BASIC DOTS COURSE MODULE
ENHANCING THE DIRECTLY OBSERVED TREATMENT, SHORT - COURSE (DOTS) STRATEGY TO CONTROL TB IN THE PHILIPPINES

Submitted to:
USAID/Manila

By:
Chemonics International Inc.
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Module 1: Basic DOTS Enhancing the Directly Observed Treatment Short-Course (DOTS) Strategy to Control TB in the Philippines

Project Overview:

Tuberculosis (TB) continues to be one of the top ten causes of morbidity and mortality in the Philippines. Two well-designed nationwide surveys have shown that no significant changes in the past 14 years have succeeded in controlling this deadly disease. One of the major obstacles is a lack of a standardized approach by physicians in approaching the management of these cases.

Recently, the strategy of Directly-Observed Treatments Short-course (DOTS) has been proposed as a uniform approach to TB cases with five basic components: political will, standardized short-course chemotherapy under proper case management conditions, use of sputum AFB smear as the initial diagnostic modality, assurance of an uninterrupted drug supply until treatment is completed, and a system of recording cases and outcome of management. This strategy was consistently shown to achieve good cure rates. TB control is possible in the context of DOTS.

The National TB Program (NTP) of the country was just evaluated and determined to be generally adequate with the expansion of DOTS services. However, because improvements were recent, the public skepticism of the public and of the private MDs may still be justified in some situations. While the government has announced intentions to involve the private MDs in their TB control programs, they are not backed by an adequate budget.

Adoption of DOTS is a formidable task, and will be most successful with the support of private MDs. Quite consistently, it has been demonstrated that the private sector plays a crucial role in TB control. A program of education, skill building, incentives (both material and non-material forms), logistical support and infrastructural reforms may encourage them to join forces with the NTP. Indeed, there is a need for the government NTP personnel to fully accept this new paradigm. Real public and private collaboration is vital if TB is to be controlled. This DOTS Course is one step toward this purpose.

Since DOTS is the most efficient way of controlling TB, adequate knowledge of this intervention is definitely critical. An awareness of available services offered at regional and local health centers is also necessary to optimize these facilities in the care of TB patients. The private and public sectors must share expertise and resources to bring about palpable results in TB control.

This training module is designed to give participants an adequate knowledge of DOTS and its implementation. This will also introduce benefits that await both the physician and patients once DOTS is successfully practiced. The concept of PPM will likewise be introduced.

Target Audience:

TB practitioners (private or government doctors; specialists or non-specialists); TB program coordinators; nurses; midwives)
Objectives of the Workshop:

At the end of this workshop, participants should be able to:
1. Describe the overall TB situation in the country.
2. Describe and explain the rationale behind the policies of the NTP.
3. Explain the definitions and diagnostic criteria used in the NTP.
4. Classify TB cases according to the NTP.
5. Assign the appropriate treatment regimen for diagnosed TB cases.
6. Describe the required follow-up procedure for each patient under treatment.
7. Assign patients the appropriate treatment outcomes at the end of treatment.
8. Be aware of the benefits to the patients and provider by using the DOTS strategy.
9. Explain the rationale for Private-Public Mix (PPM) DOTS.
10. Prefer DOTS over other approaches in TB management in terms of case finding, treatment, follow-up, and overall set-up.

General Design:

This will be a whole day (8:00am-4:30 pm) session with didactic lectures to be followed by small group discussions.

Morning lectures will focus on a background of the current TB situation in the country with focus on figures relating to this disease as well as its economic impact. This will be followed by an overview of NTP policies as well as the functions of a diagnostic committee. Subsequent lectures will tackle the comprehensive policy on TB control with emphasis on the benefit package for physicians and patients and an introduction on the concept of PPM and its potential effect on the TB situation.

Focus group discussions will help participants practice concepts they learned in the morning sessions with emphasis on case definitions, proper management, and monitoring and recording of outcome. A concluding session will guide the participants on directions they may take as certified DOTS referring physicians.

To ensure active participation from the audience, opportunities to ask questions are strategically placed all throughout the workshop. A session for Frequently Asked Questions (FAQs) will hopefully complement the proceedings by focusing on the frequent concerns of practitioners that arose during similar workshops.
## Basic DOTS Course

<table>
<thead>
<tr>
<th>TIME</th>
<th>ACTIVITY</th>
<th>SPEAKER</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 am</td>
<td>Registration</td>
<td></td>
</tr>
<tr>
<td>8:30</td>
<td>Orientation to the Course</td>
<td>Dr. Jubert Benedicto</td>
</tr>
<tr>
<td>8:45</td>
<td>Overview of Philippine Tuberculosis: Epidemiology, Burden of Illness</td>
<td>Dr. Camilo Roa</td>
</tr>
<tr>
<td>9:15</td>
<td>National TB Core Policy and Overview of Diagnostic Committee</td>
<td>Dr. Helen Hernandez</td>
</tr>
<tr>
<td>10:00</td>
<td>Q&amp;A</td>
<td></td>
</tr>
<tr>
<td>10:15</td>
<td>Break</td>
<td></td>
</tr>
<tr>
<td>10:30</td>
<td>Frequently Asked Questions</td>
<td>Dr. Jubert Benedicto</td>
</tr>
<tr>
<td>11:30</td>
<td>Q&amp;A</td>
<td></td>
</tr>
<tr>
<td>11:45</td>
<td>Overview of the PhilHealth Outpatient TB Package; Revised SSS, GSIS Policies</td>
<td>Dr. Rodrigo L.C. Romulo</td>
</tr>
<tr>
<td>12:15</td>
<td>Q&amp;A</td>
<td></td>
</tr>
<tr>
<td>12:30</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td>1:30</td>
<td>Workshop: Diagnosing and Treating Cases Using NTP</td>
<td>Facilitators: Drs. Lagahid, Hernandez, Quelapio, Benedicto, Pagcatipunan and Ms. Sarmiento</td>
</tr>
<tr>
<td>3:00</td>
<td>Break</td>
<td></td>
</tr>
<tr>
<td>3:15</td>
<td>Next Steps/Feedback</td>
<td>Dr. Rudy Pagcatipunan</td>
</tr>
<tr>
<td>4:00</td>
<td>Q &amp; A/ Wrap-up</td>
<td></td>
</tr>
<tr>
<td>4:15</td>
<td>End of Session</td>
<td></td>
</tr>
</tbody>
</table>
Introduction to the Course

Basic DOTS Workshop

DOTS Training Series
Enhancing the Directly Observed Treatment, Short-course (DOTS) Strategy to control TB in the Philippines

The Faculty
- Charles Yu, MD, MSc
- Rodrigo L.C. Romulo, MD
- Camilo Roa, MD
- Rodolfo Pagcatipunan, MD
- Amy Sarmiento
- Jubert P. Benedicto, MD
- Jaime Lagahid, MD
- Helen Hernandez, MD
- Imelda Quelapio, MD

Why are we here?
- We want to take part in TB control (private or government physician)
- DOTS is the most efficient way of controlling TB
- Collaboration or Public-Private Mix is critical
- Prefer DOTS over other approaches in TB management
Basic Rules

- One should finish the whole course to be certified. (*SIGN 4X*)
- We will only entertain participants who are here once the first lecture starts.
- You will get a certificate in the end. (PhP 500)
- Please keep all cellphones and pagers in silent mode.

- This is a module in progress.

- We are responsive to change.

- WE VALUE YOUR FEEDBACK.
CURRENT STATUS OF TB IN THE PHILIPPINES

Current Status of TB in the Philippines

Rodrigo L.C. Romulo, MD
Technical Coordinator
Philippine Tuberculosis Initiatives for the Private Sector Project (PhilTIPS)

The Burden of Tuberculosis, 2000

- 1.9 million deaths worldwide
- 98% of these deaths in the developing world
- About 350,000 deaths due to TB/HIV
- 8.7 million new cases, 80% in 22 high-burden countries (The Philippines included!)
- Multi-drug resistance (MDR TB) present in 63 of 72 countries surveyed between 1994-1999

<table>
<thead>
<tr>
<th>Top 10 Causes of Mortality 1998</th>
<th>Male</th>
<th>Female</th>
<th>Total Number</th>
<th>Rate</th>
<th>% of Total Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Diseases of the heart</td>
<td>32,260</td>
<td>23,570</td>
<td>55,830</td>
<td>76.3</td>
<td>15.8</td>
</tr>
<tr>
<td>2. Dis. vascular system</td>
<td>23,712</td>
<td>17,668</td>
<td>41,380</td>
<td>56.6</td>
<td>11.7</td>
</tr>
<tr>
<td>3. Pneumonia</td>
<td>17,632</td>
<td>16,077</td>
<td>33,709</td>
<td>46.1</td>
<td>9.5</td>
</tr>
<tr>
<td>4. Malignant Neoplasm</td>
<td>17,457</td>
<td>14,833</td>
<td>32,090</td>
<td>43.9</td>
<td>9.1</td>
</tr>
<tr>
<td>5. Accidents</td>
<td>24,160</td>
<td>5,714</td>
<td>29,874</td>
<td>40.8</td>
<td>8.5</td>
</tr>
<tr>
<td>6. Tuberculosis, all forms</td>
<td>18,874</td>
<td>9,167</td>
<td>28,041</td>
<td>38.3</td>
<td>7.9</td>
</tr>
<tr>
<td>7. COPD &amp; allied conditions</td>
<td>9,459</td>
<td>4,769</td>
<td>14,228</td>
<td>19.5</td>
<td>4.0</td>
</tr>
<tr>
<td>8. Diabetes Mellitus</td>
<td>4,262</td>
<td>4,557</td>
<td>8,819</td>
<td>12.1</td>
<td>2.5</td>
</tr>
<tr>
<td>9. Other Resp. diseases</td>
<td>3,780</td>
<td>3,736</td>
<td>7,516</td>
<td>10.3</td>
<td>2.1</td>
</tr>
<tr>
<td>10. Nephritis, nephritic</td>
<td>4,417</td>
<td>3,036</td>
<td>7,453</td>
<td>10.2</td>
<td>2.1</td>
</tr>
</tbody>
</table>

More Filipinos are dying today than ever before!
**TB in the Philippines**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>1997 NPS</th>
<th>1983 NPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>TB infection: % of population</td>
<td>63.4%</td>
<td>54.5%</td>
</tr>
<tr>
<td>Annual Risk of Infection (ARI)</td>
<td>2.3%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Smear (+) cases</td>
<td>0.31%</td>
<td>0.66%</td>
</tr>
<tr>
<td>Culture (+) cases</td>
<td>0.81%</td>
<td>0.86%</td>
</tr>
<tr>
<td>Xray (+) cases</td>
<td>4.2%</td>
<td>4.2%</td>
</tr>
</tbody>
</table>

**1997 TB National Prevalence Survey**

- Infected: 63% (16M)
- Culture (+): 600,000
- New cases: 230,000
- Inactive cases: 100,000

**TB BURDEN OF ILLNESS**

- Philippines 3rd western pacific region and 8th globally in TB cases
- 75 Filipinos die daily
- 1997 NPS half of TB symptomatics do nothing, 70% do not seek professional help
- 27 billion lost (foregone wages) annually
- 8 billion in actual wage losses
- TB robs workers 216 pesos/day for women and 451 pesos/day for men
- Total estimated cases 270,000 yearly
**BURDEN OF DISEASE**

- 514,300 DALY lost every year
  - 249,655* new cases of TB and 26,054 reported deaths
- 26% overall case fatality rate
- Incidence is rising
- Only 45% of cases are diagnosed
- Only 38% of symptomatic patients get treated

**ECONOMIC SUMMARY (2003)**

- Robs an average worker of
  - P 216 for women
  - P 451 for men
- Lost wages total P 7,900 million annually
- Costs PhP 6,500 for 6 months treatment
  - P1,000 – 4,000 drugs
  - P 200 – 700 doctor
  - P 700 – 1,800 laboratory
- Treating all 76,000 untreated patients would cost PhP 500 million
- Foregone wages & benefits due to premature death
  - PhP 27B

**Distribution of Sources of Funds For Health, 1997**

Source: HSRA, DOH, 1999

- NHIP 7%
- Personal 40%
- National Gov’t 21%
- Local Gov’t Units 18%
- Others 8%
Why TB Control has not been attained in the Philippines?

- Poverty: this leads to...
  - Malnutrition: poor resistance
  - Crowding: transmission is enhanced
  - Limited access to medical care

- A Weak NTP (until recently!):
  - It was not really national in reach initially
  - Lack in personnel, drugs and lab supplies
  - Devolution

Why TB Control has not been attained in the Philippines?

- Large and influential private MDs sector
  - Not trained in public health issues in TB
  - None utilization of the sputum AFB smears
  - None standardized treatment
  - Treatment is prescribed and self-administered
  - No defaulter follow-up
  - No system of recording nor government reporting

- Patient health seeking behavior

Health Seeking Behavior Among TB Symptomatics (NPS 1997)

- 49.1% No action taken
- 24.3% Self-medication
- 6.5% Gov't Centers
- 9.6% Private MDs

No exit data.
**DOTS and Private Practitioners**

<table>
<thead>
<tr>
<th></th>
<th>DOTS</th>
<th>PPs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diagnosis</strong></td>
<td>Sputum based</td>
<td>X-ray based</td>
</tr>
<tr>
<td><strong>Treatment</strong></td>
<td>Standardized</td>
<td>Varied Reg.</td>
</tr>
<tr>
<td><strong>Follow-up</strong></td>
<td>DOT</td>
<td>No DOT</td>
</tr>
<tr>
<td><strong>Monitoring</strong></td>
<td>Sputum exam</td>
<td>X-ray</td>
</tr>
<tr>
<td><strong>Evaluation</strong></td>
<td>Cure rate</td>
<td>Nil</td>
</tr>
</tbody>
</table>

World Health Organization

**Threats to TB Control: HIV**

Reported TB Cases in USA
1953 – 1997, CDC

![Graph showing the rise of HIV](image)

**DOTS Solution to TB Control**

<table>
<thead>
<tr>
<th>The Problem</th>
<th>DOTS Element-Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of adequate government support and financial allocations</td>
<td>Government commitment to sustained TB control activities</td>
</tr>
<tr>
<td>Filipinos’ Poor hygienic practices</td>
<td>Case detection with free sputum smear</td>
</tr>
<tr>
<td>Lack of family resources to wellness, diagnosis and complete treatment</td>
<td>A regular, uninterrupted supply of free anti-TB drugs</td>
</tr>
</tbody>
</table>
DOTS Solution to TB Control

<table>
<thead>
<tr>
<th>The Problem</th>
<th>DOTS Element-Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of standardized treatment being followed by both private and public physicians</td>
<td>Standardized treatment regimen of 6 months. Directly observed treatment (DOT)</td>
</tr>
<tr>
<td>There is also poor recording of identified TB patients and how their disease has progressed over time.</td>
<td>A standardized recording and reporting system. A defaulter follow-up procedure</td>
</tr>
</tbody>
</table>

Progress in Treatment Success under DOTS
Global Results, 1994 - 2000

WHO target 85%

<table>
<thead>
<tr>
<th>Years</th>
<th>Treatment Success Rates %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994</td>
<td>77%</td>
</tr>
<tr>
<td>1995</td>
<td>78.5</td>
</tr>
<tr>
<td>1996</td>
<td>78.4</td>
</tr>
<tr>
<td>1997</td>
<td>78.3</td>
</tr>
<tr>
<td>1998</td>
<td>81</td>
</tr>
<tr>
<td>1999</td>
<td>80.2</td>
</tr>
<tr>
<td>2000</td>
<td>84</td>
</tr>
</tbody>
</table>

Progress in DOTS Case Detection

WHO target 70%

- Need accelerated progress: target 2005
- New DOTS Framework
- Average rate of progress: target 2013
Dynamics of pulmonary TB in Peru 1980-2000

DOTS 1990

PTB falling at 6%/yr

case finding

DOTS progress in 20 high TB burden countries 1999 - 2000

TB Strategy and Operations
Stop TB Department
Communicable Diseases Cluster

WHO HEALTH ORGANIZATION

IN INVOLVING PRIVATE PRACTITIONERS
in
TUBERCULOSIS CONTROL:
ISUES, INTERVENTIONS, and
EMERGING POLICY FRAMEWORK
Coalition Building For TB Control

Controlling TB In the Philippines

Private – Public Mix

- NTP reaches out to private MDs
- Private MDs participates in NTP
- Uniform standards of diagnosis and care
- Free medicines even for private patients
- DOTS for ALL
**Private practitioners and public health: weak links in tuberculosis control**

Mukund Uplekar, Vikram Pathania and Mario Raviglione

TB Strategy and Operations, Stop TB Department, Communicable Diseases Cluster, World Health Organization, Geneva, Switzerland

**Threats to TB Control: MDR-TB**

Drug Resistance Among Pts Starting Rx (n = 326)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Total (n = 326)</th>
<th>New cases (n = 230)</th>
<th>Past treated (n = 63)</th>
<th>Status? (n = 33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any</td>
<td>99 (30%)</td>
<td>61 (27%)</td>
<td>27 (43%)</td>
<td>11 (33%)</td>
</tr>
<tr>
<td>INH</td>
<td>85 (26%)</td>
<td>51 (22%)</td>
<td>25 (40%)</td>
<td>9 (27%)</td>
</tr>
<tr>
<td>INH only</td>
<td>42 (13%)</td>
<td>35 (15%)</td>
<td>5 (8%)</td>
<td>2 (6%)</td>
</tr>
<tr>
<td>Strep.</td>
<td>33 (10%)</td>
<td>16 (7%)</td>
<td>10 (16%)</td>
<td>7 (21%)</td>
</tr>
<tr>
<td>EMB 1</td>
<td>10 (3%)</td>
<td>3 (1%)</td>
<td>6 (10%)</td>
<td>1 (3%)</td>
</tr>
<tr>
<td>MDR 2</td>
<td>25 (8%)</td>
<td>6 (3%)</td>
<td>17 (27%)</td>
<td>2 (6%)</td>
</tr>
<tr>
<td>PAS 3</td>
<td>5 (2%)</td>
<td>4 (2%)</td>
<td>1 (2%)</td>
<td>0</td>
</tr>
</tbody>
</table>

1 of them had MDR TB, 2 were resistant to Eth., INH and Streptomycin, and 13 of them (3/9/1) were resistant to INH and rifampicin only.
REVISED TUBERCULOSIS CONTROL PROGRAM

THE
REVISED TUBERCULOSIS
CONTROL PROGRAM

BACKGROUND

- 80 million population (2003)
- Department of Health sets policies, standards, guidelines
  - TB Unit
  - Centers for Health Development
- Health program implementation is the mandate of LGUs (Devolution)
  - Rural Health Units (RHUs); Health Centers
  - Barangay Health Stations (BHSs)

TB SITUATION

- One of the 20 high-burdened countries
  (WHO TB Watchlist)
- 3rd in the Western Pacific - Case Notification
- 6th leading cause of deaths (1997)
- 6th leading cause of morbidity
- Prevalence of Smear (+) cases - 3.1 /1000
  (240,000 cases)
MAJOR POLICIES ON CASEFINDING

- Direct sputum smear microscopy shall be the primary NTP diagnostic tool.

- All TB symptomatics must undergo sputum examination, with or without X-ray results.
  
  *Only contraindication is massive hemoptysis.*

- Three sputum specimens must be submitted - 
  *1st spot, early morning, 2nd spot*

Directly-Observed Treatment 
Shortcourse (D.O.T.S.)

- Political commitment
- Quality microscopy service
- Regular availability of drugs
- Standardized records & reports
- Supervised treatment

PROGRAM COMPONENTS

**CASEFINDING:**

*Objectives:*
To identify TB symptomatics
To identify & diagnose TB cases early

*Passive Casefinding* - TB symptomatics present themselves at the health facility.

*Active Casefinding* - purposive effort to find TB cases among the symptomatics who don’t seek consultation.
MAJOR POLICIES ON CASEFINDING

- Direct sputum smear microscopy shall be the primary NTP diagnostic tool.

- All TB symptomatics must undergo sputum examination, with or without X-ray results. Only contraindication is massive hemoptysis.

- Three sputum specimens must be submitted - 1st spot, early morning, 2nd spot

Passive casefinding shall be implemented in all health centers, health stations.

Sputum microscopy work shall be performed only by adequately trained health personnel.

Quality control of smear examination must be observed. Validation system must be established.

CASEHOLDING

Objectives:
To render as many Smear (+) cases as non-infectious & cured as early as possible.
To treat seriously-ill Smear (-) cases & other potentially infectious cases.

Classification of TB Cases - based on location of lesions:

- Pulmonary
  - Smear (+)
  - Smear (-)
- Extra-pulmonary
Definition of Pulmonary Case

- **Smear (+):**
  - at least two AFB (+) smears on initial examination OR
  - one AFB (+) plus radiographic abN as determined by clinician OR
  - one AFB (+) plus sputum culture positive for *M. tb*

- **Smear (-):**
  - three sputum (-) for AFB AND
  - radiographic abN for PTB AND
    - no response to a course of antibiotics and/or symptomatic meds AND
  - decision by clinician to treat with a full course of anti-TB meds

Case Definition

- **New:** never tx or on anti-TB meds for less than a month

- **Relapse:** prev tx for TB with cure or complete outcome and now bacteriologically positive

- **Failure:** while on tx, AFB (+) at 5 mos or later

- **RAD:** returns to tx with (+) bacteriology following interruption for 2 mos or more

- **Other:** starting tx again after interruption for 2 mos but smear (-)
  - smear (-) then became smear (+)
  - *chronic case:* sputum (+) at end of retreatment regimen

NTP – WHO CATEGORIES

TB Patients to be Given Treatment (ATS Class III)

- **Regimen I:** New pulmonary smear (+) cases; severe smear (-) cases
- **Regimen II:** Treatment failure, RAD, relapse, others
- **Regimen III:** New smear (-) with minimal TB on CXR
**TREATMENT REGIMENS**

<table>
<thead>
<tr>
<th>TB Treatment Regimen</th>
<th>TB Patients To Be Given Treatment</th>
<th>DRUGS AND DURATION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Initial Phase</td>
</tr>
<tr>
<td>I</td>
<td>New smear-positive PTB; new smear-negative PTB with extensive parenchymal involvement; new cases of severe forms of extra-pulmonary TB</td>
<td>2 HRZE</td>
</tr>
<tr>
<td>II</td>
<td>Previously treated smear-positive PTB; relapse; treatment failure; treatment after interruption</td>
<td>2 HRZE/HRZ</td>
</tr>
<tr>
<td>III</td>
<td>New smear-negative PTB (other than in Category I); new less severe forms of extra-pulmonary TB</td>
<td>2 HRZ</td>
</tr>
<tr>
<td>IV</td>
<td>Chronic case (still sputum-positive after supervised re-treatment)</td>
<td>Refer to specialized centers with access to second line drugs</td>
</tr>
</tbody>
</table>

**SCHEDULE OF SPUTUM FOLLOW-UP EXAMINATIONS**

- **CAT I:** 2nd, (3rd), 4th, 6th
- **CAT II:** 3rd, (4th), 5th, 8th
- **CAT III:** 2nd

**MAJOR POLICIES ON CASE HOLDING**

- Treatment of all TB cases shall be based on reliable diagnostic techniques aside from clinical findings.
- Shortcourse regimens shall be the mode of treatment for the different classifications & types of tuberculosis.
- Domiciliary treatment shall be the preferred mode of care.
No patient shall be initiated into treatment unless a case holding mechanism for the treatment compliance has been agreed upon by the patient & health workers.

The national &/or local governments shall ensure the provision of drugs to all sputum (+) TB cases.

**Supervised Treatment**

- a mechanism of ensuring treatment compliance
- TB patient is motivated to take his drugs
- Cured
  
  *Treatment Partner*

  - watches the patient take his drugs daily
  - reports & traces the patient if he defaults
  - provides health education regularly
  - motivates the patient on sputum ff-ups

**Who will undergo supervised treatment?**

*Priority are the Smear (+) TB cases*

- **Who could serve as Treatment Partner?**
  - Health Staff, Barangay Health Worker, Community Volunteer, Family Member

- **Where will D.O.T. take place?**
  - Health facility
  - Treatment Partner’s House
  - Patient’s House

- **How long is treatment supervised?**
  - Daily drug intake is supervised during the entire course of treatment.
RECORDS and REPORTS

NTP Laboratory Request Form
Laboratory Register

NTP Treatment Card
NTP Identification Card
TB Case Register

NTP Referral Form

Reports

- Quarterly Report on Laboratory
- Quarterly Report on Casefinding
- Quarterly Report on Treatment Outcomes

Objectives:
1. To know how best to assist clients / patients
2. To know how best to assist TB Program implementors

- Shall include all cases of TB, classified according to internationally accepted case definitions.
- Shall allow the calculation of the main indicators for evaluation. (Cure Rate, Case Detection Rate)
CASEFINDING

- Proportion of Sputum (+) (60%)
  \[ \frac{\text{Total No. Sputum (+) cases discovered}}{\text{Total No. of Pulmonary TB cases}} \]

- Proportion of 3 sputum examination (90%)
  \[ \frac{\text{No. TB symptomatics with 3 specimens}}{\text{Total no. TB symptomatics examined}} \]

Casefinding

- (15-20%) Positivity
  \[ \frac{\text{No. Sputum (+)s discovered}}{\text{Total no. TB Symptomatics examined}} \]

- Case Detection Rate (CDR=70%)
  \[ \frac{\text{No. of New Sputum (+) cases discovered}}{\text{TP x 145/100,000 (Incidence)}} \]

COHORT ANALYSIS

- A group of patients having the same attributes at a certain period of time to determine treatment outcome.

- Treatment Outcomes:
  - Cure Rate = 85%
  - Completion Rate
  - Tx Failure Rate
  - Defaulter Rate
  - Death Rate
  - Trans-Out Rate
### Cure Rate

\[ \text{Cure Rate} = \frac{\text{Total no. New Sputum (+) cases who got CURED}}{\text{Total no. New Sputum (+) cases evaluated}} \]

**General Attributes:**
- New, Pulmonary Sputum (+) case

**Differentiating Attribute - CURED (Tx Outcome)**
- Cure - New Sputum (+) case, completed tx, Sputum (-) at the end of treatment

### RECORDING / REPORTING:

**Objectives:**
1. To know how best to assist clients / patients
2. To know how best to assist TB Program implementors

<table>
<thead>
<tr>
<th>RECORDS</th>
<th>PERSON(s) IN-CHARGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>On Casefinding / Microscopy:</td>
<td></td>
</tr>
<tr>
<td>Symptomatic Masterlist</td>
<td>Midwife</td>
</tr>
<tr>
<td>Lab Request Form</td>
<td>Midwife, Nurse (upper)</td>
</tr>
<tr>
<td>Lab. Register</td>
<td>Medtech (lower)</td>
</tr>
</tbody>
</table>

| On Caseholding: | |
| Treatment Card | Nurse ; Midwife |
| ID Card | Nurse ; Tx Partner |
| TB Case Register | Nurse |
| Referral Form | Nurse ; Physician |

**REPORTS**
- **ALL are on quarterly basis.**
  - Casefinding for New Cases & Relapses
  - Retrospective Cohort Report
  - Drug Inventory
  - Laboratory Report
MAJOR POLICIES ON RECORDING/REPORTING:

- Shall rely on all government health facilities, including government hospitals.
- Shall include all cases of TB, classified according to internationally accepted case definitions.
- Shall include private physicians & private clinics, after agreement with parties concerned has been made.
- Shall allow the calculation of the main indicators for evaluation. (Cure Rate, Case Detection Rate)

MONITORING AND SUPERVISION

Objectives:
1. To oversee / observe the implementation
2. To re-enforce correct & good performance
3. To identify gaps & correct inadequacies
4. To refresh/update workers on new policies, trends

GUIDE IN MONITORING TREATMENT PROGRAM

- VERIFY - TB Register, Lab Register, Tx Cards
- REVIEW Tx Cards - Classification / Type of Patient Category of Treatment Sputum Follow-up Examination Drug Collection Lab Request Form
- REVIEW TB Register - Conversion Rate Sputum Follow-up Results Treatment Outcome
REVIEW Lab Register - Compliance to 3 specimens
   Positivity Rate

REVIEW Symptomatic Masterlist - 3 Sputum samples

CHECK - Entire allocation of drugs per patient
   Patient capacity of unallocated drugs
   Other supplies

REMARKS & RECOMMENDATIONS

Major Policies in Monitoring & Supervision

- Monitoring & supervision shall focus on the quality of service.
- It shall be facilitative, shall result in problem-solving & not stop on problem identification.
- Areas with poor performance shall be monitored at least every other month.
- A monitoring tool shall be used as a guide in monitoring program implementation and performance.

TB DIAGNOSTIC COMMITTEE

RATIONALE:

- About 60% of the TOTAL reported PTB Cases diagnosed by CXR (1996)
  Dr. Pierre Chaulet’s study (pilot areas of C.R.U.S.H. TB Project)

No. of cases assessed = 101

- Compatible
- Doubtful
- No PTB

Compatible w/PTB: 24.8%
No PTB: 36.6%
Doubtful: 36.5%
Overdiagnosis of PTB Cases using X-ray (over-reading)

CONSEQUENCES:
1. waste of resources (drugs and manpower)
2. psychological burden to patient
3. unnecessary toxicity of the drugs

OBJECTIVES:

To improve the quality of TB management:

Reduce the number of misdiagnosed TB cases among the Smear (-) cases

Provide judicious TB chemotherapy to the truly diagnosed Smear (-) cases

TARGET:
Smear (-) cases initiated to treatment = less than 40%

FUNCTIONS:

Review the documents of:
* TB Symptomatics who are Smear (-) and with CXR results
* Referred patients considered as PTB through X-ray

Decide if Active TB (requiring medication)
COMPOSITION:
(P provincial TBDC)
• Prov’l / City NTP Medical Coordinator
• Radiologist (Gov’t / Private)
• Clinician / Internist / Pulmonologist
• Prov’l / City NTP Nurse Coordinator

COMPOSITION:
(D district TBDC)
• Prov’l/District NTP Medical Coordinator
• Radiologist (Gov’t / Private)
• Senior Chief - Hospital
• District Chief Nurse - Hospital

Optional: MHO, Clinician, Internist, Pulmonologist

ROLES OF MEMBERS:

Provincial / City NTP Medical Coordinator
• Organizes the Committee
• Convenes the Committee regularly
• Ensures action on Committee’s decisions

Radiologist
• Reviews X-ray films with other members
• Provides radiologic analysis

Clinician/InternistPulmonologist
• Provides clinical perspective of cases
• Recommends alternatives to the non-tuberculous cases

Provincial / City NTP Nurse Coordinator
• Consolidates required documents per referred case
• Acts as Secretariat
• Follows-up the cases referred back to RHUs
MECHANICS:

1. Selection of cases for referral to TBDC by the RHU (Main HC).
   - PTB symptomatics who are Smear (-) and who underwent X-ray examination
   - Referred patients, initially claimed as having PTB by X-ray examination

2. Referral process of selected cases to the TBDC.
   - Upper portion of the Committee Referral Form
   - X-ray films - NOT results

3. Registration of all cases referred to the TBDC by the Secretariat.

4. Review / Correlation of documents for each case by the TBDC.

5. Presentation of film findings by the Radiologist.

6. Committee deliberation and consensus.
   - Diagnostic Flowcharts
   - Patient, if necessary

7. Committee’s final decision and instruction(s) to the RHU (Main HC).
   - Lower portion of the Committee Referral Form
   - Signature of Committee members

8. Implementation of Committee’s decision by the RHU (Main HC).

FREQUENCY of Meeting:
   At least 2x a month
ORGANIZING THE COMMITTEE

**PROCESS**

**CONCERNED STAFF**

**OUTPUTS**

<table>
<thead>
<tr>
<th>Initial Meeting</th>
<th>PHO / CHO NTP Coordinators, IDO-TB Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Preliminary Discussion)</td>
<td></td>
</tr>
</tbody>
</table>

- Comments
- Prospective Members
- Schedule of Briefing / Orientation

- Briefing / Orientation
- PHO / CHO NTP Coordinators, Prospective Members, IDO-TB Staff, WHO Staff / Representative
- Knowledge on the TBDC

- Solicitation of Membership
- PHO / CHO NTP Coordinators, Prospective Members, IDO-TB Staff, WHO Staff / Representative
- Solicitation Membership
- List of Members
- Agreement on Committee mechanics e.g. schedules of meetings, venue

**EVALUATION:**

3 - 6 Months after implementation with TB Partners, IDO, CHD

---

**Thank You**
WHAT ABOUT CHEST XRAYS?

- As proven by published literatures, there is no radiographic feature that correlates well with disease activity (*Recom Gr B*).

- A 30 year review of all published materials on this topic done by Dr. Anne Leung, a radiologist from Stanford University, confirmed this.

Highlights ....

- *Radiographic differentiation between active and inactive disease can only be reliably made on the basis of temporal evolution.*
  - fibrosis and calcification are features found in both healed and active disease; disease status based on their presence is unreliable

- Radiologic manifestations of PTB are dependent on several factors including prior exposure to TB, age, and underlying immune status.
Highlights ....

- Regression of radiographic abnormalities in PTB is a slow process ....
  - first 3 months of treatment: worsening
  - resolution of parenchymal abnormalities:
    - 6mos - 2yrs on CXR
    - up to 15 mos on chest CT
  - lymphadenopathy may persist for several years after treatment

Chest X-rays

- They still play a very important role in the overall management of PTB.

- Use of CXRs in PTB should be in the context of the NTP.

HOW DO WE KNOW IF OUR LAB IS ACCREDITED OR QUALIFIED?

- A TB microscopy proficiency certificate is provided to all labs who met the standard.
- Regular quality assurance checks are conducted.
- There are also provisions for re-training or refresher course in RITM if the lab fails in the regular monitoring activity.
WHERE CAN WE SEND LAB PERSONNEL TO GET CERTIFIED?

- There are current programs conducted at RITM and in Cebu (Vicente Sotto).
- This is a one week course.
- They charge a minimal fee but this is free for government microscopy centers.

WHERE ARE THE FACILITIES THAT OFFER M. TB CULTURE AND SENSITIVITY?

- RITM
- Lung Center of the Philippines
- San Lazaro
- PGH TB Lab
- UST
- Tropical Disease Foundation-MMC
- St. Lukes
- La Salle (Cavite)
- Cebu (Velez Hospital)

ARE THE ANTI-TB DRUGS FROM THE GOVERNMENT EFFECTIVE?

- Yes, they are effective. They pass rigid regulatory requirements as well as test for bioavailability before being released.
- They should be taken in the correct manner for the desired effect to be observed.
- Again, we emphasize DOTS once anti-TB meds are started.
CAN SPUTUM SMEAR(-) PATIENTS GET FREE ANTI-TB DRUGS?

- Yes, there are provisions for these cases.
- If you follow the algorithm, defined smear (-) cases can still get free meds as long as radiographically and clinically, diagnosis is compatible with PTB.
- A diagnostic committee is recommended to decide in these instances.

HOW CAN I APPLY DOTS IN MY PRIVATE PRACTICE?

- Be creative. The five components of DOTS can be started in your clinic as long as you have the proper manpower, resources, and space available.
- Network with other doctors.
- Begin collaboration with your government counterpart (PPM). **You will NOT lose your patients.**

HOW DO WE START COLLABORATION?

- Set up meetings to explore common interest in TB control. *(Leave all titles at the door)*
- Make sure that private practitioners and government physicians are present in these gatherings.
- Set objectives (short term and long range plans)
- A local coalition or diagnostic committee may be a good starting point for PPM
HOW DO I GET CERTIFIED?

- Attend a workshop on Basic DOTS for referring physicians ..... then pay PhP500 😊
PUBLIC-PRIVATE MIX (PPM) IN TB: WHAT, WHY & HOW

Charles Y. Yu, MD, MSc,FPCP,FPCCP
National Chairman, PHILCAT
Training & Certification Adviser, PhilTIPS
DLSU Professor of Medicine
Regent, Phil. College of Physicians

What countries have achieved in 2001

- Outstanding countries:
  DRC, India, Myanmar and Philippines

- Slow or no progress in other countries:
  - year 2001: year of preparation in many countries
  - year 2002: year of implementation (expect higher progress)

WHAT IS PPM?

- PPM stands for Public-Private Mix
- A relatively new concept in TB but has been seen in other initiatives
- Broadly defined as “any initiative or collaboration involving the private and public sector working towards TB control”
WHY PPM?

THE NEED FOR PRIVATE SECTOR INVOLVEMENT

1997 National Prevalence Survey (TB Symptomatics)

1997 NPS half of TB symptomatics do nothing, 70% do not seek professional help
Of those who do some action, 36% of TB patients consults PPs
Surveys show 30-60% of TB patients consult PPs
1997 NPS RESULTS

**Smear (+)s affect 20 - 59 years old**

**TB Symptomatics:**
- No action taken = 49.1%
- Self-medication = 24.3%
- Government Centers = 6.5%
- Private MDs = 9.6%
- Others = 10.5%

**TB Patients:**
- No action taken = 34.5%
- Self-medication = 22.4%
- Government Centers = 15.5%
- Private MDs = 10.4%
- Others = 17.2%

Why are TB cases “undetected”?

- Estimated TB cases
- All true TB cases
- Cases presenting to health facilities
- Cases presenting to public health facilities
- Cases presenting to DOTS facilities
- Cases correctly diagnosed by DOTS facilities
- Diagnosed cases reported by DOTS facilities

**Philippines: DOTS expanded country-wide in 5 years**

<table>
<thead>
<tr>
<th>Year</th>
<th>Population in Million</th>
<th>DOTS detection</th>
</tr>
</thead>
<tbody>
<tr>
<td>1996</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>1997</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>1998</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>1999</td>
<td>48</td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>73</td>
<td></td>
</tr>
<tr>
<td>2001</td>
<td>97</td>
<td></td>
</tr>
</tbody>
</table>
**Philippines: DOTS detection approaching targets, success rate exceeding targets**

- **1998**: 71% success rate, 20% DOTS detection
- **1999**: 87% success rate, 48% DOTS detection
- **2000**: 88% success rate, 57% DOTS detection
- **2001**: 90% success rate, 60% DOTS detection

---

**DOTS progress in 20 high TB burden countries 1999 - 2000**

- **TARGET ZONE**
  - Viet Nam
  - India
  - Indonesia

---

**NTP EVALUATION**

- Acknowledged the remarkable expansion and coverage of public sector DOTS
- Need to focus on quality-control as far as DOTS implementation is concerned
- Correct some problems in drug supplies
- Focus on promoting private-public mix (PPM) in DOTS implementation

*July 2003 NTP ext. evaluation highlights*
TB case load in the private sector, 2000

<table>
<thead>
<tr>
<th>Country</th>
<th>Retail Sales (USD Million)</th>
<th>Cost / Course (USD)</th>
<th>Estimated Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>85.3</td>
<td>100</td>
<td>853000</td>
</tr>
<tr>
<td>Indonesia</td>
<td>12.3</td>
<td>100</td>
<td>123000</td>
</tr>
<tr>
<td>Pakistan</td>
<td>11.7</td>
<td>100</td>
<td>117000</td>
</tr>
<tr>
<td>Philippines</td>
<td>16.6</td>
<td>200</td>
<td>83000</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>2.3</td>
<td>100</td>
<td>23000</td>
</tr>
</tbody>
</table>

Adapted from: The economics of TB drug development, 2001

NEED FOR PRIVATE SECTOR INVOLVEMENT

- As government reaches almost 100% coverage in the public sector, it is apparent that global and national targets of 70% detection rate cannot be reached without active involvement of the private sector
- The Philippines has a large private sector (for profit and non-profit)
- Private sector is a valuable resource available and widely utilized even by the lower income groups

SURVEY OF KAPs OF PRIVATE PRACTITIONERS

<table>
<thead>
<tr>
<th>Medicos del Mundo*</th>
<th>PhilCAT/CDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>2002</td>
</tr>
<tr>
<td>Total surveyed</td>
<td>1355</td>
</tr>
<tr>
<td>Area</td>
<td>nationwide</td>
</tr>
<tr>
<td>X-rays</td>
<td>87.9%</td>
</tr>
<tr>
<td>Sputum AFB</td>
<td>17.4</td>
</tr>
<tr>
<td>Treatment adherence</td>
<td>10.7</td>
</tr>
<tr>
<td>to NTP</td>
<td></td>
</tr>
<tr>
<td>Ave # new TB</td>
<td>5-10</td>
</tr>
<tr>
<td>pxs seen/month</td>
<td></td>
</tr>
<tr>
<td>Practice tx variations</td>
<td>64</td>
</tr>
</tbody>
</table>

*Portero JL and Rubio M. “Private practitioners and TB control in the Philippines: strangers when they meet?” In Press Trop Med and International Health

PHILIPPINES: PPM- DOTS MILESTONES

1968 NTP launched
1986 Strengthened NTP launched
24 June1994: Founding of PhilCAT
March 21,1999 Makati Med Center DOTS clinic launched
August 6,1995 UST launches first private DOTS clinic
July 2000 50% DOTS coverage
Oct.2001 PhilCAT-CDC DOTS models launched in 5 sites
March 2002 CCCAT Founded
July 2002 PhilICAT/DOH writes to GDF
GDF APPROVES PPM-DOTS DRUGS
Feb 2003 Global Fund approved
Feb14, 2003 Philhealth to launch TB OPD package, MOA signed with PhilCAT
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JICA starts DOTS 1993 in Cebu
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PPM DOTS
Case notification trend in a New Delhi PPM Model
WHAT IS DOTS?

FIVE COMPONENTS OF DOTS

- Government commitment to sustained TB control activities.
- Case detection by sputum smear microscopy among symptomatic patients self-reporting to health services.
- Standardized treatment regimen of 6–8 months for at least all confirmed sputum smear positive cases, with directly observed treatment (DOT) for at least the initial 2 months.
- A regular, uninterrupted supply of all essential antituberculosis drugs.
- A standardized recording and reporting system that allows assessment of treatment results for each patient and of the TB control program overall.

ATS Statement 2003
WHY DOTS?

Figure 3. Range and median of treatment completion rates by treatment strategy for pulmonary tuberculosis reported in 27 studies. DOT = Directly observed therapy; n = number of studies; Modified DOT = DOT given only for a portion of the treatment period, often while the patient was hospitalized; Enhanced DOT = individualized incentives and enablers were provided in addition to DOT. Reprinted by permission from Chaulk CP, Kazdanjian VA. Directly observed therapy for treatment completion of tuberculosis: consensus statement of the Public Health Tuberculosis Guidelines Panel. JAMA 1998;279:943–948.
### REVIEW OF CURRENT PHIL. PRIVATE DOTS INITIATIVES

<table>
<thead>
<tr>
<th>Initiative</th>
<th>All cases</th>
<th>New Sm (+) cases</th>
<th>Latest data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Success rate (cure/completion)</td>
<td>Success rate (cure/completion)</td>
<td>New sm +</td>
</tr>
<tr>
<td>UST TB Clinic 1995-2001</td>
<td>77.7%</td>
<td>81.5%</td>
<td>83.3%</td>
</tr>
<tr>
<td></td>
<td>26.2</td>
<td>68.5</td>
<td>83.3</td>
</tr>
<tr>
<td></td>
<td>n=336</td>
<td>n=92</td>
<td>n=12</td>
</tr>
<tr>
<td>Makati MedicalCenter Feb 99-Jan 2002</td>
<td>77.2%</td>
<td>82.6%</td>
<td>71.4%</td>
</tr>
<tr>
<td></td>
<td>35</td>
<td>81.1</td>
<td>57.1</td>
</tr>
<tr>
<td></td>
<td>n=429</td>
<td>n=132</td>
<td>n=5 Feb01-Jan03</td>
</tr>
<tr>
<td>PTSI-GSK Family DOTS</td>
<td>87.6% (Cure)</td>
<td>91.5%</td>
<td>71.4%</td>
</tr>
<tr>
<td></td>
<td>n=161*</td>
<td>n=132</td>
<td>n=7</td>
</tr>
<tr>
<td>Cavite DLSU DOTS May-Dec. 2002</td>
<td>67.6%</td>
<td>81.3%</td>
<td>71.4%</td>
</tr>
<tr>
<td></td>
<td>29.4</td>
<td>72.7%</td>
<td>71.4%</td>
</tr>
<tr>
<td></td>
<td>n=95</td>
<td>n=7</td>
<td>n=7</td>
</tr>
<tr>
<td></td>
<td>n=64</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Versus HC DOTS 95.7% n=93

### Dynamics of pulmonary TB in Peru 1980 - 2000

- **DOTS 1990**
  - Case finding
  - PTB falling at 6%/yr
**HOW CAN WE BUILD PPM-DOTS?**

**PPM structure**

- **Steward:** NTP
  - regional or local

- **PPM DOTS agency:** Local level

- **Steering committee:** NTP, PPs, health authority, academia

- **MoU**

- **Agreements**
  - PP

**DOTS Centre**

- **Type I**
- **Type II**
**Process: Steps to Establish PPMD**

1. Central workshop
2. Initial publicity
3. DOTS symposium
4. DOTS training workshop
5. Meeting for MOU
6. Launching
7. Preparatory visit by central team
8. Steering Committee or local coalition entity

**DOTS Matrix**

<table>
<thead>
<tr>
<th>Political Commitment</th>
<th>Clinical assessment</th>
<th>Smear Exam</th>
<th>X-ray Exam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis:</td>
<td>Case findings</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>DOT</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient follow up, sputum follow up, proper transfer out</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Defaulter tracing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case management</td>
<td>Clinical assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>DOT</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient follow up, sputum follow up, proper transfer out</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Defaulter tracing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug</td>
<td>NTP registry</td>
<td>NTP treatment card</td>
<td>Lab registry</td>
</tr>
<tr>
<td>Recording &amp;</td>
<td>NTP registry</td>
<td>NTP treatment card</td>
<td>Lab registry</td>
</tr>
<tr>
<td>Reporting &amp;</td>
<td>monitoring</td>
<td>Quarterly report</td>
<td></td>
</tr>
<tr>
<td>Monitoring</td>
<td>monitoring</td>
<td>Quarterly report</td>
<td></td>
</tr>
</tbody>
</table>

**Work Matrix for DOTS Implementation**

**CAVITE MODEL**

<table>
<thead>
<tr>
<th>DOTS component</th>
<th>RHUs</th>
<th>DOH</th>
<th>MDs</th>
<th>Company</th>
<th>Faith-based</th>
<th>LGUs</th>
<th>Volunteers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Political Commitment</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Referral of TB suspect</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Supply of Anti-TB drugs</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Case Finding by Microscopy</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Treatment Partner (DOT)</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Notification</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Reporting of Tx Outcome</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
Cavite Public-Private Referral System

Clinical TB Suspect

Private Sector

Public Sector

DOTS

Accredited Microscopy Centers

Smear (+)

Smear (-)

Private DOTS Center

Cavite TB Diagnostic Committee

Cavite Public-Private Referral System

PHILIPPINE DOTS CENTERS

- Hospital-based
- Clinic-based
- Workplace-based
- School-based?
- Pharmacy-based
- Single practice (franchise?)
- Church-based

• Family-based
• HMO-based

PhilCAT - CDC

Phil. TIPS

PhilCAT (CCAT)
PHILIPPINES DOTS MODELS/CENTERS

- UST DOTS CLINIC (1995)*
- MAKATI MEDICAL CENTER DOTS CENTER (1999) → DOTS PLUS*
- UNILAB DOTS CENTER* (1999)
- DLSU DOTS CENTER* (2002)
- MANILA DOCTORS DOTS CENTER (2002)
- QI DOTS CENTER
- LUNG CENTER OF THE PHIL. DOTS CENTER
- ST. PAULS DOTS CENTER, ILOILO
- FRIENDLY CARE, CUBAO*
- CENTER FOR TB IN CHILDREN

COLLABORATIVE MODELS: PPM

From: Uplekar, Lonnroth
We are here

dots started here

Quality DOTS in the public sector

Public-private mix DOTS

Private-public mix DOTS

DOTS referring physician

Trainers

Certifiers

Diagnostic Committee

TB CONTROL: Toward a TB-Free Philippines

KAYANG-KAYA KUNG SAMA-SAMA

MABUHAY AT MARAMING SALAMAT PO
**Comprehensive and Unified Policy for TB Control**

- Commissioned by Department Order of Secretary Of Health in February 2002
- Series of stakeholder meetings held; MOA signing on World TB Day (March 24) 2002
- Policy Document completed, introduced to public by Sec. Dayrit in August 2002
- Circulated to stakeholders for approval

---

**Comprehensive and Unified Policy for TB Control**

- Conference on February 26, 2003 to finalize document
- Ratification by representatives of stakeholder organizations at TB Summit March 7, 2003
- Dissemination period of 1 year before implementation
- Review after 2 years of implementation

---

**Comprehensive and Unified Policy for TB Control**

**Contents**

I. National TB Program (Core Policy)

II. Guidelines for Implementation of NTP by Private Physicians and Health Facilities

III. Guidelines for Implementation of NTP in Government Agencies

IV. SSS, GSIS and ECC TB Benefits Policies

V. PHIC TB Outpatient Benefits Package
National TB Program

- Core policy of Comprehensive and Unified Policy
- Embodies the Directly Observed Treatment, Short-course (DOTS) strategy of WHO

5 Elements of DOTS in NTP

1. Political Commitment
2. Diagnosis by Microscopy (clear standardized case definitions)
3. Direct Observation of Treatment (standardized treatment regimens)
4. Guaranteed Drug Supply
5. Recording and Reporting (standardized books and forms)

Guidelines for Government Agencies

- For GA’s with own health system: adopt NTP for managing TB patients
- For GA’s without own health system: refer TB patients to nearest center qualified to provide DOTS
**Guidelines for Private Physicians and Health Facilities**

- Use standardized definitions, diagnostic criteria and treatment regimens of NTP
- Record and report as in NTP
- Asymptomatic Pulmonary TB
- Latent TB Infection

### Comparison of TB Benefits

<table>
<thead>
<tr>
<th>SSS</th>
<th>GSIS</th>
<th>ECC</th>
<th>PHIC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Previous Medical Requirements

<table>
<thead>
<tr>
<th>SSS</th>
<th>GSIS</th>
<th>ECC</th>
<th>PHIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous Medical Requirements</td>
<td>MD certificate, Chest x-ray</td>
<td>No previous Out-patient TB benefit package</td>
<td></td>
</tr>
</tbody>
</table>
### Comparison of TB Benefits

<table>
<thead>
<tr>
<th></th>
<th>SSS</th>
<th>GSIS</th>
<th>ECC</th>
<th>PHIC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Previous Medical Requirement</strong></td>
<td>MD certificate, Chest x-ray</td>
<td>MD certificate, Chest x-ray</td>
<td>No previous Out-patient TB benefit package</td>
<td></td>
</tr>
<tr>
<td><strong>New Medical Requirements</strong></td>
<td>MD report, Sputum Acid Fast Smear results, +/- CXR (Closer to criteria used in NTP)</td>
<td>TB as diagnosed in NTP</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Types of TB patients qualified</strong></td>
<td>All forms of TB</td>
<td>All except relapse, treatment failure, return after default</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Comparison of TB Benefits**

<table>
<thead>
<tr>
<th><strong>Type of Benefit</strong></th>
<th>SSS</th>
<th>GSIS</th>
<th>ECC</th>
<th>PHIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disability</td>
<td>Disability</td>
<td>Disability for SSS members plus medical expenses</td>
<td>Out-patient benefit package paid to accredited DOTS center</td>
<td></td>
</tr>
</tbody>
</table>
### Comparison of TB Benefits

<table>
<thead>
<tr>
<th>Type of Benefit</th>
<th>SSS</th>
<th>GSIS</th>
<th>ECC</th>
<th>PHIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extension of Benefit</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previously required MD cert. and CXR; now requires AF smear results and functional assessment</td>
<td>No extension</td>
<td>Out-patient benefit package paid to accredited DOTS center</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Summary

- **Comprehensive and Unified Policy** promotes standardization of TB management in the Philippines
  - Government and Private MDs & Organizations
    - Directly through implementing guidelines
    - Indirectly through compliance with SSS, GSIS, ECC, PHIC policies
- Will allow for identification of further policy gaps in TB control
PhilHealth’s

TB Package for DOTS Clinics

Fee for Service

- utilized by PHIC in reimbursement
- physician charges separately for each patient encounter or service rendered
- expenditures increase if more services are provided or a more expensive service is substituted for a less expensive one

Case Rate

- Flat fee paid for a client’s treatment based on their diagnosis and/or presenting problem
- For this fee, the provider covers all of the services the client requires
- Also known as bundled rate or flat fee-per case
Case Rate

Normal Spontaneous Delivery (NSD) Package:
- Hospitals
- Non-hospital facilities (Lying-in)
- Severe Acute Respiratory Syndrome (SARS) Package
- Directly Observed Treatment Shortcourse (DOTS) Package

TB-DOTS Package

Basis:
- Board Resolution Nos. 485 & 490 series of 2002
- PhilHealth Circular Nos. 17 & 19 series of 2003

Providers

- Outpatient Clinics duly accredited by PhilHealth
- Only Philippine Coalition Against Tuberculosis (PhilCAT) certified DOTS clinics may apply for accreditation
- PhilHealth to accredit physicians rendering services in DOTS clinics
Providers

DOTS facilities
- Hospital-based Clinics
- HMO Clinics
- LGU Health Units
- Factory Clinics
- Church-based Clinics
- School Clinics

Providers

PhilCAT- Certified DOTS Centers:
- Friendly Care - Cubao DOTS Clinic
- San Joaquin Pasig RHU DOTS Clinic
- Unilab DOTS Clinic Mandaluyong
- Makati Medical Center DOTS Clinic
- UST DOTS Clinic
- Las Pinas District Hospital DOTS Clinic
- de la Salle University DOTS Clinic

TB-DOTS Package

- Case rate payment
- Flat rate of Php 4,000 shall be paid to facility
- For this fee, provider to cover the ff:
  - Diagnostic work-up
  - Consultation services
  - Anti-TB drugs
**TB-DOTS Package**

- Released in 2 payments:
  - 2,500 after 2nd month of treatment (Intensive Phase)
  - 1,500 after the completion of treatment (Maintenance Phase)

**TB-DOTS Package**

- Fee includes payment to:
  - Physicians
  - Other healthcare workers
  - Referral centers
  - Additional services rendered
  - Extension of treatment

**TB-DOTS Package**

**COVERAGE**

- All members of the NHIP and all qualified dependents who satisfy the criteria of benefit eligibility and are not disqualified by the exclusion criteria
**TB-DOTS Package**

**CRITERIA FOR ELIGIBILITY**

- New cases of smear positive/negative pulmonary TB
- New cases of extrapulmonary TB
- TB disease in children

**TB-DOTS Package**

**EXCLUSION**

TB-DOTS Package will not cover the following types of TB cases:

- **Failure cases** *(previous treatment, not on current treatment)*
- Relapse
- Return after default (RAD)

**TB-DOTS Package**

**CRITERIA FOR ELIGIBILITY**

For employed and Individually Paying Program (IPP) members:

3 months contribution paid within the immediate 6 months prior to enrollment at DOTS centers
TB-DOTS Package

CRITERIA FOR ELIGIBILITY

For Sponsored (Indigent), Pensioners & OFW’s:

Eligibility shall start within the date of effectivity of membership as stated in the ID card/ Eligibility certificate

Effectivity Date

All DOTS care where the date of treatment* of the intensive phase is on or after May 21, 2003

* The end of the intensive phase shall be considered as the date of treatment

Effectivity Date

Therefore:

Intensive Phase started 2 months prior to accreditation is still covered by the package.
**Reimbursement Process**

1. Submission of NTP Treatment Card or Registration to TB MIS 60 days from patients’ enrolment to the program
2. PhilHealth Form submitted with a copy of NTP Treatment Card within 60 days from completion of each treatment phase
3. Payment of providers to be made within 60 days

**Timeline**

<table>
<thead>
<tr>
<th>MAR</th>
<th>APR</th>
<th>MAY</th>
<th>JUN</th>
<th>JUL</th>
<th>AUG</th>
<th>SEP</th>
<th>OCT</th>
<th>NOV</th>
<th>DEC</th>
<th>JAN</th>
<th>FEB</th>
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<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

- Intensive
- Effectivity
- Filing
- Payment!
- Maintenance
- Filing
- Payment!

**Reimbursement Process**

- All claims application are covered by the rule on ICD-10 requirement by the Corporation
- Claims with incomplete requirements shall be returned to the facility and must be complied within 60 days
- Non-compliance shall cause denial of claim
<table>
<thead>
<tr>
<th>ICD-10 CODE</th>
<th>CONDITIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z20.1</td>
<td>Pulmonary Tuberculosis [PTB] Class 1</td>
</tr>
<tr>
<td>A15.0</td>
<td>Pulmonary Tuberculosis [PTB] Class 2,3,5 by sputum confirmation</td>
</tr>
<tr>
<td>A16.2</td>
<td>Pulmonary Tuberculosis [PTB] Class 2,3,5 by x-ray confirmation</td>
</tr>
<tr>
<td>Z03.0</td>
<td>Pulmonary Tuberculosis Class 4</td>
</tr>
</tbody>
</table>
FUTURE DIRECTIONS

FUTURE STEPS

- Basic DOTS training for referring physicians
- DOTS provider training
- DOTS certification training

PHILHEALTH CERTIFIED DOTS CENTER

- Large clear sign bearing the name of the clinic with “Philcat-Philhealth Accredited DOTS Center”
- Clean and attractive environment
- Well-ventilated area with sufficient seating for patients
- Adequate lighting
- Sputum collection area w/ appropriate ventilation
- Covered water supply for handwashing/toilets
- Covered garbage containers
- Examination room with privacy
- Examination room with linen
- Cleaning supply for the facility/clinical instruments
PHILHEALTH CERTIFIED DOTS CENTER

- Storage area for TB drugs with adequate buffer stock for registered and targeted patients
- Microscopy or access to accredited microscopy center (certificate of NTP training)
- AFB reagents/supplies

FORMS AND DOCUMENTS

- NTP forms and logbooks
- Forms showing flow-chart of procedures upon patient entry
- Written policy or procedures in the DOTS center (ICC, waste disposal, px/staff protection policy, defaulter tracing, drug inventory)
- Referral procedures (SOPs)

STAFFING/MANPOWER

- DOTS center administrator
- Physician (part time)
- Med tech (full time)
- Nurse/midwife (full time)
- Diagnostic committee member
- Person responsible for accounting
Target Audience. Physicians focusing mainly on general practitioners, family medicine, government physicians and some specialists.

Time allotment: 1 hour 30 min

Mechanics

Participants will be divided among the number of facilitators available, the ideal number is 10-15 participants per facilitator. If there are not enough facilitators, the workshop can be held in a plenary session.

Cases will then be presented one by one with emphasis on TB diagnosis and management based on the National TB Program (NTP) guidelines.

Needs

Overhead projector and a set of transparencies for each group. If projectors can’t be provided, participants could be provided printed copies of the cases for discussion.

Objectives

At the end of the session, the participants should be able to accomplish the following:

1. Diagnose and classify each case based on the NTP policy.
2. Prescribe the appropriate TB regimen based on the NTP policy.
3. Coordinate with other members of the health care system in the performance of other procedures such as sputum AFB smears, in the monitoring of treatment, and in facilitating patient referrals.
4. Prefer DOTS to other approaches in the management of TB patients.
Table 1A: Definition of Terms

<table>
<thead>
<tr>
<th>Location of Lesion</th>
<th>Sputum–Smear Examination</th>
<th>Definition of Terms</th>
</tr>
</thead>
</table>
| **Pulmonary TB (PTB)** | **Smear positive** | 1. A patient with at least two sputum specimens positive for AFB, with or without radiographic abnormalities consistent with active TB, **or**  
2. A patient with one sputum specimen positive for AFB and with radiographic abnormalities consistent with active TB as determined by a clinician, **or**  
3. A patient with one sputum specimen positive for AFB with sputum culture positive for M. tuberculosis |
| | **Smear negative** | A patient with at least three sputum specimens negative for AFB with radiographic abnormalities consistent with active TB, **and** there has been no response to a course of antibiotics and/or symptomatic medications, **and** there is a decision by a Medical Officer to treat the patient with anti-TB drugs. |
| **Extra-Pulmonary TB** | | 1. A patient with at least one mycobacterial smear / culture positive from an extra-pulmonary site (organs other than the lungs: pleura, lymph nodes, genito-urinary tract, skin, joints and bones, meninges, intestines, peritoneum and pericardium, among others), **or**  
2. A patient with histological and / or clinical evidence consistent with active TB and there is a decision by a Medical Officer to treat the patient with anti-TB drugs. |
# Table 1B: Types of TB Cases

<table>
<thead>
<tr>
<th>Types of TB Cases</th>
<th>Definition of Terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>New</td>
<td>A patient who has never had treatment for TB or who has taken anti-tuberculosis drugs for less than one month.</td>
</tr>
<tr>
<td>Relapse</td>
<td>A patient previously treated for tuberculosis who has been declared cured or treatment completed, and is diagnosed with bacteriologically positive (smear or culture) tuberculosis.</td>
</tr>
<tr>
<td>Failure</td>
<td>A patient who, while on treatment, is sputum smear positive at five months or later during the course of treatment.</td>
</tr>
<tr>
<td>Return after Default (RAD)</td>
<td>A patient who returns to treatment with positive bacteriology (smear or culture), following interruption of treatment for two months or more.</td>
</tr>
<tr>
<td>Transfer-In</td>
<td>A patient who has been transferred from another facility with proper referral slip to continue treatment.</td>
</tr>
</tbody>
</table>
| Other              | All cases that do not fit into any of the above definitions  
This group includes:  
1. A patient who is starting treatment again after interrupting treatment for more than two months and has remained or became smear-negative.  
2. A sputum smear negative patient initially before starting treatment and became sputum smear-positive during the treatment.  
3. Chronic case: a patient who is sputum positive at the end of a retreatment regimen. |
<table>
<thead>
<tr>
<th>Regimen</th>
<th>TB Patient To Be Given Treatment</th>
<th>Drugs and Duration of Treatment *</th>
<th>Dose Adjustment by Body Weight</th>
</tr>
</thead>
</table>
| **Regimen I:**   | • New pulmonary smear (+) cases  
                    • New seriously ill pulmonary smear (-) cases with extensive parenchymal involvement  
                    • New severely ill extra-pulmonary TB cases                                                  | HRZE for two months during the **intensive phase**.  
                                                                                                 | Add one tablet of INH(100mg), PZA(500mg), and EB(400mg) each for the patient with more than 50kg body weight before the initiation of the treatment. |
| 2HRZE / 4HR      |                                                                                                 | HR for 4 months during the **maintenance phase**.  |                                                                                                 |
| **Regimen II:**  | • Failure cases  
                    • Relapse cases  
                    • RAD (smear +)  
                    • Other (smear +)                                                                 | HRZES for the first two months, then HRZE for the third month during the **intensive phase**.  
                                                                                                 | HRE for the next five months during the **maintenance phase**.                                   |
| 2HRZES/1HREZ / 5HRE |                                                                                                 |                                                                                                 |                                                                                                 |
| **Regimen III:** | • New smear(-) but with minimal pulmonary TB on radiography as confirmed by a medical officer  
                    • New extra-pulmonary TB (not serious)                                                      | HRZ for 2 months during the **intensive phase**.  
                                                                                                 | Add one tablet of INH(100mg) PZA(500mg) each for the patient with more than 50 kg body weight before the initiation of the treatment. |
| 2HRZ / 4HR       |                                                                                                 | HR for 4 months during the **maintenance phase**.  |                                                                                                 |
EXERCISE

Now with that background, here are some exercises. Below are ten patients from the same area. Determine the classification (anatomic site and bacteriological result) and category (based on previous treatment) in which each patient belongs. Do so by filling up the table below. For now, ignore the last column. That will be tackled later.

Table 2: Patients and their Classification

<table>
<thead>
<tr>
<th>Patients</th>
<th>Classification of Case</th>
<th>Category</th>
<th>Treatment regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Anatomic site</td>
<td>Bacteriological results</td>
<td></td>
</tr>
<tr>
<td>1. Angel Bali, 40-year-old, male, security guard, consulted you for cough for one month, loss of appetite and weight loss. The rest of the history unremarkable. No previous illnesses or medications taken. Physical examination was normal. Based on your impression of TB, you requested for AFB sputum smear. Two of the three turned out 2+ while the third was negative.</td>
<td>P</td>
<td>Smear (+)</td>
<td>New</td>
</tr>
<tr>
<td>2. Carla Xavier, 26-year-old, female, employee consulted you for cough. She has been having productive cough for two months now and back pain for the past three weeks. Sputum exams done last week in a local hospital were all negative. She was prescribed antibiotics but did not improve. The patient’s sister was treated for PTB a year ago. You ordered a chest x-ray, which showed right upper lung field infiltrates.</td>
<td>P</td>
<td>Smear (-)</td>
<td>New</td>
</tr>
<tr>
<td>3. Andres Floro, 34-year-old, male, an AFB smear positive patient who is currently on his sixth month of treatment. Follow up smear turned out to be 2+.</td>
<td>P</td>
<td>Smear (+)</td>
<td>Failure</td>
</tr>
<tr>
<td>5. Ramona Reyes, 42-year-old, female, former resident of Cebu, was diagnosed to have smear positive PTB and is on her third week of treatment. She moved to Cavite to live with her son. An NTP referral was given to the center near her residence.</td>
<td>P</td>
<td>Smear (+)</td>
<td>Transfer in</td>
</tr>
</tbody>
</table>
### Classification of Case

<table>
<thead>
<tr>
<th>Patients</th>
<th>Anatomic site</th>
<th>Bacteriologic results</th>
<th>Category</th>
<th>Treatment regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Ignacio Lorenzo, 56-year-old, male, is a sputum positive PTB patient. On his second month of treatment, he went to Palawan and did not continue treatment there. He returned after five months. Sputum smear done on his return was 2+.</td>
<td>P</td>
<td>Smear (+)</td>
<td>Return after default</td>
<td>II</td>
</tr>
<tr>
<td>7. Rino Romero, 22-year-old, male is a new smear negative PTB patient. On his second month of treatment, sputum smear was 2+.</td>
<td>P</td>
<td>Smear (+)</td>
<td>Others [#2]</td>
<td>II</td>
</tr>
<tr>
<td>8. Jose Reyes, 42-year-old male, had cough with scant sputum and weight loss for three months. Sputum exam showed the following results: 2+, 3+, 2+.</td>
<td>P</td>
<td>Smear (+)</td>
<td>New</td>
<td>I</td>
</tr>
<tr>
<td>9. Pedro Abuel, 40-year-old, male, unemployed, was diagnosed to have sputum positive PTB.</td>
<td>P</td>
<td>Smear (+)</td>
<td>New</td>
<td>I</td>
</tr>
<tr>
<td>10. Mercy Pastor, 33-year-old, teacher, consulted for night sweats and cough. She also had weight loss of 5 kg in 3 months. Chest x-ray showed bilateral apical infiltrates. However, all of the three sputum specimens were negative.</td>
<td>P</td>
<td>Smear (-)</td>
<td>New</td>
<td>I</td>
</tr>
</tbody>
</table>
COMPUTING FOR TREATMENT OUTCOMES

These rates give us an idea of how successful we have been in achieving cure or at least completion of treatment. These are computed as shown:

a. Cure
   \[ \frac{\text{No. of new Sm (+) who completed treatment with sm (-) at the last month of treatment and at least one on previous occasion}}{\text{Total No. of new smear (+) cases admitted to treatment}} \times 100\% \]

b. Completed treatment
   \[ \frac{\text{No. of new Sm (+) who completed treatment with only 1 sm (-) result during treatment or no sputum follow-up exam}}{\text{Total No. of new smear (+) cases admitted to treatment}} \times 100\% \]

c. Died
   \[ \frac{\text{No. of new sm (+) who died during treatment}}{\text{Total No. of new smear (+) cases admitted to treatment}} \times 100\% \]

d. Treatment failure
   \[ \frac{\text{No. of new sm (+) who is positive at 5\textsuperscript{th} at least one occasion or more}}{\text{Total No. of new smear (+) cases admitted to treatment}} \times 100\% \]

e. Default
   \[ \frac{\text{No. of new sm (+) who interrupted treatment for > 2 months}}{\text{Total No. of new smear (+) cases admitted to treatment}} \times 100\% \]
Table 3: Schedule of sputum smear examination follow up

<table>
<thead>
<tr>
<th>Months of Treatment completed</th>
<th>I (2HRZE/4HR)</th>
<th>II (2HRZES/1HRZE/5HRE)</th>
<th>III (2HRZ/4HR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
<td>(-)</td>
<td>(+)</td>
</tr>
<tr>
<td>3</td>
<td>(-)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>(-)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>(-)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>(*)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>(*)</td>
<td>(*)</td>
<td>(*)</td>
</tr>
<tr>
<td>8</td>
<td>(*)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>(*)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Examined in the beginning of the month

Table 4: Comparison between DOTS and Non-DOTS

<table>
<thead>
<tr>
<th>ASPECTS</th>
<th>Non-DOTS</th>
<th>DOTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>TECHNICAL ASPECTS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case finding and diagnosis</td>
<td>Depends on unreliable, often expensive methods:</td>
<td>Depends on simple, cost-effective and reliable method:</td>
</tr>
<tr>
<td></td>
<td>- X-ray</td>
<td>- 3 sputum examinations for all infectious cases</td>
</tr>
<tr>
<td></td>
<td>- Symptomatic-based diagnosis</td>
<td>- Limited use of x-ray for specific cases</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Tightly defined symptomatic diagnosis</td>
</tr>
<tr>
<td>Patient classification / categorization</td>
<td>Often weak. As a result, the type, degree of infectiousness and treatment category are not well determined</td>
<td>Strong, ensuring the following are determined</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Anatomic site</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Bacteriological result</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Treatment category</td>
</tr>
<tr>
<td>Treatment</td>
<td>Individualized, often inappropriate or inadequate regimens for each patient</td>
<td>Standardized proven regimens for each case type</td>
</tr>
<tr>
<td></td>
<td>- No DOT</td>
<td>- DOT by a suitable trained person</td>
</tr>
<tr>
<td></td>
<td>- Little patient counseling</td>
<td>- Patient counseling</td>
</tr>
<tr>
<td></td>
<td>- Often centralized, specialized TB services to which patients have limited access</td>
<td>- Drugs may be taken daily or three times a week</td>
</tr>
<tr>
<td></td>
<td>- No structure – no flexibility or adherence to specific patient needs</td>
<td>- Flexibility - Treatment can be administered at health facility, patient’s home, or community center</td>
</tr>
<tr>
<td>Progress toward cure</td>
<td>Information by individual sometimes available but often not analyzed</td>
<td>Information recorded by individual</td>
</tr>
<tr>
<td></td>
<td>- Information by cohort almost never available</td>
<td>- Aggregate data by cohort always available</td>
</tr>
<tr>
<td>Treatment follow-up</td>
<td>Either not done at all or is unsystematic</td>
<td>Systematic</td>
</tr>
<tr>
<td></td>
<td>- Findings not acted upon</td>
<td>- Based on sputum smear microscopy</td>
</tr>
<tr>
<td></td>
<td>- Often x-ray based</td>
<td>- Findings acted upon to</td>
</tr>
<tr>
<td>ASPECTS</td>
<td>Non-DOTS</td>
<td>DOTS</td>
</tr>
<tr>
<td>---------</td>
<td>----------</td>
<td>------</td>
</tr>
<tr>
<td><strong>Main indicator</strong></td>
<td>is patient adherence</td>
<td>achieve cure</td>
</tr>
<tr>
<td><strong>Often no record</strong></td>
<td>of patients’ whereabouts</td>
<td><strong>Main indicator</strong> is patient outcome</td>
</tr>
<tr>
<td><strong>Achieve cure</strong></td>
<td></td>
<td><strong>Location of patient is kept in the register</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Results</th>
<th>Non-DOTS</th>
<th>DOTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Low treatment success</strong></td>
<td></td>
<td><strong>High sputum smear conversion rate</strong></td>
</tr>
<tr>
<td><strong>Unreliable outcome information</strong></td>
<td></td>
<td><strong>High cure rates</strong></td>
</tr>
<tr>
<td><strong>Increasing drug resistance</strong></td>
<td></td>
<td><strong>Decreased prevalence of chronic cases</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Decreased transmission of infection</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Prevention of drug resistance</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LOGISTICAL ASPECTS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug supply</strong></td>
<td></td>
</tr>
<tr>
<td>Often irregular</td>
<td>Regular, reliable supply</td>
</tr>
<tr>
<td>Often quality of drugs questionable</td>
<td>Can forecast supply for following year</td>
</tr>
<tr>
<td></td>
<td>Better quality assurance of drugs</td>
</tr>
<tr>
<td><strong>Laboratory</strong></td>
<td></td>
</tr>
<tr>
<td>Accuracy of results or adherence to safety guidelines not ensured</td>
<td>Guidelines ensure systematic, standardized practices</td>
</tr>
<tr>
<td>Lab registers often not standardized</td>
<td>Quality control, safety</td>
</tr>
<tr>
<td><strong>TB register</strong></td>
<td></td>
</tr>
<tr>
<td>May exist at national or provincial level consisting of:</td>
<td>Always exists, which permits systematic analysis of:</td>
</tr>
<tr>
<td>Variable patient information</td>
<td>Patients starting treatment</td>
</tr>
<tr>
<td>Unsystematic recording of information on type of case, progress and results</td>
<td>Progress toward cure</td>
</tr>
<tr>
<td></td>
<td>Methodical monitoring</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>POLITICAL ASPECTS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Political commitment</strong></td>
<td></td>
</tr>
<tr>
<td>Often not addressed</td>
<td>Policy of financial support</td>
</tr>
<tr>
<td>Communication activities focused mainly on patients, ignoring the policy-makers</td>
<td>Advocacy and social mobilization</td>
</tr>
</tbody>
</table>

Summary Of Pilot Workshop in Iloilo (August 8, 2003)

Around 40 specialists (infectious disease and pulmonary medicine) attended the pilot testing of the workshop on Basics DOTS for Referring Physicians. All the lecture topics received favorable feedback from the participants and each session was followed by a healthy exchange of opinion and inquiries that were adequately addressed. As the session went on, the objectives of the workshop and need for the doctors’ participation became increasingly clearer for the delegates. The interactive session in the afternoon served as a perfect complement to the didactic sessions. Cases were adequately dissected and concerns from all delegates were given due attention. The summary at the end of the workshop served to put proper direction to the tasks ahead and opportunities for those who finished the workshop.

Key Learning Points and Recommendations

- Importance of conducting an orientation session for all organizers and lecturers.
- Pay detailed attention to the venue and facilities available. Ask yourself: Will it meet the needs of the workshop considering the number of participants?
- Close coordination with a local society or organization is crucial to ensure good participation from the doctors.
- Observe time lines for each lecture and activity.
- Balance the overall conduct of the activity—lectures with interactive sessions and breaks are a good combination.
- Make sure to have clear objectives at the start and wrap up in the end by answering these initial aims. In this way, the participants will be more focused and will not feel “lost” in the end.
- A concise and complete manual to complement the lecture sessions is critical.

During the PCCP and PhilCAT Convention
August 18, 2003 Century Park Hotel

Registration:

Overall Comments:

From a recommended 80 delegates which subsequently went up to an agreed number of 120, there were at least 150 delegates who were present. Out of this number, 122 doctors submitted their evaluation forms and 95 got training certificates and paid certification fees.

The whole process of registration was relatively difficult to control because of the sheer number of doctors compared to 2-3 persons assigned to the registration process. There was no problem for those who pre-registered. However, some confusion came about when on-site registrants were vying for the limited slots. Some order was established as the session was about to begin.
Recommendations:
- Communicate the workshop effectively during publicity. Emphasize for whom it is intended and that pre-registration is a must.
- Limit the number of participants with due consideration of the physical and manpower resources available.
- Establish ground rules to participants even during publicity/prior communications.
- Increase number of personnel handling the registration process.
- The decision of the course coordinator should be final to avoid confusion.

Lecture Sessions

1. Contents and Delivery
   Overall Comments:
   The contents of each lecture was very appropriate considering the objectives of the workshop and their relationships with other didactic sessions. Overall, the delivery was quite smooth and time allotment was managed well. The healthy discussion that followed each topic can very well attest to this observation.

Recommendations:
- Orientation of all speakers as to their topics, overall flow of the workshop, and time assignment helped tremendously.
- A session on objective and introduction to the workshop and summary at the end were crucial.

2. Resource Speakers
   Overall Comments:
   The speakers were very qualified to give the lectures. It helped a lot that they were respected by the medical community and were comfortable with the assigned topics. Dr. Mads Valera was present during the PhilHealth session. Although she did not deliver the lecture, the participants appreciated her inputs and answers to their queries after that session.

Recommendations:
- For a PhilHealth authority to be present during this session if this topic will be tackled.
- For doctors from DOH to be the one to deliver the lecture on NTP highlights.
- Flexible time for open forum sessions to adequately pacify doctors’ concerns.
**Interactive Session**

*Overall Comments:*
We have decided not to proceed with the breakout sessions after careful consideration of the following factors: huge number of participants, only six facilitators available, no available breakout rooms, and poor acoustics of the venue. The “interactive” part was not compromised as we asked the participants to review the ten cases and answer them in a plenary session. Issues and concerns were answered by the facilitators who acted as panelists.

*Recommendations:*
- To have a facilitator for each 10-12 participants so that individual issues can be personally addressed.
- For the selected venue to have adequate breakout facilities. Overhead projector or flipchart should be provided per group.
- Ten cases are quite appropriate considering the allotted time. The cases should just have a range from relatively “simple” to harder ones. Be as close as possible to actual cases as seen by these practitioners.
- Definitely, prior orientation of all facilitators as to the overall conduct of this session helped a lot.

**Venue:**

*Overall Comments:*
The chosen venue was very small considering the number of participants. Furthermore, the facilities needed for the breakout sessions were lacking and the acoustic was quite dismal. Services were in general unsatisfactory.

*Recommendations:*
- A visual inspection is necessary and critical.
- A “simulation” of the overall process should be conducted in the suggested venue so that potential concerns in terms of the physical set-up can be seen and addressed.
Overall Feedback

Using the scale: 1 = very satisfactory
2 = satisfactory
3 = fair
4 = needs improvement

<table>
<thead>
<tr>
<th>Activity</th>
<th>Content Covered</th>
<th>Effectivity of Resource Person/s</th>
<th>Appropriateness of Strategy/ies Used</th>
<th>Overall Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orientation</td>
<td>1.63</td>
<td>1.56</td>
<td>1.59</td>
<td>1.59</td>
</tr>
<tr>
<td>Overview of TB: Epidemiology, Burden of Illness</td>
<td>1.33</td>
<td>1.33</td>
<td>1.27</td>
<td>1.31</td>
</tr>
<tr>
<td>National TB Core Policy and Overview of Diagnostic Committee</td>
<td>1.36</td>
<td>1.33</td>
<td>1.54</td>
<td>1.41</td>
</tr>
<tr>
<td>Q &amp; A</td>
<td>1.49</td>
<td>1.45</td>
<td>1.47</td>
<td>1.47</td>
</tr>
<tr>
<td>Frequently Asked Questions</td>
<td>1.48</td>
<td>1.43</td>
<td>1.51</td>
<td>1.47</td>
</tr>
<tr>
<td>PPM-DOTS: What, Why and How?</td>
<td>1.5</td>
<td>1.46</td>
<td>1.5</td>
<td>1.48</td>
</tr>
<tr>
<td>Q &amp; A</td>
<td>1.49</td>
<td>1.41</td>
<td>1.46</td>
<td>1.45</td>
</tr>
<tr>
<td>Overview of the PhilHealth Outpatient TB Package</td>
<td>1.64</td>
<td>1.55</td>
<td>1.61</td>
<td>1.6</td>
</tr>
<tr>
<td>Q &amp; A</td>
<td>1.49</td>
<td>1.45</td>
<td>1.46</td>
<td>1.47</td>
</tr>
</tbody>
</table>
ANNEX 1: TB DIAGNOSTIC COMMITTEE

RATIONALE

About 60% of the total reported TB cases in the country under the National TB Control Program (NTP) were diagnosed as having TB using x-ray examination. There are regions where this proportion was as high as 70% - 80%. Given the situation in many areas of the Philippines, there is a problem in the accuracy of diagnosis of TB using x-ray. Oftentimes, there is over-reading. A study of Dr. Pierre Chaulet in the three pilot areas of C.R.U.S.H. TB Project in 1997 showed that only 25% of cases diagnosed through x-ray have findings suggestive of TB. The rest have suspicious shadows only (26%) or without any evidence of TB (39%). This situation leads to waste of resources (drugs and manpower) and subjecting the patient to psychological burden and unnecessary toxicity of the drugs. To tackle this problem there is a need for a mechanism to ensure those initially diagnosed with TB through x-ray are re-assessed. It with this perspective that a TB Diagnostic Committee will be organized in selected DOTS implementing areas.

GENERAL OBJECTIVE

• To improve the quality of TB diagnosis.

SPECIFIC OBJECTIVES

1. Reduce the number of misdiagnosed TB cases among the smear negatives.
2. Provide judicious TB chemotherapy to the diagnosed smear negative cases.

TARGET

• Proportion of Smear (-) cases less than 40%.

STRATEGY

• Organization of a TB Diagnostic Committee

FUNCTIONS OF THE COMMITTEE

1. Review the documents of:
   1.1. Smear (-) Tb symptomatics who underwent chest x-ray examination.
   1.2. Referred patients initially claimed as having TB through x-ray examination.
2. Decide whether or not the patient has active tuberculosis which requires medication.
Composition and Roles of the Committee Members

Provincial / City TB Diagnostic Committee

1. **Provincial / City NTP Medical Coordinator**
   1.1. Organizes the Committee.
   1.2. Convenes the Committee regularly.
   1.3. Ensures appropriate action on the Committee decisions.

2. **Radiologist**
   2.1. Reviews the referred x-ray films together with the other Committee members.
   2.2. Provides a radiologic analysis that can serve as one of the bases for diagnosis and treatment.

3. **Clinician / Internist / Pulmonologist**
   3.1. Provides a clinical perspective of cases to correlate with the radiologic analysis.
   3.2. Recommends further laboratory work-ups or management of non-tuberculosis cases.

4. **Provincial / City NTP Nurse Coordinator**
   4.1. Consolidates the necessary documents of cases referred prior to each meeting.
   4.2. Acts as Secretariat
   4.3. Responsible for follow-up of cases referred back to the RHUs.

District TB Diagnostic Committee *(Optional)*

A District TB Diagnostic Committee may also be established to decentralize the activities of its Provincial counterpart. Likewise, this level of the Committee could unload the bulk of films which would be referred to the Province.

1. **District NTP Medical Coordinator**
   1.1. Organizes the Committee.
   1.2. Convenes the Committee regularly.
   1.3. Ensures appropriate action on the Committee decisions.

2. **Radiologist (Government or Private)**
   2.1. Reviews the referred x-ray films together with the other Committee members.
   2.2. Provides a radiologic analysis that can serve as one of the bases for diagnosis and treatment.

3. **Chief of District Hospital or Senior Resident Physician**
   3.1. Provides the venue for the meeting.
   3.2. May provide a clinical perspective of cases to correlate with the radiologic analysis.
3.3. Recommends further laboratory work-ups or management of non-tuberculosis cases.

4. **District Chief Nurse**

4.1. Consolidates the necessary documents of cases referred prior to each meeting.
4.2. Acts as Secretariat.
4.3. Responsible for follow-up of cases referred back to the RHUs.

5. **Municipal Health Officer or RHU Physician (OPTIONAL)**

5.1. Provides additional information of cases if required with the Committee.

6. **Clinician / Internist / Pulmonologist (Private, OPTIONAL)**

6.1. Provides a clinical perspective of cases to correlate with the radiologic diagnosis.
6.2. Recommends further laboratory work-ups or management of non-tuberculosis cases.

**Mechanics**

1. The RHU (*Main HC*) will select those Smear (-) TB Symptomatics who underwent X-ray examination and those referred patients initially claimed as having TB through X-ray examination. The RHU will see to it that x-ray films are the ones available and not merely the result; otherwise, the patient will undergo the process similar as to those without X-ray films.

2. The RHU will fill-up the Upper portion of the Committee Referral Form containing the patient’s history and sputum results. The completed form and x-ray films will be submitted to the Committee.

3. The Secretariat will register all the referrals to the Committee into the TB Diagnostic Committee Masterlist.

4. The Committee will review and correlate the documents of each case referred.

5. The Radiologist will read each film and will present findings.

6. The Committee will deliberate and arrive at a consensus based on the Diagnostic Flowchart. If the Committee feels the need to see the patient, then the patient will be invited to the next Committee meeting.

7. The Committee will complete and sign the Lower portion of the Committee Referral Form containing the final decision and instruction(s) to the RHU (*Main HC*) concerned.

8. The filled-up Committee Referral Form will be sent back to the referring RHU (*Main HC*) for implementation of the decision. The RHU (*Main HC*) will keep the form.
**Frequency of Meeting**

At least twice a month.

**Dissemination**

Local government units will be informed about this activity through a letter from the Provincial / City Health Office. Health Workers will be informed during their consultative meeting with the Provincial / City NTP Coordinators.

**Organization of the Committee**

1. An initial meeting will be convened to discuss the proposal. Participants will include PHO / CHO (or Representative) and NTP Coordinators (Regional, Provincial / City). TBCS and / or WHO Staff (Representative) will explain the rationale, diagnostic flowcharts (*please refer to attached Diagrams*) and other operational details of the Committee for comments and recommendations.

2. The NTP Coordinators (Provincial / City), in consultation with the PHO / CHO, will invite prospective members of the Committee for a briefing / orientation. TBCS and WHO Staff (Representative) will be enjoined to participate.

3. Solicitation of membership will be initiated by the Provincial / City NTP Coordinators with the supervision from the PHO / CHO.

4. A copy of the final list of members will be provided to the TBCS.

**Evaluation of Committee Activities**

An initial evaluation of Committee activities, in collaboration with RHO, TBCS and WHO, may be conducted 3 to 6 months after implementation.
Annex II
The association between tuberculosis (TB) and man predates written history (1). Aristotle is usually credited as being the first to recognize the contagious nature of the disease (2). Discovery of the specific infectious agent, the tubercle bacillus (*Mycobacterium tuberculosis*), did not occur for several more centuries until it was isolated by Robert Koch in 1882. The discoveries of streptomycin in 1944, paraamino salicylic acid in 1946, and isoniazid in 1952 led to the first effective cure for TB. Descriptions of airborne transmission of infection and of reactivation of dormant infection in the 1960s by Riley et al (3) and Stead and colleagues (4,5), respectively, furthered our understanding of the spread and pathogenesis of this disease.

On the basis of these past achievements, as we approach the new millennium, medical knowledge and technology have advanced to the point that TB can now be regarded as a treatable, preventable, and eradicable disease (6). However, largely because it has been neglected as a global public health issue for many years, TB remains the major cause of death from a single infectious agent among adults in developing nations. In 1993, the World Health Organization declared TB to be a global emergency (7). At current control levels, it is estimated that between 1997 and 2020, nearly 1 billion people will become newly infected and 70 million people will die from the disease (C. Dye, WHO, personal communication, 1998).

**Epidemiology**

Morbidity and mortality associated with TB are greatest in developing nations, where 95% of all cases and 98% of all deaths associated with TB occurred in 1990 (7). The highest prevalence and estimated annual risk of infection are found in Southeast Asia (rate, 237 per 100,000) and sub-Saharan Africa (rate, 191 per 100,000) (7). Of the 3.3 million cases of TB notified to the World Health Organization in 1995, 78% were from Asia, sub-Saharan Africa, and island regions (8). By contrast, during these same time periods, industrialized countries (Western Europe, Australia, Canada, Japan, New Zealand, and United States) had an average annual incidence of 23 per 100,000 and accounted for only 4% of total notified cases (7,8).

Distinct differences in the epidemiology of TB are observed between developing and industrialized nations. In countries where the standard of living is low and health resources are scarce, the risk of recent infection is high and 80% of cases involve persons in their productive years (15–59 years of age) (7). In economically developed countries where progressive declines in the incidence of TB have been achieved, the annual risk of infection is low. The majority of TB cases arise as a result of endogenous reactivation of remote infection acquired when TB was more prevalent; this results in disease rates highest in the elderly (>65 years of age). Active disease manifesting in younger patients usually arises in racial and ethnic minorities or in association with human immunodeficiency virus (HIV) infection (7).

In the United States, a total of 21,337 cases of TB (rate, 8.0 per 100,000) were reported to the Centers for Disease Control and Prevention (CDC) in 1996, representing the lowest number and rate of reported TB cases since national reporting began in 1953 (9). This was the fourth consecutive year that the number of reported TB cases had declined and improvements in TB-prevention and TB-control programs that resulted directly from increased federal resources provided to the states in the early 1990s were credited with reversing the increasing trend observed from 1985 to 1992 (9). California, New York, Texas, Florida, and Illinois were the five states that reported the highest number of cases.

During 1996, the number of reported cases in the United States decreased in each age group and in all racial and ethnic groups. Rates continued to be highest among the elderly (rate, 15.1 per 100,000). Seventy-four percent of reported cases occurred among nonwhite
rational and ethnic groups. During the past decade, a steady increase in the percentage of cases affecting foreign-born persons has been observed—from 22% of total reported cases in 1986 to 37% in 1996 (9,10). Seven countries of origin (China, Haiti, India, Korea, Mexico, Philippines, and Vietnam) accounted for 66% of the foreign-born cases in 1996.

Global emergence of multidrug-resistant (MDR) strains of M tuberculosis in recent years has greatly complicated the management and control of transmission of active cases (11,12). Although relatively few drug resistance surveys have been conducted outside industrialized nations, areas reporting high rates of MDR TB include Nepal (48%); Gujarat, India (33.8%); Bolivia (15.3%); and Korea (14.5%) (12,13). In the United States, MDR TB accounted for 1.6% of all cases with susceptibility testing results (90% of total reported cases) reported to the CDC in 1996 (14). In this CDC survey, which extended from 1993 to 1996, MDR TB cases were documented from 42 states and the District of Columbia; New York City reported 38% of all cases. Risk factors associated with drug resistance included history of TB, foreign country of birth, and co-infection with HIV (14).

**PATHOGENESIS**

M tuberculosis, the infectious agent of TB, is a thin, slightly curved bacillus that is an obligate aerobe. In comparison to other bacteria, M tuberculosis has a cell wall with a very high lipid content that resists staining by the usual Gram method. However, it accepts basic fuchsin dyes and is not easily discolorized even with acid-alcohol; this resistance to decolorization by acid-alcohol is termed acid-fast. As this property is shared only by members of the mycobacterial family and a few other organisms (Nocardia, Rhodococcus, and Corrynebacterium species), it forms the basis for the simple, rapid, and relatively specific traditional technique of identification by means of an acid-fast smear (15).

M tuberculosis is transmitted via airborne droplet nuclei that are produced when persons with pulmonary or laryngeal TB cough, sneeze, speak, or sing (16). The particles, which measure 1–5 µm in size, can be kept airborne by normal air currents for prolonged periods of time, resulting in dispersion throughout a room or building. The presence of acid-fast bacilli in the sputum smear is the main indicator of potential for transmission (17); other source patient characteristics that increase the probability of transmission include positive sputum culture for M tuberculosis, presence of cavitation on the chest radiograph, presence of TB laryngitis, and high-volume and watery respiratory secretions (17).

Infection occurs when a susceptible person inhales droplet nuclei containing tubercle bacilli. As the distribution of inhaled droplet nuclei is determined by the ventilatory pattern and volumes of the various lung lobes, the site of implantation preferentially occurs in the middle and lower lung zones, although any lobe may be affected (18,19). Once lodged in the alveolus, M tuberculosis is ingested by alveolar macrophages. Resistance to establishment of tuberculous infection is known to be under genetic control (20), and the course of infection depends on the interaction between the inherent microbicidal power of the alveolar macrophage and the virulence of the ingested bacillus (21). If the alveolar macrophage cannot destroy or inhibit M tuberculosis, the bacilli multiply within its intracellular environment, causing the host macrophage or its progeny to burst. The cycle continues as released bacilli are ingested by other alveolar macrophages and monocytes are recruited from the blood. During this period of rapid growth, tubercle bacilli are spread through lymphatic channels to regional hilar and mediastinal lymph nodes and through the bloodstream to more distant sites in the body. The logarithmic phase of bacillary growth is arrested with the development of cell-mediated immunity and delayed-type hypersensitivity at 2–10 weeks after the initial infection (21,22).

Development of specific immunity is usually adequate to limit further multiplication of the bacilli; the host remains asymptomatic, and the lesions heal (22). Some of the bacilli remain dormant and viable for many years, and this condition—referred to as latent TB infection—may be detectable only by means of a positive purified protein derivative tuberculin skin test or radiologically identifiable calcification at the site of the primary lung infection or in regional lymph nodes (1,16). In approximately 5% of infected individuals, immunity is inadequate and clinically active disease develops within 1 year of infection (22); in another 5% of the infected population, endogenous reactivation of latent infection occurs remote from time of initial infection (22).

Co-infection with HIV and M tuberculosis is the strongest known risk factor for both immediate and delayed progression from infection to active TB (23). The risk of progression to disease for co-infected persons is 5%-10% per year compared with a 5%-10% lifetime risk for HIV-negative persons (24,25). Other known risk factors for development of active TB include conditions that have defects in T-lymphocyte and/or macrophage function, such as malnutrition, drug and alcohol abuse, coexistent medi...
Postprimary TB occurs in a person who has previously been infected and has retained a degree of acquired immunity; it can result from endogenous reactivation or, less commonly, exogenous reinfection (27). Although delayed progression of latent infection may occur at any seeded site in the body, lung foci account for the majority of cases (22). Predilection of postprimary disease to involve the upper lung zones is likely due to a combination of factors including the relatively higher oxygen tension and impaired lymphatic drainage in this region (19,28).

Local control and resolution of pulmonary TB is always accompanied by some destruction of involved tissues (19). While cell-mediated immunity controls TB by activating macrophages to kill ingested bacilli, delayed-type hypersensitivity (DTH) activates macrophages to kill ingested bacilli (25). DTH sensitivity occurs at the site of initial infection or hematogenously seeded foci; this progression occurs in a small percentage of patients with primary disease and is similar in morphology and course to postprimary disease (19). Healing of TB occurs with resorption of caseous material accompanied by deposition of collagen (fibrosis) (29). Dystrophic calcification occurs commonly at sites of caseous necrosis but is not a reliable marker for lesion sterility (19,29). Viable tubercle bacilli may persist, and in the preantibiotic era, M. tuberculosis could be grown from up to 20% of calcified lesions at autopsy (19).

Endobronchial TB, defined as infection of the tracheobronchial tree as documented by microbiologic and histopathologic proof, usually occurs in association with pulmonary involvement and is believed to result most commonly from the implantation of organisms from infected sputum in persons with cavitary (progressive primary and postprimary) disease (30,31). In the absence of parenchymal cavitation, possible sources include direct extension from adjacent parenchymal infection, lymph node erosion, hematogenous spread, and extension to the peribronchial region via lymphatic drainage (31). Airway lesions typically evolve from submucosal sites of infection associated with ulceration to hyperplastic inflammatory polyps that eventually heal by fibrosis and result in circumferential stenosis (30,31).

Pleuritis may occur at any time after the initial infection. In primary TB, effusions typically develop 3–6 months after infection (32) and are believed to result from a hypersensitivity response to a small amount of tuberculoprotein released into the pleural space (22,33). Because of the paucity of organisms, pleural fluid will yield positive cultures in only 20%–40% of cases; a single closed needle biopsy of the pleura substantially increases the diagnostic yield to approximately 65%–75% (33). Pleural effusions are less commonly a manifestation of postprimary disease in which a large number of organisms are spilled into the pleural space from rupture of a cavity or adjacent parenchymal focus. In true empyemas, acid-fast smears and mycobacterial cultures are usually positive (33).

Miliary spread of TB may also occur during either primary or postprimary stages of disease. It results when a focal collection of tubercle bacilli discharges into a blood or lymph vessel, releasing a large number of viable bacilli that embolize to capillary beds in multiple organs (34). The lung is the most commonly involved organ (34). Because sputum contains acid-fast bacilli in the minority of cases, bronchoscopy with transbronchial biopsy is often necessary for diagnosis (34,35).

**CLINICAL SIGNS AND SYMPTOMS**

The clinical signs and symptoms of pulmonary TB in an infected adult are often nonspecific; complete absence of symptoms occurs in approximately 5% of active adult cases (36). Systemic manifestations include low-grade fever, anorexia,
fatigue, night sweats, and weight loss that may persist for weeks to months (22). Erythema nodosum may occur with the acute onset of TB and typically manifests at the time of development of specific immunity (22,32). The most common hematologic manifestations associated with TB are raised peripheral blood leukocyte count and anemia, each of which occurs in approximately 10% of patients (33). Hyponatremia, caused by production of an antidiuretic hormonelike substance within affected lung tissue, may occur in up to 11% of patients (37).

Cough is the most frequent symptom referable to the site of lung infection (22,33). Early in the disease, it may be nonproductive, but subsequently there usually is production of mucoid or mucopurulent sputum. Hemoptyis may also occur. Inflammation adjacent to a pleural surface can cause pleuritic chest pain; dyspnea is unusual unless extensive lung involvement is present. Rarely, patients with miliary disease may present with symptoms of respiratory failure (38).

Specific clinical manifestations of TB are influenced by the age and immune status of the infected person (32,33). Congenital TB is a rare entity associated with high mortality rates, partly because the correct diagnosis is often missed (39). Clinical presentation is similar to that caused by bacterial sepsis and other congenital infections; the most common signs are fever, failure to thrive, lymphadenopathy, hepatomegaly, and splenomegaly (39,40).

Up to 60% of children with pulmonary TB are asymptomatic and found solely through contact investigation (41). Because of the narrower diameter of their airways, younger children are more likely to have respiratory symptoms, which include cough and wheezing or rales over the involved region (42,43).

Diagnosis of TB in the elderly (≥65 years of age) is frequently delayed (44,45). In comparison to younger adults, the elderly are less likely to present with classic symptoms of cough, hemoptysis, fever, and night sweats (36). A cryptic presentation—fever of unknown origin often accompanied by pancytopenia or leukemoid reaction—is particularly common because of the greater frequency of hematogenous dissemination in this age group (36,45).

The clinical features of TB in HIV-infected persons are dependent on the severity of their immunosuppression (46,47). Persons with relatively intact cellular immune function present with symptoms similar to the non-HIV-infected individuals, and TB generally remains localized to the lung. In persons with advanced HIV disease (CD4 T-lymphocyte count, <200/mm3), pulmonary TB is often accompanied by extrapulmonary involvement, which most commonly takes the form of lymphadenitis or miliary disease (23,48). Depending on the sites of involvement, systemic or localized symptoms may predominate.

RADIOLOGY

Radiographic Screening

The purpose of screening chest radiographs is to identify persons with active TB (16). Although radiography is often used in conjunction with tuberculin skin testing, it is the initial screening method of choice when tuberculin skin test results may be unreliable, when reading of the skin test may be impractical, and/or when the risks of transmission of an undiagnosed case are high as occurs in institutional settings (jails, hospitals, long-term care facilities) (17).

Because of the considerable morbidity and mortality associated with congenital and perinatal transmission of TB, the CDC recommends that pregnant women in high-risk groups or from areas with a high prevalence of both HIV infection and TB undergo screening. In a pregnant woman with a positive tuberculin skin test, a chest radiograph with shielding of the abdomen should be performed after the 12th week of gestation (49); radiographic evaluation should be performed earlier if the woman has symptoms suggestive of pulmonary TB (49).

Radiographic screening for active TB in high-risk populations may demonstrate findings consistent with prior and/or current infection. A Ghon focus refers to the initial site of parenchymal involvement at the time of first infection; a Ranke complex is the combination of a Ghon focus and enlarged or calcified lymph
nodes; and Simon foci are apical nodules that are often calcified and result from hematogenous seeding at the time of initial infection (19).

According to a joint statement issued by the American Thoracic Society and the CDC (22), persons infected with Mycobacterium tuberculosis, as evidenced by a positive tuberculin skin test, should be classified on the basis of clinical, bacteriologic, and radiographic evaluation into one of the three following categories: (a) TB infection, no disease; (b) TB infection, clinically active; and (c) TB infection, clinically inactive. A normal chest radiograph has a high negative predictive value for the presence of active TB. However, the frequency of false-negative examinations is approximately 1% in the adult immunocompetent population (36,50) and increases to 7%–15% in HIV-seropositive individuals (51–53).

On a single screening chest radiograph, detection of any abnormality—parenchymal, nodal, or pleural—with or without associated calcification, should result in an interpretation of indeterminate disease activity (54,55) (Fig 1). Radiographic differentiation between active and inactive disease can only be reliably made on the basis of temporal evolution (22,56,57). Lack of radiographic change over a 4- to 6-month interval generally indicates inactive disease (22,56). However, because even long-term stability of radiographic findings may occasionally be associated with culture-positive disease, Miller and MacGregor (56) emphasize that such findings should be described as "radiographically stable" rather than "inactive."

Disease Manifestations
Radiologic manifestations of pulmonary TB are dependent on several host factors, including prior exposure to TB, age, and underlying immune status. In persons with normal immune function, radiologic manifestations can be logically categorized into the two distinct forms of primary and postprimary disease that develop in individuals without and with prior exposure and acquired specific immunity.

Primary disease.—Lymphadenopathy is the radiologic hallmark of primary TB (Fig 2). While enlarged nodes occur in 83%–96% of pediatric cases (58–60), the prevalence of lymphadenopathy decreases with increasing age (59). In a retrospective study of 191 children with TB, Leung et al (59) found that children 0–3 years of age (63 of 63 [100%]) had a significantly (P < .01) higher prevalence of lymphadenopathy than that of children 4–15 years of age (112 of 128 [88%]). This age-related trend appears to continue into adulthood during which a much lower frequency of lymphadenopathy has been reported, ranging from 43% (16 of 37) in a series (5) composed primarily of young adults under 35 years of age to 10% (10 of 103) in an older population of median age in the 6th decade (61).

The right paratracheal and hilar stations (Fig 3) are the most common sites of nodal involvement in primary TB, although any combination, including bilateral hilar or isolated mediastinal lymphadenopathy, may also occur (59,60,62). On contrast material–enhanced computed tomographic (CT) scans, mediastinal tuberculous lymphadenitis, particularly when nodal size exceeds 2 cm in diameter, may have a characteristic appearance consisting of central areas of low attenuation associated with peripheral rim enhancement and obliteration of surrounding perinodal fat (60,62) (Fig 4). With CT-histologic correlation, excised nodes exhibiting this pattern of enhancement have been found to contain complete central necrosis in association with a highly vascular, inflammatory, capsular and perinodal reaction (63). Although Im and colleagues (62) have suggested that this pattern of nodal enhancement is sufficiently characteristic to support a diagnosis of TB in younger patients, confirmation is necessary because similar findings may also be caused by atypical mycobacterial infection (64); lymphoma (62); metastases, particularly from testicular carci-

**Figure 7.** Chest radiograph obtained in a 25-year-old Asian woman shows volume loss of the right lung with mediastinal shift to right. At bronchoscopy, severe stenosis of right main and upper lobe bronchi was identified.

**Figure 8.** Chest radiograph obtained in a 19-year-old woman shows a large right-sided pleural effusion (curved arrows) associated with right hilar lymphadenopathy (straight arrows).
noma (65); and benign conditions such as Whipple and Crohn diseases (63).

Parenchymal opacities occur in association with and affect the same side as nodal enlargement in approximately two-thirds of pediatric cases of primary TB (59). In contrast to the age-related trend observed with lymphadenopathy, Leung et al (59) found that the prevalence of radiographically detectable parenchymal involvement was significantly \( P < 0.001 \) lower in children 0–3 years of age (32 of 63 [51%]) as compared to that in older children (100 of 128 [78%]) in whom the prevalence is similar to the 78%–84% previously reported in adults (5,61). Because of these two opposing age-related trends in frequency of radiographic manifestations, parenchymal involvement in the absence of lymphadenopathy occurs in only approximately 1% of pediatric cases (59), whereas this nonspecific pattern is observed in 38%–81% of adults with primary disease (5,61).

Parenchymal involvement in primary pulmonary TB most commonly appears as an area of homogeneous consolidation (59,61,66), although patchy, linear (58), nodular (67), and masslike (56,68) forms have also been described. Consolidation typically occurs in a segmental or lobar distribution; multifocal involvement is identified radiographically (Fig 5) in 12%–24% and found at autopsy in 16% of the affected population (18,59,66). There is no consensus as to the most common site of parenchymal involvement in primary TB, with different reports documenting upper (5,58), lower (66), or no regional predominance (59,61). However, a rightsided predominance in the distribution of Ghon foci and Ranke complexes is well recognized (5,58,59,61) and presumably reflects the greater statistical probability of an airborne infection involving the right lung.

Figure 9. Atypical distribution of postprimary TB in a 62-year-old man. (a) Chest radiograph shows a 5-cm cavitary mass with a thick, irregular wall (large arrow) and surrounding adjacent nodular opacities in the left upper lobe. An ill-defined 5-mm nodule (small arrow) is present in the contralateral, right upper lobe. (b) CT scan obtained with 7-mm collimation shows the location of the cavitary mass (arrows) in the anterior segment of left upper lobe.

Figure 10. Close-up radiographic view of the upper lung zones in a 56-year-old Hispanic man shows ill-defined parenchymal opacities (white arrows) associated with nodular and linear components in the periphery of the bilateral upper lobes. A loculated right pleural effusion (black arrows) is present.
Obstructive atelectasis and overinflation resulting primarily from compression by adjacent enlarged nodes have been reported to occur in 9%-30% and 1%-5% of children with primary TB, respectively (58,59). Distribution is typically right-sided with obstruction occurring at the level of the lobar bronchus or bronchus intermedius (58) (Fig 6). Extrinsic airway obstruction occurs much less frequently in the adult population because of their larger caliber airways and lower prevalence of lymphadenopathy. However, airway involvement by endobronchial TB in adults with primary disease may manifest radiologically as atelectasis (Fig 7) and endoluminal or peribronchial masses simulating neoplastic disease (30,68). Consolidation confined to the lower lung zones (69,70) and normal findings (30,69) are other atypical radiographic patterns well documented to be associated with endobronchial TB.

Pleural effusion is an uncommon manifestation of primary TB in infants and young children (<2 years of age) (32). The prevalence of effusion increases with age and is reported to be 6%-11% in children (58,59) and 29%-38% in adults (5,61). A pleural effusion usually develops on the same side as the site of initial tuberculous infection and is typically unilateral (32) (Fig 8). Bilateral effusions occur in 12%-18% of cases with pleural involvement (59,61,66). Although usually observed in association with parenchymal and/or nodal abnormalities, pleural effusion is the only radiographic finding indicative of the presence of primary TB in approximately 5% of adult cases (61).

Postprimary disease.—Parenchymal opacities situated in the apical and posterior segments of the upper lobes and the superior segment of the lower lobes, often associated with cavitation, are the characteristic radiographic manifestations of postprimary TB. In two large series consisting of 204 and 500 affected persons, the sites of cavitary disease were found to involve the apical and/or posterior segments of the upper lobes in 83%-85% and the superior segments of the lower lobes in 11%-14% (71,72). Parenchymal involvement occurs in more than one segment in the majority of cases (66,73); although parenchymal disease outside of typical locations is common, this distribution is usually observed in association with concomitant abnormalities in characteristic sites (50,66). An atypical distribution of disease with parenchymal opacities isolated to the anterior segment of the upper lobes or basilar segments of the lower lobes has been reported to occur in approximately 5% of cases of postprimary TB (66,72,74) (Fig 9). Prior reports (45,70,75,76) suggesting that patients with diabetes mellitus and the elderly are predisposed to atypical distributions of postprimary disease have not been confirmed with subsequent case-control studies (36,73,77).

Parenchymal involvement in postprimary TB most commonly manifests radiographically as heterogeneous opacities. In the early stages, an ill-defined area of increased opacity often associated with nodular and linear components is observed radiating outward from the hilum or in the periphery of the lung (55,56) (Fig 10). With disease progression, additional opacities develop that may coalesce and are sometimes seen in association with distortion of adjacent bronchovascular and mediastinal structures (55,56). In 3%-6% of cases of postprimary disease, tuberculomas (defined as round or oval, sharply margined lesions usually measuring between 0.5-4.0 cm) are the predominant parenchymal manifestation (56,57,74). Tuberculomas are typically solitary but may be multiple (67), have regular or irregular margins (57), and often demonstrate calcification as well as proximity to adjacent small “satellite” nodules (57,67) (Fig 11).

Cavitation in single or multiple sites is evident radiographically in 40%-45% of cases of postprimary TB (66,78). Walls of cavities may range from thin and smooth to thick and nodular (66,78); air-fluid levels have been reported to occur in 9%-21% of tuberculous cavities (66,78) (Fig 12). Bronchogenic spread of disease occurs when an area of caseous necrosis liquefies and communicates with the bronchial tree. Radiographically, bronchogenic spread is identified in approximately 20% of cases of postprimary TB (50) and manifests as multiple, ill-defined, 5- to 10-mm nodules distributed in a segmental or lobar distribution, distant from the site of cavity formation and typically involving the lower (dependent) lung zones (50,79,80) (Fig 13).

On CT scans, bronchogenic spread of infection can be identified in 95% of persons with postprimary TB (79,81). According to Im and colleagues (79,82), the most common thin-section CT findings of early bronchogenic spread are 2- to 4-mm centriflobular nodules and sharply, marginated linear branching opacities (Fig 14) which, with thin-section CT-pathologic correlation, have been shown to represent caseous necrosis within and around terminal and respiratory bronchioles (82,83). Other thin-section CT findings, in decreasing order of frequency, include 5- to 8-mm poorly defined nodules, lobular consolidation, and interlobular septal thickening (82).

Endobronchial involvement occurs in approximately 2%-4% of persons with pulmonary TB (30,68); main, upper, and lower lobe bronchi account for three-
quarters of the involved sites (68). Associated parenchymal opacities predominating in the upper lobes and segmental or lobar atelectasis are radiographically apparent in 65%–75% and 18%–25% of cases, respectively (30,68). On CT scans, endobronchial TB typically manifests as irregular or smooth circumferential bronchial narrowing associated with mural thickening (84,85) (Fig 15).

Hilar and mediastinal lymphadenopathy are uncommon manifestations of postprimary TB and occur in only approximately 5% of cases (66). Tuberculous pleural effusion, although usually regarded as a manifestation of primary disease, may occur in association with postprimary disease in up to 19% of detected cases (86). Pleural effusion is observed radiographically in 16%–18% of persons with postprimary TB and is typically unilateral in distribution (66,74,86). Although parenchymal abnormalities in characteristic locations are common associated findings, the ruptured parenchymal focus may be radiographically occult (87) (Fig 16a).

Occasionally, an air-fluid level may be demonstrable within the pleural cavity, indicating the presence of a bronchopleural fistula (66,74). Contrast-enhanced CT evaluation of postprimary tuberculous effusions typically reveals smooth thickening of visceral and parietal pleural surfaces separated by a variable amount of fluid—the “split pleura” sign (88,89) (Fig 16b). Tuberculous effusions are typically loculated and may be stable in size for years; detection of persistent fluid within a calcified fibrothorax at CT should raise concern for active disease and chronic tuberculous empyema (87,90).

Radiographic evidence of the original primary infection in the form of calcified lymph nodes and nodules and/or upper lobe fibrotic changes is found in approximately 30% of cases (30). These calcified lesions are usually located in the hilar region (66). The radiographic hallmark of postprimary TB is the presence of characteristic parenchymal abnormalities in characteristic anatomical locations. Associated pleural thickening, effusion, or both may be observed in approximately 40% of postprimary cases (66,74). Fibrosis and pleural reaction may be observed in approximately 50% of postprimary cases (66,74). The presence of these findings, especially in characteristic anatomical locations, strongly suggests the diagnosis of postprimary TB.

Although the radiographic manifestations of postprimary TB are similar to those of primary TB, there are some important differences. Postprimary TB is more likely to be bilateral and to involve the upper lobes, whereas primary TB is more likely to involve the lower lobes and to be unilateral. Postprimary TB is also more likely to involve the hilar and mediastinal lymph nodes, whereas primary TB is more likely to involve the paratracheal and paraesophageal nodes.

In summary, the radiographic manifestations of postprimary TB are similar to those of primary TB, but there are some important differences. Postprimary TB is more likely to be bilateral and to involve the upper lobes, whereas primary TB is more likely to involve the lower lobes and to be unilateral. Postprimary TB is also more likely to involve the hilar and mediastinal lymph nodes, whereas primary TB is more likely to involve the paratracheal and paraesophageal nodes.

**Figure 13.** Postprimary pattern of TB in a 54-year-old Hispanic man. (a) Radiograph obtained at presentation shows focal areas of confluent consolidation (large arrows) in the bilateral upper lobes. In the right lung, multiple ill-defined, 5–8-mm nodules (small arrows) can be identified; in the more severely affected left lung, a bronchopneumonia pattern is present predominating in the lower lobe. (b) Radiograph obtained 3 months after initiation of treatment shows that improvement has occurred, with resolution of right lung nodules. Reticulonodular opacities persist in bilateral upper and left lower lung zones.

**Figure 14.** Thin-section CT scan obtained with 1-mm collimation in a 26-year-old Hispanic man shows multiple 2–4-mm centrilobular nodules and linear, branching opacities (arrows) in the superior segment of right lower lobe.

**Figure 15.** CT scan obtained with 8-mm collimation in a 41-year-old man shows eccentric mural thickening (straight arrow) involving the proximal aspect of the medial segmental bronchus of the right middle lobe associated with endobronchial secretions (curved arrow) more distally. The patient's symptoms at presentation were a mild, non-productive cough with right-sided wheezing. Bronchial biopsy specimens contained areas of necrotizing granulomatous inflammation from which M tuberculosis was grown on culture.
CT scan of the right upper lobe shows a 2-cm nodule (arrow) with central cavitation in the nondependent region indicates the presence of a bronchopleural fistula. The small amount of air (straight arrow) seen in the pleural space may suggest the diagnosis of TB is present in up to 30% of affected persons and include consolidation, cavitation, calcified lymph nodes, and lymphadenopathy (92).

CT can demonstrate miliary disease before it becomes radiographically apparent (96,97). At thin-section CT, a mixture of both sharply and poorly defined, 1–4-mm nodules are seen in a diffuse, random distribution often associated with intra- and interlobular septal thickening (97,98) (Fig 18).

TB in acquired immunodeficiency syndrome. The radiographic manifestations of HIV-associated pulmonary TB are dependent on the level of immunosuppression at the time of overt disease (99–101). Persons with relatively intact cellular immune function demonstrate radiographic findings similar to those of non–HIV-infected individuals (47). At severe levels of immunosuppression, 10%-20% of co-infected persons have normal radiographs (51,52,100) or demonstrate findings usually associated with primary disease, regardless of prior TB exposure status (46,102) (Fig 19). In a prospective multicenter study that included 128 HIV-seropositive patients with TB in whom both chest radiographs and CD4 T-lymphocyte data were available, a significantly higher prevalence (P = .01) of mediastinal and/or hilar lymphadenopathy and a lower prevalence (P = .08) of cavitation were identified in 98 patients with a CD4 T-lymphocyte count of less than 200/mm³ as compared to 30 patients with a CD4 T-lymphocyte count equal to or greater than 200/mm³ (100). A miliary pattern of disease has also been reported to be associated with severe immunosuppression (46,51,103) (Fig 17).

CT evaluation of pulmonary TB in HIV-seropositive persons with normal radiographs usually demonstrates subtle abnormalities (51). In six patients with normal radiographs drawn from a series of 42 co-infected individuals, Leung et al (51) identified three patterns of disease on CT scans; these patterns consisted of multiple nodules (n = 3, two miliary and one endobronchial), tuberculoma (n = 2, 5 and 10 mm); and lymphadenopathy (n = 1, right paratracheal, hilar, and subcarinal stations). CT evaluation demonstrates...
mediastinal and/or hilar lymphadenopathy in up to 60%–75% of HIV-seropositive persons with pulmonary TB (51,104). As in the immunocompetent population, Pastores and colleagues (105) reported that tuberculous lymphadenitis in the HIV-seropositive population may also be associated with central low attenuation and peripheral enhancement on contrast-enhanced CT scans.

Response to Treatment

Evaluation of the response of pulmonary TB to antibiotic treatment is best assessed by means of repeated sputum examinations in patients with positive bacteriology (106); radiographic evaluation is of lesser importance, although a baseline radiograph at the completion of treatment may be useful for future comparison purposes (106). In persons with negative pretreatment sputum, radiographic and clinical evaluation become the major indicators of response to therapy and are the most common methods used in children, in whom bacteriologic confirmation is possible in only about one-third of cases (59,106).

Regression of radiographic abnormalities in pulmonary TB is a slow process (55,59) (Fig 13). In the first 3 months of treatment, worsening of radiographic findings consisting of extension of parenchymal involvement and development or enlargement of nodes may be observed in up to one-third of pediatric patients receiving appropriate therapy (59); a similar trend with progression of nodal disease has also been observed in adults with tuberculous lymphadenitis (107). The cause of the disease progression in primary TB is unknown but may be related to the effects of the hypersensitivity reaction that normally occurs 2–10 weeks after initial infection (59). In the majority of patients, parenchymal and nodal abnormalities usually regress in parallel (59). In adults, failure of radiographic findings to improve after 3 months of chemotherapy suggest drug-resistant organisms or a superimposed process (106). Resolution of parenchymal abnormalities has been observed to require from 6 months to 2 years on radiographs (59) and up to 15 months on CT scans (82). Lymphadenopathy may persist for several years after treatment (59,107).

Complications

Bronchiectasis and residual cavities (Fig 20a) are sequelae of pulmonary TB that typically involve the upper lobes and are identifiable in 71%–86% and 12%–22% of persons with prior disease on thin-section CT scans, respectively (19,81,91). An ectatic bronchus or, more commonly, a residual tuberculous cavity may be colonized by Aspergillus species; the fungus ball or aspergilloma consists of a cluster of intertwined hyphae matted together with a variable amount of mucus and cellular debris. Hemoptysis is the most clinically important consequence of aspergilloma and occurs in 50%–70% of affected patients, resulting in death in up to 5% (108). Radiographically, an aspergil-
Loma appears as a roughly spherical nodule or mass separated by a crescent-shaped area of decreased opacity from the adjacent cavity wall (108) (Fig. 20b). The characteristic CT features consist of a mobile intracavitary nodule or mass that is usually surrounded by air but may completely fill the cavity (109). On prone and supine CT images, the aspergilloma will gravitate to the dependent position (Fig. 20c, 20d).

A Rasmussen aneurysm is a pseudoaneurysm of a pulmonary artery caused by erosion from an adjacent tuberculous cavity (110); these pseudoaneurysms are uncommon and may form months to years after formation of the cavity (111). Hemoptysis is the usual presenting symptom, which may be massive (>300 mL/24 hours) and life threatening (111,112).

Arterial embolization has been demonstrated as an effective method to achieve primary control of bleeding associated with chronic tuberculous cavities (112,113).

Broncholithiasis is an uncommon complication of pulmonary TB that is characterized by calcified peribronchial nodes that either erode into or cause considerable distortion of an adjacent bronchus (114). Presenting symptoms may include cough, hemoptysis, wheezing, or evidence of recurrent pneumonia (114). Although any bronchus may be involved, a right-sided predominance has been observed (114). In addition to the presence of calcified peribronchial nodes, radiologic findings may include segmental or lobar atelectasis, obstructive pneumonitis, branching opacities in a "V" or "Y" configuration (obstructive bronchocele), and rarely, focal hyperinflation (114,115).

OTHER DIAGNOSTIC TESTS

Tuberculin Skin Test

Although neither 100% sensitive nor specific, the tuberculin skin (Mantoux) test remains the best method for detecting infection with M tuberculosis (22). In persons with reactive tuberculin tests, the major confounding factors are infection with and hypersensitivity to mycobacteria other than M tuberculosis and prior vaccination with bacille Calmette-Guérin (BCG). In general, the larger the reaction, the greater the probability that the reaction represents infection. False-negative tuberculin skin test reactions (anergy) is a problem among debilitated persons and other immunocompromised hosts, particularly those with advanced HIV infection (22). Delayed-type hypersensitivity can be assessed with skin test antigens such as tetanus toxoid or Candida species to which most healthy persons in the population are already presensitized; however, the scientific basis for anergy testing is tenuous (116).

The criteria endorsed jointly by the American Thoracic Society and the CDC for use in interpretation of the Mantoux test are intended to increase the likelihood that persons at high risk for TB will be candidates for therapy and that persons having tuberculin reactions not caused by M tuberculosis will not receive unnecessary diagnostic evaluation or therapy (116). Induration of 5 mm or greater is classified as positive in persons with recent close contact with a person with active TB, persons with HIV risk factors or proved HIV infection, and persons with radiographic evidence of prior TB. Induration of 10 mm or greater is classified as positive in persons belonging to other well-recognized high-risk groups, which include foreign-born persons who have recently arrived from countries with a high prevalence of TB; high-risk racial or ethnic minority populations; persons with medical conditions reported to increase the risk of active TB; and residents and employees of high-risk congregate settings (prisons and jails, nursing homes, and homeless shelters) (116). Induration of 15 mm or greater is classified as positive in all other persons.

Specimens

The diagnosis of pulmonary TB requires isolation and identification of M tuberculosis in a sputum or other clinical specimens. The main diagnostic procedure in persons with a productive cough
consists of smear and culture of three sputum specimens collected on different days. Sputum smears that fail to demonstrate acid-fast bacilli do not exclude the diagnosis of TB; positive acid-fast bacilli smears are found in only approximately 60% of persons with culture-positive sputum (16). This percentage decreases in the HIV-seropositive population because of their lower propensity to develop cavitary disease.

For individuals such as children who are unable to produce sputum (natural or induced), aspiration of gastric contents in the early morning may be performed; however, this method is successful in only 30%–40% of cases of pediatric TB (59). In the absence of a positive culture, the strongest evidence for TB in a child is recent exposure to an adult with active disease (117). The tuberculin skin test and chest radiography may be used to provide supportive information.

Invasive procedures may become necessary when noninvasive methods do not permit a diagnosis. In miliary TB, sputum contains acid-fast bacilli in the minority of cases, and bronchial biopsy with transtracheal aspiration of pleural fluid will yield positive cultures in only 20%–40% of cases; a single closed needle biopsy of the pleura substantially increases the diagnostic yield (33). Pleural effusions in patients with postprimary TB are true empyemas, and in this setting, acid-fast smears and mycobacterial cultures are usually positive (33).

Laboratory Identification Methods

Staining and microscopic examination.—The initial step in the laboratory diagnosis of TB is microscopic examination of smears stained by means of an acid-fast procedure. Two types of acid-fast stains are commonly used. The first is a basic fuchsin stain (Ziehl-Neelsen or Kinyoun methods) that when used in combination with light microscopy requires an average examination time of 15 minutes (118). The second and preferred method is use of an auramine-rhodamine fluorochrome stain in combination with fluorescent microscopy. The yellowish fluorescence of this acid-fast stain when taken up by M tuberculosis allows faster and more sensitive detection of the bacilli in smears (118).

Cultivation and identification of mycobacteria.—Expeditious diagnosis of TB by isolation of M tuberculosis is hampered by the slow growth rate of tubercle bacilli. Standard culture methods with specially developed media such as the Löwenstein-Jensen agar usually require 3–6 weeks for adequate growth to allow identification (119). Radiometric methods represent an important advance in the technology of mycobacterial identification. The most widely used system is BACTEC (Becton Dickson, Sparks, Md), which consists of a growth-optimized broth matrix containing carbon 14-labeled palmitic acid, a substrate that is almost specific for mycobacteria (22,119). The radiolabeled palmitic acid is metabolized by mycobacteria, resulting in release of 14CO2, which is quantified to identify presence and growth of the bacteria. The BACTEC system allows detection of M tuberculosis growth with a mean detection time of 7–13 days for smear-positive and 14–22 days for smear-negative sputum specimens (119).

Radiometric DNA probes and high-performance liquid chromatography are two methods that allow identification of cultures at the species level in 2–4 hours; each requires 107 bacilli for reliable, reproducible results (118). When either of these methods are used in conjunction with a radiometric system for primary culture, detection and identification of M tuberculosis in clinical specimens are achievable in about 2 weeks, under the best of circumstances (118,120).

Polymerase chain reaction, or PCR, is the most widely studied of the nucleic acid amplification techniques aimed at direct detection of M tuberculosis in clinical specimens without the need for prior culture. Polymerase chain reaction relies on the exponential amplification and subsequent detection of a fragment of DNA that is specific for M tuberculosis, by using a thermostable DNA polymerase (119,120). Its acceptance into the clinical setting has been hampered by reports of both false-negative and false-positive reactions caused by the presence of inhibitors and contaminants in samples, respectively (119,120).

Restriction fragment length polymorphism, or RFLP, analysis, also referred to as “DNA fingerprinting,” is a molecular biology technique that allows differentiation of unrelated strains of M tuberculosis by demonstration of nucleotide sequence differences at selected sites in their DNA genome (120,121). RFLP is a powerful epidemiologic tool that allows study of the patterns of infection within a population, with identification of the points of transmission.

Susceptibility testing.—Because of the widespread emergence of MDR M tuberculosis, drug susceptibility testing should be performed on organisms initially isolated in all patients with newly diagnosed TB (106). Testing is repeated if the patient continues to produce culture-positive sputum after 2 months of treatment (106). The direct-drug susceptibility test is performed by inoculating digested, concentrated clinical specimens onto drug-containing culture medium and comparing the growth on this to the growth on non-drug-containing medium. The best method to test susceptibility to first-line antituberculous drugs is by using the BACTEC system, which allows interpretation in as little as 5 days (118).

PREVENTIVE THERAPY AND TREATMENT

Bacille Calmette-Guérin

BCG was derived from a strain of Mycobacterium bovis attenuated through years of serial passage in culture at the Pasteur Institute in France. The effectiveness of the BCG vaccine in preventing development of active TB has been shown to vary from 0% to 80% (106). Because the ability of BCG to prevent adult forms of TB remains controversial, it is not recommended for widespread use in the United States, where the risk of infection in the general population is low (17). BCG vaccination may protect infants and young children from more severe forms of TB such as meningitis and miliary disease; in this age group, BCG vaccination is strongly recommended for those who are at high risk of acquiring infection (106).

Chemoprophylaxis

The main purpose of preventive therapy is to prevent latent infection from progressing to active TB. Taken for 6–12 months, preventive therapy with isoniazid is highly effective and can reduce risk of developing active disease by up to 90% (17,26). Because isoniazid is associated with a number of side effects, including hepatitis, recommendations for its use select candidates with positive tuberculin skin test results so as to maximize the benefit and minimize the risk to the individual (26). Patient groups who are recommended to undergo preventive therapy are outlined in a joint statement by the American Thoracic Society and the CDC (106) and include persons with HIV infection, close contacts of persons with newly diagnosed TB, recent tuberculin skin test converters, and persons...
with underlying medical conditions reported to increase risk of TB.

**Treatment for TB**

There are five first-line antituberculous medications: isoniazid, rifampin, streptomycin, ethambutol, and pyrazinamide. Drug resistance in M tuberculosis results from spontaneous chromosomal mutations conferring resistance to antituberculous medications (12). Primary drug resistance is defined as resistance occurring in a patient who is not known to have had previous treatment with antituberculous drugs and presumably results from transmission of a drug-resistant strain. Secondary or acquired drug resistance is defined as documented, increasing levels of resistance to one or more drugs in a strain recovered from a patient undergoing inadequate therapy. Because the sites of resistance for individual drugs are not linked, multidrug therapy is always used to ensure that organisms remain susceptible and to prevent the emergence of resistant strains (12).

A 6-month regimen consisting of isoniazid, rifampin, and pyrazinamide given for 2 months followed by isoniazid and rifampin for 4 months is the preferred treatment for all patients, regardless of HIV status, with fully susceptible organisms (106). Ethambutol or streptomycin is included in the initial regimen until the results of drug susceptibility testing are available. After 2 months of treatment, the results of sputum cultures in more than 85% of patients should have converted from positive to negative (106).

Treatment of MDR TB (resistance to the two most potent drugs, isoniazid and rifampin) is a difficult therapeutic problem. Treatment regimens that are more toxic, more expensive, and not as successful must be individualized on the basis of susceptibility studies and should be planned in consultation with an expert in management of TB (17,106).

**CONTROL**

Effective control of TB requires early identification, isolation, and treatment of persons with active TB. Early identification is particularly important within congregate settings to prevent transmission; the CDC has reported a number of hospital and institutional outbreaks in which TB spread among hospitalized patients and employees, resulting in several deaths due to occupationally acquired MDR TB (122–124).

Early identification of active TB requires vigilance on the part of physicians to consider this diagnosis when a patient presents with nonspecific constitutional or pulmonary symptoms for which no cause can be found. In two hospital-based studies of 32 and 85 patients with active pulmonary TB, 30% and 20% of patients, respectively, either died or were discharged before the diagnosis was made (125,126). Cited factors contributing to delayed diagnosis included low use of tuberculin skin tests and misinterpretation of chest radiographs (126). Six radiographic patterns of pulmonary TB that have been repeatedly found in association with delayed diagnosis are (a) normal findings (56,66,126,127), (b) nodule or mass (56,66,125,126), (c) parenchymal abnormalities attributed to “old” or “inactive” disease (56,66,125), (d) isolated pleural effusion (126,127), (e) isolated lymphadenopathy (126,127), and (f) parenchymal opacities located in sites other than the usual postprimary sites (56,66). Nonspecific radiographic findings, as exemplified by the latter three patterns, are typical of primary TB, a form that is increasing in incidence among adults in developed countries (61).

Because of the critical importance of rapid identification in limiting disease transmission, the most rapid and reliable diagnostic tests for M tuberculosis should be used in clinical laboratories (128,129). With respect to turnaround times from receipt of specimen in the laboratory to reporting results, the CDC recommends 24 hours for the acid-fast bacilli smear, 10–14 days for detection and identification of mycobacteria, and 15–30 days for susceptibility tests (128). The degree and duration of isolation imposed on patients with active TB are dependent on the estimated degree of infectiousness, the nature of the patient’s usual activities, and the group at risk as a consequence of transmission (17). Infected persons can usually remain at home because the additional risk of transmission to household members previously exposed is low (17). In the hospital setting, isolation of infectious individuals is mandatory to protect susceptible patients and employees from infection. Although the exact point at which patients with drug-susceptible organisms become noninfectious is difficult to define, most become noninfectious within a few days to weeks after initiation of appropriate antituberculous drugs. Three consecutive negative sputum smear examinations collected on separate days indicate an extremely low risk of transmission, and a negative culture ensures virtually no risk of transmission (17).

Noncompliance with therapy is a major problem in TB control and can lead to treatment failure, development of drug resistance, and continuing transmission. Because patient compliance cannot be predicted on the basis of demographic factors or subjective judgment of personality traits (130,131), the CDC currently recommends that all patients with TB be considered for directly observed therapy (106). Directly observed therapy means observation of the patient by a health care provider or other responsible person as the patient ingests antituberculous medications; directly observed therapy can be achieved with daily, twice weekly, or thrice weekly administration of drugs. Its implementation has been shown to be an effective method to promote patient compliance (130,132). In a small number of patients, typically homeless persons or alcoholics, who are refractory to directly observed therapy and other compliance-enhancing methods, short-term incarceration has been performed in the interests of public health (133).

**Acknowledgments:** I thank Nestor Müller, MD, and Francis Blankenberg, MD, for their generous contributions of illustrations for this article. Thanks also to Patricia Detton for her administrative help.

**References**


81. Kuhlman JE, Singha NK. Complex dis...


ANNEX IIIA

REQUEST FOR SPUTUM EXAMINATION

Health Unit_____________________________ Date ________________

Patient's name_________________________ Age ___ Sex (M/F) ___

Address____________________________________________________________________

Phone number _______ Contact person _________________________________________

Reason for examination: Diagnostic _____ Follow-up _____

Signature of person requesting examination: ______________________________________

RESULTS (to be completed in laboratory)

Laboratory serial No.

<table>
<thead>
<tr>
<th>Date</th>
<th>Specimen</th>
<th>Appearance*</th>
<th>Negative</th>
<th>1-9</th>
<th>+</th>
<th>++</th>
<th>+++</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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</table>

*Record in the appropriate box the visual appearance of sputum (blood-stained, mucopurulent, saliva)

**Use the following system:
No acid-fast bacilli (AFBs) found in at least 100 fields
1 to 9 AFBs per 100 fields
10 to 99 AFBs per 100 fields
1 to 10 AFBs per field in at least 50 fields
More than 10 AFBs per field in at least 20 fields

The completed form (with results) should be sent promptly to the requesting unit, usually a DOTS Centre

Date ___________________________ Examined by (signature) ____________________________
ANNEX IIIB

Tuberculosis Referral/Transfer form

<table>
<thead>
<tr>
<th>Name of the referring/transferring unit:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of the unit to which the patient is referred:</td>
<td></td>
</tr>
<tr>
<td>Name of the patient: Age: Sex:</td>
<td></td>
</tr>
<tr>
<td>Address where the patient is going:</td>
<td></td>
</tr>
<tr>
<td>TB No: Date treatment started: Treatment regimen:</td>
<td></td>
</tr>
<tr>
<td>Drugs patient received:</td>
<td></td>
</tr>
<tr>
<td>TB classification: Sputum examination results:</td>
<td></td>
</tr>
<tr>
<td>Reason for referral/transfer:</td>
<td></td>
</tr>
<tr>
<td>Remarks:</td>
<td></td>
</tr>
<tr>
<td>Printed name and signature:</td>
<td></td>
</tr>
<tr>
<td>Designation: Date:</td>
<td></td>
</tr>
</tbody>
</table>

Tear here

For use by the health unit where the patient has been referred/transferred.

Name of the patient: TB No. |  |
Age: Sex: Date: Referred/transferred: |  |

The above patient reported at this health unit on the date: |  |
Printed name and signature of the receiving officer: |  |
Name of the health unit: Date: |  |
(Send this part back to the referring unit as soon as the patient has reported and registered)

Tear here

For use by the health unit where the patient treatment ended.

Date treatment ended: |  |
Treatment outcome: Cured Treatment completed Died Transfer out |  |
Treatment failure Treatment interrupted (default) |  |
(Send treatment outcome to the DOTS Centre where the patient was originally registered)
**ERCUOSIS TREATMENT**

**NAME:**
**CONTACT PERSON:**
**ADDRESS:**
**PHONE:**
**ISLAND:**
**VILLAGE:**
**YEAR OF BIRTH:**
**SEX:**
**AGE:**

**SPITUM EXAMINATION RESULTS**

<table>
<thead>
<tr>
<th>Month</th>
<th>Date</th>
<th>Result</th>
<th>Weight</th>
<th>Date next appointment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<tr>
<td>6</td>
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</tr>
</tbody>
</table>

**DISEASE CLASSIFICATION**

- Pulmonary smear positive [ ]
- Pulmonary smear negative [ ]
- Extrapulmonary Site [ ]

**TYPE OF PATIENT**

- New [ ]
- Transfer in [ ]
- Relapse [ ]
- Treatment failure [ ]
- Treatment after interruption [ ]
- Other [ ]

**CONTINUATION PHASE:**

**regimen and number of tablets**

**Adults**

<table>
<thead>
<tr>
<th>R(300mg)*</th>
<th>H(300mg)</th>
<th>Z(400mg)</th>
<th>E(400mg)</th>
<th>S(1g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>[ ]</td>
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<td>[ ]</td>
</tr>
</tbody>
</table>

- Cat I (2RHZE)
- Cat II (2RHZE/3HZE)
- Cat III (2HZ)

**Children**

<table>
<thead>
<tr>
<th>R(100mg)</th>
<th>H(100mg)</th>
<th>Z(400mg)</th>
<th>S(1g)</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

- Cat I (2RHZS)
- Cat II (2RHZ)

**Day**

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28
- 29
- 30
- 31

**Remarks:**

**Enter X on day when medications were swallowed under direct observation. Draw a horizontal line through the days to indicate the number of days' supply given for self-administration.**

**The number before the letter is the duration in months of the administration of the drugs; 2RHZE/3HZE means 2 months with 5 drugs and 1 month with 4 drugs without S.**

**Treatment outcomes:**

- Cured [ ]
- Treatment completed [ ]
- Treatment failure [ ]
- Died [ ]
- Treatment interrupted [ ]
- Transferred out [ ]