

**TUBERCULOSIS CONTROL
CORE CURRICULUM FOR
PHILIPPINE MEDICAL SCHOOLS**

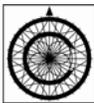
**PART I
NEEDS ASSESSMENT SURVEY ON THE
INTEGRATION OF TB CONTROL-DOTS**

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I. Background

Medical schools play a pivotal role not only in medical expertise building but also in the development of the social consciousness of future physicians. Modern societies expect these institutions to provide medical students the necessary and sufficient training in competently handling common medical and surgical problems and emergencies. But at times so much emphasis has been made on individual expertise that the consequences of their individual practice on public health are oftentimes neglected. In the case of Philippine medical schools, among these priority diseases, tuberculosis (TB) control should rank high in their list. This disease is not just consistently listed as one of the country's top causes of morbidity and mortality, its victims are those in their most productive years and therefore poses a more expensive burden on their families and communities (Department of Health, 1999; Peabody, et al, 2003). But TB is not just a clinical disease but a social problem and its eventual conquest needs a paradigm shift in the way we teach medical students in becoming responsible physicians of the future.

TB was declared a global emergency in 1993. It persists due to poverty, neglect (inadequate case detection, diagnosis and cure), changing demography and impact of the human immune deficiency virus (World Health Organization (WHO), 1997). To address this global health concern, WHO has adopted the Directly Observed Therapy Short-Course (DOTS) strategy in 1991. It recognizes DOTS as the only intervention that has consistently demonstrated high cure rates. By having a health care supervisor watch the patient swallow his pills and by having in place an infrastructure that provides free medication, free sputum diagnostic services and an efficient reporting system, the DOTS strategy effectively shifts the responsibility of curing the patient to the health system.

The Philippine National Tuberculosis Control Program (NTP) adopted DOTS strategy in 1996. Encouraged by the increase in case finding and doubling of cure rates in the initial pilot areas, the NTP rapidly expanded DOTS to involve over 95% of the country by 2000. Cure rate has exceeded the target of 85% but unfortunately, case finding rose only to 53%. In the international scenario, the WHO reported in 2001 that:

“Although DOTS has been widely accepted, many developing countries (including the Philippines) have been unable to expand coverage as rapidly as needed to achieve the global targets of detecting 70% of infectious cases and curing 85% of those detected by year 2005. Progress has been slow. In 1999, only 23% of infectious cases were detected and treated under the DOTS strategy. Today, the major obstacles to expanding TB control are political, managerial, and financial rather than technical”.

Indeed, in countries where there is a large, independent private MD practice, the success of DOTS in attaining these epidemiologic targets which necessary to reduce the TB prevalence in time, is hindered. The private MDs have their own "personalized " management interventions which developed from the knowledge they got from medical school, their experiences as clinicians seeing the highly prevalent TB cases, and the resources available in the community. The non-alignment of the private sector and the NTP, with the private practitioner, highly respected by his patients and who sees nothing wrong with his current diagnosis and management but unable to ensure drug compliance and often lacks the public health perspective and the NTP which takes a wholly public health perspective and has often ignored the private sector entirely both contribute to the continued problem of TB control in the country. Until recently, the NTP failed to provide the guidance, leadership and support over the private MDs in handling this public health condition. The result is predictable: an entirely separate "health

network” with pay-for service health care providers giving diagnostic and treatment services that, while well-meaning, are not congruent, and in many aspects, contradictory to the policies of the NTP. In context of TB, a public health issue which gets worse if the intervention is not correct or is inadequate, this is a fatal stroke!

Local literature is rife with indicators supporting the presence of the two systems. The 1997 National Prevalence Survey showed that more TB symptomatics consult the private sector than the government public health system. Incidents of mismanagement, negligible awareness and variability in the approaches employed by medical practitioners in their handling of patients with tuberculosis have been cited (Emili, J., et al, 2001). Among Filipino physicians themselves, use of multiple approaches from diagnosis, treatment, follow-up, monitoring and evaluation of patients was noted (Portero and Rubio, *Medicos del Mundo*, 2002). In a separate survey of 187 private physicians from five settings (mostly in Metro Manila and Cavite) only 50.27 percent reported awareness of DOTS. From this same survey where only 157 valid responses were recorded in this particular question, 54.79 percent admitted they are not utilizing DOTS in their private practice (Romulo, et al, 2002, PHILCAT-CDC project).

As the WHO directives specify the adoption of supporting programs for the Global DOTS Expansion Plan (GDEP), attention was also called to the lone institution responsible for the education of physicians: the medical schools. The WHO, through the Coordination Advisory and Review Group (CARG) of the Global Tuberculosis Programme (GTP), at its meeting held last November 6, 1996, recommended that:

“GTP should develop partnerships with the academic and scientific communities and other units of WHO to ensure that relevant training materials, including the medical school curriculum and nursing school teaching materials, incorporate tuberculosis and the DOTS strategy”.

In a subsequent assembly held on October 29-31, 1997 in Rome, the 25 TB expert-participants from 6 countries of the WHO regions reported that by introducing changes in medical education, research and delivery of care for TB control, medical schools have the unique opportunity to demonstrate their social responsibility (WHO, 1997). It was stated in this workshop report that medical students should graduate only after acquiring the basic “5-star” qualities of a doctor; included in these competencies are the basic knowledge, skills and attitudes pertinent to DOTS in managing TB. Graduates, then, of Philippine medical schools should not simply possess basic knowledge of TB as a disease entity but more importantly the competence in managing tuberculosis following the DOTS strategy.

In the late 1990s the Philippine College of Chest Physicians Council on Tuberculosis did some groundwork on enhancing TB education in medical schools. As a follow-up initiative to these works, the Philippine Coalition Against Tuberculosis (PhilCAT) jointly sponsored with APMC a workshop on TB in medical education in 1999. Thereafter a Task Force on TB medical education was formed in 2001. A major TB project was awarded by USAID to the Chemonics International in October 2002. Under this project called the Philippine Initiatives in the Private Sector (Phil. TIPS), the design and development of a TB DOTS syllabus was conducted. Short-term technical assistance consultants were asked to develop the project which consists of 3 parts, the needs assessment survey, the curricular design and the teaching-learning resources and modules as well as the evaluation too;

To build the baseline data on how TB control-DOTS could be integrated in Philippine medical schools, this needs assessment study was conducted. This project hoped to determine how TB controls and not just TB disease management is being covered in the curriculum of Philippine medical schools. The ultimate goal was to identify areas where knowledge, attitude and skills on controlling TB could be most appropriately strengthened and integrated with particular reference to the directly observed therapy short-course (DOTS) treatment. Such areas are proposed in a separate TB core curriculum for medical schools to adopt.

II. Objectives of the Study

- A. Determine how tuberculosis, TB control and the directly observed therapy short-course treatment are taught in medical schools in the Philippines;
- B. Describe in which content areas or topics are TB, TB control and DOTS being covered in what particular subjects.

III. Study Design

- A. *Research design.* This is a descriptive survey of how medical schools in the Philippines are teaching TB, TB control and DOTS in their respective curricula. It made use of both primary and secondary data that were analyzed qualitatively within a period of one month from mid-January to mid-February 2003.
- B. *Data collection procedures.*
 1. Review of existing curricula and course syllabi. All medical schools were requested through a written communication to furnish the Office of the Philippine Tuberculosis Initiatives for the Private Sector (Phil TIPS) a copy of their existing curriculum including syllabi that deal with TB-DOTS in any way. There were 13 curricula and sample syllabi that were received and reviewed in this study.
 2. Survey questionnaire. All deans of Philippine medical schools were requested to accomplish the survey questionnaire especially constructed for this purpose. This was administered during the annual convention of the Association of Philippine Medical Colleges held in Baguio City last January 23-25, 2003. Response rate was 56.25 percent (18 out of 32 medical schools).

The questionnaire was validated qualitatively through a series of consultation with content experts on TB-DOTS and medical education. Constructs in the questionnaire included items on awareness of deans regarding integration of TB-DOTS in their curricula, the thrusts of their school, topics and name of subjects where TB-DOTS are being covered or taught, what references are currently being used for the purpose and perceptions of respondents on the need for a single medical personnel, e. g. coordinator or overseer who would be responsible for the teaching of TB-DOTS in their medical schools. Respondents were also asked of their perceptions regarding their graduates' competence in managing TB.

3. Appraisal of relevant literature. Several general and secondary references were also reviewed and considered in this needs assessment. Investigations on TB-DOTS, how these two topics are covered in WHO reports, journal articles, bulletins, annual reports, manuals, samples of monographs and core TB-DOTS curriculum used by other countries were likewise studied.
- C. *Analysis of data.* Frequency distributions and descriptive statistics were used to organize and summarize the data. All other data were analyzed qualitatively.
- D. *Scope and limitations.* Findings of this survey were based on the reports given by the deans based on the distributed questionnaires. These were corroborated with the appropriate secondary data, e.g. sample curricula, syllabi and other reports. These results are only limited to the manifest curriculum and degree of recall of the deans while accomplishing the instrument. It is recognized that the total picture of how TB-DOTS are integrated in these medical schools could only be made more accurate if validated with students' perceptions and other output indicators like actual tests of awareness on TB-DOTS by the concerned sectors from the medical schools.

IV. Results and Discussion

Profile of participating schools. A representative sample of 18 medical schools participated in this survey. They are not just a significant majority in terms of number but also in geographical representation. The three largest geographical divisions of Luzon (separated from the national capital region), Visayas and Mindanao are fairly represented. Table 1 lists these medical schools according to their geographic origins and average number of graduates from 2000 to 2002. Figures show that these are representative not just in terms of the country's medical schools but also with regard to their geographical locations and number of graduates. Of the number of medical graduates each year, 75% roughly come from these 18 participating schools. There are six out of nine (response rate of 66.67 percent) schools representing the national capital region. Luzon has the lowest response rate of 36.36 percent (4 out of 11 schools), 62.50 percent for Visayas (5 out of 8) and 75 percent (3 out of 4) from Mindanao.

The participating schools also reflect the number of institutions with their respective curricular tracks. There were 7 (38.9 percent) who reported to be under the purely traditional and competency based curriculum. The rest reported to have a combination of varied trends in medical curricula with equally varied thrusts like having a combination of being clinically and community-oriented, public health oriented and/ or a combination of all.

Table 1. List of Participating Medical Schools, their Geographical Locations and Mean Number of Graduates from 2000-2003 (n=18)

Name of Medical School	Geographical Location	Average Number of Graduates*
1. <i>Pamantasan ng Lungsod ng Maynila</i>	National Capital Region	29.33
2. University of the Philippines Manila	National Capital Region	152
3. St. Luke's College of Medicine	National Capital Region	88.33
4. University of the East	National Capital Region	211
5. Far Eastern University	National Capital Region	258
6. University of Santo Tomas	National Capital Region	368
7. Angeles University Foundation	Luzon	22.67
8. Lyceum Northwestern	Luzon	19.67
9. De La Salle University	Luzon	151
10. University of Perpetual Help	Luzon	25
11. West Visayas State University	Visayas	61
12. Cebu Doctors College of Medicine	Visayas	50.33
13. Gullas Medical College	Visayas	To be verified
14. Southwestern University	Visayas	82.33
15. Cebu Institute of Medicine	Visayas	77.67
16. Xavier University	Mindanao	25.33
17. Mindanao State University	Mindanao	23.33
18. Davao Medical School Foundation	Mindanao	61
Grand Mean in 3 years		1,465.66

*Data obtained from the Association of Philippine Medical Colleges through its Executive Director, The Colleges of Medicine of the University of the Philippines and the St. Luke's Medical Center William H. Quasha Memorial Inc.

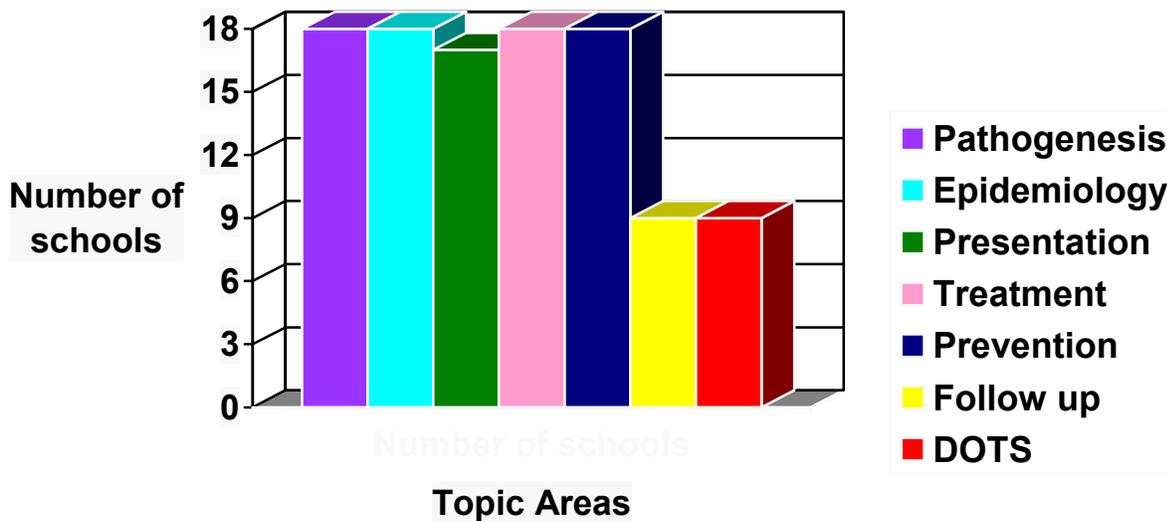
The teaching of TB-DOTS in Philippine medical schools. All participating medical schools reported confidently that their graduates are equipped with the necessary knowledge, skills and attitudes in TB-DOTS management. All the 18 respondents answered "yes", they think their graduates are equipped. This conviction of the deans can further be understood by their 100 percent affirmation that they are aware of the directly observed treatment short-course strategy as a paramount component of the National Tuberculosis Program and that such are being integrated in their respective curricula. Table 2 presents the percentage distribution of the responses regarding the three questions.

Table 2. Frequency Distribution of Responses Regarding Awareness of TB Control-DOTS Component in the Medical Curriculum (n=18)

Questions	Frequency	Percent
Are your graduates equipped with necessary knowledge, skills and attitudes on TB management?	Yes = 18 No = 0	100 -
Are you aware of the DOTS adopted by the WHO and the NTP to control TB?	Yes = 18 No = 0	100 -
Is this currently being integrated in the teaching of TB in your school?	Yes = 17 Not sure = 1	94.44 5.55

To check the internal consistency of these responses, participants were also asked what specific aspects of TB and TB control are being emphasized in their schools. Figure 1 presents the frequency distribution of these responses. Figures confirm that all respondents integrate and emphasize pathogenesis, epidemiology, treatment and prevention of TB in the various subjects and 95% of them take up clinical presentation of TB disease in detail. However, only half of them highlight follow up evaluation and DOTS strategy. Reported time devoted to these aspects ranged from one hour to eight hours combining lectures, practical exercises and laboratory sessions. It was also clear from the curricular designs and accomplished questionnaire that within these time ranges, TB is being covered as one of the disease entities under various conceptual themes like infectious diseases, study of bacteria and systems/organ studies like pulmonary and respiratory systems.

Figure 1. Different Aspects of TB-DOTS Emphasized in Philippine Medical Schools (n=18)
 Furthermore, out of the 13 course syllabi reported and documented, only seven (38.89



percent) explicitly stated DOTS as one of the primary focuses in their approach to teaching TB. All the others reported to have focused on the biomedical component of the disease.

Of those who tackled DOTS in their curriculum, two were subject-oriented (making up 28.6 percent of subject-oriented schools) and five were problem-based (45.4 percent of problem-based schools).

Again for internal consistency check, respondents were asked in what course/s and year level/s are TB, TB control and DOTS being taught. Data are presented in table 3. The figures show that TB as a cognitive code is a pervading concept that is consistently taught from first to fourth years of undergraduate medical education. The data also prove that there is vertical and horizontal integration of TB in both subject-oriented and integrated curricular tracks.

Table 3. Subjects and Year Levels Identified by Respondents
Where TB, TB Control and DOTS are Taught

Year Level	Subjects/Modules Where TB is Taught
First year	Subject: Physiology Modules: Respiratory System, Patient Education
Second year	Subjects: Preventive and Community Medicine, Pharmacology, Microbiology, Pathology, Internal Medicine Modules: Respiratory System, Research Methods, Central Nervous System, Urology
Third Year	Subjects: Medicine, Preventive and Community Medicine, Pediatrics, Surgery, Infectious Diseases, Radiology, Gynecology Modules: Children's Diseases, Musculoskeletal System, Urology, Neurology, Pulmonary Medicine, Ophthalmology and Otorhinolaryngology
Fourth Year	Subjects: Family Medicine, Infectious Diseases, Pulmonary Medicine, Internal Medicine Modules: Community-Oriented Medicine, Infectious Diseases, Pulmonary Medicine

From among the seven medical schools that reported covering TB control–DOTS in their actual syllabi, another round of review was done to see how explicitly the said subject matter is being covered. In the case of two universities that have recently turned problem based learning (PBL) in their approach, their curricular designs explicitly state the following learning objectives in a module on respiratory system taken by second year medical students:

- A. Describe the clinical presentation of the different forms of pulmonary tuberculosis;
- B. Describe the pathophysiology of primary and reactivation tuberculosis;
- C. Portray briefly extra-pulmonary tuberculosis and its manifestations;
- D. List down diagnostic tools and procedures used in confirming pulmonary tuberculosis and state findings expected;
- E. Tabulate the diagnostic classification and categorization of pulmonary TB and state the recommended treatment regimen based on guidelines:
 1. Understand the principles of anti-TB drug therapy: chemo-prophylaxis, short course chemotherapy, DOTS
 2. Enumerate the classes of anti TB drugs
 3. Understand the principles in the treatment of MDR TB
 4. Enumerate the 2nd line anti TB drugs
 5. Recognize the special problems in TB treatment and be aware of the required measures/ regimen for such problems
- F. List down strategies for the prevention of pulmonary TB

Such objectives are clearly synchronized in correlated subjects as revealed by the following outline of topics in Preventive and Community Medicine III: Health Promotion, Disease Prevention and Control taken during the third year.

- A. Promotion of health
 - 1. Meeting basic needs
 - 2. Keeping functional vitality
- B. Protection of health
 - 1. Avoidance of abuse
 - 2. Increasing host resistance
 - 3. Reduction of exposure to health risk
 - 4. Disease prevention and control

In these particular topic outlines and instructional designs, TB appears in form of a case of pulmonary TB featured for small group discussion and combined group conference. Furthermore, according to how the topics are presented, it could also be inferred that the treatment regimen and the being a public health concern of the disease are highlighted. These are two components integral to DOTS namely the diagnosis of symptomatic TB patients and the use of standardized multi-drug therapy.

In the case of a more common traditional but competency based curricular track, the various aspects of TB-DOTS are integrated both vertically and horizontally in the different subjects at various year levels. Vertical integration is apparent in the following excerpts of course syllabi in five courses namely Pathology, Pharmacology and Microbiology in the second year, Pediatrics and General Gynecology in the third year. The content and approach of the topic remains under the discipline of each subject but the material on TB could be noted as an apparent subject matter since it is repeated in the subjects.

Second year:

- A. Learning objectives in Pathology:
 - 1. Discuss the incidence, pathogenesis and morphologic features of Tuberculosis;
 - 2. Give the biologic features of the organism that explains its pathogenicity;
 - 3. Outline the important pathologic and clinical differences between the two clinical forms of TB including the possible complications;
 - 4. Discuss the principles and significance of the tuberculin test and enumerate the conditions that may result in false immunology.
- B. Learning objectives in Microbiology:
 - 1. Give the current state of TB worldwide;
 - 2. Give factors which influence increase of TB in the world;
 - 3. Discuss the important characteristics/virulent factors of the agent, in relation to the pathogenesis of the disease, host response and laboratory diagnosis;
 - 4. Enumerate the current mode of antibiotic treatment available;
 - 5. Discuss the drug sensitivity/resistance of the organisms to antibiotics;
 - 6. Enumerate ways/methods of prevention and control of the disease;
 - 7. Discuss some important features of the National Tuberculosis Program of the Philippines.

C. Learning objectives in Pharmacology

1. Discuss the properties, mechanisms of action and uses of the more important anti mycobacterium agents being used in the therapy of tuberculosis and leprosy including:
 - a. Rifampicin
 - b. Isoniazid
 - c. Pyrazinamide
 - d. Ethambutol
 - e. Dapsone
 - f. Clofazimine

Third Year:

A. Learning objectives in Medicine

1. Define tuberculosis;
2. Identify the etiology and describe the characteristics of pulmonary TB;
3. Discuss the route of transmission of pulmonary tuberculosis (PTB)
4. Trace the pathogenesis of PTB from its portal of entry to the expression of clinical disease;
5. Describe immunity to TB;
6. Discuss tuberculin hypersensitivity;
7. Enumerate the methods employed in the general diagnosis of TB;
8. Discuss first line drugs treatment of TB;
9. Discuss briefly the prevention/chemoprophylaxis, BCG vaccination and TB control programs

B. Learning objectives in Pediatrics

1. Emphasize the impact of childhood TB in the community
2. Identify the different clinical manifestations of infection in children

C. Learning objectives in General Gynecology:

1. Explain the epidemiology of PID and pelvic tuberculosis;
2. Explain the sequelae of PID and pelvic TB; how to diagnose and manage it.

Again based on how the topics are outlined and arranged, it could be deduced that the same two TB-DOTS components are being highlighted in these given courses.

The deans were also asked how TB DOTS are taught and evaluated in their respective schools. Data reveal that in both traditional, competency-based and the integrated, case-based and problem-based curricula, TB-DOTS, just like the rest of the topics covered in each year level, are taught using basically the same repertoire of teaching-learning strategies and evaluation procedures. Table 5 shows that combinations of lecturing (teacher as presenter before a large group), interactive (teachers and students in small group setting) and individualized modes of instruction are used judiciously. Persistent materials mentioned in all these settings are the use of cases, problems and records of actual patients. Evaluation of student achievement is done through a combination of written, oral and practical examinations supported by clinical cases.

Table 5. Teaching-Learning Strategies and Evaluation Procedures Used in the Teaching of TB-DOTS

Teaching-Learning Strategies	Evaluation Procedures Used
1. Presentations a. Lectures b. Clinical presentations c. Laboratory sessions	Written examination Practical and oral examinations
2. Interactive mode a. Small group discussions b. Seminars c. Preceptorials d. Ward sessions	Written examination Case presentations Oral examination
3. Exposure to the community	
4. Independent Learning	Case report

Data in table 5 reveal the usual repertoire of both teaching-learning methods and evaluation procedures to certify student achievement in the course. These data as presented by the deans in the survey and as reviewed in the official curricula show a generic approach to teaching and learning in medicine. The absence of any focus or highlight in these sets of strategies and evaluation procedures reflect that these schools have not yet developed a set of teaching-learning strategies and their corresponding evaluation instruments specifically and especially for the teaching of TB-DOTS.

With regard to instructional resources being used, diverse answers were given naming the use of standard guidelines prescribed by the World Health Organization (WHO), the Philippine Department of Health (DOH) and the Philippine TB Consensus. Only five deans reported to be using all the pertinent DOTS references that include, aside from the WHO and DOH materials, the Philippine National Tuberculosis Program, the standard guidelines of the American Thoracic Society and the Communicable Disease Control.

Corollary to the generic approach to TB-DOTS as a concept, it could also be inferred from the respondents their reason why they perceive that their graduates are equipped to manage TB patients. Preceding discussions show that TB is covered in different subjects and is being taught by consultants from various specialties or general areas of study. This explains why figures in table 6 reveal that majority of the deans are not convinced that a single authority on TB has to be identified.

Table 6. Frequency of Responses on the Expressed Need for a Single Person to be Responsible for the Teaching of TB in medical Schools (n=18)

Responses	Frequency	Percent
Yes (needed)	6	33.33
No	7	38.90
Maybe	4	22.20
No answer	1	5.60
Total	18	100.13

Tuberculosis is one of the most common infectious disease in the country and is therefore expected to be managed competently even by general practitioners. In fact, an overwhelming 94 percent (17 respondents) reported that there is indeed no single person currently assuming the responsibility of teaching TB in all year levels in their medical schools. Table 6 shows that a significant 38.90 percent said “No” (meaning not needed) in contrasts to 33.33 percent who said “Yes” (meaning needed) to a single “TB authority” in their medical schools. These figures realistically mean that TB as a global emergency is being treated in our medical schools as everybody’s business. While this fact should be welcomed, it should also be realized that the disease continues to escalate and even worsen over the years. Medical schools can certainly examine their present treatment of TB control as a component in their curriculum and take it as their accountability to improve the health standing over a period of time. The initial step toward this end could very well be having a person, or a department to be held responsible for the handling of this concept in the medical curriculum.

V. Conclusions

Philippine medical schools are confident on the readiness and competence of their graduates to manage all forms of tuberculosis patients. They reported that the various components of the disease are adequately covered in different subjects spread out in four years of medical education. This is an important assurance for the Filipinos to know that their physicians, especially the general practitioners are ready to combat the deadly disease.

Findings also reveal that the biomedical and clinical aspects of TB are emphasized. There were only seven (38.89 percent) of them who actually deal with TB control through DOTS. Consequently, DOTS is not highlighted to the same degree as the other aspects. Specific areas in the different subjects or modules where TB control and DOTS are introduced and covered are wanting.

VI. Recommendations

- A. A stronger, more concrete and comprehensive vertical and horizontal integration of TB control and DOTS in Philippine medical schools should be initiated. This can serve as core curriculum and template for all medical schools to adopt.
- B. Such core curriculum should be duly validated to be truly adoptable. Once implemented or adopted, the core curriculum should be monitored and periodically evaluated.

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VIII. Annex

January 4, 2003

Dear Colleagues,

We are a multidisciplinary team of faculty members and technical experts involved in the Philippine Tuberculosis (TB) Initiatives for the Private Sector (Philippine Tips), working to develop an effective strategy to teach tuberculosis to medical students. This shall be in congruence with the World Health Organization and the Department of Health's focus on Directly Observed Treatment, Short Course Strategy. This is part of the previous works of the APMC and PHILCAT to develop a holistic and comprehensive plan to totally eradicate TB in this country.

One of the important components of this mission is making TB a pervading concept in the entire medical curriculum. Ultimately, this would mean developing a TB Master Plan in Philippine medical education.

We would like to solicit your help by requesting you to: (1) accomplish the following questionnaire on the profile of TB in your present school curriculum, and (2) bring this together with a copy of the syllabus of the subjects/ courses / modules that are taking tuberculosis as a topic in your medical school to the APMC annual meeting on Jan.23, 2003 in Baguio City.

Your inputs would be a most important consideration in the succeeding projects of Philippine Tips. Furthermore, your participation would not just represent your institution in this study; you are also ensuring a slot for your medical school and your selected representatives to take part in our succeeding conferences and activities including their corresponding teaching-learning resources.

We thank you in advance for your participation!

Truly yours,

Dr. Sanchez, MD, MPH
APMC Executive Director

Charles Y. Yu, MD, MSc
PHILCAT Chair

**QUESTIONNAIRE ON THE PROFILE OF TEACHING TUBERCULOSIS
IN PHILIPPINE MEDICAL SCHOOLS**

MEDICAL SCHOOL: _____ DEAN: _____
 FAX NUMBER: _____ E-MAIL ADDRESS: _____
 CONTACT PERSON: _____

1. What do you think is your school's general thrust in teaching TB? Please encircle letter.
 - A. mainly clinically oriented
 - B. clinically and public health oriented
 - C. clinically and community-oriented
 - D. public health-oriented
 - E. others, please specify: _____

2. What aspect/s of TB is/are being emphasized in your school? Please encircle appropriate letter/s.
 - A. Pathogenesis and Transmission
 - B. Epidemiology
 - C. Clinical presentation
 - D. Diagnosis
 - E. Treatment
 - F. Prevention
 - G. Complications of the disease
 - H. Others, please specify: _____

3. Are you aware of the Directly Observed Treatment, Short-course Chemotherapy (DOTS) strategy adopted by the World Health Organization (WHO) and the National Tuberculosis Program (NTP)? Yes _____ No _____

4. If YES, is this currently being incorporated in the teaching of TB in your school? Yes _____ No _____

5. If YES, how is this done? Please check all appropriate letters.
 - ___ a. lectures
 - ___ b. problem-based learning, tutorials, small group discussions
 - ___ c. self-instructional modules
 - ___ d. laboratory / practicum classes
 - ___ e. community medicine
 - ___ f. clinical clerkship rotation with exposure to DOTS in RHU
 - ___ g. preceptorials with consultants
 - ___ h. others, please specify _____

6. Check which of the following references are used and available in your school.

	Used	Available
A. WHO guidelines		
B. DOH / NTP Manual of Procedures		
C. 2000 Philippine TB Consensus Guidelines		
D. ATS Guidelines		
E. CDC Guidelines		

7. Do you think the medical graduates of your school are equipped with necessary knowledge, skills and attitudes on TB management? Yes _____ No _____
8. Is there a single person responsible for TB education across all year levels in your school? Yes _____ No _____
- IF YES, please name the person _____
- Area of specialty: _____
- If NO, do you think there is a need for such a person? Yes _____ No _____

**TUBERCULOSIS CONTROL
CORE CURRICULUM FOR
PHILIPPINE MEDICAL SCHOOLS**

**PART II
TB DOTS MASTER PLAN:
CURRICULUM DESIGN FOR PBL AND
SUBJECT-CENTERED MEDICAL SCHOOLS**

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May 14, 2003

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I. Rationale

Graduates of Philippine medical schools should effectively manage tuberculosis (TB) more than any other disease. The deadly disease does not only consistently appear for many decades in the top ten leading causes of morbidity and mortality; its victims are those in their most productive years (Peabody, et al, 2003) and its danger if unattended or wrongly intervened is a sure formula for the epidemic of multiple drug resistance TB. This damage can span several generations (Department of Health, 1999). Controlling tuberculosis is both a global and national emergency and should be a primary concern of all medical schools in the Philippines.

In 1991, the World Health Organization (WHO) adopted the Directly Observed Treatment, Short-course (DOTS) strategy to control TB as a global epidemic. It is convinced that based on research evidences, DOTS is the only intervention that has consistently demonstrated high cure rates. In 1996, WHO, through its Global Tuberculosis Program (GTP) took bolder steps when it recommended that:

“GTP should develop partnerships with academic and scientific communities and other units of the WHO to ensure that relevant training materials including the medical school curriculum and nursing school teaching materials, incorporate tuberculosis and the DOTS strategy.”

From this take-off point, the Philippine Coalition Against Tuberculosis (PhilCAT), The Association of Philippine Medical Colleges (APMC), and the Philippine Tuberculosis Initiatives for the Private Sector (Phil TIPS) is collaborating with all the medical schools in the country to include TB – DOTS in their curriculum. A needs assessment was initially conducted to determine how present medical schools in the Philippines are integrating TB, TB control and DOTS in their respective curricula.

Findings reveal that while participating schools admit incorporating the various aspects of TB in all year levels, the breadth of this integration and how pervasive it is really delivered in the classes are far from being uniform or even evaluable. Furthermore, data also show that the major emphasis remains to be the generic nature of TB as an infectious disease and its being a biomedical entity. The 18 out of 32 medical schools (56.25 percent response rate) reported that they cover the pathogenesis, epidemiology, presentation, treatment and prevention of TB in their respective curricula. However, only half of them covered follow-up and DOTS specifically to control TB. This suggested further that despite awareness on DOTS, these medical schools hardly highlights DOTS as a specific recommended strategy for TB control.

II. Curricular Framework

This core curriculum presents TB, TB control and DOTS as both a biomedical and a social phenomenon. In the former, the etiology, transmission, pathogenesis, clinical presentation, diagnosis and management are all covered using the simple to complex, prerequisite learning, whole to part, and chronological organization of subject matter. As a social phenomenon, this curriculum deals with the epidemiology, burden of disease, and socio-psychological, economic and political characteristics of TB. These curricular contents are interspersed with the biomedical characteristics to present to both teachers and students the coherent learning unit of TB, TB control and DOTS.

In a nutshell, this core curriculum has the following basic features:

A. Competency-based curriculum

Regardless of the track that a given medical school is pursuing, students who have finished this core curriculum are expected to develop the same competencies and could demonstrate these under the suggested standards of performance. This is because the educational outcomes of this curriculum are all stated in behavioral and measurable terms broken down from general to specific, observable evidences of achievement.

The general competencies are:

- A. Thorough understanding of TB as a biomedical and social phenomenon
- B. Management of patients with pulmonary tuberculosis and other common forms of extrapulmonary TB
- C. Prescription of the directly observed therapy short-course (DOTS) strategy in all involvements and/or activities related to TB

Unlike the common patterns in most schools where courses are already lined up for students and that each of these courses has its own fragmented sets of competencies to be learned, this TB–DOTS curriculum kicks off from the competencies above. These serve as bases in selecting the other curricular components, namely, content, teaching – learning strategies, resources and evaluation of student achievement.

To illustrate based on first general competence, the following curriculum design has been formed. Please see Table 1.

Table 1: Sample Competency-based curriculum

General objective	Specific objectives	Subject matter	Subjects for integration	Teaching-Learning Activities	Resources	Evaluation
Demonstrate thorough understanding of TB as a biomedical and social phenomenon	Describe the overall TB burden of disease and its implications	TB Burden of disease Implications to individuals, community and country	Family Medicine Research Methods Epidemiology	Complete Module 1 Discuss Case study of a family with one member as source	Module 1 Case study PowerPoint slides	Written exam
	Follow standard procedures in performing and interpreting sputum smears	Steps in performing sputum smear Criteria for interpreting sputum smears Compliance with DOTS standard procedure	Microbiology	Watch slides of sputum smears Demonstrate sputum smear examination Return demo Plenary session to discuss interpretations and difficulties encountered	Slides of AFB smear Microbiology laboratory Module 2 NTP Manual of Procedures	Written exam Practical exam

B. Interactive in teaching-learning strategies and instructional resources.

The proposed curriculum rests on the assumption that medical students are highly motivated learners (Smith and Dollase, 1999). Since these students are also chronologically in their early adulthood stage, it is further assumed that they carry with them the traits of adult, and therefore, self-directed, learners (Rogers, 1985 and Knowles, 1987).

Considering the target learners as motivated adults and the general competencies enumerated earlier, this proposed curriculum is designed to be interactive in its repertoire of teaching-learning strategies and instructional resources. In being interactive, the dichotomy of teacher authority and student autonomy has been considered. The schema is presented in Figure 1. The teachers are advised to choose how much of each they would like to adopt in the process of covering each of the topics presented.

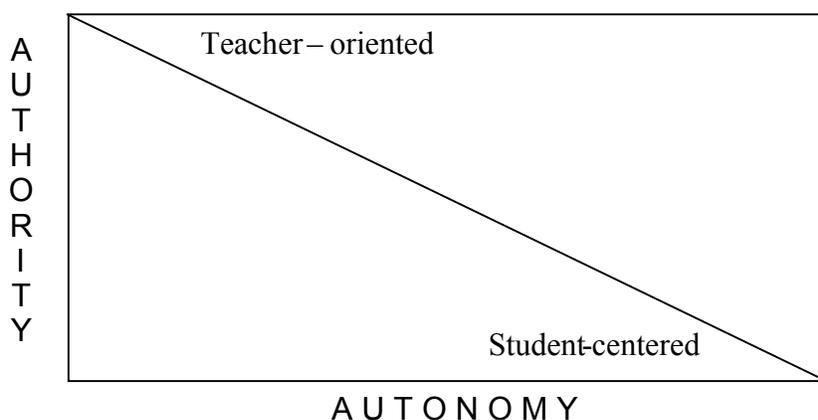


Figure 1. Continuum of Teaching – Learning repertoire

It is further suggested that the faculty members seriously consider the manifest curricular track and their personal teaching styles in covering the various lessons in this curriculum.

Corollary to this, an equally interactive set of resources is prescribed. Teachers' materials include the minimum set of slides for PowerPoint presentations, case studies and manuals with their respective scripts for presentations, laboratory sessions and small group activities. In each of these resources, a conscious effort has been made to involve the learners and to make them interact actively with the rest of the class. Table 1 shows that in covering Epidemiology and Microbiology sessions, students are engaged in interactive activities. It is hoped that through these, they develop the competence to become critical and creative problem solvers.

C. Vertically and horizontally integrated.

Integration refers to the organization of teaching matter to interrelate or unify subjects frequently taught in separate academic courses or departments (Harden, Sowden and Dunn, 1984). In this curriculum, various topics from the different disciplines have been integrated according to the three terminal competencies set. Two basic curricular concepts have been considered in this particular feature namely scope and sequence. The former refers to the range as well as the depth of studies planned in any curriculum. It concerns the adequacy of the major topics under each area of study and the provisions for a reasonable depth of treatment for each

area of study (Longstreet and Shane, 1993). Sequence on the other hand, refers to the order of studies encountered by students. Implicit in this concept is continuity or logical ordering of studies so that one leads to the next without leaving a point where more is expected or what has been learned is too little to form a basis for some future study (Longstreet and Shane, 1993).

The final product of scope and sequence as considerations for organizing content is an integrated curriculum. Such can be horizontal or vertical. Horizontal integration refers to integration among parallel disciplines such as physiology, biochemistry, medicine, etc. For example, in the third year of this core curriculum when students are in their clinical clerkship rotation, those rotating in the Department of Pediatrics are given correlate lectures on standardized treatment of TB among children to reinforce the self-study module on DOTS and transmission and pathogenesis. Within the year level, topics on pharmacology, pediatrics, medicine, physiology, microbiology and preventive medicine are integrated for the students to internalize strongly their understanding of managing TB among children. Vertical integration, on the other hand, is integration among disciplines traditionally taught in the different phases of the curriculum (Harden, Sowden and Dunn, 1984). For example, it could be noted in this curriculum that across year levels, e. g. from first to fourth years, students are expected to cover the concepts of epidemiology, pathogenesis, transmission, diagnosis, treatment, etc. in varying depths and all concluding toward DOTS. It is designed precisely to establish in the students a strong cognitive code on TB, TB control and DOTS. In the end, it is further expected that students would have a logical and coherent understanding of the phenomenon in their entire medical training. The framework of this master plan is presented in figure 2.

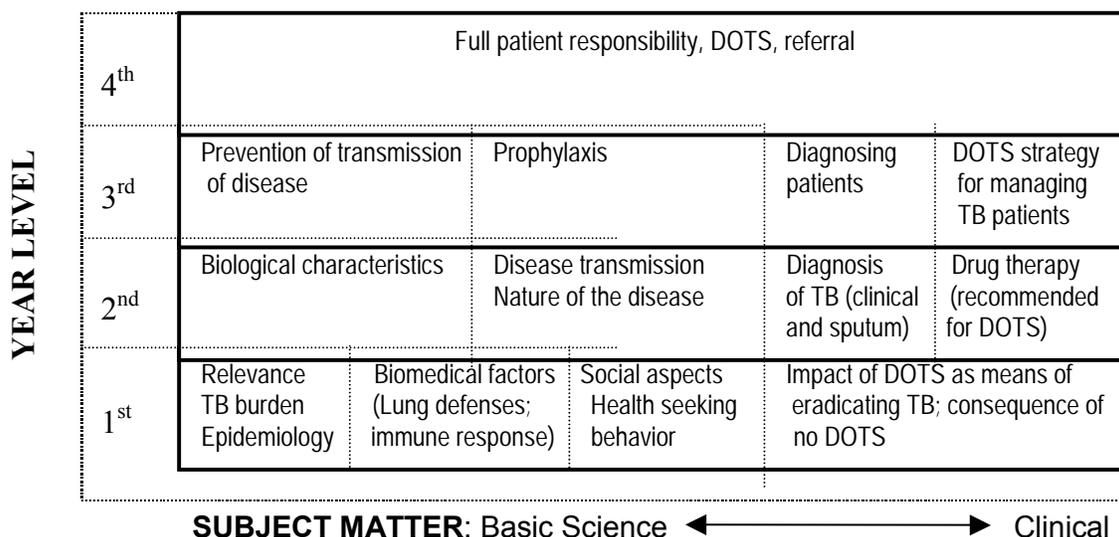


Figure 2. Curricular Framework of Integrating TB in Philippine Medical Curriculum

III. Curriculum design for Subject-Oriented Track

OBJECTIVES	CONTENT	SUBJECTS	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
Graduates of Medicine who finished this Tuberculosis (TB) Master Plan can:						
I. DEMONSTRATE THOROUGH UNDERSTANDING OF TB AS A BIOMEDICAL AND SOCIAL PHENOMENON					1 st / 2 nd year	
EPIDEMIOLOGY			Students read and complete Module 1 prior to lecture and activities in class			
1. Describe the overall TB burden of disease and its implications	TB burden of disease Implications to individuals, community, country Biopsychosocial model	Family Medicine Research Methods	Teacher discusses TB burden using case with one member as source (Case 1)	NTP Survey, 1997 Module 1	15– 30 mins.	Written exam
2. Critically examine the position of the Philippines in terms of world health statistics on TB	Global and national statistics: current data and trends Leading causes of mortality and morbidity	Family Medicine Research Methods	Teacher and students engage in interactive discussion on prevalence and incidence of TB in RP	NTP 1983 and 1997 WHO and DOH statistics	15– 30 mins. 30 mins SGL activity 40 mins plenary	
3. Discuss the factors why TB continues to plague the country	Health-seeking behavior Health care delivery systems Causes of delay Biomedical factors	Family Medicine	Students brainstorm on factors such as causes of delay, health-seeking behaviors, biomedical, environmental factors They use Case 1 as take off point	NSO, PHS, HSRA, DOH data on economic status, health care infrastructure and costs Case study 1		Case report Peer evaluation Summative assessment for Module 1

OBJECTIVES	CONTENT	SUBJECTS	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
4. Describe the efficient and novel way by which Directly Observed Therapy, Short course (DOTS) strategy can control TB	DOTS and its impact on prevalence / incidence Role of DOTS in controlling TB in the country / world	Family Medicine	Students read assigned article on DOTS Teacher gives lecture on DOTS showing its impact on TB control	Module 1 NTP manual		Written exam Summative assessment for Module 1
5. Describe the current effort to control TB in the country: the government front; the private MD front; the drive to integrate private MD management of TB cases to the NTP (private-public mix); and coalition building to broaden the support for TB control.	DOTS and its impact on prevalence / incidence Role of DOTS in controlling TB in the country / world	Family Medicine	Students work in groups on activities suggested in Module 1 A plenary session is held at the end of activities to synthesize essential points.	Module 1 NTP manual		Written exam Summative assessment for Module 1
TRANSMISSION & PATHOGENESIS			Students read ahead of lecture and discussion (Module 2 and other materials).		1 st / 2 nd	
5. Relate morphological and physiological characteristics of <i>Mycobacterium tuberculosis</i> (MTb) with its staining, antigenic and virulence properties	Morphology of MTb Physiology of MT Staining characteristics Antigenic properties Virulence factors Mutation to resistant strains	Microbiology	Teacher highlights important points using slide presentation on	Microbiology textbook Supplementary materials, slides, visual aids	1 hr	Written exam

OBJECTIVES	CONTENT	SUBJECTS	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
6. Follow standard procedures in performing and interpreting sputum smears	Steps in performing sputum smear Criteria for interpreting AFB smears Compliance to standard procedures from collection to transport of specimen	Microbiology	Teacher discusses the specificity, sensitivity of AFB sputum smear and shows slides of AFB Students watch slides Demonstration and return demonstration of performance of AFB smear on AFB (+) specimen are done Plenary session is done at the end of laboratory session to discuss interpretations and difficulties encountered by students.	Microbiology laboratory facilities Module 2	2 hrs	Practical exam
7. Explain how man develops MTb infection	MTb infection Invasion of the host by MTb Response of the host, hypersensitivity reaction Immunity and resistance	Microbiology	Teacher gives lecture on disease transmission and the body's response	Microbiology textbook Supplementary materials Module 2	1 hour	Written exam
8. Discuss the pathological consequences of TB infection	Gross and microscopic pathology of affected organs Correlation between biological characteristics of MTb and pathological changes (cavitary and non-cavitary disease)	Pathology Internal Medicine	The teacher discusses development of disease The students clarifies issues, examines pathological specimens during the Pathology laboratory period.	Pathology textbook Pathology specimens Supplementary materials	1 hour	Written exam

OBJECTIVES	CONTENT	SUBJECTS	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
9. Distinguish between TB infection and active disease	Difference between TB infection and disease Features of primary infection, TB active disease and TB inactive disease	Pediatrics Internal Medicine	Students are engaged in exercise using paper cases to distinguish between TB infection and active disease	Textbooks on Pediatrics and Internal Medicine Module	1 hour	Written exam
10. Explain the transmission of MTb within a family or community	Transmission of TB Environmental factors Host factors: Population at risk (including HIV)	Family Medicine Pediatrics Internal Medicine	Discussion on how TB is transmitted from one person to another Discussion on people at risk The class visits a nearby DOTS center or a family under DOTS, or interview a patient under DOTS or a treatment partner.	Textbooks Modules 2	1 hour Half day	Written exam Report on the visit
11. Discuss the rationale why DOTS is most instrumental in detecting and controlling TB disease	Components of DOTS Rationale of DOTS strategy	Family Medicine Microbiology	Discussion is done on DOTS components and significance. Family visit and interview a family currently under DOTS	NTP manual Modules 2, 5	As above	As above Summative assessment for Modules 2, 5
II. EVALUATE PATIENTS WITH PTB AND THE MORE COMMON FORMS OF EXTRAPULMONARY TB ACCORDING TO STANDARDIZED CRITERIA					3rd and 4th yr During clinical rotations	

OBJECTIVES	CONTENT	SUBJECTS	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
1. Identify signs and symptoms suggestive of pulmonary TB and the more common forms of extrapulmonary TB	Common complains of patients with PTB and the more common forms of extra-PTB PE findings of such patients Natural history of the disease	Medicine Pediatrics Neurology Gynecology Orthopedics ENT Ophthalmology	The teacher discusses signs and symptoms of disease with case/s as example/s, videotapes or slides. Students have preceptorials with TB patients as cases Students complete Module 3	Corresponding textbooks Videotape Clinical setting Module 3, 5		Written exam Preceptorial grades
2. Elicit relevant clinical history from a patient suspected of having TB	Elements of clinical history History of past TB treatment Symptoms of TB patients Thoroughness Confidentiality Communication skills Interpersonal skills	Medicine Pediatrics Neurology Gynecology Orthopedics ENT Ophthalmology	Teacher discusses elements of clinical history Video is presented on actual history taking or demonstration on a actual simulated patient Return demonstration is done by students Direct patient contact Preceptorials are held.	Patients Clinical facilities Module 3, 5		Practical exam
3. Perform a thorough physical examination on a patient suspected of having TB	PE technique PE findings of patients with TB Thoroughness Gentleness Interpersonal skills Concern for patient's privacy	Medicine Pediatrics Neurology Gynecology Orthopedics ENT Ophthalmology	Teacher discusses the steps in performing PE Videotape of proper PE Students practice PE on each other or actual / simulated patients Direct patient contact Preceptorials	Textbook on physical exam and physical diagnosis, Videotape on PE, Patients Module 3, 5 Clinical facilities		Practical exam Summative assessment for Modules 3, 5

OBJECTIVES	CONTENT	SUBJECTS	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
4. Performing ancillary procedures to diagnose TB: sputum smears, intradermal tuberculin test, pleural tap and lymph node aspiration	Role of ancillary steps in diagnosis of TB Steps in performing a. Sputum smear b. Intradermal test c. Gastric aspiration d. Pleural tap e. Lymph node aspiration	Clinical rotations Medicine Pediatrics Pediatrics Medicine, Surgery ENT, Surgery	During clinical rotations, preceptor discusses the role of each technique in diagnosing TB with emphasis on discriminate use of each Students do intradermal testing on each other Ancillary procedures on assigned patients under supervision are done.	Module Corresponding materials needed to do each procedure Patients Clinical facilities Module 3, 5	1 hr (discussion) 2 hrs (demo)	Written exam Direct observation
5. Recognize chest radiographic findings consistent with PTB	Role of Chest x-rays in diagnosing PTB Radiographic findings consistent with PTB Value of serial reading Differential diagnosis	Medicine Radiology	Students are given lecture on basic X-ray findings consistent with PTB, use and misuse of X-rays in diagnosing PTB Students are shown various films of cases as exercise Direct patient contact Preceptorials	X-ray plates Patients Clinical facilities Module 3, 5	1 hour lecture	Practical exam
6. Diagnose patients with tuberculosis	Diagnostic Criteria for TB Classification of TB Cases (Treatment Categories)	Medicine Pediatrics	Students study Modules Class discussion and exercises with cases Direct patient contact Preceptorials	Actual patients Patients Clinical facilities Module 3, 5	1 hr lecture each dept.	Written exam Summative assessment for Modules 3, 5
III. PRESCRIBE DOTS IN ALL INVOLVEMENTS AND ACTIVITIES RELATED TO TB					4 th year Clinical rotations and the allotted time for activities	

OBJECTIVES	CONTENT	SUBJECTS	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
1. Explain the five components of DOTS strategy	Political commitment Free sputum smear-based diagnosis Directly observed treatment Availability of free drugs Accurate recording and reporting	Family Medicine	Students study DOTS strategy using resources including Modules 4 and 5. The exercises in Module 5 are accomplished and discussed in small group.	Module 5 NTP manual WHO/DOH guidelines Articles for and against DOTS Referral forms, Health forms	2 hrs	Written exam
2. Prefer DOTS to other approaches in TB control in terms of case finding and diagnosis, treatment and follow up and organizational set up	Differences between DOTS and non-DOTS approaches, Difference between DOTS and other strategies, Advantages, disadvantages, effectiveness of DOTS	As above	Small group discussions on DOTS. The suggested debate in Module 5 may be used. The teacher synthesizes main points in the DOTS strategy Direct patient contact in the clinics and community	As above Actual patients Clinical facilities Module 5	2 hrs discussion and lecture	Written exam Direct observation of patient encounter
3. Demonstrate competence in specimen collection, staining, and interpretation of AFB smear examination on assigned patients	Role of AFB smear in diagnosing TB Skill in giving instructions to patients, specimen collection, performing and interpreting AFB smear Infection control Communication skills Interpersonal skills	Medicine Pediatrics Surgery	Students stain and interpret AFB smears of their patients Students role play on getting patient's consent	Students' skills laboratory Module 2, 5		Direct observation

OBJECTIVES	CONTENT	SUBJECTS	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
4. Distinguish anti-TB drugs in terms of their respective pharmacological characteristics, mechanisms of action, dosage, and adverse effects	Characteristics of anti-TB drugs: a. Pharmacological properties b. MOA c. Dosage d. Adverse effects	Pharmacology Internal Medicine	Teacher discusses anti-TB drugs Exercises	Pharmacology textbook Module 4	1 hour	Written exam
5. Prescribe the appropriate anti-TB chemotherapy in keeping with the National TB Program policy and according to the treatment category of patients and special indications	NTP Policy Categories of patients Treatment for special indications: Patients with liver, renal dse., HIV (+), pregnant	Pharmacology Medicine Pediatrics Obstetrics	Teacher teaches students to prescribe drugs. Students prescribe to actual patients assigned under supervision.	As above	1 hour for exercise	Exercise Written exam
6. Adhere to standardized treatment regimen for all TB patients	Standardized treatment regimen Directly observed treatment Suitable DOTS supervisors Concern for patient's well being	Family Medicine Medicine Pediatrics	During community rotation, students engage in actual patient contact	Community NTP manual Module 4, 5 Assigned patients/families		Practical exam Summative assessment of Modules 4, 5

OBJECTIVES	CONTENT	SUBJECTS	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
7. Coach TB patients and their families on the nature of the disease and how it can be treated and prevented	Family assessment tools Nature of disease Impact of illness on the family Diagnosis Treatment Prevention Communication skill Interpersonal skill Counseling skill	Family Medicine Medicine Pediatrics Gynecology ENT Neurology Ophthalmology Orthopedics	Students under supervision assess and counsel assigned patients and families Direct patient contact	Assigned patients/families Community NTP manual Module 4, 5	1 hour for discussion	Student journals Summative assessment of Modules 3, 5
8. Monitor progress of treatment by coordinating with the appropriate members of the health team or health care unit where patient is located.	Natural history of disease Expected response Possible side effects of anti-TB drugs	Family Medicine Medicine Pediatrics Gynecology ENT Neurology Ophthalmology Orthopedics	Direct patient contact in the outpatient clinic or community	As above		Student journals Summative assessment of Modules 3, 5 Duly Accomplished TB records
9. Refer patients to appropriate health care units for proper administration of DOTS	Referral system	As above	Direct patient contact Community rotation, outpatient rotation	As above		Student journals Summative assessment of Modules 3, 5 Duly Accomplished TB records

OBJECTIVES	CONTENT	SUBJECTS	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
10. Maintain an accurate recording system of DOTS patients for evaluation of treatment outcome and program performance	Recording and reporting system		Students fill up NTP forms of assigned patients	As above		Same as above
11. Engage in sustainable activities and initiatives to promote TB control in the community	Advocacy Community organizing	Family Medicine	During community rotation, students engage in actual patient contact Outpatient rotation	As above		Same as above

IV. Curriculum design for Problem-based Track

OBJECTIVES	CONTENT	LEARNING UNIT	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
Graduates of Medicine who finished this Tuberculosis (TB) Master Plan can:						
I. DEMONSTRATE THOROUGH UNDERSTANDING OF TB AS A BIOMEDICAL AND SOCIAL PHENOMENON					1st / 2nd year	
EPIDEMIOLOGY		Research Methods Epidemiology	Students read and complete Module 1 prior to activities in class			
12. Describe the overall TB burden of disease and its implications	TB burden of disease Implications to individuals, community, country		Teacher discusses TB burden	NTP Survey, 1997 Module 1	15– 30 mins.	Written exam
13. Critically examine the position of the Philippines in terms of world health statistics on TB	Global and national statistics: current data and trends Leading causes of mortality and morbidity		Teacher and students engage in interactive discussion on prevalence and incidence of TB in RP	NTP 1983 and 1997 WHO and DOH statistics	15– 30 mins.	

OBJECTIVES	CONTENT	LEARNING UNIT	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
14. Discuss the factors why TB continues to plague the country	Health-seeking behavior Health care delivery systems Causes of delay Biopsychosocial model of illness		Students engage in group activities suggested in Module 1 (role play, debate) A plenary session is held at the end of activities to synthesize essential points.	NSO, PHS, HSRA, DOH data on health care, economic status infrastructure and costs	1 hour	Case report Peer evaluation Summative assessment for Module 1
15. Describe the efficient and novel way by which Directly Observed Therapy, Short course (DOTS) strategy can control TB	DOTS and its impact on prevalence / incidence Role of DOTS in controlling TB in the country / world			Module 1 NTP manual		Written exam Summative assessment for Module 1
5. Describe the current effort to control TB in the country: the government front; the private MD front; the drive to integrate private MD management of TB cases to the NTP (private-public mix); and coalition building to broaden the support for TB control.	DOTS and its impact on prevalence / incidence Role of DOTS in controlling TB in the country / world Coalition building, PhilCAT initiatives, PhilTIPS			Module 1 NTP manual		Written exam Summative assessment for Module 1

OBJECTIVES	CONTENT	LEARNING UNIT	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
TRANSMISSION & PATHOGENESIS		Man and Disease Respiratory Diseases Infectious diseases	Students read Module 2 and other materials before coming to class.		2 nd	
6. Relate morphological and physiological characteristics of <i>Mycobacterium tuberculosis</i> (MTb) with its staining, antigenic and virulence properties	Morphology of MTb Physiology of MT Staining characteristics Antigenic properties Virulence factors Mutation to resistant strains		Students discuss Case 1: Mimi, identifies learning issues, answers them and writes down areas to study on their own They come back on assigned day to settle those issues and synthesize.	Microbiology textbook Supplementary materials, slides, visual aids	2 sessions, 2 hours each	Assessment for Module 2 Evaluation for SGT Written exam

OBJECTIVES	CONTENT	LEARNING UNIT	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
7. Follow standard procedures in performing and interpreting sputum smears	Steps in performing sputum smear Criteria for interpreting AFB smears Compliance to standard procedures from collection to transport of specimen		Teacher shows slides of AFB Demonstration and return demo of staining on AFB (+) specimen are done Plenary session is done at the end of laboratory session to discuss interpretations and difficulties encountered by students.	Microbiology laboratory facilities Module 2	2 hrs	Practical exam
8. Explain how man develops MTb infection	MTb infection Invasion of the host by MTb Response of the host, hypersensitivity reaction Immunity and resistance		Students discuss natural history of disease with Case 1 as take off point	Microbiology textbook Supplementary materials Module 2		Assessment for Module 2 Evaluation for SGT Written exam

OBJECTIVES	CONTENT	LEARNING UNIT	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
9. Discuss the pathological consequences of TB infection	Gross and microscopic pathology of affected organs Correlation between biological characteristics of MTb and pathological changes (cavitary and non-cavitary disease)		Students discuss pathological basis of TB using Case 1 They examine pathological specimens during the skills laboratory period.	Pathology textbook Pathology specimens Supplementary materials	1 hour	Assessment for Module 2 Evaluation for SGT Written exam
10. Distinguish between TB infection and active disease	Difference between TB infection and disease Features of primary infection, TB active disease and TB inactive disease		Students distinguish between these two during SGT	Textbooks on Pediatrics and Internal Medicine Cases 2 - 4 Module 2		Assessment for Module 2 Evaluation for SGT Written exam
11. Explain the transmission of MTb within a family or community	Transmission of TB Environmental factors Host factors: Population at risk		Students identify people at risk The class visits a nearby DOTS center or a family under DOTS, or interview a patient under DOTS or a treatment partner.	Textbooks Modules 1, 2	Half day	Assessment for Module 2 Reflection paper on the visit Written exam

OBJECTIVES	CONTENT	LEARNING UNIT	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
12. Discuss the rationale why DOTS is most instrumental in detecting and controlling TB disease	Components of DOTS Rationale of DOTS strategy	Family Medicine Microbiology	Case 1: Discussion is done on DOTS components and significance. Teacher discusses and class completes exercises on DOTS	NTP manual Modules 2, 5	2 hours	As above Summative assessment for Module 2
II. EVALUATE PATIENTS WITH PTB AND THE MORE COMMON FORMS OF EXTRAPULMONARY TB ACCORDING TO STANDARDIZED CRITERIA		Man and disease, Respiratory module, Infectious diseases Clinical rotations			2 nd year 3 rd or 4 th year	

OBJECTIVES	CONTENT	LEARNING UNIT	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
7. Identify signs and symptoms suggestive of pulmonary TB and the more common forms of extrapulmonary TB	Common complains of patients with PTB and the more common forms of extra-PTB PE findings of such patients Natural history of the disease	Unit on Respiratory diseases, or Infectious diseases Medicine Pediatrics Neurology Gynecology Orthopedics ENT Ophthalmology Surgery	Case 1: The group identifies the salient points in the history of Mimi Students have preceptorials with TB patients as cases Students complete Module 3 Case 2: During the rotation in Medicine, students discuss Dodo and summarizes clinical presentation of Dodo Case 3: During rotation in Pediatrics students discuss and summarizes clinical presentation of Lala	Corresponding textbooks Videotape Clinical setting Module 3	1 hour	Written exam Preceptorial grades

OBJECTIVES	CONTENT	LEARNING UNIT	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
8. Elicit relevant clinical history from a patient suspected of having TB	Elements of clinical history History of past TB treatment Symptoms of TB patients Thoroughness Confidentiality Communication skills Interpersonal skills	Medicine Pediatrics Neurology Gynecology Orthopedics ENT Ophthalmology Surgery	Video is presented on actual history taking or demonstration on actual or simulated patient Return demonstration is done by students Direct patient contact Preceptorials are held.	Patients Clinical facilities Module 3	1 hour	Practical exam Clinical history
9. Perform a thorough physical examination on a patient suspected of having TB	PE technique PE findings of patients with TB Thoroughness Gentleness Interpersonal skills Concern for patient's privacy	Medicine Pediatrics Neurology Gynecology Orthopedics ENT Ophthalmology Surgery	Videotape of proper PE Students practice PE on each other or actual / simulated patients Direct patient contact Preceptorials	Textbook on physical exam and physical diagnosis, Videotape on PE, Patients Module 3 Clinical facilities		Practical exam
					3 rd or 4 th year	

OBJECTIVES	CONTENT	LEARNING UNIT	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
10. Performing ancillary procedures to diagnose TB: sputum smears, intradermal tuberculin test, pleural tap and lymph node aspiration	<p>Role of ancillary steps in diagnosis of TB</p> <p>Steps in performing</p> <p>f. Sputum smear</p> <p>g. Intradermal test</p> <p>h. Gastric aspiration</p> <p>i. Pleural tap</p> <p>j. Lymph node aspiration</p>	<p>Clinical rotations</p> <p>Medicine</p> <p>Pediatrics</p> <p>Surgery</p> <p>ENT</p>	<p>During clinical rotations, preceptor discusses the role of each technique in diagnosing TB with emphasis on discriminate use of each</p> <p>Students do intradermal testing on each other</p> <p>Ancillary procedures on assigned patients under supervision are done.</p>	<p>Corresponding materials needed to do each procedure</p> <p>Patients</p> <p>Clinical facilities</p> <p>Module 3</p>	<p>1 hr (discussion)</p> <p>2 hrs (demo and return demo)</p>	<p>Written exam</p> <p>Direct observation</p>
11. Recognize chest radiographic findings consistent with PTB	<p>Role of Chest x-rays in diagnosing PTB</p> <p>Radiographic findings consistent with PTB</p> <p>Value of serial reading</p> <p>Differential diagnosis</p>	<p>Radiology</p> <p>Medicine</p> <p>Pediatrics</p>	<p>Basic X-ray findings consistent with PTB, use and misuse of X-rays in diagnosing PTB are discussed</p> <p>Students are shown various films of cases as exercise</p> <p>Direct patient contact</p> <p>Preceptorials</p>	<p>X-ray plates</p> <p>Patients</p> <p>Clinical facilities</p> <p>Module 3</p>	<p>1 hour lecture and exercises</p>	<p>Practical exam</p>

OBJECTIVES	CONTENT	LEARNING UNIT	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
12. Diagnose patients with tuberculosis	Diagnostic Criteria for TB Classification of TB Cases (Treatment Categories)	Medicine Pediatrics	Direct patient contact Preceptorials	Actual patients Patients Clinical facilities Module 3, 5	1 hr lecture each dept.	Written exam
III. PRESCRIBE DOTS IN ALL INVOLVEMENTS AND ACTIVITIES RELATED TO TB		Clinical rotations			3 rd or 4 th year	
12. Explain the five components of DOTS strategy	Political commitment Free sputum smear-based diagnosis Directly observed treatment Availability of free drugs Accurate recording and reporting		Students study DOTS strategy using resources including Modules 4 and 5. The exercises in Module 5 are accomplished and discussed in small group.	Module 5 NTP manual WHO/DOH guidelines Articles for and against DOTS Referral forms, Health forms	2 hrs discussion and lecture	Written exam

OBJECTIVES	CONTENT	LEARNING UNIT	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
13. Prefer DOTS to other approaches in TB control in terms of case finding and diagnosis, treatment and follow up and organizational set up	Differences between DOTS and non-DOTS approaches, Difference between DOTS and other strategies, Advantages, disadvantages, effectiveness of DOTS	As above Clinical rotations: Family Medicine Internal Medicine Pediatrics ENT Neurology Ophthalmology OB-Gynecology Orthopedics Surgery	Small group discussions on DOTS. The suggested debate in Module 5 may be used. The teacher synthesizes main points in the DOTS strategy Direct patient contact in the clinics and community	As above Actual patients Clinical facilities Module 5 NTP Manual of Procedures WHO/DOH guidelines		Written exam Direct observation of patient encounter
14. Distinguish anti-TB drugs in terms of their respective pharmacological characteristics, mechanisms of action, dosage, and adverse effects	Characteristics of anti-TB drugs: e. Pharmacological properties f. MOA g. Dosage h. Adverse effects	Pharmacology	Teacher discusses anti-TB drugs Exercises	Pharmacology textbook Module 4	1 hour	Written exam Summative assessment Module 4

OBJECTIVES	CONTENT	LEARNING UNIT	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
15. Prescribe the appropriate anti-TB chemotherapy in keeping with the National TB Program policy and according to the treatment category of patients and special indications	NTP Policy Categories of patients Treatment for special indications: Patients with liver, renal dse., HIV (+), pregnant	Pharmacology Clinical rotations	Teacher teaches students how to prescribe drugs. Students prescribe to actual patients assigned under supervision.	As above NTP guidelines Module 5	1 hour for exercise	Exercise Written exam Summative assessment Module 5
16. Coach TB patients and their families on the nature of the disease and how it can be treated and prevented	Family assessment tools Nature of disease Impact of illness on the family Diagnosis Treatment Prevention Communication skill Interpersonal skill Counseling skill	Family Medicine Medicine Pediatrics Gynecology ENT Neurology Ophthalmology Orthopedics	Students under supervision assess and counsel assigned patients and families Direct patient contact	Assigned patients/families Community NTP manual Module 4, 5		Direct observation Student journals
17. Refer patients to appropriate health care units for proper administration of DOTS	Referral system	Clinical rotations	Direct patient contact Community rotation, outpatient rotation	Assigned patients/families Community NTP manual Module 4, 5		Direct observation Student journals

OBJECTIVES	CONTENT	LEARNING UNIT	TEACHING – LEARNING ACTIVITIES	RESOURCES	TIME	EVALUATION
18. Maintain an accurate recording system of DOTS patients for evaluation of treatment outcome and program performance	Recording and reporting system	Family Medicine	Students fill up NTP forms of assigned patients	As above		Review of duly accomplished TB records
19. Engage in sustainable activities and initiatives to promote TB control in the community	Advocacy Community organizing	Family Medicine	During community rotation, students engage in actual patient contact Outpatient rotation	As above		Same as above

**TUBERCULOSIS CONTROL
CORE CURRICULUM FOR
PHILIPPINE MEDICAL SCHOOLS**

**PART III
TEACHING AND LEARNING RESOURCES**

**Camilo C. Roa Jr, M.D
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May 14, 2003

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LEARNING UNIT OF TB CONTROL (For PBL)

I. Background

Despite the availability of effective treatment, tuberculosis (TB) kills more people than any other communicable disease. No wonder that it has been declared by the World Health Organization in 1993 as a global epidemic! TB, in fact, infects one out of every three persons in the world. Our country is listed as one of the 22 high burden countries. It has remained the sixth leading killer disease in the land.

Clearly, TB is not just a biomedical problem. This ancient scourge has important socio-economic-behavioral dimensions that must be equally addressed to accomplish successfully control. Because of these, TB should not just be the concern of public health officers, the attending physicians and the poor who are supposedly the only ones affected. It is high time that TB becomes everybody's business.

Such is the pervading idea in this core curriculum for TB control that will be introduced to all Philippine medical schools. It is especially designed to be integrated to all types of curricula, e. g. subject-centered, competency-based, integrated, community-oriented or problem-based. Students from all types of curricula are expected to develop the same terminal competencies upon its completion.

While only “core” issues important to the attainment of TB control are included in this master plan, its breadth spans epidemiology, transmission and pathogenesis of the disease. The clinical presentation, diagnosis and treatment are likewise addressed. The directly observed therapy short-course (DOTS) strategy, the backbone of the National TB control program (NTP) will be discussed in depth.

To facilitate the implementation of this curriculum and at the same time to maintain generally standardized sets of minimum competencies and conditions for teaching and learning, this separate set of teaching-learning resources are being provided for all the target users: the medical teachers and their students. While these resources have been planned to adequately address the needs of these two players, the teachers are encouraged to develop additional creative activities to ensure learning.

II. Components of the Teaching-Learning Resources

This set of teaching-learning resources is composed of the following materials:

Self-study modules for teachers and students in the following areas:

Module 1: The TB Epidemic

Module 2: TB Transmission and pathogenesis

Module 3: Clinical presentation and diagnosis of TB

Module 4: Treatment of TB

Module 5: The directly observed treatment, short course (DOTS)

Teachers' guide: They contain the overall instructional design of each module from objectives, to actual subject matter, to suggested teaching-learning activities and evaluation plan to measure achievement of students' learning. This set is further composed of Microsoft Powerpoint slides for presentations and didactics, including the minimum “script” for teacher's delivery. These slides and their corresponding scripts have been prepared as such to enable

non-internists and non-pulmonologists to cover the same standardized must-knows for a given module.

Self-study modules for students: This set of self-study modules (SSM) contain essentially the same minimum knowledge and competencies that students are expected to cover in a given module. Objectives for each SSM are presented to guide students' own learning. Practice exercises and self-assessment questions are provided at the end of every important topic to build the cognitive coding of students. A complete and comprehensive set of related references are likewise listed at the end of each module to refer students to further readings as necessary or as they feel the interest to pursue related topics. These serve as reinforcement activities.

Objectives of the core TB control-DOTS curriculum for Philippine medical schools

Students who have finished this Tuberculosis (TB) Master Plan can:

DEMONSTRATE THOROUGH UNDERSTANDING OF TB AS A BIOMEDICAL AND SOCIAL PHENOMENON

a. EPIDEMIOLOGY

1. Describe the overall TB burden of disease and its implications
2. Examine the position of the Philippines in terms of world health statistics on TB
3. Discuss the factors why TB continues to plague the country and why it has to be stopped now
4. Apply the basic concepts and methodologies of Epidemiology/Clinical Epidemiology in contextualizing the TB epidemic.
5. Describe the current effort to control TB in the country: the government front; the private MD front; the drive to integrate private MD management of TB cases to the NTP (private-public mix); and coalition building to broaden the support for TB control.
6. Recognize the efficient and novel way by which Directly Observed Therapy, Short course (DOTS) strategy can control TB

b. TRANSMISSION & PATHOGENESIS

1. Relate morphological and physiological characteristics of *Mycobacterium tuberculosis* (MTb) with its staining, antigenic and virulence properties
2. Follow standard procedures in performing and interpreting sputum smears
3. Establish how man develops MTb infection
4. Discuss the pathological consequences of TB infection
5. Distinguish between TB infection and active disease
6. Explain the transmission of MTb within a family or community
7. Discuss the rationale why DOTS is most instrumental in detecting and controlling TB disease

EVALUATE PATIENTS WITH PTB AND THE MORE COMMON FORMS OF EXTRAPULMONARY TB WITH THE HIGHEST STANDARDS OF PROFESSIONALISM AND COMPETENCE

1. Identify signs and symptoms suggestive of pulmonary TB and the more common forms of extrapulmonary TB
2. Elicit relevant clinical history from a patient suspected of having TB
3. Perform a thorough physical examination on a patient suspected of having TB
4. Demonstrate competence in performing ancillary procedures to diagnose TB: sputum smears, intradermal tuberculin test, pleural tap and lymph node aspiration
5. Recognize chest radiographic findings consistent with PTB
6. Diagnose patients with tuberculosis

PRESCRIBE DOTS IN ALL INVOLVEMENTS AND ACTIVITIES RELATED TO TB

1. Explain the five components of DOTS strategy
2. Prefer DOTS to other approaches in TB control in terms of case finding and diagnosis, treatment and follow up and organizational set up
3. Demonstrate competence in specimen collection, staining, and interpretation of AFB smear examination on assigned patients
4. Distinguish anti-TB drugs in terms of their respective pharmacological characteristics, costs, mechanisms of action, dosage, and adverse effects
5. Prescribe the appropriate anti-TB chemotherapy in keeping with the National TB Program policy and according to the treatment category of patients and special indications
6. Adhere to standardized treatment regimen for all TB patients
7. Coach TB patients and their families on the nature of the disease and how it can be treated
8. Monitor progress of treatment by coordinating with the appropriate members of the health team or health care unit where patient is located.
9. Refer patients to appropriate health care units for proper administration of DOTS
10. Maintain an accurate recording system of DOTS patients for evaluation of treatment outcome and program performance
11. Engage in sustainable activities and initiatives to promote TB control in the community

III. Management plan for the teaching-learning resources

It is hoped that all medical schools using this core TB curriculum have a specially designated TB coordinator who holds a regular office in campus. This TB coordinator is expected to perform the following duties:

Coordinate with the various departments the final schedule of classes per semester or term where the different SSMs would be integrated.

Make sure that all the teachers and students are furnished with copies of the appropriate SSMs at least one week before the actual teaching-learning contact. Since previous arrangements between the Office of the Dean and the Philippine Tuberculosis Initiatives for the Private Sector (Phil TIPS) has been done prior to the actual classes, it is expected that their medical school has been provided the complete set of all SSMs in their original forms.

More than anybody in the medical school where they teach, the TB coordinator is a Phil TIPS-trained medical teacher. He/she is expected to be the TB-DOTS expert who the other teachers and students can approach for any problem regarding the SSMs.

Serve as custodian of all the master copies of the SSMs and slides for reference.

Coordinate regularly with Phil TIPS regarding the progress and future evaluation of the core curriculum

IV. Acknowledgment

Sincerest gratitude is given to the following institutions that gave permission to use their presentations slides and other resources for this curriculum:

Philippine Coalition Against Tuberculosis (PHILCAT)
The Lung Study Group of the Philippines
World Health Organization
Department of Health

MODULE I. THE TB EPIDEMIC (FOR TEACHERS)

Suggested year level: First and/ or second year

Suggested subjects for insertion/integration:

1. Family and Community Medicine
2. Preventive Medicine
3. Epidemiology/Clinical Epidemiology

Duration:

1. Approximately 20 to 30 minutes of lecture
2. Around 5 minutes for orientation, 15 minutes for small group activity and 30 to 40 minutes for plenary and closure

Specific Objectives: At the end of this module, students can:

1. Describe the overall tuberculosis (TB) burden of disease (BOD) and its implications to the Philippines;
2. Examine the position of the Philippines in terms of world statistics on TB;
3. Discuss the factors why TB continues to plague the country and why it has to be controlled now;
4. Apply the basic concepts and methodologies of Epidemiology/Clinical Epidemiology in contextualizing the TB epidemic.
5. Describe the current effort to control TB in the country: the government front; the private MD front; the drive to integrate private MD management of TB cases to the NTP (private-public mix); and coalition building to broaden the support for TB control.
6. Recognize the efficient and novel way by which Directly Observed Therapy, Short course (DOTS) strategy can control TB

Minimum Content:

1. Frame 2: The global burden of TB

Slides: Epidemiology slides showing the world map and the global TB burden including the 22 countries on the map

Focus: (Please update statistics as necessary). As of 1999, about one-third of the world's population (\approx 2 billion people) was infected by MTb and at risk of developing the active disease. About 8.4 million people develop active TB every year and 2 million die (WHO, 2001). TB accounts for 2.5% of the global burden of disease, for 26% of preventable deaths. It is a leading infectious cause of death among young women.

Around 95% of global TB cases and 99% of deaths occur in developing countries. From these figures, 75% of cases involve the economically most productive age group (15-54 years old). An average of 3 to 4 months of work are lost if an adult is afflicted with TB; it also results to the loss of 20-30% of

annual household income and an average of 15 years of income if the patient dies from their disease.

With the rapid aggravation of multiple-drug resistance TB and human immunodeficiency virus (HIV), the risk of contacting the disease has increased two to three folds in the 1990's (WHO, 2001). In 1993, the WHO declared that TB is a global emergency. When the World Health Assembly (WHA) met in March 2000 in Amsterdam, all member countries called for accelerated expansion of TB control measures and for increased political commitment and financial resources for global TB management. The WHA also came up with a list of 22 high-burden countries where 80 percent of the global TB burden is identified. The 22 belong to the undeveloped and developing countries. The Republic of the Philippines ranks seventh in this list of high-TB burden countries.

2. Frame 3: The burden of TB disease in the Philippines

Slides: Slides on the top 10 causes of mortality and morbidity, table below, Peabody, et al (2003) slides on the economic burden, DOH statistics on the national budget for health and a pie graph on sources of funding for health

Focus: Figures on the TB burden in the Philippines prove that despite local and global efforts to control the epidemic, the disease is hardly contained in the country. Comparisons of the 1983 and 1997 National Tuberculosis Prevalence Surveys show the basic parameters:

Table 1: Basic Parameters of Burden of disease

Parameter	1983 NTPS	1997 NTPS
Percent of population infected by MTb	54.50 %	63.40 %
Annual risk of infection (ARI)	2.50 %	2.30 %
Smear (+) cases	0.66 %	0.31 %
Culture (+) cases	0.86 %	0.81 %
X-ray (+) cases	4.20 %	4.20 %

All forms of TB consistently ranked as the fifth leading cause of mortality from 1994 to 1996. It dropped to number six in 1997 but the number of deaths actually was higher than that of the previous year. TB is also in the top 5 or 6 leading causes of morbidity from 1994 and as projected until 2002 (DOH, 1999).

Furthermore, as of 1999, a total of 234,000 TB cases have been recorded in the Philippines. Incidence rate was 314 cases per 100,000 populations (WHO, 2001). These figures rose to 249,655 cases in 2001 and 26,054 deaths.

A recent study established the economic burden of TB in the Philippines. Peabody, et al (2003) applied mathematical computations of the 1997 to

1999 national statistics on TB and proved that TB robs an average Filipino worker of P216 for women and P415 for men in daily wages. These total to at least P7.900 million annually. It also means 514, 300 disability adjusted life years (DALY) lost every year. DALY figures mean that out of the 249,655 new cases identified, 26,054 deaths have been recorded and that incidence rate is increasing. The same study shows that considering the number of cases identified to be infectious, a total of P6, 500 for six months is required to complete the prescribed treatment of TB patients. Furthermore, if all the 76,000 untreated patients would be given the treatment, an additional P500. 000 million would be required.

On the other hand, in 1998, government support to health was a meager 2.83 percent of the P540.786 billion national budget. In fact, this total budget of the Department of Health (DOH) has remained within the 2 to 3.5 percent of the national budget from 1996 to 1998. This is far from the WHO-prescribed national appropriation of at least 5 percent of the national budgets among developing countries. Reports from the DOH also reveal that in terms of total funds for health, a huge percent has to come from out-of-pocket allocation from the individual families themselves. Figures below show the distribution (DOH, 1999):

Table 2: Percentage distribution of sources of funds for health (1997)

Sources of funds	Allocation (%)
Individual	46
National government	21
Local government	18
Others	8
National Health Insurance Program	7
Total	100

To a country where 39.40 percent of the population is below the incidence of poverty (NEDA, 2000), household spending on health or treatment of a diseased member of the family is clearly not a high priority. In the Philippines, the more basic expenditures that household put their daily and/or monthly wages include only food, shelter, housing and electricity (NEDA, 2000).

3. Frame 4: Slow progress in controlling TB

Slides: Slides on the NTP health seeking behavior survey, photos of urban and rural families showing poor hygienic practices, and on the NTP survey results of how physicians treat TB differently

Focus: Break the class into at least two groups to do any of the following:

Activity (1): The two groups represent two families from a rural and from an urban area. Challenge the groups to present a role-play activity on the typical household routine of a preferably big family. The presentation should show

how the family relates to each member especially in relation to food preparation, hygiene, sleeping arrangements, and general maintenance of the household.

Activity (2): The two groups represent either the “good” or “bad” habits of Filipinos that contribute to the spread of MTb infection. A brainstorming session may be done to explore the nature of each good or bad habit.

Activity (3): The two groups are assigned a prior reading on how private and public physicians manage TB. The two groups debate on how private and government physicians approach TB management.

Teachers then facilitate a plenary or post-group discussion to cover the following minimum topics. They are the basic concepts dealing with the slow progress in controlling TB.

- a. Filipinos have some inherently unhygienic habits. Washing of hands, applying antiseptics, cleaning the utensils and even food items before cooking is not commonly practiced. In fact, habits of spitting, not covering the mouth when coughing and sneezing, sharing of utensils while eating and cooking are common.
- b. Filipinos are financially in need and do not even allocate special funds for a diseased member of their families. This is supported by the national tuberculosis prevalence survey conducted in 1997. Two groups of TB patients were asked how they managed their conditions and they gave out the following answers:

	Symptomatics (n = 2358)	Sm (+) cases (n = 76)
None	43.0%	32.9%
Self-medication	31.6%	25.0%
Private MD	11.8%	17.1%
Health Centers	7.5%	17.1%
Hospitals	4.4%	8.0%
Others	1.7%	

These figures show that a significant proportion of the population do not do anything to address their infectious condition. In fact, the combined proportion of those who reported seeking help from doctors did not offset those who reported to self-medicate.

- c. Filipinos have a poor understanding of TB as a disease. Patients think they are infectious all the time such that they take it upon themselves to be distant or not socialize. The stigma of being a TB patient pervades in all types of communities across the country. Compliance with medications

is poor and patients often stop taking medicines when they start to feel better already.

- d. Lack of standardized treatment being followed by private and, until recently, the public physicians in managing various types of TB. In their undergraduate years as well as during their postgraduate training, MDs have been taught to individualize patient management. This clinical approach does not augur well to managing public health conditions like TB. Although standards have existed in the government NTP, the lack of resources and presence of external influences like use of medicines for electioneering resulted in inability for the public MDs to comply.
- e. There is also poor recording of identified TB patients and how their disease has progressed over time. TB is a reportable disease but nobody complies as this entails additional paper works with no added compensation. No sanctions have ever been slapped to non-reporting MDs.

4. Frame 5: DOTS

Slides: Slides on the DOTS components

Focus: The combined factors of lack of adequate government support, financial crisis of majority of the population and poor hygienic practices of the Filipinos in general contribute to the aggravation of the TB epidemic. The same factors explain why the identified TB patients stay sick and infectious.

For a TB Control program to be effective, it should properly address all of these aggravating factors. Table 3 summarizes these factors and the elements that a TB control program should have to succeed.

Table 3: Aggravating factors and elements of an effective TB control Strategy

Problem	Elements of an effective TB Control Program
Inadequate government support and financial allocations	Government commitment to sustained TB control activities
Poor hygienic practices Lack of knowledge regarding disease transmission Refusal to seek medical help due to stigma of disease	Proper counseling by health providers
Lack of family resources for medical consultation and diagnostic examinations of symptomatic patients	Free diagnostic examinations (specifically, sputum smear microscopy) for patients self-reporting to health services

Problem	Elements of an effective TB Control Program
Lack of resources to support and maintain treatment of identified TB patients	A regular, uninterrupted supply of all essential anti-TB drugs
Poor compliance with anti-TB medications	Counseling of patients A regular, uninterrupted supply of all essential anti-TB drugs Directly observed treatment by a committed treatment partner
Lack of standardized treatment being followed by both private and public physicians	Standardized treatment regimen of all confirmed cases
Poor recording of identified TB patients and how their disease has progressed over time.	A standardized recording and reporting system that allows assessment of treatment results for each patient and of the TB control program

These elements listed in the second column are the components of the strategy currently adopted by the World Health Organization to control TB. This is the Directly Observed Treatment, Short course (DOTS) strategy. In a nutshell, the DOTS addresses all the aggravating factors identified above. Its five basic elements clearly demonstrate that they would address these factors:

- Political (government and other stakeholders) commitment to sustained TB control activities
- Case detection by sputum smear microscopy among symptomatic patients self-reporting to health services
- Standardized treatment regimen of six to eight months for at least all confirmed sputum smear positive cases, with directly observed treatment (DOT) for at least the initial two months
- A regular, uninterrupted supply of all essential anti-TB drugs
- A standardized recording and reporting system that allows assessment of treatment results for each patient and of the TB control program

Integral to the DOTS strategy are the basic principles of making the TB patients and their health care givers enter a mutual agreement to take care of the former until full recovery. This basic principle includes intensive counseling, education of the patients about the nature of their disease and full adherence to the treatment plan.

Exactly what does political commitment entail? It means providing the resources needed to support the NTP and the DOTS elements. Funds automatically provided for in the national budget. Free medicines are available for all. Competent microscopy centers are present in all centers.

The strengthened NTP is a joint venture of the DOH, the LGUs and the private sector. The DOH formulates plans and policies, oversees program implementation, provides logistics (such as drugs, laboratory supplies, educational materials), and collates and analyzes reports and recommendations of the LGUs. The LGUs in turn formulate local plans and policies and implement them accordingly.

Provincial or city medical NTP coordinators are designated and given their respective responsibilities. This way, the smooth implementation, monitoring and evaluation of activities are ensured. Private MD activities are “in synch with the NTP” to serve as program implementers for TB control. Ideally, private medical practice is aligned with the NTP policies and the private MDs are implementers of the NTP.

The second to the fourth DOTS components refer to the health care givers to be in constant contact with the identified TB patients. These workers make sure that the patients have been properly identified through the standardized sputum examination and that the schedule of treatment has been recorded accurately. The health care workers personally administer the patients’ ingestion of the anti-TB drugs from a period of two to six months in the clinics and when necessary, at home. Supply of these drugs is free as provided by the national and local governments through the local health and DOTS centers.

The last component aims to accurately document the progress of treatment and tracking of patients. This is a most important component to ensure progress of the DOTS program as a strategy to control TB.

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MODULE I. THE TB EPIDEMIC (FOR STUDENTS)

Specific Objectives: At the end of this module, students can:

1. Describe the overall tuberculosis (TB) burden of disease (BOD) and its implications to the Philippines;
2. Examine the position of the Philippines in terms of world statistics on TB;
3. Discuss the factors why TB continues to plague the country and why it has to be controlled now;
4. Apply the basic concepts and methodologies of Epidemiology/Clinical Epidemiology in contextualizing the TB epidemic.
5. Describe the current effort to control TB in the country: the government front; the private MD front; the drive to integrate private MD management of TB cases to the NTP (private-public mix); and coalition building to broaden the support for TB control.
6. Recognize the efficient and novel way by which Directly Observed Therapy, Short course (DOTS) strategy can control TB

Minimum Content:

1. Frame 2: The global burden of TB

Focus: (Please update statistics as necessary). As of 1999, about one-third of the world's population (\approx 2 billion people) was infected by MTb and at risk of developing the active disease. About 8.4 million people develop active TB every year and 2 million die (WHO, 2001). TB accounts for 2.5% of the global burden of disease, for 26% of preventable deaths. It is a leading infectious cause of death among young women.

Around 95% of global TB cases and 99% of deaths occur in developing countries. From these figures, 75% of cases involve the economically most productive age group (15-54 years old). An average of 3 to 4 months of work are lost if an adult is afflicted with TB; it also results to the loss of 20-30% of annual household income and an average of 15 years of income if the patient dies from their disease.

With the rapid aggravation of multiple-drug resistance TB and human immunodeficiency virus (HIV), the risk of contracting the disease has increased two to three folds in the 1990's (WHO, 2001). In 1993, the WHO declared that TB is a global emergency. When the World Health Assembly (WHA) met in March 2000 in Amsterdam, all member countries called for accelerated expansion of TB control measures and for increased political commitment and financial resources for global TB management. The WHA also came up with a list of 22 high-burden countries where 80 percent of the global TB burden is identified. The 22 belong to the undeveloped and developing countries. The Republic of the Philippines ranks seventh in this list of high-TB burden countries.

2. Frame 3: The burden of TB disease in the Philippines

Focus: Figures on the TB burden in the Philippines prove that despite local and global efforts to control the epidemic, the disease is hardly contained in the country. Comparisons of the 1983 and 1997 National Tuberculosis Prevalence Surveys show the basic parameters:

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On the other hand, in 1998, government support to health was a meager 2.83 percent of the P540.786 billion national budget. In fact, this total budget of the Department of Health (DOH) has remained within the 2 to 3.5 percent of the national budget from 1996 to 1998. This is far from the WHO-prescribed national appropriation of at least 5 percent of the national budgets among developing countries. Reports from the DOH also reveal that in terms of total funds for health, a huge percent has to come from out-of-pocket allocation from the individual families themselves. Figures below show the distribution (DOH, 1999):

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Sources of funds	Allocation (%)
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National Health Insurance Program	7
Total	100

To a country where 39.40 percent of the population is below the incidence of poverty (NEDA, 2000), household spending on health or treatment of a diseased member of the family is clearly not a high priority. In the Philippines, the more basic expenditures that household put their daily and/or monthly wages include only food, shelter, housing and electricity (NEDA, 2000).

3. Frame 4: Slow progress in controlling TB

Focus: The class is broken into at least two groups to do any of the following:

Activity (1): The two groups represent two families from a rural and from an urban area. Challenge the groups to present a role-play activity on the typical household routine of a preferably big family. The presentation should show how the family relates to each member especially in relation to food preparation, hygiene, sleeping arrangements, and general maintenance of the household.

Activity (2): The two groups represent either the “good” or “bad” habits of Filipinos that contribute to the spread of MTb infection. A brainstorming session may be done to explore the nature of each good or bad habit.

Activity (3): The two groups are assigned a prior reading on how private and public physicians manage TB. The two groups debate on how private and government physicians approach TB management.

4. Frame 5: DOTS

Focus: The combined factors of lack of adequate government support, financial crisis of majority of the population and poor hygienic practices of the Filipinos in general contribute to the aggravation of the TB epidemic. The same factors explain why the identified TB patients stay sick and infectious.

For a TB Control program to be effective, it should properly address all of these aggravating factors. Table 3 summarizes these factors and the elements that a TB control program should have to succeed.

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Problem	Elements of an effective TB Control Program
Inadequate government support and financial allocations	Government commitment to sustained TB control activities
Poor hygienic practices Lack of knowledge regarding disease transmission Refusal to seek medical help due to stigma of disease	Proper counseling by health providers
Lack of family resources for medical consultation and diagnostic examinations of symptomatic patients	Free diagnostic examinations (specifically, sputum smear microscopy) for patients self-reporting to health services
Lack of resources to support and maintain treatment of identified TB patients	A regular, uninterrupted supply of all essential anti-TB drugs
Poor compliance with anti-TB medications	Counseling of patients A regular, uninterrupted supply of all essential anti-TB drugs Directly observed treatment by a committed treatment partner
Lack of standardized treatment being followed by both private and public physicians	Standardized treatment regimen of all confirmed cases
Poor recording of identified TB patients and how their disease has progressed over time.	A standardized recording and reporting system that allows assessment of treatment results for each patient and of the TB control program

These elements listed in the second column are the components of the strategy currently adopted by the World Health Organization to control TB. This is the Directly Observed Treatment, Short course (DOTS) strategy. In a nutshell, the DOTS addresses all the aggravating factors identified above. Its five basic elements clearly demonstrate that they would address these factors:

- Political (government and other stakeholders) commitment to sustained TB control activities
- Case detection by sputum smear microscopy among symptomatic patients self-reporting to health services
- Standardized treatment regimen of six to eight months for at least all confirmed sputum smear positive cases, with directly observed treatment (DOT) for at least the initial two months
- A regular, uninterrupted supply of all essential anti-TB drugs
- A standardized recording and reporting system that allows assessment of treatment results for each patient and of the TB control program

Integral to the DOTS strategy are the basic principles of making the TB patients and their health care givers enter a mutual agreement to take care of the former until full recovery. This basic principle includes intensive counseling, education of the patients about the nature of their disease and full adherence to the treatment plan.

Exactly what does political commitment entail? It means providing the resources needed to support the NTP and the DOTS elements. Funds automatically provided for in the national budget. Free medicines are available for all. Competent microscopy centers are present in all centers. The strengthened NTP is a joint venture of the DOH, the LGUs and the private sector. The DOH formulates plans and policies, oversees program implementation, provides logistics (such as drugs, laboratory supplies, educational materials), and collates and analyzes reports and recommendations of the LGUs. The LGUs in turn formulate local plans and policies and implement them accordingly.

Provincial or city medical NTP coordinators are designated and given their respective responsibilities. This way, the smooth implementation, monitoring and evaluation of activities are ensured. Ideally, private medical practice is aligned with the NTP policies and the private MDs are implementers of the NTP.

The second to the fourth DOTS components refer to the health care givers to be in constant contact with the identified TB patients. These workers make sure that the patients have been properly identified through the standardized sputum examination and that the schedule of treatment has been recorded accurately. The health care workers personally administer the patients' ingestion of the anti-TB drugs from a period of two to six months in the clinics and when necessary, at home. Supply of these drugs is free as provided by the national and local governments through the local health and DOTS centers.

The last component aims to accurately document the progress of treatment and tracking of patients. This is a most important component to ensure progress of the DOTS program as a strategy to control TB.

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MODULE 2: TRANSMISSION AND PATHOGENESIS OF TUBERCULOSIS (FOR TEACHERS)

Suggested year level: Second year

Suggested subjects for insertion/integration:

1. Microbiology
2. Pathology

Duration:

1. One hour of lecture in Microbiology
2. One laboratory session for AFB staining and interpretation of results in Microbiology (2 hours)
3. One hour of lecture in Pathology for TB although some principles included in lectures on basic principles in pathology
4. One laboratory session in Pathology (2 hours)

General Objective: At the end of this module, students can DEMONSTRATE THOROUGH UNDERSTANDING OF TB AS A BIOMEDICAL AND SOCIAL PHENOMENON

Specific Objectives:

1. Relate morphological and physiological characteristics of *Mycobacterium tuberculosis* (MTb) with its staining, antigenic and virulence properties
2. Follow standard procedures in performing and interpreting sputum smears
3. Explain how man develops MTb infection
4. Discuss the pathological consequences of TB infection
5. Distinguish TB infection from active disease
6. Explain the transmission of MTb within a family or community
7. Discuss the rationale why DOTS is most instrumental in detecting and controlling TB disease

Content

MYCOBACTERIUM TUBERCULOSIS

I. Historical considerations

- A. Tuberculosis (TB) is an ancient disease that has been recognized in bones of Egyptian mummies.
- B. Isolation by Robert Koch (1882)
 1. Proof that *Mycobacterium tuberculosis* (MTb) causes the disease tuberculosis
 - a. Bacillus is constantly associated with disease
 - b. Bacillus is isolated in pure culture from infected individuals
 - c. Disease is reproduced in experimental animals when the isolates are introduced to them
 - d. Bacillus is recovered in pure culture from these experimentally infected animals

2. This became the basis for the **Koch's postulate**, the tenet that infectious disease experts use to establish the etiology of an infectious disease.

II. Morphology of MTb

- A. These are **Acid-fast bacilli** (AFB): Stain with difficulty but once stained, they do not decolorize with acid alcohol.
- B. General morphologic characteristics and their clinical significance:
 1. Slender, straight, or slightly curved, non-sporogenous, non-encapsulated bacilli measuring 0.2 – 0.5 by 1 – 4 micrometer
 2. Gram-positive but difficult to identify using this stain.
 3. Ziehl-Neelsen stain: red rods in sky blue background
 4. AFB
 - a. Attributable to high lipid content.
 - b. Physical integrity is needed to demonstrate this
 - c. Hydrophobicity of layer follows complexing dye with mycolic acid residues in the cell wall. This prevents exit of carbolfuchsin trapped inside the cell.
 5. Composition of the cell wall: Related to antigenic properties
 - a. Peptidoglycans
 - b. Wax D – enhances immunogenicity of antigen

III. Physiology of Mycobacterium tuberculosis

- A. Cultural characteristics:
 1. MTb is **slow growing** but grows on simple medium such as Lowenstein-Jensen or BACTEC.
 2. Culturing of clinical specimens increases the rates of case detection because of the higher sensitivity of culture compared to smear microscopy
 3. Rapid methods can be used to complement conventional methods for the recovery of MTb. The only well established rapid method for detecting the bacteria in clinical specimens is the BACTEC 460. Growth of MTb can be detected within a few days.
 4. Small, dry, scaly colonies with corrugated surfaces
 5. They are **obligate aerobes** and will not grow in the absence of oxygen.



Think! If the growth of MTb is enhanced in areas where oxygen tension is high, in what part of the body will it thrive best and rapidly multiply?

In the APICES of the lungs where the oxygen tension is highest in the body as the result of high ventilation: perfusion ratio. Review your lesson in Lung Physiology.

- B. Microbial robustness: resistance to effects of:
1. Drying – MTb remains alive and virulent in dried sputum and can be stored for up to 12 years!
 2. Sunlight – It is destroyed in direct sunlight within two hours in cultures but in sputum, it takes 20 – 30 hours before it is killed. If there is no sun, sputum remains viable for 6 – 8 months in dried sputum and in weeks in putrefying sputum. Droplets adhering to dust are infectious for 1 – 1½ weeks.
 3. Chemicals – MTb is difficult to disinfect. Five percent solution of phenol is usually used. It is likewise killed by pasteurization.



These facts clearly show the importance of **educating TB patients** on simple yet important things like spitting on the ground. They will likely transmit bacteria to others this way.

- C. Antigenic structure
1. Cell wall structures: polysaccharides, proteins, peptides
 2. Cytoplasmic proteins
 3. Seibert proteins A and B elicit skin reactions more potent than PPD.
- D. Virulence factors
1. TB is an enigma! It has no toxins and its antigenic structures are not related to its virulence.
 2. The virulence of the strain is related to other factors:
 - a. Pattern of culture
 - i. Virulent: serpentine cords with bacilli in parallel arrangement
 - ii. Avirulent: random brush – heap pattern
 - b. Cord factor
 - c. Catalase
 - d. Tuberculoproteins

Read on virulence and antigenic factors of MTb. Summarize the salient points in the space below.



If antigenic factors are not significant in determining the virulence of the MTb strain, what then is their clinical significance?

IV. Examination of the Sputum specimen

(Based on IUATLD. (2000). *Technical Guide Sputum Examination for Tuberculosis by Direct Microscopy in Low Income Countries.*)



In the laboratory, you will be examining sputum specimens using Ziehl-Neelsen staining technique summarized below. This exercise is important not only because it will demonstrate how MTb looks like under the microscope but because, in the future, you will be requesting or performing this examination for TB suspects. This is in keeping with the DOTS strategy. Do you remember the components of DOTS? Review Module 1 (TB Epidemic). Remember, too, that even if you will just do one smear in the laboratory this year, actual patients will need three sputum exams. Read on the reason why three specimens are recommended.

A. Smearing

1. Properly label the clean glass slides to be used.
2. Open the sputum container carefully to avoid aerosol production.
3. Break a stick applicator, choose a purulent particle of the sputum and with the broken end of the applicator, break up larger particles of the specimen.
4. Spread the sputum evenly over the central area of a clean glass slide with a rotational motion. Discard the applicator properly.
5. Recap the sputum container but do not discard until the results are recorded.

B. Fixing

1. Air dry smears. Do not fix moist slides.
2. Fix dry smears by passing the slide side up over the flame 3 – 5 times for about 4 seconds only. Do not overheat slides.
3. Place slides on dryer with smeared surface upwards and air dry for thirty minutes.

C. Staining

1. Cover the slides with Ziehl's carbol fuchsin solution.
2. Heat the slides from underneath using Bunsen burner or alcohol lamp until vapor starts to rise. But do not allow the staining solution to boil or dry up.
3. Keep slides covered with hot staining solution for about five minutes.
4. Rinse the smear with tap water to remove excess carbol fuchsin.
5. Drain off excess water. The sputum smears should now appear red.

D. Decolorizing

1. Flood the smear with sulfuric acid or acid-alcohol for about three minutes. The smear should become almost colorless.
2. Rinse the smear with tap water to wash away the acid-alcohol.

E. Counterstaining

1. Cover the smear with 0.3% Methylene Blue stain for one minute.

2. Rinse the smear with tap water and air dry. Do not place under the sun to dry.

F. Examination

1. Examine the slide under oil immersion lens.
2. Scan the long axis three times and count the number of acid fast bacilli seen

V. Reporting sputum smear results:

Reporting of results is crucial since it not only says whether or not a patient has AFB but it also reflects his degree of infectivity. The table below shows the standard interpretation based on the number of bacilli present.

Table 1: Interpretation of AFB Stain (NTP 2001 Manual of Procedures)

Number of Bacilli Seen	Interpretation
Zero in at least 100 fields	No acid fast bacilli seen
1 – 9	+
10 – 299	++
300 and above	+++



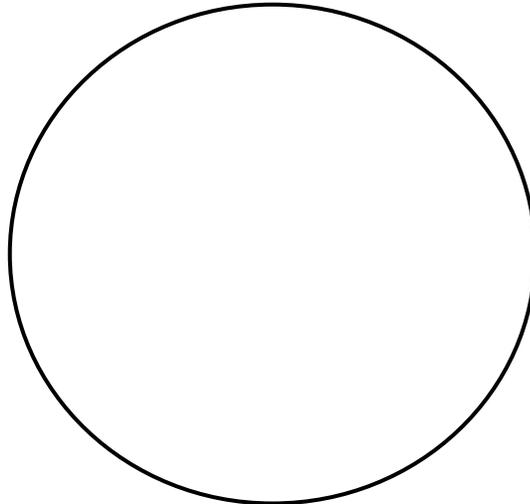
In a nutshell, the Ziehl-Neelsen staining procedure requires:

- **STAINING** with hot Ziehl’s solution for five minutes.
- **DECOLORIZING** with acid-alcohol for three minutes.
- **COUNTERSTAINING** with Methylene blue for one minute.

In the laboratory, you will be given specimens to examine. Draw and color what you see in the microscope in the space provided. Indicate your interpretation. If your slide contains no AFB, make sure you take a look at the findings of those who have AFB in their slides. Have your preceptor check your work.

AFB as seen in Oil immersion view

Interpretation: _____



The bacterium is not the only thing responsible for the development of the disease. The environment and the host are crucial factors as well. These two interact with each other, in the light of the exposure, infection and eventual progression into disease and death. In short, let us follow the natural history of tuberculosis.

EXPOSURE TO MTb

The major factors that determine the risk of exposure to MTb include:

1. Number of infectious cases in the community – If there is no MTb source, there will be no exposure and therefore there will be no TB!
2. Duration of their infectiousness – Exposure is greatly increased with longer periods of infectiousness of TB patients. Early and adequate intervention makes these cases non-infectious faster, decreasing the risk of exposure of people in the community.
3. Number and nature of interactions between an infectious case and a susceptible contact
 - a. Population density – the number of people in a given area
 - b. Family size – the number of exposed children, sleeping arrangements and responsibilities for caring for the child
 - c. Age of source of infection – Parents expose their children more to the infection than do grandparents due to generally longer contact time with them. Aside from this inter-generational contact, intra-generation social interaction is a key to transmission of TB. People of the same age group tend to socialize more closely thus increasing exposure among members of the same generation.

- d. Gender – Different societies have markedly different social interactions by gender. Exposure to infectious cases then would likewise vary for men and women in these societies.
4. Climactic conditions – As previously mentioned, MTb exposed to direct sunlight die rather quickly in contrast to those confined indoors with poor ventilation and protected from sunlight.

INFECTION WITH MTb

The risk factors for becoming infected with MTb include:

1. The infectious patient

For transmission to take place, a TB patient must be able to produce infectious droplets. These are the patients with TB of the respiratory tract. Coughing, sneezing, talking and, yes, even singing produce droplets! Half of these droplets are still suspended in the air half an hour after. This gives ample time for the poor, unsuspecting listener to breathe in.



Whenever you are assigned to a TB patient, do not forget to **advise him** to cover his mouth and nose when he coughs (tactfully of course). This decreases the number of infectious droplets in the air and is thus important for the sake of those around him, including you. Add this to your advice regarding spitting.

Another thing to consider is that the degree of infectiousness is not uniform among all patients but correlates with the number of bacilli in the sputum. Recall the AFB smear interpretation. Do you now appreciate the significance of accurately reporting results of the smear?

2. Exogenous factors / environmental factors
 - a. The number and size of infectious droplet nuclei

The greater the number of airborne particles per volume of air (the so-called infectious particle density) is, the greater is the chance of infection of a susceptible host. This is why household contacts, who are nearer to the patient in the enclosed home environment are at greater risk than casual contact.

The risk for infection is highest when the individual is exposed to a smear positive PTB case, lower when exposed to a smear negative PTB case and lower still from an extrapulmonary TB case.

It sounds logical that the bigger droplets the greater the bacillary load and, ergo, the more likely these are to cause infection compared to the smaller ones. Right? Before you nod in agreement, consider this! To

be transmissible through the air, the infectious droplet nuclei should be buoyant in the air for several hours. Larger ones immediately fall to the ground before a susceptible person inhales them. Moreover, the larger ones are trapped in the mucociliary system of the tracheobronchial tree, swept up and swallowed. On the other hand the smaller ones (about 1 – 5 mm in diameter) remain suspended and reach the alveoli, leading to infection. In short, beware of the “SMALL but terrible” droplet nuclei!



TRUE OR FALSE: You should always wear a surgical mask whenever you are with a TB patient to protect yourself from the droplet nuclei that he is scattering all around whenever he coughs, talks or sings.

FALSE. In this case, wearing a surgical mask on your part gives you nothing more than a false sense of security since this cannot filter out particles of less than 5 mm (the smaller, more terrible ones, remember?). Besides, this mask does not fit snugly around the nose and mouth.

- b. Duration of exposure of the susceptible person to the particle density – This further increases the risk of household contact. Not only are they closer to the patient, they also stay with him longer.
- c. Air circulation and ventilation
Ventilation dramatically dilutes the concentration of infectious droplet nuclei. This is why the windows should be open whenever you supervise sputum collection of TB suspects.

You must have heard so many times that “squatters” are prone to infections. Well now you know that this is not just nonsense talk of advocates for human rights. It does have sound scientific basis. Numerous factors, in fact, favor transmission: the infectious patient’s coughing, sneezing, singing and spitting, increased infectious particle density and longer duration of exposure to family members and close contacts, and lack of ventilation and sunlight in the crowded, cramped shacks.

3. Host factors

When the bacillus enters the alveoli commonly at in the lower lobes, it either manages to establish infection (primary infection among susceptible persons) or it is killed (in those with previously established immunity). The host's immune competence plays an important role in preventing growth of MTb.

What happens now when factors favor infection? During the initial phase of MTb invasion, there develops a small area of pneumonitis in the vicinity (alveoli) MTb deposition with lymphangitis extending to the hilar nodes, which generally become swollen. Subsequently, in the next few days to a few weeks, the TB bacilli get in to the lymph and are carried via the large lymphatic ducts and its drainage to the systemic circulation. Seeding of the rest of the body ensues. In the lungs, both the upper and lower lungs are hematogenously seeded.

At about this time, the host immune competence stimulated by the initial infection becomes established preventing MTB growth at the seeded sites. Although humoral antibodies appear, they are present in low titers. These antibodies are bactericidal and even if they enhance phagocytosis, MTb flourish inside phagocytes. Sensitized T cells are the ones which play an important role in resistance to MTb. Products from these are chemotactic to macrophages, thus there is enhanced aggregation of macrophages at the cite of infection. There is also enhanced phagocytic potentials of macrophages. Therefore hypersensitivity is associated with increased ability to phagocytose and inhibit intracellular replication of MTb. Overall, this leads to increased resistance to disease.

Latent TB is this stage of quiescence where viable TB exists in tightly guarded granulomas erected by the cell-mediated arm of the immunologic system.

Reactivation TB exists when the immune competence fails and MTb in one or more sites starts to proliferate damaging the tissue. In those where immune competence never really got established, the primary infection quickly leads to TB disease with on-going tissue damage. The signs and symptoms of TB disease become manifest.

In the lungs, tissue breakdown occurs in active TB. As the tuberculosis focus in the body increases in size, it also becomes progressively anaerobic and acidic. Bacilli growth then slows down and some bacilli are destroyed. However there occurs a sudden surge in multiplication of bacilli when the lesions erode into natural air passages such as bronchi. Inside cavitary lesions, bacillary count can be 1000 times more than closed caseous lesions.

These bacilli are coughed out in the sputum and into the air for the next susceptible host to inhale, thereby, completing the TB life cycle.

TB DISEASE

Think! We know that patients infected with MTb need not exhibit any symptoms. What about patients with TB active disease? Are all these patients symptomatic?

The great majority of patients with active disease will have constitutional symptoms but a small proportion with ongoing organ damage (which by definition is active

Again, TB active disease means there is evidence of on-going organ damage (lung or another organ). This is seen in:

- 1) Primary TB or primary complex diseases – seen immediately after TB primary infection in a minority of cases
- 2) Secondary TB or post primary TB or reactivation TB – seen after a prolonged period of latent TB infection
- 3) Relapse after an interim period of being “cured” – seen when MTb survivors of previous treatment grow again as the surrounding milieu becomes favorable. Effective treatment, no matter how prolonged, does not completely eliminate the MTb population.
- 4) Re-infection TB – seen when successful infection by another TB strain occurs despite previously acquired immunity. This is a rarity and is seen only if the exposure occurred at the time when the person’s immune system became incompetent as in AIDS and the intake of immunosuppressive drugs for cancer.

There may be TB inactive disease, which means that there is evidence of residual organ damage; TB organisms are no longer actively multiplying although as explained above, viable dormant organisms persist and contained by the granulomatous reaction. This occurs either:

- 1) Spontaneously (no treatment) in 30% of TB cases
- 2) As a treatment outcome (over 95% in completely treated non-resistant cases)

Infection with MTb is necessary but, fortunately, not sufficient to cause active disease. In short, not everyone who has been infected develops the TB disease. Only around 5 - 10% will. The rest will harbor the bacilli but will never become symptomatic.

What factors determine who will progress from being infected to having the disease? The risk of being infected is largely due to exogenous factors, development of the disease on the other hand is determined by the cellular immune system of the individual. Hence, conditions that impair this system can allow progression to disease soon after the initial infection (primary TB or primary complex disease) or after a variable period (usually years) of bacillary dormancy (post primary or secondary or reactivation TB).

In the article “International Course on the Management of Tuberculosis Laboratory Networks in Low-Income Countries,” by the International Union Against Tuberculosis and Lung Disease (IUATLD) and WHO, conditions that increase the risk of developing TB disease among infected hosts were discussed. These are summarized in the table below.

Table2: Conditions that increase the risk of TB disease and supporting evidences

Conditions that increase the risk of developing TB disease	Evidences from studies
Inherent host factors	
Genetic factors	<ul style="list-style-type: none"> - Concordance for TB risk among twins - Body build – Incidence of TB is 2.2 to 4 times higher in those whose body weight is below ideal - HLA types – HLA types such as A-11B15 and DR2 increase odds of TB - Blood groups – Risk of TB disease is higher among those with blood type AB or B - Hemophilia – Exposed children with hemophilia are more likely to develop the disease - Virgin populations – The risk of disease among infected persons is higher among those with no previous contact with TB
Age and gender	<ul style="list-style-type: none"> - Up to 2 years, TB infection is more likely to evolve into a highly lethal form - Little difference in susceptibility to TB between boys and girls until puberty.
Medical conditions of the host	
HIV infection	<ul style="list-style-type: none"> - Powerful factor in progression to disease - Persons who are infected with HIV and MTb rapidly develop TB disease - Correlated with the number of CD4 lymphocytes
Spontaneously healed TB with fibrotic residuals	<ul style="list-style-type: none"> - A third of TB cases may remit in the absence of treatment. Recurrence rate is low but still higher than those “cured” with complete treatment.
Diabetes mellitus	<ul style="list-style-type: none"> - The incidence of TB among diabetics is three times higher than that of the general population. But this did not adjust for TB infection
Silicosis	<ul style="list-style-type: none"> - TB is common among miners and patients with silicosis.
Corticosteroid treatment	<ul style="list-style-type: none"> - Experimental studies and individual case reports implicate corticosteroid treatment as a risk factor for TB. No such correlation has been found with prolonged use of inhaled steroids.
Malignancies	<ul style="list-style-type: none"> - Malignant lymphomas, lung cancer, lymphosarcoma, cancers of the head and neck are associated with increased TB morbidity.
Renal failure	<ul style="list-style-type: none"> - Patients with end-stage renal disease and those on hemodialysis are at higher risk of TB
Gastrectomy	<ul style="list-style-type: none"> - This is associated with high TB morbidity as this is a risk factor or associated with another risk factor such as lower body weight of these patients.
Jejunioileal bypass	<ul style="list-style-type: none"> - This might be a risk factor for TB
Environmental factors	
Socio-economic factors	<ul style="list-style-type: none"> - Overcrowding and unfavorable living conditions increase risk of transmission - Malnourished when they are infected have a higher risk of developing the disease

Conditions that increase the risk of developing TB disease	Evidences from studies
Substance abuse	<ol style="list-style-type: none"> 1. Smoking – The odds for TB increase with increase in the number of cigarettes smoked 2. Injection drug abuse –There is a higher risk of TB among IV drug users (this was prior to HIV discovery) 3. Alcohol abuse – A causal association is inconclusive
Nutrition	<ol style="list-style-type: none"> 1. Malnutrition – It affects the immune system. 2. Diet – Vegetarian (especially lacto-vegetarian) diet is a risk in developing TB
Factors associated with etiologic agent	
Infecting dose effect	<ul style="list-style-type: none"> - The risk of disease is greater if infection was caused by a sputum smear positive individual (who is assumed to be expelling more bacilli) compared to a sputum negative individual.
Virulence	<ul style="list-style-type: none"> - Different strains have different virulence.
Resistance	<ul style="list-style-type: none"> - Source cases with drug resistant strains will remain infectious for a much longer time due to the reduced efficiency of chemotherapy.

 Remember these conditions and always look for them in patients with TB! Adequate treatment also requires attention to these concomitant conditions.

Now, it's time once more to hit the books. The book ***Pathologic Basis of Disease*** by Robbins has a comprehensive discussion on TB under the Chapter on Infectious Diseases. What is nice about the discussion in this book is the references the author makes to microbiological concepts that we have already learned earlier on and some points on the clinical presentation of TB. You may use other references, which you prefer. It will be helpful to read before your scheduled lecture.

PATHOLOGY

After reading your text and listening to the lecture, complete these two tables.

Table 3: Difference between acute and chronic inflammation

Features	Acute inflammation	Chronic inflammation
Stimulus	Transient	1. Persistent 2. Repeated bouts of acute inflammation 3. Insidious
Clinical presentation	Heat, redness, swelling, pain, loss of function	Depends on the nature of the stimulus
Pathologic changes	Hemodynamic changes: Transient vasoconstriction of arterioles followed by vasodilatation, increased permeability of micro-vasculature, WBCs (neutrophils and macrophages): leukocytic margination, emigration, phagocytosis, Mediators: vasoactive amines (histamine, serotonin), proteases (kinin, complement system, coagulation-fibrinolytic system), prostaglandins, neutrophil products, etc.	Infiltration by mononuclear cells (macrophages, lymphocytes, plasma cells) Proliferation of fibroblasts resulting in increased deposition of collagen Proliferation of small blood vessels Cell-mediated immune reaction

* Remember that chronic and acute responses may be superimposed. And hallmarks of one may be seen in the other as well.

Table 4: The various pathological findings in TB

Pathological findings	Description
Granuloma	- small, 1–2 mm collections of macrophages surrounded by a rim of lymphocytes, fibroblasts, plasma cells and neutrophils
Epithelioid cell	- characteristic cell of the granuloma; a modified macrophage with abundant, pale-pink cytoplasm; similar to epithelial cells (hence, the term epithelioid)
Langhans' giant cell	- macrophages which coalesced or fused together with internal nuclear division without cytoplasmic divisions
Tuberculous granuloma	- classic granuloma in TB with central caseous necrosis
Caseous necrosis	- most characteristic hallmark of TB - grossly appears as soft, friable, whitish-gray debris resembling clumps of cheesy material - microscopically, appears as amorphous granular debris where cells are not totally liquefied but outlines are not clear
Ghon lesion	- initial focus of TB infection in the lung parenchyma; usually

Pathological findings	Description
	in the lower lobes (reflecting the area receiving the greatest volume of inspired air) <ul style="list-style-type: none"> - 1.0–1.5 cm area of gray-white inflammatory consolidation sharply circumscribed from the surrounding lung tissue - Ghon complex – combination of the Ghon lesion plus lymph node involvement

In the laboratory, look for these findings in the specimens that you will be shown. Draw and color them to help you remember. As you do, recall the description you have summarized from the textbook. You may do so at the back of this module or on a separate sheet and attach it to the module.

What disease entities likewise present with granulomatous inflammation?

1. Leprosy
2. Sarcoidosis
3. Brucellosis
4. Tularemia
5. Syphilis
6. Glanders
7. Lymphogranuloma inguinale
8. Cat-scratch fever
9. Berylliosis
10. Some of the mycoses
11. Reactions to lipids

How then do you differentiate these from TB?

1. Caseous necrosis
2. Presence of MTb

Describe the potential course of reactivation PTB:

1. Healing, scarring, calcification
2. Progressive PTB wherein the initial parenchymal infection spreads to other areas of the lung
3. Spread to the pleura leading to pleural effusion, fibrosis, adhesions, empyema
4. Erosion into the bronchi leading to endotracheobronchial TB and laryngeal TB
5. Swallowing of bacilli leading to intestinal TB
6. Miliary TB when the MTb reaches the lymphatics and blood and seed distant organs at a time when the immune system is unable to contain the infection. This may immediately follow the primary infection (“first bacteremia”) although, as a rule, this does not occur as cell mediated immunity is fortuitously acquired at this time. More commonly, it follows after a caseous focus in reactivation TB drains to the circulation (“second bacteremia”). This is seen as small yellow-white foci like millet seeds in the sites involved. These lesions do not have the chance to grow as the patient dies quickly unless treatment is immediately initiated.

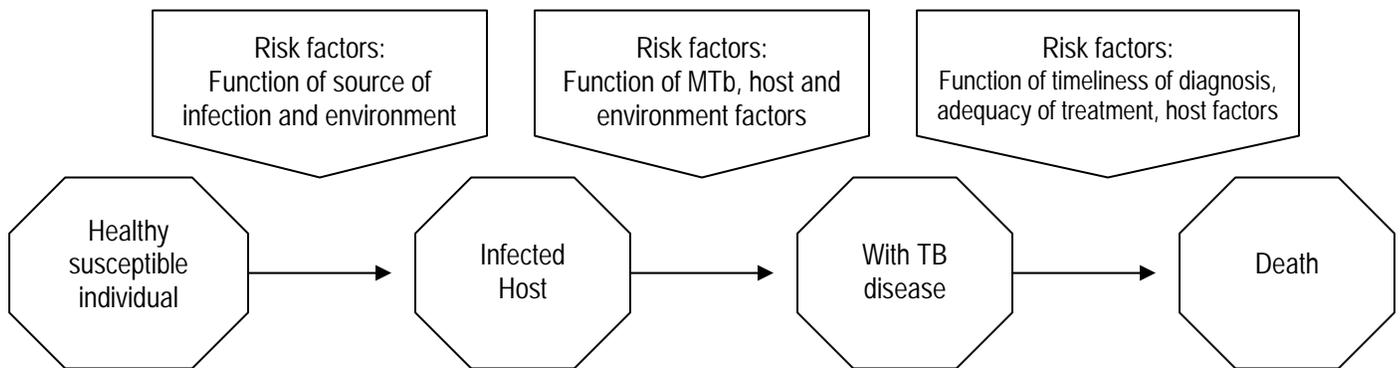
- Isolated organ involvement wherein TB affects only one organ such as meninges, kidneys, adrenals, bones, fallopian tubes and epididymides.

TB DEATHS

Mostly, mortalities due to TB depend on the site and type of disease and timeliness of diagnosis and appropriateness of intervention. Thirty to forty percent of sputum positive patients who remain untreated die within one year; 50 to 70% die within five to seven years.

Currently an estimated 1.5M people die annually from this preventable and treatable disease!

Let's review the natural history of the disease through this Figure 1:



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MODULE 2: TRANSMISSION AND PATHOGENESIS OF TUBERCULOSIS (FOR STUDENTS)

General Objective: At the end of this module, students can DEMONSTRATE THOROUGH UNDERSTANDING OF TB AS A BIOMEDICAL AND SOCIAL PHENOMENON

Specific Objectives:

1. Relate morphological and physiological characteristics of *Mycobacterium tuberculosis* (MTb) with its staining, antigenic and virulence properties
2. Follow standard procedures in performing and interpreting sputum smears
3. Explain how man develops MTb infection
4. Discuss the pathological consequences of TB infection
5. Distinguish TB infection from active disease
6. Explain the transmission of MTb within a family or community
7. Discuss the rationale why DOTS is most instrumental in detecting and controlling TB disease

Content

MYCOBACTERIUM TUBERCULOSIS

I. Historical considerations

- A. Tuberculosis (TB) is an ancient disease that has been recognized in bones of Egyptian mummies.
- B. Isolation by Robert Koch (1882)
 1. Proof that *Mycobacterium tuberculosis* (MTb) causes the disease tuberculosis
 - a. Bacillus is constantly associated with disease
 - b. Bacillus is isolated in pure culture from infected individuals
 - c. Disease is reproduced in experimental animals when the isolates are introduced to them
 - d. Bacillus is recovered in pure culture from these experimentally infected animals
 2. This became the basis for the **Koch's postulate**, the tenet that infectious disease experts use to establish the etiology an infectious disease.

II. Morphology of MTb

- A. These are **Acid-fast bacilli** (AFB): Stain with difficulty but once stained, they do not decolorize with acid alcohol.
- B. General morphologic characteristics and their clinical significance:
 1. Slender, straight, or slightly curved, non-sporogenous, non-encapsulated bacilli measuring 0.2 – 0.5 by 1 – 4 micrometer
 2. Gram-positive but difficult to identify using this stain.

3. Ziehl-Neelsen stain: red rods in sky blue background
4. AFB
 - a. Attributable to high lipid content.
 - b. Physical integrity is needed to demonstrate this
 - c. Hydrophobicity of layer follows complexing dye with mycolic acid residues in the cell wall. This prevents exit of carbolfuchsin trapped inside the cell.
5. Composition of the cell wall: Related to antigenic properties
 - a. Peptidoglycans
 - b. Wax D – enhances immunogenicity of antigen

III. Physiology of *Mycobacterium tuberculosis*

A. Cultural characteristics:

1. MTb is **slow growing** but grows on simple medium such as Lowenstein-Jensen or BACTEC.
2. Culturing of clinical specimens increases the rates of case detection because of the higher sensitivity of culture compared to smear microscopy
3. Rapid methods can be used to complement conventional methods for the recovery of MTb. The only well established rapid method for detecting the bacteria in clinical specimens is the BACTEC 460. Growth of MTb can be detected within a few days.
4. Small, dry, scaly colonies with corrugated surfaces



Think! If the growth of MTb is enhanced in areas where oxygen tension is high, in what part of the body will it thrive best and rapidly multiply?

In the APICES of the lungs where the oxygen tension is highest in the body as the result of high ventilation : perfusion ratio. Review your lesson in Lung Physiology.

5. They are **obligate aerobes** and will not grow in the absence of oxygen.
- #### B. Microbial robustness: resistance to effects of:
1. Drying – MTb remains alive and virulent in dried sputum and can be stored for up to 12 years!
 2. Sunlight – It is destroyed in direct sunlight within two hours in cultures but in sputum, it takes 20 – 30 hours before it is killed. If there is no sun, sputum remains viable for 6 – 8 months in dried sputum and in weeks in putrefying sputum. Droplets adhering to dust are infectious for 1 – 1½ weeks.



These facts clearly show the importance of **educating TB patients** on simple yet important things like spitting on the ground. They will likely transmit bacteria to others this way.

3. Chemicals – MTb is difficult to disinfect. Five percent solution of phenol is usually used. It is likewise killed by pasteurization.

C. Antigenic structure

1. Cell wall structures: polysaccharides, proteins, peptides
2. Cytoplasmic proteins
3. Seibert proteins A and B elicit skin reactions more potent than PPD.

D. Virulence factors

1. TB is an enigma! It has no toxins and its antigenic structures are not related to its virulence.
2. The virulence of the strain is related to other factors:
 - a. Pattern of culture
 - i. Virulent: serpentine cords with bacilli in parallel arrangement
 - ii. Avirulent: random brush – heap pattern
 - b. Cord factor
 - c. Catalase
 - d. Tuberculoproteins

Read on virulence and antigenic factors of MTb. Summarize the salient points in the space below.



If antigenic factors are not significant in determining the virulence of the MTb strain, what then is their clinical significance?

IV. Examination of the Sputum specimen

(Based on IUATLD. (2000). *Technical Guide Sputum Examination for Tuberculosis by Direct Microscopy in Low Income Countries.*)



In the laboratory, you will be examining sputum specimens using Ziehl-Neelsen staining technique summarized below. This exercise is important not only because it will demonstrate how MTb looks like under the microscope but because, in the future, you will be requesting or performing this examination for TB suspects. This is in keeping with the DOTS strategy. Do you remember the components of DOTS? Review Module 1 (TB Epidemic). Remember, too, that even if you will just do one smear in the laboratory this year, actual patients will need three sputum exams. Read on the reason why three specimens are recommended.

A. Smearing

1. Properly label the clean glass slides to be used.
2. Open the sputum container carefully to avoid aerosol production.
3. Break a stick applicator, choose a purulent particle of the sputum and with the broken end of the applicator, break up larger particles of the specimen.
4. Spread the sputum evenly over the central area of a clean glass slide with a rotational motion. Discard the applicator properly.
5. Recap the sputum container but do not discard until the results are recorded.

B. Fixing

1. Air dry smears. Do not fix moist slides.
2. Fix dry smears by passing the slide side up over the flame 3 – 5 times for about 4 seconds only. Do not overheat slides.
3. Place slides on dryer with smeared surface upwards and air dry for thirty minutes.

C. Staining

1. Cover the slides with Ziehl's carbol fuchsin solution.
2. Heat the slides from underneath using Bunsen burner or alcohol lamp until vapor starts to rise. But do not allow the staining solution to boil or dry up.
3. Keep slides covered with hot staining solution for about five minutes.
4. Rinse the smear with tap water to remove excess carbol fuchsin.
5. Drain off excess water. The sputum smears should now appear red.

D. Decolorizing

1. Flood the smear with sulfuric acid or acid-alcohol for about three minutes. The smear should become almost colorless.
2. Rinse the smear with tap water to wash away the acid-alcohol.

E. Counterstaining

1. Cover the smear with 0.3% Methylene Blue stain for one minute.
2. Rinse the smear with tap water and air dry. Do not place under the sun to dry.

F. Examination

1. Examine the slide under oil immersion lens.
2. Scan the long axis three times and count the number of acid fast bacilli seen

V. Reporting sputum smear results:

Reporting of results is crucial since it not only says whether or not a patient has AFB but it also reflects his degree of infectivity. The table below shows the standard interpretation based on the number of bacilli present.

Table 1: Interpretation of AFB Stain (NTP 2001 Manual of Procedures)

Number of Bacilli Seen	Interpretation
Zero in at least 100 fields	No acid fast bacilli seen
1 – 9	+
10 – 299	++
300 and above	+++



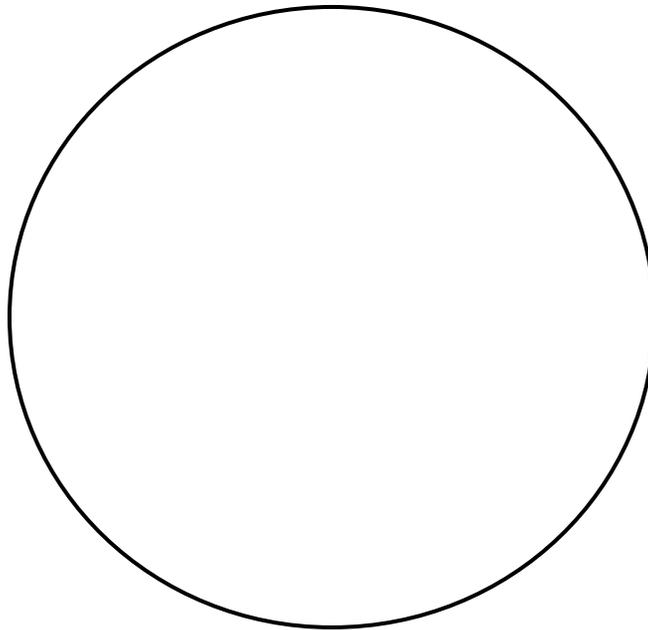
In a nutshell, the Ziehl-Neelsen staining procedure requires:

- **STAINING** with hot Ziehl's solution for five minutes.
- **DECOLORIZING** with acid-alcohol for three minutes.
- **COUNTERSTAINING** with Methylene blue for one minute.

In the laboratory, you will be given specimens to examine. Draw and color what you see in the microscope in the space provided. Indicate your interpretation. If your slide contains no AFB, make sure you take a look at the findings of those who have AFB in their slides. Have your preceptor check your work.

AFB as seen in Oil immersion view

Interpretation: _____



The bacterium is not the only thing responsible for the development of the disease. The environment and the host are crucial factors as well. These two interact with each other, in the light of the exposure, infection and eventual progression into disease and death. In short, let us follow the natural history of tuberculosis.

EXPOSURE TO MTb

The major factors that determine the risk of exposure to MTb include:

1. Number of infectious cases in the community – If there is no MTb source, there will be no exposure and therefore there will be no TB!
2. Duration of their infectiousness – Exposure is greatly increased with longer periods of infectiousness of TB patients. Early and adequate intervention makes these cases non-infectious faster, decreasing the risk of exposure of people in the community.
3. Number and nature of interactions between an infectious case and a susceptible contact
 - a. Population density – the number of people in a given area
 - b. Family size – the number of exposed children, sleeping arrangements and responsibilities for caring for the child
 - c. Age of source of infection – Parents expose their children more to the infection than do grandparents due to generally longer contact time with them. Aside from this inter-generational contact, intra-generation social interaction is a key to transmission of TB. People of the same age group tend to socialize more closely thus increasing exposure among members of the same generation.

- d. Gender – Different societies have markedly different social interactions by gender. Exposure to infectious cases then would likewise vary for men and women in these societies.
- 4. Climactic conditions – As previously mentioned, MTb exposed to direct sunlight die rather quickly in contrast to those confined indoors with poor ventilation and protected from sunlight.

INFECTION WITH MTb

The risk factors for becoming infected with MTb include:

1. The infectious patient

For transmission to take place, a TB patient must be able to produce infectious droplets. These are the patients with TB of the respiratory tract. Coughing, sneezing, talking and, yes, even singing produce droplets! Half of these droplets are still suspended in the air half an hour after. This gives ample time for the poor, unsuspecting listener to breathe in.



Whenever you are assigned to a TB patient, do not forget to **advise him** to cover his mouth and nose when he coughs (tactfully of course). This decreases the number of infectious droplets in the air and is thus important for the sake of those around him, including you. Add this to your advice regarding spitting.

Another thing to consider is that the degree of infectiousness is not uniform among all patients but correlates with the number of bacilli in the sputum. Recall the AFB smear interpretation. Do you now appreciate the significance of accurately reporting results of the smear?

2. Exogenous factors / environmental factors
 - a. The number and size of infectious droplet nuclei

The greater the number of airborne particles per volume of air (the so-called infectious particle density) is, the greater is the chance of infection of a susceptible host. This is why household contacts, who are nearer to the patient in the enclosed home environment are at greater risk than casual contact.

The risk for infection is highest when the individual is exposed to a smear positive PTB case, lower when exposed to a smear negative PTB case and lower still from an extrapulmonary TB case.

It sounds logical that the bigger droplets the greater the bacillary load and, ergo, the more likely these are to cause infection compared to the smaller ones. Right? Before you nod in agreement, consider this! To be transmissible through the air, the infectious droplet nuclei should be buoyant in the air for several hours. Larger ones immediately fall to the ground before a susceptible person inhales them. Moreover, the larger ones are trapped in the mucociliary system of the tracheobronchial tree, swept up and swallowed. On the other hand the smaller ones (about 1 – 5 mm in diameter) remain suspended and reach the alveoli, leading to infection. In short, beware of the “SMALL but terrible” droplet nuclei!



TRUE OR FALSE: You should always wear a surgical mask whenever you are with a TB patient to protect yourself from the droplet nuclei that he is scattering all around whenever he coughs, talks or sings.

FALSE. In this case, wearing a surgical mask on your part gives you nothing more than a false sense of security since this cannot filter out particles of less than 5 mm (the smaller, more terrible ones, remember?). Besides, this mask does not fit snugly around the nose and mouth.

- b. Duration of exposure of the susceptible person to the particle density – This further increases the risk of household contact. Not only are they closer to the patient, they also stay with him longer.
- c. Air circulation and ventilation

Ventilation dramatically dilutes the concentration of infectious droplet nuclei. This is why the windows should be open whenever you supervise sputum collection of TB suspects.

You must have heard so many times that “squatters” are prone to infections. Well now you know that this is not just nonsense talk of advocates for human rights. It does have sound scientific basis. Numerous factors, in fact, favor transmission: the infectious patient’s coughing, sneezing, singing and spitting, increased infectious particle density and longer duration of exposure to family members and close contacts, and lack of ventilation and sunlight in the crowded, cramped shacks.

3. Host factors

When the bacillus enters the alveoli commonly at in the lower lobes, it either manages to establish infection (primary infection among susceptible persons) or it is killed (in those with previously established immunity). The host’s immune competence plays an important role in preventing growth of MTb.

What happens now when factors favor infection? During the initial phase of MTb invasion, there develops a small area of pneumonitis in the vicinity (alveoli) MTb deposition with lymphangitis extending to the hilar nodes, which generally become swollen. Subsequently, in the next few days to a few weeks, the TB bacilli get in to the lymph and are carried via the large lymphatic ducts and its drainage to the systemic circulation. Seeding of the rest of the body ensues. In the lungs, both the upper and lower lungs are hematogenously seeded.

At about this time, the host immune competence stimulated by the initial infection becomes established preventing MTB growth at the seeded sites. Although humoral antibodies appear, they are present in low titers. These antibodies are bactericidal and even if they enhance phagocytosis, MTb flourish inside phagocytes. Sensitized T cells are the ones which play an important role in resistance to MTb. Products from these are chemotactic to macrophages, thus there is enhanced aggregation of macrophages at the site of infection. There is also enhanced phagocytic potentials of macrophages. Therefore hypersensitivity is associated with increased ability to phagocytose and inhibit intracellular replication of MTb. Overall, this leads to increased resistance to disease.

Latent TB is this stage of quiescence where viable TB exists in tightly guarded granulomas erected by the cell-mediated arm of the immunologic system.

Reactivation TB exists when the immune competence fails and MTb in one or more sites starts to proliferate damaging the tissue. In those where immune competence never really got established, the primary infection quickly leads to TB disease with on-going tissue damage. The signs and symptoms of TB disease become manifest.

In the lungs, tissue breakdown occurs in active TB. As the tuberculosis focus in the body increases in size, it also becomes progressively anaerobic and acidic. Bacilli

growth then slows down and some bacilli are destroyed. However there occurs a sudden surge in multiplication of bacilli when the lesions erode into natural air passages such as bronchi. Inside cavitory lesions, bacillary count can be 1000 times more than closed caseous lesions.

These bacilli are coughed out in the sputum and into the air for the next susceptible host to inhale, thereby, completing the TB life cycle.

Think! We know that patients infected with MTb need not exhibit any symptoms. What about patients with TB active disease? Are all these patients symptomatic?

The great majority of patients with active disease will have constitutional symptoms but a small proportion with ongoing organ damage (which by definition is active

TB DISEASE

Again, TB active disease means there is evidence of on-going organ damage (lung or another organ). This is seen in:

- 1) Primary TB or primary complex diseases – seen immediately after TB primary infection in a minority of cases
- 2) Secondary TB or post primary TB or reactivation TB – seen after a prolonged period of latent TB infection
- 3) Relapse after an interim period of being “cured” – seen when MTb survivors of previous treatment grow again as the surrounding milieu becomes favorable. Effective treatment, no matter how prolonged, does not completely eliminate the MTb population.
- 4) Re-infection TB – seen when successful infection by another TB strain occurs despite previously acquired immunity. This is a rarity and is seen only if the exposure occurred at the time when the person’s immune system became incompetent as in AIDS and the intake of immunosuppressive drugs for cancer.

There may be TB inactive disease, which means that there is evidence of residual organ damage; TB organisms are no longer actively multiplying although as explained above, viable dormant organisms persist and contained by the granulomatous reaction. This occurs either:

- 1) Spontaneously (no treatment) in 30% of TB cases
- 2) As a treatment outcome (over 95% in completely treated non-resistant cases)

Infection with MTb is necessary but, fortunately, not sufficient to cause active disease. In short, not everyone who has been infected develops the TB disease. Only around 5 - 10% will. The rest will harbor the bacilli but will never become symptomatic.

What factors determine who will progress from being infected to having the disease? The risk of being infected is largely due to exogenous factors, development of the disease on the other hand is determined by the cellular immune system of the individual. Hence, conditions that impair this system can allow progression to disease soon after the initial infection (primary TB or primary complex disease) or after a variable period (usually years) of bacillary dormancy (post primary or secondary or reactivation TB).

In the article “International Course on the Management of Tuberculosis Laboratory Networks in Low-Income Countries,” by the International Union Against Tuberculosis and Lung Disease (IUATLD) and WHO, conditions that increase the risk of developing TB disease among infected hosts were discussed. These are summarized in the table below.

Table2: Conditions that increase the risk of TB disease and supporting evidences

Conditions that increase the risk of developing TB disease	Evidences from studies
Inherent host factors	
Genetic factors	<ul style="list-style-type: none"> - Concordance for TB risk among twins - Body build – Incidence of TB is 2.2 to 4 times higher in those whose body weight is below ideal - HLA types – HLA types such as A-11B15 and DR2 increase odds of TB - Blood groups – Risk of TB disease is higher among those with blood type AB or B - Hemophilia – Exposed children with hemophilia are more likely to develop the disease - Virgin populations – The risk of disease among infected persons is higher among those with no previous contact with TB
Age and gender	<ul style="list-style-type: none"> - Up to 2 years, TB infection is more likely to evolve into a highly lethal form - Little difference in susceptibility to TB between boys and girls until puberty.
Medical conditions of the host	
HIV infection	<ul style="list-style-type: none"> - Powerful factor in progression to disease - Persons who are infected with HIV and MTb rapidly develop TB disease - Correlated with the number of CD4 lymphocytes
Spontaneously healed TB with fibrotic residuals	<ul style="list-style-type: none"> - A third of TB cases may remit in the absence of treatment. Recurrence rate is low but still higher than those “cured” with complete treatment.
Diabetes mellitus	<ul style="list-style-type: none"> - The incidence of TB among diabetics is three times higher than that of the general population. But this did not adjust for TB infection
Silicosis	<ul style="list-style-type: none"> - TB is common among miners and patients with silicosis.
Corticosteroid treatment	<ul style="list-style-type: none"> - Experimental studies and individual case reports implicate corticosteroid treatment as a risk factor for TB. No such correlation has been found with prolonged use of inhaled steroids.
Malignancies	<ul style="list-style-type: none"> - Malignant lymphomas, lung cancer, lymphosarcoma, cancers of the head and neck are associated with increased TB morbidity.
Renal failure	<ul style="list-style-type: none"> - Patients with end-stage renal disease and those on hemodialysis are at higher risk of TB
Gastrectomy	<ul style="list-style-type: none"> - This is associated with high TB morbidity as this is a risk factor or

Conditions that increase the risk of developing TB disease	Evidences from studies
	associated with another risk factor such as lower body weight of these patients.
Jejunioileal bypass	- This might be a risk factor for TB
Environmental factors	
Socio-economic factors	<ul style="list-style-type: none"> - Overcrowding and unfavorable living conditions increase risk of transmission - Malnourished when they are infected have a higher risk of developing the disease
Substance abuse	<ul style="list-style-type: none"> 4. Smoking – The odds for TB increase with increase in the number of cigarettes smoked 5. Injection drug abuse –There is a higher risk of TB among IV drug users (this was prior to HIV discovery) 6. Alcohol abuse – A causal association is inconclusive
Nutrition	<ul style="list-style-type: none"> 3. Malnutrition – It affects the immune system. 4. Diet – Vegetarian (especially lacto-vegetarian) diet is a risk in developing TB
Factors associated with etiologic agent	
Infecting dose effect	- The risk of disease is greater if infection was caused by a sputum smear positive individual (who is assumed to be expelling more bacilli) compared to a sputum negative individual.
Virulence	- Different strains have different virulence.
Resistance	- Source cases with drug resistant strains will remain infectious for a much longer time due to the reduced efficiency of chemotherapy.

 **Remember these conditions and always look for them in patients with TB! Adequate treatment also requires attention to these concomitant conditions.**

PATHOLOGY

Now, it's time once more to hit the books. The book ***Pathologic Basis of Disease*** by Robbins has a comprehensive discussion on TB under the Chapter on Infectious Diseases. What is nice about the discussion in this book is the references the author makes to microbiological concepts that we have already learned earlier on and some points on the clinical presentation of TB. You may use other references, which you prefer. It will be helpful to read before your scheduled lecture.

After reading your text and listening to the lecture, complete these two tables.

Table 3: Difference between acute and chronic inflammation

Features	Acute inflammation	Chronic inflammation
Stimulus		
Clinical presentation		
Pathologic changes		

* Remember that chronic and acute responses may be superimposed. And hallmarks of one may be seen in the other as well.

Table 4: The various pathological findings in TB

Pathological findings	Description
Granuloma	
Epithelioid cell	
Langhans' giant cell	

Pathological findings	Description
Tuberculous granuloma	
Caseous necrosis	
Ghon lesion	

In the laboratory, look for these findings in the specimens that you will be shown. Draw and color them to help you remember. As you do, recall the description you have summarized from the textbook. You may do so at the back of this module or on a separate sheet and attach it to the module.

What disease entities likewise present with granulomatous inflammation?

How then do you differentiate these from TB?

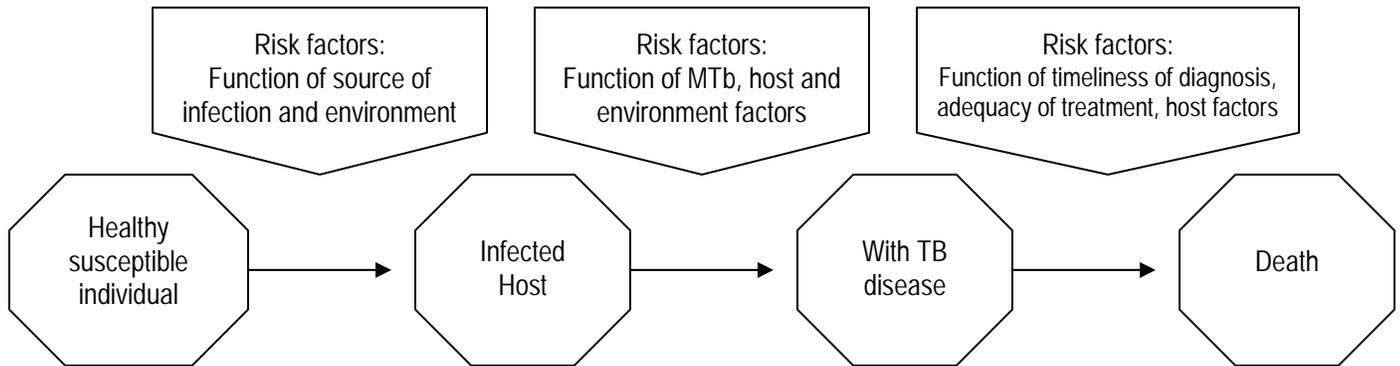
Describe the potential course of reactivation PTB:

TB DEATHS

Mostly, mortalities due to TB depend on the site and type of disease and timeliness of diagnosis and appropriateness of intervention. Thirty to forty percent of sputum positive patients who remain untreated die within one year; 50 to 70% die within five to seven years.

Currently an estimated 1.5M people die annually from this preventable and treatable disease!

Let's review the natural history of the disease through this Figure 1:



References:

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Robbins SL and Angell M. (1976). *Basic Pathology*. Philadelphia: WB Saunders.

Rieder HL. (1999). *Epidemiologic Basis of Tuberculosis Control*. Paris: International Union Against Tuberculosis and Lung Disease.

MODULE 3. CLINICAL PRESENTATION AND DIAGNOSIS OF TUBERCULOSIS (FOR TEACHERS)

Suggested year level: Third and/or fourth year

Suggested subjects for insertion/integration: *All clinical subjects especially:*

1. Internal Medicine
2. Pediatrics
3. Family and Community Medicine
4. Radiology
5. Neurosciences
6. Obstetrics and Gynecology
7. Otorhinolaryngology
8. Ophthalmology
9. Orthopedics

Duration: *Entire clinical rotation in each of the clinical departments*

General Objective: At the end of this module, students can: EVALUATE PATIENTS WITH PTB AND THE MORE COMMON FORMS OF EXTRAPULMONARY TB WITH THE HIGHEST STANDARDS OF PROFESSIONALISM AND COMPETENCE

Specific objectives:

1. Identify signs and symptoms suggestive of pulmonary TB and the more common forms of extrapulmonary TB
2. Elicit relevant clinical history from a patient suspected of having TB
3. Perform a thorough physical examination on a patient suspected of having TB
4. Demonstrate competence in performing ancillary procedures to diagnose TB: sputum smears, intradermal tuberculin test, pleural tap and lymph node aspiration
5. Recognize chest radiographic findings consistent with PTB
6. Accurately diagnose patients with tuberculosis

Content:

Now that after the discussion on what happens to the human body when infected with MTb, you need to be able to recognize this disease in every patient. When should you suspect TB? Everything starts with the patient's history and physical examination findings.

CLINICAL HISTORY

- A. Clinical presentation
 1. There is no consistent symptom pathognomic for PTB
 2. PTB does not have to be symptomatic, especially in the older age group
 3. Symptoms that should raise the suspicion of PTB

- a. Local symptoms
 - i. Cough of two or more weeks duration
Only chronic cough consistently discriminates PTB from non-TB respiratory disease
 - ii. Hemoptysis or recurrent blood-streaked sputum – present in 25% of patients
 - iii. Chest and / or back pains not referable to musculoskeletal disorder
 - iv. Shortness of breath. Dyspnea may be due to an old or ongoing damage to the lungs and therefore, it may persist despite cure
 - b. Constitutional symptoms: One or more of the following
 - i. Fever and chills – Fever is intermittent and contrary to popular belief, does not commonly occur in the afternoon.
 - ii. Progressive weight loss
 - iii. Tiredness
 - iv. Night sweats
- B. Past Medical History
- 1. Past history of TB as well as previous treatment received
 - 2. Vaccination to BCG and previous PPD examination results
 - 3. Disease conditions that increase the risk for TB as these should likewise be controlled
- C. Family and Social History
- 1. Exposure to TB in the family and close contacts

Physical Examination Findings:

For the counterpart skills in performing physical examination, please instruct students to follow their schedule rotation in the respective clinical areas.

Diagnostic Examinations

- 1. Sputum smear examination
 - a. Review the rationale and process of doing sputum smear
 - b. This is found to be a more specific and more objective examination than chest radiographs.
- 2. Chest radiograph
 - a. Suggestive findings: Nodular, alveolar, interstitial infiltrates in the upper lung fields
 - b. Other findings include pleural effusion, adenopathy, cavitation, reticular infiltrates, and patchy infiltrate consolidation
 - c. Chest x-ray findings cannot confirm the diagnosis of TB. One study demonstrated that hilar or mediastinal lymphadenopathy & diffuse reticulo-nodular infiltration may individually correlated with the presence of active PTB in the presence of a respiratory or

- constitutional symptom suggestive of respiratory disease. Many other studies failed to show correlation between radiologic findings in the initial film and disease activity.
- d. X-ray is unreliable for diagnosing and monitoring treatment of tuberculosis
 1. 10 – 15% of culture-positive TB patients were not diagnosed by x-ray
 2. 40% of patients diagnosed as having TB on the basis of X-ray alone do not have an active TB
 - e. For smear-negative individuals, however, it appears acceptable to base a presumptive diagnosis of PTB on the chest x-ray findings. This may be sufficient to initiate treatment. However, no case of TB should be treated with no work-up other than the chest x-ray alone. The clinical response to treatment should then be closely monitored and ideally documented with radiographs in the next three months.
3. Culture
- a. Definitive diagnosis of tuberculosis can only be done by culturing clinical specimens through methods based on a combination of liquid or biphasic (solid and liquid) media together with solid media.
 - b. Rapid methods can be used to complement conventional methods. The only well established rapid method for detecting MTb in specimens is the BACTEC 460. Comparison between detection time and rates for MTb isolates between the BACTEC 460 method and conventional culture media is shown in the table below.
 - c. Identification of MTb isolates: Conventional cultural and biochemical tests along with newer methods which include, high performance liquid chromatography (HPLC) or growth inhibition in the BACTEC 460 NAP test. Typical turnaround time for confirmation of *M. tuberculosis* is 21 days from specimen receipt in the laboratory. Conventional biochemical and cultural testing is also useful for the identification MOTT species, turnaround times may be longer depending on the species of mycobacterium. Because of the cost of the reagents and in maintaining the lab, BACTEC and similar high tech tests are not part of the NTP.
 - d. Drug susceptibility testing of *M. tuberculosis*: Isolates of the *M. tuberculosis* complex are first tested against first line anti-tuberculosis agents, isoniazid (INH), streptomycin (SM), rifampin (RIF), ethambutol (EMB). As a rule, drug susceptibility testing of INH and RIF is more reliable than drug susceptibility testing of SM, EMB. Drug susceptibility testing of drug resistant *M. tuberculosis* for second line drugs should be available in areas with high rates of MDR-TB. However, this is less reliable than testing of first line drugs. Conventional methods of drug susceptibility testing are complex and yield results 2 to 3 months after specimen receipt. To generate drug susceptibility results within a week, testing is performed using the BACTEC 460 rapid radiometric method. The

average turnaround time is less than 30 days from the time of specimen receipt.

Let us now compare these examinations in terms of the time it takes from the moment the specimen is sent to the laboratory until the result is obtained:

Table 1: Microbiological tests and time from specimen receipt to reporting:

Tests	Conventional Lab (NTP)	Bactec Lab
AFB smear	1 day	1 day
Culture report	2 – 4 weeks	1 – 2 weeks
M.TB identification	4 – 6 weeks	2 – 3 weeks
Drug Susceptibility	8 or more weeks	3 – 4 weeks

Knowing this, write down the test that you will request for in the following:

Table 2: Appropriate tests for Various Situations

Situations / Cases	Test/s to be requested:		
	AFB smear	MTb Culture	Drug sensitivity
Smear (-) patients with symptoms highly suggestive of PTB and suggestive chest x-rays	/	/	
PTB suspect who has not taken any anti-TB drug in the past	/		
Smear (+) patient on treatment	/		
Smear (+) or (-) patients suspected of MDRTB.	/	/	/
Smear (+) patients with a fall & rise phenomenon	/	/	/
Case of Relapse.	/	/	/
Active cases previously treated for > 3 mos.	/	/	/
Treatment failure.	/	/	/

In summary, the indications for the various microbiological tests are:

1. AFB smear: all suspected cases of tuberculosis
2. MTb culture
 - a. Smear (-) patients with symptoms highly suggestive of PTB and suggestive chest x-rays.
3. MTb culture and drug sensitivity
 - a. Smear (+) or (-) patients suspected of MDRTB.
 - b. Smear (+) patients with a fall & rise phenomenon
 - c. All cases of relapse.
 - d. All active cases previously treated for > 3 mos.
 - e. All cases of treatment failure.

- a. Intradermal tuberculin test
 - a. Review the basis for PPD testing from your textbook.
 - b. In the Philippines, TB is highly prevalent. A positive PPD cannot make a diagnosis of tuberculosis. Recent infection can only be established if serial PPD tests have been done... a practice not common in the country.
 - c. A negative PPD may help rule out TB provided factors that technically affect the tuberculin reaction (like anergy, subcutaneous injection, integrity of the test material, etc) are absent.
 - d. The purpose of targeted testing is to find:
 - 1. Patients with latent TB infection who could benefit from treatment. Treating latent TB is not the priority in TB control as this is less cost-effective when compared to treating smear (+) cases. Furthermore, in situations like the one we have, this approach may siphon off scarce resources from the NTP.
 - 2. Patients with TB disease who could benefit from treatment
- b. Steps in Performing the PPD test:
 - 1. Inject intradermally 0.1 ml of 5 TU PPD tuberculin
 - 2. Produce a wheal 6 mm to 10 mm in diameter
 - 3. Read reaction 48-72 hours after injection
 - 4. Measure only induration
 - 5. Record reaction in millimeters
- c. Interpreting results:
 - 1. 5 mm is classified as positive in
 - a) HIV-positive persons
 - b) Recent contacts of TB case
 - c) Persons with fibrotic changes on chest radiograph consistent with old healed TB
 - d) Patients with organ transplants and other immunosuppressed patients
 - 2. 10 mm is classified as positive in
 - a) Recent arrivals from high-prevalence countries
 - b) Injection drug users
 - c) Residents and employees of high-risk congregate settings
 - d) Mycobacteriology laboratory personnel
 - e) Persons with clinical conditions that place them at high risk
 - f) Children <4 years of age, or children and adolescents exposed to adults in high-risk categories

Let us summarize the diagnostic examinations for TB.

Table 3: Comparison among the Diagnostic Tests to diagnose active PTB

Test characteristic	Sputum AFB smear	Sputum M. Tb culture	Chest x-ray PA view	ELISA	PPD
Sensitivity	50% - 60 %; needs 10,000 bacilli/specimen to be seen; 3 samples needed	>60 % up to 90%; positive even if there are only 1000 bacilli/specimen	80%; additional views may be needed	High but not standardized or validated with the local TB strain	High for TB infection but anergy states and other technical factors can make it negative
Specificity	> 97%	> 99%	70%, significant no. of false (+)	Low; useful to discover other diagnosis or concurrent disease	Indicate TB infection and not necessarily active disease
Field applicability	High – results are quick	Low – result are delayed	Low – needs good machine, a good technician and an experienced radiologist	Not standardized, not applicable to peripheral labs	Low - more useful to exclude TB than diagnose its presence
Cost	Free to low	High	Low to moderate	Moderate	Low to moderate
Other programmatic concerns applicability issues:	Free from NTP!; messy but it is the main parameter to gauge cure under the NTP	BACTEC and PCR are sensitive but not specific for active TB. Their use in the field setting is limited by cost and availability issues	The tendency of low-volume small x-ray labs to cut cost by delaying reagent replenishment impairs the quality if the radiograph	Standardization is not yet complete in the local setting	Background “noise” due to high prevalence of TB infection in the country limits its diagnostic value for active TB

Adult versus Pediatric TB

Generally TB in children follows primary TB infection while that of adult TB represents reactivation of previous infected foci. The table below summarizes the differences in the clinical features of the two.

Table 4: Differences in Clinical Features between Pediatric and Adult TB

Clinical features	Pediatric TB	Adult TB
TB pathogenetic stage	Primary tuberculosis	Secondary (re-infection) TB
Main diagnostic confirmation	Clinical features + history of exposure of a smear positive case	Bacteriology (AFB smear and if warranted, culture)
Bacillary load	Low, hence, low infectiousness	High load (especially cavitory disease), therefore, highly infectious
Treatment needed	2-3 drugs	4-5 drugs
DOT Mandatory	Yes – usually by parent	Yes – by health worker

Read the comprehensive discussion on the clinical presentation of TB among adults and children in your textbooks.

COMMON EXTRAPULMONARY SITES

Tuberculosis can affect major organs in the body. What do you think will be the clinical presentation of patients with the following extrapulmonary sites?

Complete the table below.

Table 5: Clinical presentation of the more common Extrapulmonary Sites

Extrapulmonary site	Clinical presentation
<ul style="list-style-type: none"> Pleura 	Symptoms include pain on the back and sides. There may be dullness on percussion.
<ul style="list-style-type: none"> Central nervous system 	In children, early signs include apathy, vomiting, headache During the late stage, neck stiffness, seizure, lethargy, coma Lumbar puncture is the diagnostic test (elevated opening pressure, lymphocytes [30-300 cells/mm³] and protein [0.6-2g/L], decreased sugar to less than half of normal [0.45-0.5g/L], and pellicle formation. The presence of AFB in the smear is diagnostic.
<ul style="list-style-type: none"> Lymphatic system 	This is usually cervical, rarely axillary or inguinal. Nodes are firm, with diameters more than 2 mm, painless and are not matted. Months later, they can soften and become fistulous. Histopathology and culture studies will confirm the diagnosis.
<ul style="list-style-type: none"> Cardiovascular system 	Patients may present with cough, dyspnea, orthopnea, chest pain and bipedal edema. Constitutional symptoms may also be present. Cardiac findings are consistent with pericarditis (distant heart sounds, pericardial friction rub, and rarely pulsus paradoxus). Echocardiogram is important test. Examination of pericardial fluid is used to establish the diagnosis.
<ul style="list-style-type: none"> Gastrointestinal system 	Any part of the digestive system may be involved. Involvement of the colon presents with chronic diarrhea which may be bloody due to ulcers in the colon especially the ileocecal area and abdominal pain or discomfort. Masses in the GIT may present with signs and symptoms of obstruction such as vomiting in proximal gut involvement and bowel changes (overflow diarrhea or constipation) in the lower gut. This may also be seen if there is lymph node adhesion. Involvement of the liver may present as obstructive jaundice due to obstruction at the porta hepatis. Hepatomegaly may likewise be appreciated. Peritoneal involvement is usually suspected in patients with ascites. Rarely the pancreas may be involved. It may be silent or may present as acute pancreatitis. Biopsy and AFB smear and culture of the involved areas are important.
<ul style="list-style-type: none"> Genitourinary systems 	This usually occurs late in the course of TB. TB is usually suspected in patients with dysuria, hematuria, flank pain and pyuria. Fever is not commonly seen. Patients may present with recurrent infections with negative urine cultures.
<ul style="list-style-type: none"> Bones and joints 	The vertebrae are most commonly affected (specifically the lower thoracic, lumbar and lumbosacral). Patients may have angular deformities, limp (with or without history of trauma), and swelling of the involved bones and joints. Plain radiograph studies reveal typical findings in Pott's disease or bone involvement. ESR may be elevated due to inflammation (distinguishing it from malignancy). Diagnosis is established by biopsy of the bone or synovium for histopathology and culture
<ul style="list-style-type: none"> Ear 	This is considered in patients with chronic otitis media who do not improve with standard

Extrapulmonary site	Clinical presentation
	medical treatment.
<ul style="list-style-type: none"> • Eyes 	The uvea is most frequently involved. Choroidal tubercles are appreciated on funduscopy. Biopsy and culture specimens are only obtained in the case of keratitis, orbital TB or lid involvement.
<ul style="list-style-type: none"> • Skin 	This can be classified into three: <ol style="list-style-type: none"> 1. From an exogenous source (present as ulcer, hyperkeratotic papule, wart) 2. From an endogenous source (includes sinus tract, abscesses, ulcer at the body orifice) 3. From hematogenous spread (as lupus vulgaris, multiple papules and pustules, nodules and abscesses) Definitive diagnosis is reached through biopsy, AFB stain and culture.
<ul style="list-style-type: none"> • Miliary TB 	This may occur within weeks of primary infection or may be a later consequence of erosion of a TB lesion into a blood vessel. Chest Xray shows diffuse small micronodular shadows.

Your patients are your best teachers, they say. You may forget some details contained in your books but you will remember those patients assigned to you in the wards and outpatient clinics.

Don't let those opportunities pass. Using the space below, briefly summarize the medical history, PE findings, laboratory results and clinical course of your patients. Look at them again when a new patient comes and compare. It would be good to jot down a case for each type of patient (adult, pediatric, neurologic, gynecologic, etc). Let this module be your "TB Bank" you can refer to in the future.

References:

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MODULE 3. CLINICAL PRESENTATION AND DIAGNOSIS OF TUBERCULOSIS (FOR STUDENTS)

General Objective: At the end of this module, students can: EVALUATE PATIENTS WITH PTB AND THE MORE COMMON FORMS OF EXTRAPULMONARY TB WITH THE HIGHEST STANDARDS OF PROFESSIONALISM AND COMPETENCE

Specific objectives:

1. Identify signs and symptoms suggestive of pulmonary TB and the more common forms of extrapulmonary TB
2. Elicit relevant clinical history from a patient suspected of having TB
3. Perform a thorough physical examination on a patient suspected of having TB
4. Demonstrate competence in performing ancillary procedures to diagnose TB: sputum smears, intradermal tuberculin test, pleural tap and lymph node aspiration
5. Recognize chest radiographic findings consistent with PTB
6. Accurately diagnose patients with tuberculosis

Content:

Now that after the discussion on what happens to the human body when infected with MTb, you need to be able to recognize this disease in every patient. When should you suspect TB? Everything starts with the patient's history and physical examination findings.

CLINICAL HISTORY

1. Clinical presentation

- a. There is no consistent symptom pathognomic for PTB
- b. PTB does not have to be symptomatic, especially in the older age group
- c. Symptoms that should raise the suspicion of PTB
 - i) Local symptoms
 - (1) Cough of two or more weeks duration
 - (2) Only chronic cough consistently discriminates PTB from non-TB respiratory disease
 - (3) Hemoptysis or recurrent blood-streaked sputum – present in 25% of patients
 - (4) Chest and / or back pains not referable to musculoskeletal disorder
 - (5) Shortness of breath. Dyspnea may be due to an old or ongoing damage to the lungs and therefore, it may persist despite cure
 - ii) Constitutional symptoms: One or more of the following

- (1) Fever and chills – Fever is intermittent and contrary to popular belief, does not commonly occur in the afternoon.
- (2) Progressive weight loss
- (3) Tiredness
- (4) Night sweats

- 2. Past Medical History
 - a. Past history of TB as well as previous treatment received
 - b. Vaccination to BCG and previous PPD examination results
 - c. Disease conditions that increase the risk for TB as these should likewise be controlled
- 3. Family and Social History
 - a. Exposure to TB in the family and close contacts

Physical Examination Findings:

For the counterpart skills in performing physical examination, please instruct students to follow their schedule rotation in the respective clinical areas.

Diagnostic Examinations

- 1) Sputum smear examination
 - a) Review the rationale and process of doing sputum smear
 - b) This is found to be a more specific and more objective examination than chest radiographs.
- 2) Chest radiograph
 - a) Suggestive findings: Nodular, alveolar, interstitial infiltrates in the upper lung fields
 - (1) b. Other findings include pleural effusion, adenopathy, cavitation, reticular infiltrates, and patchy infiltrate consolidation
 - a) Chest x-ray findings cannot confirm the diagnosis of TB. One study demonstrated that hilar or mediastinal lymphadenopathy & diffuse reticulo-nodular infiltration may individually correlated with the presence of active PTB in the presence of a respiratory or constitutional symptom suggestive of respiratory disease. Many other studies failed to show correlation between radiologic findings in the initial film and disease activity.
 - (1) d. X-ray is unreliable for diagnosing and monitoring treatment of tuberculosis
 - (1) 10 – 15% of culture-positive TB patients were not diagnosed by x-ray
 - (1) 40% of patients diagnosed as having TB on the basis of X-ray alone do not have an active TB
 - c) For smear-negative individuals, however, it appears acceptable to base a presumptive diagnosis of PTB on the chest x-ray findings. This may be

sufficient to initiate treatment. However, no case of TB should be treated with no work-up other than the chest x-ray alone. The clinical response to treatment should then be closely monitored and ideally documented with radiographs in the next three months.

3. Culture

- a. Definitive diagnosis of tuberculosis can only be done by culturing clinical specimens through methods based on a combination of liquid or biphasic (solid and liquid) media together with solid media.
- b. Rapid methods can be used to complement conventional methods. The only well established rapid method for detecting MTb in specimens is the BACTEC 460. Comparison between detection time and rates for MTb isolates between the BACTEC 460 method and conventional culture media is shown in the table below.
- c. Identification of MTb isolates: Conventional cultural and biochemical tests along with newer methods which include, high performance liquid chromatography (HPLC) or growth inhibition in the BACTEC 460 NAP test. Typical turnaround time for confirmation of *M. tuberculosis* is 21 days from specimen receipt in the laboratory. Conventional biochemical and cultural testing is also useful for the identification MOTT species, turnaround times may be longer depending on the species of mycobacterium. Because of the cost of the reagents and in maintaining the lab, BACTEC and similar high tech tests are not part of the NTP.
- e. Drug susceptibility testing of *M. tuberculosis*: Isolates of the *M. tuberculosis* complex are first tested against first line anti-tuberculosis agents, isoniazid (INH), streptomycin (SM), rifampin (RIF), ethambutol (EMB). As a rule, drug susceptibility testing of INH and RIF is more reliable than drug susceptibility testing of SM, EMB. Drug susceptibility testing of drug resistant *M. tuberculosis* for second line drugs should be available in areas with high rates of MDR-TB. However, this is less reliable than testing of first line drugs. Conventional methods of drug susceptibility testing are complex and yield results 2 to 3 months after specimen receipt. To generate drug susceptibility results within a week, testing is performed using the BACTEC 460 rapid radiometric method. The average turnaround time is less than 30 days from the time of specimen receipt.

Let us now compare these examinations in terms of the time it takes from the moment the specimen is sent to the laboratory until the result is obtained:

Table 1: Microbiological tests and time from specimen receipt to reporting:

Tests	Conventional Lab (NTP)	Bactec Lab
AFB smear	1 day	1 day
Culture report	2 – 4 weeks	1 – 2 weeks
M.TB identification	4 – 6 weeks	2 – 3 weeks
Drug Susceptibility	8 or more weeks	3 – 4 weeks

Knowing this, write down the test that you will request for in the following:

Table 2: Appropriate tests for Various Situations

Situations / Cases	Test/s to be requested:		
	AFB smear	MTb Culture	Drug sensitivity
Smear (-) patients with symptoms highly suggestive of PTB and suggestive chest x-rays			
PTB suspect who has not taken any anti-TB drug in the past			
Smear (+) patient on treatment			
Smear (+) or (-) patients suspected of MDRTB.			
Smear (+) patients with a fall & rise phenomenon			
Case of Relapse.			
Active cases previously treated for > 3 mos.			
Treatment failure.			

2. Intradermal tuberculin test
 - a. Review the basis for PPD testing from your textbook.
 - b. In the Philippines, TB is highly prevalent. A positive PPD cannot make a diagnosis of tuberculosis. Recent infection can only be established if serial PPD tests have been done... a practice not common in the country.
 - c. A negative PPD may help rule out TB provided factors that technically affect the tuberculin reaction (like anergy, subcutaneous injection, integrity of the test material, etc) are absent.
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 1. Patients with latent TB infection who could benefit from treatment. Treating latent TB is not the priority in TB control as this is less cost-effective when compared to treating smear (+) cases. Furthermore, in situations like the one we have, this approach may siphon off scarce resources from the NTP.
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- e. Steps in Performing the PPD test:
 1. Inject intradermally 0.1 ml of 5 TU PPD tuberculin
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 1. *5 mm is classified as positive in*
 1. HIV-positive persons
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 4. Patients with organ transplants and other immunosuppressed patients
 2. *10 mm is classified as positive in*
 1. Recent arrivals from high-prevalence countries
 2. Injection drug users
 3. Residents and employees of high-risk congregate settings
 4. Mycobacteriology laboratory personnel
 5. Persons with clinical conditions that place them at high risk
 6. Children <4 years of age, or children and adolescents exposed to adults in high-risk categories

Let us summarize the diagnostic examinations for TB.

Table 3: Comparison among the Diagnostic Tests to diagnose active PTB

Test characteristic	Sputum AFB smear	Sputum M. Tb culture	Chest x-ray PA view	ELISA	PPD
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Specificity	> 97%	> 99%	70%, significant no. of false (+)	Low; useful to discover other diagnosis or concurrent disease	Indicate TB infection and not necessarily active disease
Field applicability	High – results are quick	Low – result are delayed	Low – needs good machine, a	Not standardized, not applicable	Low - more useful to exclude TB

Test characteristic	Sputum AFB smear	Sputum M. Tb culture	Chest x-ray PA view	ELISA	PPD
			good technician and an experienced radiologist	to peripheral labs	than diagnose its presence
Cost	Free to low	High	Low to moderate	Moderate	Low to moderate
Other programmatic concerns applicability issues:	Free from NTP!; messy but it is the main parameter to gauge cure under the NTP	BACTEC and PCR are sensitive but not specific for active TB. Their use in the field setting is limited by cost and availability issues	The tendency of low-volume small x-ray labs to cut cost by delaying reagent replenishment impairs the quality if the radiograph	Standardization is not yet complete in the local setting	Background "noise" due to high prevalence of TB infection in the country limits its diagnostic value for active TB

Adult versus Pediatric TB

Generally TB in children follows primary TB infection while that of adult TB represents reactivation of previous infected foci. The table below summarizes the differences in the clinical features of the two.

Table 4: Differences in Clinical Features between Pediatric and Adult TB

Clinical features	Pediatric TB	Adult TB
TB pathogenetic stage	Primary tuberculosis	Secondary (re-infection) TB
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Treatment needed	2-3 drugs	4-5 drugs
DOT Mandatory	Yes – usually by parent	Yes – by health worker

Read the comprehensive discussion on the clinical presentation of TB among adults and children in your textbooks.

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<ul style="list-style-type: none"> • Central nervous system 	
<ul style="list-style-type: none"> • Lymphatic system 	
<ul style="list-style-type: none"> • Cardiovascular system 	
<ul style="list-style-type: none"> • Gastrointestinal system 	
<ul style="list-style-type: none"> • Genitourinary systems 	
<ul style="list-style-type: none"> • Bones and joints 	
<ul style="list-style-type: none"> • Ear 	
<ul style="list-style-type: none"> • Eyes 	
<ul style="list-style-type: none"> • Skin 	
<ul style="list-style-type: none"> • Miliary TB 	

Your patients are your best teachers, they say. You may forget some details contained in your books but you will remember those patients assigned to you in the wards and outpatient clinics.

Don't let those opportunities pass. Using the space below, briefly summarize the medical history, PE findings, laboratory results and clinical course of your patients. Look at them again when a new patient comes and compare. It would be good to jot down a case for each type of patient (adult, pediatric, neurologic, gynecologic, etc). Let this module be your "TB Bank" you can refer to in the future.

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MODULE 4. TREATMENT OF TUBERCULOSIS (FOR TEACHERS)

Suggested year level: Third and/or fourth year medicine proper

Suggested subject for insertion/integration:

1. Pharmacology
2. Medicine
3. Pediatrics

Duration:

1. Approximately 1 hour lecture
2. Class Activity

General Objective: At the end of this module, students can PRESCRIBE DOTS IN ALL INVOLVEMENTS AND ACTIVITIES RELATED TO TB

Specific Objectives:

1. Distinguish anti-TB drugs in terms of their respective pharmacological characteristics, mechanisms of action, dosage, adverse effects and cost
2. Explain why the anti-TB treatment requires the use of several drug simultaneously
3. Prescribe the appropriate anti-TB chemotherapy in keeping with the National TB Program policy and according to the treatment category of patients and special indications
4. Adhere to standardized treatment regimen for all TB patients

Content:

Once a patient has been diagnosed to have TB disease, appropriate treatment should be administered not only to cure the patient but also to prevent further transmission of the disease.

MTb has the natural inclination to form resistant mutants. After hundreds of multiplication, resistance to drugs will be exhibited by some bacilli even without prior antibiotic exposure. The higher the bacillary population, the greater is the chance of finding these pre-existing mutants. When streptomycin was initially used alone, almost all cases relapsed after an initial dramatic regression of the x-ray lesion. In addition to failure of treatment, the whole post-treatment MTb population in these patients became resistant. The antibiotic eliminated sensitive organisms but allowed the small population of resistant mutants to flourish. This antibiotic-induced selection for resistant strains results in the “fall and rise” phenomenon where the sputum AFB smear in a patient converts to negative but reverts to being positive as treatment goes on.

Simultaneous resistance to two or more drugs is less likely since you will have to multiply the numerical probabilities of resistance to each drug. Nonetheless, in cavitory lesions, the numbers may be such that mutants to 2 drugs might be naturally present. Hence, treatment of TB disease should include 3 or more simultaneously administered drugs. Mono- and sequential therapies are major errors. The use of such “poor” regimens and the on and off intake of patients to what may have initially been sound regimens are contributory reasons why TB locally is still high and MDR-TB is rising. Comment on the following adages:

1. “If you can’t treat TB well, it is better not to treat the patient at all!”
2. “Do not add a single drug to a failing regimen!”

MTb exists in three distinct habitats; namely in aerated cavities, in closed caseous lesions and inside macrophages. This creates an additional hurdle in instituting effective treatment. The internal environments of these habitats are different such that the bacillary population and drug effectiveness vary. For example, streptomycin, the most efficient drug for rapidly multiplying bacilli in cavitory lesions, does not penetrate the macrophage. In the same way, pyrazinamide, an agent concentrated inside macrophages and which acts best in the acidic intracellular pH is poorly active in cavitory lesions. Both Rifampicin and INH penetrate all environments but in the Philippines, INH resistance is high due to its long use as a “lung vitamin”.

Clearly, to effect lasting cure, MTb has to be acted upon by several drugs at all sites. In 1998, the National Consensus on Tuberculosis, the first evidence-based guidelines on TB was published in the country. It provided recommendations on the treatment of TB including treatment of TB in special situations like pregnancy, liver disease, and renal disease, among others.

NATIONAL TB CONTROL PROGRAM:

The policies of the National TB Control Program on management of proven TB patients state that:

- A. Treatment of all TB cases shall be based on reliable diagnostic technique, namely, sputum smear examination aside from clinical findings.
- B. Domiciliary treatment shall be the preferred mode of care.
- C. Patients recommended for hospitalization are those with the following conditions:
 1. massive hemoptysis
 2. pleural effusion obliterating more than ½ of a lung field
 3. military TB
 4. TB meningitis
 5. TB pneumonia
 6. those requiring surgical intervention

- 7. those with complications
- D. No patient shall initiate treatment unless the patient and health workers have agreed upon a case holding mechanism for treatment compliance.
- E. The national (regional) and local government units shall ensure the provision of drugs to all sputum positive TB cases.



REMEMBER the targets of the program are:

1. **Cure at least 85 percent of the sputum smear-positive TB patients discovered.**
2. **Detect at least 70 percent of the estimated new sputum smear-positive TB cases.**

TREATMENT REGIMEN FOR TB:

Table1: Treatment Regimens for TB

Regimen	TB Patient To Be Given Treatment	Dose Adjustment by Body Weight in kg
Regimen I 2HRZE / 4HR	New pulmonary smear (+) cases New seriously ill pulmonary smear (-) cases with extensive parenchymal involvement New severely ill extra-pulmonary TB cases	Add one tablet of INH (100mg), PZA (500mg), and Ethambutol (400mg) each for the patient with more than 50kg body weight before the initiation of the treatment.
Regimen II 2HRZES/ 1HREZ / 5HRE	Previously treated smear (+) PTB with relapse, treatment failure, return after default	
Regimen III 2HRZ / 4HR	Smear (-) PTB other than Cat I Extrapulmonary TB, less severely ill	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.

(Legend: The number before the letters represents the number of months the drug is to be taken.
H = INH, R=Rifampicin, Z=Pyrazinamide, E=Ethambutol)

From DOH (2001). *Manual of Procedures for the National Tuberculosis Control Program*. Manila: DOH.

Go back to your textbook and read on the specific characteristics of these drugs in terms of mechanism of action, dosage, indications, contraindications, and side effects. After your readings and class discussions, consider these issues:



Why should you tell your patient that it is best to take INH and Rifampicin as a single dose before meals?

These exhibit concentration-dependent microbial killing. So, to ensure high serum peak concentrations, they should be taken together in an empty stomach. The same reason holds why the dose for these should not be divided. Dosing all drugs together also facilitates supervision by a treatment partner.



Why are fixed-drug combination with INH and other drugs encouraged?

Regimens different from those mentioned have resulted in inferior cure rates. Therefore standardization of treatment both government centers and private practitioners is important. This is the treatment adopted by DOTS. It is not enough that you know these by heart. You should also realize by now that part of the responsibility of physicians is to encourage patients to comply with treatment. This can be effectively carried out through proper counseling of patients and through directly observed treatment (DOT) with a responsible and committed treatment partner.

Again, all of these will be futile if patients do not have the means to procure the drugs. Thus, the success of the regimen greatly depends on an uninterrupted supply of drugs as provided by the government that is committed to

carrying this out. Recall that these are the components of Directly Observed Treatment, Short-course (DOTS) strategy.

In short DOTS is necessary to ensure success of treatment of TB patients.

Now let's summarize the regimens for children based on the National Consensus on Childhood Tuberculosis published in 1997. Basically, children should receive the same treatment regimen as adults.

Table 2: Dosage Recommendation for the Initial Treatment of TB

Drugs	Daily dosage in mg per kg BW (Maximum dose)		2 – 3 times a week in mg per kg BW (Maximum dose)	
	Less than or equal to 12 years old	More than 12 years	Less than or equal to 12 years old	More than 12 years
INH	5-10 (300 mg)	5 (300 mg)	20-40 (900 mg)	15 (900 mg)
Rifampicin	10-15 (600 mg)	10 (600 mg)	10-20 (600 mg)	10 (600 mg)
Pyrazinamide	15-30 (2 g)	15-30 (2 g)	50-70 (4g)	50-70 (4g)
Ethambutol	15-25 for the 1 st 2 months then 15 (2.5 g)	15-25 (2.5 g)	30 3X a week or 50 2X a week (2.5 g)	30 3X a week or 50 2X a week (2.5 g)
Streptomycin	20-30 (1 g)	15 (1 g)	25 – 30 (1.5 g if given 2X a week or 1 g if given 3X a week)	25 – 30 (1.5 g if given 2X a week or 1 g if given 3X a week)

From: Philippine Pediatric Society, Pediatric Infectious Disease Society of the Philippines and Philippine Coalition Against Tuberculosis. (1997). *National Consensus on Childhood Tuberculosis*. Manila: Pediatrica, Inc.

Adverse Effects of Anti-Tb Agents:

The table below summarizes the important side effects of these drugs and how to manage these.

Table 3: Side Effects of Major anti-TB drugs

Side effects	Drug (s) Responsible	What to do?
Minor side effects – Patient should be encouraged to continue taking medicines.		
1. Gastrointestinal intolerance	Rifampicin	Give medication at bedtime.
2. Mild skin reactions	Any kind of drugs	Give anti-histamines.
3. Orange-red colored urine	Rifampicin	Reassure the patient.
4. Pain at the injection site	Streptomycin	Apply warm compress. Rotate sites of injection.
5. Burning sensation in the feet from peripheral neuropathy	Isoniazid	Give Pyridoxine (Vitamin B6): 100 – 200mg daily for treatment 10mg daily for prevention.
6. Arthralgia due to hyperuricemia	Pyrazinamide	Give aspirin or NSAID.
7. Flu-like symptoms	Rifampicin	Give antipyretics.
Major side effects: Discontinue taking medicines and refer to MHO / CHO immediately.		
1. Severe skin rash from hypersensitivity	Any kind of drugs (especially streptomycin)	Discontinue anti-TB drugs and refer to MHO / CHO.
2. Jaundice secondary to hepatitis	Any kind of drugs (especially Isoniazid, Rifampicin and Pyrazinamide)	Discontinue anti-TB drugs and refer to MHO / CHO. If symptoms subside, resume treatment and monitor clinically.
3. Impairment of visual acuity and color vision due to optic neuritis	Ethambutol	Discontinue Ethambutol Refer to an ophthalmologist.
4. Hearing impairment, ringing of the ear and dizziness due to the damage of cranial nerve VIII	Streptomycin	Discontinue anti-TB drugs and refer to MHO / CHO.
5. Oliguria or albuminuria due to renal disorder	Streptomycin Rifampicin	
6. Psychosis and convulsion	Isoniazid	
7. Thrombocytopenia, anemia, shock	Rifampicin	

From: Task Force on Tuberculosis. (2000). *Diagnosis, Treatment and Control of Tuberculosis*. Volume 1, No. 3. Quezon City: Philippine Society for Microbiology and Infectious Diseases and the Philippine College of Physicians.

Treatment of Special Cases:

Some of the patients that you will handle may have concomitant diseases or other conditions that will require an alteration in the treatment regimen. Let us highlight some of them based on the recommendations of the Task Force on Tuberculosis. *Diagnosis, Treatment and Control of Tuberculosis* published in 2000.

- I. Pregnancy and Lactation
 - A. AFB (+) / Culture (+) ± Chest X-ray evidence of TB
 1. HIV (-) / (-) Risk factors for HIV, immunocompetent:
9 HRE or 6 months after culture conversion (If sensitive to INH and Rifampicin, give Ethambutol for 3months only)
 2. HIV (+) / (+) Risk factors for HIV, immunocompromised:
12 HRE or 9 months after culture conversion (PZA may be used after the first trimester)
 3. MDR TB suspect
Treatment must rely on second line drugs.
 - B. AFB (-) / Culture (-) + Chest X-ray evidence of TB
 1. HIV (-) / (-) Risk factors for HIV, immunocompetent
 - a. Non-cavitary disease:
9 HER
 - b. Cavitary disease:
12 HER
 2. HIV (+) / (+) Risk factors for HIV, immunocompromised:
12 HRE
- II. Liver disease
 - A. Viral hepatitis carrier / Past history of acute hepatitis / excessive alcohol consumption without evidence of chronic liver disease:
Usual regimen
 - B. Patients with established chronic liver disease:
2 SHRE / 6 HR or 2 SHE / 10 SE
 - C. Patients with hepatic failure:
SEh OR SEr (Reduced doses of INH (h) or Rifampicin (r))
 - D. Patients with acute hepatitis unrelated to TB or anti-TB treatment:
Clinical judgment necessary. If necessary to treat TB, 3 SE / 6 HR
Monitor liver function closely.
- III. Renal insufficiency: 2 HRZ / 6 HR
- IV. Elderly (patients over 65 years of age): 9HR
- V. HIV positive or AIDS patients:
 - A. AFB (+):

- 2 HRZE / 4-7 HR (altered depending on culture and sensitivity results)
- B. Susceptibility test not available: 9 HRZE
- C. MDR suspect:
1. Use at least three drugs to which organism is susceptible
 2. Avoid drugs previously administered
 3. Tailor regimen to avoid toxicities
 4. Monitor closely
- VI. Extrapulmonary TB:
Manage according to the drug regimen outline for PTB.

Chemoprophylaxis and Treatment of Latent TB:

Do you recall the difference between TB infection and active disease? Review Module 2 on Transmission and Pathogenesis.

Here are some issues on treatment of latent TB infection:

- The likelihood of progression from latent infection (LTBI) to active disease is 5 – 10% in a subject's life span. This is highest in the initial two years after infection and becomes miniscule thereafter.
- Recent converters may be reasonable targets for treatment but in a high-prevalence country like ours, this is hard to determine. Can you figure out why? If not, go back to Module 1 on TB Epidemic and review the table showing the prevalence of infection.
- The size of PPD reaction has not been shown to identify who will need treatment for latent infection
- Wrongly giving prophylactic regimen to patients in whom it is difficult to detect active TB will be tantamount to monotherapy. This leads to resistance. How?
 - Let's say we erroneously label as LTBI someone who actually has silent TB disease (again recall that some patients may have TB disease but be asymptomatic), that's one mistake!
 - Furthermore, we give him prophylaxis with INH and another drug. That's another mistake! Why? High INH resistance rates in our community will make INH treatment useless and will unnecessarily expose patients to the risk INH side effects. Since INH is useless, our poor patient is practically receiving just one drug.
 - Unknowingly, we are treating a patient with active TB disease with monotherapy! Now, you know better.
- Chemoprophylaxis and treatment of latent TB are less cost effective compared to treating smear (+) TB disease.
- There is paucity of evidence to support treatment of LTBI treatment other than large INH trials in western countries where INH resistance is low. In short, in our country, LTBI treatment is not clearly needed.

References:

Department of Health. (2001). *Manual of Procedures for the National Tuberculosis Control Program*. Manila: DOH.

Philippine Pediatric Society, Pediatric Infectious Disease Society of the Philippines and Philippine Coalition Against Tuberculosis. (1997). *National Consensus on Childhood Tuberculosis*. Manila: PEDIATRICA, Inc.

Task Force on Tuberculosis. (2000). *Diagnosis, Treatment and Control of Tuberculosis*. Volume 1, No. 3. Quezon City: Philippine Society for Microbiology and Infectious Diseases and the Philippine College of Physicians.

MODULE 4. TREATMENT OF TUBERCULOSIS (FOR STUDENTS)

General Objective: At the end of this module, students can PRESCRIBE DOTS IN ALL INVOLVEMENTS AND ACTIVITIES RELATED TO TB

Specific Objectives:

1. Distinguish anti-TB drugs in terms of their respective pharmacological characteristics, mechanisms of action, dosage, adverse effects and cost
2. Explain why the anti-TB treatment requires the use of several drug simultaneously
3. Prescribe the appropriate anti-TB chemotherapy in keeping with the National TB Program policy and according to the treatment category of patients and special indications
4. Adhere to standardized treatment regimen for all TB patients

Content:

Once a patient has been diagnosed to have TB disease, appropriate treatment should be administered not only to cure the patient but also to prevent further transmission of the disease.

MTb has the natural inclination to form resistant mutants. After hundreds of multiplication, resistance to drugs will be exhibited by some bacilli even without prior antibiotic exposure. The higher the bacillary population, the greater is the chance of finding these pre-existing mutants. When streptomycin was initially used alone, almost all cases relapsed after an initial dramatic regression of the x-ray lesion. In addition to failure of treatment, the whole post-treatment MTb population in these patients became resistant. The antibiotic eliminated sensitive organisms but allowed the small population of resistant mutants to flourish. This antibiotic-induced selection for resistant strains results in the “fall and rise” phenomenon where the sputum AFB smear in a patient converts to negative but reverts to being positive as treatment goes on.

Simultaneous resistance to two or more drugs is less likely since you will have to multiply the numerical probabilities of resistance to each drug. Nonetheless, in cavitory lesions, the numbers may be such that mutants to 2 drugs might be naturally present. Hence, treatment of TB disease should include 3 or more simultaneously administered drugs. Mono- and sequential therapies are major errors. The use of such “poor” regimens and the on and off intake of patients to what may have initially been sound regimens are contributory reasons why TB locally is still high and MDR-TB is rising. Comment on the following adages:

1. “If you can’t treat TB well, it is better not to treat the patient at all!”
2. “Do not add a single drug to a failing regimen!”

MTb exists in three distinct habitats; namely in aerated cavities, in closed caseous lesions and inside macrophages. This creates an additional hurdle in instituting effective treatment. The internal environments of these habitats are different such that the bacillary population and drug effectiveness vary. For example, streptomycin, the most efficient drug for rapidly multiplying bacilli in cavitory lesions, does not penetrate the macrophage. In the same way, pyrazinamide, an agent concentrated inside macrophages and which acts best in the acidic intracellular pH is poorly active in cavitory lesions. Both Rifampicin and INH penetrate all environments but in the Philippines, INH resistance is high due to its long use as a “lung vitamin”.

Clearly, to effect lasting cure, MTb has to be acted upon by several drugs at all sites. In 1998, the National Consensus on Tuberculosis, the first evidence-based guidelines on TB was published in the country. It provided recommendations on the treatment of TB including treatment of TB in special situations like pregnancy, liver disease, and renal disease, among others.

NATIONAL TB CONTROL PROGRAM:

The policies of the National TB Control Program on management of proven TB patients state that:

- A. Treatment of all TB cases shall be based on reliable diagnostic technique, namely, sputum smear examination aside from clinical findings.
- B. Domiciliary treatment shall be the preferred mode of care.
- C. Patients recommended for hospitalization are those with the following conditions:
 1. massive hemoptysis
 2. pleural effusion obliterating more than $\frac{1}{2}$ of a lung field
 3. military TB
 4. TB meningitis
 5. TB pneumonia
 6. those requiring surgical intervention
 7. those with complications
- D. No patient shall initiate treatment unless the patient and health workers have agreed upon a case holding mechanism for treatment compliance.
- E. The national (regional) and local government units shall ensure the provision of drugs to all sputum positive TB cases.

 REMEMBER the targets of the program are:

3. Cure at least 85 percent of the sputum smear-positive TB patients discovered.

4. Detect at least 70 percent of the estimated new sputum smear-positive TB cases.

TREATMENT REGIMEN FOR TB:

Table1: Treatment Regimens for TB

Regimen	TB Patient To Be Given Treatment	Dose Adjustment by Body Weight in kg
Regimen I 2HRZE / 4HR	New pulmonary smear (+) cases New seriously ill pulmonary smear (-) cases with extensive parenchymal involvement New severely ill extra-pulmonary TB cases	Add one tablet of INH (100mg), PZA (500mg), and Ethambutol (400mg) each for the patient with more than 50kg body weight before the initiation of the treatment.
Regimen II 2HRZES/ 1HREZ / 5HRE	Previously treated smear (+) PTB with relapse, treatment failure, return after default	
Regimen III 2HRZ / 4HR	Smear (-) PTB other than Cat I Extrapulmonary TB, less severely ill	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.

(Legend: The number before the letters represents the number of months the drug is to be taken. H = INH, R=Rifampicin, Z=Pyrazinamide, E=Ethambutol)

From DOH (2001). *Manual of Procedures for the National Tuberculosis Control Program*. Manila: DOH.

Go back to your textbook and read on the specific characteristics of these drugs in terms of mechanism of action, dosage, indications, contraindications, and side effects. After your readings and class discussions, consider these issues:



Why should you tell your patient that it is best to take INH and Rifampicin as a single dose before meals?

These exhibit concentration-dependent microbial killing. So, to ensure high serum peak concentrations, they should be taken together in an empty stomach. The same reason holds why the dose for these should not be divided. Dosing all drugs together also facilitates supervision by a treatment partner.



Why are fixed-drug combination with INH and other drugs encouraged?

Regimens different from those mentioned have resulted in inferior cure rates. Therefore standardization of treatment both government centers and private practitioners is important. This is the treatment adopted by DOTS. It is not enough that you know these by heart. You should also realize by now that part of the responsibility of physicians is to encourage patients to comply with treatment. This can be effectively carried out through proper counseling of patients and through directly observed treatment (DOT) with a responsible and committed treatment partner.

Again, all of these will be futile if patients do not have the means to procure the drugs. Thus, the success of the regimen greatly depends on an uninterrupted supply of drugs as provided by the government that is committed to

carrying this out. Recall that these are the components of Directly Observed Treatment, Short-course (DOTS) strategy.

In short DOTS is necessary to ensure success of treatment of TB patients.

Now let's summarize the regimens for children based on the National Consensus on Childhood Tuberculosis published in 1997. Basically, children should receive the same treatment regimen as adults.

Table 2: Dosage Recommendation for the Initial Treatment of TB

Drugs	Daily dosage in mg per kg BW (Maximum dose)		2 – 3 times a week in mg per kg BW (Maximum dose)	
	Less than or equal to 12 years old	More than 12 years	Less than or equal to 12 years old	More than 12 years
INH	5-10 (300 mg)	5 (300 mg)	20-40 (900 mg)	15 (900 mg)
Rifampicin	10-15 (600 mg)	10 (600 mg)	10-20 (600 mg)	10 (600 mg)
Pyrazinamide	15-30 (2 g)	15-30 (2 g)	50-70 (4g)	50-70 (4g)
Ethambutol	15-25 for the 1 st 2 months then 15 (2.5 g)	15-25 (2.5 g)	30 3X a week or 50 2X a week (2.5 g)	30 3X a week or 50 2X a week (2.5 g)
Streptomycin	20-30 (1 g)	15 (1 g)	25 – 30 (1.5 g if given 2X a week or 1 g if given 3X a week)	25 – 30 (1.5 g if given 2X a week or 1 g if given 3X a week)

From: Philippine Pediatric Society, Pediatric Infectious Disease Society of the Philippines and Philippine Coalition Against Tuberculosis. (1997). *National Consensus on Childhood Tuberculosis*. Manila: Pediatrica, Inc.

Adverse Effects of Anti-Tb Agents:

The table below summarizes the important side effects of these drugs and how to manage these.

Table 3: Side Effects of Major anti-TB drugs

Side effects	Drug (s) Responsible	What to do?
Minor side effects – Patient should be encouraged to continue taking medicines.		
1. Gastrointestinal intolerance	Rifampicin	Give medication at bedtime.
2. Mild skin reactions	Any kind of drugs	Give anti-histamines.
3. Orange-red colored urine	Rifampicin	Reassure the patient.
4. Pain at the injection site	Streptomycin	Apply warm compress. Rotate sites of injection.
5. Burning sensation in the feet from peripheral neuropathy	Isoniazid	Give Pyridoxine (Vitamin B6): 100 – 200mg daily for treatment 10mg daily for prevention.
6. Arthralgia due to hyperuricemia	Pyrazinamide	Give aspirin or NSAID.
7. Flu-like symptoms	Rifampicin	Give antipyretics.
Major side effects: Discontinue taking medicines and refer to MHO / CHO immediately.		
1. Severe skin rash from hypersensitivity	Any kind of drugs (especially streptomycin)	Discontinue anti-TB drugs and refer to MHO / CHO.
2. Jaundice secondary to hepatitis	Any kind of drugs (especially Isoniazid, Rifampicin and Pyrazinamide)	Discontinue anti-TB drugs and refer to MHO / CHO. If symptoms subside, resume treatment and monitor clinically.
3. Impairment of visual acuity and color vision due to optic neuritis	Ethambutol	Discontinue Ethambutol Refer to an ophthalmologist.
4. Hearing impairment, ringing of the ear and dizziness due to the damage of cranial nerve VIII	Streptomycin	Discontinue anti-TB drugs and refer to MHO / CHO.
5. Oliguria or albuminuria due to renal disorder	Streptomycin Rifampicin	
6. Psychosis and convulsion	Isoniazid	
7. Thrombocytopenia, anemia, shock	Rifampicin	

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Treatment of Special Cases:

Some of the patients that you will handle may have concomitant diseases or other conditions that will require an alteration in the treatment regimen. Let us highlight some of them based on the recommendations of the Task Force on Tuberculosis. *Diagnosis, Treatment and Control of Tuberculosis* published in 2000.

I. Pregnancy and Lactation

- A. AFB (+) / Culture (+) ± Chest X-ray evidence of TB
 - 1. HIV (-) / (-) Risk factors for HIV, immunocompetent:
9 HRE or 6 months after culture conversion (If sensitive to INH and Rifampicin, give Ethambutol for 3months only)
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12 HRE or 9 months after culture conversion (PZA may be used after the first trimester)
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Treatment must rely on second line drugs.
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9 HER
 - b. Cavitary disease:
12 HER
 - 2. HIV (+) / (+) Risk factors for HIV, immunocompromised:
12 HRE

II. Liver disease

- C. Viral hepatitis carrier / Past history of acute hepatitis / excessive alcohol consumption without evidence of chronic liver disease:
Usual regimen
- D. Patients with established chronic liver disease:
2 SHRE / 6 HR or 2 SHE / 10 SE
- E. Patients with hepatic failure:
SEh OR SEr (Reduced doses of INH (h) or Rifampicin (r))
- F. Patients with acute hepatitis unrelated to TB or anti-TB treatment:
Clinical judgment necessary. If necessary to treat TB, 3 SE / 6 HR
Monitor liver function closely.

III. Renal insufficiency: 2 HRZ / 6 HR

IV. Elderly (patients over 65 years of age): 9HR

- V. HIV positive or AIDS patients:
- A. AFB (+): 2 HRZE / 4-7 HR (altered depending on culture and sensitivity results)
 - B. Susceptibility test not available: 9 HRZE
 - C. MDR suspect:
 - A. Use at least three drugs to which organism is susceptible
 - B. Avoid drugs previously administered
 - C. Tailor regimen to avoid toxicities
 - D. Monitor closely
- VI. Extrapulmonary TB:
Manage according to the drug regimen outline for PTB.

Chemoprophylaxis and Treatment of Latent TB:

Do you recall the difference between TB infection and active disease? Review Module 2 on Transmission and Pathogenesis.

Here are some issues on treatment of latent TB infection:

- The likelihood of progression from latent infection (LTBI) to active disease is 5 – 10% in a subject's life span. This is highest in the initial two years after infection and becomes miniscule thereafter.
- Recent converters may be reasonable targets for treatment but in a high-prevalence country like ours, this is hard to determine. Can you figure out why? If not, go back to Module 1 on TB Epidemic and review the table showing the prevalence of infection.
- The size of PPD reaction has not been shown to identify who will need treatment for latent infection
- Wrongly giving prophylactic regimen to patients in whom it is difficult to detect active TB will be tantamount to monotherapy. This leads to resistance. How?
 - Let's say we erroneously label as LTBI someone who actually has silent TB disease (again recall that some patients may have TB disease but be asymptomatic), that's one mistake!
 - Furthermore, we give him prophylaxis with INH and another drug. That's another mistake! Why? High INH resistance rates in our community will make INH treatment useless and will unnecessarily expose patients to the risk INH side effects. Since INH is useless, our poor patient is practically receiving just one drug.
 - Unknowingly, we are treating a patient with active TB disease with monotherapy! Now, you know better.
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- There is paucity of evidence to support treatment of LTBI treatment other than large INH trials in western countries where INH resistance is low. In short, in our country, LTBI treatment is not clearly needed.

References:

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MODULE 5. DIRECTLY OBSERVED TREATMENT, SHORT-COURSE (DOTS) STRATEGY (FOR TEACHERS)

Suggested year level: Fourth year

Suggested subjects for insertion/integration:

1. Family and Community Medicine
2. Internal Medicine

Duration:

1. Approximately 1 hour lecture
2. Around 2-3 hours on activities
3. Visit to DOTS centers or Family visits (3 hours)

General Objectives: At the end of this module, students can PRESCRIBE DOTS IN ALL INVOLVEMENTS AND ACTIVITIES RELATED TO TB

Specific Objectives:

1. Explain the five components of DOTS strategy
2. Prefer DOTS to other approaches in TB control in terms of case finding and diagnosis, treatment and follow up and organizational set up
3. Demonstrate competence in specimen collection, staining, and interpretation of AFB smear examination on assigned patients
4. Distinguish anti-TB drugs in terms of their respective pharmacological characteristics, mechanisms of action, dosage, and adverse effects
5. Prescribe the appropriate anti-TB chemotherapy in keeping with the National TB Program policy and according to the treatment category of patients and special indications
6. Adhere to standardized treatment regimen for all TB patients
7. Coach TB patients and their families on the nature of the disease and how it can be treated
8. Monitor progress of treatment by coordinating with the appropriate members of the health team or health care unit where patient is located.
9. Refer patients to appropriate health care units for proper administration of DOTS
10. Maintain an accurate recording system of DOTS patients for evaluation of treatment outcome and program performance
11. Engage in sustainable activities and initiatives to promote TB control in the community

Content:**INTRODUCTION**

Tuberculosis (TB) has been presented as a biomedical and social phenomenon. This infection progresses into a potentially fatal disease. The clinical presentation of patients with this disease, diagnosis and treatment have been discussed. A lot of things are known about TB. In fact, it has been a century since MTb was discovered. For more than half a century, all the known drugs to kill this bacterium have been available for use. What is truly disturbing is the fact that despite all these, TB continues to plague the world. It still kills more people than any other communicable disease globally.

How do we control the epidemic that is TB? A patient with TB infects 10–15 persons annually. Hence, the most effective approach to control the disease is to cure the source of infection so that he can no longer infect other persons. Cure then is so to speak the best prevention.

The most effective strategy pushed by the World Health Organization (WHO) to control TB is the directly observed treatment, short course or DOTS.

 With WHO support, many countries have fully adopted DOTS to control TB. In these countries, DOTS led to higher active TB detection rates and doubling of the cure rates. On the other hand, a few studies appeared in the literature claiming that there is no convincing evidence to prove that direct observation of therapy (DOT) improves cure. Read the following articles:

1. Communicable Diseases Cluster Prevention and Control World Health Organization. (1999). *What is DOTS? A guide to understanding the WHO-recommended TB control strategy known as DOTS*. Geneva: WHO. Chapters 1-3.
2. "Lack of evidence that Directly Observed Therapy (DOT) improves cure or treatment completion rates in patients with tuberculosis." Global Health Council. <http://www.globalhealth.org>. Issue 2, 2002.
3. You may look for other articles on this topic in the Internet



Debate on the issue:

To DOTS or not to DOTS, that is the question.

COMPONENTS OF DOTS

DOTS is a comprehensive strategy that includes, among others, DOT. For the DOTS strategy to work, the following components must be present:

- Political (government and other stakeholder) commitment to sustained TB control activities
- Case detection by sputum smear microscopy among symptomatic patients self-reporting to health services
- Standardized treatment regimen of six to eight months for at least all confirmed sputum smear positive cases, with directly observed treatment (DOT) for at least the initial two months
- A regular, uninterrupted supply of all essential anti-TB drugs
- A standardized recording and reporting system that allows assessment of treatment results for each patient and of the TB control program

POLITICAL COMMITMENT TO SUSTAINED TB CONTROL ACTIVITIES

This is necessary for the implementation and maintenance of the other four components. This necessitates recognition by the government of the degree of the problem and the decision to make its control a priority.

In 1978, the Department of Health (DOH) implemented a nationwide TB Control Program (NTP) and this remains a priority public health program. Cumulative enrichments that included, among others, stronger mechanisms of adherence like DOTS, higher financial and logistical support by the government and international agencies, and integration with structural changes brought about by the recent health reform agenda, strengthened the NTP. Its mission is “to ensure that TB diagnostic, treatment and information services are available and accessible to the communities in collaboration with the local government units (LGUs) and other partners.”

The program is targeting a cure of at least 85% of the sputum smear-positive TB patients and detecting at least 70% of the estimated new sputum smear-positive TB cases. In countries that have achieved these targets, the prevalence of TB progressively declined.

Exactly what does political commitment entail? For the government, it means making available the resources needed to support the NTP. The national budget should have a regular allocation of funds for the NTP thereby ensuring adequate and well-motivated personnel, free microscopy services and free drugs for all. Total budget allocated for this is US \$109M, for 2002 alone, it is US \$21M. This may seem substantial but still, there is a budget gap of US \$25M.

Partnership with international aid agencies and other international NGOs for financial and technical assistance is being sought to make up for the deficiency. Collaboration with local groups is pursued to ensure broad support from within

the country. Misunderstanding with other key players in TB like the private MDs, the MD specialty societies and the academe can only adversely affect the NTP's implementation .

Within the government health service, political commitment means carrying out a national program which will work in the devolved administrative set up. Centrally, the DOH formulates plans and policies, oversees program implementation, provides logistics (such as drugs, laboratory supplies, educational materials), and collates and analyzes reports and recommendations of the LGUs. The LGUs in turn formulate local plans and policies and implement them accordingly. Provincial or city medical NTP coordinators are designated and given their respective responsibilities. This way, the smooth implementation, monitoring and evaluation of activities are ensured.

With this political will, the DOTS strategy of the NTP expanded quickly from 17% population coverage in 1998 to over 97% in 2000 (WHO Report, 2002). In fact 45% of smear-positive cases have been included in the program. Treatment success in 2000 was 88% under DOTS.

CASE DETECTION BY SPUTUM SMEAR MICROSCOPY

I. Rationale for Using Sputum Smear to Detect TB

Sputum examination for AFB smear (direct microscopy) is the primary tool used to diagnose PTB implemented by the NTP. It is reliable, economical and readily available. It must be done prior to treatment. The only contraindication is massive hemoptysis.

The chest x-ray is not a suitable primary tool. It does not reliably indicate active disease, the infectiousness of the case, nor the point of cure. Most TB cases will have residual scars on chest x-rays even after bacteriologic cure. Furthermore, maintaining a high quality x-ray facility would entail high costs of re-supplying materials, buying and maintaining machines and retaining expert personnel...issues that will be very difficult to address on a nationwide scale.

II. Guidelines for collecting sputum

(Akhtar M et al., (2000). *Technical Guide: Sputum Examination for Tuberculosis by Direct Microscopy in Low Income Countries.*)



Remember! Your risk of being infected is high when the TB suspect coughs. Hence, the sputum specimen should be collected carefully following the recommended guidelines.

A. During sputum collection:

1. The patient should fully understand the importance of the sputum smear microscopy in diagnosing TB. Therefore, take time to get his permission for the procedure, clearly explain the rationale and conduct of the procedure and explain the results.
2. Whenever possible, sputum collection should be done in open air. If this is not feasible, it should be collected in an empty, well-ventilated room. Make sure that no one is standing in front of the patient when he collects his sputum.
3. Ask the patient to rinse his mouth with water before producing sputum.
4. Give him a sputum container, which has the proper label on the side of the container and not on the lid.
5. Demonstrate to the patient how to cough up sputum. Ask him to breathe deeply three times, bring the container close to the mouth and cough deeply into it. This is called the “SPOT” specimen.
6. Make sure that what the patient has coughed up is not only saliva but 3 – 5 mL of sputum. Otherwise, he should repeat coughing until he produces enough sputum. The specimen may be termed “salivary” which is mainly saliva, “purulent” when it looks like pus, and “muco-purulent” when there yellowish particles in the mucus, or “bloody” when it contains blood. It is important to note the presence of blood as this may interfere with the smear reading.
7. When the outside of a container is contaminated with sputum, the patient should wipe the container clean and discard properly whatever is used to clean the container.

B. After sputum collection:

1. Place the lid on the container and firmly close it.
2. If the container will be brought to the laboratory immediately, put it inside a special box for transport.
3. If the container will not be sent immediately to the laboratory, keep it in a cool place away from sunlight and heat. Refrigerate it if possible.
4. Wash your hands after handling specimen.
5. A new container should be given to the patient and instructed to properly collect the second sputum specimen at home in the morning. This is the “MORNING” specimen. He should then return the specimen container to the health center as soon as possible.
6. When he does, a third specimen, another “SPOT” specimen, should be taken following the same procedure.

C. Transporting sputum specimens

1. The specimens should be examined not later than four days after collection. However sputum received four days after collection should still be examined since dead bacilli may still be appreciated on microscopy.
2. The specimens should be packed carefully for transport in a special box, with accompanying proper request for sputum examination form.

3. In far-flung areas where immediate examination of specimen is not possible, smearing and fixing before transporting the sputum should be done.
4. After specimens are taken from sputum containers, the container properly disposed.

III. Spotting the errors:



Read the case below.

MO, a BHW suspected Mimi of having PTB. She then filled out NTP Laboratory request form and proceeded to collecting sputum specimen from the patient. She led her into a closed room to avoid spreading the infection to other patients, stood by her side and told her to cough up sputum. After collection, MO immediately closed the sputum container, placed it in the box containing the other specimens inside the cupboard above the stove.

Mimi returned the next day, Wednesday, as instructed, and MO collected the second specimen. After collecting the specimen, it was placed in the box. All specimens were then sent to the laboratory on Friday morning. These were for examination the next Monday.



Enumerate the errors in the manner the sputum specimens of Mimi were collected.

The errors are the following:

1. Mimi should have rinsed her mouth with water before producing sputum.
2. The sputum should have been collected in open air or at least in an empty, well-ventilated room. (Ask the student why this is important.)
3. MO should have demonstrated the proper way to cough up sputum and should have asked the patient to inhale deeply and cough.
4. MO should have inspected the specimen to see if it is not just saliva but around 3 – 5 mL of sputum. If the specimen did not seem adequate, it should have been repeated until there was adequate sputum collected.
5. Three sputum specimens should have been collected. A spot sputum collection on the first day. Then the patient should have been instructed to collect the sputum at home. The third is another spot collection when the patient came back to submit the second specimen.

6. The specimen should have been placed in a cool place away from sunlight and not on top of the stove where the heat from the stove could destroy the bacteria. (Recall that sunlight could destroy the bacilli and physical integrity is important in identifying them during staining.)
7. Specimens should have been examined within four days from collection. The Tuesday and Wednesday specimens would be more than four days old come Monday, the day of sputum examination.

IV. Examination and Interpretation of Sputum Smears

Recall the steps in performing the sputum smear. Go back to the module on Transmission and Pathogenesis, if necessary.

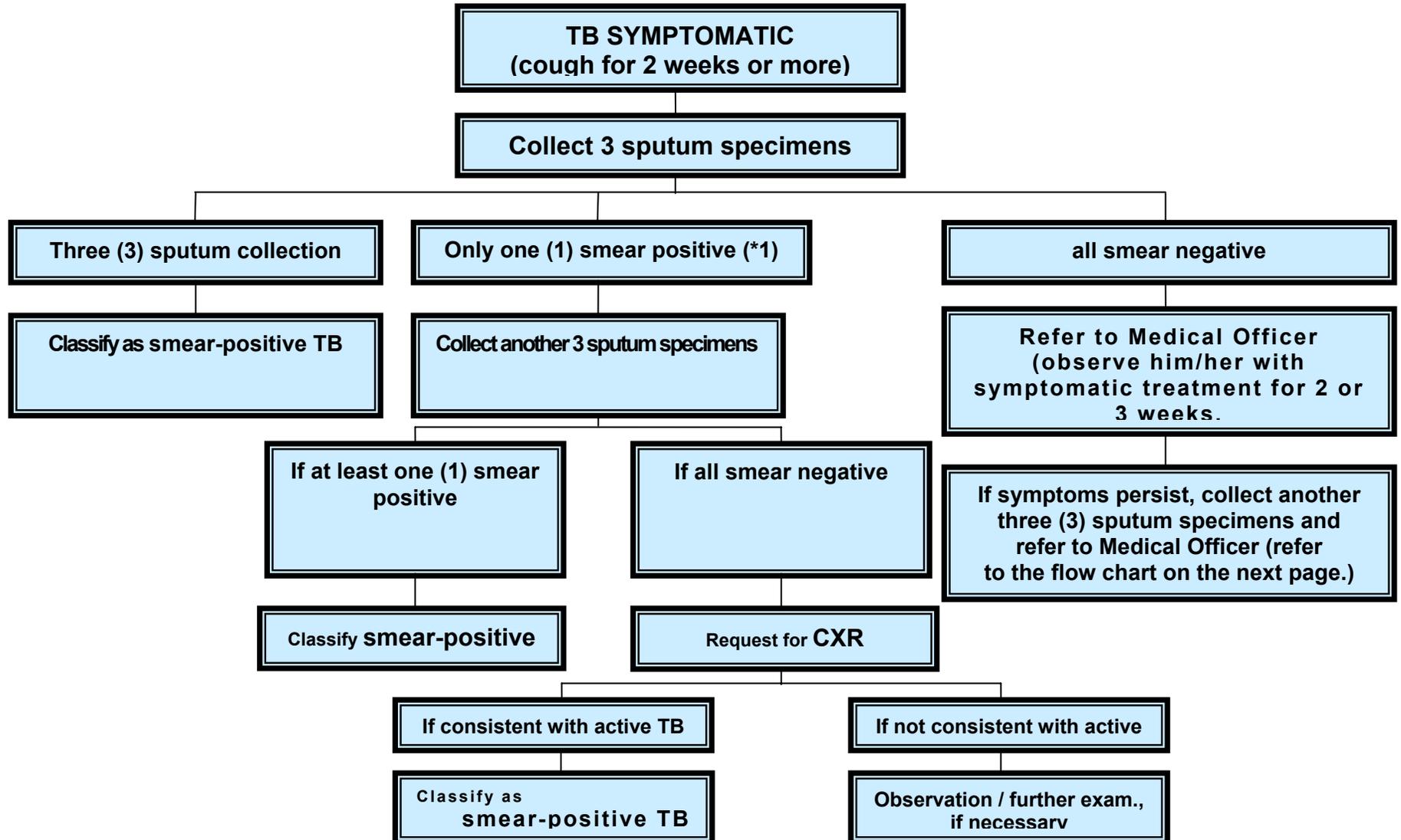


What is the significance of the proper interpretation of the number of AFB identified?

V. Establishing the Diagnosis

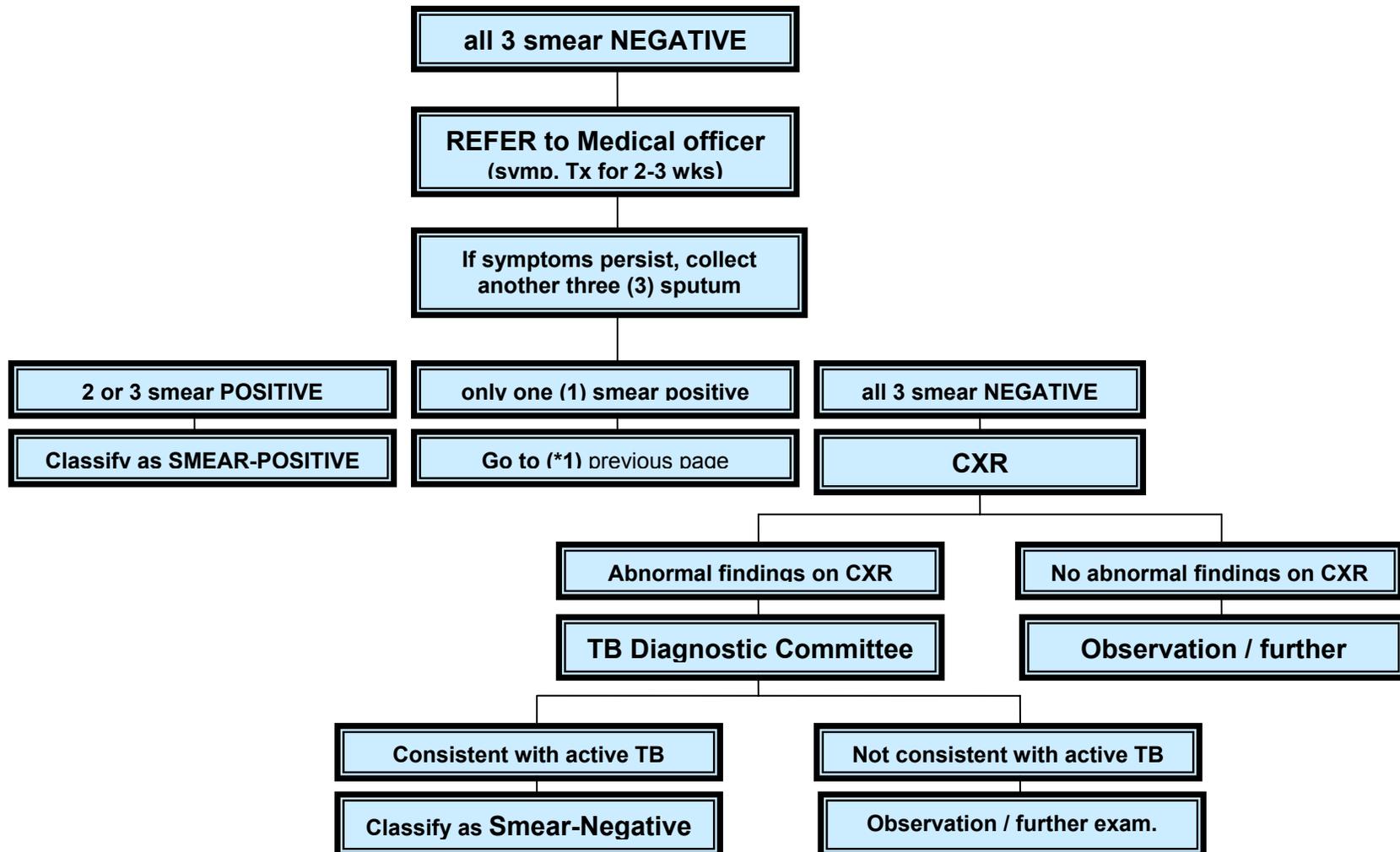
What is the next step after establishing the diagnosis of TB? The algorithms from the NTP Manual of Procedures are shown in the two pages that follow.

FLOW CHART FOR THE DIAGNOSIS OF PULMONARY TUBERCULOSIS



SAMPLE FLOW CHART FOR THE DIAGNOSIS OF SMEAR-NEGATIVE PULMONARY TUBERCULOSIS

This flow chart is a sample for making decision of MHO / CHO. Arrangement may be required in accordance with the patient condition as well as the available resources on TB control. The diagnostic committee is composed of 3 “learned” experts, usually the radiologist, the NTP officer and a local specialist.



VI. Classification and Categories of Patients

A. Classification: According to the 2001 Manual of Procedures, TB cases shall be classified based on the location of involved site and sputum smear result. Hence classification is –

1. Anatomical site of disease – pulmonary or extra-pulmonary. If a patient has both pulmonary and extra-pulmonary TB, classify him as pulmonary TB. A patient has extra-pulmonary TB if:
 1. There is at least one smear or culture positive for MTb from an extra-pulmonary site, OR
 2. There is 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.
2. Bacteriological results – sputum smear positive or negative.
 - a. Smear positive patients have
 1. At least two sputum specimens positive for AFB, OR
 2. One sputum specimen positive for AFB with radiographic abnormalities consistent with active TB, OR
 3. One sputum specimen positive for AFB with sputum culture positive for MTb.
 - b. Smear negative patients are those with three sputum specimens negative for AFB with
 1. Radiographic findings consistent with active PTB, AND
 2. With no response to antibiotics or symptomatic medications, AND,
 3. There is a decision by a medical officer to treat the patient with anti-TB drugs.

B. They shall be categorized based on the history of anti-TB treatment history.

Table 1: Categories of TB Patients

Types of TB Cases	Definition of Terms
New	A patient who has never had treatment for TB or who has taken anti-tuberculosis drugs for less than one month.
Relapse	A patient previously treated for tuberculosis who has been declared cured or treatment completed, and is diagnosed with bacteriologically positive (smear or culture) tuberculosis.
Failure	A patient who, while on treatment, is sputum smear positive at five months or later during the course of treatment.
Return after Default (RAD)	A patient who returns to treatment with positive bacteriology (smear or culture), following interruption of treatment for two months or more.
Transfer-In	A patient who has been transferred from another facility with proper referral slip to continue treatment.
Other	All cases that do not fit into any of the above definitions This group includes: <ol style="list-style-type: none"> 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 re-treatment regimen.

From: Department of Health. (2001). *Manual of Procedures for the National Tuberculosis Control Program*. Manila: DOH.

 EXERCISE 1:

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

Patients	Classification of Case		Category	Treatment regimen
	Anatomic site	Bacteriological results		
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.	P	Smear (+)	New	I
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.	P	Smear (-)	New	I
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+.	P	Smear (+)	Failure	II
4. Felisa Andaya, 55-year-old, female, consulted for fever and cough of three months duration. She self-medicated with Paracetamol and Guaiafenesin. Past history is remarkable for PTB, sputum (+), treated for six months and declared cured in 2001. You requested for sputum smear which revealed 2+, 2+, and 1+.	P	Smear (+)	Relapse	II

Patients	Classification of Case		Category	Treatment regimen
	Anatomic site	Bacteriological results		
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.	P	Smear (+)	Transfer in	I
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+.	P	Smear (+)	Return after default	II
7. Rino Romero, 22-year-old, male is a new smear negative PTB patient. On his second month of treatment, sputum smear was 2+.	P	Smear (+)	Others [#2]	II
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+.	P	Smear (+)	New	I
9. Pedro Abuel, 40-year-old, male, unemployed, was diagnosed to have sputum positive PTB.	P	Smear (+)	New	I
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.	P	Smear (-)	New	I

DIRECTLY OBSERVED TREATMENT (DOT)

Directly observed treatment means that the so-called **treatment partner** watches the patient swallow the tablets daily during treatment. Hence, we can be sure that the right drugs at the right doses and at the right intervals are taken.



Think about this. This strategy is obviously a labor-intensive one. Imagine meeting someone day in and day out for 180 days or so! And why? So you can look at him swallow his pills. Will you really be willing to be a treatment partner? If you start to scratch your head, just recall the burden that the deadliest communicable disease has wrought and the evidence of the effectiveness of the strategy. Besides, if he were your father, would you not want to make sure he gets well? Even if your feelings are not that strong but the patient is part of the household, still DOTS will ensure that you or the others in the family will not be continually exposed since he will become non-infectious when he completes treatment!

Who will undergo DOT? All smear positive TB cases should undergo DOT. Who will be the treatment partner? A member of the health center or clinic staff, a member of the community (e.g., BHW, local government official or former TB patients), and as last priority, a family member can take on this role. This can be done in a place that is accessible and convenient to both, such as health facility, treatment partner's house, patient's place of work or house.

Relying on family members to do the DOT brings in the question of their effectiveness. Among Filipinos, the close family ties, however, may prove to be the enabling factor for this manner of supervision to work. Unlike the practice in western countries, a family member almost always accompanies the patient for medical consultation. This bond is stronger than the stigma that TB carries (Mark Nichter). Family members continue to provide personal care to their patients despite the diagnosis of TB, even resistant TB! Still to ensure that DOT by a family member works, a system of identification, recruitment, education and skill building, accountability, follow-up and formative evaluation has to be in place.



Recall the various treatment regimens discussed in the Module 4 on Treatment of TB, page 3.



EXERCISE 2:

Now go back to the ten patients in Exercise I and the last column in the table that you were asked to ignore. Go back to that column. Label this as “Treatment regimen” and fill up the cells with the appropriate therapy for each patient.

REGULAR, UNINTERRUPTED SUPPLY OF ALL ESSENTIAL ANTI-TB DRUGS

Ensuring steady supply of drug stocks at all levels is important if we are to achieve the national target for cure and eventually, control of TB in the country. What is the use of actually observing the patient take his medications if there is no free supply of medications and the patient cannot buy his own?

The government allots adequate resources for this. What is essential too is the accurate and correct information that will help in planning and maintaining the supply of necessary drugs. These data include the number of cases per treatment category, the drugs used and the existing drugs.

This gives rise to the next component.

STANDARDIZED RECORDING AND REPORTING SYSTEM

I. Recording and reporting

The recording and reporting system is used to evaluate both the patient’s progress and treatment outcome. Data from the NTP system will be the basis for evaluating the program’s overall performance, identifying problems and in implementing solutions. The importance of this recording system cannot be over emphasized!

This consists of:

- Laboratory register – containing log of all patients with sputum smear tests done
 - Serial number
 - Results of sputum examinations
- Patient treatment cards – detailing the regular intake of drugs and follow up sputum examinations. A sample is shown on page 16.
 - Basic information about the patient
 - Diagnosis (as to location and bacteriological classification)
 - Drug administration
- TB register – containing list of patients being treated and their progress. This is shown on page 17 and 20.

EXERCISE 3:

Return to the ten patients.

1. Fill up the NTP Treatment card for Mr. Angel Bali. The form is in the next page. What additional data do you need ask so that you can complete the form?
2. Now please fill up the first part of the NTP register form attached after the NTP card with data available in Exercise 1 and 2 for all ten patients. You will learn how to fill up the second part of the NTP register form (progress of the patient) later.

TB REGISTER

Month / Year: _____

DATE OF REGIS-TRATION	TB CASE NUMBER	NAME	AGE	SEX	ADDRESS	HEALTH FACILITY (BHS/RHU)	CLASS OF TB DIAG. (P/EP)	TYPE OF PATIENT						CATEGORY OF TREATMENT	
								New	Relapse	Trans In	Return After Default	Failure	Others		
		1. Angel Bali	40	M			P	/							Cat I
		2. Carla Xavier	26	F			P	/							Cat I
		3. Andres Floro	34	M			P					/			Cat II
		4. Felisa Andaya	55	F			P		/						Cat II
		5. Ramona Reyes	42	F			P			/					Cat I
		6. Ignacio Lorenzo	56	M			P				/				Cat II
		7. Rino Romero	22	M			P						/		Cat II
		8. Jose Reyes	42	M			P	/							Cat I
		9. Pedro Abuel	40	M			P	/							Cat I
		10. Mercy Pastor	33	F			P	/							Cat I

FOLLOW UP SMEAR EXAMINATION OF SPUTUM

So far, the diagnosis of patients using sputum smear has been discussed. You can also correctly register them. The next thing is to know when to repeat sputum smear examination of our patients.

The table below summarizes the schedule for this based on the category to which the patient belongs as recommended by the NTP.

Table 3: Schedule of sputum smear examination follow up

Months of Treatment completed	Patient Treatment Category				
	I (2HRZE/4HR)		II (2HRZES/1HRZE/5HRE)		III (2HRZ/4HR)
2	/				/
	(-)	(+)			
3			/		
			(-)	(+)	
4	/			/	
5		/	/		
6	/*			/	
7		/*			
8			/*		
9				/*	

* Examined in the beginning of the month

 Notice then that generally, the patient's sputum is examined at the end of the intensive phase, regularly around every two months during the maintenance phase and at the beginning of the last month of treatment.

EXERCISE 4:

Because of your persistence, our ten patients had follow up sputum examinations. The results reflected in the second part of the TB register shown on the next page. Classify the patients according to the outcome of their therapy by ticking the appropriate box under the column "Treatment Outcome."

TB Register (continuation)

NAME OF RHU: _____

DATE START TX	SPUTUM EXAMINATION RESULTS							TREATMENT OUTCOME					Type of treatment partner	REMARKS	
	(Upper Space: Date of Exam)				(Lower Space: Result)			(Write exact date of last intake of drugs)							
	BEFORE TX	2 nd month	3 rd month	4 th month	5 th month	6 th month	≥ 7 th month	Cured	Treatment completed	Died	Treatment Failure	Default	Trans. Out		
1.	2+	Neg		Neg		Neg		/							
2.	Neg	Neg				Neg			/						
3.	2+										/				
4.	2+	Neg		Neg		Neg		/							
5.	1+	Neg		Neg		Neg		/							
6.	2+	Neg		Neg		Neg		/							
7.	2+			Neg					/						
8.	3+	Neg		Neg		Neg		/							
9.	2+	Neg										/			Went to Palawan
10.	Neg	Neg		Neg		2+						/			

II. Cohort analysis

Cohort analysis is simply a tool to determine the effectiveness of TB control in an area. This means reporting certain parameters or indicators of treatment progress or success. A cohort consists of TB patients registered during a certain period of time.

This is reported as:

- Smear conversion report quarterly
- Treatment success rates (meaning those who get cured and those who completed treatment) quarterly and annually

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
- $$= \frac{\text{No. of new sm (+) who is positive at 5th at least one on occasion or more}}{\text{Total No. of new smear (+) cases admitted to treatment}} \times 100\%$$
- e. Default
- $$= \frac{\text{No. of new sm (+) who interrupted treatment for } \geq 2 \text{ months}}{\text{Total No. of new smear (+) cases admitted to treatment}} \times 100\%$$

f. Trans-out

$$= \frac{\text{No. of new sm (+) who were transferred to another facility with proper referral form}}{\text{Total No. of new smear (+) cases admitted to treatment}} \times 100\%$$

EXERCISE 4

Go back to the data from our ten patients one last time! Compute for the different rates by applying the above formulae.



How do the figures you have obtained compare with the national target? If cure rates were not reached, what are the possible reasons for this? Propose ways to investigate why.

Possible areas to investigate:

- Review the manner in which treatment is being administered
- Ask patients to determine if they are properly informed of the nature of their illness, the consequences of the disease and the treatment regimen.
- Review the register for errors



What are the five components of DOTS?

Knowing these, compare DOTS with non-DOTS strategies. Do so by filling up the table below and discuss each item.

Table 4: Comparison between DOTS and Non-DOTS

ASPECTS	Non-DOTS	DOTS
TECHNICAL ASPECTS		
Case finding and diagnosis	Depends on unreliable, often expensive methods: <ul style="list-style-type: none"> • X-ray • Symptomatic-based diagnosis 	Depends on simple, cost-effective and reliable method: <ul style="list-style-type: none"> • 3 sputum examinations for all infectious cases • Limited use of x-ray for specific cases • Tightly defined symptomatic diagnosis
Patient classification / categorization	<ul style="list-style-type: none"> • Often weak. As a result, the type, degree of infectiousness and treatment category are not well determined 	Strong, ensuring the following are determined <ul style="list-style-type: none"> • Anatomic site • Bacteriological result • Treatment category
Treatment	<ul style="list-style-type: none"> • Individualized, often inappropriate or inadequate regimens for each patient • No DOT • Little patient counseling • Often centralized, specialized TB services to which patients have limited access • No structure – no flexibility or adherence to specific patient needs 	<ul style="list-style-type: none"> • Standardized proven regimens for each case type • DOT by a suitable trained person • Patient counseling • Drugs may be taken daily or three times a week • Flexibility - Treatment can be administered at health facility, patient's home, or community center
Progress toward cure	<ul style="list-style-type: none"> • Information by individual sometimes available but often not analyzed • Information by cohort almost never available 	<ul style="list-style-type: none"> • Information recorded by individual • Aggregate data by cohort always available
Treatment follow-up	<ul style="list-style-type: none"> • Either not done at all or is unsystematic 	<ul style="list-style-type: none"> • Systematic • Based on sputum smear

ASPECTS	Non-DOTS	DOTS
	<ul style="list-style-type: none"> • Findings not acted upon • Often x-ray based • Main indicator is patient adherence • Often no record of patients' whereabouts 	microscopy <ul style="list-style-type: none"> • Findings acted upon to achieve cure • Main indicator is patient outcome • Location of patient is kept in the register
Results	<ul style="list-style-type: none"> • Low treatment success • Unreliable outcome information • Increasing drug resistance 	<ul style="list-style-type: none"> • High sputum smear conversion rate • High cure rates • Decreased prevalence of chronic cases • Decreased transmission of infection • Prevention of drug resistance
LOGISTICAL ASPECTS		
Drug supply	<ul style="list-style-type: none"> • Often irregular • Often quality of drugs questionable 	<ul style="list-style-type: none"> • Regular, reliable supply • Can forecast supply for following year • Better quality assurance of drugs
Laboratory	<ul style="list-style-type: none"> • Accuracy of results or adherence to safety guidelines not ensured • Lab registers often not standardized 	<ul style="list-style-type: none"> • Guidelines ensure systematic, standardized practices • Quality control, safety
TB register	<ul style="list-style-type: none"> • May exist at national or provincial level consisting of: <ul style="list-style-type: none"> ○ Variable patient information ○ Unsystematic recording of information on type of case, progress and results 	<ul style="list-style-type: none"> • Always exists, which permits systematic analysis consisting of: <ul style="list-style-type: none"> ○ Patients starting treatment ○ Progress toward cure ○ Methodical monitoring
POLITICAL ASPECTS		
Political commitment	<ul style="list-style-type: none"> • Often not addressed • Communication activities focused mainly on patients, ignoring the policy-makers 	<ul style="list-style-type: none"> • Policy of financial support • Advocacy and social mobilization

From: Communicable Diseases Cluster Prevention and Control World Health Organization. (1999). *What is DOTS? A guide to understanding the WHO-recommended TB control strategy known as DOTS.* Geneva: WHO.

References:

Communicable Diseases Cluster Prevention and Control World Health Organization. (1999). *What is DOTS? A guide to understanding the WHO-recommended TB control strategy known as DOTS*. Geneva: WHO.

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“Lack of evidence that Directly Observed Therapy (DOT) improves cure or treatment completion rates in patients with tuberculosis.” Global Health Council. <http://www.globalhealth.org>. Issue 2, 2002.

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MODULE 5. DIRECTLY OBSERVED TREATMENT, SHORT-COURSE (DOTS) STRATEGY (FOR STUDENTS)

General Objectives: At the end of this module, students can PRESCRIBE DOTS IN ALL INVOLVEMENTS AND ACTIVITIES RELATED TO TB

Specific Objectives:

1. Explain the five components of DOTS strategy
2. Prefer DOTS to other approaches in TB control in terms of case finding and diagnosis, treatment and follow up and organizational set up
3. Demonstrate competence in specimen collection, staining, and interpretation of AFB smear examination on assigned patients
4. Distinguish anti-TB drugs in terms of their respective pharmacological characteristics, mechanisms of action, dosage, and adverse effects
5. Prescribe the appropriate anti-TB chemotherapy in keeping with the National TB Program policy and according to the treatment category of patients and special indications
6. Adhere to standardized treatment regimen for all TB patients
7. Coach TB patients and their families on the nature of the disease and how it can be treated
8. Monitor progress of treatment by coordinating with the appropriate members of the health team or health care unit where patient is located.
9. Refer patients to appropriate health care units for proper administration of DOTS
10. Maintain an accurate recording system of DOTS patients for evaluation of treatment outcome and program performance
11. Engage in sustainable activities and initiatives to promote TB control in the community

Content:**INTRODUCTION**

Tuberculosis (TB) has been presented as a biomedical and social phenomenon. This infection progresses into a potentially fatal disease. The clinical presentation of patients with this disease, diagnosis and treatment have been discussed. A lot of things are known about TB. In fact, it has been a century since MTb was discovered. For more than half a century, all the known drugs to kill this bacterium have been available for use. What is truly disturbing is the fact that despite all these, TB continues to plague the world. It still kills more people than any other communicable disease globally.

How do we control the epidemic that is TB? A patient with TB infects 10–15 persons annually. Hence, the most effective approach to control the disease is to cure the source of infection so that he can no longer infect other persons. Cure then is so to speak the best prevention.

The most effective strategy pushed by the World Health Organization (WHO) to control TB is the directly observed treatment, short course or DOTS.

 With WHO support, many countries have fully adopted DOTS to control TB. In these countries, DOTS led to higher active TB detection rates and doubling of the cure rates. On the other hand, a few studies appeared in the literature claiming that there is no convincing evidence to prove that direct observation of therapy (DOT) improves cure. Read the following articles:

1. Communicable Diseases Cluster Prevention and Control World Health Organization. (1999). *What is DOTS? A guide to understanding the WHO-recommended TB control strategy known as DOTS*. Geneva: WHO. Chapters 1-3.
2. "Lack of evidence that Directly Observed Therapy (DOT) improves cure or treatment completion rates in patients with tuberculosis." Global Health Council. <http://www.globalhealth.org>. Issue 2, 2002.
3. You may look for other articles on this topic in the Internet.



Debate on the issue:
To DOTS or not to DOTS, that is the question.

COMPONENTS OF DOTS

DOTS is a comprehensive strategy that includes, among others, DOT. For the DOTS strategy to work, the following components must be present:

- Political (government and other stakeholder) commitment to sustained TB control activities
- Case detection by sputum smear microscopy among symptomatic patients self-reporting to health services
- Standardized treatment regimen of six to eight months for at least all confirmed sputum smear positive cases, with directly observed treatment (DOT) for at least the initial two months
- A regular, uninterrupted supply of all essential anti-TB drugs
- A standardized recording and reporting system that allows assessment of treatment results for each patient and of the TB control program

POLITICAL COMMITMENT TO SUSTAINED TB CONTROL ACTIVITIES

This is necessary for the implementation and maintenance of the other four components. This necessitates recognition by the government of the degree of the problem and the decision to make its control a priority.

In 1978, the Department of Health (DOH) implemented a nationwide TB Control Program (NTP) and this remains a priority public health program. Cumulative enrichments that included, among others, stronger mechanisms of adherence like DOTS, higher financial and logistical support by the government and international agencies, and integration with structural changes brought about by the recent health reform agenda, strengthened the NTP. Its mission is “to ensure that TB diagnostic, treatment and information services are available and accessible to the communities in collaboration with the local government units (LGUs) and other partners.”

The program is targeting a cure of at least 85% of the sputum smear-positive TB patients and detecting at least 70% of the estimated new sputum smear-positive TB cases. In countries that have achieved these targets, the prevalence of TB progressively declined.

Exactly what does political commitment entail? For the government, it means making available the resources needed to support the NTP. The national budget should have a regular allocation of funds for the NTP thereby ensuring adequate and well-motivated personnel, free microscopy services and free drugs for all. Total budget allocated for this is US \$109M, for 2002 alone, it is US \$21M. This may seem substantial but still, there is a budget gap of US \$25M.

Partnership with international aid agencies and other international NGOs for financial and technical assistance is being sought to make up for the deficiency. Collaboration with local groups is pursued to ensure broad support from within the country. Misunderstanding with other key players in TB like the private MDs, the MD specialty societies and the academe can only adversely affect the NTP's implementation .

Within the government health service, political commitment means carrying out a national program which will work in the devolved administrative set up. Centrally, the DOH formulates plans and policies, oversees program implementation, provides logistics (such as drugs, laboratory supplies, educational materials), and collates and analyzes reports and recommendations of the LGUs. The LGUs in turn formulate local plans and policies and implement them accordingly. Provincial or city medical NTP coordinators are designated and given their respective responsibilities. This way, the smooth implementation, monitoring and evaluation of activities are ensured.

With this political will, the DOTS strategy of the NTP expanded quickly from 17% population coverage in 1998 to over 97% in 2000 (WHO Report, 2002). In fact 45% of smear-positive cases have been included in the program. Treatment success in 2000 was 88% under DOTS.

CASE DETECTION BY SPUTUM SMEAR MICROSCOPY

I. Rationale for Using Sputum Smear to Detect TB

Sputum examination for AFB smear (direct microscopy) is the primary tool used to diagnose PTB implemented by the NTP. It is reliable, economical and readily available. It must be done prior to treatment. The only contraindication is massive hemoptysis.

The chest x-ray is not a suitable primary tool. It does not reliably indicate active disease, the infectiousness of the case, nor the point of cure. Most TB cases will have residual scars on chest x-rays even after bacteriologic cure. Furthermore, maintaining a high quality x-ray facility would entail high costs of re-supplying materials, buying and maintaining machines and retaining expert personnel...issues that will be very difficult to address on a nationwide scale.

II. Guidelines for collecting sputum

(Akhtar M et al., (2000). *Technical Guide: Sputum Examination for Tuberculosis by Direct Microscopy in Low Income Countries.*)



Remember! Your risk of being infected is high when the TB suspect coughs. Hence, the sputum specimen should be collected carefully following the recommended guidelines.

A. During sputum collection:

8. The patient should fully understand the importance of the sputum smear microscopy in diagnosing TB. Therefore, take time to get his permission for the procedure, clearly explain the rationale and conduct of the procedure and explain the results.
9. Whenever possible, sputum collection should be done in open air. If this is not feasible, it should be collected in an empty, well-ventilated room. Make sure that no one is standing in front of the patient when he collects his sputum.
10. Ask the patient to rinse his mouth with water before producing sputum.
11. Give him a sputum container, which has the proper label on the side of the container and not on the lid.
12. Demonstrate to the patient how to cough up sputum. Ask him to breathe deeply three times, bring the container close to the mouth and cough deeply into it. This is called the “SPOT” specimen.
13. Make sure that what the patient has coughed up is not only saliva but 3 – 5 mL of sputum. Otherwise, he should repeat coughing until he produces enough sputum. The specimen may be termed “salivary” which is mainly saliva, “purulent” when it looks like pus, and “muco-purulent” when there yellowish particles in the mucus, or “bloody” when it contains blood. It is important to note the presence of blood as this may interfere with the smear reading.
14. When the outside of a container is contaminated with sputum, the patient should wipe the container clean and discard properly whatever is used to clean the container.

B. After sputum collection:

7. Place the lid on the container and firmly close it.
8. If the container will be brought to the laboratory immediately, put it inside a special box for transport.
9. If the container will not be sent immediately to the laboratory, keep it in a cool place away from sunlight and heat. Refrigerate it if possible.
10. Wash your hands after handling specimen.
11. A new container should be given to the patient and instructed to properly collect the second sputum specimen at home in the morning. This is the “MORNING” specimen. He should then return the specimen container to the health center as soon as possible.
12. When he does, a third specimen, another “SPOT” specimen, should be taken following the same procedure.

C. Transporting sputum specimens

5. The specimens should be examined not later than four days after collection. However sputum received four days after collection should still be examined since dead bacilli may still be appreciated on microscopy.

6. The specimens should be packed carefully for transport in a special box, with accompanying proper request for sputum examination form.
7. In far-flung areas where immediate examination of specimen is not possible, smearing and fixing before transporting the sputum should be done.
8. After specimens are taken from sputum containers, the container properly disposed.

III. Spotting the errors:



Read the case below.

MO, a BHW suspected Mimi of having PTB. She then filled out NTP Laboratory request form and proceeded to collecting sputum specimen from the patient. She led her into a closed room to avoid spreading the infection to other patients, stood by her side and told her to cough up sputum. After collection, MO immediately closed the sputum container, placed it in the box containing the other specimens inside the cupboard above the stove.

Mimi returned the next day, Wednesday, as instructed, and MO collected the second specimen. After collecting the specimen, it was placed in the box. All specimens were then sent to the laboratory on Friday morning. These were for examination the next Monday.



Enumerate the errors in the manner the sputum specimens of Mimi were collected.

IV. Examination and Interpretation of Sputum Smears

Recall the steps in performing the sputum smear. Go back to the module on Transmission and Pathogenesis, if necessary.

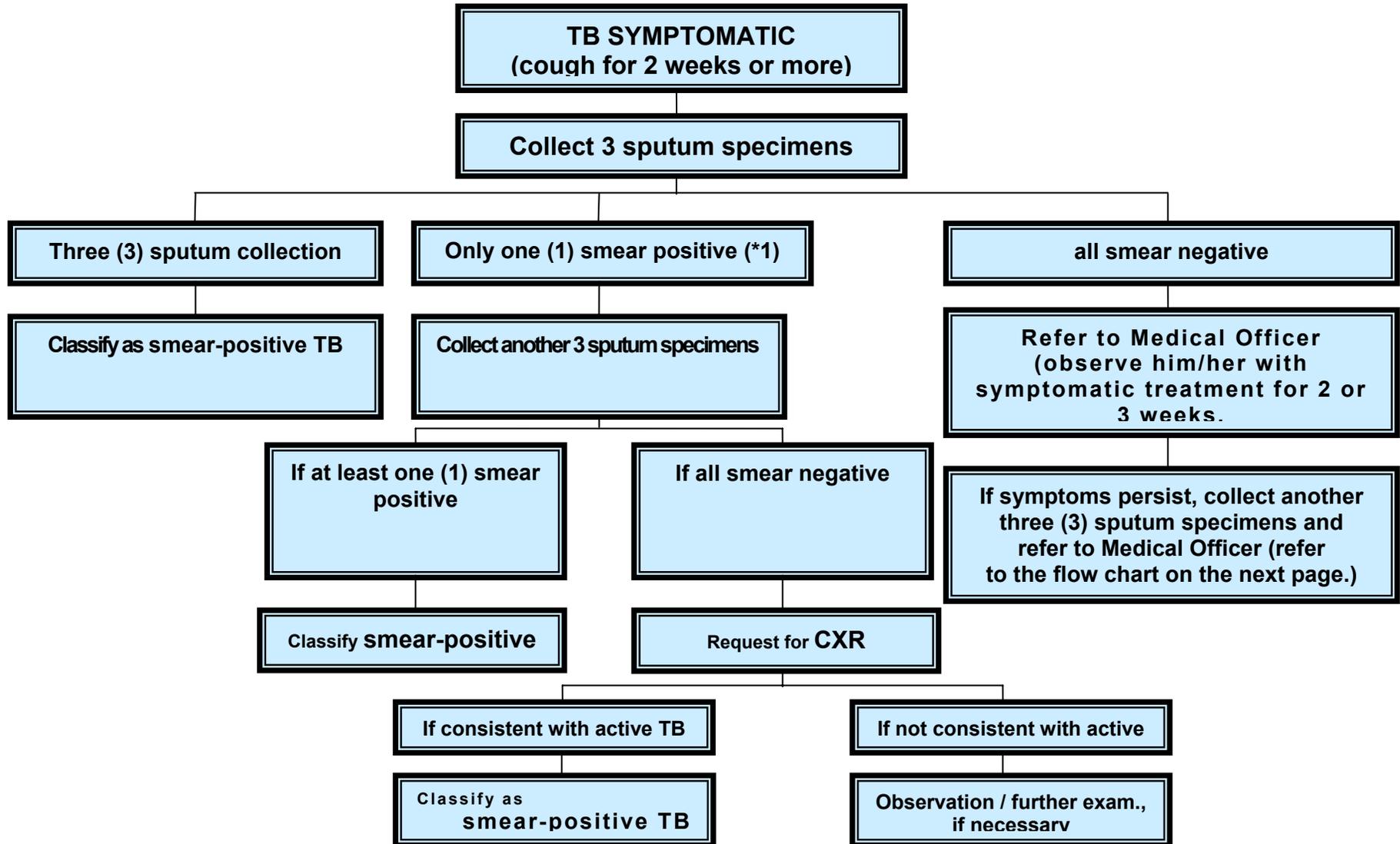


What is the significance of the proper interpretation of the number of AFB identified?

V. Establishing the Diagnosis

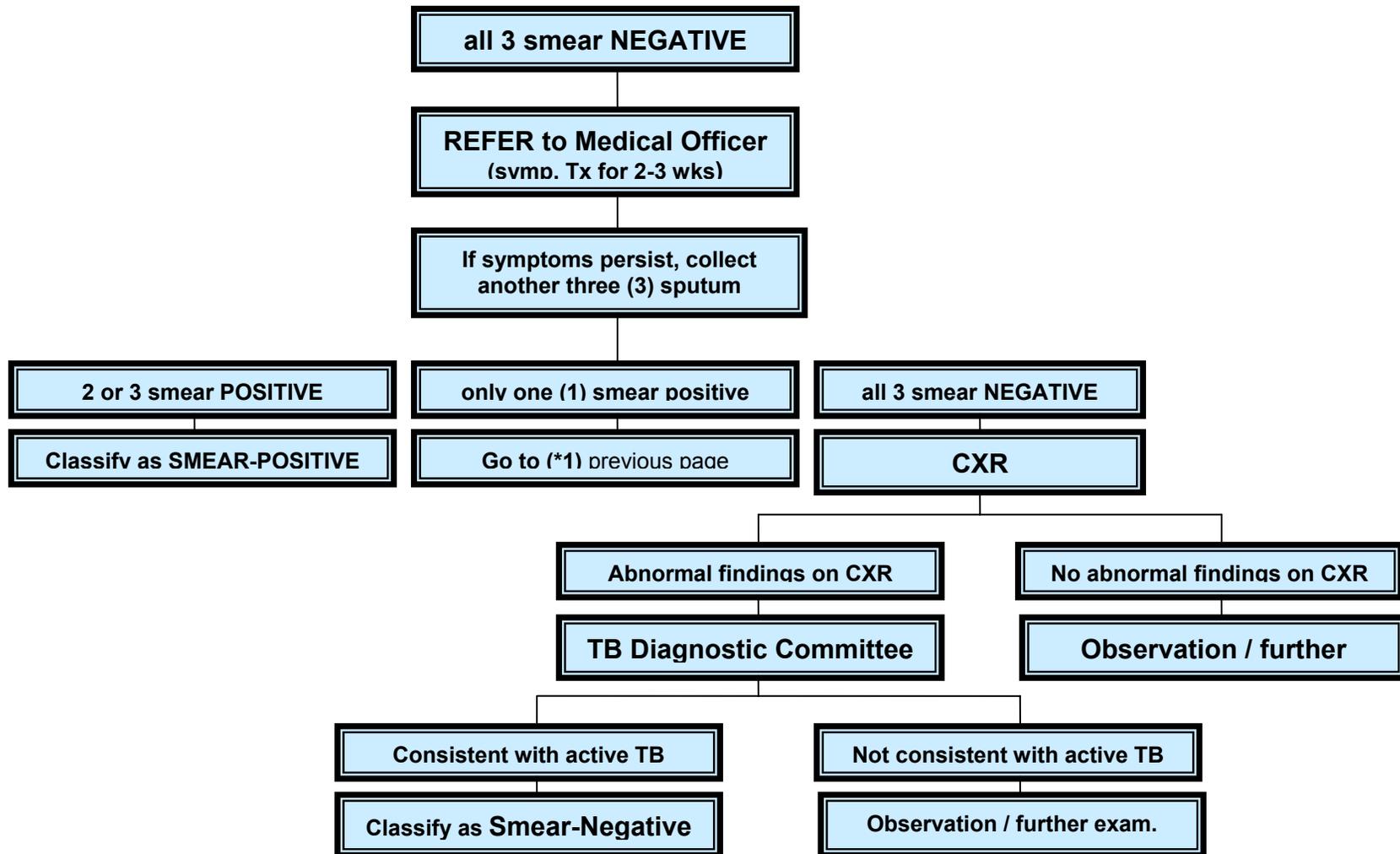
What is the next step after establishing the diagnosis of TB? The algorithms from the NTP Manual of Procedures are shown in the two pages that follow.

FLOW CHART FOR THE DIAGNOSIS OF PULMONARY TUBERCULOSIS



SAMPLE FLOW CHART FOR THE DIAGNOSIS OF SMEAR-NEGATIVE PULMONARY TUBERCULOSIS

This flow chart is a sample for making decision of MHO / CHO. Arrangement may be required in accordance with the patient condition as well as the available resources on TB control. The diagnostic committee is composed of 3 “learned” experts, usually the radiologist, the NTP officer and a local specialist.



VI. Classification and Categories of Patients

A. Classification: According to the 2001 Manual of Procedures, TB cases shall be classified based on the location of involved site and sputum smear result. Hence classification is –

3. Anatomical site of disease – pulmonary or extra-pulmonary. If a patient has both pulmonary and extra-pulmonary TB, classify him as pulmonary TB. A patient has extra-pulmonary TB if:
 1. There is at least one smear or culture positive for MTb from an extra-pulmonary site, OR
 2. There is 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.
4. Bacteriological results – sputum smear positive or negative.
 - a. Smear positive patients have
 1. At least two sputum specimens positive for AFB, OR
 2. One sputum specimen positive for AFB with radiographic abnormalities consistent with active TB, OR
 3. One sputum specimen positive for AFB with sputum culture positive for MTb.
 - b. Smear negative patients are those with three sputum specimens negative for AFB with
 1. Radiographic findings consistent with active PTB, AND
 2. With no response to antibiotics or symptomatic medications, AND,
 3. There is a decision by a medical officer to treat the patient with anti-TB drugs.

B. They shall be categorized based on the history of anti-TB treatment history.

Table 1: Categories of TB Patients

Types of TB Cases	Definition of Terms
New	A patient who has never had treatment for TB or who has taken anti-tuberculosis drugs for less than one month.
Relapse	A patient previously treated for tuberculosis who has been declared cured or treatment completed, and is diagnosed with bacteriologically positive (smear or culture) tuberculosis.
Failure	A patient who, while on treatment, is sputum smear positive at five months or later during the course of treatment.
Return after Default (RAD)	A patient who returns to treatment with positive bacteriology (smear or culture), following interruption of treatment for two months or more.
Transfer-In	A patient who has been transferred from another facility with proper referral slip to continue treatment.
Other	All cases that do not fit into any of the above definitions This group includes: <ol style="list-style-type: none"> 4. A patient who is starting treatment again after interrupting treatment for more than two months and has remained or became smear-negative. 5. A sputum smear negative patient initially before starting treatment and became sputum smear-positive during the treatment. 6. Chronic case: a patient who is sputum positive at the end of a re-treatment regimen.

From: Department of Health. (2001). *Manual of Procedures for the National Tuberculosis Control Program*. Manila: DOH.

 EXERCISE 1:

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

Patients	Classification of Case		Category	
	Anatomic site	Bacteriological results		
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.				
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.				
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+.				
4. Felisa Andaya, 55-year-old, female, consulted for fever and cough of three months duration. She self-medicated with Paracetamol and Guaiafenesin. Past history is remarkable for PTB, sputum (+), treated for six months and declared cured in 2001. You requested for sputum smear which revealed 2+, 2+, and 1+.				

Patients	Classification of Case		Category	
	Anatomic site	Bacteriological results		
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.				
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+.				
7. Rino Romero, 22-year-old, male is a new smear negative PTB patient. On his second month of treatment, sputum smear was 2+.				
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+.				
9. Pedro Abuel, 40-year-old, male, unemployed, was diagnosed to have sputum positive PTB.				
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.				

DIRECTLY OBSERVED TREATMENT (DOT)

Directly observed treatment means that the so-called **treatment partner** watches the patient swallow the tablets daily during treatment. Hence, we can be sure that the right drugs at the right doses and at the right intervals are taken.



Think about this. This strategy is obviously a labor-intensive one. Imagine meeting someone day in and day out for 180 days or so! And why? So you can look at him swallow his pills. Will you really be willing to be a treatment partner? If you start to scratch your head, just recall the burden that the deadliest communicable disease has wrought and the evidence of the effectiveness of the strategy. Besides, if he were your father, would you not want to make sure he gets well? Even if your feelings are not that strong but the patient is part of the household, still DOTS will ensure that you or the others in the family will not be continually exposed since he will become non-infectious when he completes treatment!

Who will undergo DOT? All smear positive TB cases should undergo DOT. Who will be the treatment partner? A member of the health center or clinic staff, a member of the community (e.g., BHW, local government official or former TB patients), and as last priority, a family member can take on this role. This can be done in a place that is accessible and convenient to both, such as health facility, treatment partner's house, patient's place of work or house.

Relying on family members to do the DOT brings in the question of their effectiveness. Among Filipinos, the close family ties, however, may prove to be the enabling factor for this manner of supervision to work. Unlike the practice in western countries, a family member almost always accompanies the patient for medical consultation. This bond is stronger than the stigma that TB carries (Mark Nichter). Family members continue to provide personal care to their patients despite the diagnosis of TB, even resistant TB! Still to ensure that DOT by a family member works, a system of identification, recruitment, education and skill building, accountability, follow-up and formative evaluation has to be in place.



Recall the various treatment regimens discussed in the Module 4 on Treatment of TB, page 3.



EXERCISE 2:

Now go back to the ten patients in Exercise I and the last column in the table that you were asked to ignore. Go back to that column. Label this as “Treatment regimen” and fill up the cells with the appropriate therapy for each patient.

REGULAR, UNINTERRUPTED SUPPLY OF ALL ESSENTIAL ANTI-TB DRUGS

Ensuring steady supply of drug stocks at all levels is important if we are to achieve the national target for cure and eventually, control of TB in the country. What is the use of actually observing the patient take his medications if there is no free supply of medications and the patient cannot buy his own?

The government allots adequate resources for this. What is essential too is the accurate and correct information that will help in planning and maintaining the supply of necessary drugs. These data include the number of cases per treatment category, the drugs used and the existing drugs.

This gives rise to the next component.

STANDARDIZED RECORDING AND REPORTING SYSTEM

I. Recording and reporting

The recording and reporting system is used to evaluate both the patient ‘s progress and treatment outcome. Data from the NTP system will be the basis for evaluating the program’s overall performance, identifying problems and in implementing solutions. The importance of this recording system cannot be over emphasized!

This consists of:

- Laboratory register – containing log of all patients with sputum smear tests done

- Serial number
- Results of sputum examinations
- Patient treatment cards – detailing the regular intake of drugs and follow up sputum examinations. A sample is shown on page 16.
 - Basic information about the patient
 - Diagnosis (as to location and bacteriological classification)
 - Drug administration
- TB register – containing list of patients being treated and their progress. This is shown on page 17 and 20.

**EXERCISE 3:**

Return to the ten patients.

3. Fill up the NTP Treatment card for Mr. Angel Bali. The form is in the next page. What additional data do you need ask so that you can complete the form?
4. Now please fill up the first part of the NTP register form attached after the NTP card with data available in Exercise 1 and 2 for all ten patients. You will learn how to fill up the second part of the NTP register form (progress of the patient) later.

TB REGISTER

Month / Year: _____

DATE OF REGIS-TRATION	TB CASE NUMBER	NAME	AGE	SEX	ADDRESS	HEALTH FACILITY (BHS/RHU)	CLASS OF TB DIAG. (P/EP)	TYPE OF PATIENT						CATEGORY OF TREATMENT
								New	Relapse	Trans In	Return After Default	Failure	Others	
		11.												
		12.												
		13.												
		14.												
		15.												
		16.												
		17.												
		18.												
		19.												
		20.												

FOLLOW UP SMEAR EXAMINATION OF SPUTUM

So far, the diagnosis of patients using sputum smear has been discussed. You can also correctly register them. The next thing is to know when to repeat sputum smear examination of our patients.

The table below summarizes the schedule for this based on the category to which the patient belongs as recommended by the NTP.

Table 3: Schedule of sputum smear examination follow up

Months of Treatment completed	Patient Treatment Category				
	I (2HRZE/4HR)		II (2HRZES/1HRZE/5HRE)		III (2HRZ/4HR)
2	/				/
	(-)	(+)			
3			/		
			(-)	(+)	
4	/			/	
5		/	/		
6	/*			/	
7		/*			
8			/*		
9				/*	

* Examined in the beginning of the month



Notice then that generally, the patient's sputum is examined at the end of the intensive phase, regularly around every two months during the maintenance phase and at the beginning of the last month of treatment.

EXERCISE 4:

Because of your persistence, our ten patients had follow up sputum examinations. The results reflected in the second part of the TB register shown on the next page. Classify the patients according to the outcome of their therapy by ticking the appropriate box under the column "Treatment Outcome."

TB Register (continuation)

NAME OF RHU: _____

DATE START TX	SPUTUM EXAMINATION RESULTS							TREATMENT OUTCOME					Type of treatment partner	REMARKS	
	BEFORE TX	2 nd month	3 rd month	4 th month	5 th month	6 th month	≥ 7 th month	(Write exact date of last intake of drugs)							
								Cured	Treatment completed	Died	Treatment Failure	Default	Trans. Out		
11.	2+	Neg		Neg		Neg									
12.	Neg	Neg				Neg									
13.	2+														
14.	2+	Neg		Neg		Neg									
15.	1+	Neg		Neg		Neg									
16.	2+	Neg		Neg		Neg									
17.	2+			Neg											
18.	3+	Neg		Neg		Neg									
19.	2+	Neg													Went to Palawan
20.	Neg	Neg		Neg		2+									

II. Cohort analysis

Cohort analysis is simply a tool to determine the effectiveness of TB control in an area. This means reporting certain parameters or indicators of treatment progress or success. A cohort consists of TB patients registered during a certain period of time.

This is reported as:

- Smear conversion report quarterly
- Treatment success rates (meaning those who get cured and those who completed treatment) quarterly and annually

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
- $$= \frac{\text{No. of new sm (+) who is positive at 5th at least one on occasion or more}}{\text{Total No. of new smear (+) cases admitted to treatment}} \times 100\%$$
- e. Default
- $$= \frac{\text{No. of new sm (+) who interrupted treatment for } \geq 2 \text{ months}}{\text{Total No. of new smear (+) cases admitted to treatment}} \times 100\%$$

f. Trans-out

$$= \frac{\text{No. of new sm (+) who were transferred to another facility with proper referral form}}{\text{Total No. of new smear (+) cases admitted to treatment}} \times 100\%$$

 **EXERCISE 4**

Go back to the data from our ten patients one last time! Compute for the different rates by applying the above formulae.

 How do the figures you have obtained compare with the national target? If cure rates were not reached, what are the possible reasons for this? Propose ways to investigate why.

 **What are the five components of DOTS?**
 Knowing these, compare DOTS with non-DOTS strategies. Do so by filling up the table below and discuss each item.

Table 4: Comparison between DOTS and Non-DOTS

ASPECTS	Non-DOTS	DOTS
TECHNICAL ASPECTS		
Case finding and diagnosis		
Patient classification / categorization		
Treatment		

ASPECTS	Non-DOTS	DOTS
Progress toward cure		
Treatment follow-up		
Results		
LOGISTICAL ASPECTS		
Drug supply		
Laboratory		
TB register		
POLITICAL ASPECTS		
Political commitment		

From: Communicable Diseases Cluster Prevention and Control World Health Organization. (1999). *What is DOTS? A guide to understanding the WHO-recommended TB control strategy known as DOTS*. Geneva: WHO.

References:

Communicable Diseases Cluster Prevention and Control World Health Organization. (1999). *What is DOTS? A guide to understanding the WHO-recommended TB control strategy known as DOTS*. Geneva: WHO.

Department of Health. (2001). *Manual of Procedures for the National Tuberculosis Control Program*. Manila: DOH.

“Lack of evidence that Directly Observed Therapy (DOT) improves cure or treatment completion rates in patients with tuberculosis.” Global Health Council. <http://www.globalhealth.org>. Issue 2, 2002.

Philippines Coalition Against Tuberculosis. *Manual for Tuberculosis Management in the Philippines*.

TB Control Service and Department of Health. (2001). *Revised National Tuberculosis Control and Prevention Program Training Modules*.

LEARNING UNIT ON TUBERCULOSIS CONTROL

Suggested year level:

1. 1st year - Epidemiology
2. 2nd year - Transmission, Pathogenesis, Natural History of Disease, Diagnosis and Management, DOTS
3. 3rd and 4th year - Diagnosis, Management and DOTS

Suggested learning unit or module for integration:

4. Epidemiology or Research Methods
5. Man in Health and Disease or the Abnormal Man
 - a. Respiratory System
 - b. Infectious Diseases
6. Clinical Rotations

Duration:

3. Unit on Tuberculosis
 - a. Discussion and exercises (2 hours)
 - b. Skills laboratory sessions (2 hours)
 - c. Community visit (3 hours)
4. Clinical rotations
 - a. Case 2 (Internal Medicine) (2 hours)
 - b. Case 3 (Pediatrics) (2 hours)

Suggested schedule for Unit on Tuberculosis (2nd year)

Time	Day 1	Day 2
8:00 – 9:00	Case 1: Mimi, 1 st session	Case1: Mimi, 2 nd session
9:00 – 10:00		
10:00 – 11:00	Skills Laboratory 1: Sputum AFB smears (staining/interpretation)	Discussion / debate and exercises on DOTS
11:00 – 12:00		
12: 00 – 1:00	Lunch	Lunch
1:00 – 2:00	Skills Laboratory 2: Examining pathological specimens	Community visit or Interview with DOTS patient/s
2:00 – 3:00	Skills Laboratory 2: Interpreting Chest x-rays	
3:00 – 4:00		

Case 1:

Objectives:

1. Identify signs and symptoms suggestive of pulmonary TB
2. Relate these morphological and physiological characteristics of MTb with its staining, antigenic and virulence properties.
3. Explain how man develops MTb infection
4. Explain the transmission of MTb within a family or community.
5. Describe the overall TB burden of disease and its implications.
6. Discuss the factors why TB continues to plague the country and why it has to be stopped now
7. Distinguish anti-TB drugs in terms of their respective pharmacological characteristics, mechanisms of action, dosage, and adverse effects
8. Discuss the rationale why DOTS is most instrumental in detecting and controlling TB disease
9. Prefer DOTS to other approaches in TB control

Perspectives:

The main points of this case are:

Population aspects:

- TB Burden of disease
- The Problem of TB in the Philippines
- DOTS as the WHO and DOH strategy to control TB

Behavior:

- Stigma of TB
- Health-seeking behavior of Filipinos
- Factors affecting transmission of infection
- Factors affecting compliance of patients to medications

Life science

- Microbiology: Biological characteristics of MTb
- Pathogenesis/ Pathology: Natural course of the disease
- Clinical presentation of TB
- Diagnosis through sputum smear versus Chest x-ray
- Pharmacology: Treatment of TB
- DOTS strategy

Case summary:

Mimi, a 35-year-old, female consulted for cough.

She has been having cough with scant sputum since six months ago. She self-medicated with an antitussive but no relief was noted. Three weeks ago, she started to have low-grade fever, night sweats and generalized body weakness. She then consulted at the local health center and was told to have upper respiratory tract infection for which she was given Amoxycillin. However her symptoms persisted and she lost 10 pounds since then.

Mimi said had “Primary Complex” when she was a child and was treated with unrecalled medications.

She lives in a 25 square meter-rented room with minimal ventilation in Tondo, Manila with her husband, their five children and her parents. She worked as a janitress in a government hospital but has stopped working since two weeks ago due to her illness.

Guide questions

1. Summarize the pertinent points in the history.
 - a. *constitutional symptoms*
 - 1) *fever*
 - 2) *night sweats*
 - 3) *weight loss*
 - b. *localized symptoms*
 - 1) *cough*
 - 2) *back pain*
 - 3) *dyspnea*
2. Review the mechanism of cough.
3. What conditions give can present as chronic cough?
4. How does one establish the diagnosis of TB in this patient?
Sputum smear examination
5. What are the morphological and physiological properties of MTb?
 - a. *Morphological properties*
Acid-fast (AFB), slender, straight, Gram-positive bacilli
 - b. *Physiological properties*
Cultural characteristics: Slow growing
Obligate aerobes
Resistance to drying; destroyed by sunlight and chemicals
6. How do these properties affect the staining, antigenic and virulence properties of the organism?

Because of their large lipid content, they stain with difficulty but once stained, they do not decolorize with acid alcohol. This is an important
Its antigenic properties are the basis for PPD examination
Virulent strains are identified with serpentine cords while avirulent strains develop random brush – heap patterns
7. Describe the way in which Mimi could have developed PTB.
Primary infection during childhood, which probably became latent

Exposed to MTb either at home or in the workplace
Cell mediated immune response
Reactivation of previous infection
Damage to lungs
Constitutional symptoms and local symptoms

8. What do you think were Mimi's reasons for not seeking medical help sooner?
(Review Module 1)

9. What conditions favor transmission of TB in Mimi's household?
Small, poorly ventilated house
Large family size
Health practices

10. What is the recommended treatment regimen for Mimi?
2HRZE/4HR

11. Describe the components of DOTS. How can these facilitate treatment of Mimi?

- 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 six to eight months for at least all confirmed sputum smear positive cases, with directly observed treatment (DOT) for at least the initial two months
- A regular, uninterrupted supply of all essential anti-TB drugs
- A standardized recording and reporting system that allows assessment of treatment results for each patient and of the TB control program

12. How can DOTS aid in controlling TB disease?
(Refer to Module 1 and Module 5)

References:

Modules 1 – 5

Microbiology textbooks

Pathology textbooks

Communicable Diseases Cluster Prevention and Control World Health Organization. (1999). *What is DOTS? A guide to understanding the WHO-recommended TB control strategy known as DOTS*. Geneva: WHO.

Department of Health. (2001). *Manual of Procedures for the National Tuberculosis Control Program*. Manila: DOH.

Case 2:**Objectives:**

1. Identify signs and symptoms suggestive of extrapulmonary TB
2. Discuss the pathological consequences of TB infection
3. Explain the transmission of MTb within a family or community
4. Prescribe the appropriate anti-TB chemotherapy in keeping with the National TB Program policy and according to the treatment category of patients and special indications
5. Adhere to standardized treatment regimen for all TB patients

Case summary:

Dodo, Mimi's husband, a 38-year-old male was rushed to the emergency room for passage of bloody stools

Patient has been noted to be icteric and to lose weight since four months prior to admission. He likewise complained of generalized weakness. Three months PTA, there was progressive abdominal enlargement, associated with bloating and early satiety. Two months PTA, patient started to have on and off watery diarrhea relieved with intake of Loperamide. Two days of consult, he passed out an estimated 200 mL of bloody stools. This recurred on the day of admission. He was then brought to this institution.

Past history:

Patient has been diagnosed to have gouty arthritis six months ago. For this he regularly takes Ibuprofen and Prednisone tablets. He has likewise been diagnosed to have diabetes mellitus and is on irregular intake of hypoglycemic agent. In 1999, Dodo had Hepatitis A diagnosed by serology. He is currently asymptomatic. He denied previous history of PTB.

Physical examination:

Patient is fairly nourished with buffalo hump at the nape

Vital signs: BP = 90/60 HR = 110 RR = 18 Temp = 37.2 degrees C

Pale conjunctivae, icteric sclerae, (-) cervical lymphadenopathy

Chest: (+) draining sinus with whitish mucopurulent discharge at the level of the third ICS, no spider angiomas, equal chest expansion, bronchovesicular sounds, no crackles

Distinct heart sounds, regular rhythm, (-) murmurs

Abdomen globular, normoactive bowel sounds, liver span = 12 cm, nodular, firm, palpable 3 cm below the right subcostal margin, obliterated Traube's space, (+) fluid wave

Rectal exam: good sphincter tone, no masses palpated, (+) fresh blood on withdrawal of examining finger.

Dodo was subsequently admitted with the initial impression of Disseminated TB. AFB smear of the whitish discharge from the sinus and stools was done. These turned out positive for AFB. Plain abdominal X-ray showed calcifications in the right upper quadrant. Ultrasonography of the liver showed 5 X 4 X 4 cm mass in the right lobe of the liver. Barium enema showed demonstrated a mass at the ileocecal area. Biopsy of the liver mass was done and histopathological examination revealed caseation necrosis.

Guide questions:

1. Summarize the salient points in the history of Dodo.
 - Constitutional symptoms
 - Weight loss
 - Generalized body weakness
 - Local symptoms
 - Jaundice
 - Abdominal enlargement
 - Chronic diarrhea
 - Hematochezia
2. What were the factors that could have contributed to Dodo's infection?
 - a. Infectiousness of person with TB

MORE EFFICIENT TRANSMISSION
 Cavitory disease: billions of bacilli
 Sputum AFB smear +++
 Coughing (& sneezing & talking)
 Household contact

LESS EFFICIENT TRANSMISSION
 Non-cavitory disease
 Sputum AFB smear negative
 Not coughing
 Casual contact
 Outdoor contact very unlikely

- b. Environment in which exposure occurred
 - c. Duration of exposure (especially when there is a close contact)
 - d. Virulence of the organism
 - e. Immune system of patient, corticosteroid therapy, Diabetes mellitus
3. What are the common types of extrapulmonary TB?
 (See Module 3 on Clinical Presentation and Diagnosis)
4. How can transmission of MTb be minimized in the family? Community?
 Hospital setting?
 (See Module 2 on Transmission and Pathogenesis)
5. What is the recommended treatment regimen for Dodo? Consider his other medical conditions.
 2HRZE/4HR

References:
 Pathology textbooks
 Internal Medicine textbooks
 Modules 1, 2, 3, and 5

V. Case 3**Objectives:**

1. Differentiate primary TB and reactivation TB
2. Distinguish between TB infection and active disease
3. Accurately diagnose patients with TB infection and disease
4. Prescribe the appropriate anti-TB chemotherapy in children

VI. Case Summary:

Lala, Mimi and Dodo's 3-year-old daughter, was brought to the local health center for check up. She has been noted to have poor appetite, and recurrent cough and cold for about two months and undocumented low grade fever.

At the health center, Lala was found to weigh 11 kg. She also had multiple supraclavicular lymph nodes measuring around 1.0 cm.

VII. Guide questions:

1. Describe the clinical presentation of TB in children. Which are present in Lala?
A child who has active TB has 3 or more of the following:
 - a. Exposure to an adult with active disease (in this case the parents)
 - b. Signs and symptoms suggestive of TB (weight loss/lack of weight gain, anorexia, respiratory symptoms)
 - c. Positive Mantoux tuberculin test
 - d. Abnormal Chest x-ray suggestive of TB
 - e. Laboratory findings suggestive of TB (histological, cytological, immunological or molecular)
 - f. Gold standard is positive culture \pm AFB smear (+)
2. What tests can be done to confirm this?
As above. If Lala can cough out sputum then this can be tested for AFB. In young children where diagnosis cannot be definitively determined, gastric aspirate can be used.
3. How effective is Mantoux test in diagnosing TB?
It remains the best means for detecting infection with MTb, short of culture. It is based on the immunologic reaction of the body to the antigenic component of the organism. It however cannot diagnose active disease.
4. What is the role of BCG vaccination in prevention of TB infection and disease? Does it have any role as diagnostic test?
BCG (Bacillus of Calmette and Guerin) is supposed to produce an innocuous primary infection instead of the more dangerous primary infection due to MTb. It enhances cell-mediated immunity with minimal risk of progressive disease. According to the National TB Program, BCG

immunization of infants and children will reduce serious extrapulmonary forms of TB. It is likewise diagnostic of TB infection. In the presence of infection, there is an accelerated reaction (i.e., presence of an induration of 5 mm or more by the 2nd – 3rd day, pustule on the 5th – 7th day, or healing within 2 – 3 weeks).

5. How does TB differ in children compared to adults?
(Refer to Module 3 Clinical Presentation and Diagnosis)
6. Tabulate the differences between TB infection and active disease.
(Refer to Module 3)
7. How will you treat Lala?
(Refer to Module 4)

References:

Pediatrics Textbooks

Philippine Pediatric Society, Pediatric Infectious Disease Society of the Philippines and Philippine Coalition Against Tuberculosis. (1997). National Consensus on Childhood Tuberculosis. Manila: Pediatrica, Inc.

Module 3 and 4

POSTTEST FOR MODULE 2

I. Put a check (/) before each factor that retards the growth of MTb

- 1. Sunlight
- 2. Heat
- 3. Alcohol
- 4. Oxygen
- 5. Phenol

II. Differentiate TB infection from active disease by completing the table below

Characteristic	TB infection	TB active disease
Exposure		
Diagnostic examination		
Bacillary load		
Infectiousness		
Treatment warranted		

III. Write TRUE if the statement is correct and FALSE if the statement is incorrect.

- 1. The most effective way to prevent the spread of TB is to properly identify and treat infectious cases.
- 2. The more the acid-fast bacilli identified in the sputum smear, the more responsive the patient is to therapy and therefore the less infectious he is.
- 3. Supervised collection of sputum of TB suspects should be done in an enclosed room as much as possible to avoid spreading the organism and infecting other patients.
- 4. The initial site of TB infection is usually the apices of the lungs.
- 5. The more organs are involved the more infectious the patient is compared to patients with pulmonary involvement only.
- 6. Resistance to TB infection mainly depends on patient's cell mediated immunity
- 7. Patients with impaired T lymphocytes quickly develop TB disease.
- 8. The pathological hallmark of TB is granulomatous inflammation.
- 9. MTB appears red on Ziehl Neelsen stain and blue on Gram stain.
- 10. Miliary TB appears as small foci because untreated patients die before these foci have a chance to grow in size.

POSTTEST FOR MODULE 3

Determine which of the following warrant/s sputum AFB smear examination by putting a check (/) on the space provided?

- _____ 1. 25-year-old, male with weight loss, fever usually at night, no cough, (+) multiple cervical and axillary enlarged lymph nodes, obliterated Traube's space.
- _____ 2. 32-year-old, female with back pains of two months duration, three weeks history of cough with scanty sputum, unresponsive to one-week course of Cotrimoxazole.
- _____ 3. 50-year-old, male, chronic smoker with cough for one year, and recently had hemoptysis, night sweats, weight loss
- _____ 4. 52-year-old, male, hypertensive, post-AMI patient with progressive exertional dyspnea, orthopnea, and cough with pink, frothy sputum. PE showed neck vein engorgement, bilateral crackles from mid to base, and bipedal edema.
- _____ 5. 70-year-old female, with six month-history of constipation and passage of goat stool-like stools, hematochezia and weight loss. Three weeks history of dyspnea. PE showed fixed, matted supraclavicular nodes on the left. Chest X-ray showed multiple cannon ball lesions.
- _____ 6. 18-year-old, female student with three months history of cough, weight loss who had one episode of hemoptysis three days ago which resolved.
- _____ 7. 12-year-old, male, stuporous, with cough of three weeks duration and two week-history of drowsiness and vomiting. Patient had meningeal signs and lumbar tap revealed (+) AFB.
- _____ 8. 44-year-old male with cough for two months, tiredness, weight loss. Few hours ago, he had massive hemoptysis and was brought to the ER for pallor and dizziness.
- _____ 9. 20-year-old, female, nursing student, asymptomatic, with chest X-ray findings of apical infiltrates, PPD (+), with previous treatment of triple antituberculous agents when she was a teenager.
- _____ 10. 7-year-old, girl with cough with whitish sputum and low-grade fever for one week. On PE, she has tonsillopharyngeal congestion and cervical lymphadenopathy.

POSTTEST FOR MODULE 4

Decide which of the following patients require treatment. For these patients, identify the appropriate antituberculous regimen.

1. 18-year-old male with cough with scanty, whitish sputum usually occurring in the mornings and associated with frequent sneezing and rhinorrhea. Chest X-ray shows fibrosis in the right upper lung field.
2. 25-year-old housewife who has completed antituberculous treatment for six months with repeat sputum smear showing AFB (+).
3. 70-year-old, male with cough with sputum found to be AFB (+)
4. 24-year-old, pregnant patient on the 8 weeks AOG, with one-month history of productive cough, weight loss, night sweats, cavitory lesion on Chest X-ray, AFB smear (-)
5. 30-year-old male diagnosed to have smear-positive TB with history of hepatitis B infection one year ago. He is currently asymptomatic, HBs Ag (+), ALT of 50 IU/L (normal is up to 35).
6. 20-year-old, former dancer, HIV (+), AFB (++), with no culture and sensitivity studies available in their town
7. 45-year-old, asymptomatic laundrywoman with chest X-ray showing bilateral apical infiltrates, previously diagnosed and treated to have pulmonary tuberculosis
8. 7-year-old, female, 20 kg, diagnosed to have PTB and completed two months treatment with triple antituberculous agents. She is currently well.
9. 38-year-old, male, with chronic diarrhea. Stool was found to be AFB (+).
10. 28-year-old, janitor, with one month history of productive cough, weight loss unresponsive to antibiotics cavitory lesions on Chest X-ray, positive history of PTB in the family

POSTTEST FOR MODULE 5

- I. Describe how the present health care system is managing infectious diseases in general and TB in particular, with respect to the following areas:
 1. Determination of population at risk for the infection
 2. Detection of actual cases
 3. Degree of responsibility of government and private physicians
 4. Accountability of the government
 5. Coping mechanisms of patients and their families and consequences of these

- II. Discuss how DOTS addresses the issues in Item I.

- III. DOTS as a strategy could be taken not just as a means to combat a global epidemic; once its components are in their proper places, it is also a strategy of introducing a systematic way of correcting our present health care system. Explain your thoughts on DOTS as a strategy of planned change.

1. Answer Key

Module 1:

- I. Answers may vary according to existing minimum wage and prices of drugs. (Please include latest figures.)
- II. Please refer to the Table on Aggravating Factors addressed by DOTS
- III. Ans
 - a. Number of smear (+) cases
 - b. Number of smear (+) cases, Annual mortality
 - c. Annual risk of infection

Module 2:

- I. 1, 2, 5
- II. Table comparing TB infection and Active disease

Characteristic	TB infection	TB active disease
Exposure	+	+
Diagnostic examination	PPD	AFB smear and/or culture
Bacillary load	Low	High
Infectiousness	Low	High
Treatment warranted	None	Standard treatment regimen

- III. 1. T 2. F 3. F 4. F 5. F 6. T 7. T 8. F 9. T 10. T

Module 3: 2, 3, 6

Module 4:

- 2. 2HRZE/4HR 3. 9HR 4. 12 HRE 5. 2HRZE/4HR 6. 9HRZE
- 8. 4[H (200 mg/day) R (300 mg/day)] 9. 2HRZE/4HR 10. 2HRZE/4HR

Module 5:

The following minimum discussions must be considered in providing feedback to students' works:

- I. The present health care system is too individualistic. People at risk of infection are not identified unless they seek consultation with the duly recognized health care facility. There is a generally fragmented way of treating patients since both public and private physicians do not tracking the progress of their patients if the latter fail to return for consultation. There is no one who is directly responsible for it! Meanwhile, the epidemic continues and causes grave consequences especially for those who started treatment, failed to sustain the medications and result to multiple drug resistance.
- II. DOTS is a strategy that synchronizes all the concerned sectors to address TB as a global epidemic. The government is mandated to lay down the infrastructures for the distribution of free medicines on a national scale, standardize treatment and manner of implementation through the appropriate agencies and train the personnel responsible for these functions. The

recording system of DOTS is a mechanism to assure that patients are properly tracked down and the progress of their treatment monitored and quality controlled. Public and private physicians on the other hand, are also being mandated to support DOTS by referring them to the DOTS center for continuous treatment and follow up of medications. While this will admittedly reduce their contact time with their patients, the responsibility they give up on them is virtually transferred to those stationed in the community. Such management relay can be a potentially classic example of shared responsibility!

**TUBERCULOSIS CONTROL
CORE CURRICULUM FOR
PHILIPPINE MEDICAL SCHOOLS**

**PART IV
EVALUATION PLAN**

TABLE OF CONTENTS

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Evaluation Plan

I. Rationale

This evaluation plan serves as the last component of the TB Control Core Curriculum for Philippine Medical Schools. It presents the different self-assessment questions and exercises belonging to each module for formative assessment. It also includes the final examinations and their corresponding blueprints for summative assessment purposes. Such instruments have been prepared in this package to facilitate the actual evaluation and adoption of this plan for TB teachers.

Copies of this component of the master curriculum are limited only to the TB teachers and their coordinators. Students should therefore be discouraged from acquiring this package.

II. Types of Evaluation

This evaluation plan has both formative and summative components. For formative purposes, the self-assessment questions (SAQs) distributed in the various sections of modules 1 to 5 are provided. These SAQs are meant to guide both students and faculty members to monitor performance of the learners. Teachers are encouraged to follow-up with the students their accomplishment of the SAQs at any time for appropriate feedback.

For summative evaluation, a 20-item written examination is presented in this plan. It is suggested that this examination be incorporated by the concerned faculty members to their actual written test at the end of the unit or topic where the modules have been accomplished. The blueprint of both these SAQs and final examination are presented in this plan.

III. Blueprint

The entire TB control core curriculum consists of three general objectives for students to acquire. Upon completion of this curriculum, students can:

- A. Demonstrate thorough understanding of TB as a biomedical and social phenomenon;
- B. Evaluate patients with pulmonary TB and the more common forms of extrapulmonary TB according to standardized criteria and
- C. Prescribe DOTS in all involvements and activities related to TB

In accordance to these general competencies, and in consistency with the presented curricular framework, the content, teaching and learning activities and resources, this evaluation plan is also designed to foster a balanced development for students in terms of acquisition of knowledge, developing skills and desired attitudes. Furthermore, the plan is also progressive and developmental as it conforms to the taxonomy of the three

domains of learning knowledge, skills and attitudes. This evaluation plan is captured in the blueprints presented below:

Table 1. Evaluation Blueprint According to Domains of Learning

Objectives	Blueprint According to Domains of Learning		
	Knowledge	Skills	Attitudes
Demonstrate thorough understanding of TB as a biomedical and social phenomenon	Family Medicine Research Methods Epidemiology Microbiology Pathology Medicine Pediatrics	Collection, Preparation and interpretation of AFB smear Case detection Problem solving Interpreting statistical data	Empathy Concern for patients and their families Hygiene and sanitation Intellectual honesty and vigor
Evaluate patients with pulmonary TB and the more common forms of extrapulmonary TB according to standardized criteria	Family Medicine Medicine Pediatrics Neurology Gynecology Surgery Orthopedics Otorhinolaryngology Ophthalmology Radiology	Relating with peers, consultants, tutors, patients, their <i>bantays</i> and other members of the health team Collection, Preparation and interpretation of AFB smear Reading X-rays Clinical problem solving skills	All of the above Inquisitiveness Compassion Social consciousness
Prescribe DOTS in all involvements and activities related to TB	Family Medicine Medicine Pediatrics Neurology Gynecology Surgery Orthopedics Otorhinolaryngology Ophthalmology Radiology	All of the above Relating with private and public physicians in dealing with TB Referring patients to the proper channels Advocacy initiatives	All of the above Altruism Advocacy

Table 2. Evaluation Blueprint According to Instruments Presented

N. B. The blueprint for formative assessment is presented in regular fonts while those for the 20-item summative examination are printed in italics.

Objectives	Knowledge	Skills	Attitudes
1. Demonstrate thorough understanding of TB as a biomedical and social phenomenon	SAQs in module 1 Exercises and SAQs in module 2 <i>Case report</i> <i>20-item written exam</i>	Practical examination	SAQs in module 1 Exercises and SAQs in module 2 Process evaluation report <i>Reflection paper on community visit</i>
2. Evaluate patients with pulmonary TB and the more common forms of extrapulmonary TB according to standardized criteria	SAQs in Module 1 Exercises and SAQs in Module 2 SAQs in Module 3 SAQs in Module 4 <i>Case report</i> <i>20-item written exam</i>	Demo and return demo on AFB smear, eliciting clinical history, doing PE and reading X-rays <i>Practical examinations on:</i> <i>1. Collecting, preparation & interpretation of AFB smear</i> <i>2. Eliciting clinical history</i> <i>3. Performing PE</i> <i>4. Reading X-rays</i>	Process evaluation report Direct observation using checklist of learners' attitudes itemized above <i>Direct observation using checklist of learners' attitudes itemized above</i>
3. Prescribe DOTS in all involvements and activities related to TB	SAQs in module 4 Exercises and SAQs in module 5 Community report <i>20-item written exam</i>	Direct observation and Record review of accomplished forms <i>Same as above</i>	Process evaluation report <i>Direct observation using checklist of learners' attitudes</i>

IV. Blueprint for Written exam

Objectives	Content	Recall	Comprehension	Problem solving
I. DEMONSTRATE THOROUGH UNDERSTANDING OF TB AS A BIOMEDICAL AND SOCIAL PHENOMENON	Characteristics of MTb AFB staining Exposure Infection Response of host Development of disease Pathological consequences of disease Transmission and factors associated with it	4	1	2
II. EVALUATE PATIENTS WITH PTB AND THE MORE COMMON FORMS OF EXTRA-PTB ACCORDING TO STANDARDIZED CRITERIA	Clinical presentation of PTB and the more common forms of extra-PTB Chest X-ray findings Other diagnostic exams Diagnostic Criteria	0	1	5
III. PRESCRIBE DOTS IN ALL INVOLVEMENTS AND ACTIVITIES RELATED TO TB	Components of DOTS Difference between DOTS and other strategies Characteristics of anti-TB drugs Standard regimens Management of special cases	1	1	5
Total		5	3	12

Multiple-choice questions: Encircle the letter corresponding to the best answer.

1. A 15-year-old female has been noted to have frequent cough and fever, anorexia and easily gets tired. Her grandmother brought her to an herbolario who said this was a case of “usog.” After four weeks of being treated with herbal concoctions, she did not improve. She was finally brought to the health center by the mother and was diagnosed to have TB. She does not want to enroll in the DOTS program because she feels her friends will start to avoid her once they found out her diagnosis. In which way does DOTS ensure cure for this case?
 - a. The treatment partner will see to it that the grandmother will not interfere with her medication.
 - b. Compliance is assured by proper patient and family education and close monitoring.
 - c. With regular follow up at the center, the patient and her friends will ultimately understand that TB is curable.

- d. DOTS strategy will likewise identify other TB cases in the family, even if they are still asymptomatic.
2. What characteristic of MTB is responsible for its Acid-fast bacilli character?
 - a. Mucopolysaccharides
 - b. Lipid content of cell wall
 - c. Gram negative character
 - d. Artifact
 3. What is a small collection of macrophage surrounded by lymphocytes, fibroblasts, and neutrophils with amorphous granular cell debris at the center?
 - a. Tuberculous granuloma
 - b. Caseation necrosis
 - c. Ghon complex
 - d. Miliary tuberculosis
 4. Which of the following describes primary TB infection?
 - a. TB infection in infants and children
 - b. Infection after initial exposure to MTb
 - c. Infection with no other TB complications
 5. Which is/are possible consequences of primary PTB?
 - a. Ghon lesion
 - b. Miliary TB
 - c. TB meningitis
 - d. All of the above
 6. Which is immune response of the human body to reactivation?
 - a. T cell mediated immune response
 - b. IgG mediated
 - c. Complement mediated
 - d. All of the above
 7. A 40-year-old nursing aid in your hospital experienced three-week cough and fever. Sputum turned out to be positive for AFB. Two months ago she started to eat only one meal per day so as to lose weight and has since lost 20% of her weight. She had previous primary infection. Which of the following explains her condition?
 - a. Reactivation of primary lesion
 - b. Mutation of non-virulent to virulent strain
 - c. Development of autoimmune disease
 - d. Exposure to exogenous MTb from the hospital to which the body is not yet sensitized
 8. What is the main reason why sputum smear microscopy is preferred over chest X-rays in diagnosing TB?
 - a. Sputum smear microscopy is readily available in both hospital and local health centers

- b. X-ray is unreliable in diagnosing active disease and monitoring treatment response
 - c. Chest X-ray results regardless of clinical presentation can not be used as basis for initiating treatment with anti-TB agents
 - d. Sputum smear microscopy is more sensitive than Chest X-ray.
9. A patient undergoes quadruple antituberculous therapy. On sputum follow up at five months on treatment, he is found to be AFB positive. To what TB category does he belong?
- a. New case
 - b. Relapse
 - c. Failure
 - d. Return after default
10. What is the most effective way to prevent transmission of TB in the community?
- a. Mass BCG vaccination
 - b. Isolation of all known cases of TB
 - c. Adequate treatment of all cases of TB
 - d. Wearing of masks of all close contacts
11. Computing for TB treatment outcomes requires getting the quotient of two values. The denominator is the total number of smear positive cases admitted to treatment. What is the numerator used in computing the cure rate?
- a. Number of new smear positive patients who have completed treatment with two smear negative results
 - b. Number of new or relapse smear positive cases who completed treatment
 - c. Number of smear positive cases who converted at any time during the course of treatment
 - d. Number of smear positive cases who improved clinically during the course of treatment
12. Why do some studies reveal that directly observed treatment does not consistently result in cure?
- a. The success of directly observed treatment, short course (DOTS) strategy is only effective in developed countries with few cases and adequate finances to support the program.
 - b. To be successful, directly observed treatment must be implemented together with a regular supply of medication and accurate monitoring.
 - c. The effectiveness of the program cannot be appreciated early on since untreated asymptomatic TB infections may still become infectious later on.
 - d. Directly observed treatment is labor-intensive and overall, its effectiveness in cure rate is not compensatory to the resources allotted for the program.

Supply type. In the appropriate box, write down the most cost-effective diagnostic examination and recommended treatment regimen for each of the following:

Cases	Diagnostic exam	Treatment regimen
1. 35-year-old female, office clerk with one-month history of cough, weight loss and tiredness. Chest X-ray showed bilateral apical infiltrates. Patient has never been treated for PTB	<i>Sputum smear</i>	<i>2 HRZE/4HR</i>
2. 28-year-old housewife, diagnosed to have PTB on 35-weeks AOG. She was given INH, Rifampicin, and Ethambutol for six weeks. She complained of blurring of vision.	<i>Complete ophthalmologic examination</i>	<i>Shift Ethambutol to PZA</i>
3. 50-year-old, jeepney driver, diagnosed to smear positive PTB. He has alcoholic liver disease. On his fourth week of treatment with quadruple anti-TB agents, he became icteric with tea-colored urine. HbsAg was negative.	<i>ALT</i>	<i>Discontinue drugs until work up is done</i>
4. 18-year-old, male, with previous history of PTB, presenting with drowsiness, and headache. Neurological examination showed meningeal signs. Chest X-ray is normal.	<i>Lumbar tap</i>	<i>2HRZE/4HR</i>

(Answers to MCQs are underlined and Supply type answers are in *italics*)

V. Self assessment questions for formative purposes

POSTTEST FOR MODULE 1

- I. Given: SG, a 30-year-old, security guard receiving minimum daily wage, father of four, was diagnosed to have PTB. He was laid off from work because of this and his wife, a laundrywoman earning P3500/month became the breadwinner of the family. He was prescribed quadruple anti-TB agents, namely INH (300 mg/day), Rifampicin (300 mg/day), PZA, (1.0 g/day), and Ethambutol (800 mg/day) for two months, then Rifampicin and INH for four months.
 - a. During the intensive phase of treatment (initial two months), how much is the economic burden on SG's family?
 - b. If SG has to spend P20/day for transportation to go to the nearby DOTS center, will you advice him to still enroll in the program?

- II. Enumerate the components of DOTS strategy and summarize the rationale for each.

- III. Some of the most used indicators to determine TB burden are the annual risk of infection, number of smear (+) cases and annual TB mortality.
 - a. Which of these may initially increase as a result of a more effective program for case finding or detection?
 - b. Which will decline as a result of timely diagnosis and intervention?
 - c. Which may remain the same or almost the same due to widespread vaccination with BCG?

POSTTEST FOR MODULE 2

- I. Put a check (/) before each factor that retards the growth of MTb
- 1. Sunlight
 - 2. Heat
 - 3. Alcohol
 - 4. Oxygen
 - 5. Phenol

- II. Differentiate TB infection from active disease by completing the table below

Characteristic	TB infection	TB active disease
Exposure		
Diagnostic examination		
Bacillary load		
Infectiousness		
Treatment warranted		

- III. Write TRUE if the statement is correct and FALSE if the statement is incorrect.

- 1. The most effective way to prevent the spread of TB is to properly identify and treat infectious cases.
- 2. The more the acid-fast bacilli identified in the sputum smear, the more responsive the patient is to therapy and therefore the less infectious he is.
- 3. Supervised collection of sputum of TB suspects should be done in an enclosed room as much as possible to avoid spreading the organism and infecting other patients.
- 4. The initial site of TB infection is usually the apices of the lungs.
- 5. The more organs are involved the more infectious the patient is compared to patients with pulmonary involvement only.
- 6. Resistance to TB infection mainly depends on patient's cell mediated immunity
- 7. Patients with impaired T lymphocytes quickly develop TB disease.
- 8. The pathological hallmark of TB is granulomatous inflammation.
- 9. MTB appears red on Ziehl Neelsen stain and blue on Gram stain.
- 10. Miliary TB appears as small foci because untreated patients die before these foci have a chance to grow in size.

POSTTEST FOR MODULE 3

Determine which of the following warrant/s sputum AFB smear examination by putting a check (/) on the space provided?

- _____ 1. 25-year-old, male with weight loss, fever usually at night, no cough, (+) multiple cervical and axillary enlarged lymph nodes, obliterated Traube's space.
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- _____ 10. 7-year-old, girl with cough with whitish sputum and low-grade fever for one week. On PE, she has tonsillopharyngeal congestion and cervical lymphadenopathy.

POSTTEST FOR MODULE 4

Decide which of the following patients require treatment. For these patients, identify the appropriate antituberculous regimen.

1. 18-year-old male with cough with scanty, whitish sputum usually occurring in the mornings and associated with frequent sneezing and rhinorrhea. Chest X-ray shows fibrosis in the right upper lung field.
2. 25-year-old housewife who has completed antituberculous treatment for six months with repeat sputum smear showing AFB (+).
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4. 24-year-old, pregnant patient on the 8 weeks AOG, with one-month history of productive cough, weight loss, night sweats, cavitory lesion on Chest X-ray, AFB smear (-)
5. 30-year-old male diagnosed to have smear-positive TB with history of hepatitis B infection one year ago. He is currently asymptomatic, HBs Ag (+), ALT of 50 IU/L (normal is up to 35).
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10. 28-year-old, janitor, with one month history of productive cough, weight loss unresponsive to antibiotics cavitory lesions on Chest X-ray, positive history of PTB in the family

POSTTEST FOR MODULE 5

- I. Describe how the present health care system is managing infectious diseases in general and TB in particular, with respect to the following areas:
 1. Determination of population at risk for the infection
 2. Detection of actual cases
 3. Degree of responsibility of government and private physicians
 4. Accountability of the government
 5. Coping mechanisms of patients and their families and consequences of these

- II. Discuss how DOTS addresses the issues in Item I.

- III. DOTS as a strategy could be taken not just as a means to combat a global epidemic; once its components are in their proper places, it is also a strategy of introducing a systematic way of correcting our present health care system. Explain your thoughts on DOTS as a strategy of planned change.

1. **Answer Key**

Module 1:

- I. Answers may vary according to existing minimum wage and prices of drugs. (Please include latest figures.)
- II. Please refer to the Table on Aggravating Factors addressed by DOTS
- III. Ans
 - a. Number of smear (+) cases
 - b. Number of smear (+) cases, Annual mortality
 - c. Annual risk of infection

Module 2:

- I. 1, 2, 5
- II. Table comparing TB infection and Active disease

Characteristic	TB infection	TB active disease
Exposure	+	+
Diagnostic examination	PPD	AFB smear and/or culture
Bacillary load	Low	High
Infectiousness	Low	High
Treatment warranted	None	Standard treatment regimen

- III. 1. T 2. F 3. F 4. F 5. F 6. T 7. T 8. F 9. T 10. T

Module 3: 2, 3, 6

Module 4:

- 2. 2HRZE/4HR 3. 9HR 4. 12 HRE 5. 2HRZE/4HR
- 6. 9HRZE 8. 4[H (200 mg/day) R (300 mg/day)]
- 9. HRZE/4HR 10. 2HRZE/4HR

Module 5:

The following minimum discussions must be considered in providing feedback to students' works:

- I. The present health care system is too individualistic. People at risk of infection are not identified unless they seek consultation with the duly recognized health care facility. There is a generally fragmented way of treating patients since both public and private physicians do not tracking the progress of their patients if the latter fail to return for consultation. There is no one who is directly responsible for it! Meanwhile, the epidemic continues and causes grave consequences especially for those who started treatment, failed to sustain the medications and result to multiple drug resistance.
- II. DOTS is a strategy that synchronizes all the concerned sectors to address TB as a global epidemic. The government is mandated to lay down the infrastructures for the distribution of free medicines on a national scale, standardize treatment and manner of implementation through the appropriate

agencies and train the personnel responsible for these functions. The recording system of DOTS is a mechanism to assure that patients are properly tracked down and the progress of their treatment monitored and quality controlled. Public and private physicians on the other hand, are also being mandated to support DOTS by referring them to the DOTS center for continuous treatment and follow up of medications. While this will admittedly reduce their contact time with their patients, the responsibility they give up on them is virtually transferred to those stationed in the community. Such management relay can be a potentially classic example of shared responsibility!

Table: Objectives, Content and Time allotment for each Subject handling TB

SUBJECT	YEAR LEVEL	OBJECTIVES	CONTENT	TIME ALLOTMENT
Epidemiology Research Methods	1 st	I. DEMONSTRATE THOROUGH UNDERSTANDING OF TB AS A BIOMEDICAL AND SOCIAL PHENOMENON		
		1. Describe the overall TB burden of disease and its implications	TB burden of disease Implications to individuals, community, country Biopsychosocial model	15 – 30 minutes
		2. Critically examine the position of the Philippines in terms of world health statistics on TB	Global and national statistics: current data and trends Leading causes of mortality and morbidity	
		3. Discuss the factors why TB continues to plague the country	Health-seeking behavior Health care delivery systems Causes of delay Biomedical factors	30 minutes small group activities and 30 minutes plenary
		4. Apply the basic concepts and methodologies of Epidemiology/Clinical Epidemiology in contextualizing the TB epidemic.	Basic concepts in Epidemiology	
		5. Describe the current effort to control TB in the country: the government front; the private MD front; the drive to integrate private MD management of TB cases to the NTP (private-public mix); and coalition building to broaden the support for TB control.	DOTS and its impact on prevalence / incidence Role of DOTS in controlling TB in the country / world	30 minutes
		6. Describe the efficient and novel way by which Directly Observed Therapy, Short course (DOTS) strategy can control TB	DOTS and its impact on prevalence / incidence Role of DOTS in controlling TB in the country / world	

SUBJECT	YEAR LEVEL	OBJECTIVES	CONTENT	TIME ALLOTMENT
Microbiology	2 nd	I. DEMONSTRATE THOROUGH UNDERSTANDING OF TB AS A BIOMEDICAL AND SOCIAL PHENOMENON		
		1. Relate morphological and physiological characteristics of <i>Mycobacterium tuberculosis</i> (MTb) with its staining, antigenic and virulence properties	Morphology of MTb Physiology of MTb Staining characteristics Antigenic properties Virulence factors Mutation to resistant strains	20 minutes
		2. Follow standard procedures in performing and interpreting sputum smears	Steps in performing sputum smear Criteria for interpreting AFB smears Compliance to standard procedures from collection to transport of specimen	2 hours
		3. Explain how man develops MTb infection	MTb infection Invasion of the host by MTb Response of the host, hypersensitivity reaction Immunity and resistance	40 minutes
		4. Discuss the rationale why DOTS is most instrumental in detecting and controlling TB disease	Components of DOTS Rationale of DOTS strategy	
Pathology	2 nd	I. DEMONSTRATE THOROUGH UNDERSTANDING OF TB AS A BIOMEDICAL AND SOCIAL PHENOMENON		

SUBJECT	YEAR LEVEL	OBJECTIVES	CONTENT	TIME ALLOTMENT
		1. Discuss the pathological consequences of TB infection	Gross and microscopic pathology of affected organs Correlation between biological characteristics of MTb and pathological changes (cavitary and non-cavitary disease)	1 hour lecture, discussion 1 hour laboratory session
Family Medicine	2 nd	I. DEMONSTRATE THOROUGH UNDERSTANDING OF TB AS A BIOMEDICAL AND SOCIAL PHENOMENON		
		1. Explain the transmission of MTb within a family or community	Transmission of TB Environmental factors Host factors: Population at risk (including HIV)	Half day visit to DOTS center or community
		2. Discuss the rationale why DOTS is most instrumental in detecting and controlling TB disease	Components of DOTS Rationale of DOTS strategy	30 minutes
	4 th	III. PRESCRIBE DOTS IN ALL INVOLVEMENTS AND ACTIVITIES RELATED TO TB		
		3. Adhere to standardized treatment regimen for all TB patients	Standardized treatment regimen Directly observed treatment Suitable DOTS supervisors Concern for patient's well being	
		4. Coach TB patients and their families on the nature of the disease and how it can be treated and prevented	Family assessment tools Nature of disease Impact of illness on the family Diagnosis Treatment Prevention Communication skill Interpersonal skill Counseling skill	

SUBJECT	YEAR LEVEL	OBJECTIVES	CONTENT	TIME ALLOTMENT
		5. Refer patients to appropriate health care units for proper administration of DOTS	Referral system	
		6. Maintain an accurate recording system of DOTS patients for evaluation of treatment outcome and program performance	Recording and reporting system	
		7. Engage in sustainable activities and initiatives to promote TB control in the community	Advocacy Community organizing	
Internal Medicine	2 nd	I. DEMONSTRATE THOROUGH UNDERSTANDING OF TB AS A BIOMEDICAL AND SOCIAL PHENOMENON		
		1. Distinguish between TB infection and active disease	Difference between TB infection and disease Features of primary infection, TB active disease and TB inactive disease	1 hour
		2. Explain the transmission of MTb within a family or community	Transmission of TB Environmental factors Host factors: Population at risk (including HIV)	
		II. EVALUATE PATIENTS WITH PTB AND THE MORE COMMON FORMS OF EXTRAPULMONARY TB ACCORDING TO STANDARDIZED CRITERIA		
		8. Identify signs and symptoms suggestive of pulmonary TB and the more common forms of extrapulmonary TB	Common complains of patients with PTB and the more common forms of extra-PTB PE findings of such patients Natural history of the disease	1 hour

SUBJECT	YEAR LEVEL	OBJECTIVES	CONTENT	TIME ALLOTMENT
	2 nd	9. Elicit relevant clinical history from a patient suspected of having TB	Elements of clinical history History of past TB treatment Symptoms of TB patients Thoroughness Confidentiality Communication skills Interpersonal skills	1 hour
	3 rd	10. Perform a thorough physical examination on a patient suspected of having TB	PE technique PE findings of patients with TB Thoroughness Gentleness Interpersonal skills Concern for patient's privacy	1 hour
	4 th	11. Perform ancillary procedures to diagnose TB: sputum smears, intradermal tuberculin test, pleural tap and lymph node aspiration	Role of ancillary tests in diagnosis of TB Steps in performing a. Sputum smear b. Pleural tap c. Lymph node aspiration	1 hour discussion, demonstration, return demonstration
		12. Recognize chest radiographic findings consistent with PTB	Role of Chest x-rays in diagnosing PTB Radiographic findings consistent with PTB Value of serial reading Differential diagnosis	
		13. Diagnose patients with tuberculosis	Diagnostic Criteria for TB Classification of TB Cases (Treatment Categories)	
		III. PRESCRIBE DOTS IN ALL INVOLVEMENTS AND ACTIVITIES RELATED TO TB		

SUBJECT	YEAR LEVEL	OBJECTIVES	CONTENT	TIME ALLOTMENT
		14. Explain the five components of DOTS strategy	Political commitment Free sputum smear-based diagnosis Directly observed treatment Availability of free drugs Accurate recording and reporting	
		15. Prefer DOTS to other approaches in TB control in terms of case finding and diagnosis, treatment and follow up and organizational set up	Differences between DOTS and non-DOTS approaches, Difference between DOTS and other strategies, Advantages, disadvantages, effectiveness of DOTS	
		16. Prescribe the appropriate anti-TB chemotherapy in keeping with the National TB Program policy and according to the treatment category of patients and special indications	NTP Policy Categories of patients Treatment for special indications: Patients with liver, renal dse., HIV (+), pregnant	
		17. Adhere to standardized treatment regimen for all TB patients	Standardized treatment regimen Directly observed treatment Suitable DOTS supervisors Concern for patient's well being	
Pediatrics	2 nd	I. DEMONSTRATE THOROUGH UNDERSTANDING OF TB AS A BIOMEDICAL AND SOCIAL PHENOMENON 1. Distinguish between TB infection and active disease	Difference between TB infection and disease Features of primary infection, TB active disease and TB inactive disease	1 hour

SUBJECT	YEAR LEVEL	OBJECTIVES	CONTENT	TIME ALLOTMENT
		2. Explain the transmission of MTb within a family or community	Transmission of TB Environmental factors Host factors: Population at risk (including HIV)	
		II. EVALUATE PATIENTS WITH PTB AND THE MORE COMMON FORMS OF EXTRAPULMONARY TB ACCORDING TO STANDARDIZED CRITERIA		
		3. Elicit relevant clinical history from a patient suspected of having TB	Elements of clinical history History of past TB treatment Symptoms of TB patients Thoroughness Confidentiality Communication skills Interpersonal skills	1 hour
		4. Elicit relevant clinical history from a patient suspected of having TB	Elements of clinical history History of past TB treatment Symptoms of TB patients Thoroughness Confidentiality Communication skills Interpersonal skills	hour
		5. Perform a thorough physical examination on a patient suspected of having TB	PE technique PE findings of patients with TB Thoroughness Gentleness Interpersonal skills Concern for patient's privacy	1 hour

SUBJECT	YEAR LEVEL	OBJECTIVES	CONTENT	TIME ALLOTMENT
	4 th	6. Perform ancillary procedures to diagnose TB: sputum smears, intradermal tuberculin test, pleural tap and lymph node aspiration	Role of ancillary steps in diagnosis of TB Steps in performing a. Sputum smear b. Intradermal test c. Gastric aspiration d. Pleural tap e. Lymph node aspiration	1 hour Discussion, demonstration, return demonstration
		7. Recognize chest radiographic findings consistent with PTB	Role of Chest x-rays in diagnosing PTB Radiographic findings consistent with PTB Value of serial reading Differential diagnosis	
		8. Diagnose patients with tuberculosis	Diagnostic Criteria for TB Classification of TB Cases (Treatment Categories)	1 hour discussion
		III. PRESCRIBE DOTS IN ALL INVOLVEMENTS AND ACTIVITIES RELATED TO TB		
		9. Explain the five components of DOTS strategy	Political commitment Free sputum smear-based diagnosis Directly observed treatment Availability of free drugs Accurate recording and reporting	
		10. Prefer DOTS to other approaches in TB control in terms of case finding and diagnosis, treatment and follow up and organizational set up	Differences between DOTS and non-DOTS approaches, Difference between DOTS and other strategies, Advantages, disadvantages, effectiveness of DOTS	

SUBJECT	YEAR LEVEL	OBJECTIVES	CONTENT	TIME ALLOTMENT
	4 th	11. Prescribe the appropriate anti-TB chemotherapy in keeping with the National TB Program policy and according to the treatment category of patients and special indications	NTP Policy Categories of patients Treatment for special indications: Patients with liver, renal dse., HIV (+), pregnant	
		12. Adhere to standardized treatment regimen for all TB patients	Standardized treatment regimen Directly observed treatment Suitable DOTS supervisors Concern for patient's well being	
		13. Coach TB patients and their families on the nature of the disease and how it can be treated and prevented	Family assessment tools Nature of disease Impact of illness on the family Diagnosis Treatment Prevention Communication skill Interpersonal skill Counseling skill	
		14. Refer patients to appropriate health care units for proper administration of DOTS	Referral system	
Radiology	4 th	1. Recognize chest radiographic findings consistent with PTB	Role of Chest x-rays in diagnosing PTB Radiographic findings consistent with PTB Value of serial reading Differential diagnosis	1 hour
Pharmacology	3 rd or 4 th	1. Prescribe the appropriate anti-TB chemotherapy in keeping with the National TB Program policy and according to the treatment category of patients and special indications	NTP Policy Categories of patients Treatment for special indications: Patients with liver, renal dse., HIV (+), pregnant	

SUBJECT	YEAR LEVEL	OBJECTIVES	CONTENT	TIME ALLOTMENT
		2. Adhere to standardized treatment regimen for all TB patients	Standardized treatment regimen Directly observed treatment Suitable DOTS supervisors Concern for patient's well being	
ENT Neurology OB- Gynecology Ophthalmology Orthopedics Surgery	4th	II. EVALUATE PATIENTS WITH PTB AND THE MORE COMMON FORMS OF EXTRAPULMONARY TB ACCORDING TO STANDARDIZED CRITERIA		
		1. Identify signs and symptoms suggestive of pulmonary TB and the more common forms of extrapulmonary TB	Common complains of patients with PTB and the more common forms of extra-PTB PE findings of such patients Natural history of the disease	
		2. Elicit relevant clinical history from a patient suspected of having TB	Elements of clinical history History of past TB treatment Symptoms of TB patients Thoroughness Confidentiality Communication skills Interpersonal skills	
		3. Perform a thorough physical examination on a patient suspected of having TB	PE technique PE findings of patients with TB Thoroughness Gentleness Interpersonal skills Concern for patient's privacy	