TB is a leading infectious cause of death among women [3].

**Figure 2. Percentage of new smear-positive TB cases by age, Regional distribution, 2005**

**TB/HIV**

The HIV epidemic has had a significant impact on the global crisis of TB, and in many parts of the world, has fuelled the TB epidemic. One-third of the approximate 33 million persons living with HIV are also infected with TB. This deadly combination of TB and HIV has had disastrous effects on both disease populations. In persons already infected with TB, HIV infection facilitates the progression to active TB disease.

The epidemic of HIV/AIDS has had a significant impact on TB incidence and associated deaths, especially in Africa. Globally, 11% of new cases of TB in adults (15-49 years old) were infected
with HIV in 2005. This percentage was much higher in Africa (Table 2). Of all HIV-infected TB patients in the world, 80% are in Africa – 19% can be found in South Africa alone [2].

<table>
<thead>
<tr>
<th>HIV Prevalence in Incident Adult TB Cases (%)</th>
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<tbody>
<tr>
<td>Africa</td>
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<tr>
<td>Americas</td>
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<tr>
<td>Eastern Mediterranean</td>
</tr>
<tr>
<td>Europe</td>
</tr>
<tr>
<td>South-East Asia</td>
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<tr>
<td>Western Pacific</td>
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<td><strong>GLOBAL</strong></td>
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Many countries with the highest estimated TB incidence have the highest rates of HIV co-infection (data not shown). In 2005, Swaziland had both the highest estimated TB incidence (1,262/100,000) and the highest estimated incidence in HIV-positive adults (672/100,000). All other countries (with the exception of Djibouti) with the highest estimated incidence in HIV-positive adults can be found in the African region¹ (Figure 3).

**Figure 3. Countries with the highest estimated TB incidence in HIV-positive adults, and corresponding mortality rate, 2005**

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**Multidrug-Resistant (MDR) TB and Extensively Drug-Resistant (XDR) TB**

Multidrug-resistant (MDR) TB is TB that is resistant to both isoniazid and rifampicin, and extensively drug-resistant (XDR) TB is MDR-TB that is also resistant to any fluoroquinolone, and at least 1 second-line injectable drug. Since isoniazid and rifampicin are the cornerstone drugs of anti-TB therapy, treatment and cure of a TB patient is greatly threatened if the patient has MDR-TB, and the chances for cure can be lower than 30% for patients with XDR-TB. Both MDR-TB and XDR-TB are great threats to global TB control.

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¹ While Djibouti is on the African continent, it is considered part of the WHO Eastern Mediterranean Region.
Although the magnitude of global drug-resistance is mostly unknown due to the lack of laboratory infrastructure and capacity in most countries, reliable estimates have been proposed by WHO [4] from an analysis of national surveys of 184 countries. Globally, 424,205 new and previously treated TB cases in 2004 were estimated to be resistant to at least isoniazid and rifampicin (Table 3). The proportion of MDR-TB cases among all TB cases varied among regions, with the highest proportion (15.4%) found in Eastern Europe. It is estimated that 3 countries – China, India and the Russian Federation – account for more than 60% of the global burden of MDR-TB.

Table 3. Estimated numbers of MDR-TB cases among new and previously treated TB cases, 2004

<table>
<thead>
<tr>
<th>Region2</th>
<th>Estimated Number of MDR-TB cases</th>
<th>Proportion of MDR-TB Cases Among all TB Cases (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>New TB cases</td>
<td>Previously treated TB cases</td>
</tr>
<tr>
<td>Africa</td>
<td>44,662</td>
<td>13,929</td>
</tr>
<tr>
<td>Central Europe</td>
<td>783</td>
<td>679</td>
</tr>
<tr>
<td>Eastern Europe</td>
<td>34,645</td>
<td>31,208</td>
</tr>
<tr>
<td>Eastern Mediterranean</td>
<td>10,313</td>
<td>8,017</td>
</tr>
<tr>
<td>Established market economies</td>
<td>1,045</td>
<td>636</td>
</tr>
<tr>
<td>Latin America</td>
<td>6,531</td>
<td>4,770</td>
</tr>
<tr>
<td>South-East Asia</td>
<td>65,495</td>
<td>49,473</td>
</tr>
<tr>
<td>Western Pacific</td>
<td>79,322</td>
<td>72,697</td>
</tr>
<tr>
<td>GLOBAL (2004)</td>
<td><strong>242,796</strong></td>
<td><strong>181,409</strong></td>
</tr>
</tbody>
</table>

As of October 2007, 41 countries have confirmed the presence of XDR-TB. A survey of 17,690 TB isolates collected during the years 2000-2004 from 25 reference laboratories on 6 continents found that 2% were XDR [5]. Further analysis on MDR-TB isolates from the United States (1993-2004), Latvia (2000-2002) and South Korea (2004) found that 4%, 19% and 15% were XDR, respectively.

See Annex 1 for regional TB epidemiology, associated challenges and high TB burden countries.

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2 WHO Regions are further divided into epidemiological sub-regions
Topic 2: TB Control on a Global Scale: The Stop TB Strategy and the International Standards for TB Care

History of DOTS and the Stop TB Strategy
In 1991, the World Health Assembly recognized the growing importance of TB as a global public health problem. In response, the World Health Organization (WHO) developed a new framework for TB control for National TB Control Programmes (NTP) around the world, and a global strategy for TB control was introduced called DOTS. DOTS originally stood for Directly Observed Therapy, Short-Course. This acronym was soon abandoned and the term “DOTS” became a brand name for the WHO-recommended TB control strategy around the world. The original 5 elements of the DOTS strategy included:

1. Political commitment
2. Case detection using sputum microscopy among persons seeking care for prolonged cough
3. Standardized short-course chemotherapy under proper case-management conditions including directly observed treatment
4. Regular drug supply
5. Standardized recording and reporting system that allows assessment of individual patients as well as overall program performance

The World Health Assembly set 2 important targets for global TB control by 2005: detect 70% of all new sputum-smear positive TB cases every year, and successfully treat 85% of these cases. By 2005, only 62% of new sputum-smear positive TB cases were detected globally and 84% of them were successfully treated, meaning that the global targets had been narrowly missed. However, there were great regional variations in case detection and treatment success (see Table 4). The Americas and Western Pacific Regions were the only regions to reach the 70% case detection target; South-East Asia and the Western Pacific Regions were the only regions to reach the 85% treatment success target.

Table 4. Case detection (2005) and treatment success (2004 cohort) rates of new smear-positive cases (%)

<table>
<thead>
<tr>
<th>Region</th>
<th>Case detection rate of new smear-positive cases (%), 2005</th>
<th>Treatment success rate of new smear-positive cases (%), 2004 cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Africa</td>
<td>51%</td>
<td>74%</td>
</tr>
<tr>
<td>Americas</td>
<td>80%</td>
<td>80%</td>
</tr>
<tr>
<td>Eastern Mediterranean</td>
<td>45%</td>
<td>83%</td>
</tr>
<tr>
<td>Europe</td>
<td>48%</td>
<td>74%</td>
</tr>
<tr>
<td>Southeast Asia</td>
<td>64%</td>
<td>87%</td>
</tr>
<tr>
<td>Western Pacific</td>
<td>78%</td>
<td>91%</td>
</tr>
<tr>
<td>GLOBAL</td>
<td>62%</td>
<td>84%</td>
</tr>
</tbody>
</table>

A more thorough analysis into why targets were not reached globally and in many regions highlighted 2 major difficulties in managing TB: TB linked to HIV/AIDS, especially in Africa, and TB that is drug resistant, especially in Eastern Europe and countries of the former Soviet Union. These difficulties combined with other deficiencies of the DOTS strategy stressed the need for a broader enhanced TB control framework that included strategies for TB/HIV, drug resistance, public and private providers, and other important aspects of TB control not addressed in the original 5 elements of DOTS.
The Stop TB Strategy: The Internationally Recommended Strategy to Control TB

In recognition of the evolving needs and challenges not addressed by the original DOTS strategy, the Stop TB Strategy was developed in 2006 to expand and enhance DOTS and meet existing and new global TB targets: the Millennium Development Goals (MDGs) [1] developed by the United Nations and the Stop TB Partnership [2]. The MDG specific to TB is Target 8, “to have halted by 2015 and begun to reverse the incidence of malaria and other major diseases”, and Indicator 23 (prevalence and death rates associated with tuberculosis) and Indicator 24 (proportion of tuberculosis cases detected and cured under DOTS). The Stop TB Partnership 2015 target is that the global burden of TB will be reduced by 50% relative to 1990 levels (reducing global TB prevalence to 155 per 100,000 or lower and deaths to 14 per 100,000 per year or lower). The Stop TB Partnership 2050 target is that the global incidence of TB disease will be less than 1 case per million persons per year. The 6 principal components of this strategy are listed in the box below. Each principal will be discussed in further detail in the text that follows.

There are 6 principal components of the Stop TB Strategy [2]:

**The Components of the Stop TB Strategy**
- Pursue high-quality DOTS expansion and enhancement
- Address TB/HIV, MDR-TB and other challenges
- Contribute to health system strengthening
- Engage all care providers
- Empower people with TB and communities
- Enable and promote research

All of the responsibilities and roles of hospital and health care facility managers around the management and control of TB can be related to one of the following 6 components.

1. **Pursue high-quality DOTS expansion and enhancement.** This will be achieved through:
   a. Political commitment with increased and sustained financing
   b. Case detection through quality-assured bacteriology
   c. Standardized treatment, with supervision and patient support
   d. An effective drug supply and management system
   e. Monitoring and evaluation system, and impact measurement

This component is the cornerstone of the Stop TB Strategy and builds on the original 5 elements of DOTS. Successful TB control in a country starts with implementing these basic, but essential elements, and all further components should build upon this solid foundation. Practical guidance for health care facility managers in important topics under this component are found in Session 3.

Management of tuberculosis in children should be consistent with all the components of the Stop TB Strategy; however, diagnosis and treatment of TB in children can be complex and may require special guidance [3].

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[3] The Stop TB Partnership (http://www.stoptb.org/) was established in 2000 to eliminate tuberculosis as a public health problem and ultimately to realize a world free of TB. It comprises a network of more than 500 international organisations, countries, donors from the public and private sectors, and nongovernmental and governmental organisations that have expressed an interest in working together to achieve this goal.
2. **Address TB/HIV, MDR-TB and other challenges.** This will be achieved through:
   a. Implementing collaborative TB/HIV activities
   b. Preventing and controlling MDR-TB
   c. Addressing prisoners, refugees and other high-risk groups and situations

   The problems of TB/HIV co-infection and multidrug resistant TB have been recognized as two of the more important issues concerning the management of TB patients. Without effective strategies in place for the management and treatment of TB/HIV and prevention and treatment of MDR-TB, efforts to control TB will fail. More about MDR-TB and TB/HIV and the role of hospitals and health facilities in these areas can be found in Session 3.

   The risk of developing TB infection and disease significantly increases in crowded settings such as prisons and refugee camps. It is estimated that rates of active TB in prisoners and prison populations throughout the world can be more than 100 times greater than TB rates in civilian populations [4, 5]. Characteristics of prisoners increase their risk for TB infection and disease:
   - Prisoners often come from high TB risk population groups (i.e. alcohol or drug abusers, homeless, or mentally ill) without proper access to health services as a civilian
   - Prisoners live in overcrowded, poorly ventilated areas where exposure to TB bacilli is increased
   - Prisoners are at increased risk to develop TB from latent infection due to higher rates of comorbidity with other diseases including HIV and poorer nutritional status

   Other special populations that need focused attention include migratory workers, illegal immigrants, cross-border populations, homeless and orphaned persons, ethnic minorities, other marginalized groups, and alcohol and drug abusers.

3. **Contribute to health system strengthening.** This will be achieved through:
   a. Actively participating in efforts to improve system-wide policy, human resources, financing, management, service delivery, and information systems
   b. Sharing innovations that strengthen systems, including the Practical Approach to Lung Health (PAL)
   c. Adapting innovations from other fields

   Resources in many countries, especially developing countries, are limited. Therefore, disease control strategies that will be the most successful are those that participate in initiatives designed to strengthen overall health systems and improve access to quality services. TB control strategies need to fit within overall national initiatives to strengthen health systems, while accelerating and sustaining the impact of TB control [6]. As hospital and health care facility managers incorporate the principles of sound TB control into their facilities, they will also help to strengthen the overall health services in their facility and community.

4. **Engage all care providers.** This will be achieved through:
   a. Public-Public and Public-Private Mix (PPM) approaches
   b. International Standards for Tuberculosis Care (ISTC)
Many persons with TB symptoms go to a private health care provider when they first get sick. Until recently, most countries did not have effective strategies to engage all private (and public) care givers in TB control, and many providers were not following internationally-recommended strategies to manage TB suspects and cases. Without adequate approaches to engage all providers, case detection and treatment success rates will remain low while rates of drug-resistant TB increase [7].

The International Standards for TB Care will be discussed in detail at the end of this topic.

5. **Empower people with TB, and communities.** This will be achieved through:
   a. Advocacy, communication and social mobilization
   b. Community participation in TB care
   c. Patients’ Charter for Tuberculosis Care

To meet global TB control targets, all sectors of society have to be involved in the fight against TB, especially people with TB and communities. In order to build a greater commitment to fight TB, strategies must be in place to raise knowledge about TB at both the government and general public levels, and the demand for quality TB care and services should come from all sectors. Community participation involves establishing relationships between the health sector and the communities of current and cured TB patients, including patient groups and community volunteers.

The Patients’ Charter for Tuberculosis Care [8] outlines the rights and responsibilities of people with TB and is based on prior national and international health and human rights charters. Its purpose is to empower people with TB and communities, and outlines ways that patients, communities, health care providers and governments can work together. More on community participation and the Patients’ Charter are found in Topic 3 of Session 1. Hospital and health facility managers should ensure that their health facilities provide TB services that meet and respect the rights laid out in this Charter.

6. **Enable and promote research.** This will be achieved through:
   a. Programme-based operational research
   b. Research to develop new diagnostics, drugs and vaccines

Operational research done at local levels can help to establish evidence-based best practices that will improve TB case detection and management of TB patients. Often National TB Control Programmes have a wealth of data and information that, if correctly examined, could significantly contribute to strengthening local and global TB control strategies.

There is a serious shortage of research to develop new TB diagnostics, drugs and vaccines. Without new tools to diagnose and treat patients, global targets will be all the more difficult to reach. Some hospitals or health care facilities may be involved in TB research, though many will not. However, in the future, hospitals and health care facilities may be involved in diagnostic or treatment procedures developed through this type of research.
The International Standards for TB Care

The International Standards for TB Care (ISTC) were developed as a resource to engage all care providers in the diagnosis and treatment of TB. The Standards provide evidenced-based principles of a widely accepted level of care that all health care practitioners should attain in the management of patients either with TB or suspected of having TB. According to the ISTC document, the Standards:

“are intended to facilitate the effective engagement of all care providers in delivering high-quality care for patients of all ages, including those with sputum smear-positive, sputum smear-negative, and extrapulmonary TB, TB caused by drug-resistant M. tuberculosis organisms, and TB combined with HIV infection” [9].

The Standards lay out (see Annex 2):

- Basic principles of care for persons either with TB or suspected of having TB including prompt and accurate diagnosis
- Standardized treatment with appropriate support and supervision, and monitored response to treatment
- Essential public health responsibilities like contact investigations and reporting

Regardless of the region or country, the Standards are applicable, and in many situations, the level of care may exceed the Standards; however, they should not replace national or local TB control guidelines.
Topic 3: The Role of the National TB Control Programme and the Community in TB Control Activities

National TB Control Programme (NTP)
NTPs are established in a country by the government, and are responsible for the planning, implementation, monitoring, and evaluation of TB control activities for the population. The objectives of the NTP are to diagnose and successfully treat as many TB patients as possible, and thus reduce transmission of \textit{M. tuberculosis} in a community annually, with a goal of reducing the TB burden.

The organisation and guidance of NTPs, and their relationships with hospitals and health care facilities differ by country, and hospital managers should consult and follow the guidance of the NTP in their own country. In general, the structure and organisation of NTPs are similar, and an overview of the organisation of NTPs is outlined below.

Structure and responsibilities
The NTP operates at the central, regional/provincial, and district levels [1].

- **Central**: The central unit is managed by an NTP manager who directs the operations of the entire NTP. Other staff at the central NTP unit often includes the director of the National TB Reference Laboratory and focal points (or deputy directors) for specific TB topics such as human resource development, TB/HIV, drug management, epidemiology and surveillance, etc. The main responsibilities of the central unit include:
  - Planning all operations in implementing, monitoring and evaluating the NTP
  - Coordination and supervision of the NTP
  - Acquisition and distribution of anti-TB drugs, laboratory equipment and supplies, and other supplies needed by the NTP
  - Training and human resource development of all NTP staff

- **Regional/provincial**: At this level, the regional or provincial TB director is responsible for carrying out the TB control activities in the region in conjunction with the central unit, and appoints a regional TB coordinator for management of activities. The main responsibilities of the regional unit include:
  - Coordination and supervision of TB control activities (including case-finding and treatment of TB) in the districts including periodic visits to each district
  - Organising training programmes and supervising human resource development in the region
  - Collecting quarterly reports on case-finding and treatment from each district, and assembling into a regional report for the central unit

- **District**: In each district, the district chief medical officer is responsible for the TB control activities, in consultation with the regional TB coordinator. The main responsibilities of the district unit include:
  - Implementation of TB control activities through the staff at district health services
  - Supervision of treatment throughout the district ensuring that appropriate TB treatment regimens are followed, TB patients are appropriately managed and offered DOT, and patients failing treatment are referred to the district chief medical officer or regional TB coordinator for possible re-treatment
- Extending TB control activities and case-finding to all existing health care facilities in the district
- Visiting district microscopy centres periodically to ensure that all newly diagnosed cases are appropriately managed
- Supervising updating and accuracy of the district TB register
- Procuring TB supplies for the district, and distributing to the health care facilities in the district

**Hospitals and health care facilities**: The responsibilities of each hospital and health care facility include:

- Following NTP guidelines and policies for TB control including medical care of TB patients, case-finding and treatment of TB
- Ensuring a continuous supply of anti-TB drugs and other TB supplies and equipment
- Maintaining and submitting accurate records for all TB patients
- Providing health education to patients and the community

**Relationship of the NTP with hospitals and health care facilities**

Each hospital and health care facility that performs any TB control activity should have a relationship with the NTP that benefits *both the patient and the health care facility*. The NTP is a valuable resource for the health care facility and can help to ensure appropriate management of all TB patients diagnosed and treated in the facility. In addition to providing the latest technical guidance for TB, the NTP can recommend activities based on best practices of the country and other countries in the region.

Common relationships between health facilities and the NTP may include:

- Completion of TB case registers and forms by the health care facility and submission to the NTP
- Coordination with the NTP to estimate the amount of anti-TB drugs needed, ensuring an adequate uninterrupted supply of drugs for patients
- Periodic supervisory visits from the district medical chief officer or regional TB coordinator to the health care facility
- Following NTP guidelines to diagnose and treat TB patients at the health care facility
- Consultation with NTP staff or facilities (including National Referral Laboratory) to manage TB patients at the health care facility
- Attendance of health care facility staff at training programmes on TB control given by the NTP
- Immediate reporting of local TB control problems or concerns, such as in increase in drug resistance, an outbreak, or a potential drug shortage to the NTP
Community
Successful TB control requires the contribution of many partners including the community. In the era of the HIV/AIDS epidemic when the need for health services is greater than what many national health systems can provide, community participation in health service delivery is crucial [2]. Involving community members in TB control can include activities such as [3]:

- Raising awareness of TB
- Advocating for adequate resources and proper care
- Identification and referral of TB suspects
- Support of patients during treatment

Who is the “community”?
Members of the community involved in TB control activities can be community health workers, community volunteers or TB treatment supporters. These community persons do not generally receive a salary from the NTP or the health department but may receive various incentives such as reduced or free health care or transportation such as a bicycle. A TB treatment supporter can be a patient relative, friend or employer, community health worker, traditional healer or home-based care provider. The TB treatment supporter works closely with the hospital or health care facility and provides psychological and social support for the duration of TB treatment, and verifies that the patient takes each dose of treatment through direct observation. This involvement can be a great benefit to the patient, and also has the benefit of ensuring that appropriate treatment is completed.

Patients’ Charter for Tuberculosis Care
The Patients’ Charter for Tuberculosis Care [4] was developed in 2006 by TB patients throughout the world. It outlines the rights and responsibilities of people with TB with the objective to empower people with TB and communities. It was developed in conjunction with the International Standards for TB Care and aims to make the patient-provider relationship mutually beneficial. The Charter sets out the ways in which patients, communities, health care providers and governments can work together to improve health care and TB control services.
Session 2: TB Basics: Transmission, Pathogenesis, Diagnosis and Treatment
(Prepared by the New Jersey Medical School Global Tuberculosis Institute)

This session provides the hospital or health care facility manager with the fundamental knowledge of the key principles of TB transmission, pathogenesis, diagnosis and treatment. It is important for the manager to have a basic understanding of TB so as to ensure that sound control policies and practices are implemented in their facility.

Tuberculosis is an infectious disease caused by the bacterium *Mycobacterium tuberculosis* (*M. tuberculosis*). It is spread from person to person when an infectious airborne droplet is transmitted through the air during coughing, speaking, sneezing or singing. People who are sick with TB in their lungs are infectious and can transmit TB to others. It only takes a small number of the TB germs, or bacilli, to infect another person.

Transmission
There are many factors that impact transmission of bacilli from an infectious person to someone not infected with *M. tuberculosis*:

- **Infectiousness** of the person with TB disease: people who expel many TB bacilli into the air are considered more infectious than people who expel few or no bacilli. Infectiousness is often related to the type of TB disease (pulmonary or laryngeal versus extrapulmonary, or sputum smear-positive versus sputum smear-negative). Although patients with sputum smear-positive TB are much more likely to transmit TB bacilli than patients with sputum smear-negative TB, there is evidence that patients with smear-negative TB can transmit TB bacilli [1]. The greatest risk of infection exists when a person is continually exposed to someone within his or her household who has untreated sputum smear-positive pulmonary TB. The risk for transmitting infection from a person with sputum smear-negative pulmonary TB is low, and with extrapulmonary TB, it is even lower.

- **Environment** in which the exposure occurred (includes location and ventilation). Transmission is more likely to occur in areas where the volume of shared space is small and there is a lack of ventilation and direct sunlight.

- **Duration** of exposure. The risk of infection increases as one spends a longer period of time breathing air shared with an infectious TB patient.

- **Intensity** of exposure. The risk of infection increases with a higher number of mycobacterial generated by the infectious TB patient due to:
  - Disease of the lungs, upper airways or larynx
  - Presence of cough or other forceful expiratory measures (sneezing, singing, etc.), in particular when the patient fails to cover the mouth and nose when coughing or sneezing
  - Presence and extent of cavitation by chest x-ray
  - Insufficient treatment

Other factors such as HIV status, lack of personal protective equipment, and lung pathology also often impact transmission of TB bacilli from one person to another. Transmission of TB bacilli has also been linked to close contact with infectious TB patients during procedures generating aerosols, such as bronchoscopy, endotracheal intubation or suctioning, open abscess irrigation, autopsy, sputum induction or aerosol treatments [2].
Although drug-resistant TB is no more infectious than drug-sensitive TB, the delay in correctly diagnosing drug-resistant forms of TB, consequently delaying proper specific treatment, may lead to a longer infectious period than usual. This may then likely increase the number of individuals and encounters of exposure to the infectious patient.

Pathogenesis

Development of TB infection

To establish M. tuberculosis infection, TB bacilli must reach the alveoli of the lung. As discussed above, inhalation is the most likely mode of transmission of TB bacilli from an infectious person. Once the bacilli reach the alveoli, resident alveolar macrophages ingest and kill most bacilli. Surviving bacilli replicate inside the macrophage and are released when the macrophage dies. The TB bacilli may then travel via the bloodstream to more distant organs and tissues, including areas where TB disease is most likely to develop: the apex of the lung, kidneys, brain, bone and lymph nodes.

Dissemination of TB bacilli prepares the immune system for defensive action causing the destruction of the majority of bacilli and the formation of a granuloma. It is at this point that latent TB infection has been established, and is usually detectable 2-12 weeks after infection. Either the Mantoux tuberculin skin test or an interferon-gamma release assay (such as QuantiFERON®-TB test or T-SPOT) [3, 4] can be used to detect latent TB infection in a person. The Mantoux tuberculin skin test [5] measures a delayed-type hypersensitivity reaction in persons, and the interferon gamma release assay is a blood test that measures and compares the amount of interferon-gamma released by blood cells in response to antigens. The immune system of a healthy person is usually able to control the replication of the TB bacilli, and no further progression occurs.

A person with latent TB infection (LTBI) does not have TB symptoms, is not infectious, has no radiographic evidence of TB disease, and is not considered to be a case of TB.

In some countries, persons with LTBI are given anti-TB medications to prevent the development of disease [5].

Role of BCG vaccine:

BCG, or bacille Calmette-Guérin, is a vaccine for TB disease. It is used in many countries that have a high prevalence of TB to prevent the most serious forms of TB in young children (TB meningitis and miliary TB). Although the BCG vaccine may cause a positive tuberculin skin test
reaction, its reactivity of the tuberculin skin test in persons with BCG vaccine likely wanes over time. A positive tuberculin skin test result in an adult is likely due to TB infection and not the BCG vaccine, even in a person documented to have received BCG.

There are some groups of persons who are at an increased risk of getting TB infection, due to increased risk of exposure to TB:

- Person living with a person with active TB
- Health care workers
- Prisoners, ex-prisoners and staff working in prisons
- Socially vulnerable populations (i.e. homeless, unemployed, migrants, refugees)
- People who abuse alcohol or drugs

**Development of TB disease**

In some people infected with TB bacilli, the immune system is not able to keep the bacilli from multiplying and TB infection progresses to TB disease (also known as ‘active’ TB disease). This can happen soon after initial infection, or many years after infection. Approximately 10% of persons with LTBI will develop TB disease within their lifetime. TB disease most commonly develops in the lungs (pulmonary), but can develop in any organ or tissue of the body (extrapulmonary). Extrapulmonary TB is more common in immunosuppressed persons and young children, and is often accompanied by pulmonary TB. In areas where there is a high rate of TB/HIV infection, the percentage of extrapulmonary TB may be high, as patients with HIV are more likely to develop extrapulmonary TB than those not infected with HIV. There are a number of factors that may increase the chances that a person with TB infection progresses to TB disease:

- **HIV infection.** Persons infected with both TB and HIV have a 10% chance of developing disease each year. HIV infection is the strongest known risk factor to develop TB disease in persons with LTBI
- **Infection with** *M. tuberculosis* within the past 2 years
- **Previous TB disease,** especially in a person who received inadequate treatment
- **Alcohol or drug use,** especially intravenous drug use
- **Silicosis**
- **Diabetes mellitus**
- **Immunosuppressive therapies,** especially prolonged corticosteroid use
- **Renal/liver failure**
- **Malnutrition or low body weight,** especially 10% or more below ideal

**Diagnosis of TB Disease [7]**

The diagnosis of TB disease uses a variety of clinical and microbiological techniques. The changing epidemiology of TB, especially the surge of patients infected with both TB and HIV, has made the diagnosis of TB even more challenging.
A person suspected of having TB disease may have the following symptoms:
- Fever
- Cough (≥3 weeks)
- Chest pain
- Night sweats
- Weight loss
- Fatigue
- Hemoptysis (coughing up of blood)
- Decreased appetite

A person with extrapulmonary TB may have symptoms specific to disease site.

Diagnosis of TB in suspect persons should always include a thorough medical history and a physical examination, and then other “tests” according to the initial evaluation. These tests may include:

- Tests for TB infection (Mantoux tuberculin skin test or interferon gamma release assay)
- Chest radiograph
- Direct microscopic examination of sputum (stains) for acid-fast bacilli (AFB)
- Conventional or radiometric mycobacterial culture techniques

Both tests for TB infection and chest radiographs are considered general tests that can help to identify potential sites of disease (pulmonary versus extrapulmonary) and the extent of TB disease. While they do not definitively prove *M. tuberculosis* as the cause of disease, these tests can be performed relatively quickly and without much burden to the patient.

- **Test for TB infection** (Mantoux tuberculin skin test or interferon gamma release assay): Although these tests are mostly thought of as a test for TB infection (as discussed above), it may be useful to be able to confirm the presence of infection in someone suspected of having TB disease. However, caution must be used not to exclude the possibility of TB disease in a person with a negative test for TB infection, especially in HIV-infected persons. There are characteristics of patients, like malnutrition, extensive or unusual forms of TB disease, and immunosuppression that may result in falsely negative tests. Despite the limitations of the tests for TB infection, they may provide useful information to a clinician in diagnosing TB disease and should be considered in the diagnostic algorithm.

- **Chest radiographs**: Since many patients have TB involving the lungs, chest radiographs can be a useful tool in both the differential diagnosis of disease and determining the extent of disease. Chest radiograph findings of persons with TB disease often include abnormalities in the upper lobe or in the superior segments of the lower lobe, pleural involvement, lymphadenopathy and cavitation. Lesions can, however, appear in any part of the lung, especially in persons with HIV infection. Chest radiograph abnormalities may be suggestive of TB, but since they can never on their own be diagnostic, they should not be used alone to diagnose TB disease.

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6 Other diagnostic tests exist but are beyond the scope of this material.
Examination of the sputum for mycobacteria (through microscopic stain or culture) confirms the clinical diagnosis of TB by identifying *M. tuberculosis* in a patient specimen.

- **AFB stains:** Persons suspected of having pulmonary or laryngeal TB should have 2-3 sputum specimens (preferably one collected in early morning) examined by smear microscopy for AFB. Mycobacterium bacteria are one of only a few types of bacteria that are considered acid-fast, and the 2 most common staining techniques used to identify *M. tuberculosis* are the Ziehl-Neelsen or Kinyoun (traditional) technique and auramine/rhodamine (fluorochrome) technique. Both staining techniques are relatively rapid (results should be available in 24 hours), inexpensive and easy to perform. Fluorescence microscopy is used in some settings that examine a large number of specimens (i.e. more than 50 per day). The advantage of using fluorescence microscopy for AFB is that it uses a lower power objective which means that it will take less time to examine the same area than the other microscopy techniques. However, fluorescence microscopy is more costly and requires more technical capacity than the other traditional microscopy techniques [8].

The number of AFB seen microscopically is directly related to the infectiousness and extent of TB disease in a person – the greater the number of AFB, the more infectious the person. There are international recommendations (WHO and the Union) for quantifying AFB smear results:

<table>
<thead>
<tr>
<th>Reporting scale</th>
<th>AFB seen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>No AFB seen in at least 100 fields</td>
</tr>
<tr>
<td>(actual number)</td>
<td>1-9 AFB per 100 fields</td>
</tr>
<tr>
<td>1+</td>
<td>10-99 AFB per 100 fields</td>
</tr>
<tr>
<td>2+</td>
<td>1-10 AFB per field in at least 50 fields</td>
</tr>
<tr>
<td>3+</td>
<td>Greater than 10 AFB per field in at least 20 fields</td>
</tr>
</tbody>
</table>

- It is important to realize that many pulmonary TB patients have negative AFB smears; this is due to the low sensitivity of the test. Another disadvantage of AFB staining is that it may have a low specificity to diagnose TB disease, especially in populations with a high prevalence of mycobacteria other than *M. tuberculosis*. This means that other acid-fast organisms, such as *M. avium complex*, will also stain positive for AFB. AFB staining also does not distinguish between live and dead TB bacilli.

- **Conventional or radiometric culture techniques:** Culture remains the “gold standard” for diagnosis of TB; however, it is not yet available in a number of settings because of cost and other programmatic limitations (e.g. culture requires a moderately well-equipped laboratory). Culture is more sensitive than AFB staining and can also allow speciation and drug susceptibility testing. Results of culture can be expected within 10-14 days when rapid radiometric methods or used, or 6-12 weeks when conventional tests are used. In settings where resources for culture are available and not limited, culture examination should be done for all specimens regardless of AFB smear results, and the initial *M. tuberculosis* isolate should be tested for resistance to first-line anti-tuberculosis drugs. Second-line drug susceptibility testing (if available) should be limited to specimens from patients who have previously been treated for TB, or have been in contact with a patient with known drug resistance. Drug-susceptibility tests (first and second-line) should be repeated for patients who are not responding to treatment or have positive cultures 3 months into treatment. Once the mycobacteria have been grown in culture, the use of nucleic acid probes is a sophisticated technique available in resource-rich settings to further identify species of *M. tuberculosis*. 

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The success of confirming TB using microbiological laboratory techniques depends on the quality of the specimen and the quality of the laboratory. As mentioned above, 2-3 sputum specimens should be collected from a person suspected of pulmonary TB disease. At least one of the specimens should be collected in early morning. Collection of specimens in the hospital or clinic should be done in an isolated, well-ventilated area or a specific sputum collection room or booth.

Health care workers should properly instruct a patient on how to collect sputum, and sputum “induction” techniques can be used in persons unable to cough up sputum. Pulmonary specimens can also be collected through a bronchoscopy or gastric aspiration. Infection control precautions must be in place during bronchoscopy procedures since transmission could take place through the aerosols that are generated by the procedure. Gastric aspirations are often used to collect specimens from infants and children who are unable to produce sputum. Clinical specimens from non-pulmonary sites can be collected and transported to the laboratory for AFB smear and culture analysis. Care must be taken not to include formalin or other preservatives in tissue specimens since they kill or inhibit the growth of any TB bacilli.

Diagnostic of TB in children
Diagnosis of paediatric TB is especially challenging. Infants and children are usually unable to produce sputum so that bacteriological confirmation of TB is not possible. A diagnosis of TB is usually based on the following criteria: close contact to a source case, a positive tuberculin skin test, and chest radiograph findings consistent with TB. The effect of previous vaccination with BCG can complicate the interpretation of a positive tuberculin skin test results. However, studies have shown that reactivity to the tuberculin skin test is reduced by at least 50% by 9-12 months of age in children given BCG vaccine, and by 80-90% in children 3-5 years of age [9].

Treatment of TB Disease
With appropriate treatment and adequate patient management, TB is curable in more than 90% of patients with drug-susceptible disease. The modern treatment strategy for TB is based on standardized short-course chemotherapy regimens and proper patient management to ensure completion of treatment and cure. Internationally tested and accepted regimens for TB treatment have been developed by experts in many countries such as the United States (American Thoracic Society) [10] and Great Britain (British Thoracic Society) [11], and by international organisations such as the World Health Organization [12] and the International Union Against Tuberculosis and Lung Disease [13].

The goals of TB treatment are both:
- to cure the individual patient
- to minimize transmission of *M. tuberculosis* to others

An appropriate treatment regimen for TB should also:
- prevent deaths
- prevent relapse of TB
- prevent the development of acquired drug resistance
Successful treatment of a TB patient benefits both the patient and the community, and the responsibility for successful treatment lies with the health care provider, not only for prescribing an appropriate treatment regimen but also to ensure completion of therapy [14].

**Treatment supervision and patient support**

Proper case management with supervision and patient support must be part of any successful TB treatment strategy. Treatment that is supervised improves patient adherence to anti-tuberculosis drugs thereby increasing the likelihood for cure and decreasing the development of drug resistance. It also enables early identification of adverse drug reactions and clinical worsening of TB. Directly observed therapy (DOT) is one way of supervising treatment and occurs when a health worker or other treatment supporter directly administers, observes and records every dose of a patient’s TB medication. DOT may take place at a health facility, in the workplace, in the community, or at home, and should be provided by someone accepted by the patient who is trained and supervised by local health services. While supervised treatment with DOT is recommended for all TB patients, there are certain groups of TB patients who may especially benefit from supervision including patients with HIV co-infection, a history of TB disease, homelessness, a history of incarceration, psychiatric disorders, and alcohol or drug abuse.

**Anti-tuberculosis drugs**

The essential first-line anti-tuberculosis drugs, their main properties, dose form and recommended doses can be found in Table 5 below (modified from WHO Treatment of tuberculosis: guidelines for national programmes, 2nd edition). Anti-tuberculosis drugs are also available in fixed-dose combinations (FDC) tablets and are strongly recommended for the treatment of TB. Advantages and disadvantages of FDC drugs are provided in Table 6.

<table>
<thead>
<tr>
<th>Essential First-Line Drugs (abbreviation)</th>
<th>Property</th>
<th>Dose form</th>
<th>Recommended dose (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid (H)</td>
<td>Bactericidal (most powerful)</td>
<td>Tablet</td>
<td>5</td>
</tr>
<tr>
<td>Rifampin (R) or Rifampicin (R)</td>
<td>Bactericidal (most powerful), sterilizing</td>
<td>Tablet or capsule</td>
<td>10</td>
</tr>
<tr>
<td>Pyrazinamide (Z)</td>
<td>Bactericidal (against certain populations of TB bacilli)</td>
<td>Tablet</td>
<td>25</td>
</tr>
<tr>
<td>Streptomycin (S)</td>
<td>Bactericidal (against rapidly multiplying TB bacilli)</td>
<td>Powder for injection</td>
<td>15</td>
</tr>
<tr>
<td>Ethambutol (E)</td>
<td>Prevent emergence of resistant TB bacilli</td>
<td>Tablet</td>
<td>15</td>
</tr>
</tbody>
</table>
Table 6. Advantages and disadvantage of fixed-dose combination TB drugs

<table>
<thead>
<tr>
<th>Fixed-dose combination TB drugs</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Less likelihood of prescription errors since dosing recommendations are clearer</td>
<td>• Prescription errors can lead to excess dosage and risk of toxicity</td>
</tr>
<tr>
<td></td>
<td>• Easier adjustment of dose according to patient weight</td>
<td>• Prescription errors can lead to reduced dosage, sub-inhibitory concentrations and risk of developing drug resistance</td>
</tr>
<tr>
<td></td>
<td>• Increased patient adherence since there are fewer tablets to ingest</td>
<td>• Decreased directly observed therapy in situations where health care workers believe adherence is guaranteed</td>
</tr>
<tr>
<td></td>
<td>• Patients cannot self-select which drugs to take if treatment is not observed</td>
<td>• Possibility of poor rifampin/rifampicin bioavailability</td>
</tr>
</tbody>
</table>

Treatment regimes

Treatment regimens for new cases of TB have an initial (or intensive) phase lasting 2 months and a continuation phase lasting 4 months or more (Table 7). The initial phase of treatment usually includes a standard 4-drug regimen of isoniazid, rifampicin, pyrazinamide and ethambutol for 2 months. During the initial 2 months of treatment, TB bacilli are rapidly killed and a person becomes non-infectious typically within 2 weeks. Generally, the patient’s symptoms will markedly decrease and smears will convert from positive to negative in the first 2 months of treatment.

The standard treatment regimen in the continuation phase includes isoniazid and rifampicin for an additional 4 months. To ensure appropriate treatment and reduce the risk of acquired drug-resistance, TB treatment regimens must contain multiple drugs to which the organisms are susceptible. Treatment with a single drug or the addition of a single drug to a failing TB regimen can lead to the development of resistance to that drug.

Treatment regimens for previously treated TB patients (patients who failed previous treatment, relapsed or defaulted) include more drugs for more months in both the initial and continuation phases since these patients are at a higher risk of acquiring drug-resistant forms of TB. Likewise, patients with known drug-resistant forms of TB are given alternate treatment regimens that include second-line anti-tuberculosis drugs for 18-24 months (see Drug Resistance section). Similarly, the treatment of extrapulmonary TB and TB in special situations (like pregnancy, liver dysfunction, acute hepatitis, renal failure, and HIV infection) may call for special or alternative treatment regimens.
### Table 7. Recommended treatment regimens
(Abbreviated from WHO treatment guidelines; see guidelines for detailed information)\(^7\) [12].

<table>
<thead>
<tr>
<th>TB patients</th>
<th>TB treatment regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Initial phase</strong></td>
</tr>
<tr>
<td>New smear-positive</td>
<td>2 HRZE [preferred]</td>
</tr>
<tr>
<td>New smear-negative pulmonary (with extensive parenchymal involvement, HIV disease or severe forms of extrapulmonary TB) [Category I]</td>
<td>2 (HRZE)_3 [optional]</td>
</tr>
<tr>
<td>Previously treated smear-positive pulmonary (includes relapse and treatment after default) [Category II]</td>
<td>2 HRZES / 1 HRZE [preferred]</td>
</tr>
<tr>
<td></td>
<td>2 (HRZES)_3 / 1 (HRZE)_3 [optional]</td>
</tr>
<tr>
<td>Treatment failure of new patients [Category II]</td>
<td>Standardized or individualized regimens should be used. If not available, then use:</td>
</tr>
<tr>
<td></td>
<td>2 HRZES / 1 HRZE [preferred]</td>
</tr>
<tr>
<td></td>
<td>2 (HRZES)_3 / 1 (HRZE)_3 [optional]</td>
</tr>
<tr>
<td>New smear-negative pulmonary</td>
<td>2 HRZE [preferred]</td>
</tr>
<tr>
<td>Less severe forms of extrapulmonary [Category III]</td>
<td>2 (HRZE)_3 [optional]</td>
</tr>
<tr>
<td>Chronic (still sputum-positive after supervised re-treatment</td>
<td>2 HRZE [optional]</td>
</tr>
<tr>
<td>Proven or suspected MDR-TB [Category IV]</td>
<td>Standardized or individualized regimens should be used. Treatment of patients in this category should be under the responsibility of a physician with expertise in drug-resistant TB</td>
</tr>
</tbody>
</table>

**Treatment of TB in children**

Treatment of TB in children often requires some special considerations [9]:

- Since children usually develop TB disease as an immediate consequence of primary infection, they typically have fewer mycobacteria than adults. Therefore, anti-TB drug resistance that develops during treatment is usually uncommon in children. Most drug resistance found in children is usually a result of primary infection with a drug-resistant strain.
- Children are more likely than adults to develop extrapulmonary forms of TB, particularly disseminated disease and TB meningitis.
- The pharmacokinetics of anti-TB drugs differs between children and adults. Children tend to tolerate larger doses per kilogram of body weight and have fewer adverse reactions than adults.
- Children may have problems absorbing the available dosage forms of anti-TB drugs since most are formulated for adults. When possible, paediatric formulations should be used.

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\(^7\) For information on all TB treatment regimens, we recommend that you consult with your National TB Control Program or WHO recommendations.
Monitoring of treatment

Once TB is diagnosed in a person, follow-up AFB smears should be done to assess infectiousness and monitor the patient’s response to anti-TB treatment. During the initial phase of treatment, specimens should be collected every 2 weeks until they are AFB smear negative. Ideally in the continuation phase of treatment, specimens should be collected monthly until 2 consecutive specimens examined by culture are negative.

<table>
<thead>
<tr>
<th>Conversion of culture results from positive to negative is one of the most important objective measures of response to treatment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• In settings where culture is not routinely used, smear-conversion from positive to negative after diminishing of the number of organisms on serial smears can be used to monitor response to therapy.</td>
</tr>
<tr>
<td>• In patients with smear-negative pulmonary or extrapulmonary TB disease, improvements in clinical symptoms should be assessed to monitor response to therapy.</td>
</tr>
</tbody>
</table>

Monthly patient visits to the treating physician should include a physical exam, a review of the importance of adherence to therapy, monitoring for signs or symptoms of adverse drug reactions, screening for use of alcohol and other potentially hepatotoxic drugs, and plans to continue treatment. Chest radiographs may be repeated for patients with culture-negative TB or in settings where culture is not routinely used.

A comprehensive set of guidelines for the care and control of TB have been developed for nurses by the International Council of Nurses, and include measures to treat TB, guidelines for patient care including nursing principles, and organisational and workforce issues (http://www.icn.ch/tb/TB_MDRTB_Guideline.pdf) [15].
Session 3: The Role of Health Facility Care Managers in Programmatic TB Control
(Prepared by the New Jersey Medical School Global Tuberculosis Institute)

This session consists of 8 topics that provide specific information and guidance for the hospital and health care facility managers on TB control issues including TB/HIV, drug resistance, infection control, monitoring and evaluation, laboratory services, management of anti-TB drugs, budgeting and planning, and human resource development.

Topic 1: The Impact of HIV on the TB Epidemic

The HIV epidemic has had a significant impact on the global crisis of TB, and in many parts of the world, has fuelled the TB epidemic. One-third of the approximate 33 million persons living with HIV are also infected with TB. This deadly combination of TB and HIV has had disastrous effects on both disease populations. In persons already infected with TB, HIV infection facilitates the progression to active TB disease. The annual risk of developing TB from a latent infection is approximately 10% for persons also infected with HIV, compared with a lifetime risk of around 10% in persons not infected with HIV. HIV also increases the rate of recurrent TB, due to incomplete cure from prior anti-TB therapy (relapse) or exogenous re-infection. Within a community, the risk of transmission of TB bacilli increases as the number of TB cases among persons with HIV increases, creating a reservoir of infection in the population.

TB disease facilitates the progression of HIV to AIDS, and in many countries persons infected with HIV develop TB as the first manifestation of AIDS. TB is a leading cause of death among people living with HIV and has been shown to kill up to 50% of all AIDS patients worldwide. Without proper treatment, 90% of persons living with HIV will die within months of contracting TB. However, appropriate TB treatment and cure can significantly delay the development of AIDS in persons infected with HIV.

There are special considerations when diagnosing and treating a person co-infected with both TB and HIV [1, 2]:

- TB is more difficult to diagnose in persons infected with HIV. Persons with HIV have a much reduced sensitivity to the Mantoux tuberculin skin test and may often test negative when they are in fact infected with TB bacilli. It is not yet known if interferon gamma release assays also have a reduced sensitivity in HIV-infected persons; however caution should be taken when interpreting negative results of the assay in a person infected with HIV.

- As HIV progresses in an individual, it is more likely that his or her TB clinical presentation will be “atypical” (e.g. with disseminated disease, lymph node involvement and other extrapulmonary disease). Similarly, persons with HIV may have more unusual chest radiographic findings than persons not infected with HIV.

- Although in general the proportion of positive sputum smears and cultures is the same in HIV-infected persons as in persons not infected with HIV, the rates of smear-negative pulmonary and extrapulmonary TB has been rising in countries with HIV epidemics [3]. This poses a significant challenge in diagnosing TB in persons infected with HIV, especially in resource-poor countries.

In general, treatment of TB in persons infected with HIV is the same for persons not infected with TB. Since the risk of death from TB is much higher in persons with HIV infection, treatment
support (i.e. DOT) can be especially beneficial to ensure cure and treatment success. Similarly, patients with both diseases should be on daily therapy at least during the intensive phase of treatment. It has been shown that TB cases infected with HIV are among those that relapse after the use of intermittent therapy in the continuation phase [4].

There are, however, some situations during the treatment of TB in persons infected with HIV that warrant careful consideration:

- May be an increased risk for acquired drug resistance, especially rifampicin. This may be due to decreased absorption of the drug in persons infected with HIV, or due to the use of rifabutin as a prophylaxis for prior *M. avium* disease. However, there has yet to be a clear association between HIV infection and MDR-TB in population-based studies.

- Possible drug interactions can occur between TB drugs and antiretroviral therapy (ART). This is a particular concern with rifampicin. The concomitant use of rifampicin and ART may result in a decreased suboptimal concentration of the antiretroviral drug or an increased concentration of rifampicin resulting in drug toxicity. When drug interactions are a concern, many physicians prefer to use rifabutin as it has been shown not to interfere as much with ART as rifampicin.

- May be an increased risk of immune reconstitution inflammatory syndrome (paradoxical reactions) in patients on ART.

The decision when to start ART in patients co-infected with both TB and HIV depends on a number of factors. There is a high mortality rate in these patients and so treatment of both diseases at the same time can substantially reduce the risk of death. ART will increase one’s CD4 count and may decrease the risk of TB relapse or exogenous reinfection. However, there is the possibility of drug interactions and toxicity, along with an increased risk of immune reconstitution inflammatory syndrome (especially in the early intensive phase). It is suggested to refer to the guidelines set out by the National TB Control Programme and National AIDS Control Programme (or equivalent) in each country.

**TB/HIV Collaborative Activities**

The World Health Organization set forth an *Interim Policy on Collaborative TB/HIV Activities* to guide countries on how to develop practices and policies to manage their duel epidemics of TB and HIV [5]. The recommended collaborative TB/HIV activities are:

1. **To establish the mechanisms for collaboration between TB and HIV/AIDS programmes.** This can be accomplished through the following activities:
   a. Set up a coordinating body for TB/HIV activities effective at all levels
   b. Conduct surveillance of HIV prevalence among TB patients
   c. Carry out joint TB/HIV planning
   d. Conduct monitoring and evaluation

In many countries, TB and HIV/AIDS programmes have separate objectives and rarely work together. Since each disease has a profound impact on the other, mechanisms need to be established that foster collaboration between the 2 programmes, and allow for mobilization of resources for joint TB/HIV activities. Planning for joint TB/HIV activities should be part of both the National TB Control Plan and the National AIDS Control Plan, and responsibilities of both Programmes need to be explicitly defined.
2. **Decrease the burden of TB in people living with HIV/AIDS.** This can be accomplished through the following activities:
   a. Establish intensified TB case-finding
   b. Introduce isoniazid preventive therapy
   c. Ensure TB infection control in health care and congregate settings

By decreasing the amount of TB in people infected with HIV, a country can reduce the number of people dying from TB-related HIV/AIDS and lessen TB transmission in the general community. By strengthening screening activities for TB symptoms in HIV populations, a community can more easily identify and diagnose TB cases earlier leading to improved treatment outcomes and decreased mortality. The use of isoniazid in HIV-infected persons with latent TB infection can significantly reduce the risk of developing TB disease thereby reducing their risk of progressing from HIV to AIDS. However, the use of isoniazid preventive therapy may not be effective in areas with a high prevalence of isoniazid resistance or MDR-TB. Infection control measures should be in place in health care and congregate settings where TB and HIV patients mix to reduce the risk of transmission of TB to persons infected with HIV.

3. **Decrease the burden of HIV in TB patients.** This can be accomplished through the following activities:
   a. Provide HIV testing and counselling
   b. Introduce HIV prevention methods
   c. Introduce co-trimoxazole preventive therapy
   d. Ensure HIV/AIDS care and support
   e. Introduce antiretroviral therapy

The consistent interaction of TB patients and health care workers during appropriate TB treatment (i.e. with directly observed therapy) offers unique opportunities to reach the patient in many health-related areas. Since many persons with HIV do not know that they are infected, the offer of HIV counselling and testing for TB patients may provide an entry point for many HIV-infected persons to know their status and start ART or other supportive treatment.

Implementing all or some of these activities in a country with TB and HIV epidemics will lead to better collaboration between TB and HIV/AIDS programmes, improvements in the quality of care and life for persons affected by these 2 diseases, and decreases in the burden of both diseases in future populations.
Summary of TB/AIDS Issues for Hospital and Health Care Facility Managers

As described above, TB/AIDS can present a number of challenges for hospital and health facility managers. In order to address these challenges, the role of hospital and health care facility managers may include:

- Minimizing risk of TB transmission to patients and staff with HIV/AIDS through implementation of appropriate infection control policies (this will be discussed further in Topic 3)
- Ensuring that appropriate treatment is provided for TB/AIDS co-infected patients, including those on ART
- Ensuring that policies, procedures and trained staff are in place to screen for TB in patients with HIV/AIDS
- Ensuring provision of voluntary counselling and testing to screen for HIV in patients infected with TB
- Ensuring confidentiality of patients and staff with HIV, while minimizing risk of transmission
- Establishing and maintaining communication and coordination with HIV/AIDS programmes
Topic 2: Multidrug-Resistant TB and Extensively Drug-Resistant TB

Multidrug-resistant tuberculosis (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB) pose a serious threat to the maintenance of an effective TB control strategy in many countries in the world, especially those with a high TB burden. Drug resistance is caused by inadequate or incomplete treatment, which may be a result of irregular intake of anti-TB drugs or inadequate regimens. It can also be caused by an interruption in the supply of essential drugs, or by poor quality drugs. If a patient has not completed treatment successfully, or if the treatment is ineffective, he or she continues to transmit M. tuberculosis, which may be resistant to primary drugs. MDR-TB requires approximately 2 years of treatment and thus takes much longer to cure than drug-susceptible TB. Drugs to treat MDR-TB also cost more and are less effective. Patients with XDR-TB may require even longer and costlier treatment.

Resistance to anti-TB drugs in strains of M. tuberculosis is a man-made phenomenon. Spontaneous occurrences of drug-resistant mutations in M. tuberculosis strains that have never been in contact with anti-TB drugs rarely occur: 1 organism in 10^8 TB bacilli will “naturally” be resistant to rifampicin; 1 organism in 10^6 TB bacilli will “naturally” be resistant to isoniazid and streptomycin; and 1 organism in 10^4 TB bacilli will “naturally” be resistant to ethambutol. Since TB bacilli replicate extremely slowly, drug resistance by this natural mechanism is unlikely to significantly affect the treatment or cure of a person with active TB disease.

History and Definitions of Drug Resistance

The problem of drug resistance first occurred in the 1940s with the introduction of streptomycin. While TB patients responded to the streptomycin at first and symptoms lessened, patients eventually “relapsed” during the course of treatment and were not cured – the TB bacilli had adapted to the streptomycin and developed biochemical ways to resist the drug. However, streptomycin given with another drug (PAS or isoniazid) lessened the likelihood of developing drug resistance and increased treatment success. Even with the advent of multidrug therapy, rates of anti-TB drug resistance increased in the late 1960s as TB treatment shifted to outpatient care and compliance to treatment decreased.

There are 4 forms of resistance to anti-TB drugs:

1. **Monodrug resistance**: resistance to only 1 anti-TB drug
2. **Polydrug resistance**: resistance to more than 1 anti-TB drug but not to both isoniazid and rifampicin
3. **Multidrug resistance**: resistance to at least isoniazid and rifampicin
4. **Extensively drug resistance**: resistance to isoniazid, rifampicin, any fluoroquinolone, and at least 1 second-line injectable drug (amikacin, kanamycin or capreomycin)

Since isoniazid and rifampicin are the cornerstone drugs of anti-TB therapy, treatment and cure of a TB patient is greatly threatened if the patient has MDR-TB, and the chances for cure can be lower than 30% for patients with XDR-TB. Both MDR-TB and XDR-TB are great threats to global TB control.

Patients can develop drug-resistant TB by 1 of 2 mechanisms:

1. **Primary resistance.** A patient is infected with a drug-resistant strain, has never had previous treatment for TB, and develops resistance to anti-TB drugs at the onset of disease.
2. **Acquired resistance** (also called ‘secondary’). A patient originally infected with a drug susceptible strain of *M. tuberculosis* will develop drug resistance as a result of inappropriate or inadequate treatment.
Drug resistance can develop in a person because of factors attributable to the physician or health care worker, the TB control programme, and/or the patient.

- **Physician or health care worker factors.** Very often physicians prescribe inappropriate therapy for TB patients that include suboptimal doses and/or too few drugs. Multiple drug therapy is the standard of care for TB patients. Adding a single drug to a failing treatment regimen is an unfortunate common practice for physicians unaware of appropriate TB treatment recommendations, and one that often leads to drug resistance.

- **TB control programme factors.** It is often the responsibility of the national TB control programme to provide an adequate supply of quality anti-TB drugs for all patients under its jurisdiction. If the drugs are of suboptimal quality or if there is a stock-out of drugs in the middle of a patient’s treatment, resulting in treatment interruption, the likelihood for drug resistance significantly increases. Techniques and strategies for preventing problems due to inappropriate drug management are also highly appropriate to hospital and health care facility managers with regard to other medications not specifically used for TB. Other TB control programme factors include the organisation of treatment and DOT services.

- **Patient factors.** Non-adherence of the patient to his or her prescribed treatment has been considered one of the most common causes of acquired drug resistance. Patients may take fewer doses of one drug than prescribed or not take a drug at all. This may be related to programmatic factors, such as provision of DOT in a convenient location. Patients provided with effective DOT or other treatment support are much less likely to acquire drug resistance than patients with self-administered therapy. With support from a health care worker, side effects of the drugs or other problems with the drug therapy can be noticed and remedied before drug resistance emerges. Another patient factor that may influence drug resistance is a patient’s inability to fully absorb therapeutic doses of drugs. This may be caused by other underlying medical conditions or drug-drug interactions.

### Groups of persons who are at an increased risk for drug resistant TB:

- Persons who have a history of treatment with anti-TB medications
- Persons who have received inadequate treatment for more than 2 weeks (including treatment with single drugs, suboptimal doses or insufficient duration of treatment)
- Persons who were in contact with patients known to have drug-resistant TB
- Persons born or living in areas with a high prevalence of drug-resistant TB
- Persons whose smear or culture results remain positive after 2-3 months of therapy with anti-TB drugs

### Diagnosis of Drug-Resistant TB

In settings with adequate resources and technical capacity, including an appropriate laboratory which could also be applicable to a general facility for non-TB activities, all patients diagnosed with TB should have specimens tested for susceptibility to first-line anti-TB drugs (isoniazid, rifampicin, ethambutol and streptomycin). If drug resistance is found, then the specimen should be further tested for susceptibility to pyrazinamide and second-line anti-TB drugs. In settings where it is not possible to provide drug susceptibility testing (DST) for all patients, priority should be given to patients at most risk for having drug-resistant disease including chronic cases who have
failed retreatment regimens and persons with known exposure to a drug-resistant case (or persons designated under the policy of the national TB control programme) [1]. DST should also be strongly considered in patients also infected with HIV since MDR-TB can be particularly deadly in persons with both TB and HIV.

There are a number of methods used to determine the susceptibility of a *M. tuberculosis* specimen. These DST methods can be grouped into 3 categories: 1. Conventional methods based on observation of growth, 2. Rapid methods to detect metabolic inhibition, and 3. Molecular methods to detect drug-resistant genetic mutations [2, 3].

1. **Conventional methods based on observation of growth:** Conventional methods test the ability of a specimen to grow on agar or in broth that contains a “critical” concentration of an anti-TB drug\(^8\). If the specimen is able to grow at the “critical” concentration, then it is considered resistant to the anti-TB drug. These methods are used in most settings with limited resources since they are the least expensive. However, they also have the longest turnaround times, often with results reported 30 or more days after initiation of the test. The agar “proportion method” is the most common conventional DST method used. Other conventional methods include the “absolute concentration method” and the “resistant ratio method”.

2. **Rapid methods to detect metabolic inhibition:** Rapid DST methods have been developed and shorten the time from collection of the specimen to reporting of results to less than 30 days. The most commonly used rapid DST methods measure either the rate of carbon dioxide production (i.e. Becton Dickinson BACTEC™ 460TB Automated Mycobacterial Detection and Susceptibility Testing System) or oxygen consumption (i.e. Becton Dickinson BACTEC™ MGIT™ 960 Mycobacteria Growth Indicator Tube System). These methods are often not found in developing countries with the highest burdens of TB and MDR-TB because they are expensive to run and maintain, and require more advanced technical capacity of the laboratory.

3. **Molecular methods to detect drug resistant genetic mutations:** Recent research has identified mutations in *M. tuberculosis* that confer resistance to many of the anti-TB drugs. The mutations that cause resistance to rifampicin are the best elucidated and can be mapped to a single rpoB gene, and techniques developed to identify rifampicin mutations can be performed with a fair amount of confidence. Mutations that cause resistance to isoniazid and other anti-TB drugs are less well understood making it impossible for these techniques to capture all drug resistant strains. Techniques using molecular methods are prohibitively costly in many settings and require a sophisticated laboratory with capacity for DNA amplification.

In general, DST of first-line drugs (with the exception of pyrazinamide) is easier than that of second-line drugs. In most countries, second-line DST is only done in a special laboratory or specimens are sent to a regional supranational reference laboratory for testing. Guidelines for second-line DST have been developed by the WHO [4].

**Treatment of Drug-Resistant TB**

There are many excellent guidelines for the treatment of MDR-TB including those developed by the WHO [5], the CDC/American Thoracic Society [6], the World Medical Association (http://lupin-nma.net/) [7] and the International Council of Nurses (http://www.icn.ch/tb/TB_MDRTB_Guideline.pdf) [8]; however, to ensure the greatest success,

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\(^8\) The “critical” concentration of an anti-TB drug is one that kills wild strains of *M. tuberculosis* (or strains that have never come into contact with the drug).
treatment of patients with MDR-TB should be under the responsibility of a physician with expertise in drug-resistant TB.

There are 3 MDR-TB treatment strategies that countries can follow depending on the level of laboratory technical capacity and resources, reliability of DST results, and knowledge of drug resistance patterns through local surveys. These strategies include:

1. **Standardized treatment regimens**: These regimens are based on local drug resistance patterns of specific treatment categories determined through drug-resistant surveys conducted according to international standards or other reliable data. The same treatment will be given to all patients of one defined group. When available, DST should be performed to confirm all MDR-TB cases. A standardized regimen must include at least 4-5 effective drugs to adequately cover most patients and strategies for patient support including DOT.

2. **Empirical treatment regimens**: These regimens are based on the patient’s history of anti-TB treatment (with first- or second-line drugs), the DST profiles of any known contacts, and local drug resistance patterns. If individual DST results become available, then the empirical regimen should be adjusted accordingly.

3. **Individualized treatment regimen**: These regimens are mostly based on individual DST results; however it is important to consider the patient’s history of anti-TB treatment (with first- or second-line drugs) and contact with any known MDR-TB patients. With individualized treatment regimens, it is crucial to interpret DST results correctly and understand the limitations of the susceptibility test for each anti-TB drug. It is also possible for the patient to acquire drug resistance from the time the specimen was collected and DST results become available, thereby affecting the treatment regimen.

**Anti-TB drugs used in the treatment of MDR-TB**

First-line anti-TB drugs (see Table 5, Session 2) are isoniazid, rifampicin, pyrazinamide, streptomycin and ethambutol. When first-line drugs are not able to be used in a TB treatment regimen because of resistance, there are more toxic and less effective drugs that can be used (second-line drugs). Since they are not as efficacious, they also must be used for a much longer time to cure the patient (Table 8).
### Table 8. Second-line anti-tuberculosis drugs [1, 6, 9]

<table>
<thead>
<tr>
<th>Second-Line Drugsa (abbreviation)</th>
<th>Property</th>
<th>Recommended daily dose (mg/kg)</th>
<th>Common side effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kanamycin (Km)</td>
<td>Bactericidal</td>
<td>15-20</td>
<td>Pain at injection site, proteinuria, serum electrolyte disturbances</td>
</tr>
<tr>
<td>Amikacin (Am)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capreomycin (Cm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vioymycin (Vi)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ciprofloxacin (Cfx)</td>
<td>Bactericidal</td>
<td>1500</td>
<td>Generally well tolerated and absorbed</td>
</tr>
<tr>
<td>Ofloxacin (Ofx)</td>
<td></td>
<td>800</td>
<td></td>
</tr>
<tr>
<td>Levofloxacin (Lfx)</td>
<td></td>
<td>750</td>
<td></td>
</tr>
<tr>
<td>Moxifloxacin (Mfx)b</td>
<td></td>
<td>400</td>
<td></td>
</tr>
<tr>
<td>Cycloserine (Cs)</td>
<td>Bacteriostatic</td>
<td>500-1000</td>
<td>Neurologic and psychiatric disturbances (headaches, irritability, sleep disturbances, aggression, tremors)</td>
</tr>
<tr>
<td>Ethionamide (Eto) or Prothionamide (Pto)</td>
<td>Bacteriostatic or bacteriostatic</td>
<td>500-1000</td>
<td>GI symptoms (nausea, vomiting, diarrhea, abdominal pain, loss of appetite), metallic taste, hypothyroidism</td>
</tr>
<tr>
<td>p-aminoosalicylic acid (PAS)</td>
<td>Bacteriostatic</td>
<td>According to manufacturer</td>
<td>GI symptoms (nausea, vomiting, diarrhea), hypersensitivity, hypothyroidism</td>
</tr>
</tbody>
</table>

a There are other drugs used in the treatment of MDR-TB (Clofazimine, Amoxicillin/Clavulanate, Clarithromycin, Linezolid) but they are not recommended for routine use for the treatment of MDR-TB.

b Use of this drug is not recommended for use in MDR-TB treatment regimens because long-term safety and efficacy have not yet been shown.

The World Health Organization also uses an anti-TB drug “grouping” system to help better define appropriate treatment regimens for MDR-TB:

**Group 1:** First-line oral anti-TB drugs: *isoniazid, rifampicin, ethambutol, pyrazinamide*

**Group 2:** Injectable anti-TB drugs: *streptomycin, kanamycin, amikacin, capreomycin, viomycin*

**Group 3:** Fluoroquinolones: *ciprofloxacin, ofloxacin, levofloxacin, moxifloxacin*

**Group 4:** Oral bacteriostatic second-line anti-TB drugs: *ethionamide, protonamide, cycloserine, PAS*

**Group 5:** Anti-TB drugs not recommended for use in MDR-TB patients except when there are no other susceptible drugs available from other groups: *clofazimine, amoxicillin/clavulanate, clarithromycin, linezolid*

Examples of recommended individualized treatment regimens using the Group system:
A. In patients resistant to **Isoniazid** and **Rifampicin**, the recommended individualized treatment regimen includes:

- Pyrazinamide
- Ethambutol
- A Group 2 injectable drug (Streptomycin is desired)
- A Group 3 fluoroquinolone drug
- One or two Group 4 drugs (depending on reliability of Pyrazinamide and Ethambutol susceptibility results and extent of disease)

In patients resistant to **Isoniazid**, **Rifampicin** and **Ethambutol** or **Pyrazinamide**, the recommended individualized treatment regimen includes:

- Pyrazinamide or Ethambutol (if susceptible)
- A Group 2 injectable drug (Streptomycin is desired)
- A Group 3 fluoroquinolone drug
- Two or more Group 4 drugs (depending on reliability of Pyrazinamide and Ethambutol susceptibility results and extent of disease)

The following are basic principles to guide the treatment of MDR-TB patients (from the *Guidelines for the programmatic management of drug-resistant tuberculosis*. Geneva, World Health Organization, 2006):

- Treatment regimens should be based on:
  - Patient’s history of anti-TB treatment (with first- or second-line drugs)
  - Anti-TB drugs and treatment regimens used in the area
  - Prevalence of drug-resistant TB in the area (both first- and second-line)
- Treatment regimens should consist of at least 4 effective drugs (with certain or almost certain drug susceptibility profiles)
- Anti-TB drugs should be given at least 6 days a week
- Dosage of anti-TB drugs should be determined by body weight
- A Group 2 injectable drug should be used for a minimum of 6 months
- Treatment of MDR-TB patients should last a minimum of 18 months beyond culture conversion
- DOT and other patient support should be provided for the entire duration of treatment
- DST, if reliably available, should be used to guide and monitor treatment
- Infection control principles should be followed, including the use of administrative, environmental, and personal respiratory controls (see following topic on Infection Control for more information)
Global MDR-TB Strategy and the Green Light Committee

Global recommendations for the programmatic management of MDR-TB cases were not initially included in the original DOTS strategy developed in the mid 1990s. At that time, most countries did not have established basic TB control practices. The limited resources available were prioritized to diagnose and treat drug susceptible TB cases. However, in 1997, a drug resistance survey of 35 countries confirmed the fears of the global TB community – drug resistance was widespread throughout the world and was at a critically high level in some areas, especially countries of the former Soviet Union. The following year TB experts agreed to face MDR-TB programmatically, and “DOTS-Plus” emerged as the strategy National TB Control Programmes could follow to manage their drug-resistant patients. In 2006, new guidelines on the programmatic management of MDR-TB patients were developed in line with the Stop TB Strategy and provide the most up-to-date international standards for MDR-TB control [5].

One of the greatest challenges the global TB community faced with the introduction of DOTS-Plus pilot projects was the prohibitively high cost of second-line anti-TB drugs. Out of the need to approach MDR-TB as a human rights issue, a coalition of TB partners organised the Green Light Committee (GLC) in 2000 as a way to negotiate prices of drugs with producers and create sound technical policies for the management of MDR-TB patients [10]. In order for countries to take advantage of the lower negotiated prices of second-line drugs, the GLC must approve a formal proposal of planned MDR-TB activities in the country. This practice will help to ensure that second-line drugs are used in a safe and rational way so as to prevent the emergence of “super” drug-resistant strains of *M. tuberculosis*. As of the end of 2006, 51 GLC-approved MDR-TB projects were underway in 41 countries for the treatment of almost 25,000 MDR-TB patients.

Extensively Drug-Resistant TB

Recognition and definition of XDR-TB

Extensively drug-resistant (XDR) TB is a form of *M. tuberculosis* that is resistant to at least isoniazid, rifampicin, any fluoroquinolone, and at least 1 second-line injectable drug (amikacin, kanamycin or capreomycin). Although XDR-TB has existed for a long time, it was only recently defined in 2005 [11] when the U.S. Centers for Disease Control and Prevention, WHO and 14 supranational laboratories undertook a survey to determine the extent that second-line anti-TB drug resistance had emerged. The survey included 17,690 TB isolates from 48 countries during the period 2000-2004. Results of the survey showed that 20% of the isolates were MDR and 2% were XDR. The survey reported that 4%, 19% and 15% of the MDR-TB cases in the United States, Latvia and South Korea were XDR, respectively. Although the occurrence of XDR-TB is considered rare, more than 40 countries had reported at least one case of XDR-TB as of the end of 2006.

Although XDR-TB had been recognized as a major global threat to the TB community long before 2006, it garnered the attention of the world when an outbreak of HIV-associated XDR-TB was reported in Tugela Ferry, KwaZulu-Natal Province, South Africa from January 2005 to March 2006 – at approximately the same time XDR-TB was formally defined [12]. Of the 221 patients diagnosed with MDR-TB, 53 had XDR-TB. All 44 of the XDR-TB patients tested for

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9 Armenia, Azerbaijan, Bangladesh, Belize, Bolivia, Burkina Faso, Cambodia, Costa Rica, DR Congo, Dominican Republic, Ecuador, El Salvador, Egypt, Estonia, Georgia, Guinea, Haiti, Honduras, India, Jordan, Kenya, Kyrgyzstan, Latvia, Lebanon, Lithuania, Malawi, Mexico, Moldova, Mongolia, Nepal, Nicaragua, Paraguay, Peru, the Philippines, Romania, Russian Federation, Rwanda, Syria, Timor-Leste, Tunisia, Uzbekistan

10 Supranational reference laboratories provide second-line drug susceptibility testing and quality control for first-line drug susceptibility testing for a wide geographic area.
HIV were infected. Nearly all of the patients (98%) with XDR-TB died within a median range of 16 days from time of diagnosis.

**Development of XDR-TB**
A person develops XDR-TB the same way that a person develops MDR-TB: either by being infected with an XDR-TB strain, or by developing it from a strain of drug-susceptible TB or MDR-TB as a result of inadequate or inappropriate treatment. XDR-TB often develops from MDR-TB when second-line drugs are misused or mismanaged, especially when TB control programmes are poorly run. It is likely that extensively-resistant TB bacilli are as transmissible from person to person as drug-susceptible TB bacilli.

**Diagnosis and treatment of XDR-TB**
Although the principles of diagnosis and treatment of XDR-TB are similar to those for MDR-TB, the management of a patient with XDR-TB is highly complex. The treatment of XDR-TB has serious limitations since the TB bacilli will be resistant to more drugs. XDR-TB is also associated with a higher mortality than MDR-TB because of these treatment limitations. The above mentioned CDC/WHO survey found that patients in the United States with XDR-TB were 64% more likely to die during treatment than patients with MDR-TB. In Latvia, patients with XDR-TB were 54% more likely to die or have treatment failure than patients with MDR-TB. Both the United States and Latvia have excellent TB and MDR-TB control programmes, which is a testament to the seriousness of the threat of XDR-TB to global TB control. In general, it is thought that cure of a patient with XDR-TB is possible for up to 30% of cases in a good TB control programme.

**Global Task Force on XDR-TB**
In October 2006, the WHO Stop TB and HIV departments convened a meeting of experts to form the Global Task Force on XDR-TB to respond to this emerging threat to public health and TB control. The following recommendations were issued to the global TB community [13]:

1. Strengthen TB control in countries according to the Stop TB Strategy and in line with the Global Plan to Stop TB, 2006-2015, with simultaneous scaling up of universal access to HIV treatment and care
2. Scale up the programmatic management of MDR-TB and XDR-TB in settings of high and low HIV prevalence
3. Strengthen laboratory services, including the deployment of rapid diagnostic tests
4. Expand MDR-TB and XDR-TB surveillance and include HIV testing when possible
5. Rapidly develop and implement appropriate infection control measures in health care settings and other risk areas
6. Strengthen advocacy, communication and social mobilization to promote effective prevention, treatment and control of XDR-TB, especially in high HIV prevalence areas
7. Pursue ways to raise the resources and funding required to address XDR-TB
8. Promote research and development of new tools to diagnose and treat XDR-TB
Summary of MDR and XDR-TB Issues for Hospital and Health Care Facility Managers

Management and control of drug-resistant TB is a significant challenge to overall TB control. Hospitals and health care facilities can have an important role in preventing, diagnosing and treating drug-resistant TB. Some of the roles and responsibilities of hospital and health care facility managers may include, but are not limited to:

- Ensuring that policies, procedures and trained staff are in place for prompt diagnosis and effective treatment of drug susceptible TB in order to prevent development of drug resistance
- Developing and implementing policies for strict, specific use of anti-TB drugs in the facility to avoid development of drug resistance
- Ensuring appropriate procedures are in place for timely detection of MDR and XDR-TB
- If drug resistant TB is treated in the facility, ensuring that effective infection control procedures are implemented to prevent transmission of drug-resistant TB strains
Topic 3: TB Infection Control

Nosocomial transmission of both drug-susceptible and drug-resistant TB has been reported in health care facilities, and health care workers are among those at an increased risk of getting infected with *M. tuberculosis* by the nature of their work. Effective TB infection control in health care settings depends on [1]:

- Early detection of TB cases
- Isolation of persons with infectious TB to prevent airborne transmission
- Treatment of persons with infectious TB

In order to prevent transmission of *M. tuberculosis* to patients and health care workers, all health care facilities should have an infection control programme that targets these areas and should be based on 3 levels of infection control: **administrative or managerial controls** (plans and policies), **environmental controls** (physical measures), and **personal respiratory protection**. Good infection control practices appropriate to TB may be applicable in general health care facilities.

**Administrative Controls**

Administrative controls are used as the primary strategy for infection control and have the greatest impact on preventing TB transmission within facilities. If properly used, they will reduce the risk of exposing uninfected persons to persons who have infectious TB. The 5 main components to administrative controls include [2]:

1. **TB infection control plan**. As part of administrative controls, there should be a written TB infection control plan established for the facility that outlines policies and protocols for the prompt recognition, separation, provision of services, investigation for TB, and referral of patients with suspected or confirmed TB disease. See Annex 3 for a template of a TB infection control plan.

2. **Administrative support for procedures in the plan**. There should be an appointed infection control officer for the facility to oversee the infection control plan, monitor the plan’s implementation and provide infection control training for facility staff.

3. **Education and training of facility staff**. All staff working in the facility should understand the importance of infection control policies and protocols and their specific role in implementing them.

4. **Education of patients and increasing community awareness**. Educating communities and patients to recognize the symptoms of TB is important to prevent the spread of TB from one person to another, especially in HIV-prevalent areas. Persons should learn how to seek care for TB symptoms and how to protect themselves from exposure to TB.

5. **Coordinating efforts with local health departments and other disease programmes like HIV/AIDS**. These efforts will facilitate implementation of appropriate contact investigations for patients and health care workers with TB disease. Coordination with HIV/AIDS programmes will help to prevent TB in persons with HIV, which is one of the main TB/HIV collaborative activities of the Stop TB Strategy.

When resources allow, other administrative controls include [3]:

- Conducting a TB risk assessment of the setting
- Ensuring the timely availability of recommended laboratory processing, testing, and reporting of results
- Ensuring proper cleaning and sterilization or disinfection of potentially contaminated equipment
• Screening and evaluating health care workers who are at risk for TB disease or who might be exposed to *M. tuberculosis* (i.e. TB screening programme)

• Using appropriate signage advising respiratory hygiene and cough etiquette

**Environmental Controls**

The second level of infection control is the use of environmental controls to prevent the spread and reduce the concentration of infectious droplet nuclei in the air. Environmental controls work by either controlling the source of infection by ventilation techniques or by cleaning air contaminated with TB droplet nuclei. Ventilation techniques can be natural or mechanical and are defined as techniques that cause the movement of air in a building or replacement of air in a building with air from outside. Ventilation works by diluting the concentration of droplet nuclei containing *M. tuberculosis*. Facilities that do not have resources for mechanical ventilation can use natural ventilation from open doors and windows that let in outside air, or fans to help distribute air in a room.

Air contaminated with *M. tuberculosis* droplet nuclei can be cleaned by using high efficiency particulate air (HEPA) filtration or ultraviolet germicidal irradiation (UVGI). The use of HEPA filters are highly recommended for air contaminated with infectious droplet nuclei that is recirculated or exhausted directly to the outside. When exposed to sufficient UVGI, TB bacilli is killed, however, caution must be used when using such devices because of the risk of adverse reactions such as acute and chronic skin and eye changes.

The most ideal ventilation design is one that allows fresh or clean air to be mechanically and constantly pulled into a room with infectious TB droplet nuclei (such as a TB examining room or patient isolation room). The contaminated air is continuously and directionally exhausted to the outside and away from non-infected persons or areas. Mechanical ventilation equipment and air ducts require periodic professional inspection, cleaning and maintenance. Smoke tubes can be used to “spot check” the direction of airflow but should not replace professional evaluation. In settings where mechanical ventilation is possible, 6 or more air changes per hour is the minimum, and 12 or more air changes per hour is recommended [3].

Physical considerations in design and construction of a health care facility can also serve as environmental controls for transmission of TB. Some examples include:

• **Patient examining room**: The preferred location of the patient examining room or space is one that would minimize unnecessary exposure of non-infected persons to infectious TB patients. Rooms that are used to examine TB patients should be in a location that will not place infectious TB patients into or near crowded areas with little ventilation.

• **Patient waiting area**: The waiting area should be spacious and well ventilated. A separate waiting area may be necessary for paediatric patients and immunocompromised patients, such as those with HIV.

• **Sputum collection area**: Sputum collection for TB diagnosis should be done in a ventilated room, booth or area, or outside in the open air away from other people. Toilets or other enclosed areas should not be used as alternative sputum collection sites. **Garbage disposal**: A facility system of disposing infectious wastes should meet the requirements of the local government. If there are no such requirements in place, then waste disposal should be incorporated into the facility infection control plan.

• **Diagnostic/treatment procedure rooms**: Enhanced ventilation should be provided in high risk areas where cough or aerosol producing procedures are performed (i.e. bronchoscopy, inhalation therapy, radiology and autopsy).
- **Isolation rooms or areas:** Patients with infectious TB should be placed in isolated rooms or areas. Ideally, these areas should be designed for single occupancy with controlled ventilation, negative pressure and air filtration. Isolation rooms should be located at the farthest entry point of a wing or ward, with air flow moving from “clean” to “contaminated”.

**Personal Respiratory Protection**

The use of personal respiratory protection is the third infection control level and should be used in situations that pose a relatively high risk for exposure to TB. Respirators are often unavailable in settings with limited resources. Administrative and environmental controls can minimize the number of areas where exposure to infectious TB disease can occur, but will only reduce the risk in the certain areas where risk is the greatest such as [1]:

- Areas where patients with suspected or confirmed infectious TB are being isolated
- Rooms where cough inducing or aerosol generating procedures are being performed on patients with suspected or confirmed infectious TB
- Rooms or specialized treatment centres treating patients with MDR or XDR-TB

Persons working in the laboratory and conducting aerosol-producing procedures may require the use of personal respirators if the work is not performed in biosafety cabinets.

The use of personal respiratory protection should be part of a programme that includes training of health care workers on personal protection, the selection of appropriate well-fitting respirators, and training of patients on respiratory hygiene and cough etiquette. For recommendations on the type of respirator to use, facilities should consult either the CDC *Guidelines for preventing the transmission of Mycobacterium tuberculosis in health-care settings* [3] or the WHO addendum to the guidelines, *Tuberculosis infection-control in the era of expanding HIV care and treatment* [2]. It should be noted that respirators are different from face or surgical masks, and the latter does not protect facility staff or patients from TB.

**Practical Infection Control Considerations**

- The specific TB infection control plan adopted by a health care facility will depend on whether or not the facility will diagnose and treat patients with TB or if the facility will only triage and then transfer patients with suspected or confirmed TB disease.
- All health care workers that have any face-to-face contact with patients with suspected or confirmed TB disease should be considered in the TB infection control plan, including paid, unpaid, full-time, part-time, community health workers, temporary and contract workers.
- Patients with suspected or confirmed TB disease should be considered infectious if they:
  - Have pulmonary TB disease (lungs, airway or larynx)
  - Are coughing or are undergoing cough inducing procedures
  - Have sputum smears positive for AFB

These patients may be considered infectious if they are not on anti-TB treatment or have just started anti-TB treatment, or if they have a poor clinical or bacteriologic response to anti-TB treatment.
• Patients with extrapulmonary TB are not usually infectious. They may be infectious if they have:
  – Concomitant pulmonary disease
  – Non-pulmonary disease in the oral cavity or larynx
  – TB disease that includes an open abscess or lesion, especially if the drainage fluid from the abscess or lesion is extensive or there is aerosolization of the drainage fluid

• Patients with confirmed TB disease should remain in isolation while hospitalized until:
  – They have had 3 negative sputum smears collected on different days
  – Demonstrate clinical improvement
  – Are on adequate anti-TB treatment

• Patients with MDR or XDR-TB should be isolated until infectiousness is ruled out by culture since their infectiousness may last several weeks or months. Isolation throughout hospitalization may be considered for patients with MDR or XDR-TB since these patients are more likely to experience treatment failure or relapse and prolonged infectiousness.
Topic 4: Monitoring, Evaluation and Surveillance of TB Activities

Definitions

Monitoring of TB control services is the routine tracking of disease control programmes or health facilities using input, process, and outcome data that are collected on a regular, ongoing basis [1]. Through monitoring, health facilities and national TB control programs can assess whether or not planned TB control activities are carried out according to schedule, and lets programmes know whether or not they are progressing towards TB control targets and if TB services are being utilized.

Evaluation of TB services can take place through process evaluation or outcome and impact evaluation. Process evaluation measures the quality and integrity of TB programme implementation, and the extent to which the target population is using TB control services. Outcome and impact evaluations measure results and the effect of the TB programme on the target population. An outcome evaluation will inform a programme if stated objectives are being achieved, and an impact evaluation determines how much of the desired outcome is due to changes in the programme (i.e. what “impact” the programme is having). Impact evaluations, such as TB prevalence surveys, can be complex, time consuming and costly, and so they are not routinely done.

Surveillance is the routine collection of data to track TB disease trends over time. Data can be collected through routine reporting of TB cases or through special TB surveys or studies. Surveillance data is usually collected at the health facility level and sent up through district, regional and national channels.

Importance of Monitoring, Evaluation and Surveillance

Monitoring and evaluation (M&E) of TB services should be included in all health care facilities that offer such services. The level of M&E will depend on the numbers of TB cases diagnosed and treated at the facility and the number of services available at the facility; however, a basic framework should be in place in all facilities. Monitoring and evaluation of TB control services should be done in close collaboration with the National TB Control Programme. A proper M&E system can provide health facility managers with important information to:

- Assist in strategic planning for TB services
- Inform TB programme design and implementation
- Make decisions regarding budgetary allocation based on priorities for human and financial resources

Developing a Monitoring and Evaluation System

The basic M&E framework used by a TB programme or health facility offering TB services should include the following [1]:

- **Input measures**: including policy environment; human and financial resources; and infrastructure
- **Process measures**: including management; training; drug management; laboratories; communication; and advocacy
- **Output measures**: including diagnostic services and treatment services (including accessibility to); improved knowledge; attitudes and practices; and reduced stigma
- **Outcome measures**: including case detection; and case treatment
- **Impact measures**: including reduced prevalence of TB infection and TB disease; and reduced TB morbidity and mortality

A good M&E system should include a designated M&E unit in the facility or programme, clear goals, indicators, and a system for data collection, analysis, use, and dissemination. Indicators are important in this system and are defined as specific measures of programme performance that are tracked repeatedly over time. A list of suggested indicators to monitor TB services at the health care facility and national level are given in Annex 4, and are based on the global experiences of countries and national TB control programmes.

Information on TB data collection can be found in Annex 5.
Topic 5: Laboratory Services for TB Control

Laboratory Network

Laboratories are the cornerstone to the diagnosis, treatment and monitoring of TB and a reliable laboratory network is essential to controlling TB in a community. Delays in laboratory confirmation of TB and reporting of drug susceptibility results can lead to delays in initiation of treatment, prolonged infectiousness, inappropriate treatment, and missed opportunities to prevent transmission [1]. In order to ensure prompt and reliable laboratory testing and results, a relationship needs to exist between the laboratories, the TB control programme or health care facility, and the clinician. Good management of TB patients requires that all of these key TB groups work together to share the responsibility of timely and accurate laboratory results. (Many of the principles below are applicable in the administration of general clinical diagnostic laboratories in settings not specifically related to TB).

The technical variability of laboratory TB diagnostic techniques usually requires that several levels of laboratories are needed for proper diagnosis and case management, especially in countries with limited resources. In many countries, the levels of laboratories include [2]:

- **Local or peripheral level**: Laboratories at this level are usually located within the primary health-care centres and perform only sputum smear microscopy of locally obtained specimens of pulmonary TB suspects. The laboratory at this level usually serves all the diagnostic needs of the facility and there is no special unit for mycobacteriology.

- **Intermediate level** (regional, provincial and district): Laboratories at this level perform sputum smear microscopy for TB suspects within their jurisdiction. In addition, intermediate level laboratories may perform culture or drug susceptibility testing depending on financial resources and technical workforce. Often these laboratories specialize in mycobacteriology. Monitoring and supervision including external quality assurance (EQA) of smear microscopy of local or peripheral level laboratories may be done by intermediate level laboratories. The same monitoring and supervision teams often deliver on-site training based on findings of the EQA. Some intermediate laboratories provide supplies and reagents to the local or peripheral laboratories in their area.

- **Central or National Reference Laboratory (NRL)**: This level of laboratory is established within the National TB Control Programme and is responsible for coordinating the organisation and function of the laboratory network. The NRL develops technical standards and guidelines to be followed by the entire laboratory network, and is responsible for training all laboratory staff on standard operating procedures. Supervision and external quality assurance is routinely performed by the NRL, and they often perform laboratory operational research to evaluate new methods and standard operating procedures. The NRL may be the only laboratory in the country that has adequate culture facilities and can perform anti-TB drug susceptibility testing (first- and second-line). A network of Supranational Reference Laboratories was developed by WHO and partners to aid NRLs in conducting quality-assured anti-TB drug susceptibility testing in conjunction with national or area anti-TB drug resistance surveillance.

- **Private, public, voluntary and corporate sector laboratories**: Many countries have large private and public health sectors that provide TB services to all segments of the population and include general and specialized public hospitals, nongovernmental organisations, and prison, military and railway health services. Efforts should be made at all levels to include private and public sector laboratories in TB control laboratory activities such as monitoring, supervision and training.
TB Laboratory Methods

There are several laboratory methods used to diagnose, treat and manage persons with suspected or confirmed TB. Before any of the methods can be performed it is necessary to have a properly collected specimen which is described in Session 2 – TB Basics: Transmission, Pathogenesis, Diagnosis and Treatment. The specimen must undergo digestion and decontamination to eliminate the more rapidly growing bacteria in the specimen. This is usually done by using detergents or enzymes (i.e. sodium hydroxide [NaOH] or N-acetyl-L-cystein [NALC]).

Laboratory methods

1. AFB smear examination: Staining for AFB includes traditional methods such as Ziehl-Neelsen or Kinyoun techniques and the more advanced method of fluorescence microscopy and is described in Session 2 – TB Basics: Transmission, Pathogenesis, Diagnosis and Treatment. Results of smear examination should be available within 24 hours of specimen collection. Laboratories often set their own guidelines for quantifying AFB smear results (i.e. rare/1+, few/2+, moderate/3+, numerous/4+). Understanding the AFB quantification can help in many aspects of patient management, such as the need for contact investigation.

2. Culture: Conventional or radiometric culture techniques are used to grow AFB in the laboratory and confirm the diagnosis of TB. These methods are described in Session 2 – TB Basics: Transmission, Pathogenesis, Diagnosis and Treatment. Culture results are important to confirm smear-positive cases of TB, and to diagnose smear-negative cases of TB. In settings with unlimited resources, all specimens should be cultured. In settings with limited resources, the NRL should have a policy for prioritizing specimens for culture. The United States Centers for Disease Control and Prevention recommends that culture reports should be available within 21 days (less than 14 days when liquid medium is used); however NRL guidelines and standards should be consulted for national recommendations.

3. Drug susceptibility testing (DST): Testing for susceptibility to first- and second-line anti-TB drugs is done either through conventional, rapid or molecular methods, and is described in Session 3 – Topic 2: Multidrug-Resistant TB and Extensively Drug-Resistant TB. For the greatest impact on patient management, DST should be done on all initial M. tuberculosis isolates, however in resource-limited areas, priorities should be set by the NRL on which isolates to test.

4. Nucleic acid amplification (NAA): A nucleic acid amplification test is used to directly detect M. tuberculosis in AFB smear-positive pulmonary specimens. Commercial names for the NAA test include the Amplified Mycobacterium Tuberculosis Direct Test® (MTD) or Amplicor Mycobacterium Tuberculosis Test®. This test is often referred to as PCR (polymerase chain reaction); however PCR is just one type of NAA. The advantage of the NAA test is that it can confirm a positive AFB smear as M. tuberculosis within a day of the positive AFB smear result. Some limitations include the high cost and the sophisticated laboratory and technical expertise needed to perform the test.

5. Molecular genotyping: Molecular or DNA genotyping is a laboratory approach used to determine if M. tuberculosis isolates are genetically related [3]. The primary genotyping methods include IS6110-based restriction fragment length polymorphism (RFLP), spoligotyping, and mycobacterial interspersed repetitive units (MIRU). Both spoligotyping and MIRU analysis are based on PCR. Genotyping can be used in a TB control programme to:
   a. Evaluate nosocomial and community TB transmission through contact and outbreak investigations
b. Evaluate suspected cases of laboratory cross-contamination  
c. Distinguish TB patients that have relapsed versus those who have been re-infected  
d. Distinguish acquired versus primary anti-TB drug resistance  
e. Distinguish recent (non-native) transmission of TB from endemic strains of TB  

Like NAA tests, molecular genotyping is costly and needs sophisticated laboratory equipment and personnel to perform, and results may not be readily available to make an impact on clinical decisions.

Some laboratory methodology issues to consider include the interpretation of results and common sources of delays:

**Interpretation of results**

- A positive AFB smear result is only a “presumptive” diagnosis of TB; the result may indicate that the isolate is a mycobacterium other than *M. tuberculosis*. In this regard, it is useful to understand the local epidemiology of non-tuberculous mycobacteria.  
- Many TB patients (including pulmonary and extrapulmonary cases) have negative AFB smears. In the absence of culture facilities, health facilities should follow algorithms developed by the NTP to diagnose smear-negative TB patients.  
- Results for culture done on solid medium can take 6-12 weeks; caution should be exercised that negative results are not reported too early.  
- Different laboratories may use different concentrations of drugs when testing drug susceptibilities. When there are questions regarding the reliability of DST, patient treatment history and contacts with known drug-resistant TB cases should also be used to determine the appropriate treatment regimen.

**Common sources of delays**

- When providers or laboratories refer specimens to other laboratories for testing, there can be a delay in the reporting of results to the appropriate health care facility. This can be especially problematic when private or public providers or laboratories are involved.  
- There may be delays in the reporting of laboratory results when there is a significant amount of time needed to transport the specimen from the collection point to the laboratory (or other logistical barrier), or when the submission of the specimen from the collection point to the laboratory is delayed.  
- Depending on the workload, laboratories may do periodic, rather than daily, AFB testing of specimens.

Many of these delays can be avoided through increased communication and coordination of all the key TB groups (laboratories, the TB control programme or health facility, and the clinician).
Planning for TB Laboratory Activities

Laboratory equipment, reagents and supplies
There should be an adequate number of properly maintained laboratory equipment and a continuous supply of quality laboratory reagents and supplies available. Health facility managers can accurately plan and budget for necessary lab reagents and supplies by looking at the number and percentage of patients with a smear positive examination result out of all patients recorded and reported in the previous year. A list of standard equipment, reagents and supplies necessary for one peripheral/microscopy laboratory can be found in Annex 6[4]. Further information and lists of standard equipment, reagents and supplies for culture and drug susceptibility testing laboratories can be found within the Planning and Budgeting Tool for TB Control on the WHO Stop TB Department website [4].

Laboratory staffing and training
Although there is a widespread scarcity of human resources in health care in many countries, there is a particular lack of qualified staff working in TB-related laboratories. Many factors attribute to this including [5]:

- Facility financial constraints to recruit and train an adequate number of laboratory staff
- Rotation of trained laboratory staff within and between health facilities and services
- Negative perception of sputum smear microscopy as “cumbersome, tedious and not pleasant to perform”
- Poor morale and motivation of laboratory staff related to low salaries and poor working conditions
- Limited opportunities in many facilities for persons working in laboratories to develop their career, and an overall lack of interest among young persons in the laboratory profession

Health facility managers can ensure proper training of all laboratory staff through in-service training by experienced staff or through dedicated training provided by the National TB Control Programme or local non-governmental organisations working in TB control. There should be a training plan in place relative to the types of TB laboratory services available at the facility. Supervision, evaluation and feedback mechanisms should be in place to improve laboratory services and staff motivation.

Summary of TB Laboratory Issues for Hospital and Health Care Facility Managers
Laboratory services are essential for effective TB control. The roles and responsibilities of health care facility managers will differ, depending on the setting and type of facility, however some common roles for health care facility managers may include:

- Establishing and maintaining coordination and communication between health facility, laboratories, TB control programme and clinicians to minimize delays in reporting and thus initiation of appropriate treatment

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11 A planning and budgeting tool for TB control programmes was developed by the WHO within the framework of both the Stop TB Strategy and the Global Plan to Stop TB, 2006 – 2015. This list of standard laboratory equipment, reagents and supplies was taken from this tool.
• Ensuring that health care facility staff understands the principles of different laboratory tests and implications for treatment
• Establishing an effective system for transportation of samples to laboratories
• For health care facilities with a laboratory on site:
  – Ensuring that laboratory is properly maintained and adequately supplied
  – Developing or working with NTP or other partners to address staffing and training needs in laboratory
  – Ensuring that an infection control plan (see Topic 3) incorporates the laboratory and that the plan is correctly implemented
  – Establishing a quality control program
Topic 6: Management of Anti-TB Drugs

An effective drug supply and management system is essential to ensure an uninterrupted and sustained supply of quality-assured anti-TB drugs. A national system should be in place to plan, procure, distribute and maintain adequate stocks of anti-TB drugs to all relevant health facilities.

Basic Elements of Anti-TB Drug Management

(Much of the information for this topic has been modified from an anti-TB drug management guide developed by Rational Pharmaceutical Management Plus in 2005, “Managing Pharmaceuticals and Commodities for Tuberculosis: A Guide for National Tuberculosis Programs” ) [1]. The basic elements of anti-TB drug management include a policy and legal framework, selection and quantification, procurement, use, distribution, and management support.

Policy and legal framework

National drug laws including registration should be in place and the use of anti-TB drugs by all providers should be strictly monitored. Individual countries may have their own national procurement laws (including importation of essential or non-essential drugs).

Selection and quantification

Selection is the process of establishing and using a list of essential medicines. Selection of anti-TB drugs should be based on standard treatment regimens, drug costs, local anti-TB drug resistance patterns, and management and distribution capacities of local authorities. In the absence of national or other international recommendations, facilities can consult the WHO Model List of Essential Medicines for the minimum anti-TB drugs for TB control (see Annex 7) [2]. Selection of anti-TB drugs should include the use of fixed-dose combination drugs and patient kits.

A fixed-dose combination (FDC) drug is the combination in a single tablet of 2, 3, or 4 anti-TB medicines. There are obvious advantages for the patient, the health care facility, and the community when FDC drugs are routinely used in the management of patients with TB (see Table 6, Session 2). FDCs can be used in settings where DOT is a challenge and self-administered treatment is necessary, however, the use of FDCs in combination with DOT should be the standard of care.

There should be an existing plan and individual anti-TB drug supply available to replace the FDC treatment regimen in the event that one of the drugs in the FDC is identified as causing adverse effects.

A patient kit is assembled to contain a full course of TB treatment (both intensive and continuous phases). Programmes can build their own kits from loose drugs or can purchase already assembled patient kits from sources like the Global TB Drug Facility12 [3]. There are usually 2 different patient kits – one for Category I or III patients and another for Category II patients. Patient kits can ease the management of TB patients for the health care worker since the kit contains all predetermined medicines for one patient in one box. Patient kits can also simplify the ordering, distribution, stock management and inventory control of anti-TB drugs since one patient kit is easier to manage than many vials of loose drugs. Patient kits have also been known to improve patient adherence to the TB treatment regimen because many patients feel ownership of their kit and can visualize the completion of their treatment. As with FDCs, health workers will need training on the use of patient kits, and how to assemble them from loose drugs, if applicable.

12 The Global Drug Facility is a mechanism developed by the Stop TB Partnership to provide preferentially priced quality anti-TB drugs to countries. The GDF provides a unique package of services, including technical assistance in TB drug management and monitoring of TB drug use, as well as procurement of high-quality TB drugs at relatively low cost.
Quantification is the process of estimating the amount of anti-TB drugs needed to ensure an uninterrupted supply over a period of time (usually 1 year). Quantification is necessary in a health care facility or TB control programme for a number of reasons, but most importantly to prepare appropriate drug budgets, avoid anti-TB drug stockouts, and plan for new and expanding TB control activities [1]. Drug stockouts result when there is a deficiency in the numbers of drugs to adequately treat all TB patients. They can result from a miscalculation of anti-TB drug needs, delays in drug delivery, or other programmatic problems or issues. To avoid stockouts, facilities should have an adequate “buffer” stock of anti-TB drugs in the facility. Most facilities and TB control programmes use 1 of 3 methods for quantification:

1. Morbidity based (estimates drug needs on the number of expected TB cases)
2. Consumption based (estimates drug needs based on past consumption)
3. Adjusted-consumption based (estimates based on data from a similar region or health facility where the number of expected cases is known)

**Procurement**

Procurement is the process through which a health facility or TB control programme acquires anti-TB drugs and supplies. In many cases anti-TB drugs are procured through the NTP and distributed to appropriate health care facilities. To be effective, procurement should ensure the availability of high-quality appropriate anti-TB drugs in the correct quantities at the lowest cost possible. First-line anti-TB drugs are usually inexpensive and often procured through local providers; however, many TB control programmes use the services of the Global TB Drug Facility to obtain quality anti-TB drugs either through grants or direct procurement [3]. Procurement of second-line anti-TB drugs is more difficult because these drugs are more expensive and not usually available in local markets. As discussed in Session 3 – Topic 2: Multidrug-Resistant TB and Extensively Drug-Resistant TB, the Green Light Committee is an excellent resource to inquire about the procurement and use of second-line anti-TB drugs.

**Distribution**

A competent distribution system ensures a continuous flow of anti-TB drugs and supplies from a central point to health facilities and clinics managing TB patients. There are a number of important components of the distribution system to consider: design elements of the system (degree of centralization and number of different levels, push versus pull ordering, geographic or population coverage), the information system (inventory control, records and forms, consumption reports), storage capabilities (locations, building design and conditions, materials handling systems, order picking systems), and delivery mechanisms (collection versus delivery, transportation, vehicle procurement and maintenance, routing, scheduling).

The distribution system must work in concert to ensure that anti-TB drugs are available to all TB patients during the entire regimen. Overall the distribution system must facilitate the distribution activities of the drug management cycle and this includes having an effective mechanism in place to clear anti-TB drugs through customs in a timely manner, transporting anti-TB drugs to the central storage facility and then to health facilities and clinics in a timely manner, keeping accurate records, and maintaining adequate stocks of anti-TB drugs (including a buffer supply) in appropriate storage facilities.
Use
The rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community. In a health care facility or TB control programme, rational use of anti-TB drugs should include the following criteria [1]:

- Correct anti-TB drug should be used
- Prescription of the drug is based on sound medical considerations
- The anti-TB drug should be appropriate in regards to efficacy, safety, suitability for the patient and cost
- No contraindications should exist and the likelihood for adverse side effects should be minimal

All these criteria should encourage patient adherence to the full course of anti-TB treatment. The use of first-line anti-TB drugs can follow internationally accepted and recommended treatment regimens and strategies for improving patient adherence (i.e. DOT). It is more difficult to ensure proper use of second-line anti-TB drugs for the treatment of drug-resistant TB. The variability of drug resistance patterns and individual tolerance to the drugs (i.e. amount and severity of side effects) will affect the case-by-case use of second-line anti-TB drugs. To prevent the spread of drug-resistant TB in a community, adherence to second-line drugs need to be closely monitored for all patients. It is encouraged that the use of second-line anti-TB drugs be monitored and guided by the GLC as discussed above.

Management support
In order to ensure that quality anti-TB drugs are available to TB patients, effective management support of all components of the drug management process is necessary. This support should be coming from all organisational levels of the programme – from the central National TB Programme manager to the managers of health facilities and clinics responsible for the care of the TB patients. Drug management support includes organisation and management, financing and sustainability, information management, and human resources management.

Summary of Drug Management Issues for Hospital and Health Care Facility Managers
An uninterrupted supply of anti-TB drugs is a critical piece in the management of patients with TB. Depending on country and NTP policy, the role and responsibilities of health care facility managers will differ; however some common roles for health care facility managers around management of anti-TB drugs may include:

- In conjunction with the TB programme, estimating the amount of anti-TB drugs needed to ensure an uninterrupted supply, including a buffer stock
- Being aware of the drug supply chain and appropriate methods to procure and distribute anti-TB drugs
- Ensuring drugs are stored and used appropriately
- Ensuring that all staff are trained in the rational use of anti-TB drugs
Topic 7: Budgeting and Planning for TB Services

Global Budgeting and Planning of TB Control Activities

TB control using internationally recommended strategies (i.e. DOTS, Stop TB Strategy) is one of the most cost-effective disease control strategies that a country or community can adopt. It does, however, require financial resources and a certain amount of planning.

Cost-effectiveness of TB control activities

Several cost and cost-effectiveness studies have been done in low- and middle-income countries. Some of the main findings of these studies include the following [1]:

- Short-course chemotherapy is more cost-effective than the longer treatment regimens used for TB patients until the late 1980s.
- Short-course chemotherapy for TB disease is one of the most cost-effective health interventions available compared to interventions for other conditions and diseases.
- Outpatient and community-based care of TB patients is less expensive and more cost-effective than inpatient treatment of TB patients. In low-income countries, the health system cost per TB patient treated in an outpatient or community setting was between US$ 100 - $200 (2001 prices) compared to US$200 - $350 when treatment includes hospitalization for the first 2 months.
- Treatment of new drug-susceptible smear-positive patients under a DOTS programme is the most cost-effective TB control intervention. Treatment of smear-negative and extrapulmonary TB cases is more costly than treatment of smear-positive TB cases, however treating smear-negative and extrapulmonary cases is still cost-effective in DOTS programmes.
- Although the costs associated with treatment of MDR-TB patients can be magnitudes higher than treatment of drug-susceptible TB patients, MDR-TB treatment has been found to be cost-effective in DOTS programmes.
- Treatment of TB patients also infected with HIV (with or without supportive antiretroviral therapy) is less cost-effective than treating patients only with TB, however, the cost per year of life saved is worth the cost of the intervention.
- Treatment of persons with latent TB infection is most cost-effective during outbreak situations and when it is targeted at patients with latent TB infection who are also infected with HIV.
- BCG vaccination to prevent severe forms of childhood TB is cost-effective.
- The cost-effectiveness of TB control activities depends on the local TB epidemiology such as whether or not TB is epidemic or endemic and the rates of HIV-infection and MDR-TB.

The Global Plan to Stop TB, 2006 – 2015

The Global Plan to Stop TB, 2006 – 2015 [2] was developed in response to the TB-specific MDGs and related Stop TB Partnership targets for TB control, and describes what needs to be done at the regional level to meet the global targets.

In response to the Plan, WHO developed a Planning and Budgeting Tool for TB Control to prepare for TB control activities in general at national and sub-national levels [3]. The Tool helps to ensure that TB control plans are in line with the Global Plan, especially for newer components of the Stop TB Strategy (i.e. TB/HIV, PPM and MDR-TB). The Tool is available on the WHO website.
Planning and Budgeting for TB Control Activities – Guidance for Health Facility Managers

Most countries provide national funds for specific activities related to TB control and these funds are usually managed by the NTP. Additional financial resources to support TB-related activities – like staff and infrastructure – are often shared by other disease programme budgets and general health service budgets. However, in many cases, it is the responsibility of the individual hospital or health care facility to plan for and financially support TB control activities.

The Planning and Budgeting Tool for TB Control can be used by hospitals and health care facilities to help to identify necessary inputs for specific activities that are relevant to the TB control activities in a facility. For example, the Tool provides excellent guidance in the following areas that may help hospital and health care facility managers budget and plan for TB control activities:

First-line drugs
- Estimates drug needs and cost based on the number of different categories of TB patients
- Provides estimates based on patient kits and blister packages of FDC drugs
- Estimates buffer stock based on estimated number of different categories of patients and average cost per patient of anti-TB drugs
- Determines drug management costs including procurement, storage and distribution costs

Routine management and supervision activities
- While the Tool includes many inputs for the national level, it also provides inputs and costs associated with office space, equipment and supplies, and infrastructure upgrades, retrofits and renovations

Laboratory (A list of suggested items needed for a peripheral microscopy laboratory is provided in Annex 5)
- Provides inputs and associated costs for microscopy, culture and drug susceptibility testing laboratories.
- Estimates costs for quality assurance (both internal and external) and training activities

Patient support
- Estimates the cost of incentives and enablers for patients (i.e. food packages, transportation vouchers) and health care workers (i.e. incentives/enablers for performing DOT)

MDR-TB
- Allows a country or community to extrapolate available MDR-TB data from a similar country to their local situation
- Estimates costs for the management of MDR-TB patients including first- and second-line anti-TB drugs, hospitalization, DOT visits, and medical/drug adverse events
- Estimates costs for MDR-TB training of health care staff and necessary infection control equipment and supplies

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13 A health facility should contact their National TB Control Programme or the Green Light Committee for assistance in planning and implementing activities for the management of MDR-TB patients.
TB/HIV collaborative activities

- Estimates costs associated with conducting surveillance in countries and areas with low HIV prevalence
- Estimates costs associated with activities in areas with high HIV prevalence to decrease the burden of TB in people living with HIV/AIDS such as screening and isoniazid preventive treatment (6-month cost)
- Suggests activities and inputs to decrease the burden of HIV/AIDS in TB patients including costs associated with counselling and testing, HIV prevention, HIV care and treatment, and anti-retroviral therapy and co-trimoxazole therapy
Topic 8: Human Resource Development for TB Control

Health Care Workforce Crisis
In most regions of the world, there is a serious health care workforce crisis that affects all aspects of health delivery systems and disease control programmes. Managers of hospitals and health care facilities must cope with the effect of this crisis on a regular basis. Some of the better characterized reasons for this crisis include [1]:

- An overall decrease in funding for health care resulting in competition between health and disease programmes in a country or community for qualified staff (i.e. health sector reform and TB control).
- Low salaries and poor working conditions leading to an exodus of qualified health care workers to more developed countries or to working for international non-governmental organisations within the borders (“brain-drain”).
- The AIDS epidemic which has had a profound impact on the morale (i.e. having an increased workload with many negative outcomes) and availability of health care workers (i.e. workers becoming ill or having to care for ill family members), especially in Africa.
- Stigmatization of working in health, especially in the era of HIV/AIDS, since it is often perceived that health care staff are at an increased risk of HIV infection. The same can be said of TB and MDR-TB workers, especially laboratory workers, who may be fearful of becoming infected during AFB processing.

These issues are contributing to a decreased recruitment of qualified staff and fewer young people coming into the health field. The health workforce crisis is especially impacting TB control since properly implemented TB control activities and management of TB patients can be highly dependent on staff – especially the DOT aspect of treatment. The neglect of human resource development (HRD) has been identified as a main barrier to global expansion of TB control activities, and MDG and Stop TB Partnership targets will not be met or sustained without a competent group of well-trained health care workers and managers in place.

Human Resource Development: Training and Staff
(Much of the information for this topic has been modified from a document developed by WHO and the Task Force Training workgroup of the Tuberculosis Coalition for Technical Assistance on the strategic approach for human resource development in a country) [2].

For many years, NTPs have emphasized training activities for health care workers and managers involved in TB control. However, these efforts have not always been as effective as hoped. There are number of reasons for this. There is often an assumption that information conveyed to a training participant is always learned, however, the training methods used will affect whether the information was learned. A carefully developed training that incorporates the principles of adult learning and utilizing different methods and activities, including practice sessions for new skills, is much more likely to result in acquisition of knowledge and skills. There are a number of resources at the end of this section that can be useful in developing and implementing trainings.

Another incorrect assumption about training is that as long as health care workers and managers have been trained they will perform the desired actions and perform them well. However, experience has shown that merely presenting information is not enough to change a person’s behaviour. For example, in a training on infection control in MDR-TB units, which covered the 3 levels of infection control, simply telling a health care worker to use personal respiratory protection while in an MDR-TB unit might not result in that desired behaviour. A training would need to ensure that the health care worker understands why use of personal respiratory protection
is important, how to use the respiratory protection correctly, and feels like they have the skills and ability to make this change. It is also important to note that, outside of training, in order for a certain behaviour to occur, an enabling environment for this behaviour must exist. For the example of using personal respiratory protection, this may include an adequate supply of N-95 personal respirators located conveniently outside the door to the MDR-TB ward, and a sign posted on the door reminding staff of the policy or using N-95 respirators (as well as the other infection control procedures).

Another common incorrect assumption is that TB training activities are no longer needed when all region or districts in a country are covered by DOTS, or when all staff have been trained. As noted above, simply conducting training is not enough to ensure correct implementation of the information presented in the training program. Monitoring and supervision of staff after the training, as well as periodic refresher training is also necessary. Further, due to staff turnover, it may be necessary to regularly offer complete training for new staff.

A great deal of work is being carried out in effective HRD for TB programmes, and as training activities in TB programmes have increased, there has been a concerted global effort to focus on:

- The quality of training
- Better management of training programmes
- Evaluation of trainings including ongoing follow-up after training

Though training is a very important component of HRD, TB control programmes often think only of training activities as fulfilling the requirement of HRD. However, there are other staffing issues that also encompass HRD that programmes need to focus on including:

- Staff rotation and turnover
- Working conditions
- Geographical distribution of health care staff
- Performance monitoring and supervision
- The development of a career structure for each employee

The long-term goal for HRD for TB control is to reach and sustain a situation where:

“Staff at different levels of the health system have the skills, knowledge and attitudes necessary to successfully implement and sustain TB control activities including the implementation of new and revised strategies and tools and in relation to HIV management.”

In order to reach this goal, national and sub-national TB control programmes need to develop and implement a comprehensive strategy for HRD. The strategy should be part of the national plan to control tuberculosis and should include mechanisms for the following [3]:

- Establish/improve existing in-service training programmes for TB control
- Establish/improve existing systems and structures to identify performance deficiencies related to lack of skills and to enable staff to acquire the necessary competencies for TB control activities
• Establish/improve existing systems to identify new staff working in TB control and have them participate in appropriate trainings
• Review and revise basic training programmes for medical doctors, nurses and other health workers involved in TB control activities
• Coordinate TB-related training with staff in other disease programmes such as HIV/AIDS

Specific activities to implement a HRD strategy in a hospital or health care facility are found in Table 9 [2]. However, hospital and health facility managers should undertake this process in conjunction with the NTP, to ensure that it is consistent with the national HRD strategy. The NTP may also have tools and resources available that can assist in this process.

TB Control Training Resources
There are a number of excellent training guides on general and specific topics of TB control for health facility staff. A list of some of them includes:

• Self-study modules on TB. United States, Centers for Disease Control and Prevention http://www2.cdc.gov/PHTN/tbmodules/Default.htm
• Tuberculosis Case Management for Nurses: Self-Study Modules. United States, New Jersey Medical School, Global Tuberculosis Institute http://www.umdnj.edu/globaltb/products/tbcasemgmtmodules.htm
<table>
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<th>Component</th>
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| Establish/revise organisational structure to manage HRD                  | • Assign a focal point to coordinate trainings  
• Appoint a training coordination group with members from training institutions, field staff, professional organisations, etc.  
• Determine roles and functions for training management |
| Plan for the future                                                      | • Establish goals for HRD in TB control  
• Develop strategy to reach the goal |
| Review current situation                                                 | • Review and list functions and tasks by level and by professional category and develop/revise job descriptions for staff involved in TB control in line with current TB control policies  
• Review current existing training-related activities in the context of who is being trained, in what kind of training programme, and the material and methodologies used  
• Conduct training needs assessment, analyze data and determine key areas for improvement |
| Prepare short- and medium-term plans for HRD for TB control at different levels | • Establish short- and medium-term objectives  
• Develop activities for each objective (i.e. develop/revise training programmes and training material, select and train course facilitators)  
• Prepare organisation of training courses |
| Develop system for follow-up after training and links to overall TB programme supervision | • Establish the organisational structure for follow-up after training  
• Train supervisors for follow-up on training |
| Manage and use information for management of HR for TB control          | • Determine what information is needed  
• Assess existing data management procedures  
• Take action to improve data management procedures |
Effective Hospital Management Workbook

(Prepared by Health Development International)

Session 4: The Four Tasks of Management

Introduction

Orientation
  Management Practices and Activities
  The Profession of Management

The Four Tasks of Management

Planning
  Determining Your Customer’s Needs
  Developing Your Mission, Vision and Values
  Strategic Planning
  Strategic Planning Outline
  Planning Exercise
  Financial Planning
  How to Make Planning Effective in Your Hospital

Organising
  Developing Organisational Structure
  Selecting People
  Effective Delegation
  Organising Teams

Leading
  Leadership Styles
  Motivating People
  Problem Solving

Checking
  Develop Systems for Checking the Work of Your Team
  Continuous Improvement
Session 4: The Four Tasks of Management: Introduction

Introduction

Hospitals, clinics and health programs in many countries face problems related to poor management. In developing countries they generally serve poor populations, operate with low budgets, staff shortages, and insufficiently trained staff. As a result, they have poorly maintained equipment and facilities, shortages of medicines and supplies, and an unending parade of new medical technology that they can hardly afford. Hospitals in different countries also face problems unique to their country.

Management has become a profession with skills that can take a lifetime to learn and master. This workshop provides a solid introduction to a lifetime of learning how management skills can help a hospital or health organisation to continually improve its ability to meet the needs of the people it serves.

The design elements of the workshop have remained focused around the practices and activities managers use in their work: planning, organising, leading and checking. It has also retained an interactive teaching method that enables participants to apply the knowledge to their own culture through group exercises and discussions. The workshop is continually improving based on contemporary thought, feedback from participants, and a growing awareness of the challenges in each culture.

Orientation

These questions are focused on the role of hospitals, but they can also be applied to clinics and other health care programs.

What is the most important goal of a hospital?

Hospitals play a unique role in every society. They are primarily designed to heal people burdened with illness, but they can also do much more. They can be organisations that work to prevent illness by educating their communities, collaborating with others to bring clean water and sanitation to the region, and modeling good health habits.

Hospitals need to be managed well if they are to achieve these goals. They must focus on the services that the people find most valuable, and manage their resources to grow so they can respond to more needs as the community grows. Hospitals that are managed well will find ways to serve all segments of the community, including those who are least able to pay for the care they need.
What is the most important indicator of a hospital’s success?

The most important indicator of a hospital’s success is the satisfaction of its patients and community, its doctors and hospital staff, hospital regulating agencies, and the owners of the hospital. The owner can be the government, a private corporation, a church or a non-governmental agency.

There are other indicators, of course. These include the clinical results of its medical care, the quality of its facilities and services, efficiency and productivity of its systems, competencies of its managers, professionals and staff, and its financial capability to grow and keep up with new advances in medical care.

How do managers impact the hospital’s success?

Hospital managers need to keep the organisation working and improving. They have to manage people, money, facilities, supplies and equipment efficiently and effectively to meet the current and the future health needs of the community. They have to be masters of change for continuous improvement, understanding that everything they do has an impact on the future ability of the hospital to heal people, prevent illness and contribute to the economic structure of the community. Well-managed hospitals are great places to work and great places to receive care. Managers develop the culture of the organisation to make it happen.
Management Tasks and Activities

**Planning**

With your team, determine your:
1. Customers’ needs
2. Guiding purposes
3. Strategic plan
4. Financial requirements to be sustainable

**Organising**

1. Structure the organisation
2. Select the right people
3. Delegate meaningful tasks
4. Organise teams
5. Set standards of good work
6. Set policies, systems and procedures for consistent results

**Leading**

1. Understand your leadership style
2. Personal self-development
3. Motivate people to give their best
4. Involve people in decision-making and problem solving

**Checking**

1. Compare work with plans and standards through visits, meetings and reports
2. Improve continuously
The Profession of Management

What is management?

It is the science and art of achieving a common purpose and goals with other people. It is the work of planning, organising and leading teams, and checking the results to accomplish goals.

*The fundamental task of management remains the same: to make people capable of joint performance through common goals, common values, the right structure, and the training and development they need to perform and to respond to change.*

*Peter Drucker*

Drucker also noted these characteristics of management:

- Management is about human beings
- It is deeply embedded in culture
- Every enterprise requires commitment to common goals and shared values
- Management must enable the enterprise and each of its members to grow and develop as needs and opportunities change
- Every enterprise is composed of people with different skills and knowledge doing many different kinds of work
- Market standing, innovation, productivity, development of people, quality, and financial results – all are crucial to an organisation’s performance and to its survival
- Results exist on the outside. The result of a business is a satisfied customer.

Growing into Management
How is the practice of management different from the practice of medicine?

Physicians often rise to hospital leadership responsibility with little or no training in management. The roles are very different, and it may take time for physicians to make the adjustment. Here are some key differences:

- Managers focus on accomplishing goals by coordinating the work of other people. Physicians focus on treating one patient at a time.

- Physicians strive for 100% accuracy in diagnosing and treating patients by getting all the information they need to make good medical decisions. Managers have to work with incomplete information all the time, and are fortunate to be right about 80% of the time.

- Physicians are taught to think independently, but as managers their effectiveness depends on leading teams to think, talk, and make decisions together, building on the strengths of each member.

Physicians can also bring qualities to their work as managers that they learn as physicians, for example:

- They can use the scientific method to solve problems in organisations as well as in clinical studies.

- They can bring a genuine compassion for people to their role as a manager. Wise managers care about their employees and their community just as they care about their individual patients.

- Physicians who are skilled managers can also share their clinical judgment as they make management decisions to establish new services, improve the quality of care, and train their management team to improve the effectiveness of the hospital.

What managers do in [different countries] is the same. How they do it might be quite different. Thus one of the basic challenges managers in developing countries face is to identify those parts of their own traditions, history, and culture that can be used as management building blocks.

Peter Drucker
The History of Management as a Profession

1911: Frederick Taylor, an American engineer wrote “The Principles of Scientific Management,” These principles were used in America during World Wars I and II by American manufacturers of military machines for the war. They employed ordinary housewives in manufacturing by breaking complex methods into simple steps. This enabled the US to make large numbers of war material that made a difference in winning the war.

1923: Alfred Sloan, president of General Motors allowed his Division leaders to make major decisions with price controls and budgets provided by a central executive. This decentralized leadership helped make GM the leading car and truck manufacturer in the world.

1927-1932: The "Hawthorne Experiments" in America found that wages are not enough to motivate employees. Their emotional needs must also be addressed. The experiments showed the disadvantages of authoritarian leadership and the advantages of group decision-making.

1938: The Hewlett-Packard Company started "Management by Wandering Around," that encouraged bosses to leave their offices and chat with their employees.

1946: Peter Drucker (born in 1909) the best known management thinker of the 20th century writes his first of 36 books on management, “Concept of the Corporation.” He wrote: “Management can make people’s strengths effective and their weaknesses irrelevant.”

1950: Dr. Edwards Deming, an American consultant lectures in Japan on the concept of “quality management.” Ten years later, Japanese products began beating American products. One lesson: When an employee makes a mistake, it is more often the fault of the SYSTEM than it is the fault of the employee.

1978: James Burns, a presidential biographer and scholar, writes about the importance of social responsibility among organisations. One lesson: A leader's job is to determine how his company and his employees can benefit society.


1994: Jim Collins and Jerry Porras wrote “Built to Last: Successful Habits of Visionary Companies” Lessons from companies that lasted more than 50 years. One lesson: “Try many things and keep what works.”

2001: Jim Collins wrote, “Good to Great: Why Some Companies Make the Leap... and Others Don't.” One lesson: “Be passionate about your business.”
The Most Important Principle of Management: **FOCUS**

**The 80/20 Principle:** Focusing on the most important 20 percent of the work that we do (the “Critical Few”) can produce 80 percent of our expected results.
The $25,000 Idea of Ivy Lee

A management consultant by the name of Ivy Lee offered the following advice to the president of a small steel company who was complaining that he was too overloaded with work.

He told the president that this simple method would increase his company’s efficiency and profitability by at least 50%. Lee needed only 20 minutes of the president’s time. He said if the president would try it for a few weeks, he could then pay or not pay Lee whatever he wanted. The president accepted the offer and got the following advice:

1. Write down the SIX most important things you have to do tomorrow.
2. Number them in order of their importance.
3. The following day, start with number one until it is done, then number two, and so on. (If you are interrupted, keep going back to the number you were working on.)
4. If you cannot do an item on the list, move it to the next day and get on with the next.
5. Make this your daily routine until it becomes a habit.

The meeting lasted only 30 minutes. The president used Lee's idea, and had his departmental managers and supervisors use it too. After a few weeks Lee got a letter thanking him for his idea and a check for $25,000 for Lee's half-hour of work.

When they met again years later, the president admitted to Lee that it had been, in his opinion, the best investment he'd ever made and that one idea had been largely responsible for his once small steel company becoming a dominating force in the industry.
Topic 1: The Four Tasks of Management - Planning

Planning is a process that looks at the future, compares it with the present, and works to fill the gap between the two.

The steps in planning:

1. Determine the community needs the organisation will work to fill
2. Define the purposes of the organisation in meeting those needs
3. Develop plans that outline goals to achieve the desired changes
4. Determine the minimum financial requirements to be sustainable
Looking Outside: Determining Your Customer’s Needs

Planning begins with understanding the needs of your customers. Hospitals have different kinds of customers, and each of them has different kinds of needs. Think about the kinds of comments you have received or recurring problems you have faced from the following kinds of customers. What are the opportunities those comments and problems might offer for your hospital?

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<td>People in the Community</td>
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*It is with non-customers that changes always start.*

*What is value to the customer is always something quite different from what is value or quality to the supplier.*

*Peter Drucker*
Organizational Needs Assessment: SWOT Analysis

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<th>Strengths</th>
<th>Weaknesses</th>
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<tr>
<td>Opportunities</td>
<td>Threats</td>
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Developing Your Mission, Vision and Values

When you understand the needs of your customers, you can begin to solve them, beginning with developing your vision, mission and values statements (see Annex 8).

Why do you need these statements?

They provide a focus, inspiration and guide for the work of everyone in your organisation.

The truth about guiding statements

In many organisations, these guiding statements are hollow promises, wishful desires or misleading hopes. But our work with organisations around the globe has shown us that health care organisations frequently experience difficulties that could have been avoided if they had carefully crafted – and followed – mission, vision and values statements. Here is some of the wisdom we have learned:

- Every organisation has a mission, vision, and values, whether it knows it or not.
- Watch how the organisation works more than listening to what it says.
- If you want to know the truth about an organisation, ask its customers rather than its leaders.

How are they distinguished?

<table>
<thead>
<tr>
<th>Mission</th>
<th>What are our purposes?</th>
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<tr>
<td>Vision</td>
<td>What are our ambitions?</td>
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<tr>
<td>Values</td>
<td>What are our rules of conduct?</td>
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Some organisations combine the mission and vision into a single statement.

A few guiding questions

- What would your patients tell you about your mission, vision and values?
- What gaps are there between what you want to be and what you are?
- How can you demonstrate that your organisation is all it claims to be?
What is a Mission Statement?

The main reason for your organisation's existence

- Answer “Who are we?”
- Explain the purpose of the organisation
- Describe how the organisation is unique
- Offer direction and discernment for business decisions
- Imply what you are NOT going to be/do

Actually, “What is our business?” is almost always a difficult question and the right answer is usually anything but obvious.

“What will our business be?” aims at adaptation to anticipated changes. But there is also the need to ask “What should our business be?”

Businesses that fail to ask this question are likely to miss their major opportunity.

Peter Drucker

Health Organisation Examples:

Our hospital is the leading referral center for tertiary cases north of Manila, offering a wide range of diversified services in strategic locations to meet existing needs in the field of health. (Lorma Medical Center, Philippines)

To become the best health system in America. (Baptist Hospital, Pensacola, Florida)

What kinds of patients does your hospital serve and what services do you provide better than other health organisations?

What is your Mission Statement?
What is a Vision Statement?

A statement about how you will achieve your mission
- Answer “Where are we going?”
- Imagine the possibilities
- Inspire people with hope
- Stretch the organisation
- Reflect the future market expectations

Examples:

To provide the best quality in personalized health care, with dedication, Holistic approach and Christian concern. (Lorma Medical Center, Philippines)

To provide superior service based on Christian values to improve the quality of life for people and communities served. (Baptist Hospital, Pensacola, Florida)

Henry Ford: “I will build a motor car for the great multitude... It will be so low in price that no man making a good salary will be unable to own one - and enjoy with his family the blessing of hours in God’s great open spaces. When I’m through, everyone will be able to afford one... The horse will have disappeared from our highways, the automobile will be taken for granted, and a large number...will be employed at good wages.”

What kind of hospital are you hoping to become and what unique strategies will you use to get there?

What is your Vision Statement?
What are Core Values?

- Answer “How will we conduct ourselves in achieving our ambitions?”
- Make obvious the not-so-obvious foundational assumptions and beliefs
- Set a standard of accountable behavior
- Attract people who can help you most

Example 1: (Lorma Medical Center, Philippines)

Our work shall be guided by the following values:

- Personalized service
- Christian concern for patients and employees
- Dedication
- Harmony and family-based relationships
- Clean conducive environment
- Professional and technological growth
- Holistic development of the individual

Example 2: Pensacola Baptist Hospital (US)

Pensacola Baptist Hospital’s VALUES are used to recruit, orient and train employees, to reinforce the culture of excellence, and to guide decision-making.

- Integrity: Maintaining the highest standards of behavior; encompassing honesty, ethics, and doing the right things for the right reasons.
- Vision: The ability and willingness to look forward to the future and make decisions necessary to accomplish important goals.
- Innovation: Capable of extraordinary creativity and willing to explore new approaches to improving quality of life for all persons.
- Superior Service: Committed to providing excellent service and compassionate care.
- Stewardship: Dedicated to responsible stewardship of the organisation’s assets and financial resources, and to community service.
- Teamwork: An abiding respect for others, and a sustaining commitment to work together.

What are your hospital’s core values?
Case study

West Pond Hospital is in an area that has a growing incidence of tuberculosis and other communicable diseases. The median income in the region is below the national average and the education and employment measures also indicate that the population is suffering from the effects of poverty. The overcrowded hospital serves a broad range of medical needs in the community, but has a reputation for rude service and poor quality. Patients are afraid to go there when they get sick for fear that they will die from diseases they acquire from other patients.

If you are appointed to be the manager of West Pond Hospital, what can you do to focus the organisation to meet the needs of the community and rebuild its reputation?
Strategic Planning

What is it?

Strategic planning is a process used to build an agreement about the most important goals your organisation should achieve in the next few years. Most organisations make their plans for the next three to five years at a time, refining them annually based on changes in their working environment.

Why is it important?

The planning process is important to make sure that the hospital responds to the changing needs of its customers and outside organisations, and to make sure that everyone in the hospital knows what actions will lead to the achievements they intend.

What is to be included?

Strategic plans should include:

- Goals for changes that will advance the hospital's mission and vision
- Specific actions to achieve those goals in the next year
- The priorities of those actions
- A clear assignment of responsibility for carrying out those actions

Strategic Plan Outline
Creating S.M.A.R.T. Goals

Specific
Measurable
Attainable
Realistic
Timely

Specific - A specific goal has a much greater chance of being accomplished than a general goal. To set a specific goal you must answer the six "W" questions:

- Who: Who is involved?
- What: What do I want to accomplish?
- Where: Identify a location.
- When: Establish a time frame.
- Which: Identify requirements and constraints.
- Why: Specific reasons, purpose or benefits of accomplishing the goal.

EXAMPLE: A general goal would be, "Improve customer service." But a specific goal would say, "Earn ratings of ‘good’ or ‘excellent’ in patient satisfaction surveys from 80% of all patients in 12 months."

Measurable - Establish concrete criteria for measuring progress toward the attainment of each goal you set. When you measure your progress, you stay on track, reach your target dates, and experience the exhilaration of achievement that spurs you on to continued effort required to reach your goal. To determine if your goal is measurable, ask questions such as......How much? How many? How will I know when it is accomplished?

Attainable - When you identify goals that are most important to you, you begin to figure out ways you can make them come true. You develop the attitudes, abilities, skills, and financial capacity to reach them. You begin seeing previously overlooked opportunities to bring yourself closer to the achievement of your goals. You can attain most any goal you set when you plan your steps wisely and establish a time frame that allows you to carry out those steps. Goals that may have seemed far away and out of reach eventually move closer and become attainable, not because your goals shrink, but because you grow and expand to match them. When you list your goals you build your self-image. You see yourself as worthy of these goals, and develop the traits and personality that allow you to possess them.

Realistic - To be realistic, a goal must represent an objective toward which you are both willing and able to work. A goal can be both high and realistic; you are the only one who can decide just how high your goal should be. But be sure that every goal represents substantial progress. A high goal is frequently easier to reach than a low one because a low goal exerts low motivational force. Some of the hardest jobs you ever accomplished actually seem easy simply because they were a labor of love. Your goal is probably realistic if you truly believe that it can be accomplished. Additional ways to know if your goal is realistic is to determine if you have accomplished anything similar in the past or ask yourself what conditions would have to exist to accomplish this goal.

Timely - A goal should be grounded within a time frame. With no time frame tied to it there's no sense of urgency. If you want to lose 10 lbs, when do you want to lose it by? "Someday" won't work. But if you anchor it within a timeframe, "by May 1st", then you've set your unconscious mind into motion to begin working on the goal.

T can also stand for Tangible - A goal is tangible when you can experience it with one of the senses, that is, taste, touch, smell, sight or hearing. When your goal is tangible you have a better chance of making it specific and measurable and thus attainable.
Strategic Planning Outline

Planning is a process more than a product, but your research about the needs of the community and the ideas to meet those needs should be written down and shared with those responsible for implementing the plan.

For an example of a simple strategic plan see Annex 9. Additional resources are also available online at http://sites.google.com/site/hdi/Home.

2009 Strategic Plan for
_________________________ Hospital

External Needs Assessment

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Internal Needs Assessment

Organizational Needs Assessment: SWOT Analysis

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Guiding Purposes *(See Annex 10)*

Mission

Vision

Values

Three-year Goals *(See Annexes 11abc for examples of three year goal plans)*

1.

2.

3.

4.

5.

Annual Plan

For Goal #____:

<table>
<thead>
<tr>
<th>Activities required</th>
<th>Measurement</th>
<th>Responsibility</th>
<th>Deadline</th>
<th>Progress (date)</th>
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Financial Planning

*Above all, management needs to know the minimum profitability required by the risks of the business and by its commitments to the future.*

Peter Drucker

Healthcare services **add value** to people’s lives by enabling them to return to work, to earn money for the needs of their family, and to improve their living conditions. Healthcare managers need to price services so they will add value to the lives of those they serve and cover all costs required to stay in business. That requires a financial plan. The purposes of financial planning are to:

- Make sure that services pay for themselves
- Build financial reserves for future development
- Satisfy the needs of the owners of the hospital

Financial planning requires managers to anticipate the income needs for these costs:

1. Direct costs – supplies, wages of direct-care staff
2. Indirect costs – utilities, wages of support staff
3. Working capital – enough cash to cover at least 30 days of normal expenses
4. Capital improvements – reserves to pay for new equipment and facilities
5. Profit – future working capital for new business development
Financial Reports and Plans

Accounting standards vary somewhat in each culture, but the essential information every manager must understand includes these two financial statements:

**Balance Sheet (Photo)**
- Assets  What you own
- Liabilities  What you owe
- Equity  Owned free and clear

**Income Statement (Video)**
- Income  What comes in
- Expense  What goes out
- Profit  What’s left

Every hospital needs to prepare reports for government officials and other authorities, and you should use the same information for planning whenever possible. Managers may find that they want additional information for making internal decisions and tracking trends in revenue and expense. They may need to analyze the revenue and expense of each department to identify ways to become more efficient and effective.

Financial plans may include the following parts:

- Annual operating budget, detailed by department
- Annual capital budget for new purchases
- Forecasts of the volume of services
- Financial projections for new projects outlined in the strategic plan
- Plans for financing new projects either from reserves or from outside sources

Computer spreadsheets can help managers prepare budgets. Budgets should be based on forecasts of services that customers will need and the costs of providing those services. You can use information from the previous year to build an operating budget for existing services. You will want to make adjustments for changes that you can predict.

Creating a budget for new projects requires the manager to review the following *(Sample Hospital Budget Format - See Annex 12)*:

- Income forecasts based on the volume of services you expect and the assumptions you make
- Expense forecasts related to that project
Principles for financial stability and sustainability

1. To manage an activity or department, you have to be able to measure its cash flow. Set up systems that allow you to measure the cost of each major activity and compare the cost to the revenue generated by that activity. If it is losing money, you have four options:
   a. Reduce the costs
   b. Increase the fees
   c. Increase the volume of services
   d. Stop doing the activity

2. When you are considering starting a new service, make projections of the volume of services that customers (patients) will use. If you don’t have historical data to use in making projections, develop assumptions that you can evaluate. Then you can test those assumptions by:
   a. Asking potential users of the service whether they would find value in it at the price you project you will need to charge
   b. Talking with other managers who have tried similar new ventures
   c. Researching the experience of other hospitals or clinics

3. The services that will be most successful are those that improve (or add value to) the lives of those who use them. Evaluate how each service you provide improves the lives of your patients and your community, and commit to improving that value continuously.

4. The annual operating budget can be used as a tool to evaluate which services to develop and which ones might need to be stopped, based on their profitability and on their importance to accomplishing the vision, mission and values of the organisation. By tracking revenues and costs over several years, you can identify trends. Those trends can help you forecast future cash flows, allowing you to make intentional decisions about the services you provide.

5. Financial information needs to get to each manager that is responsible for an activity. Department managers may not need to know every detail, but they need to know if their department has positive or negative cash flow if they are to improve the financial performance within their responsibility.

6. To stay in business, managers need to stop doing things that hurt the organisation financially and do more of the things that help it.
Financial Planning Exercise

1. What information will you need to examine periodically to improve the financial performance of your organisation or department? Design some of the headings of the monthly report you will want to develop.

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2. What else can your organisation do to add value to the lives of your patients?
How to Make Planning Effective in Your Hospital

1. **Set aside time for planning**, preferably away from the office, to minimize interruptions.

2. **Make a planning schedule or calendar** that includes dates to do the following:
   - Needs analysis and SWOT analysis to identify changes externally and internally
   - Annual review of the organisation’s Mission, Vision and Values
   - Annual review of Strategic Plan for the next 3 years
   - Annual Operating and Capital Budgets

3. **Choose the Critical Few (80/20 Principle)** in determining priorities and objectives

4. **Identify the people to involve in your planning.**
   - Who will participate?
   - Who will approve?
   - Who needs to be informed?

5. **Integrate financial plans with the strategic plans.**

6. **Prevent and overcome resistance to the plan.**
   - By planning with your team – involving the people who will be affected
   - By introducing change gradually
   - By obtaining understanding and acceptance
Topic 2: The Four Tasks of Management - Organising

1. Developing Organisation Structure

Organise tasks and responsibilities to departments according to the skills required to accomplish them effectively and efficiently. Establish clear lines of authority and accountability.

2. Selecting People

Choose people for positions based on their ability to accomplish the tasks of the organisation today and in the future. Learn to select people on the basis of their character as well as their experience and their ability to learn.

3. Delegating

Entrust others with responsibility (work) and authority (the freedom to do that work), and creating accountability (including reporting requirements) for results.

4. Developing Effective Teams

Form teams composed of people within departments or from several different departments to identify problems or inefficiencies and propose solutions. Work toward improving the dynamics of teams.

5. Set Standards of Good Work

Establish clear performance expectations for each job and each employee. Train and re-train employees to meet or exceed those standards consistently.

6. Set Policies, Systems and Procedures

Employees need to know how to perform tasks consistently to achieve the organisation’s mission. Policies, systems and procedures are valuable training tools for getting consistent results.
Developing Organisational Structure

Key concepts for designing an efficient and effective organisational structure:

- **Accountability**
  An organisational chart can map out the lines of authority and accountability, but remember that teams also need to be flexible enough to work across departments.

- **Organisational Levels:**
  Fewer levels make communication and coordination throughout the organisation easier and more effective.

- **Span Of Control:**
  The number of people who can be effectively supervised by one manager tends to be more at the lower levels and less at the higher levels.

Once you have drawn the organisational structure, look at how people actually work together. Evaluate the effectiveness and efficiency of your structure with questions like these:

1. Do decisions get made appropriately at each level? If not, why not?
2. How well do people communicate within each level? What can be done to improve communication?
3. Does each department have a reasonable span of control?

*Instead of searching for the right organisation, management needs to learn to look for, to develop, to test the organisation that fits the task.*

*Peter Drucker*
Organisational Structure Exercise

Draw a simple version of your current organisational structure and share it with your group. Ask them for feedback on the efficiency and effectiveness of your structure, using the questions on page 92.
Selecting People

Managers need to select and develop the staff in their departments that are needed to get the work done. That includes:

- Determining how many people are required
- Choosing the people that are best able to accomplish the tasks their job requires
- Choosing the people who are good for the future of the organisation
- Developing the skills of each employee through training, evaluation and coaching

In some cases, managers may have little influence on who will work for them. But when managers can build their own teams and manage them wisely, they can develop effective work groups and accomplish more than the managers who cannot choose their staff.

Building solid teams begins with selecting good people. Selecting good people requires the ability to ask meaningful open-ended questions and to listen well in interviews. Here are some examples of some thoughtful interview questions:

1. How has your training and experience prepared you to make a positive difference in this department?
2. What would you like to learn to advance your skills?
3. What would your co-workers tell me about you?
4. Why do you want to work for this organisation rather than other organisations?

And for discerning character:

5. What would your co-workers tell me about you?
6. What three things are most important to you?
7. How do you hope to be remembered?

Other suggestions for interviewing:

1. Ask open-ended questions rather than yes/no questions. Get the person to talk.
2. Have two or three interviewers for each conversation. Different people will pick up different perspectives from the interview.
3. Watch for body language that might either affirm or contradict what the person is saying.
Exercise: Interviewing Skills

In your group, select one person to be a candidate for a position you are trying to fill. Tell the person about the job you are trying to fill and then conduct an interview as if they are applying for the position. Then ask for feedback from the rest of the group about your interviewing techniques.

Lessons learned:
**Effective Delegation**

**The Process of Delegation**

There must be a clear understanding and agreement between a manager and each of his team members about:

- The results that are expected when the employee has performed the work
- The authority and tools to be used
- How the team member will be held accountable

**What Delegation is Not:**

- Not “dumping”
- Not abdication of authority
- Not loss of control
- Not avoiding decisions

**Options for Delegating**

1. “Research how to solve this problem and tell me what you find.”
2. “Research how to solve this problem and give me your recommendations.”
3. “Solve the problem and tell me how you did it.”
4. “Just solve the problem. I don’t need to know how you did it.”
Why Some Managers Have Difficulty Delegating

1. A manager may think, “Delegating takes more time than doing it myself.” In the end, this is not true.

2. A manager may claim that he cannot delegate because his team members lack experience. But the only way they can get the necessary experience and grow and develop on their jobs is to learn by doing.

3. A manager may think, “Mistakes are too costly.”

4. A manager may think “team members are specialists without the necessary overall knowledge required by many decisions.”

A key principle in planning an efficient organisation is this:
Delegate each task to the lowest level at which it can be competently performed.

Organising Teams

Managers often find that they can accomplish more by organising their employees into teams, sharing responsibilities for accomplishing certain tasks in ways that build on each person’s strengths. But it can be difficult for people to work together cooperatively. Patrick Lencioni wrote about the difficulties in his book, The Five Dysfunctions of a Team. They are:

1. The Absence of Trust – People need to learn to trust each other if they are going to work together. That means they need to be open and honest with each other so they will all be willing to ask for help when it is needed. Good managers draw out the best in each member of the team and build on the unique strengths of each person.

2. The Fear of Conflict – Members of the team need to be confident with each other so they can raise problems and solve them together. Avoiding conflicts leads to more problems and wastes the time and energy of the group. Managers need to be open to criticism so they can model how to resolve conflicts in a healthy way.

3. The Lack of Commitment – When people are focused more on their own goals than on the goals of the team, they make it difficult for the group to accomplish its purposes. Managers can build teamwork by inspiring commitment to common goals.

4. Avoidance of Accountability – Teams that allow members to get by with minimum effort or with a pattern of mistakes don’t work well together. Wise managers set standards of performance and respect for those standards, encouraging everyone to produce excellent work.

5. Not Paying Attention to Results – Teams might develop all the qualities mentioned above, but if they don’t achieve their goals, they will still be ineffective. The best managers keep the goals in clear focus and celebrate with the team when they achieve those goals.

What challenges do you face in working with teams, and how can they be overcome?
Set Standards of Good Work

Employees generally want to do a good job, but they need to know the manager’s standards for what a good job looks like. Acceptable standards can differ from one person to another. A clean toilet to one person may not be clean to another. A project may look well done to one person but not to another person with different standards. Satisfactory performance may mean different things to different people.

To set standards of good work, managers use the following tools:

1. Develop job descriptions for each position, outlining the tasks to be accomplished and the standards for performance of each task.

2. Develop orientation and training processes that demonstrate the standards for performance. Use a combination of written and verbal instructions, videos, exercises and tests to make sure that each employee understands the expectations.

3. Create checklists for complex and important tasks that employees can use to achieve consistent results.

4. Periodically conduct in-service training to introduce new techniques or to review established procedures to make sure all employees are up-to-date with how to use equipment and how to meet the work standards.

5. Invite employees to submit ideas for improving the work standards. Those who do the work are most likely to see potential ways to improve their effectiveness and efficiency. When new methods are adopted, re-train everyone to achieve the best results.

Policies, Systems and Procedures

Policies are guidelines on how to handle recurrent situations or problems important to the organisation. They should be reviewed annually.

- Policies help staff to make decisions on recurrent situations that do not need the attention of senior management.
- Policies usually apply to the entire organisation.

Examples: Personnel policies, medical staff policies, policies on cooperation with government and other agencies, policy on staff training, etc.

Example:

General Policies on Safety in the Hospital Compound

1. Each department in will be responsible for developing a concise department safety manual for its customers and employees as soon as possible.

2. This safety manual will be developed under the leadership of the department head with the involvement and participation of the staff.
3. Before implementation, the safety manual needs to be approved and signed by the Department Head, Medical Director and Executive Vice President.

4. Each department head will be responsible for reviewing and updating its safety manual annually during the month of June, the first month of the Lorma fiscal year.

5. It is the policy of this hospital to prohibit firearms within the compound of the hospital. Exceptions to this policy will be made upon the discretion of the Administrator or the Medical Director in extreme situations.

What new policies do you need in your hospital?

Systems are groups of activities or parts that relate to one major event or process. These activities may involve different departments of the organisation but they are all part of the same process. When a mistake occurs, the root cause may be the system -- not only the employee making a mistake.

Examples: financial system, personnel training system, vehicle or equipment maintenance systems, etc.

Example:

Preventive maintenance program

The preventive maintenance of every piece of medical equipment and environment is done through programmed period, e.g.

- Weekly
- Monthly
- Quarterly
- Semi-annually.

The equipment that falls under the category of invasive equipments shall be checked on a monthly preventive program maintenance, e.g. Patient monitoring equipment, defibrillator monitors, infusion pumps, syringe pumps, electrocardiograph, central nurse station, telemetry monitors, anesthesia patient monitors, recovery room monitors, respiratory equipments, ventilators.

The equipment for laboratory examinations are to be checked on a quarterly basis, e.g. Hematology analyzers, biochemistry analyzers, spectrophotometers, cell counters, binocular microscopes, histopathology equipment, serology equipment, blood bank equipment, bacteriology equipment, research fluorescence microscopy, blood collection units, photometers, centrifuges, and other laboratory equipment and instruments.

What systems need attention in your hospital?
**Procedures** are step-by-step guides for important recurrent activities that need to be done consistently in the same way.

**Examples:** Personnel-related procedures such as employee recruitment, orientation and training, getting vacations or leaves, disciplinary, etc.

**Other examples:** Sputum collection and exam procedures, DOTS, DOTS Plus, purchasing, vehicle repairs and maintenance, etc.

**Example:**

**Procedure on Reporting of a Dispensing Error**

1. Once a dispensing error is identified, get back the medication immediately and hold the administration of the drug if dispensed within the hospital.
2. Exhaust all efforts to contact the recipient of the dispensed drug if the drug cannot be recalled.
3. Pharmacist makes an immediate verbal report followed by a written report to the Division Chief with copies to the Hospital Administrator, and the Medical Director.
4. Letter of Explanation from the employee(s) concerned to the Chief Pharmacist.
5. Inquiry by the Division Chief to determine if the dispensing error is a human error or a system error.
6. Appropriate Response from the Division Chief/Department Head.
7. Correct system error.
8. Final report by the Division Chief with recommendations to the Human Resource Department Manager.

**What procedures need to be written in your organisation?**

**Case Study**

East Pond Hospital has had the same department managers for over ten years. Each manager has become comfortable in their position, although the hospital has had five different Presidents in the past ten years. The managers have learned to work independent of each other, but the reputations of the managers in the laboratory and nursing departments are much worse than the reputations of the other managers. The lab and nursing managers complain constantly about how their departments are overworked. A new President has just been appointed, and he is asking your advice about how to get the department managers to work together.

**How would you advise the new President to organise the managers and help them work together?**
Topic 3: The Four Tasks of Management - Leading

One does not “manage” people. The task is to lead people. And the goal is to make productive the specific strengths and knowledge of each individual.

Peter Drucker

Implementing well-designed plans requires strong and wise leaders. Leadership is an art that begins with self-knowledge and grows by experience in helping others become all they can be. Some people have natural leadership abilities that inspire other to follow them, but all leaders can improve by:

1. Understanding leadership styles
2. Developing personal self-discipline
3. Motivating people to make full use of their talents
4. Creating an environment that fosters creative problem-solving

Blind Man Exercise

Lessons learned:
Personal/Cultural Perceptions of Leadership

What do you look for in a Leader?

1. **Individual Exercise:**
   - Think of a person who had the biggest influence in your life.
   - Think of that person’s qualities and actions that made an impact in your life.
   - List the qualities and actions of that person which you believe were responsible for that influence and impact.

<table>
<thead>
<tr>
<th>Quality</th>
<th>Person Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. **Group work on Qualities of a Good Leader**

Discuss and make a list of what your group believes are the most important qualities and actions of a leader in your country. (Use the results of the individual exercise above as a basis for your list)
Leadership Styles

Autocratic Style
- Appropriate for fire chief
- Requires unquestioned authority
- Emphasizes structure and order
- Weakness: Can be abrasive when trust is not earned or when the issues and the audience require another style

Laissez-faire Style
- Appropriate for brainstorming
- Requires setting authority aside
- Emphasizes creativity
- Weakness: Can frustrate those who prefer (demand) orderly conduct at all times

Participatory Style
- Appropriate for building consensus
- Requires shared authority
- Emphasizes equality of input
- Weaknesses:
  - Can be time-consuming
  - Each participant has effective veto power

Collaborative Style
- Appropriate for resolving conflicts
- Requires mutual respect/authority
- Emphasizes reasonable outcomes
- Weakness: Difficult to accomplish consistently

Which style of leadership do you usually use?
Servant Leadership

Servant leadership is another style that managers can consider. It was made popular by Robert Greenleaf, who described it this way:

“The servant-leader is servant first… It begins with the natural feeling that one wants to serve, to serve first. Then conscious choice brings one to aspire to lead. He or she is sharply different from the person who is leader first, perhaps because of the need to assuage an unusual power drive or to acquire material possessions. For such it will be a later choice to serve – after leadership is established. The leader-first and the servant-first are two extreme types. Between them there are shadings and blends that are part of the infinite variety of human nature.”

How does the concept of servant-leadership fit with your culture?

What benefits might result from adopting servant-leadership in your organisation?

Motivating People

Motivating people means inspiring, encouraging and causing them to take effective action. If people cannot do their work with enthusiasm, they will usually not do the job very well. Psychologist Abraham Maslow identified that we all have basic human needs that need to be fulfilled, and we are all motivated to fill those needs. The basic needs must be fulfilled before we can address the more advanced needs.
Abraham Maslow’s “Basic Human Needs”

- **Self-Actualization (Full use of talents)**
- **Esteem Needs**
- **Social Needs**
- **Safety Needs**
- **Physiological Needs**

Four Stages of Learning

1. Unconscious Incompetence – we don’t know what we don’t know
2. Conscious Incompetence – we begin to understand our limitations
3. Conscious Competence – we learn by following models
4. Unconscious Competence – we do things by intuition
Problem Solving

“It isn’t that they can’t see the solution. It is that they can’t see the problem.”
(Charles Kettering)

“We can’t solve problems using the same kind of thinking we used to create them.”
(Albert Einstein)

All employees need to solve problems.

- Janitors solve the problems of dirty rooms.
- Laboratory workers solve problems of helping doctors diagnose patients.
- Nurses solve problems of comforting patients and providing support to doctors.
- Doctors solve diagnosis and treatment problems of patients.
- Managers solve problems in their departments by coordinating the work of others.

Effective managers recognize the need for creativity, especially to accomplish the first two steps in traditional problem-solving. They also know that they can increase their effectiveness as managers if they can motivate and support their team members to be creative as well.

The traditional method can work well for many management problems:

1. Frame the problem
   - ask 5 whys
   - consider opposites
   - look for metaphors

2. Brainstorm ideas
   - be an Explorer
   - no evaluation
   - stepping stones
   - get lots of them
   - stop idea killers

3. Evaluate and prioritize
   - be an Artist
   - create models
   - combine ideas
   - weigh the risks and benefits
   - consider consequences
   - narrow the choices
4. **Decide**
   - be a Judge
   - involve those who have to live with it
   - avoid “analysis paralysis”
   - make the hard call with courage

5. **Implement**
   - be a Warrior
   - make sure you have the right tools

6. **Evaluate**
   - accept, reject or refine
   - listen to feedback
   - research the impact
   - continuous learning
Creative Problem Solving - Thinking Outside The Box

Creative or innovative solutions can solve several problems at once, improve overall performance, result in greater economy, or greater efficiency.

Nine dots exercise:

Instructions: Connect all nine dots drawing four straight lines without retracting a line or lifting your pen or pencil off the paper.

● ● ●
● ● ●
● ● ●

How many squares are there in this box?
Brainstorming

Brainstorming can be an essential technique that managers can use for a variety of situations including planning, problem-solving and dealing with interpersonal conflicts. The process for brainstorming is fairly simple:

1. Invite people who have a responsibility for solving the specific problem you are focused on.
2. Structure enough time and a comfortable setting to have an open and free discussion that encourages creative ideas to flow.
3. Give everyone a chance to speak, and make it clear that each voice is to be treated with respect. In the idea-development stage, there should be no blame and no shame for any idea.
4. Use a white board or large paper to state the problem you are trying to solve, and to capture ideas that people present for solving it.
5. Work toward building a consensus about the best ideas to try. Set up a follow-up meeting to report on the results of the test.

Brainstorming Exercise

In your group, conduct a brainstorming session around one issue presented by a member of your group.

Lessons learned:
Five Principles for Interpersonal Problem Solving:

1. Listen with understanding rather than evaluation
2. Clarify nature of conflict
3. Recognize and accept the feelings of the individuals involved
4. Suggest ideas for resolving the differences
5. Create ways to improve communication and prevent further conflicts

In your own culture, what are some effective ways to solve interpersonal problems?

What are some barriers to solving interpersonal problems?
Case Study – Leadership

Dr. Liu has been the manager of the pediatrics department at North Pond Hospital for several years. He is well-liked by the employees in the department because of his gentle nature, but they are sometimes frustrated that he is too nice. In the past two months there have been seven occasions when he overlooked medication errors that could have resulted in injury to patients. He did not want to correct the people involved for fear that they would be upset with him.

How would you counsel Dr. Liu to develop his leadership skills? How would you check to make sure he responds to your counseling?
Topic 4: The Four Tasks of Management - Checking

Checking

Management is not complete with planning, organising and leading. Managers also need to develop systems for checking on the work of their team members to assure that the desired results are achieved, and to set the stage for continuous improvement.

The activities of checking include:

1. Developing systems for monitoring results and making adjustments
2. Improve continuously
113

Develop Systems for Checking the Work of Your Team

1. Review the work in progress and compare with standards
   - Who does the review?
   - What do you review?
   - How do you review?
     - Spot checks
     - Visits
     - Meetings
     - Reports

Four kinds of reports:
   - Narrative
   - Statistical
   - Financial
   - Other: graphs and charts, multimedia presentations, etc.

Five characteristics of a good report:
   1. Identifies the person responsible
   2. Compares performance with standards
   3. Understandable
   4. Timely
   5. Provides priority information (“must have” vs. “nice to have”)

2. Evaluating the Outcome (Results)

3. Make Adjustments In The Work As Required

4. Appreciate Good Performance
Examples of Periodic Report Formats

Example 1: Statistical Comparison

<table>
<thead>
<tr>
<th>Units of Service</th>
<th>This Month</th>
<th>YTD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actual</td>
<td>Target</td>
</tr>
<tr>
<td>Cardiology</td>
<td>741</td>
<td>300</td>
</tr>
<tr>
<td>Dermatology</td>
<td>192</td>
<td>171</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>812</td>
<td>637</td>
</tr>
<tr>
<td>Endocrinology</td>
<td>164</td>
<td>152</td>
</tr>
<tr>
<td>Gastroenterology</td>
<td>57</td>
<td>200</td>
</tr>
</tbody>
</table>

Example 2: Agenda for Meeting

1. Review of progress on project plans
2. Lessons learned so far
3. Unexpected challenges and recommendations for overcoming them
4. Work I need help with or work that should be given to senior management
5. Schedule for the next review meeting

Example 3: Simple Report

“Give me a report each Monday that shows all the good things that happened in your department the week before.”

Example 4: Three-Question Format:

1. What is going well with your job?
2. What are your biggest challenges?
3. What should we do next to help you be successful?

Exercise: Design Report Forms

What methods would you propose to use to check the work of your team members? What forms would you like to design for each critical process, and what would they look like?
Continuous Improvement

Organisational Culture

Managers set the tone for continuous improvement by creating a culture that encourages creativity and innovation. They build on strengths in people and programs to strive for better results each year. They also look for new ways to accomplish tasks with fewer resources, using technology wisely. They model good communication habits to keep their teams working together in ways that minimize wasteful conflicts. They inspire their employees to be responsible and efficient in everything they do.

Kaizen

The Japanese manufacturers have introduced principles for continuous improvement they call kaizen. Kaizen is a daily activity whose purpose goes beyond simple productivity improvement. It is also a process that, when done correctly, humanizes the workplace, eliminates overly hard work (both mental and physical), and teaches people how to perform experiments on their work using the scientific method and how to learn to spot and eliminate waste in business processes.

To be most effective kaizen must operate with three principles in place:

1. Consider the process and the results (not results only) so that actions to achieve effects are surfaced.

2. Systemic thinking of the whole process in order to avoid creating problems elsewhere in the process.

3. A learning, non-judgmental, non-blaming (because blaming is wasteful) approach and intent will allow the re-examination of the assumptions that resulted in the current process.
POLC Model

The tasks and skills we have introduced in this workshop can also be seen as a model for continuous improvement.
Stellar Performance Model

The Stellar Performance Model can be used to help organisations understand how to improve continuously.

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Secrets of Successful Organisations

Planning:

1. **Singular vision.** They choose a singular Vision of success where they can be the best.

2. **One bold goal.** At any one time, they have a bold goal that motivates and inspires the staff, creates momentum and stimulates progress.
   
   (“Let’s land a man on the moon and bring him safely back to earth in the next 9 years.”
   
   Pres. John F Kennedy)

3. **Focus on opportunities.** They focus more on their opportunities and less on their problems.

4. **Use technology to accelerate momentum** to achieve their vision and mission.

Organising:

5. **Staff for today and the future.** They carefully select staff that fit in with the culture and will be good not only for initial responsibilities for also for the future of the organisation.

6. **Homegrown leaders.** Most of their leaders come from within the organisation.

Leadership:

7. **Personal humility.** Their leaders combine personal humility (saying “we” more than “I”), with professional will and dedication.

8. **Strong spirit.** A strong “spirit” or “culture” pervades the organisation.

Follow-up

9. **Experimentation.** They try a lot of stuff and keep what works.

10. **Continuous improvement.** They don’t stop improving.

Sources:

“*Good to Great.*” Why Some Companies Make the Leap … and Others Don’t.

By Jim Collins, HarperCollins Publishers, NY (1, 4, 7)

“*Built to Last.*” Successful Habit of Visionary Companies

By James C. Collins and Jerry I. Porras. HarperCollins Publishers, NY (2, 6, 8, 9, 10)

“*Managing in a Time of Great Change.*”

By Peter F. Drucker, Truman Talley Books/Penguin Books, NY, etc. (3, 5)
Questions and Answers
The questions in this section have been prepared and designed to assist the participant in assessing how well the content of the course has been learned. The answers are spread throughout the reading material.

Policy and governance

*Please provide hospital classification references in your country/state?* (e.g. district (first referral), specialty/regional etc)

*Is the geographical area or population group served by your hospital defined by?*
  - national policy
  - patient behaviour

*Who is responsible for overall policy and management at your hospital level?*

*How are relations between the clinical, ancillary and administrative departments governed?*

*How are staff training needs in the hospital determined, and by who?*

Describe, if any, current in-house training procedures/programmes.

*Does the hospital operate a system of resource allocation for staff training?*

*Are there staff motivation programmes? If yes, please provide descriptions.*

Define the relationship between your hospital, clinics and other healthcare facilities in your catchment area in identification, treatment of active MDR-TB and TB:
  - Organisationally separate or related?
  - Co-ordination?

*Do referral arrangements exist? If yes, what form do they take?*

*Are patients, TB or others, able to turn directly to the hospital as out-patients or in-patients?*
Management and Human Resources

List the medical/nursing/administrative staff assigned in the following primary process of conducting TB surveillance and case management:

a) Identification of suspected or active TB cases
b) Collection of patient information
c) Conducting interviews
d) Planning for follow-up care

How is interaction between departments (e.g. clinical, Information, HR, administration, etc.) governed?

How is the performance of each department assessed?

What is the level and nature of involvement, if any, from the local community?

Finance

Who is responsible for preparing and approving annual budgets?

Is the budgetary process linked to departmental goals and objectives?

Are financial targets/allocations related to priorities set by national or local authorities?

What are the major sources of revenue for the hospital (e.g. central, regional government, private sector, etc.)?

What are the methods of receiving revenues (e.g. international/national grants, donations, etc.)?

Who is responsible for setting drug, equipment and other expenditure and cost targets?

Are drug procurement and administration policies governed by international/national/local/institutional priorities?

List the key departments involved in the hospital’s drug procurement, administrative activities.

What procedures are envisaged or recommended to reach or provide services free of charge to the inaccessible patients or those from low-income families?

What procedures exist to ensure your hospital together with other healthcare settings within your catchment area has adequate funding for the different groups of population?
Infrastructure, purchase of equipment/supplies and services

Describe the established guidelines for procurement of drugs, equipment and services.

Are there established procedures for the following? If yes, please describe and confirm whether they are internationally nationally/locally governed?
   a) large volume/value purchases of equipment, drugs, goods and services;
   b) infrastructure projects

What procedures exist to ensure adequate and continuous maintenance your hospital’s equipment and infrastructure?

Describe the established technology assessment procedures for new and existing equipment, services and drugs.

Is there a dedicated staff team (clinical and administrative) assigned to manage these activities?

Information management

What are the established procedures for identifying the hospital’s needs in regard to:
   a) Patients:
      – TB case investigation
      – Diagnostic evaluation
      – Drug regime treatment, therapy, monitoring, etc
      – Catchment population involvement and needs
   b) Medical, nursing and other members of the multi-disciplinary team
   c) Revenue sources and providing authorities
   d) Regulatory authorities (international/national/local/in-house)

What procedures exist to define the data/information to be collected?

What procedures have been established to plan, design and ensure continuous update of the clinical and information management system (software, hardware and personnel)?

What established guidelines exist for converting data collected for management information purposes?

What procedures have been established to determine how, when, where and to whom information is reported/transmitted?

What standard procedures have been established to develop, gather, review and maintain medical records?

Is there a system of aggregating data from medical records for clinical decision-making purposes?

Is the department, if any, responsible for the information management activities central or decentralized?
Quality

Has your hospital established or planned to establish quality assurance programmes?

In which areas of activities, epidemiology, etc have these been or are to be established?

How do the quality assurance programmes enable your hospital to:
   a) provide healthcare services appropriate to the needs of the target population
   b) reduce risks to patients and staff
   c) ensure equitable access to the different income patient groups and staff
   d) promote education and training among staff and patient
   e) assure cost-effectiveness

What measures have been introduced to ensure effective and proper communication of new procedures (clinical, administrative and others) to relevant departments?

Does the hospital implement an accreditation system? If yes, is it compulsory or voluntary?
References

Session 1 - Topic 1


Session 1 – Topic 2


Session 1 – Topic 3


Session 2


Session 3 – Topic 1


Session 3 – Topic 2


Session 3 – Topic 3


Session 3 – Topic 4

Session 3 – Topic 5

Session 3 – Topic 6

Session 3 – Topic 7
Session 3 – Topic 8


Annex 1


Annex 5


Annex 20

Annex

Annex 1: Regional TB Snapshots and High-Burden TB Countries

TB data from every country is aggregated according to 6 geographically defined WHO regions: Africa, The Americas, Eastern Mediterranean, Europe, South-East Asia, and Western Pacific (Figure 4).

The following snapshots of TB in the 6 WHO regions are drawn from several WHO reports, primarily The Global Plan to Stop TB, 2006–2015. The snapshots focus on the broad situation and challenges in each region, though not all challenges occur in each country within the region [1, 2].

African Region

Almost one-third of new TB cases in the world occurred in the countries of sub-Saharan Africa in 2005. Africa has the highest TB incidence and mortality rates – nearly double of any other region. Both incidence and mortality have been steadily increasing since the mid-1990’s due to an increase in the recognition of new cases, and the HIV epidemic (Figure 5). TB has a tremendous impact on countries in the African Region. There are 9 high TB burden countries in the African Region (DR Congo, Ethiopia, Kenya, Tanzania, Mozambique, Nigeria, South Africa, Uganda, and Zimbabwe), comprising 70% of the TB burden in the region. Some TB challenges facing the region include:

- The impact of HIV on increasing TB prevalence
- Widespread poverty and weak health systems
- Lack of infrastructure and access to health delivery facilities
- Difficulties maintaining adequate staffing to address the burden of TB and human resource development
- Lack of adequate quality controlled laboratory services

14 Excluding Djibouti, Somalia and Sudan. These 3 countries are included in the Eastern Mediterranean Region.
Figure 5. TB incidence (all forms & smear-positive) and mortality (all forms) 
African Region, 1995-2005

Americas Region
While the Americas Region includes countries of both North and South America, the TB burden is predominately limited to countries of Latin America. Brazil is the only country in this region considered a high TB burden country, and contributes nearly one-third of all new TB cases in the region. Since many countries in the region have strong national TB control programs, the incidence and mortality of TB has steadily declined over the past decade (Figure 6). In 2005, there were about 350,000 new cases of TB and 50,000 deaths. The Americas have the lowest TB incidence and mortality rate of all regions. Some challenges facing the Americas include:

- Ensuring progress towards TB control targets of all countries in Latin America with a high TB burden
- Recent health sector reforms
- Political/social instability
- Poverty
- Rapid spread of HIV/AIDS
Eastern Mediterranean Region

The Eastern Mediterranean region contains a number of diverse countries on 2 different continents. There is a generalized HIV epidemic in some countries (Djibouti, Somalia and Sudan) fostering increasingly high TB incidence rates, and countries where strong and experienced TB control programs (i.e. Morocco and Tunisia) have caused a decline in TB incidence. Globally, 6% of all new TB cases occurred in the Eastern Mediterranean region in 2005. Afghanistan and Pakistan are the 2 high TB burden countries in the region and account for about 60% of the new TB cases in the region. TB incidence has gradually increased over the past decade while TB mortality has been on the decline since 2001 (Figure 7). Some challenges facing the Eastern Mediterranean region include:

- The impact of complex emergencies on sustained TB control services
- Low TB case detection
- Expanding private health care sector mostly uninvolved in TB control
- The increasing impact of HIV on TB

Figure 6. TB incidence (all forms & smear-positive) and mortality (all forms) Americas Region, 1995-2005

![Graph showing TB incidence and mortality in the Americas Region from 1995 to 2005](image)

Figure 7. TB incidence (all forms & smear-positive) and mortality (all forms) Eastern Mediterranean Region, 1995-2005

![Graph showing TB incidence and mortality in the Eastern Mediterranean Region from 1995 to 2005](image)
European Region
Although all European countries are included in the analysis of TB incidence and mortality (Figure 8), the majority of new TB cases and deaths occur in Eastern Europe and countries of the former Soviet Union. The collapse of the Soviet Union in the early 1990’s led to a significant increase in the number of new TB cases and deaths in Europe; however, this trend has started to reverse. Although the Russian Federation is the only high TB burden country in this region, several countries such as Romania and the Ukraine have significant burdens of TB, while the Central Asian Republics (Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan and Uzbekistan) have considerably high TB incidence rates. Some challenges facing the European region include:

- The wide extent of drug resistance, including MDR-TB, throughout the region
- TB control in prisons
- TB control in socially vulnerable groups such as the homeless, unemployed, alcohol and drug addicts, and ex-prisoners
- Lack of laboratory capacity, especially to detect drug-resistant strains of TB
- The rapid spread of HIV particularly among intravenous drug users

Figure 8. TB incidence (all forms & smear-positive) and mortality (all forms)
European Region, 1995-2005

South-East Asia Region
The South-East Asia Region accounts for the greatest global burden of TB in the world, and the second highest TB incidence rate (behind Africa). Nearly all (96%) of the new TB cases in Southeast Asia in 2005 were diagnosed in the 5 high TB burden countries of the region (Bangladesh, India, Indonesia, Myanmar and Thailand), with 60% of new cases occurring in India alone. While TB incidence has slightly increased over the past decade, deaths from TB have significantly dropped since 1998 (Figure 9). Much of the success in TB control in this region results from strong political commitment and large investments in improved infrastructure. Some challenges facing the Southeast Asia region include:

- Involving the large numbers of public and private health care providers in TB control
- The impact and increasing magnitude of the HIV epidemic
- Some of the highest global estimates of MDR-TB (India)
- Sustaining the quality of TB control services
Western Pacific Region
The number of new TB cases in the Western Pacific region has remained constant since 1995 and deaths from TB have been steadily declining (Figure 10). The 4 high TB burden countries (Cambodia, China, Philippines, Viet Nam) together account for more than 90% of all cases in this region. In 2005, China alone contributed 15% of new TB cases to the global total. Of all regions, the Western Pacific detects and successfully treats the greatest numbers of estimated new cases. One of the region’s strengths is a strong laboratory network with improved capacity to detect MDR-TB cases. Some challenges facing the Western Pacific region:

- Sustaining achievements in TB case detection and treatment success
- Involving the large numbers of public and private health care providers in TB control
- The unknown impact of the HIV epidemic on TB control
- Some of the highest global estimates of MDR-TB (China)
Of the 8.8 million new cases of TB in 2005, 80% of the cases were in 22 countries called high-TB burden countries. India and China are the 2 countries with the most burden of TB in the world (Table 10), each accounting for over 1 million new cases of TB every year, and more than 500,000 deaths combined in 2005.

Table 10. Estimated TB incidence (all forms and smear-positive) and mortality (all forms) of the 22 high-TB burden countries, 2005

<table>
<thead>
<tr>
<th>Country</th>
<th>TB incidence, all forms (per 100,000)</th>
<th>TB incidence, smear-positive (per 100,000)</th>
<th>Mortality, all forms (per 100,000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 India</td>
<td>1,851,661 (168)</td>
<td>826,663 (75)</td>
<td>322,322 (29)</td>
</tr>
<tr>
<td>2 China</td>
<td>1,319,328 (100)</td>
<td>593,311 (45)</td>
<td>204,603 (16)</td>
</tr>
<tr>
<td>3 Indonesia</td>
<td>532,871 (239)</td>
<td>239,504 (108)</td>
<td>91,663 (41)</td>
</tr>
<tr>
<td>4 Nigeria</td>
<td>371,642 (283)</td>
<td>162,123 (123)</td>
<td>99,938 (76)</td>
</tr>
<tr>
<td>5 Bangladesh</td>
<td>321,996 (227)</td>
<td>144,880 (102)</td>
<td>66,423 (47)</td>
</tr>
<tr>
<td>6 Pakistan</td>
<td>286,291 (181)</td>
<td>128,724 (82)</td>
<td>59,202 (37)</td>
</tr>
<tr>
<td>7 South Africa</td>
<td>284,538 (600)</td>
<td>116,31 (245)</td>
<td>33,654 (71)</td>
</tr>
<tr>
<td>8 Ethiopia</td>
<td>266,288 (344)</td>
<td>117,822 (152)</td>
<td>56,490 (73)</td>
</tr>
<tr>
<td>9 Philippines</td>
<td>241,879 (291)</td>
<td>108,824 (131)</td>
<td>38,964 (47)</td>
</tr>
<tr>
<td>10 Kenya</td>
<td>219,582 (641)</td>
<td>94,449 (276)</td>
<td>47,880 (140)</td>
</tr>
<tr>
<td>11 DR Congo</td>
<td>204,977 (356)</td>
<td>89,814 (156)</td>
<td>42,294 (73)</td>
</tr>
<tr>
<td>12 Russian Federation</td>
<td>170,422 (119)</td>
<td>75,937 (53)</td>
<td>28,477 (20)</td>
</tr>
<tr>
<td>13 Viet Nam</td>
<td>147,566 (175)</td>
<td>66,138 (79)</td>
<td>19,149 (23)</td>
</tr>
<tr>
<td>14 UR Tanzania</td>
<td>131,078 (342)</td>
<td>56,262 (147)</td>
<td>28,772 (75)</td>
</tr>
<tr>
<td>15 Brazil</td>
<td>111,050 (60)</td>
<td>49,019 (26)</td>
<td>15,189 (8)</td>
</tr>
<tr>
<td>16 Uganda</td>
<td>106,285 (369)</td>
<td>45,567 (158)</td>
<td>26,094 (91)</td>
</tr>
<tr>
<td>17 Thailand</td>
<td>91,374 (142)</td>
<td>40,649 (63)</td>
<td>12,191 (19)</td>
</tr>
<tr>
<td>18 Mozambique</td>
<td>88,533 (447)</td>
<td>36,673 (185)</td>
<td>24,498 (124)</td>
</tr>
<tr>
<td>19 Myanmar</td>
<td>86,345 (171)</td>
<td>38,442 (76)</td>
<td>7,523 (15)</td>
</tr>
<tr>
<td>20 Zimbabwe</td>
<td>78,187 (601)</td>
<td>31,847 (245)</td>
<td>16,967 (130)</td>
</tr>
<tr>
<td>21 Cambodia</td>
<td>71,130 (506)</td>
<td>31,750 (226)</td>
<td>12,281 (87)</td>
</tr>
<tr>
<td>22 Afghanistan</td>
<td>50,249 (168)</td>
<td>22,611 (76)</td>
<td>10,427 (35)</td>
</tr>
</tbody>
</table>
## Annex 2: The International Standards for TB Care

### The International Standards for TB Care: Standards for Diagnosis

<table>
<thead>
<tr>
<th>Standards for Diagnosis</th>
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<tbody>
<tr>
<td>1</td>
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<td>3</td>
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<td>6</td>
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</tbody>
</table>
The International Standards for TB Care: Standards for Treatment

<table>
<thead>
<tr>
<th>Standards for Treatment</th>
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</thead>
<tbody>
<tr>
<td><strong>7</strong></td>
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<td><strong>8</strong></td>
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<td><strong>13</strong></td>
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<tr>
<td><strong>14</strong></td>
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<tr>
<td><strong>15</strong></td>
</tr>
</tbody>
</table>
### The International Standards for TB Care: Standards for Public Health Responsibilities

<table>
<thead>
<tr>
<th></th>
<th>Standards for Public Health Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>All providers of care for patients with TB should ensure that persons (especially children under 5 years of age 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 under 5 years of age and persons with HIV infection who have been in contact with an infectious case should be evaluated for both latent infection with <em>M. tuberculosis</em> and for active TB.</td>
</tr>
<tr>
<td>17</td>
<td>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.</td>
</tr>
</tbody>
</table>
Annex 3: Template – Infection Control Plan

The following sample infection control plan is from:

SAMPLE INFECTION CONTROL PLAN

Policy and Procedures

Purpose: Early identification, separation, receipt of services, and referral of patients with TB disease is essential in preventing the spread of TB.

Lead: __________________________ has the responsibility for overseeing the implementation of these policies and its procedures, and reports to ___________________ (i.e. District Health Executive Committee, etc.)

The plan may include, but not be limited to, the following policy areas and procedures:

Policy 1: Screening patients to identify persons with symptoms or recent history of TB disease

Procedures:
1. Before patients enter an enclosed part of the facility, a designated staff person should ask each adult and any child capable of coughing forcefully (usually age 14 or older) about symptoms or recent history of TB. The questioning should occur before patients wait in line for long periods to register or obtain services.

2. Many combinations of symptoms have been recommended as sensitive and specific for TB. A simple screen is:
   “Do you have a cough?” If patient answers “yes”, ask:
   “For how long have you been coughing?”
   An adult who has coughed for two weeks or more may be considered a TB suspect for pulmonary TB.

   To determine whether a patient may be under investigation or a diagnosed case of TB, who may still be infectious, ask:
   “Are you being investigated or treated for TB?”

   If the answer to either question is “yes,” the screen classifies the patient as a TB suspect or case, and s/he should be managed as described in the procedures under policies 2 – 5 below.

3. As patients who are not identified as a TB suspect or case on the initial symptoms screen enter an examination room with the clinical officer, nurse, or counsellor, they should again be asked the simple screening questions. Those patients who report a cough of 2 or more weeks or who are being investigated or treated for TB should be managed as follows in the procedures under policies 2 – 5 below. Staff seeing patients in examination rooms should
report patients they find to be a suspect or case to the infection control officer in a timely manner so that factors contributing to the potential exposure (e.g., an emergency or short staffing interfering with the designated person screening all patients) can be documented and corrected.

Policy 2: Instructions on cough hygiene

Procedures:
1. Patients who are found to be TB suspects or cases should immediately be informed about the importance of cough hygiene and handed tissues (or pieces of cloth) and instructed to cover their mouths and noses when they cough. Alternatively, patients should be given a face mask, and asked to wear it while in the facility. Patients should also be instructed to dispose of used tissues or masks in identified no-touch receptacles and not on the ground.

When tissues, cloths or face masks are not available, clients should be instructed to lift their arm up and cover their nose and mouth with the inner surface of the arm or forearm when they cough or sneeze. M. tuberculosis cannot be spread from the hands, but other serious lung infections can.

2. No-touch receptacles for disposal of used tissues and masks should be available in the waiting areas.

Policy 3: Placing TB suspects and cases in a separate waiting area

Procedures:
1. A staff person should direct or escort the patient to a separate waiting area. This special waiting area should have the highest natural ventilation possible. Patients should be assured of their place in the line for registration and/or services.

Policy 4: Triaging TB suspects and cases to the head of the line to receive services in the facility

Procedures:
1. TB suspects and cases should be moved to the head of the line for whatever services they want or need, e.g., VCT, medication refills, or medical investigation. This reduces the duration of potential exposure while they wait in the facility and may be an incentive to disclose information during screening.

Policy 5: Referring TB suspects to TB diagnostic services

Procedures:
1. ________________ is the designated staff person to counsel patients about obtaining TB diagnostic services.

2. Patients will be referred to ________________ (TB diagnostic centre the health care facility has a previously negotiated agreement).

3. Patients should be given a card with the name, location, and operating hours of the TB diagnostic centre. The card should also have the name of the referring facility on it, with date of referral marked. These cards can be collected at the TB centre and used as an anonymous check on number of referrals who successfully obtain TB services.
Policy 6: Using and maintaining environmental control measures

Procedures:
1. ____________________ is the designated staff person to check on environmental control measures and maintain a log of monitoring and maintenance.

2. Windows and doors should be checked on a daily basis to assure they are in proper position (open or closed as called for in the plan). Generally, all windows and doors should be open when natural ventilation is the primary environmental control to allow for the free, unencumbered movement of air (e.g., across room, from window to door or vice versa). Generally, all windows and doors should be closed when using mechanical ventilation to ensure air movement in a controlled manner (air from supply vent and from slots either under or in door toward the exhaust vent).

3. Fans should be checked on a monthly basis to assure they are clean, are pulling (or pushing) the correct amount of air, and are pulling (or pushing) air in the correct direction.

Policy 7: Providing confidential TB and HIV services to health care workers and staff

Procedures:
1. Health care workers and all other staff working at the facility should be educated about the signs and symptoms of TB and encouraged to seek investigations promptly if they develop symptoms and signs suggestive of TB.

2. Health care workers and other staff should be informed about the special specific risks for TB for HIV-infected persons.

3. Health care workers and staff should be encouraged to undergo HIV testing, and given information on relevant HIV care resources.

4. Staff training should include reduction of stigma of TB and HIV.

5. ____________________ is responsible for determining when staff who develop TB disease may return to work.

6. Staff who develop TB disease may return to work when determined to be no longer infectious after:
   a. Having completed at least two weeks of standard anti-TB therapy; and
   b. Exhibiting clinical improvement; and
   c. Having continued medical supervision and monitoring of treatment until cured; and
   d. Where possible, having had three consecutive negative sputum smears obtained on three different days with at least one morning specimen. (Note: Frequent evaluation of sputum smear status may not be done routinely in resource-limited settings.)
Policy 8: Training of staff on all aspects of TB and the TB infection control plan

Procedures:
1. ________________ is the designated staff person to provide training to new staff as they are hired, and to maintain a log indicating who has had initial training.
2. ________________ is the designated staff person to provide annual training to all staff and to maintain a log indicating who has attended training. This may be incorporated into a broader training topic or be stand alone TB infection control training.

Policy 9: Monitoring the TB infection control plan’s implementation

Procedures:
1. Determine the frequency of the infection control plan
   a. During initiation of procedures, monitoring and evaluation should be done frequently, perhaps monthly or bi-monthly.
   b. When procedures are running well, less frequent evaluation will be necessary – at a minimum, annually.
2. Evaluate the screening process
   a. Were patients with significant cough missed when entering the facility and only detected at a later time or in the examination room?
   b. What correctable factors were associated with these potential exposures?
3. Evaluate the success of referrals to the TB diagnostic centre
   a. Did referred patients access care?
   b. Did referred patients have TB disease?
   c. What changes in screening or referral process should be made, if any?
4. Evaluate the training process
   a. Did all new staff receive training on TB infection control during their induction?
   b. Did all staff receive annual re-training on TB infection control?
5. Revise the infection control plan to reflect changes in staff responsibilities, policies, and procedures
6. Develop a plan for correcting inappropriate practices or failure to adhere to institutional policies
   a. Identify incentives to participate fully and adhere to policies
   b. Identify corrective actions if policies are not followed
### Annex 4: National Compendium of Indicators for Monitoring and Evaluation of Tuberculosis Control Programmes

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>INDICATORS</td>
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</tr>
<tr>
<td></td>
<td>TB case detection rate</td>
<td></td>
<td></td>
<td>Existence of comprehensive laboratory network</td>
<td>Patients under direct observation of therapy</td>
</tr>
<tr>
<td></td>
<td>Treatment success rate</td>
<td>Case notification rate</td>
<td></td>
<td>TB microscopy coverage</td>
<td>New TB patients who were prescribed the correct regimen</td>
</tr>
<tr>
<td></td>
<td>DOTS coverage</td>
<td>New smear-positive pulmonary TB case notification rate</td>
<td>National TB policy</td>
<td>TB microscopy units with adequate workloads</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Surveillance of MDR-TB</td>
<td>New pulmonary TB cases with no smear result</td>
<td>National TB programme manual</td>
<td>TB microscopy units submitting slides for rechecking</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HIV seroprevalence among TB patients</td>
<td>Retreatment TB cases</td>
<td>NTP medium-term development plan and budget</td>
<td>TB suspects who are smear-positive</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>New extrapulmonary TB cases</td>
<td>NTP annual work plan and budget</td>
<td>Smear-negative cases properly diagnosed</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>New TB cases with no smear conversion result</td>
<td>Peripheral units with work plan and budget</td>
<td>Detected smear-positive cases registered for treatment (inverse of primary default rate)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sputum conversion rate at end of initial phase</td>
<td>Financial resources committed to NTP from the government</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cure rate</td>
<td>Annual NTP budget allocated to implement TB control as required by medium-term plan</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Treatment completion rate</td>
<td>Key NTP staff positions filled</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Death rate</td>
<td>Interinstitutional coordination of TB control</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Treatment failure rate</td>
<td>Existence and dissemination of NTP annual report</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Default rate</td>
<td>National TB control policy addresses links between TB and HIV</td>
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<tr>
<td></td>
<td></td>
<td>Transfer-out rate</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Retreatment failure rate</td>
<td></td>
<td></td>
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<tr>
<td>SECTIONS</td>
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<tr>
<td>-------------------------------------------------------------------------</td>
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<tr>
<td>6. Drug management</td>
<td></td>
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<tr>
<td>7. Recording and reporting</td>
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<tr>
<td>8. Supervision</td>
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<tr>
<td>9. Human resource development</td>
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<tr>
<td>10. Health systems</td>
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</tbody>
</table>

**INDICATORS**

- Existence of a quality assurance system for drug management
- Anti-TB drugs meeting international minimum quality standards
- Existence of buffer stock at central, regional, or district-level facility
- Accuracy of stock records for anti-TB drugs
- Time anti-TB drugs are out of stock – storage facilities
- Time anti-TB drugs are out of stock – treatment facilities
- Basic management units where anti-TB drugs are available
- Anti-TB drug samples that fail quality control tests
- Completeness of reporting to NTP
- Accuracy of reporting to NTP
- Supervision of DOTS implementation
- Existence of supervision guidelines
- TB microscopy units with at least one laboratory technician trained in AFB microscopy
- Health care units with at least one health care professional trained in TB case detection and treatment
- Adequate staffing at all levels to enable implementation of DOTS
- Equitable distribution of DOTS (Stop TB Strategy)
Annex 5: TB Data Collection

To properly conduct M&E, TB data need to be collected from a variety of sources:

1. **Routinely collected health information** at TB treatment facilities and microscopy units. Data should be collected on standard reporting forms. WHO convened an expert group in 2006 to revise and adapt TB recording and reporting forms for use by countries. Forms can be adapted to local standards and include [1]:
   a. Request for sputum collection
   b. Register of TB suspects
   c. TB laboratory register
   d. TB treatment card
   e. District TB register
   f. Quarterly report on sputum conversion
   g. Quarterly report on TB case registration
   h. Quarterly report on TB treatment outcomes
   i. Quarterly report on programme management
   j. TB referral/transfer

2. **Special TB surveys or studies** can provide information about epidemiological or behavioural indicators that can be obtained through routine data collection or M&E. In most countries, these surveys and studies are limited because of their high cost and necessary technical capability. Some examples of special surveys include:
   k. **TB prevalence surveys** provide data on the number of persons with TB in the general population, and can provide information on the trend of TB disease over time.
   l. **Serological surveys** can provide information on representative numbers of TB patients who are also infected with HIV.
   m. **Population-based surveys** can be useful to gauge the general knowledge, attitudes and behaviours of persons about TB in a community, for example.
   n. **Vital registration surveys** can be used to gain information on the annual TB mortality rate, or deaths attributable to TB in a community.
   o. **Tuberculin surveys** can be used to measure the prevalence of TB infection and to estimate the risk of infection in a community.
   p. **Drug resistance surveillance** provides information on the amount of resistance to anti-TB drugs among new and previously treated TB cases.
   q. **Health facility surveys** provide information on the availability, functioning, and quality of TB services in a facility.

3. **Global TB data** is collected at the national level and compiled by WHO’s Stop TB Department annually. Data are analyzed to determine the progress in TB control for each country and region. The annual WHO TB control report provides information on global, regional and national estimated TB incidence, TB case notifications, and treatment outcomes [2]. These data can be used at all levels for M&E of TB control and services.
### Annex 6: Standard Equipment, Reagents and Materials/Supplies Needed for One Peripheral Laboratory

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Reagents</th>
<th>Supplies</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 watt spare bulbs</td>
<td>Litres needed of Acid-ethanol (for ZN staining)</td>
<td>Adhesive labels (for sputum containers)</td>
</tr>
<tr>
<td>50 cm nickel-chrome wires</td>
<td>Litres needed of Aqueous methylene blue</td>
<td>Applicators (wooden)</td>
</tr>
<tr>
<td>Binocular light microscopes</td>
<td>Litres needed of Carbolfuchsia</td>
<td>Cotton (packages)</td>
</tr>
<tr>
<td>Bottle, brown glass, 100 ml,</td>
<td>Litres needed of Methanol (for burner)</td>
<td>Filter paper (15cm) (box)</td>
</tr>
<tr>
<td>Bowls (50x30cm)</td>
<td>Litres needed of Methylated spirit</td>
<td>Gloves (pair)</td>
</tr>
<tr>
<td>Buckets, 12 l,</td>
<td>Litres needed of Sodium hypochlorite</td>
<td>Lens tissue (box)</td>
</tr>
<tr>
<td>Bunsen burner</td>
<td>Millilitres needed of ImmERSION oil</td>
<td>Overall (2 per person)</td>
</tr>
<tr>
<td>BUTANE gas cylinders</td>
<td>Millilitres needed of Xylene or Toluene</td>
<td>Paper towels (roll)</td>
</tr>
<tr>
<td>Drop bottle, glass, 100 ml,</td>
<td></td>
<td>Pens (black/blue and red)</td>
</tr>
<tr>
<td>Drop bottle, plastic, 10 ml, (for immersion oil)</td>
<td></td>
<td>Slides (25x75mm, 1.1-1.3mm thick)</td>
</tr>
<tr>
<td>Flask, brown glass, 1000 ml,</td>
<td></td>
<td>Sputum container, plastic, disposable (45 to 50 ml)</td>
</tr>
<tr>
<td>Forceps, 15 cm,</td>
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</tr>
<tr>
<td>Funnel (45 or 60 mm)</td>
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<td></td>
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<tr>
<td>Funnel (90 or 125 mm)</td>
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<td></td>
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<tr>
<td>Glass marker (diamond point)</td>
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<td></td>
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<tr>
<td>Loop holder</td>
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<tr>
<td>Measuring cylinder, glass 100 ml,</td>
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<tr>
<td>Microscope lamps</td>
<td></td>
<td></td>
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<tr>
<td>Pressure cooker</td>
<td></td>
<td></td>
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<tr>
<td>Scissors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slide storage box</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slide-boxes (for 100 slides)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slide-rack, plastic, (for 12-25 slides)</td>
<td></td>
<td></td>
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<tr>
<td>Spirit lamps</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staining rack</td>
<td></td>
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<tr>
<td>Timers (with alarm)</td>
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<tr>
<td>Transfer safety cabinets</td>
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<tr>
<td>Volumetric flask, glass or pyrex, 500 ml,</td>
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<tr>
<td>Wash bottles (500 ml)</td>
<td></td>
<td></td>
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<tr>
<td>Waste receptacles</td>
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<td></td>
</tr>
<tr>
<td>Water still</td>
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</tbody>
</table>

*Serving around 100,000 population and examining 2,000 sputum specimens by Ziehl-Neelson microscopy*
### Annex 7: List of Essential Anti-TB Medicines

<table>
<thead>
<tr>
<th>Anti-TB drug</th>
<th>Form and concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethambutol</td>
<td>Tablet: 100, 400 mg (hydrochloride)</td>
</tr>
<tr>
<td>Isoniazid</td>
<td>Tablet: 100, 300 mg</td>
</tr>
<tr>
<td></td>
<td>Tablet (scored): 50 mg</td>
</tr>
<tr>
<td>Isoniazid + Ethambutol</td>
<td>Tablet: 150 mg + 400 mg</td>
</tr>
<tr>
<td>Pyrazinamide</td>
<td>Tablet: 400, 500 mg</td>
</tr>
<tr>
<td></td>
<td>Tablet (dispersible): 150 mg</td>
</tr>
<tr>
<td></td>
<td>Tablet (scored): 150 mg</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>Capsule or tablet: 150 mg; 300 mg</td>
</tr>
<tr>
<td>Streptomycin</td>
<td>Powder for injection: 1 g (as sulfate) in vial</td>
</tr>
</tbody>
</table>

**Fixed-dose combination anti-TB drugs**

<table>
<thead>
<tr>
<th>Anti-TB drug</th>
<th>Form and concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rifampicin + Isoniazid</td>
<td>Tablet: 60 mg + 30 mg; 150 mg + 75 mg; 300 mg + 150 mg</td>
</tr>
<tr>
<td></td>
<td>60 mg + 60 mg (For intermittent use three times weekly)</td>
</tr>
<tr>
<td></td>
<td>150 mg + 150 mg (For intermittent use three times weekly)</td>
</tr>
<tr>
<td>Rifampicin + Isoniazid + Ethambutol</td>
<td>Tablet: 150 mg + 75 mg + 275 mg</td>
</tr>
<tr>
<td>Rifampicin + Isoniazid + Pyrazinamide</td>
<td>Tablet: 60 mg + 30 mg + 150 mg; 150 mg + 75 mg + 400 mg</td>
</tr>
<tr>
<td></td>
<td>150 mg + 150 mg + 500 mg (For intermittent use three times weekly)</td>
</tr>
<tr>
<td>Rifampicin + Isoniazid + Pyrazinamide + Ethambutol</td>
<td>Tablet: 150 mg + 75 mg + 400 mg + 275 mg</td>
</tr>
</tbody>
</table>

**Complementary List**

*Reserve second-line drugs for the treatment of MDR-TB should be used in specialized centres adhering to WHO standards for TB control*

<table>
<thead>
<tr>
<th>Anti-TB drug</th>
<th>Form and concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amikacin</td>
<td>Powder for injection: 1000 mg in vial</td>
</tr>
<tr>
<td>p-aminosalicylic acid</td>
<td>Granules: 4 g in sachet</td>
</tr>
<tr>
<td></td>
<td>Tablet: 500 mg</td>
</tr>
<tr>
<td>Capreomycin</td>
<td>Powder for injection: 1000 mg in vial</td>
</tr>
<tr>
<td>Cycloserine</td>
<td>Capsule or tablet: 250 mg</td>
</tr>
<tr>
<td>Ethionamide</td>
<td>Tablet: 125 mg; 250 mg</td>
</tr>
<tr>
<td>Kanamycin</td>
<td>Powder for injection: 1000 mg in vial</td>
</tr>
<tr>
<td>Ofloxacin*</td>
<td>Tablet: 200 mg; 400 mg</td>
</tr>
<tr>
<td></td>
<td>*Levofloxacin may be an alternative based on availability and programme considerations.</td>
</tr>
</tbody>
</table>
Annex 8: Mission, Vision and Values Statement

Mission

We serve the people of this province with world-class diagnosis and treatment of communicable diseases.

Vision

We will be known as a model of medical excellence and financial success that other hospitals throughout the country will want to follow.

Values

- Respect – for every patient, worker and member of the community
- Honesty – no tolerance for corruption
- Compassion – showing love for those who suffer
Annex 9: Example of a Strategic Plan

2009 Strategic Plan for
_________________________ Hospital

<table>
<thead>
<tr>
<th>Needs Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customers</td>
</tr>
<tr>
<td>Patients</td>
</tr>
<tr>
<td>Needs not being addressed</td>
</tr>
<tr>
<td>Patients are unhappy with our service and frequently have conflicts with physicians.</td>
</tr>
<tr>
<td>Families of patients</td>
</tr>
<tr>
<td>Owners</td>
</tr>
<tr>
<td>People in the Community</td>
</tr>
<tr>
<td>Needs not being addressed</td>
</tr>
<tr>
<td>The hospital has expenses that exceed revenues by 10% which makes the owners unhappy.</td>
</tr>
<tr>
<td>People delay getting the care they need, fearing that they will catch a communicable disease at the hospital.</td>
</tr>
</tbody>
</table>
Annex 10: Example of Three Year Goals Plan

Three-year Goals

1. We want to earn the confidence of patients who choose this hospital as measured by patient satisfaction surveys. We want to achieve at least 80% ratings at the level of ‘good’ or better in three years.

2. We will achieve a positive cash flow for the hospital by 2011.

3. We intend to change the reputation of the hospital to be a place for getting well rather than getting sick.

4.

5.
**Annex 11a: Example of Three Year Goals Plan**

**Annual Plan**

For Goal #1: We want to earn the confidence of patients who choose this hospital as measured by patient satisfaction surveys. We want to achieve at least 80% ratings at the level of ‘good’ or better in three years.

<table>
<thead>
<tr>
<th>Activities required</th>
<th>Responsibility</th>
<th>Deadline</th>
<th>Progress (date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop a patient satisfaction survey</td>
<td>Management team</td>
<td>2 months</td>
<td></td>
</tr>
<tr>
<td>Implement the survey with every patient</td>
<td>Human resources manager</td>
<td>3 months</td>
<td></td>
</tr>
<tr>
<td>Analyze the results</td>
<td>Management team</td>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>Act on recommendations from the survey</td>
<td>Management team</td>
<td>7 months</td>
<td></td>
</tr>
</tbody>
</table>
Annex 11b: Example of Three Year Goals Plan

Annual Plan
For Goal # 2: We will achieve a positive cash flow for the hospital by 2011.

<table>
<thead>
<tr>
<th>Activities required</th>
<th>Responsibility</th>
<th>Deadline</th>
<th>Progress (date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analyze revenue and expense for each department</td>
<td>Financial manager and President</td>
<td>2 months</td>
<td></td>
</tr>
<tr>
<td>Share summary of analysis with department managers and lead brainstorming for solutions</td>
<td>Financial manager and President, department managers</td>
<td>3 months</td>
<td></td>
</tr>
<tr>
<td>Implement selected ideas for improving cash flow in each department</td>
<td>Department managers</td>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>Check the results and make adjustments</td>
<td>Department managers, financial manager and President</td>
<td>Monthly after 6 months</td>
<td></td>
</tr>
</tbody>
</table>
Annex 11c: Example of Three Year Goals Plan

**Annual Plan**

For Goal # 3: We intend to change the reputation of the hospital to be a place for getting well rather than getting sick.

<table>
<thead>
<tr>
<th>Activities required</th>
<th>Responsibility</th>
<th>Deadline</th>
<th>Progress (date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gather data about the rates of infection that are acquired in the hospital</td>
<td>Nurse manager</td>
<td>2 months</td>
<td></td>
</tr>
<tr>
<td>Share the data with the management team, and brainstorm ideas for reducing infections</td>
<td>Nurse manager and management team</td>
<td>3 months</td>
<td></td>
</tr>
<tr>
<td>Implement the recommendations and track results</td>
<td>Nurse manager and management team</td>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>Share the improved results with the public through news articles and other methods</td>
<td>President</td>
<td>12 months</td>
<td></td>
</tr>
</tbody>
</table>
## Annex 12: Sample Hospital Budget Format

<table>
<thead>
<tr>
<th>Budget Format</th>
<th>Last Year</th>
<th>Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Departments</td>
<td>Total</td>
</tr>
<tr>
<td><strong>Income</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-patient routine services</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-patient supplies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-patient clinical services</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professional fees</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outpatient clinical services</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other income</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total income</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Deductions from Income</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discounts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bad debts</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total deductions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Net revenue</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Operating expenses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salaries and wages</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employee taxes and benefits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical supplies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repair and maintenance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Utilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professional fees</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Travel expenses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Director’s fees and expenses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Travel expenses/rep.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General administrative expense</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Miscellaneous</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total expenses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Net operating profit</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Annex 13: Workshop Daily Evaluation Form

Topics: ________________________________ Date: __________________

Over-all impressions of the day:

What parts were of limited value for you?

What are the most important concepts that you learned from today’s sessions?

As a result of today’s sessions, what do you plan to use in your work? (Please be specific)

What other topics would you like to learn more about?

<table>
<thead>
<tr>
<th>Please rate effectiveness of:</th>
<th>LOW (Circle the right number)</th>
<th>HIGH</th>
</tr>
</thead>
<tbody>
<tr>
<td>WORKSHOP CONTENT</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>TRAINERS</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>MATERIALS</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
</tbody>
</table>

Was the amount of material presented? – (Check one)

______ Too much?
______ Just right?
______ Too little?
Welcome to the Effective Hospital Management Workshop from Health Development International (HDI). This workshop is the result of many years of study and experimentation in developing countries around the globe, and it is part of a larger mission and vision. In this workshop, you will learn about the importance of a clear mission, vision and set of values. We like to practice what we preach, so here are our statements:

The Mission
Health Development International is a charitable non-profit organisation whose mission is to help hospitals and clinics in developing countries become self-sustaining enterprises known for their quality of care and concern for community.

The Vision
We will set new standards about how medicine and business are to be done based on principles of compassion, justice, and organisational soundness. As a result of our work, there will be models of sustainable hospitals and clinics in developing countries that will raise the standards of care for all, inspire medical and business excellence and lead the field in continual improvement.

Values
- Health care delivery should be a sustainable enterprise in every culture.
- Ethical principles should be the foundation for making wise decisions
- Everyone should have access to basic medical care

HDI is supported by donations and grants from individuals and organisations that are excited about our mission, vision and values. As HDI develops, services will expand to include individual consultations by volunteer trainers and consultants and to finding international funding sources for our client organisations.

Dr. Rufi Macagba
This workshop was originally developed by Dr. Rufi Macagba, the founder of HDI, based on his lifetime of learning, experimentation, and teaching of hospital management around the world. Dr. Macagba began as a surgeon at his family-owned hospital in San Fernando, Philippines. Lorma Hospital was founded by his parents in 1934, and the enterprise has grown to 160 beds by earning a reputation for excellent medical quality and personalized service. The family has also developed a 5,000-student Christian college and initiated a community development organisation to improve health services for the poor in the region.

Dr. Macagba first encountered the challenges of management when he assumed the leadership of Lorma Hospital in the mid-1960s. He found initial training through the Louis Allen management workshop, which formed the basis of his experimentation at Lorma. He later joined World Vision and Food for the Hungry, at which he developed a management training workshop for use in developing countries. HDI was formed in 1990 to enable Dr. Macagba to share his management wisdom with ministries as the opportunities presented themselves.
Workshop Presenter: Ken Hekman, President, Health Development International
Kenh@healthdevelopment.org

Professional Experience

- Founder and President, The Hekman Group, Holland, Michigan USA. The Hekman Group is a management consulting firm focusing on the business development needs of physicians. We have served over 400 medical groups across the US since 1990.
- Medical Group Administrator, Michigan, USA. Led a dramatic turnaround for a physician-owned multi-specialty medical group
- Nursing Home Administrator, California USA. Achieved the highest rating possible for quality of care through a continuous improvement process
- Health Planner, Michigan USA. Analyzed the health status of the population and hospital efficiency in southwest Michigan

Education

- M.B.A., Marketing and International Business, 1991 Grand Valley State University, Grand Rapids, MI USA
- B.A., Sociology and Psychology, 1975 Calvin College, Grand Rapids, MI USA

Credentials

- Fellow in the American College of Medical Practice Executives
- Member of the Medical Group Management Association since 1986
- Practice Partner with the Michigan State Medical Society
- Consultant to members of the American Academy of Family Physicians
- Faculty for the Bayer Institute for Healthcare Communication

Publications

- Treasures of Darkness (iUniverse.com, 2001)
- Numerous articles through the Medical Group Management Association

International Service

- Mr. Hekman has served as a strategic planner and management trainer since 1999 in China, Honduras, Kenya, Kyrgyzstan, Romania, Tanzania and Thailand
- He became the President of Health Development International 2007.
Annex 15: Tuberculosis Programmes in the Prison Environment

Pitfalls and limitations of tuberculosis programmes in the prison environment

Five years into the 21st century, one would think that the on-going WHO “DOTS strategy” for management of tuberculosis should have been accepted, adopted and implemented worldwide, and all the more so in such places as prisons, known to be important sources of all contagious diseases, including TB. Management of the disease, many would think, should be “easier” in the prison setting, as one does not have to run around the countryside looking for patients; it would seem relatively easy to create different compartments for patients in different stages of treatment; and where, theoretically, it would seem patients should comply with the treatment.

Unfortunately, any such assumptions are most usually wrong as far as many prisons are concerned – and this is true for prisons all over the world, particularly in Latin America, Africa, SE Asia and the countries of the former Soviet Union.

TB management is more complicated among prisoners, and if health staff are not aware of the many pitfalls to be found in correctional settings, a TB programme can become a nightmare to run.

Prisons are often, especially in developing countries, unhealthy places, that import, concentrate, propagate, worsen and export tuberculosis.

The prisoner population is usually made up mainly of the poor, forlorn, unhealthy and often devil-may-care-about-health members of the population. TB is indeed a disease of poverty, and all the side effects of poverty contribute to neglect of health and risky behaviours, which can only increase the prevalence of the disease. Those people who are committed to prison are more likely than the outside population to already have TB, therefore bringing it into the prison.

Overcrowding and bad ventilation are very often realities of prison life – creating ideal conditions for contagion. Incoming prisoners are often not screened, but put into overcrowded conditions where contagion is rife.

Treatment programmes are often poorly organised, by untrained, unmotivated staff. It is not surprising that TB cases get worse, lacking proper treatment and wholesome food.

Prisoners are transferred and moved about constantly within prison systems, and even those who do get access to treatment often have to interrupt it, or are released without any follow-up provided for.

Prisoners are also an unruly population, with many of them eager to profit from any and all situations. Once prisoners feel better (generally after two to three weeks of treatment) they may try to not take their medicines, so as to trade or sell them, smuggle them to their family, or just hold on to them “for a rainy day”. Interruptions of treatment, combined with “self medication” – also rampant in prisons – is a recipe for creating resistant strains of the mycobacterium. Finally, in many countries, TB wards tend to have better conditions and better food than “usual” prison wards. Therefore, prisoners try to “cheat” on their sputum exams, trading or otherwise obtaining “positive” samples of sputum that they try to pass off as their own – and thereby staying on in the more comfortable hospital settings.

These pitfalls and limitations need to be known by all health staff working in prisons, if TB management and treatment is to be efficient and successful. Prisoners certainly have the right to receive correct treatment – but health staff have to take precautions to ensure quality care is not misused.