National Tuberculosis Control Program

MANUAL OF PROCEDURES

5th Edition

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Manual of Procedures of the National Tuberculosis Control Program 5th Edition

National TB Control Program
MANUAL OF PROCEDURES FIFTH EDITION
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Foreword

This National Tuberculosis Control Program Manual of Procedures, 5th ed. (MOP) for the is the basis for the implementation of the tuberculosis control program in all DOTS facilities in the Philippines.

The MOP seeks to accomplish the following: (a) provide technical policies and guidelines on the diagnosis, treatment and counselling of TB patients, (b) specify procedures on how to put in place important NTP support health systems such as logistics, recording and reporting, and monitoring and evaluation systems, (c) guide the different organizational levels on how to conduct monitoring, evaluation, and supervision, and (d) prescribe the roles and tasks of those involved in the management of the TB control program including TB service provision.

Earlier versions of the NTP Manual of Procedures were conceived in the 1960s. However, the first MOP was developed in 1980. It highlighted the use of sputum microscopy as the primary diagnostic tool and introduced the Standard Drug Regimen for TB treatment. In 1988, the first MOP was revised. This 2nd edition presented the results of the 1981 – 83 First National TB Prevalence Survey (NTPS) and provided for the adoption of the Short Course Chemotherapy (SCC) for the management of TB cases.

In 1997, the Technical Guidelines of the New TB Control Program was developed by the Department of Health (DOH), in collaboration with DOH-JICA (Japan International Cooperative Agency) Public Health Development Project and the World Health Organization (WHO) Western Pacific Regional Office (WPRO), in accordance with recommendations lifted from the external evaluation conducted in 1993. This document emphasized the DOTS Strategy (Directly Observed Treatment-Short Course) as the NTP's core framework for a nationwide TB control strategy.

The third edition of the NTP MOP was written in 2001. This publication transformed the previous Technical Guidelines into a Manual of Procedures that would be useful not only in training, but also in providing instructions or procedures for the guidance of all health personnel in their delivery of TB services.

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In 2004, DOH initiated the revision of the MOP 4th edition that included the use of fixed dose combination anti-TB drugs and the adoption of external quality assurance, public-private mix DOTS, strengthening of the TB Diagnostic Committees, DOTS facility certification and accreditation, and the development of the health promotion plan specific to TB.

This MOP, 5th ed. adds the following vital components: a) integration of guidelines for the diagnosis and treatment of adult and pediatric TB cases, susceptible, and drug-resistant TB cases, b) introduction of intensified case finding for vulnerable groups, c) inclusion of the new diagnostic tools in the algorithm, d) inclusion of new chapters on TB prevention, TB-DOTS referral system, and DOTS certification and accreditation, and e) adoption of records and reports based on new international standards.

The primary users of this MOP are health service providers (physicians, nurses, medical technologists, midwives, community volunteers) implementing DOTS in the different service delivery points: public health facilities such as health centers and rural health units, public hospitals, clinics of other government agencies; or private health facilities such as private clinics, private hospitals, laboratories and pharmacies. The secondary users of this MOP are the TB control program managers at the national, regional, provincial and city levels who will be guided when they plan, implement, monitor and evaluate the TB control activities in their areas. Thirdly, this MOP could also be used by policy makers at the national and local levels, national and international donors, and program advocates.

Many institutions, groups, and individuals participated in the development of this MOP, 5th ed. The MOP Technical Writing Group initially reviewed and introduced the changes based on the technical guidelines issued by the WHO, advocated through the International Standard on TB Care, collected experiences from the field, as well as feedback from other local and international partners. The Technical Review Panel provided expert advice. The draft MOP underwent a series of consultations with different stakeholders to ensure its technical validity, soundness, feasibility and acceptability.

To keep it abreast with developments in the health care industry, the MOP will be regularly reviewed and updated to ensure that they are responsive to the needs of Philippine health care providers, supportive of the DOH strategic direction, and consistent with international standards in TB care.

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Preface

This National Tuberculosis Control Program Manual of Procedures, 5th ed. provides the updated standardized policies and guidelines on the provision of quality TB care and the necessary systems to put in place to enable us to address the problem of TB. All health care providers, therefore, whether public or private, must provide TB diagnostic, treatment and counselling services to patients in accordance with this MOP. This will ensure that TB patients get cured, duration of TB transmission is reduced, and poor outcomes are prevented.

The economic burden of TB in the country due to premature mortality and morbidity totalled PhP8 billion pesos with 500,000 disability adjusted life years lost annually. The Department of Health, in coordination with its partners, leads and coordinates efforts to control TB. The main approach is to detect all TB cases promptly, treat them properly, and notify them fully. This is part of the Universal Health Care or *Kalusugang Pangkalahatan* that will enable the Philippines to achieve its Millennium Development Goals and the objectives of the 2010 – 2016 Philippine Plan of Action to Control Tuberculosis. The MOP is a major tool of this activity.

Involvement of many stakeholders, both local and international, in the development of this MOP ensured that the policies and guidelines are consistent with the international standards, and are feasible and acceptable. They include the members of the Technical Writing Group and the Technical Review Panel and representatives from the DOTS facilities, provincial and city health offices, regional health offices, non-governmental organizations, private organizations and other government offices. I wish to thank them all, including our partners from the World Health Organization, U.S. Agency for International Development, the Global Fund Against AIDS, TB and Malaria, the Japan International Cooperation Agency, and the Korean International Cooperation Agency. I also commend the Disease Prevention and Control Bureau for orchestrating the processes of updating this MOP.

I call on all health organizations and facilities to ensure that all their health care providers possess the capability to provide quality TB care through training and supervision. Only through well trained cadres could our fight against TB bring us closer to our vision of a TB-free Philippines.

ENRIQUE T. ONA, MD, FPCS, FACS
Secretary of Health

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Abbreviations and Acronyms

ACSM	advocacy, communication, and social mobilization
ADR	adverse drug reactions
AFB	Acid Fast Bacilli
ART	anti-retroviral therapy
BCC	Behavior Change Communication
BHS	barangay health station
BHW	barangay health worker
BJMP	Bureau of Jail Management and Penology
BuCor	Bureau of Corrections
CBO	community-based organization
CDR	case detection rate
CHO	city health office/officer
CHT	community health team
CNR	case notification rate
CXR	Chest x-ray
DOH	Department of Health
DOT	directly observed treatment
DOTS	directly observed treatment, short-course
DPCB	Disease Prevention and Control Bureau
DRS	drug resistance survey
DR-TB	Drug-resistant tuberculosis
DSSM	direct sputum smear microscopy
DST	drug susceptibility test
EPTB	extra-pulmonary TB
EQA	external quality assurance
FDA	Food and Drug Administration
FDC	fixed dose combination
FHSIS	Field Health Service Information System
HIV	human immunodeficiency virus
IEC	information, education, and communication
INH	Isoniazid
IPCC	interpersonal communication competence
IPT	Isoniazid Preventive Treatment
ISTC	International Standards on TB Care
ITIS	integrated TB information system
KP	*Kalusugang Pangkalahatan*
LED FM	Light Emitting Diode Flourescence MIcroscopy
LGU	local government unit
LPA	line probe assay
LTBI	latent tuberculosis infection
MDG	millennium development goals
MDR-TB	Multidrug-resistant tuberculosis
NASPCP	National AIDS STI Prevention and Control Program
NCC	National Coordinating Committee
NEC	National Epidemiology Center

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NOSIRS	National Online Stock Inventory Report
NPS/NTPS	National TB Prevalence Survey
NTP	National Tuberculosis Control Program
NTRL	National TB Reference Laboratory
PhilHealth/PHIC	Philippine Health Insurance Corporation
PhilPACT	Philippine Plan of Action to Control TB
PHO	provincial health office/officer
PICT	Provider-Initiated Counseling and Testing
PLHIV	people living with HIV
PMDT	Programmatic Management of Drug-Resistant TB
PPD	purified protein derivative
PPMD	public–-private mix DOTS
PZA	Pyrazinamide
QAS	quality assurance system
RCC	regional coordinating committee
RHU	rural health unit
RIF	Rifampicin
RO	Regional Office
RR-TB	Rifampicin-resistant tuberculosis
RSS	Remote Smearing Station
SDF	single dose formulations
TA	Technical Assistance
TAP	Technical Assistance Provider
TBDC	TB Diagnostic Committee
TBIC	Tuberculosis Infection Control
TML	Tuberculosis Microscopy Laboratory
TSR	treatment success rate
TST	Tuberculin skin test
UHC	universal health care
WHO	World Health Organization
XDR-TB	Extensively drug-resistant tuberculosis
Xpert MTB/RIF	GeneXpert Mycobacterium tuberculosis/Rifampicin assay

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CHAPTER 1

Introduction

The Magnitude of Tuberculosis in the Philippines

Tuberculosis or TB is an infectious disease caused by the bacteria called Mycobacterium tuberculosis. It is transmitted from a TB patient to another person through coughing, sneezing and spitting. Thus, close contacts, especially household members, could be infected with TB. Lungs are commonly affected but it could also affect other organs such as the kidney, bones, liver and others. TB is curable and preventable. However, incomplete or irregular treatment may lead to drug-resistant TB or even death.

Tuberculosis is a major public health problem in the Philippines. In 2010, TB was the 6th leading cause of mortality with a rate of 26.3 deaths for every 100,000 population and accounts for 5.1% of total deaths.[1] This is slightly lower than the five-year average of 28.6 deaths per 100,000 population. More males died (17,103) compared to females (7,611).

The country had conducted three National TB Prevalence Survey (NTPS) that describe the magnitude and the trend of the TB problem. The results were as follows:

Table No.1 - National TB Prevalence Surveys 1983-2007

Indicators	NTPS 1983[2]	NTPS 1997[3]	NTPS 2007[4]
Prevalence of culture-positive TB	8.6/1,000	3.1/1,000	4.7/1,000
Prevalence of sputum smear-positive TB	6.6/1,000	3.1/1,000	2.0/1,000
Prevalence of those with CXR findings suggestive of TB	4.2%	4.2%	6.3%
Annual Rate of Infection	2.5%	2.3%	2.1%
Rate of TB symptomatic	17.0%	18.4%	13.5%

TB is more prevalent among males compared to females and among the 25 – 55 year old age group. It is also higher among the malnourished and diabetics. The 1997 survey showed that prevalence of TB among the urban poor in Metro Manila is twice that of the general population.

The first national Drug Resistance Survey was done in 2003 – 2004 and revealed the following prevalence of drug resistance: 4% among the new cases, 21% among the re-treatment cases, and 5.7% combined.[5] The second National Drug Resistance Survey was done in 2011 – 2012 and showed a decrease in the prevalence of drug resistance among new cases from 4% to 2%. However, there was no change in the prevalence of drug resistance re-treatment cases which remained at 21%.

The Philippines and its Health Care Delivery System

The Philippines, an archipelago with 7,100 islands, has a population of around 97 million in 2012 with a population growth rate of 1.9%. Geographically, it is divided into three main islands – namely Luzon, Visayas and Mindanao. There are 17 regions, including the Autonomous Region of Muslim Mindanao, 82 provinces, 135 cities and 1,493 municipalities. Functional literacy rate is high at 86%. In 2011, the country was categorized as a low to middle income country with gross national income per capita of $4,160.[6]

The decentralized health care system is managed, coordinated and regulated by the Department of Health (DOH) that is composed of the Central Office, 17 Regional Offices

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(ROs) and retained hospitals. Integrated basic health services including TB diagnostic and treatment services are provided by 2,314 rural health units (RHUs)/health centers (HCs) and 16,219 barangay health stations (BHS) that are under the local municipal/city government units. Majority of the RHUs/HCs have a TB microscopy laboratory that provides Direct Sputum Smear Microscopy (DSSM). The locally-managed Provincial Health Office (PHO)/City Health Office (CHO) provide technical oversight over these peripheral health units. Communities support these health units through the community health teams (CHTs) that include barangay health workers (BHWs).

The private sector is also engaged in the production and provision of health goods and services through private clinics, hospitals and laboratories, drug stores, and other facilities. The DOH encourages public-private sector collaboration in health.

DOH priorities and strategies are contained in its health agenda called Universal Health Care (UHC) or *Kalusugang Pangkalahatan* (KP) that aims to ensure financial risk protection for the poor, provide access to quality health services, and attain health related Millennium Development Goals (MDGs). Specific health targets including that for TB control are contained in the National Objectives for Health.

The National TB Control Program (NTP)

The NTP is one of the public health programs being managed and coordinated by the Infectious Diseases for Prevention and Control Division (IDPCD) of the Disease Prevention and Control Bureau (DPCB) of the DOH. The NTP has the mandate to develop TB control policies, standards and guidelines, formulate the national strategic plan, manage program logistics, provide leadership and technical assistance (TA) to the lower health offices/units, manage data, and monitor and evaluate the program. The program's TB diagnostic and treatment protocols and strategies are in accordance with the global strategy of STOP TB Partnership and the policies of World Health Organization (WHO) and the International Standards for TB Care (ISTC).

The NTP works closely with various offices of the DOH such as the Health Promotion and Communications Service (HPCS) for advocacy, communication and social mobilization, the Epidemiology Bureau (EB) and Knowledge Management and Information Technology Service (KMITS) for data management, Health Policy Development and Planning Bureau (HPDPB) for policy and strategic plan formulation, Material Management Division (MMD), Central Office Bids and Awards Committee (COBAC) and Food and Drug Administration (FDA) for drug and supplies management, the National TB Reference Laboratory of the Research Institute for Tropical Medicine (NTRL-RITM) for laboratory network, Lung Center of the Philippines (LCP) for MDR-TB related research and training activities and the 17 ROs for technical support to the implementing units. It also coordinates with the Philippine Health Insurance Corporation (PhilHealth) for TB-DOTS accreditation and utilization of the TB-DOTS outpatient benefit package.

The DOH Regional Offices (RO) through their Regional NTP teams, manage TB at the regional level while the provincial health and city health offices, through their provincial/city teams are responsible for TB control efforts in provinces and cities. TB diagnostic and treatment services that are in accordance with NTP protocol are provided by DOTS facilities which could either be the public health facilities such as the RHUs, health centers, hospitals; other public health facilities such as school clinics, military hospitals, prison/jail clinics; NTP-engaged private facilities such as private clinics, private hospitals, private laboratories, drug stores and others. Community groups such as the community health teams and barangay health workers participate in community-level activities.

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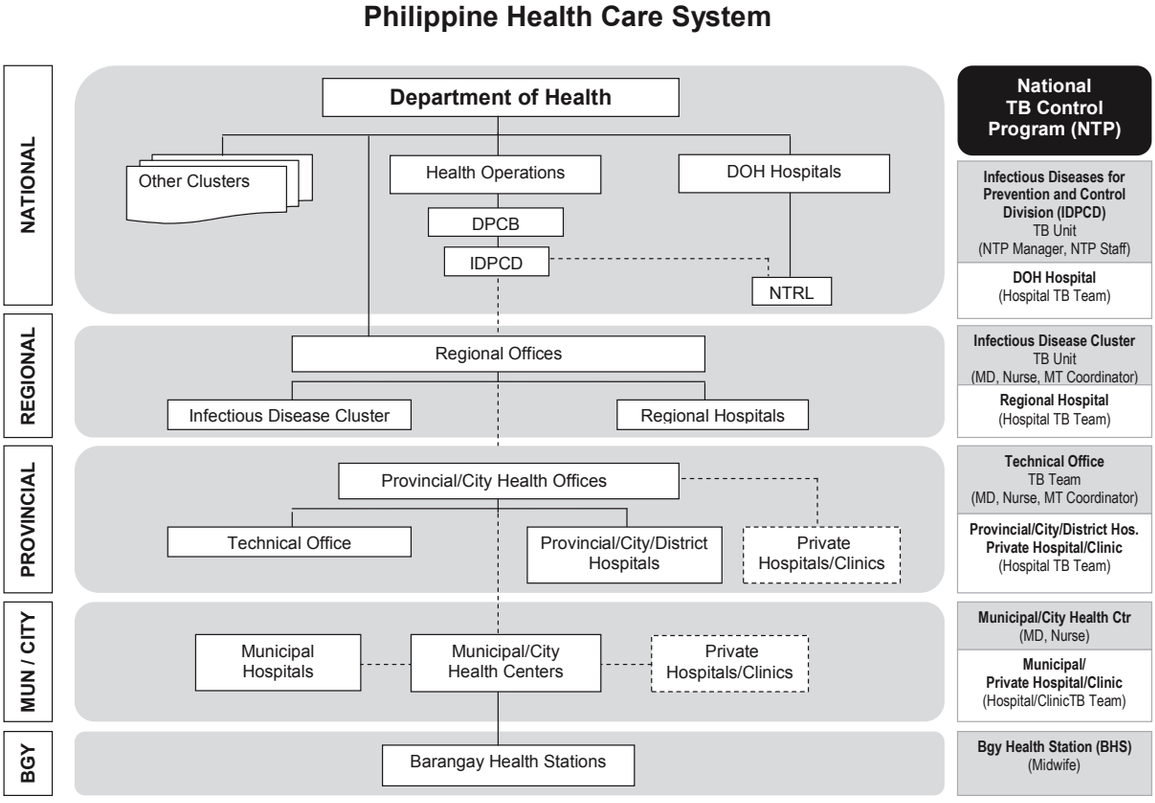
NTP closely works with the 17 government offices and five private organizations in compliance with the Comprehensive and Unified Policy (CUP) issued by the Office of the President in 2003.[7] Under the framework of public-private collaboration in TB-DOTS, NTP collaborates with non-governmental organizations such as the Philippine Coalition Against TB (PhilCAT), a consortium of 60 groups, and the 100-year old Philippine TB Society, Inc. (PTSI) and many other organizations. Various developmental partners and their projects provide technical and financial support to NTP such as the WHO, United States Agency for International Development (USAID), Global Fund Against AIDS, TB and Malaria (Global Fund), Research Institute of TB/Japan Anti-TB Association (RIT/JATA), Korean Foundation for International Health (KOFIH) and Korean International Cooperation Agency (KOICA).

Figure No. 1- Organizational Structure of the Country's Health Delivery System Including the Different Units Supporting the NTP



Past Efforts to Control TB in the Country

National efforts to control TB in the country started more than 100 years ago with the establishment of a non-governmental organization, the Philippine TB Society, Inc. (PTSI). It included Quezon Institute and many provincial branches. The Sweepstakes Law (RA 4130) was passed to establish the Philippine Charity Sweepstakes Office primarily to fund the operations of PTSI. The Philippine TB Commission, under the Philippine Health Service, was organized in 1932 through the passage of Republic Act 3743. In 1950, the Commission evolved into the Division of Tuberculosis under the Secretary of Health that, in turn, created the TB Center that collaborated with the TB ward of the San Lazaro Hospital.

In 1954, the Philippine Congress passed the Tuberculosis Law (RA 1136). The Division of TB was placed under the Director of the National Tuberculosis Center of the Philippines (NTCP)

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established at the DOH compound. The close collaboration between the Ministry of Health and the PTSI led to the establishment of the National Institute of Tuberculosis in 1976 that conducted operational studies including the first National TB Prevalence Survey (NTPS) that helped NTP strengthen its strategies. The TB Control Service (TBCS), with around 30 staff, was created under the Office of Public Health Services of the Department of Heath after the EDSA People Power in 1986. In 2000, with the re-organization of the DOH, the TBCS was disbanded and some of its staff were absorbed by the newly created Infectious Disease Office (IDO) of the National Center for Disease Prevention and Control (NCDPC). In 2013, rationalization of the DOH central and regional offices was implemented and the number of staff was decreased. Integration of programs and activities was advocated to cope with the changes.

Technical approaches to TB management have substantially changed over the years. Before the 1970s, BCG immunization as a preventive tool was implemented nationwide with the help of UNICEF. Chest X-ray (CXR) examination was then utilized as the main diagnostic tool. The 12-month standardized treatment composed of INH and Streptomycin was used to treat TB and patients were hospitalized.

In 1978, sputum microscopy as a primary TB diagnostic tool and ambulatory treatment were adopted as policies of the organized National TB Control Program (NTP). The short course chemotherapy composed of Isoniazid, Rifampicin, and Pyrazinamide was prescribed as the indicative mode of treatment over a period of six (6) months since 1987. Public-private mix DOTS (PPMD) was implemented in 2003 together with DOTS certification and accreditation of health facilities. Guidelines for the diagnosis and treatment of children was issued by DOH in 2004.[8] Management of multi-drug resistant TB cases started in 1999 and was mainstreamed into the NTP in 2008 through the integration of Programmatic Management of Drug-resistant -TB (PMDT) into NTP.[9] In 2011, the NTP introduced rapid TB diagnostic tools such as Line Probe Assay (LPA), Mycobacterium Growth Indicator Tube (MGIT) and Xpert MTB/RIF.

Current key initiatives to respond to the TB problem

The overarching strategy of the NTP is the DOTS or directly observed treatment short course that was started in the country in 1996. It has five basic elements, (a) availability of quality assured sputum microscopy, (b) uninterrupted supply of anti-TB drugs, (c) supervised treatment, (d) patient and program monitoring, and (e) political will. This was expanded under the WHO-endorsed STOP TB strategy that the country adopted from 2006 – 2010. In 2010, DOH issued the 2010 – 2016 Philippine Plan of Action to Control TB (PhilPACT) as the roadmap for controlling TB.

Key Initiatives of the NTP

1. **Public-private mix DOTS (PPMD)** – Engagement of the private sector such as private practitioners, pharmacies, and hospitals to adopt the NTP policies and guidelines and, hence, support the TB control efforts. PPMD staff were trained on TB-DOTS including the referral system. They either manage TB cases or refer them to other DOTS facilities. Around 6% of total TB cases nationwide were contributed by this initiative in 2008.

2. **Enhanced hospital TB-DOTS** – Strengthening of the internal and external referral systems and quality of TB diagnosis and treatment in hospitals.[10] Hospitals could either act as a referring hospital or DOTS-providing hospital. All or most of the TB cases are referred to the DOTS facilities and the outcomes are tracked. A pilot study from 2010-2012 showed that 73% of around 13,000 TB cases were successfully referred to health centers and RHUs.

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3. **Programmatic Management of Drug-resistant TB (PMDT)** – Provision of diagnostic and treatment services to drug-resistant TB through the treatment centers, satellite treatment centers and treatment sites. The NTP coordinates PMDT while the Lung Center of the Philippines (LCP) is responsible for research and capability-building. In 2012, only 23% of estimated MDR-TB cases had been provided with quality assured second line anti-TB drugs.

4. **TB HIV collaborative activities** – Close coordination between the NTP and National AIDS/STI Prevention and Control Program (NASPCP) to provide services to those patients with TB and HIV co-infection. Key activities include provider-initiated HIV counselling and testing (PICT) for TB patients and screening for TB among people living with HIV (PLHIV).

5. **TB in jails/prisons** - Ensuring access to TB diagnosis and treatment by the inmates of jails and prisons. The Department of Justice (DOJ) through the Bureau of Corrections (BuCor) and the Department of Interior and Local Governments (DILG) through the Bureau of Jail Management and Penology (BJMP) coordinates with DOH in implementing this program.

6. **TB-DOTS certification and accreditation** – Ensuring the provision of quality TB services and generating financial support through the PhilHealth TB-DOTS outpatient benefit package. DOTS facilities are certified by DOH through the ROs based on ten DOTS standards. These facilities are later accredited by PhilHealth. Reimbursements amounting to PHP 4, 000 per new TB patient from PhilHealth could be used for the referring physician, purchase of other drugs, support for EQA, monetary incentive to health workers and other activities that will improve program implementation.

7. **Expansion of TB laboratory services** – Enabling better access to TB microscopy services through the establishment of more TB microscopy centers such as those in the hospitals and in the private sector. There are currently 18 culture centers. Plans are underway to expand this number to 29 culture centers by 2016. There are currently three (3) DST centers, with plans equally underway to expand to seven (7) by 2016. Sixteen health facilities were provided with Xpert MTB/RIF – a new rapid diagnostic tool that detects rifampicin resistance in just two hours. There are plans to expand access to Xpert MTB/RIF through the provision of at least one (1) machine per province or highly urbanized city.

8. **Community TB care** – Ensuring community participation to improve TB diagnosis and management. TB task forces consisting of former TB patients, community volunteers and members of faith-based organizations were organized to educate the community about TB, refer presumptive TB to DOTS facilities, and act as treatment partners. This also includes the formation and strengthening of TB patient support groups.

NTP Performance

The Philippines subscribes to the Millennium Develop Goal (MDG) set by the United Nations (UN) that must be achieved by 2015. Based on the 2013 WHO Global TB report, the status of TB MDGs and STOP TB strategy goals are as follows: [11]

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Table No. 2 - Impact Indicators, Baseline Compared with Current Performance

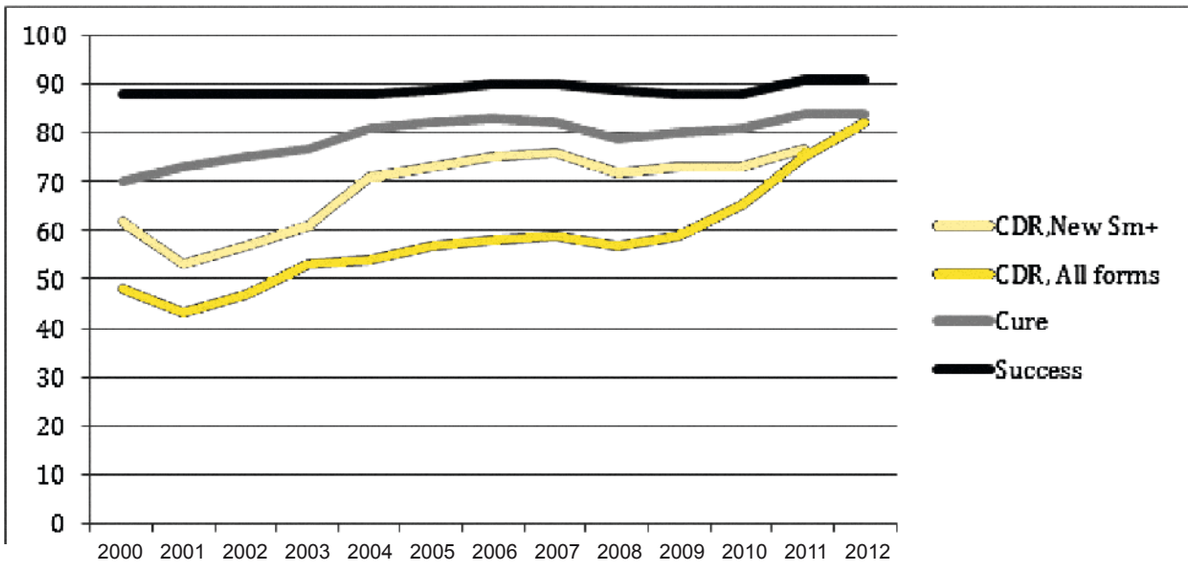
Indicator	Baseline in 1990 (Rate Per 100,000)	2012 (Rate Per 100,000)	2012 (Estimated number)
TB incidence	393	265	260,000
TB prevalence	1,000	461	450,000
TB mortality	55	24	23,000

According to the WHO, the Philippines is one of the seven countries that have already achieved the MDGs in 2012.

Two major indicators are used to measure the progress of TB control – the case detection rate (CDR) and the treatment success rate (TSR). In 2010, the WHO strongly suggested that CDR of all forms of TB be used instead of the CDR of new smear-positive TB cases since the incidence of the latter group is quite uncertain. Internationally, TSR is used instead of the cure rate.

By 2012, the country's CDR, all forms, was 82% while the treatment success rate was 90%.[12] CDR by region varied from 46% to 114% while Treatment Success Rate varied from 71% to 94%. Figure 2 below show the trend of program performance from 2000 to 2011.

Figure No. 2 - Trends in TB Case Detection Rate, Cure Rate and Treatment Success Rate. Philippines. 2000-2012



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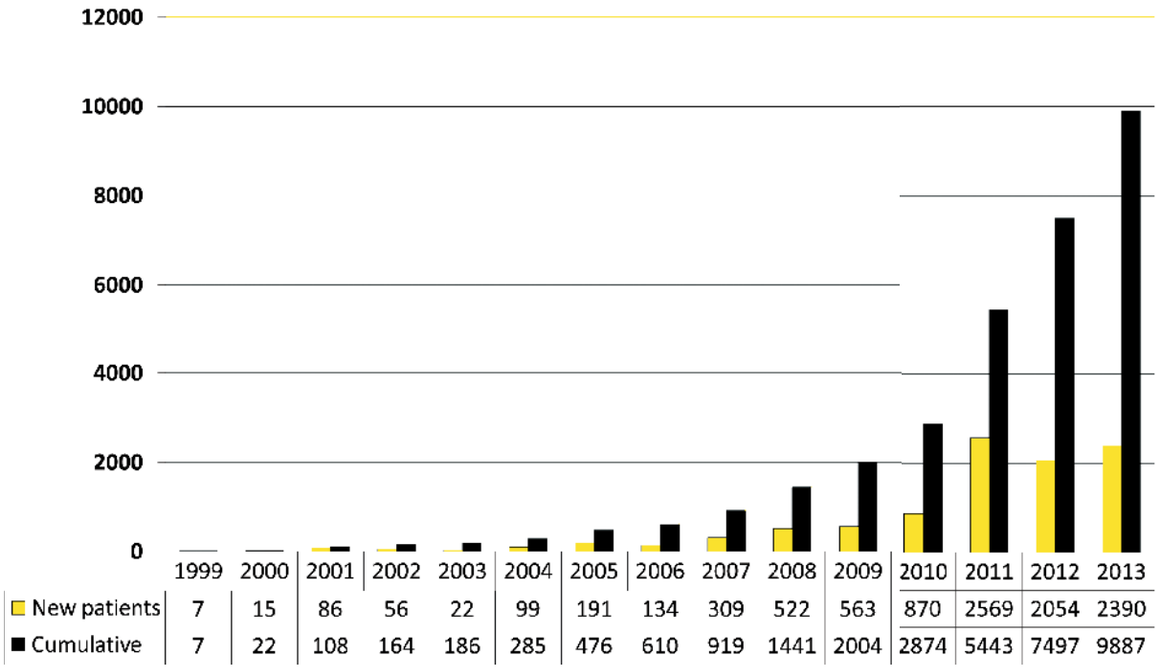
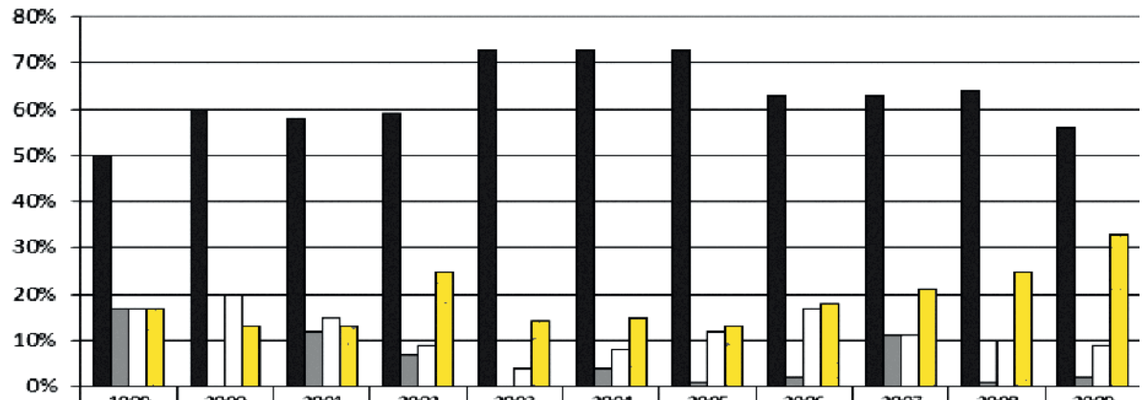
For PMDT, enrolment of DR-TB cases continuously increased since inception in 1999 *(see **Figure 3** below)*. To date, there had been a total of 9,887 DR-TB patients enrolled in treatment protocols with more than 2,000 patients enrolled annually since 2011. However, case holding is the major challenge, as the rate of default continued to increase annually *(see **Figure 4** below)*.

Figure No. 3 - DR-TB Cases Initiated on Treatment Annually and Cumulatively under PMDT, Philippines, 1999-2013.



	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
New patients	7	15	86	56	22	99	191	134	309	522	563	870	2569	2054	2390
Cumulative	7	22	108	164	186	285	476	610	919	1441	2004	2874	5443	7497	9887

Figure No. 4 - Treatment Outcomes of DR-TB Cases Under PMDT. Philippines, 1999-2009.



	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Success	50%	60%	58%	59%	73%	73%	73%	63%	63%	64%	56%
Failure	17%	0%	12%	7%	0%	4%	1%	2%	11%	1%	2%
Died	17%	20%	15%	9%	4%	8%	12%	17%	11%	10%	9%
Default	17%	13%	13%	25%	14%	15%	13%	18%	21%	25%	33%

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Vision, goals, objectives and strategies of the National TB Control Program

Based on the updated 2010 – 2016 Philippine Plan of Action to Control TB (PhilPACT), the NTP's vision, goals, targets and objectives are as follows[13]:

Vision: TB-free Philippines

Goal: By 2016, the following should have been achieved;

Incidence Rate:	246/100,000
Prevalence Rate:	414/100,000
Mortality Rate:	23/100,000

Targets by 2016:

Case Detection Rate, all forms	90%
Treatment success rate, all forms	90%
Case Detection Rate, MDR-TB	62% (of estimated MDR among notified TB cases)
Treatment success rate of MDR-TB cases	75%

Objectives and Strategies:

Table No. 3 - PhilPACT Objectives and Strategies

PhilPACT Objectives (UHC pillars)	Strategies
1. Reduce local variation in TB control performance (Governance and health information).	1. Localize implementation of TB control. 2. Monitor health system performance.
2. Scale up and sustain coverage of DOTS implementation (Health service delivery and human resource).	3. Engage both public and private health care providers. 4. Promote and strengthen positive behaviour of communities. 5. Address MDR-TB, TB/HIV, and needs of vulnerable population.
6. Ensure provision of quality TB services (Regulation)	6. Regulate and make available quality TB diagnostic tests and drugs. 7. Certify and accredit TB care providers.
8. Reduce out-of-pocket expenses related to TB care (Financing)	8. Secure adequate funding and improve allocation and efficiency of fund utilization.

The updated plan contains 32 performance indicators.

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Roles and Functions of Different Offices Organizations and Health Workers Involved in NTP

The NTP is coordinated and implemented by various organizations. The Table below states the specific roles of each organization.

Table No. 4 - Roles and Functions of Collaborating Agencies

Office	Functions of the Office/Staff
Department of Health	**Infectious Disease for Prevention and Control Division through the NTP staff** • Formulates national policies, standards, plans and programs on TB control. • Ensures allocation of budget for program implementation. • Sets policies and standards for DOTS certification. • Responsible for the selection, quantification, allocation and monitoring of anti-TB drugs and supplies. • Coordinates with COBAC and MMD for the procurement and distribution of NTP logistics. • Exercises overall coordination among all NTP stakeholders. • Coordinates the formulation and implementation of the advocacy, communication and social mobilization plan and activities with the National Center for Health Promotion. • Provides technical support to ROs and LGUs including capacity building for the regional staff. • Manages the consolidation and analysis of data and dissemination of TB information. • Conducts regular monitoring and evaluation of the program. • Coordinates/conducts operational/clinical researches on TB **Regional Offices through the regional NTP coordinators** • Develop regional work and financial plan. • Ensure dissemination of and compliance to NTP policies and standards. • Conduct advocacy, social mobilization and communication activities. • Exercise overall coordination among regional NTP stakeholders. • Ensure adequacy of logistics such as anti-TB drugs and laboratory supplies • Provide regular TA to provinces and cities including capability-building. • Monitor and evaluate implementation of NTP. • Collate and analyze NTP reports. • Submit regularly all NTP reports to IPPCD thru the KMITS using the ITIS.

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Local government units - provincial/city level	**Provincial/City Health Office through the designated Provincial/TB coordinators** • Develop provincial/city plan, policies and programs on TB control. • Provide and mobilize resources for the implementation of the TB control efforts. • Implement advocacy, social mobilization and communication activities. • Engage and organize partners from both the public and private sector to support NTP. • Manage the drugs and supplies for the provinces or cities to ensure uninterrupted supply. • Conduct capability-building activities. • Monitor, supervise and evaluate implementation of NTP. • Collate, analyse and submit quarterly reports. • Manage the implementation of QA for laboratory. • Mobilize resources for existing TBDC or other forms of improving diagnosis of smear-negative TB cases.
LGU - municipal/city level and other health facility	**Rural Health Units/Health Centers and other DOTS facilities through their staff** • Develop local plan to control TB. • Conduct advocacy, social mobilization and communication activities. • Provide diagnostic services to presumptive TB most especially the DSSM. • Participate in the external quality assessment for DSSM. • Ensure adequacy of first line anti-TB drugs and laboratory supplies. • Register TB cases and initiate treatment. • Ensure that patient treatment is supervised and monitored. • Fill-up and maintain different NTP records. • Prepare, review and submit NTP reports. • Refer cases to appropriate facilities based on their needs. • Refer presumptive DR-TB to PMDT facilities or provide services for DR-TB cases.

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Hospitals (under DOH, LGU or private)	**Hospitals through the hospital TB coordinators** • Develop and implement plans and policies on TB-DOTS implementation. • Establish, strengthen and maintain the internal and external TB referral system. • Provide TB diagnostic, treatment and counselling services to patients according to national policies and international standards. • Participate in the EQA for DSSM. • Collaborate with other DOTS facility to ensure that referred TB cases are properly managed. • Coordinate with the regional, provincial or city TB coordinators to ensure adequate drugs and supplies. • Submit quarterly NTP reports to CHO/PHO. Mobilize resources to support TB control.
Partners (CUP agencies, technical assistance providers, donor agencies, etc.)	• Participate in the formulation of TB control plans, policies, guidelines and standards. • Conduct advocacy, social mobilization and communication activities on TB specially for the private sector. • Participate in the initiation and implementation NTP initiatives such as PPMD, PMDT, TB in children, etc. • Assist in mobilization and management of resources including human resources. • Participate in the certification of private DOTS facilities. • Participate in monitoring and evaluation of the implementation of NTP initiatives. • Provide technical and/or financial assistance to different NTP initiatives.

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Functions of Health Service Providers

At the service delivery points, each of the different types of health workers from physicians to barangay health workers contribute to NTP implementation and progress. Below are the specific functions of each type of health worker.

Table No. 5 - Roles and Functions of Health Workers

Physician	• Organize planning and evaluation of TB control activities in DOTS facilities. • Ensure that all staff have been trained on TB DOTS. • Supervise staff to ensure proper implementation of NTP policies and guidelines. • Evaluate presumptive TB based on clinical and laboratory evidence. • Prescribe appropriate treatment. • Manage adverse reactions. • Provide continuous health education and counseling to all TB patients under treatment. • Refer TB patients to other health facilities if needed. • Encourage community and family support to TB control. • Mobilize and utilize resources in the area for TB control. • Coordinate with the local chief executives to ensure funds and personnel are available for program implementation. • Coordinate with other TB stakeholders to ensure that all detected TB cases are reported and services provided are within the NTP policies and guidelines.
Nurse	• Manage the process of detecting TB cases in coordination with other staff. • Assist the physician in counselling and initiating treatment of TB patient. • Accomplish the NTP treatment card. • Agree with TB patient the mode of DOT including the treatment partner. • Supervise midwives to ensure proper implementation of DOTS. • Maintain and update the Presumptive TB Masterlist and TB register. • Facilitate requisition and distribution of anti-TB drugs, laboratory supplies and forms. • Maintain records on logistics and ensure proper storage of drugs. • Provide continuous health education to all patients. • Conduct training of health workers and community volunteers. • Prepare, analyse and submit the quarterly reports.

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Midwife	• Under the supervision of the nurse, do the following: - Identify presumptive TB patients and ensure proper collection and transport of sputum specimen. - Refer all diagnosed TB patients to physician and nurse for clinical evaluation and initiation of treatment. - Maintain and update NTP treatment cards. • Implement DOT with treatment partners: - Provide continuous health education to patients. - Supervise intake of anti-TB drugs. - Collect sputum for follow-up examination. - Report and retrieve defaulters within 2 days. - Refer patients with adverse reactions to physician for evaluation and management. - Supervise and mentor treatment partners.
Medical Technologists/ Microscopists	• Do DSSM for diagnosis and follow-up. • Perform Xpert MTB/RIF examination as needed. • Perform HIV testing for TB patients as needed. • Inform the referring health worker or facility of the result of DSSM or Xpert MTB/RIF. • Maintain and update the NTP laboratory register. • Prepare quarterly report on laboratory services and submit to the nurse or physician. • Do internal quality control within the laboratory. • Prepare and submit quarterly laboratory supplies requirement to the nurse. • Store sputum smears for sampling of the provincial/city TB coordinators for blinded re-checking. • Ensure that microscope and Xpert MTB/RIF machine are properly maintained and functional.
Barangay Health Workers/Community Health Volunteers	• Identify and refer presumptive TB to DOTS facility for sputum collection. • Collect and ensure transport of sputum specimen. • Assist health staff in doing DOT to TB patient. • Keep and update the NTP ID cards. • Report and retrieve defaulters within two days. • Attend regular consultation with the health personnel, together with patient and treatment partners. • Refer patient with adverse reaction to the health personnel. • Provide health education to the patient, family members and the community.

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2

CHAPTER

Case Finding

I. INTRODUCTION

Case finding is the identification and diagnosis of TB cases among individuals with signs and symptoms presumptive of tuberculosis. The current approach to case finding includes passive and intensified case finding. The available tests utilized by the program for diagnosing TB are direct sputum smear microscopy, TB culture and drug susceptibility test, tuberculin skin test and rapid molecular diagnostic tests.

Direct sputum smear microscopy (DSSM) is fundamental to the detection of infectious cases and is recommended for case finding among adults and children who can expectorate. It is the primary diagnostic method adopted by the NTP among such individuals because:

1. It provides a definitive diagnosis of active TB;
2. The procedure is simple;
3. It is economical; and,
4. A microscopy center could be put up even in remote areas.

DSSM serves as one of the bases for categorizing TB cases according to standard case definition. This is also used to: a) monitor progress of patients with TB while they are on anti–TB treatment; and, b) confirm cure at the end of treatment.

CXR is used to complement bacteriologic testing in making a diagnosis. However, it has low specificity and does not differentiate drug-susceptible from drug-resistant disease.

TB culture and drug susceptibility test (DST) using solid (Ogawa or Lowenstein Jensen) or liquid media (MGIT) is a routine diagnostic test for drug-resistant TB cases under the NTP. It is also used for TB prevalence surveys, drug resistance surveillance, research and other special cases.

Tuberculin skin test (TST) is a basic screening tool for TB infection among children using purified protein derivative (PPD) tuberculin solution to trigger a delayed hypersensitivity reaction among those previously infected. Also known as the PPD test or Mantoux test, it is one of the criteria used in determining disease activity among children.

Rapid molecular diagnostic tests endorsed by the WHO will be utilized by the NTP. Currently, WHO-endorsed available diagnostic tests in the country are Xpert MTB/RIF and Line-Probe Assay (LPA) for first line drugs. Xpert MTB/RIF assay is a rapid test that detects *Mycobacterium tuberculosis* and rifampicin resistance.

II. OBJECTIVE

Early identification and diagnosis of TB cases.

III. DEFINITION of TERMS

A. DOTS facility – A health care facility, whether public or private, that provides TB-DOTS services in accordance with the policies and guidelines of the National TB Control Program (NTP), DOH.

B. Turnaround time – The time from collection of first sputum sample to initiation of treatment for TB. The desired turnaround time is five (5) working days.

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C. **Passive case finding** – When symptomatic patients are screened for disease activity upon consultation at the health facility.

D. **Active case finding** – A health worker's purposive effort to find TB cases in the community or among those who do not consult with personnel in a DOTS facility.

E. **Intensified case finding** – Active case finding among individuals belonging to special or defined populations (e.g., high-risk groups including those who consult or find themselves at the facility for other purposes):

1. **Close contact** – A person who shared an enclosed space, such as the household, a social gathering place, workplace or facility, for extended periods within the day with the index case during the 3 months before commencement of the current treatment episode.[14]
2. **High-risk clinical groups** – Individuals with clinical conditions that put them at risk of contracting TB disease, particularly those with immune-compromised states (e.g., HIV/AIDS, diabetes, end-stage renal disease, cancer, connective tissue diseases, autoimmune diseases, silicosis, patients who underwent gastrectomy or solid organ transplantation and patients on prolonged systemic steroids).[15]
3. **High-risk populations** – Persons with known high incidence of TB, particularly those in closed environments or living in congregate settings that promote easy disease transmission (e.g., inmates, elderly, Indigenous Peoples, urban/rural poor).[15]

F. **Children** – Any person who is less than 15 years old.

G. **Contact investigation** – A systematic process intended to identify previously undiagnosed cases of TB among the contacts of an index case.[14]

H. **Index case** – The initially-identified TB case of any age in a specific household or other comparable setting in which others may have been exposed. The index case may or may not be the source case.[14]

I. **Source case**- A person with infectious TB who is responsible for transmitting TB to another person. A source case could be any of the following: a smear-positive TB case (adult or child) undergoing treatment for TB, a person (usually adult) who has undergone TB treatment in the past, or a person (usually adult) who is not yet on treatment but has laboratory results suggestive of active TB.[14]

J. **Presumptive TB** – Any person whether adult or child with signs and/or symptoms suggestive of TB whether pulmonary or extra-pulmonary, or those with CXR findings suggestive of active TB. [16] *(Refer to **Identification of Presumptive TB** on page 21 for operational definition of signs and symptoms.)*

K. **Presumptive Drug-resistant TB (DR-TB)** – Any person whether adult or child, who belongs to any of the DR-TB high-risk groups, such as: re-treatment cases, new TB cases that are contacts of confirmed DR-TB cases or non-converter of Category I, and people living with HIV with signs and symptoms of TB.

L. **TB exposure** – A condition in which an individual is in close contact with an active adultTB case, but without any signs and symptoms of TB, with negative TST reaction, and no radiologic and laboratory findings suggestive of TB.

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M. TB infection or latent TB infection (LTBI) – A condition in which an individual has no signs and symptoms presumptive of TB nor radiologic or laboratory evidence, but has a positive TST reaction.

N. TB disease – A presumptive TB who after clinical and diagnostic evaluation is confirmed to have TB.

Classifications of TB Disease[16]

1. Classification based on bacteriological status

a. Bacteriologically-confirmed – A TB patient from whom a biological specimen is positive by smear microscopy, culture or rapid diagnostic tests (such as Xpert MTB/RIF).

b. Clinically-diagnosed – A PTB patient who does not fulfill the criteria for bacteriological confirmation but has been diagnosed with active TB by a clinician or other medical practitioner who has decided to give the patient a full course of TB treatment. This definition includes cases diagnosed on the basis of CXR abnormalities or suggestive histology, and extra-pulmonary cases without laboratory confirmation.

2. Classification based on anatomical site

a. Pulmonary TB (PTB) – Refers to a case of tuberculosis involving the lung parenchyma. A patient with both pulmonary and extra-pulmonary TB should be classified as a case of pulmonary TB.

b. Extra-pulmonary TB (EPTB) – Refers to a case of tuberculosis involving organs other than the lungs (e.g., larynx, pleura, lymph nodes, abdomen, genito-urinary tract, skin, joints and bones, meninges). Histologically-diagnosed EPTB through biopsy of appropriate sites will be considered clinically-diagnosed TB. Laryngeal TB, though likely sputum smear-positive, is considered an extra-pulmonary case in the absence of lung infiltrates on CXR.

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Table No. 6 - TB Disease Classification Based on Anatomical Site and Bacteriological Status

Anatomical Site	Bacteriological status	Definition of Terms	
Pulmonary (PTB)	Bacteriologically-confirmed	Smear-positive	A patient with at least one (1) sputum specimen positive for AFB, with or without radiographic abnormalities consistent with active TB
		Culture-positive	A patient with positive sputum culture for MTB complex, with or without radiographic abnormalities consistent with active TB
		Rapid diagnostic test-positive	A patient with sputum positive for MTB complex using rapid diagnostic modalities such as Xpert MTB/RIF, with or without radiographic abnormalities consistent
	Clinically-diagnosed	A patient with two (2) sputum specimens negative for AFB or MTB, or with smear not done due to specified conditions but with radiographic abnormalities consistent with active TB; and there has been no response to a course of empiric antibiotics and/or symptomatic medications; and who has been decided (either by the physician and/or TBDC) to have TB disease requiring a full course of anti-TB chemotherapy **OR** A child (less than 15 years old) with two (2) sputum specimens negative for AFB or with smear not done, who fulfills three (3) of the five (5) criteria for disease activity (i.e., signs and symptoms suggestive of TB, exposure to an active TB case, positive tuberculin test, abnormal chest radiograph suggestive of TB, and other laboratory findings suggestive of tuberculosis); and who has been decided (either by the physician and/or TBDC) to have TB disease requiring a full course of anti-TB chemotherapy **OR** A patient with laboratory or strong clinical evidence for HIV/AIDS with two (2) sputum specimens negative for AFB or MTB or with smear not done due to specified conditions but who, regardless of radiographic results, has been decided (either by physician and/or TBDC) to have TB disease requiring a full course of anti-TB chemotherapy.	

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Extra-pulmonary (EPTB)	Bacteriologically-confirmed	A patient with a smear/culture/rapid diagnostic test from a biological specimen in an extra-pulmonary site (i.e., organs other than the lungs) positive for AFB or MTB complex
	Clinically-diagnosed	A patient with histological and/or clinical or radiologic evidence consistent with active extra-pulmonary TB and there is a decision by a physician to treat the patient with anti-TB drugs

3. Classification based on history of previous treatment

a. New case – A patient who has never had treatment for TB or who has taken anti-TB drugs for less than one (<1) month. Isoniazid preventive therapy or other preventive regimens are not considered as previous TB treatment.

b. Retreatment case – A patient who has been previously treated with anti-TB drugs for at least one (1) month in the past.

4. Classification based on drug-susceptibility testing

a. Monoresistant-TB – Resistance to one first-line anti-TB drug only.

b. Polydrug-resistant TB – Resistance to more than one first-line anti-TB drug (other than both Isoniazid and Rifampicin).

c. Multidrug-resistant TB (MDR-TB) – Resistance to at least both Isoniazid and Rifampicin.

d. Extensively drug-resistant TB (XDR-TB) – Resistance to any fluoroquinolone and to at least one of three second-line injectable drugs (Capreomycin, Kanamycin and Amikacin), in addition to multidrug resistance.

e. Rifampicin-resistant TB (RR-TB) – Resistance to Rifampicin detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs. It includes any resistance to Rifampicin, whether monoresistance, multidrug resistance, polydrug resistance or extensive drug resistance.

IV. POLICIES

A. Both passive and intensified case finding activities shall be implemented in all DOTS facilities.

B. Intensified case finding shall be done among close contacts, high risk clinical groups, and high-risk populations. Priority for close contact investigation shall be among household members. If feasible, screen other contacts of bacteriologically-confirmed TB cases, DR-TB patients and index childhood TB cases.[14, 15]

C. Direct Sputum Smear Microscopy (DSSM), whether by light or fluorescence microscopy, shall be the primary diagnostic tool in NTP case finding. All presumptive TB who could expectorate - whether pulmonary or extra-pulmonary - shall undergo DSSM prior to treatment initiation. However, non-compliance with DSSM should not be a deterrent to treatment initiation among EPTB cases.

D. All presumptive TB should undergo DSSM unless this is not possible due to the following situations:

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- Mentally incapacitated as decided by a specialist or medical institution
- Debilitated or bedridden
- Children unable to expectorate
- Patients unable to produce sputum despite sputum induction

E. Two sputum specimens of good quality shall be collected, either as frontloading (i.e., spot-spot one-hour apart) or spot-early morning specimens, based on the patient's preference.[17] The two specimens should be collected at most within 3 days.

F. Available rapid diagnostic test (e.g., Xpert MTB/RIF) shall be used for TB diagnosis among presumptive DR-TB, PLHIV with signs and symptoms of TB, smear-negative adults with CXR findings suggestive of TB smear-negative children and EPTB.[18]

G. If Xpert MTB/RIF is inaccessible, smear-negative patients shall be evaluated by the DOTS physician who shall decide using clinical criteria and best clinical judgment. If in doubt, the case may be referred to a clinician/specialist within the area or to a TB Diagnostic Committee (TBDC) as long as the recommendation could be made within two (2) weeks.

H. Tuberculin skin test (TST) shall not be used as the sole basis for TB diagnosis. It shall be used as a screening tool for children. A 10mm induration is considered a positive TST reaction. Only trained health worker shall do the testing and reading.

I. All DOTS facilities, whether public or private are encouraged to establish their own in-house microscopy unit. However, in cases where this is not possible, access to an officially linked NTP-accredited microscopy unit would be acceptable.

J. All municipalities and cities shall ensure access to quality-assured microscopy services. One microscopy center shall cater to, at most, 100,000 population. In difficult to access areas, remote smearing stations (RSS) manned by trained volunteers could be established.

K. All laboratories providing DSSM services or other TB diagnostic tests, whether public or private, shall participate in the External Quality Assessment (EQA) system of the NTP.

L. All presumptive DR-TB shall be referred to the nearest DOTS facility with PMDT services for screening or an Xpert MTB/RIF site for testing.

M. All PLHIV shall be screened for TB co-infection.

V. PROCEDURES

A. Identification of Presumptive TB

1. Note the patient's general information on the individual treatment record or patient's chart.

2. Ask or check for **clinical signs and symptoms** to identify a presumptive TB.

   a. For patients **15 years old and above**, a presumptive TB has any of the following:

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i. Cough of at least 2 weeks duration with or without the following symptoms:

- Significant and unintentional weight loss;
- Fever;
- Bloody sputum (hemoptysis);
- Chest/back pains not referable to any musculoskeletal disorders;
- Easy fatigability or malaise;
- Night sweats; and,
- Shortness of breath or difficulty of breathing.

ii. Unexplained Cough of any duration in:

- A close contact of a known active TB case;
- High-risk clinical groups (e.g., HIV/AIDS, diabetes, end-stage renal disease,cancer connective tissue diseases, autoimmune diseases, silicosis, patients who underwent gastrectomy or solid organ transplantation and patients on prolonged systemic steroids); and,
- High risk populations (e.g., elderly, urban poor, inmates and other congregate settings).

b. For patients **below 15 years old**, a presumptive PTB has any of the following:

i. At least three (3) of the following clinical criteria:

- Coughing/wheezing of 2 weeks or more, especially if unexplained;
- Unexplained fever of 2 weeks or more after common causes such as malaria or pneumonia have been excluded;
- Loss of weight/failure to gain weight/weight faltering/loss of appetite;
- Failure to respond to 2 weeks of appropriate antibiotic therapy for lower respiratory tract infection;
- Failure to regain previous state of health 2 weeks after a viral infection or exanthema (e.g., measles); and,
- Fatigue, reduced playfulness, or lethargy (e.g., child has lost his/her normal energy).

ii. Any one (1) of the above signs and symptoms (e.g., clinical criteria) in a child who is a close contact of a known active TB case.

c. CXR findings suggestive of PTB, with or without symptoms, regardless of age.

d. Presumptive extra-pulmonary TB may have any of the following:

- Gibbus, especially of recent onset (resulting from vertebral TB);
- Non-painful enlarged cervical lymphadenopathy with or without fistula formation;

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- Neck stiffness (or nuchal rigidity) and/or drowsiness suggestive of meningitis that is not responding to antibiotic treatment, with a sub-acute onset or raised intracranial pressure;
- Pleural effusion;
- Pericardial effusion;
- Distended abdomen (i.e., big liver and spleen) with ascites;
- Non-painful enlarged joint; and
- Signs of tuberculin hypersensitivity (e.g., phlyctenular conjunctivitis, erythema nodosum).

3. Ask and verify the following:

   a. History of previous anti-TB treatment and its details
   b. Exposure to active TB cases or presumptive TB (including MDR-TB, if applicable) within the workplace, family or household
   c. Presence of clinical or other high-risk factors (e.g., HIV/AIDS, diabetes, end-stage renal disease, cancer, connective tissue diseases, autoimmune diseases, silicosis, patients who underwent gastrectomy or solid organ transplantation and patients on prolonged systemic steroids)

4. Once identified as a presumptive TB, record the patient in **Form 1. Presumptive TB Masterlist**.

B. Collection and Transport of Sputum Specimens

1. Motivate the presumptive TB to undergo DSSM. Explain the importance of the procedure and that of submitting two (2) sputum specimens. The only contraindication to collecting sputum for DSSM is massive hemoptysis which is expectoration of large volumes of blood (200-600 ml in 24 hours) from the respiratory tract.[19] Blood streaked sputum can still be examined.

   For PLHIV with signs and symptoms of TB, refer the patient to a DOTS facility with PMDT services for screening or to an Xpert MTB/RIF site for testing.

2. Prepare the sputum cups and the **Form 2a. NTP Laboratory Request Form**. Label the body of the sputum cup (i.e., not the lid), indicating patient's complete name, and order of specimen collection (i.e., 1st, and 2nd).

   For Xpert MTB/RIF, prepare a sputum cup or 50ml conical tube and **Form 2a. NTP Laboratory Request Form**. Label the body of the sputum cup/conical tube, indicating patient's complete name and indicating specimen for Xpert.

3. Demonstrate how to produce quality sputum. Mucus from the nose and throat, and saliva from the mouth are NOT good specimens. Advise the patient to:

   a. Clean mouth by thoroughly rinsing with water. Food particles or other solid particulates may inhibit the test for Xpert MTB/RIF.

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b. Breathe deeply, hold breath for a second or two, and then exhale slowly. Repeat the entire sequence two (2) more times.

c. Cough strongly after inhaling deeply for the third time and try to bring up sputum from deep within the lungs.

d. Expectorate the sputum in the sputum cup or conical tube.

e. Collect at least 1 teaspoonful (5-10ml) for DSSM. For Xpert MTB/RIF, sputum sample should not be less than one (1) ml.

f. Examine the specimen to see that it is not just saliva. Repeat the process if necessary.

Sputum induction for individuals unable to expectorate should be done only in facilities where the staff is trained, supplies and equipment are available, and infection control measures are in place.

4. Observe proper precautions against infection during the demonstration. Stay behind the patient. Collect specimen in a well-ventilated designated sputum collection area, or outside the DOTS facility.

5. Collect the first specimen (i.e., spot) at the time of the first consultation. Collect the second spot specimen after at least an hour, or the following morning. If the second sputum specimen is not submitted within three days from the first specimen, a new set of two (2) sputum specimens should be collected unless the first specimen already tests positive for AFB.

6. Check quantity and quality of sputum. Wipe off the external surface of the sputum cup or conical tube if needed and wash your hand thoroughly with soap and water.

7. Seal the sputum cup or conical tube, pack it securely, and transport it to a microscopy center or Xpert MTB/RIF site together with the completely filled up **Form 2a. NTP Laboratory Request Form**.

8. If the specimen cannot be sent to a microscopy unit early enough, prepare the smears immediately and then store them appropriately. Smearing can be done by trained volunteers before transport to the microscopy center.

9. Inform the patient when to return for follow-up consultation regarding the results.

C. Procedure for direct sputum smear microscopy

DSSM may be performed using either conventional Ziehl-Neelsen microscopy or fluorescence microscopy (FM). Fluorescence microscopy using light-emitting diodes (LED) as the microscope light source is also known as LED-FM. Fluorescence microscopy has increased sensitivity and can be five (5) times faster.

1. Record the patient information in the **Form 3. NTP Laboratory Register (Microscopy and GX)**.

2. Smear, fix, and stain each slide.

3. Read each slide and interpret the result. Table 2 below shows the interpretation of results for both conventional and fluorescence microscopy.

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Table No. 7 - DSSM Results and Interpretation

IUATLD/ WHO Scale	Conventional Light Microscopy	Fluorescence Microscopy	
		200x magnification 1 length = 30 fields	400x magnification; 1 length = 40 fields
0	No AFB seen in 300 oil immersion field (OIF)	No AFB observed/1 length	No AFB observed/1 length
Confirmation required*		Confirmation required*	1-2 AFB/1 length
+n	1-9 AFB seen in 100 OIF	5-49 AFB/1 length	3-24 AFB/1 length
1+	10 – 99 AFB seen in 100 OIF	3-24 AFB/1field	1-6 AFB/1 field
2+	1-10 AFB/OIF in at least 50 fields	25-250/1 field	7-60/1 field
3+	>10 AFB/OIF in at least 20 fields	>250 / 1 field	>60 / 1 field

4. Interpret the results of the two specimens and write the final laboratory diagnosis in the lower portion of **Form 2a. NTP Laboratory Request Form** for DSSM and on the Remarks column of **Form 3. NTP Laboratory Register (Microscopy and GX).** Laboratory diagnoses are classified as follows:

   • Positive = At least one sputum smear is positive for AFB;
   • Negative = Both sputum smears are negative for AFB.

5. Send the request form with its corresponding results back to requesting unit within three (3) working days.

D. Procedure for Xpert MTB/RIF

1. Record the patient information in **Form 3. NTP Laboratory Register (Microscopy and Xpert MTB/RIF)**.

2. Prepare the Xpert MTB/RIF cartridge, process the sputum sample and load it in the Xpert MTB/RIF machine. Start the test.

3. When the test is finished, view test result. Xpert MTB/RIF results are reported as follows:

Table No. 8 - Xpert MTB/RIF Results and Interpretation

T	MTB detected, Rifampicin resistance not detected.
RR	MTB detected, Rifampicin resistance detected.
TI	MTB detected, Rifampicin resistance indeterminate.
N	MTB not detected.
I	Invalid/no result/error.

4. Interpret the result and write the final laboratory diagnosis in the lower portion of **Form 2a. NTP Laboratory Request Form** and in **Form 3. NTP Laboratory Register (Microscopy and Xpert MTB/RIF)**.

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5. Send the request form with its corresponding results back to the requesting unit within three (3) working days.

E. Tuberculin skin testing (for patients less than 15 years old)

1. Perform the TST according to the standard set of procedures.

2. Read and interpret the test between 48 to 72 hours from the time it was administered. A positive TST is an area of induration of the skin with diameter of 10mm or more.

F. Diagnosis of extra-pulmonary TB (EPTB)

Extra-pulmonary TB can be diagnosed clinically by the DOTS physician. As necessary, refer presumptive EPTB to a medical specialist and/or facilities capable of performing appropriate diagnostic procedures.

Extra-pulmonary TB can also be confirmed bacteriologically using Xpert MTB/RIF for body fluids such as cerebrospinal fluid (CSF) and gastric aspirate. Tissues/biopsy specimens (e.g., lymph node tissue aspirate) processed in accordance with national policies can also be used. Pleural fluid shall not be used for Xpert MTB/RIF.[20]

G. Decision on diagnosis based on laboratory results *(see Figure No. 5 on page 31)*

1. If sputum smear-positive, classify as **bacteriologically-confirmed PTB**.

2. For patients who are at least 15 years old with negative DSSM results or DSSM not done, refer the patient for CXR.

   a. If CXR findings are suggestive of TB and patient has access to Xpert MTB/RIF, refer the patient to an Xpert MTB/RIF site for testing.

   b. If CXR findings are suggestive of TB but patient has no access to Xpert MTB/RIF or could not expectorate, the DOTS physician will use his best clinical judgment to decide if active TB. Referral to a specialist or a TB Diagnostic Committee may be done if reasonably accessible or able to render a decision within 2 weeks. If the physician or TBDC decides to treat as active TB, classify as **clinically-diagnosed PTB**.

   c. If CXR is normal or not suggestive of TB, investigate for other causes of cough or refer to a specialist.

3. For patients **below 15 years old** who are smear-negative but can expectorate, refer to an Xpert MTB/RIF site if accessible. If patient has no access to an Xpert MTB/RIF site or cannot expectorate, perform TST. If TST is negative, request for CXR.

   a. Decide to treat as active TB if the child has any three of the following criteria[19]
      i. Positive exposure to an adult/adolescent with active TB disease;
      ii. Positive tuberculin test (a positive TST confirms TB infection after exposure);
      iii. Positive signs and symptoms suggestive of TB;
      iv. Abnormal chest radiograph suggestive of TB;
      v. Laboratory findings suggestive or indicative of TB.

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b. If patient fulfills three (3) out of five (5) criteria, classify as **clinically-diagnosed PTB**.

c. If patient does not fulfil at least three (3) out of five (5) criteria, investigate further or refer to a specialist.

4. If Xpert MTB/RIF is done and tests positive for MTB, classify as **bacteriologically-confirmed PTB**. Cases that are Rifampicin-resistant should be referred to a DOTS facility with PMDT services for DR-TB treatment. Cases that are Rifampicin-sensitive may be treated with first line drugs based on registration group *(see **Chapter 2 Case Finding** on page 15)*.

   If Xpert MTB/RIF result is negative for MTB, investigate further or refer to a specialist. The physician may still decide to treat based on the clinical criteria.

   If Xpert MTB/RIF result is invalid/no result/error or indeterminate, investigate the reason for the result. If the error is not due to the machine or module, repeat the test or the physician may decide based on other diagnostic tests (e.g., CXR) or clinical criteria.

5. If diagnosed **EPTB** (either bacteriological, histological or clinical), manage accordingly.

6. Classify all diagnosed TB cases (whether bacteriologically-confirmed or clinically-diagnosed) as new or retreatment cases based on the history of previous treatments. Refer all retreatment cases to a DOTS facility with PMDT services for MDR screening or an Xpert site for testing if not previously done.

7. If a presumptive TB is assessed as **not TB**, evaluate the patient for other differential diagnoses. Re-assess using DSSM if needed. If not symptomatic, assure the patient and advise him/her to follow-up anytime he/she develops symptoms.

H. Intensified case finding

1. Screening household contacts of susceptible TB cases

   a. Once a case is registered for treatment, interview the index case and explain the importance of contact investigation.

   b. Ask for the name of all household members, regardless of age, and list all of them in **Form 4. TB Treatment/IPT Card**.

   c. Instruct index case to bring all household members to the DOTS facility. Household contacts should be evaluated within 7 days from treatment initiation of the index case to ensure prompt diagnosis.

   d. Once the contacts are at the DOTS facility, interview each of them (or their caregivers) for signs and symptoms of TB, and history of TB diagnosis and treatment.

   e. If CXR is available and feasible (e.g., provided for free by the facility, or affordable to the patient), perform CXR on all household members whether symptomatic or not.

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f. All household contacts identified to be a presumptive TB shall be evaluated based on the NTP case finding procedures.

g. All asymptomatic household contacts less than 5 years old of a bacteriologically-confirmed index case shall undergo TST. If TST is negative, these contacts should be given IPT. If TST is positive, rule out TB disease with CXR before giving IPT. *(Refer to **Figure No. 6** on page 32)*

However, if TST and CXR are not available, the child contact of a bacteriologically-confirmed index case can be given IPT based on the physician's clinical assessment.[21]

h. All asymptomatic household contacts less than 5 years old of a clinically-diagnosed index case shall undergo TST. If TST is negative, do not give IPT and advise to seek/consult immediately if signs and symptoms of TB develop. If TST is positive, give IPT.

i. All asymptomatic household contacts 5 years old and above (with normal CXR findings, if done) are advised to seek/consult immediately if signs and symptoms of TB develop.

j. Update **Form 4. TB Treatment/IPT Card** (of the index case) once household contacts have been screened and results of diagnostic procedure become available.

k. All children given IPT are recorded using the separate **Form 4. TB Treatment/IPT Card** and registered in **Form 9. IPT Register**. The procedure for IPT is discussed in **Chapter 4 on the Prevention of TB.**

2. Screening household contacts of DR-TB cases

a. Evaluate all household contacts of diagnosed DR-TB cases by screening for signs and symptoms and CXR.

b. Refer all household contacts identified as presumptive TB to a DOTS facility with PMDT services for DR-TB screening.

c. All household contacts that have no signs and symptoms nor CXR findings should be advised to immediately return to the DOTS facility if signs and symptoms of TB develop.

3. Screening in jails and prisons[22]

a. TB case finding activities among inmates should be implemented during routine procedures that inmates undergo:

i. Upon entry to the jail or prison;
ii. During detention through cough surveillance;
iii. Prior to transfer of inmates to another jail or prison; and,
iv. Prior to release of inmates back to the community.

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b. The specific procedures are outlined and discussed in the policies and guidelines of the Bureau of Jail Management and Penology and the Bureau of Corrections.

4. TB in urban and rural poor areas

The following procedure shall be used by community volunteers, community health teams (CHTs), and BHWs in referring presumptive TB identified in the community during house-to-house visits:

a. Volunteers should be oriented on how to identify possible signs and symptoms of TB. They could utilize this information in identifying presumptive TB during their routine household visits and other activities (e.g., *Operation Timbang*) in the community.

b. For each member of the household with signs and symptoms of TB as identified by the volunteer, a referral form recognized by the local DOTS facility should be accomplished. This referral form could be modifications of any existing community referral forms.

c. The referral form should be given to the patient or caregiver with the instruction that they immediately go to the DOTS facility.

d. Once the patient consults the DOTS facility, the staff should follow the routine diagnostic procedure for TB.

e. Referred patients who do not consult the DOTS facility should be followed-up by the community volunteer.

5. People living with HIV (PLHIV)[23]

a. All PLHIV at the Social Hygiene Clinic or Treatment Hub shall undergo TB screening: symptomatic screening (e.g., cough of any duration, fever, night sweats, loss of weight) and CXR. If symptomatic, sputum shall be collected for Xpert MTB/RIF. *(See **Annex A** on page 154).*

b. TB screening for PLHIV should be done upon HIV diagnosis and annually during follow-up visit.

c. TB treatment shall start once the patient is found to have active TB based on the Xpert MTB/RIF testing or if with radiographic findings consistent with TB.

d. PLHIV with RR-TB shall be referred to a DOTS facility with PMDT services.

e. PLHIV with no active TB (no symptoms, negative for TB in Xpert MTB/RIF and CXR) shall be given IPT for 6 months *(see **Chapter 4. Prevention of TB** on page 53).*

f. All PLHIV given IPT are recorded using **Form 4. TB Treatment/IPT Card** and registered in **Form 9. IPT Register**.

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6. TB during disasters

Following a disaster situation and after the acute relief operations, the objective is to re-establish TB services to reduce mortality and morbidity due to interrupted treatment arising from lack of follow-up, drugs, facilities, and human resource. The strategies to achieve this objective and the algorithm to ensure that all existing TB patients resume treatment will be detailed in the DOH technical guidelines for TB in disasters.

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Figure No. 5 - Diagnostic Algorithm

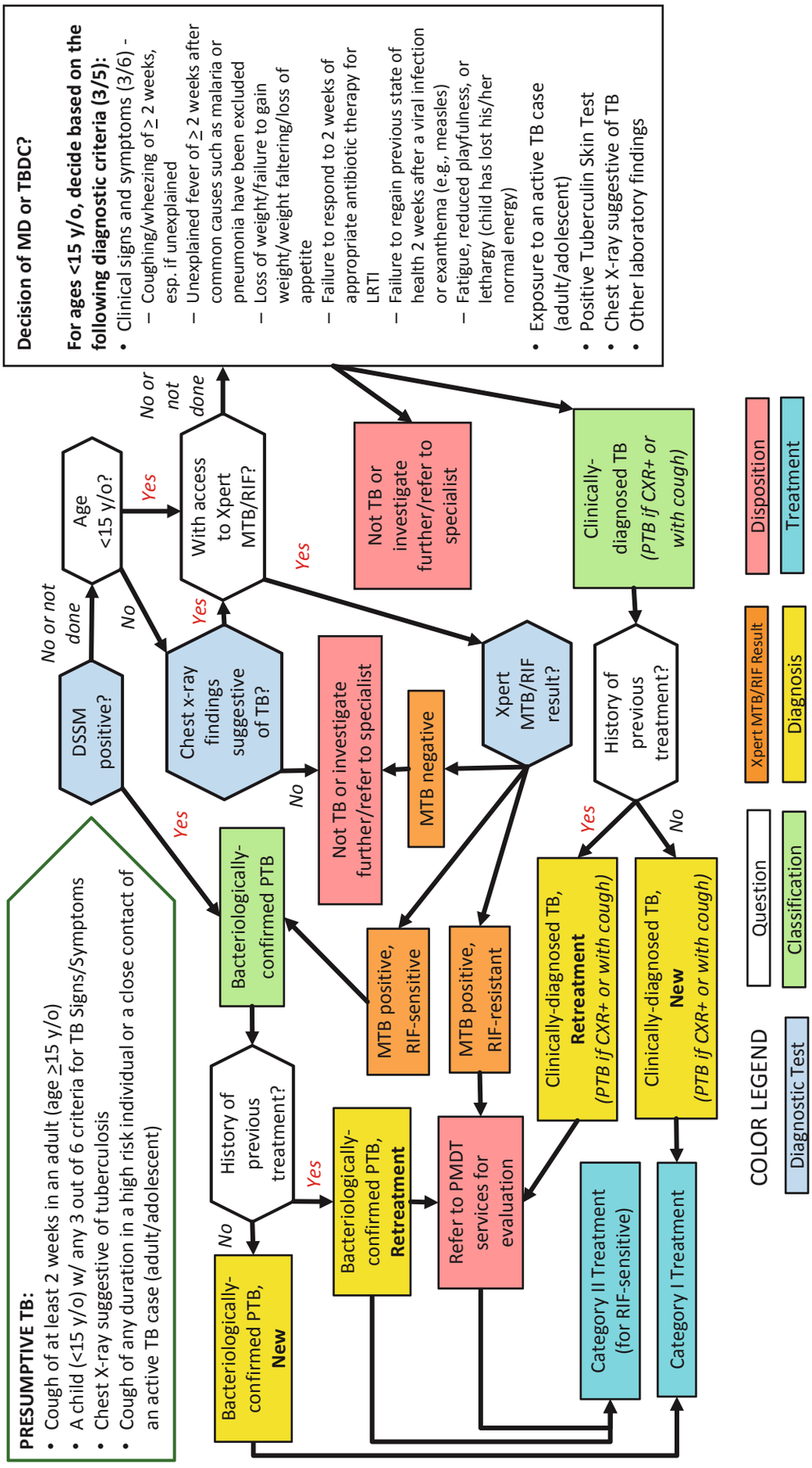

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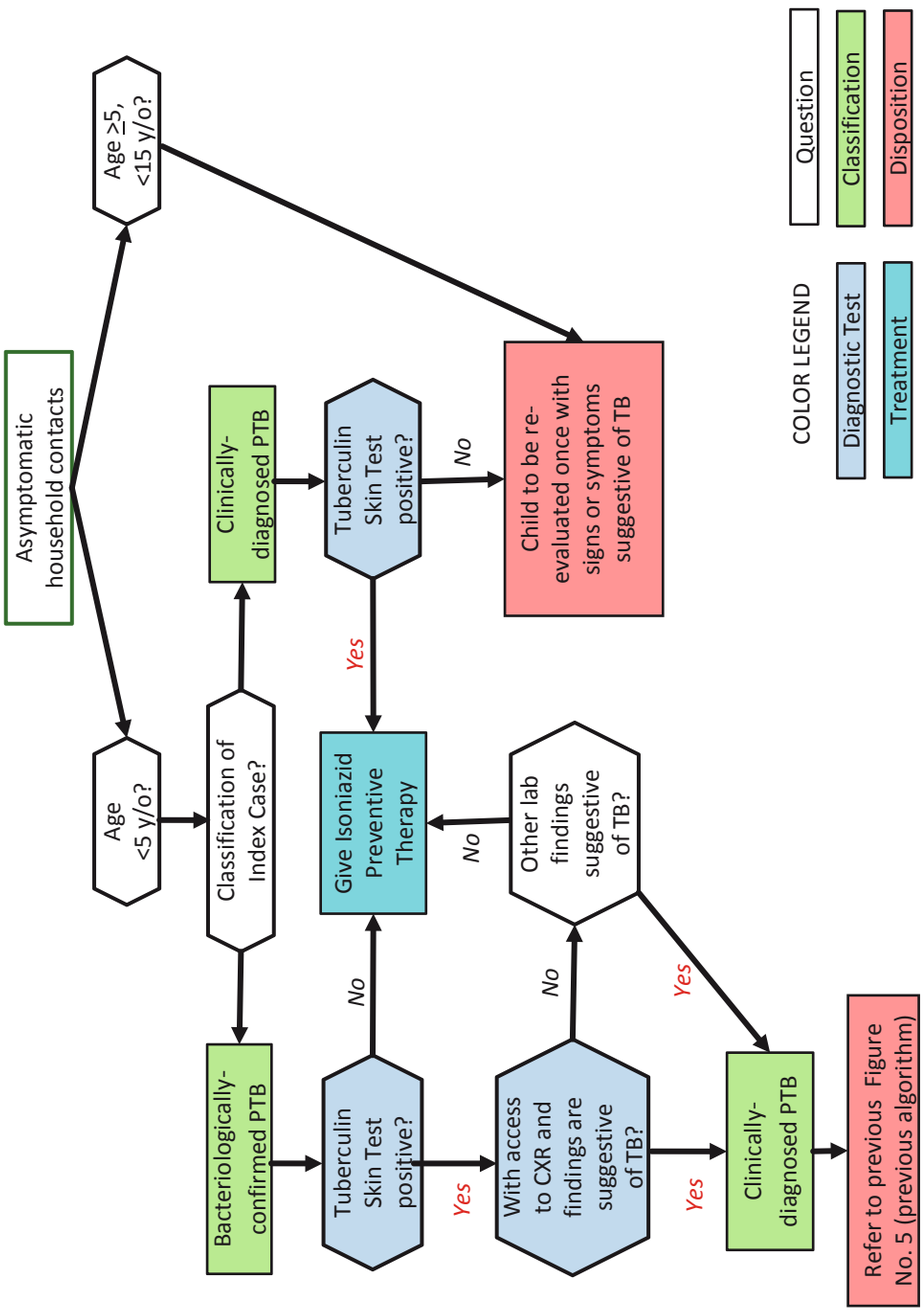
Figure No. 6 - Screening of Pediatric Drug-Susceptible Household Contacts of TB



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CHAPTER 3

Case Holding

I. INTRODUCTION

Case holding is the set of procedures which ensures that patients complete their treatment. While effective anti-TB drugs are available in the country, there are still many TB patients who are not cured because they stop taking anti-TB drugs or take them irregularly. This may lead to chronic infectious illness, drug resistance, or death. The best way to prevent the occurrence of these events is through the regular intake of appropriate drugs for the prescribed duration.

Case holding involves assignment of the appropriate treatment regimen based on diagnosis and previous history of treatment, supervised drug intake with support to patients, and monitoring responses to treatment through follow-up sputum smear microscopy.

II. OBJECTIVE

To ensure effective and complete treatment of all TB cases for both adults and children.

III. DEFINITION of TERMS

A. TB Disease Registration Group[16] - Cases are assigned a registration group based on history of previous treatment in addition to classification based on anatomical site and bacteriologic confirmation. The registration groups of TB cases is necessary in determining the correct treatment regimen.

Table No. 9 - TB Disease Registration Groups

Registration Group		Definition of Terms
New		A patient who has never had treatment for TB* or who has taken anti-TB drugs for less than one (<1) month.
Retreatment	Relapse	A patient previously treated for TB, who has been declared cured or treatment completed in their most recent treatment episode, and is presently diagnosed with bacteriologically-confirmed or clinically-diagnosed TB.
	Treatment After Failure	A patient who has been previously treated for TB and whose treatment failed at the end of their most recent course. *(See definition of Failed treatment outcome in Section H)*; This includes: • A patient whose sputum smear or culture is positive at 5 months or later during treatment. • A clinically-diagnosed patient (e.g., child or EPTB) for whom sputum examination cannot be done and who does not show clinical improvement anytime during treatment.
	Treatment After Lost to Follow-up (TALF)	A patient who was previously treated for TB but was lost to follow-up for two months or more in their most recent course of treatment and is currently diagnosed with either bacteriologically-confirmed or clinically-diagnosed TB.
	Previous Treatment Outcome Unknown (PTOU)	Patients who have been previously treated for TB but whose outcomes after their most recent course of treatment are unknown or undocumented.
Other		Patients who do not fit into any of the categories listed above.

**Prophylaxis and treatment for latent TB infection (LTBI) are not counted as anti-TB treatment*

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Patients who had been registered in a DOTS facility and are transferred to another DOTS facility with proper referral slip to continue the current treatment regimen, or Transfer-in patients, will be designated a registration group based on the registration group of the referring facility aside from Transfer-in. These cases should NOT be reported in the case-finding and case-holding quarterly reports since they will be reported by the referring facility.

B. Directly Observed Treatment (DOT) - DOT is a method developed to ensure treatment compliance by providing constant and motivational supervision to TB patients. DOT works by having a responsible person, referred to as treatment partner, watch the TB patient take anti-TB drugs every day during the whole course of treatment.

C. Drug formulations

1. Fixed–dose combination (FDCs) – Two or more first-line anti-TB drugs are combined in one tablet. There are 2-, 3-, or 4-drug fixed-dose combinations, namely: HR, HRE and HRZE. These are usually provided in kits with boxes of blister packs corresponding to treatment phases of an average-weight patient.

2. Single drug formulation (SDF) – Each drug is prepared individually, either as tablet, capsule, syrup or injectable (Streptomycin) form.

IV. POLICIES

A. All diagnosed TB cases shall be provided with adequate and appropriate anti-TB treatment regimen promptly.

B. Anti-TB treatment shall be done through a patient-centered, directly observed treatment (DOT) to foster adherence. DOT should be carried out in settings that are most accessible and acceptable to the patient. Exert all efforts to decentralize DR-TB patients as soon as possible to a treatment facility most accessible to the patient.

C. Anti-TB treatment regimen shall be based on anatomical site, and bacteriologic status including drug resistance and history of prior treatment. Except in cases of adverse drug reactions and special circumstances requiring treatment modifications, TB treatment under the NTP shall conform to standardized regimens specified in the Table below.

Table No. 10 - Recommended Treatment Regimen for Adults and Children[24, 25]

Category of Treatment	Classification and Registration Group	Treatment Regimen
Category I	Pulmonary TB, new (whether bacteriologically-confirmed or clinically-diagnosed) Extra-pulmonary TB, new (whether bacteriologically-confirmed or clinically-diagnosed) except CNS/ bones or joints	2HRZE/4HR
Category Ia	Extra-pulmonary TB, new (CNS/bones or joints)	2HRZE/10HR

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Category II	Pulmonary or extra-pulmonary, Previously treated drug-susceptible TB (whether bacteriologically-confirmed or clinically-diagnosed) • Relapse • Treatment After Failure • Treatment After Lost to Follow-up (TALF) • Previous Treatment Outcome Unknown • Other	2HRZES/1HRZE /5HRE
Category IIa	Extra-pulmonary, Previously treated drug-susceptible TB (whether bacteriologically-confirmed or clinically-diagnosed - CNS/bones or joints)	2HRZES/1HRZE /9HRE
Standard Regimen Drug-resistant (SRDR)	Rifampicin-resistant TB or Multidrug-resistant TB	ZKmLfxPtoCs • Individualized once DST result is available • Treatment duration for at least 18 months
XDR-TB Regimen	Extensively drug-resistant TB	Individualized based on DST result and history of previous treatment

Legend: R - Rifampicin, I - Isoniazid, E - Ethambutol, Z - Pyrazinamide, S - Streptomycin, Km - Kanamycin. Lfx - Levofloxacin, Pto - Prothionamide. C - Cycloserine.

D. All retreatment patients should be screened for MDR-TB before initiating Category II treatment regimen. Initiating Category II treatment regimen without MDR-TB screening can only be done in areas where access to PMDT services is not possible.

E. A patient's anti-TB regimen shall be comprised of at least four (4) first-line drugs. Fixed-dose combination (FDC) should be used – except in children unable to take tablet formulations.

F. The national and local government units (LGUs) shall ensure provision of drugs to all TB cases. LGUs should allocate funds for drugs and supplies in the event of unforeseen supply interruptions to ensure the continuity of treatment within their areas of jurisdiction.

G. Quality of FDCs must be ensured. FDCs must be ordered from a source with a track record of producing FDCs according to WHO-prescribed strength and standard of quality.

H. Out-patient treatment shall be the preferred mode of care. However, patients with life-threatening conditions shall be recommended for hospitalization.

I. A TB patient diagnosed during confinement in a hospital may start treatment using NTP drug supply upon the approval of the hospital TB team. Once discharged, the patient shall be referred by the hospital TB team to a DOTS facility for registration and continuation of the assigned standard treatment regimen.

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J. Treatment response of PTB patients shall be monitored through follow-up DSSM and clinical signs and symptoms. All adverse drug reactions (ADRs), whether minor or major, shall be reported using the official reporting form of the FDA. *(See **Annex B** on page 155).*

K. Tracking mechanism for patients lost to follow-up shall be put in place to ensure that patients who fail to follow-up as scheduled are immediately traced.

L. Appropriate infection control measures shall be observed at all times based on "Guidelines on Infection Control for TB and Other Airborne Infectious Diseases."

M. All registered TB patients in Category A and B sites, shall be offered PICT.[23]

Category A and B sites are areas for prioritization based on the number of reported cases, HIV prevalence, Most At Risk Population (MARP) size, results of the Rapid Assessment of HIV vulnerability, and presence of multiple risks as categorized by the Philippine National AIDS Council. *(See **Annex C. List of Category A and B Areas** on page 156).*

N. All confirmed drug-resistant TB cases shall be offered PICT.

V. PROCEDURES

A. Initiation of treatment and registration

1. Inform the patient that he/she has TB disease and motivate him/her to undergo treatment. For patients less than 18 years old, talk to the parent/guardian regarding the need for the child to undergo treatment. Provide, as necessary, the following key messages for TB patients and their families:

   - The need for at least six to eight (6-8) months of supervised, well-documented TB treatment with good compliance;
   - Free anti-TB drugs in a DOTS program;
   - Public health facilities offer free bacteriology services (DSSM, Xpert MTB/RIF and/or MTB culture and DST);
   - Schedule of follow-up DSSM for monitoring;
   - Tracing mechanism if lost to follow-up by which the patient will be contacted;
   - How to address possible adverse drug reactions;
   - Relevance of contact investigation;
   - Cough etiquette and other pertinent infection control measures;

2. Do pre-treatment evaluation. Address all pertinent health issues appropriately then assign the corresponding treatment regimen based on the patient's disease site and registration group. Refer patients to appropriate specialists or health institutions for any needed interventions not available in your health facility (e.g., ART, diabetes control, smoking cessation program, visual or hearing acuity tests, monitoring of liver enzymes, etc.).

3. Accomplish **Form 4. TB Treatment/IPT Card** and two (2) **Form 5. NTP ID Cards** - one for the patient and the other for the treatment partner.

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4. Discuss with the patient and decide who will be the most appropriate treatment partner and where the treatment will be administered if it is not possible to receive treatment at the DOTS facility.

   DOT can be done in any accessible and convenient place for the patient (e.g., DOTS facility, treatment partner's house, patient's place of work, or patient's house) as long as the treatment partner can effectively ensure the patient's intake of the prescribed drugs and monitor his/her reactions to the drugs. Any of the following could serve as treatment partner: a) DOTS facility staff, such as the midwife or the nurse; or b) a trained community member, such as the BHW, local government official, or a former TB patient.

   Trained family members may be assigned to administer oral medications during weekends and holidays; or as the sole treatment partner in special/exceptional cases, such as:

   - Poor access to a DOTS facility due to geographical barriers (including temporarily displaced populations);
   - Debilitated and/or bed-ridden patients;
   - DOT schedule is in conflict with the patient's work/school schedule and unable to access other DOTS facilities;
   - Cultural beliefs that limit the choice of a treatment partner (e.g., indigenous peoples);
   - Treatment of children;
   - Post-disaster scenarios.

   In such cases where a family member is the treatment partner, drug supply is to be distributed on a weekly basis or as agreed by the health worker and the family member.

   Streptomycin intramuscular injections are to be administered only by trained and authorized health personnel. Patients with no access to such services during weekends/holidays may forego Streptomycin doses during weekends/holidays provided they still complete the recommended number of doses (i.e., 56 doses).

5. Ask if the patient is a PhilHealth member or a qualified dependent; and if so, record the corresponding PhilHealth Identification Number (PIN) in the **Form 4. TB Treatment/IPT Card**. *(See Chapter 9 Procedures on PhilHealth Claims Processing on page 129)*

6. Start the appropriate Standard Regimen and watch the patient take the initial dose of medications. Refer to the Tables on the next page for the dosage.

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Table No. 11 - Treatment Category I (2HRZE/4HR)

Body Weight (Kgs.)	Intensive Phase 2 months of (HRZE) daily	Continuation Phase 4 months* of (HR) daily
	No. of tablets per day	
30 – 37	2	2
38 – 54	3	3
55 – 70	4	4
> 70	5	5

** 10 months for Category Ia*

Table No. 12 - Treatment Category II (2HRZES/HRZE/5HRE)

Body Weight (Kgs.)	Intensive Phase (daily)			Continuation Phase (daily)
	First 2 months		Third month	4th to 8th month**
	HRZE No. of tablets	S (1g/2ml)	HRZE No. of tablets	HRE No. of tablets
30 – 37	2	1 g ***	2	2
38 – 54	3		3	3
55 – 70	4		4	4
> 70	5		5	5

***4th to 12th month for Category IIa*
**** For patients with BW <50 kgs and those > 60 yrs old consider 500-700mg or 10mg/kg/day*

Table No. 13 - Drug Dosage per Kg Body Weight (If using SDFs)

Drug	Adults[25]	Children[26]
Isoniazid (H)	5 (4-6) mg/kg, not to exceed 400mg daily	10 (10-15) mg/kg, not to exceed 300mg daily
Rifampicin (R)	10 (8-12) mg/kg, not to exceed 600mg daily	15 (10-20) mg/kg, not to exceed 600mg daily
Pyrazinamide (Z)	25 (20-30) mg/kg, not to exceed 2g daily	30 (20-40) mg/kg, not to exceed 2g daily
Ethambutol (E)	15 (15-20) mg/kg, not to exceed 1.2g daily	20 (15-25) mg/kg, not to exceed 1.2g daily
Streptomycin (S)	15 (12-18) mg/kg, not to exceed 1g daily	30 (20-40) mg/kg, not to exceed 1g daily

Note: Dosage for children are higher since there are more metabolizing enzymes among children than adults leading to faster metabolism.[27]

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Table No. 14 - Drug Administration According to Kg Body Weight for Children

Body Weight (Kgs.)	Isoniazid (200mg/5ml)	Rifampicin (200mg/5ml)	Pyrazinamide (250mg/5ml)	Ethambutol (400mg/tab)	Streptomycin* (1g/2ml)
	10mg/kg	15mg/kg	30mg/kg	20mg/kg	30mg/kg
	ml	ml	ml	Tablet	ml
2.1-3	0.75	1.00	1.75	1/8*	0.18
3.1-4	1.00	1.50	2.50	1/4*	0.24
4.1-5	1.25	2.00	3.00		0.3
5.1-6	1.50	2.25	3.50		0.36
6.1-7	1.75	2.50	4.25		0.42
7.1-8	2.00	3.00	4.75	1/2	0.48
8.1-9	2.25	3.50	5.50		0.54
9.1-10	2.50	3.75	6.00		0.6
10.1-11	2.75	4.00	6.50		0.66
11.1-12	3.00	4.50	7.25		0.72
12.1-13	3.25	5.00	7.75	3/4	0.78
13.1-14	3.50	5.25	8.50		0.84
14.1-15	3.75	5.50	9.00		0.9
15.1-16	4.00	6.00	9.50		0.96
16.1-17	4.25	6.50	10.25		1.02
17.1-18	4.50	6.75	10.75		1.08
18.1-19	4.75	7.00	11.50	1	1.14
19.1-20	5.00	7.50	12.00		1.20
20.1-21	5.25	8.00	12.50		1.26
21.1-22	5.50	8.25	13.25		1.32
22.1-23	5.75	8.50	13.75		1.38
23.1-24	6.00	9.00	14.50		1.44
24.1-25	6.25	9.50	15.00	1+1/4	1.5
25.1-26	6.50	9.75	15.50		1.56
26.1-27	6.75	10.00	16.00		1.62
27.1-28	7.00	10.50	16.75		1.68
28.1-29	7.25	11.00	17.50	1+1/2	1.74
29.1-30	7.50	11.25	18.00		1.8

**If the child is a newborn (less than 4 weeks), consider referral to a pediatrician so that Streptomycin can be used instead of Ethambutol.*

7. Acknowledge the treatment administered by affixing your initials in **Form 4. TB Treatment/IPT Card** and **Form 5. NTP ID Card**.

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8. Register the patient in **Form 6a. TB register**. Assign a TB case number.

9. In Category A or B sites and among all DRTB cases, offer PICT to all patients aged 15 years old and above. If the patient consents to testing, refer the patient to a trained medical technologist for testing. If patient does not consent, offer testing again during subsequent visits. Results of HIV screening will be written in **Form 2b. NTP Laboratory Result Form for HIV testing** and sent to the physician.

B. Follow-up clinic visits

1. During follow-up, ask for the patient's **Form 5. NTP ID Card** and inquire how he/she has been since the last clinic visit. Ask the patient about the following:

   a. General well-being;
   b. Progression or resolution of symptoms;
   c. Adverse drug reactions or side effects;
   d. Compliance to treatment and DOTS;
   e. Any problem or concerns regarding the treatment so far.

   Address all issues appropriately and refer to attending physician or specialist if needed. Give positive feedback on the patient's treatment (e.g., weight gain and/or resolution of other symptoms as good signs of clinical response). Record the interaction in the individual treatment record or patient's chart and/or in **Form 4. TB Treatment/IPT Card**.

2. If the patient underwent HIV testing, the physician should provide post-test counselling. A reactive result on the HIV screening test necessitates confirmatory testing. Refer again the patient to the medical technologist for blood extraction and send specimens to STI-AIDS Central Cooperative Laboratory. Refer the patient to a treatment hub for anti-retroviral treatment (ART) if confirmatory test is positive.

3. Weigh the patient monthly and record this in **Form 4. TB Treatment/IPT Card**. Note if additional tablets or dose adjustments are required, patients should gain enough weight to be re-classified into the next dosing category.

4. Always check if the patient is scheduled to shift treatment phases and/or if he/she is due for follow-up DSSM *(see next section)*. If so, advise the patient accordingly and provide the necessary sputum cups.

5. For patients qualified for PhilHealth's TB/DOTS Outpatient Benefit Package in the accredited DOTS facility, file the appropriate Claim Form at the end of each treatment phase. *(See **Chapter 9. Procedure on PhilHealth Claims Processing** on page 129 and refer to **Annex E** on page 160);*

6. Acknowledge the patient once he/she has completed the entire treatment duration for his/her treatment category.

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C. Monitoring Response to Treatment

Treatment response of PTB patients shall be monitored by follow-up DSSM (i.e., one specimen for each instance) according to the standard schedule below[25].

Figure No. 7 - Schedule of Follow-up DSSM for Category I Patients[25]

Months of Treatment					
1	2	3	4	5	6
[INTENSIVE PHASE]		[- - - - - - - CONTINUATION PHASE			- - - - - - -]
	●			●	●
				If sm+, label as "failed"	If sm+, label as "failed"

If smear-positive at month 2, obtain sputum again at month 3. If smear-positive at month 3, refer to PMDT.

[INTENSIVE PHASE]		[- - - - - - - CONTINUATION PHASE			- - - - - - -]
	●	●		●	●
	sm+	if sm +, refer to PMDT		if sm+, label as "failed"	if sm+, label as "failed"

Figure No. 8 - Schedule of Follow-up DSSM for Category II patients[24]

Months of Treatment							
1	2	3	4	5	6	7	8
[INTENSIVE PHASE]			[- - - - - - - CONTINUATION PHASE				- - - - - - -]
		●		●			●
		if sm+, refer to PMDT		if sm+, label as "failed"			if sm+, label as "failed"

1. For new cases on Category I, follow-up DSSM shall be done at the end of the intensive phase, at the end of the 5th month, and at the end of treatment.

   a. If sputum positive at the end of the intensive phase, proceed to the continuation phase but repeat DSSM at the end of the 3rd month.

      i) If still smear-positive at the end of the 3rd month, refer to a DOTS facility with PMDT services for screening or to an Xpert MTB/RIF site for testing. Continue treatment while waiting for PMDT recommendations or Xpert MTB/RIF result.

      ii) If smear-negative at the end of the 3rd month, repeat DSSM at the end of the 5th month.

      If smear-negative at the end of intensive phase, repeat DSSM at the end of the 5th month. *(Note: For clinically-diagnosed new patients, no need to repeat DSSM follow-up at the 5th month and end of treatment if already smear-negative at end of intensive phase).*

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b. If smear-positive at the end of the 5th month, classify outcome as treatment failed and refer to a DOTS facility with PMDT services for screening or to an Xpert MTB/RIF site for testing. *(See **Section I. Treatment Outcomes** on page 51).*

If sputum-negative at 5th month, repeat DSSM at the end of treatment.

c. If smear-positive at the end of treatment, classify outcome as treatment failed and refer to a DOTS Facility with PMDT services for screening or to an Xpert MTB/RIF site for testing.

If sputum-negative at the end of treatment, classify outcome as cured or treatment completed. *(See **Section I. Treatment Outcomes** on page 51).*

2. For retreatment cases on Category II, follow-up DSSM shall be done at the end of the intensive phase, at the end of the 5th month, and at the end of treatment.

a. If smear-positive at the end of the intensive phase, refer to a DOTS facility with PMDT services for screening. Start continuation phase while waiting for PMDT recommendations.

If sputum-negative at the end of the intensive phase, repeat DSSM at the end of the 5th month.

b. If smear-positive at the end of the 5th month, classify outcome as treatment failed and refer to a DOTS facility with PMDT services for screening *(See **Section I. Treatment Outcomes** on page 51)* or to an Xpert MTB/RIF site for testing.

If smear-negative at 5th month, repeat DSSM at the end of treatment.

c. If smear-positive at the end of treatment, classify outcome as treatment failed and refer to a DOTS facility with PMDT services for screening or to an Xpert MTB/RIF site for testing.

If smear-negative at the end of treatment, classify outcome as cured or treatment completed. *(See **Section I. Treatment Outcomes** on page 51).*

3. For EPTB patients and patients where DSSM was not done, treatment response will be assessed clinically (e.g., weight gain, resolution of symptoms).

D. Managing adverse drug reactions during treatment

1. Closely monitor the occurrence of minor and major reactions to drugs, especially during the intensive phase. Manage minor reactions appropriately *(See **Table No. 15 - Guide in Managing Adverse Reactions to Anti-TB Drugs** on page 44)*. There are major side effects that necessitate withdrawal of the responsible drug; hence the need to switch to single-dose formulation (SDF). Refer such cases to a hospital for appropriate management of adverse drug reactions (ADRs) most especially for anaphylaxis. Report all cases of ADRs by filing the **Adverse Drug Reaction(s) Form** *(see **Annex B** on page 153)* and submit to DOH through channels.

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Table No. 15 - Guide in Managing Adverse Reactions to Anti-TB Drugs

Adverse Reactions	Drug(s) probably responsible	Management
Minor		
1. Gastro-intestinal intolerance	Rifampicin/Isoniazid/ Pyrazinamide	Give drugs at bedtime or with small meals.
2. Mild or localized 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 due to peripheral neuropathy	Isoniazid	Give Pyridoxine (Vitamin B6): 50-100 mg daily for treatment, 10 mg daily for prevention.
6. Arthralgia due to hyperuricemia	Pyrazinamide	Give aspirin or NSAID. If symptoms persist, consider gout and request for blood chemistry (uric acid determination) and manage accordingly.
7. Flu-like symptoms (fever, muscle pains, inflammation of the respiratory tract)	Rifampicin	Give antipyretics.
Major		
1. Severe skin rash due to hypersensitivity	Any kind of drugs (especially Streptomycin)	Discontinue anti-TB drugs and refer to appropriate specialist.
2. Jaundice due to hepatitis	Any kind of drugs (especially Isoniazid, Rifampicin, and Pyrazinamide)	Discontinue anti-TB drugs and refer to appropriate specialist. If symptoms subside, resume treatment and monitor clinically.
3. Impairment of visual acuity and color vision due to optic neuritis	Ethambutol	Discontinue Ethambutol and refer to an ophthalmologist.
4. Hearing impairment, ringing of the ear, and dizziness due to damage of the eighth cranial nerve	Streptomycin	Discontinue Streptomycin and refer to appropriate specialist .
5. Oliguria or albuminuria due to renal disorder	Streptomycin/ Rifampicin	Discontinue anti-TB drugs and refer to appropriate specialist.
6. Psychosis and convulsion	Isoniazid	Discontinue Isoniazid and refer to appropriate specialist.
7. Thrombocytopenia, anemia, shock	Rifampicin	Discontinue anti-TB drugs and refer to appropriate specialist

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2. There might be a need to switch to SDF whenever side effects to one or more components of the FDC are suspected. SDFs are to be provided according to the SDF dosage guide.

3. Once the ADR has resolved, reintroduce anti-TB drugs one by one following the schedule below.[28]

Table No. 16 - Reintroduction of Anti-TB Drugs Following Drug Reaction

Drug	Likelihood of Causing a Reaction	Challenge Doses		
		Day 1	Day 2	Day 3
Isoniazid	**Least likely**	50mg	300mg	full dose
Rifampicin		75mg	300mg	full dose
Pyrazinamide		250mg	1000mg	full dose
Ethambutol		100mg	500mg	full dose
Streptomycin	**Most likely**	125mg	500mg	full dose

Start with the drug least likely to be responsible for the reaction at a small challenge dose, (i.e., 50 mg Isoniazid). The dose is gradually increased over three (3) days. If there is no reaction after the 3rd day, add the second drug at a small challenge dose, (i.e., 75 mg Rifampicin). The procedure is repeated, adding in one drug at a time and gradually increasing the dose. A reaction after adding in a particular drug identifies that drug as the one responsible for the reaction.

4. Once the adverse reaction to a drug is confirmed, the offending drug must be replaced with another drug. For patients with major drug reactions to all first line drugs, refer to DOTS facilities with PMDT services or specialist for proper treatment regimen.

E. Deciding when an adult PTB patient is no longer infectious during treatment

1. In situations where the adult patient needs a certificate to return to work, assess the patient's infectiousness based on DSSM results and clinical improvement during treatment.

2. For bacteriologically-confirmed adult patients, sputum microscopy examination can be done one (1) month after start of treatment ***for purposes of certifying that the patient can return to work/school***. Issue a certificate that the patient is no longer infectious and can safety return to work/school only after demonstrating sputum conversion to smear-negative. No bacteriologically-confirmed case should be allowed to return to work without a negative follow-up smear examination.

3. For clinically-diagnosed adult patients (smear-negative or smear not done), it is possible to issue a certificate that the patient is no longer infectious and can safely return to work/school after two (2) weeks of appropriate and adequate therapy for as long as treatment compliance is assured and there is clinical improvement or no clinical deterioration.

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F. Management of Cases Who Interrupted Treatment[29]

1. Patients who fail to follow-up as scheduled should be immediately traced through: telephone call, text message or home/workplace visit. Assess the cause of interruption and agree on solutions.

2. If patient interrupted treatment for less than one (1) month, continue the treatment and prolong it to compensate for missed doses.

3. If patient interrupted treatment for more than one (1) month but less than two (2) months, do the following:

   a. Repeat the DSSM.
   b. If the DSSM is negative, continue the treatment and prolong to compensate for missed doses.
   c. If the DSSM is positive, check how long the patient has been treated.
      i. If treatment received is less than five (5) months, continue treatment and prolong to compensate for missed doses.
      ii. If treatment received is five (5) months or more, close the treatment card, classify the patient as having a treatment outcome of "Treatment Failed" *(see **Section I. Treatment Outcomes** on page 51)* and refer the patient to a PMDT Treatment Facility for MDR screening.

4. If the patient interrupted treatment for two (2) months or more, classify as having a treatment outcome of "Lost to Follow-up" *(see **Section I. Treatment Outcomes** on page 51)*. Close the previous registration, repeat DSSM and follow the case-finding policies and procedures.

Table No. 17 - Management of Cases Who Interrupted Treatment

Length of Interruption	Do DSSM if >1 Month Interruption	How long has patient been treated?	Disposition
Less than 1 month	Continue treatment and prolong to compensate		
	Negative DSSM	Continue treatment and prolong to compensate	
More than 1 month	Positive DSSM	Less than 5 months	Continue treatment and prolong to compensate
		More than 5 months	Classify as "Treatment Failed"
More than 2 months	Classify as "Lost to Follow-up"		

G. Treatment Modifications for Special Situations[24]

1. Pregnancy

Ascertain whether or not a woman is pregnant before she starts TB treatment. Most anti-tuberculosis drugs are safe for pregnant women, **except Streptomycin**,

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which is ototoxic to the fetus. Advise a pregnant woman that successful treatment of TB with the recommended standardized treatment regimen (i.e., 2HRZE/4HR) is important for a successful outcome of pregnancy. Pregnant women taking Isoniazid should be given Pyridoxine (Vitamin B_6) at 25 mg/day.

2. Breastfeeding

A breastfeeding woman afflicted with TB should receive a full course of TB treatment. Timely and properly applied chemotherapy is the best way to prevent transmission of tubercle bacilli to the baby. In lactating mothers on treatment, most anti-tuberculosis drugs will be found in the breast milk in concentrations equal to only a small fraction of the therapeutic dose used in infants. However, effects of such exposure on infants have not been established. It is recommended that lactating mothers feed their infants before taking medications.

Supplemental Pyridoxine (i.e., Vitamin B_6) should be given at 5-10 mg/day to the infant who is taking INH or whose breastfeeding mother is taking INH.[21]

3. Oral Contraceptives

Rifampicin interacts with oral contraceptive medications with a risk of decreased protective efficacy against pregnancy. Advise a woman receiving oral contraceptives while on Rifampicin treatment that she has the following options: 1) take an oral contraceptive pill containing a higher dose of estrogen (50u), following consultation with a clinician; or 2) use another form of contraception.

4. Liver Disease or History of Liver Disease

Isoniazid, Rifampicin, and Pyrazinamide are all associated with hepatitis. Of the three drugs, Rifampicin is least likely to cause hepatocellular damage, although it is associated with cholestatic jaundice. Of the three agents, Pyrazinamide is the most hepatotoxic.

Treatment should be interrupted and, generally, a modified or alternative regimen used for those with ALT elevation more than three times the upper limit of normal (ULN) in the presence of hepatitis symptoms and/or jaundice. If ALT is elevated five times the ULN, treatment should likewise be interrupted even in the absence of symptoms. Refer to appropriate specialist if needed.

It is necessary to wait for the liver function tests to revert to normal and clinical symptoms (e.g., nausea, abdominal pain) to resolve before reintroducing the anti-TB drugs. If it is not possible to perform liver function tests, it is advisable to wait an extra two (2) weeks after resolution of jaundice and upper abdominal tenderness before restarting TB treatment. Once drug-induced hepatitis has resolved, the drugs are reintroduced one at a time, beginning with Rifampicin. After three to seven (3-7) days, Isoniazid may be reintroduced. In patients who have experienced jaundice but tolerate the reintroduction of Rifampicin and Isoniazid, it is advisable to avoid Pyrazinamide. If symptoms recur or liver function tests become abnormal as the drugs are reintro-duced, the last drug added should be stopped.

Patients with the following conditions can receive the usual short course chemotherapy regimens provided there is no clinical evidence of chronic liver

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disease: hepatitis virus carriage; a past history of acute hepatitis; and excessive alcohol consumption. However, hepatotoxic reactions to anti-tuberculosis drugs may be more common among these patients and should therefore be anticipated.

5. Established Chronic Liver Disease

Patients with chronic liver disease should not receive Pyrazinamide. Alternative regimens are 2SHRE/6HR, 9RHE, or 2SHE/10HE.

6. Acute Hepatitis (e.g., Acute Viral Hepatitis)

It is not common for a patient to have TB concurrently with acute hepatitis unrelated to TB or TB treatment. Clinical judgment is necessary. In some cases, it is possible to defer TB treatment until the acute hepatitis has been resolved. When it is necessary to treat TB during acute hepatitis, the safest option is the combination of SE for three months and, once the hepatitis has resolved, a continuation phase of six months Isoniazid and Rifampicin (i.e., 3SE/6HR). If the hepatitis has not been resolved, SE should be continued for a total of twelve (12) months (i.e., 12SE).

7. Renal Failure

Isoniazid and Rifampicin are eliminated by biliary excretion. These drugs, therefore, can be given in normal dosages to patients with renal failure. Patients with severe renal failure should receive Isoniazid with Pyridoxine to prevent peripheral neuropathy.

Streptomycin, Ethambutol and metabolites of Pyrazinamide are excreted by the kidney, and doses should be adjusted *(see **Table No. 18** below)*. If possible, Streptomycin should be avoided in patients with renal failure.

Table No. 18 - Dosing Recommendations for Patients with Reduced Renal Function or Receiving Hemodialysis

Drug	Change in frequency?	Recommended Dose and Frequency for patients with creatinine clearance <30mL/min or for patients receiving hemodialysis
Isoniazid	No change	300mg once daily; or 900mg three times per week
Rifampicin	No change	600mg once daily; or 600mg three times per week
Pyrazinamide	Yes	25-35mg/kg per dose three times per week (not daily)
Ethambutol	Yes	15-25mg/kg per dose three times per week (not daily)
Streptomycin	Yes	12-15mg/kg per dose two or three times per week

Noting the above recommendations, it would therefore be possible to give a 4-drug FDC (HRZE) three times per week and then give a 2-drug FDC (HR) for the rest of the week during the intensive phase. Continuation phase may proceed with 4HR. Otherwise, another safe option is 2HRZ/4HR. It is recommended that anti-TB medications be taken after hemodialysis.

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8. TB/HIV co-infection

In patients with HIV-related TB, the priority is to treat TB, especially bacteriologically-confirmed PTB to stop transmission. However, patients with HIV-related TB can have Anti-Retroviral Therapy (ART) and anti-TB treatment at the same time, if managed carefully. Careful evaluation is necessary in judging when to start ART. For example, in a patient with a high risk of death during the period of TB treatment (i.e., disseminated TB and/or CD4count <200/mm3), it may be necessary to start ART concomitantly with TB treatment. On the other hand, for a patient with bacteriologically-confirmed PTB as the first manifestation of HIV infection and who does not appear to be at risk of dying, it may be safer to defer ART until the initial phase of TB treatment has been completed. This decreases the risk of immune reconstitution syndrome and avoids the risk of drug interaction between Rifampicin and a Protease Inhibitor (PI). Possible options include the following:

- Defer ART until completion of TB treatment.
- Defer ART until the completion of the intensive phase of TB treatment and then use Ethambutol and Isoniazid in the continuation phase.
- Treat TB with a Rifampicin-containing regimen and use efavirenz + two Nucleoside Reverse Transcriptase Inhibitors (NsRTIs).

Patients with TB/HIV co-infection should also receive Co-Trimoxazole as prophylaxis for other infections. Persons with HIV infection who, after careful evaluation, do not have active tuberculosis should be treated for presumed latent tuberculosis infection with Isoniazid preventive therapy *(See **Chapter 4** on page 53).*

H. Drug Interactions During TB Treatment[30]

Drug interactions can occur during TB treatment and potentially change the pharmacologic effects of another drug that is given concomitantly. Clinically significant drug interactions are seen mostly with Rifamficin, Isoniazid, and Fluoroquinolones. Elderly individuals with significant co-morbidities, as well as the immune-compromised patients (e.g., HIV/AIDS patients) are at higher risk of developing drug interactions during TB treatment.

Important drug-drug interactions of Rifampicin, Isoniazid and other TB drugs are shown in Tables 19-21. To minimize drug interactions, it is advisable that drugs be administered 12 hours apart.

Table No. 19 - Rifampicin Interactions with Various Drug Categories

Drug Category	Rifampicin Interaction
Anti-hypertensive medications	• Markedly reduces levels of Calcium channel blockers (Nifedipine, Amlodipine, Verapamil). • Reduces levels of B-blockers (Propranolol, Carvedilol). • Isolated reports of interaction with ACE inhibitors (Captopril, Enalapril, Lisinopril) but minor clinical significance • No interactions found with diuretics (Thiazides, Spironolactone, Furosemide).

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Analgesics	• Increases clearance of Paracetamol (but clinical importance not yet established). • Decreases levels of Diclofenac. • No interaction with Aspirin and Ibuprofen. • Reduces opioid levels (Morphine, Codeine).
Antifungals	• Markedly reduces serum concentration of antifungals (Ketoconazole, Itraconazole). • Serum Rifampicin levels can also be reduced with concurrent use of Ketoconazole.
Anti-retroviral agents (ARV)	• Reduces levels of Efavirenz (EFV), Ritonavir and Nevirapine. • Increases clearance of Zidovudine. • No interactions found with Didanozine, Lamivudine.
Anti-epileptics	• One report of increased level and toxicity of Carbamazepine when H and R is given together. • Reduces levels of Phenytoin and Valproic acid.

Table No. 20 - Isoniazid Drug Interactions

Drug Category/Drugs	Isoniazid Interaction
Antacids	• INH absorption is reduced with concurrent use of Aluminum hydroxide (give INH at least one hour before the antacid).
Carbamazepine	• Increases levels of Carbamazepine markedly and rapidly.
Oral contraceptives	• Few cases of failures reported; risk of contraceptive failure is low with concurrent use of INH.
Paracetamol	• Potential toxicity of Paracetamol even at normal dose when used with INH; more studies are needed.
Phenytoin	• Increases levels of Phenytoin with concurrent use of INH
Theophylline	• Plasma level of Theophylline may be increased

Table No. 21 - Interactions of Other Anti-TB Drugs

Drugs	Drug Interaction
Ethambutol and Pyrazinamide	• May interact with thiazide diuretics to cause elevated serum uric acid levels
Pyrazinamide	• May interact with Allopurinol and Probenicid and cause elevated uric acid levels
Streptomycin	• Increases risk of ototoxicity or nephrotoxicity when used with ototoxic or nephrotoxic drugs • Exercise caution when used with anesthetics and neuromuscular blocking agents as Streptomycin can prolong the neuromuscular blockade and potentially lead to respiratory depression
Fluoroquinolones (second-line treatment)	• Increases serum Theophylline level • Increases anti-coagulant effect of Warfarin • Concurrent use with sucralfate and antacids containing aluminum, calcium, or magnesium may reduce absorption of quinolones Serum level of Ciprofloxacin is reduced with concurrent use of Didanosine.

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I. Treatment Outcomes

1. Determine the treatment outcome of patients based on completion of treatment regimen, DSSM follow-up results and clinical improvement *(See **Tables 22** and **23** for **Outcomes of Drug-susceptible and Drug-resistant TB Cases** respectively on pages 51 and 52).*

2. Record the treatment outcome in **Form 4. TB Treatment/IPT Card and Form 6a. TB Register.**

3. Using the completely filled-out **Form 5. NTP ID Card**, issue a Certificate of Treatment Completion/Cure as a form of recognition for the patient's achievement.

Table No. 22 - Treatment Outcomes for Drug-susceptible TB Cases[16]

Outcome	Definition
Cured	A patient with bacteriologically-confirmed TB at the beginning of treatment and who was smear- or culture-negative in the last month of treatment and on at least one previous occasion in the continuation phase.
Treatment Completed	A patient who completes treatment without evidence of failure but with no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because tests were not done or because results are unavailable. This group includes: • A bacteriologically-confirmed patient who has completed treatment but without DSSM follow-up in the last month of treatment and on at least one previous occasion. • A clinically diagnosed patient who has completed treatment.
Treatment Failed	A patient whose sputum smear or culture is positive at five (5) months or later during treatment. **OR** A clinically-diagnosed patient (child or EPTB) for whom sputum examination cannot be done and who does not show clinical improvement anytime during treatment.
Died	A patient who dies for any reason during the course of treatment.
Lost to Follow-up	A patient whose treatment was interrupted for two (2) consecutive months or more.
Not Evaluated	A patient for whom no treatment outcome is assigned. This includes cases transferred to another DOTS facility and whose treatment outcome is unknown.

Note: A patient who is diagnosed to have DR-TB anytime during treatment (i.e., before being declared treatment failed in the 5th month) shall be excluded from the cohort and is not assigned an outcome if they are started on second line drug regimen. However, if treatment with a second-line drug regimen is not possible, the patient is kept in the main TB cohort and assigned an outcome from among those listed above.

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Table No. 23 - Treatment Outcomes for RR-TB/MDR-TB/XDR-TB Patients[16]

Outcome	Definition
Cured	A patient with bacteriologically-confirmed RR-TB/MDR-TB/XDR-TB who has completed at least eighteen (18) months of treatment without evidence of failure **AND** three or more consecutive cultures taken at least thirty (30) days apart are negative after the intensive phase
Treatment Completed	A patient who completes at least eighteen (18) months of treatment without evidence of failure **BUT** no record that three or more consecutive cultures taken at least thirty (30) days apart are negative after the intensive phase.
Treatment Failed	Treatment terminated or need for permanent regimen change of at least two anti-TB drugs because of: • Lack of conversion** by the end of the intensive phase*, or • Bacteriological reversion** in the continuation phase after conversion** to negative, or • Evidence of additional acquired resistance to fluoroquinolones or second-line injectable drugs, or • Adverse drug reactions (ADRs).
Died	A patient who dies for any reason during the course of treatment.
Lost to Follow-Up	A patient whose treatment was interrupted for two (2) consecutive months or more.
Not Evaluated	A patient for whom no treatment outcome is assigned. (This includes cases "transferred out" to another treatment unit and whose treatment outcome is unknown).
Treatment Success	The sum of cured and treatment completed.

**For Treatment failed, lack of conversion by the end of the intensive phase implies that the patient does not convert within the intensive phase applied by the program. The intensive phase is a minimum of six (6) months of second line anti-TB treatment. If the patient does not convert, a cut-off of eight (8) months of treatment is applied to determine the criteria for treatment failed.*

*** The terms "conversion" and "reversion" of culture as used here are defined as follows:*
Conversion (to negative): culture is considered to have converted to negative when two consecutive cultures, taken at least thirty (30) days apart, are found to be negative. In such a case, the specimen collection date of the first negative culture is used as the date of conversion.

Reversion (to positive): culture is considered to have reverted to positive when, after an initial conversion, two consecutive cultures, taken at least thirty (30) days apart, are found to be positive. For the purpose of defining Treatment failed, reversion is considered only when it occurs in the continuation phase.

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CHAPTER 4

Prevention of TB

I. INTRODUCTION

Prevention of TB depends largely on preventing exposure and infection. For vulnerable populations such as young children (i.e., 0-4 years old) and people living with HIV (PLHIV) who are already exposed or infected, the aim is preventing progression to TB disease.

Prevention of TB can be achieved through the following: TB infection control (TB IC), universal use of BCG and Isoniazid Preventive Therapy (IPT).

II. OBJECTIVE

To effectively implement TB preventive measures in DOTS facilities, congregate settings (jails/prisons, residential institutions), workplace and households.

III. DEFINITION OF TERMS

A. TB Infection Control (TB IC) – Specific measures and work practices that reduce the likelihood of spreading the TB bacteria to others.

B. Administrative control – Measures that will reduce risk of TB transmission by preventing the generation of droplet nuclei or reducing exposure to droplet nuclei. This type of control has the greatest impact on preventing the spread of TB.

C. Environmental control – Measures that will reduce the concentration of infectious droplets in the air especially in areas where contamination of air is likely.

D. Respiratory protection controls – Measures that involve selection and proper use of respirators to protect one from inhaling droplet nuclei.

E. Respirator – A special type of closely-fitted mask with the capacity to filter particles to protect users from inhaling infectious droplet nuclei.

F. Managerial activities – Essential separate set of measures to facilitate the smooth implementation of the three (3) components of TB IC: administrative, environmental and respiratory protection controls.

IV. POLICIES

A. All DOTS facilities and TB laboratories should implement TB IC interventions, following in order of hierarchy: administrative, environmental and respiratory controls.

B. Managerial activities shall ensure that the above interventions are implemented.

C. Use of respirators shall be limited to identified high-risk areas. Only respirators that meet international standards (e.g., NIOSH-certified N95 or CE-certified FFP2) shall be used. Proper training and "fit test" shall be undertaken for identified health care workers who will use respirators. Fit testing shall be done every year if the same respirator type will be used or every time before a new respirator type will be distributed.

D. DOTS facility staff shall ensure that TB patients are informed about TB IC measures for their households, workplace and community.

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E. All infants should be given a single dose of BCG except those who are known to be HIV positive, those whose HIV status is unknown but who are born to HIV-positive mothers and those whose symptoms are suggestive of HIV.

F. Isoniazid Preventive Therapy for six (6) months shall be given to all eligible child household contacts and PLHIV once TB disease has been ruled out.

G. In the absence of PPD, symptomatic screening could be used alone to screen household contacts and identify children who will benefit from Isoniazid Preventive Therapy. The unavailability of PPD shall not deter the provision of IPT to 0-4 year old children who are household contacts of bacteriologically-confirmed index cases.

H. IPT should not be given to child contacts of drug-resistant TB.

V. PROCEDURES

A. TB Infection Control at the DOTS facilities

Specific measures are provided in the "Guidelines on Infection Control for TB and Other Airborne Infectious Diseases" issued by the DOH.[31]

1. Managerial activities will ensure the smooth and effective implementation of the administrative, environmental and respiratory protection control measures. This includes:

    a. Developing a facility TB IC plan;
    b. Organizing the infection control committee or team who will be responsible for the implementation of the TB IC plan;
    c. Performing risk assessment of health care facilities *(see **Annex D. Assessment Checklist for Healthcare Facilities and Other Congregate Settings** on page 157);*
    d. Rethinking the use of available spaces and considering the renovation of existing facilities or construction of new ones to optimize implementation of controls;
    e. Conducting on-site surveillance of TB disease among health care workers and assessing the facility; and
    f. Monitoring and evaluating the set of TB IC measures.

2. Administrative Controls are the **first line of defense**, and the most important level in the hierarchy of TB IC. It is the first priority regardless of available resources. Administrative control measures include:

    a. Promptly identifying people with TB symptoms (triage), examples are -
        i. Placing notices that one must immediately inform staff about cough lasting for two (2) weeks or more; and
        ii. Assigning staff to screen persons with cough and to collect sputum.
    b. Separating or isolating infectious patients
        i. Designating waiting areas for presumptive TB or TB patients; and

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ii. Informing patients, staff and visitors by placing visible signages on restricted areas *(e.g., "you are entering an infection precaution area")*

c. Controlling the spread of pathogens

i. Placing signs and posters about cough etiquette

ii. Providing tissue papers, disposable surgical masks or ordinary cloth face masks to coughing patients and infectious TB patients; and

iii. Providing daily health education on cough etiquette.

d. Minimizing the time spent by patients in health care facility

i. Managing patient flow by moving presumptive TB to the front of the waiting queue; and

ii. Minimize time spent receiving services by giving patients specific time slots or additional staff during busy days/hours.

e. Reducing diagnostic delays

i. Use of rapid diagnostic tests when available; and

ii. Reduce turn-around time for DSSM and other diagnostic tests.

f. Early initiation of treatment for TB patients

g. Providing a package of prevention, treatment and care interventions for staff (e.g., CXR as part of annual physical examination), including HIV prevention, anti-retroviral treatment and IPT for HIV positive staff.

3. Environmental control includes technologies for the removal or inactivation of airborne infectious droplet nuclei. It is considered as the second line of defense for preventing the spread of TB and, in combination with the right administrative controls, will reduce the risk of infection. Cost-effective environmental control measures that could be used at the DOTS facilities are natural ventilation and mixed-mode mechanical ventilation (i.e., use of fans together with natural ventilation).

For DOTS facilities, the following are practical and simple measures that could be adopted:

a. Open windows and doors to improve natural ventilation;

b. Evaluate and document direction of airflow daily in high-risk areas within the DOTS facility. Use smoke test (incense sticks or mosquito coil) to visualize air movement;

c. Place or re-arrange furniture and seating such that staff-patient interaction occur with airflow passing from health worker to patient or between health worker and patient, rather than from patient to health worker (i.e., airflow from "clean to dirty");

d. Ensure that fans are clean and working properly.

4. Respiratory protection control is considered the **last line of defense**.

a. Based on the risk-assessment, identify who will wear respirators, where and when respirators will be used;

b. Perform fit test; and

c. Train staff on how to wear, care for, maintain and dispose of the respirator.

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B. TB IC measures within the household that health care workers should advise TB patients:

1. The importance of early detection and treatment of TB, and prompt screening of household contacts.
2. Methods to reduce exposure:

    a. Cough etiquette (i.e., covering mouth and nose when sneezing or coughing);
    b. Minimizing time spent by infectious TB patients in crowded public places; and
    c. Opening windows and removing any obstruction to ventilation in rooms where TB patient sleeps or spends much time.

C. TB IC measures mentioned above could be used and implemented in congregate settings like jails and prisons.

D. Procedure for the administration of BCG vaccine is discussed under the **Expanded Program on Immunization.**

E. Isoniazid Preventive Therapy

1. IPT for six (6) months shall be given to the following:

    a. Children less than five (5) years old without signs and symptoms of TB and without radiographic findings suggestive of TB, and who are household contacts[21] of -
        i. A bacteriologically-confirmed TB case regardless of TST results; or
        ii. A clinically-diagnosed TB case (if the child has a positive TST result).

    b. PLHIV with no signs and symptoms of TB regardless of age.[23]

2. Children qualified for IPT could be identified through household contact investigation[14] (as described in Chapter 2).

3. After ruling-out any signs and symptoms suggestive of TB, start INH at 10mg/kg. *(Refer to **Table No. 14 - Drug Administration per Kg Body Weight for Children** on page 40)..*

4. Accomplish **Form 4. TB Treatment/IPT Card** and register the child in **Form 9. IPT Register.**

5. Administer IPT for six (6) months. Assess the child at least every two (2) months and check for presence of signs or symptoms of TB. Weigh monthly and adjust dosage of INH accordingly if the child gains weight.

6. If the child develops any sign or symptom, evaluate for TB according to case finding procedures. If the child is assessed to have TB disease, stop IPT, start treatment for TB disease and declare IPT outcome as failed.

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7. After six (6) months of IPT, determine the outcome of IPT and record in **Form 4 and Form 9:**

    a. **Completed IPT** – a child who has completed six (6) months of IPT and remains well or asymptomatic during the entire period.
    b. **Lost to Follow-up** – a child who interrupted IPT for two (2) consecutive months or more.
    c. **Died** - a child who dies for any reason during the course of therapy.
    d. **Failed** – a child who developed TB disease (pulmonary or EPTB) anytime while on IPT.
    e. **Not Evaluated** - a child who has been transferred to another health facility with proper referral slip of continuation of IPT and whose treatment outcome is not known.

F. Baby born to mother with TB disease[21]

The risk of the baby being infected with TB is highest if a mother was diagnosed of TB at the time of delivery or shortly thereafter. In this case, it is very important that health workers should assess the newborn at once.

1. Assess the newborn. If the newborn is not well, refer it to a specialist/pediatrician.

2. If the newborn is well (absence of any signs or symptoms presumptive of TB), do not give BCG first. Instead give IPT for three (3) months. Give Pyridoxine at 5-10 mg/day.

3. After three (3) months, perform TST.

4. If TST is negative, stop IPT and give BCG. Assign **Completed IPT** as treatment outcome and record in **Form 4**.

5. If TST is positive and baby remains well, continue IPT for another three (3) months.

6. After six (6) months of IPT and if the baby remains well, give BCG.

7. If TST is not available and the newborn is well, the newborn should receive six (6) months of IPT followed by BCG immunization.

8. If the mother is taking anti-TB drugs, she can safely continue to breastfeed. However it would be better to advice the mother to feed the baby before taking the anti-TB drugs. Mother and baby should stay together and the baby may be breastfed while on IPT.

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CHAPTER 5

Recording and Reporting

I. INTRODUCTION

Recording and reporting are important in the implementation of a successful TB control program.

Availability of records ensures provision of appropriate and effective care for patients. Through efficient recording, health workers can monitor that each presumptive TB is examined and, if applicable, treated and cured. Records, therefore, should contain accurate, complete, and up-to-date information on patient's diagnosis, treatment, follow-up examinations, and treatment outcome.

Aside from information on the patient's coverage and care, reports also provide information on program efficiency and effectiveness, including availability of drugs and other supplies at the DOTS facilities. This section of the Manual of Procedures is designed to generate and provide the minimum set of information, required for program planning at different levels.

Records and reports have been revised to take into consideration the changes in program indicators, introduction of new tools, changes in case definitions based on WHO guidelines and program initiatives under PhilPACT.

II. OBJECTIVES

The objectives of recording and reporting are to:

- Document patient and program information that would ensure high-quality patient care, a continuum of care among referred TB cases, and information sharing among health care providers.
- Provide tools to help staff in providing adequate services to individual patients.
- Allow program managers at different levels of the health care system in the NTP to monitor and evaluate program performance in a standardized and internationally-comparable manner.

III. POLICIES

A. Recording and reporting for NTP shall be implemented in all DOTS facilities whether public or private. All NTP records should be kept for at least seven (7) years before properly being discarded.

B. Recording and reporting shall include all cases of TB, classified according to internationally accepted case definitions. Quarterly reports should reflect the sex, age, registration group and source of cases reported from various units in the province/city/municipality.

C. Confidentiality of patient records shall be observed at all times.

D. Recording and reporting for NTP shall use the FHSIS network for routine reporting and feedback.

E. The Integrated TB Information System (I-TIS) shall be the official electronic TB information system.

F. All quarterly reports should be sent to the DOH through channels (DOTS facility to PHO/CHO to RO to DPCB-DOH) based on agreed timeline.

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G. Records and reports shall allow for the calculation of the main indicators for program evaluation. *(See **Chapter 10. Monitoring, Supervision and Evaluation for the Indicators** on page 137).*

H. The NTP shall release official data annually based on the key program indicators. Request for other data shall be coursed through a formal letter to the NTP stating the intended use of the data.

IV. PROCEDURES FOR RECORDING

Below is a summary of the various recording and reporting forms to be used under the NTP. The records and reports are for both susceptible TB and DR-TB cases, adult and children, registered in DOTS facilities. This section will describe how each record/forms will be accomplished.

Table No. 24 - Summary of Recording and Reporting Forms

Records	Reports
1. Form 1. Presumptive TB Masterlist 2. Form 2a. NTP Laboratory Request Form 3. Form 2b. NTP Laboratory Result Form for HIV Testing of TB Patients 4. Form 3. NTP Laboratory Register (Microscopy and GX) 5. Form 4. TB Treatment/IPT card 6. Form 5. NTP ID Card 7. Form 6a. Drug-susceptible TB Register 8. Form 6b. DR-TB Register 9. Form 7. NTP Referral Form 10. Form 8. Hospital TB Referral Logbook 11. Form 9. IPT Register	1. Report 1. Quarterly Report on TB Microscopy and GX Laboratory Examinations 2. Report 2. Quarterly Report on EQA for TB Microscopy 3. Report 3a. Quarterly Report on Case Finding of Drug-susceptible TB Cases and IPT 4. Report 3b. Quarterly Report on DR-TB Cases 5. Report 4. Quarterly Report on Drug and Supply Inventory and Requirement 6. Report 5a. Quarterly Report on Treatment Outcome of Drug-susceptible TB Cases 7. Report 5b. Quarterly Report on Interim Treatment Outcome of DR-TB Cases 8. Report 5c. Annual Report on Treatment Outcome of DR-TB Cases 9. Report 6. Quarterly Report of Hospital TB Referrals

A. Form 1. Presumptive TB Masterlist

The Presumptive TB Masterlist will provide information on all presumptive TB seen in the DOTS facility and will help the health worker to decide on the following:

1. If a child fulfills the criteria of a TB case [three (3) out of five (5) criteria].
2. If a child will be given IPT.
3. If the presumptive TB is for DRTB screening referral.
4. When and where to trace patients who do not return for follow-up.

This record will be maintained at the DOTS facility (e.g., RHU or health center) including those with PMDT services. Maintaining a **Presumptive TB Masterlist** in the BHS is optional.

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Accomplish the **Presumptive TB Masterlist** as follows *(See **Form 1** on page 63)*:

Column 1: Write the date of consultation (mm/dd/yy) when the patient was identified as a presumptive TB.

Column 2: Write the name of presumptive TB. Family name first, all in capital letters, then the first name and the middle name.

Column 3: Write the age of the patient in years (as of the last birthday). If less than one (1) year old, write the age in months (as of last completed month).

Column 4: Write **F** for female and **M** for male.

Column 5: Write the complete address of the patient. Include where he/she can be contacted (telephone or mobile) once the diagnostic test result is available.

Column 6: If patient is referred from another facility or practitioner (e.g. hospital, PPMD unit or private physician), write the name of the referring unit or practitioner. Write also the name of the BHS if referred from there. Write **walk-in** if not referred by anyone.

Column 7: Write **Y** if the patient is a household contact of a known TB case and **N** if not a household contact.

Column 8: Write the date/s (mm/dd/yy) when the sputum specimen/s was/were collected and the result of the examination. *(See **Table No. 7** on page 25)*. If DSSM was not done, write **ND**. Use red ink if the result is positive.

Column 9: Write the date (mm/dd/yy) when the TST was read and the result. If TST was not done, write **ND** (e.g., for adult patients).

Column 10: Write the date (mm/dd/yy) when the CXR was done and the result. If CXR was not done, write **ND**.

Column 11: Write date (mm/dd/yy) and results of other diagnostic tests done (e.g., Xpert MTB/RIF).

Column 12: Write **Y** if the patient has been identified as a presumptive DR-TB. If not considered a presumptive DR-TB, write **N**.

Column 13: If the patient is eventually registered for treatment, write the **TB case number**. If the patient is assessed as not a TB case, indicate **not TB**. If the patient is referred to another facility, write the reason for referral and the outcome of referral (i.e., accepted or lost). Write other pertinent information in the remarks column.

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Form 1. Presumptive TB Masterlist

Date of Consult (MM/DD/YY)	Name (SURNAME/ First Name/ Middle Name)	Age	Sex (M/F)	Address & Contact Number	Name of Referring Unit	HH Contact of a TB Case? (Y/N)	Sputum Examination Date Collected (MM/DD/YY)/ Result		TST Date Read (MM/DD/YY)/ Reading	CXR Date Examined (MM/DD/YY)/ Result	Other Diagnostic Tests	Presumptive DR-TB? (Y/N)	Remarks (if registered: TB Case Number and Date Started; if referred: Name of DOTS Facility, reason & outcome of referral; or Not TB)
							1st	2nd					
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)		(9)	(10)	(11)	(12)	(13)

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B. Form 2a. NTP Laboratory Request Form

The NTP Laboratory Request Form will be used by DOTS facilities to request for DSSM, Xpert MTB/RIF, LPA, TB Culture (TBC) or Drug-susceptibility Test (DST). It will also be the result form for DSSM and Xpert MTB/RIF. Results of LPA, TB Culture and DST will be recorded in separate result forms. If two or more tests are simultaneously being requested from the same TB laboratory, only a single request form is required.

The upper half of the NTP Laboratory Request Form will be accomplished by the requesting DOTS facility as follows *(See **Form 2a** on page 66)*:

1. Indicate the name of the collection unit (e.g., the DOTS Facility, the TB Laboratory – Microscopy Center or Xpert Site – or the Remote Smearing Station).

2. Write the date (mm/dd/yy) when the exam was requested.

3. Write the name of the physician requesting for the diagnostic examination.

4. Write the full name of the patient. Family name first, all in capital letters, then the first name and the middle name.

5. Write the age in completed years (or months if less than one (1) year old), and indicate the sex with a check mark (✓) in the appropriate for male (**M**) or female (**F**).

6. Indicate with a check mark (✓) the history of previous treatment. If a retreatment case, determine the registration group (i.e., assume patient has **active TB**) and indicate with a check mark (✓). (Specifying the registration group may be deferred if for DSSM only).

7. Indicate with a check mark (✓) whether presumptive pulmonary or extra-pulmonary TB. If extra-pulmonary, specify the anatomical site and the type of specimen.

8. Indicate with a check mark (✓) the reason for examination, whether for diagnosis or for follow-up. If for follow-up, write the TB case number.

   If this is a repeat examination for diagnosis, state the reason for repeating (e.g., invalid/indeterminate result for Xpert).

   If DSSM is being done outside the routine follow-up schedule (e.g., certification of non-infectiousness or after treatment interruption), consider as Follow-up and specify the reason in this section.

9. Indicate with a check mark (✓) the type of specimen, whether sputum or other specimens. If other, specify what specimen is being tested.

10. Indicate the test being requested by checking DSSM, Xpert MTB/RIF, TB Culture, DST or LPA.

11. Indicate the date (mm/dd/yy) of collection of the specimen(s)/date if both specimens where collected on the same day, and 2 dates if collected on 2 separate days.

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12. Write the name and designation of the specimen collector or DOTS facility staff who accomplished the form. Affix the signature over the printed name.

The bottom half of the Laboratory Request Form will be for the results of DSSM and/or Xpert MTB/RIF. This will be accomplished by the TB laboratory as follows:

1. Write the Laboratory Serial number. This will be obtained from **Form 3a. NTP Laboratory Register (Microscopy and GX)** .

2. Write the date (mm/dd/yy) the specimen was received at the laboratory.

3. Under the corresponding column (i.e., specimen 1 or 2 for DSSM or under Xpert MTB/RIF column) describe the visual appearance of the specimen, whether **salivary, muco-purulent, blood-stained,** etc.

4. Indicate the reading. *(Refer to* ***Table No. 7 - DSSM Results and Interpretation*** *and* ***Table No. 8 - Xpert MTB/RIF Results and Interpretation****)*

5. For DSSM, write the final laboratory diagnosis whether **positive** or **negative**. Use red ink for a positive result.

6. Write the date of examination (i.e., when the reading was done - mm/dd/yy).

7. Write the name of the medical technologist or microscopist/Xpert MTB/RIF technician. Affix the signature over the printed name.

8. The completed Form (with Result) should be sent to the treatment unit for recording. A separate Result for Culture, DST and LPA will be issued.

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Form 2a. NTP Laboratory Request Form

To be filled out by Health Worker

Name of Collection Unit: _____ **Date of Request:** _____

Name of Requesting Physician: _____

Name of Patient: _____ **Age:** _____ **Sex:** [ ] M [ ] F

Address: _____ **Contact #:** _____

Registration Group: [ ] New [ ] Retreatment [ ] Other
○ Relapse ○ Treatment After Failure ○ TALF ○ PTOU

Anatomical Site: [ ] Pulmonary [ ] Extra-pulmonary Site: _____

Reason for Examination: [ ] Diagnosis [ ] Follow-up TB Case No. _____
[ ] Baseline (for PMDT) Month of Follow-up (for PMDT): _____

Repeat collection? [ ] No [ ] Yes Reason: _____

Type of Specimen: [ ] Sputum [ ] Other Specify: _____

Test Requested: [ ] DSSM [ ] Culture [ ] LPA
[ ] Xpert MTB/RIF [ ] DST if for DST, GX result: _____

Specimen	Date of Collection
1	
2	

Name of Specimen Collector: _____ **Designation:** _____
Signature over Printed Name

Portion below to be filled-out by Medical Technologist/ Microscopist/ GX Technician

Laboratory Serial Number: _____ **Date Received:** _____

	Smear Microscopy		**Xpert MTB/ RIF**
Specimen	**1**	**2***	
Visual Appearance**			
Reading			
Lab. Diagnosis			

*Specimen # 2 not applicable if follow-up **Muco-purulent, blood-stained, salivary, etc.

Date of examination: _____ **Examined by:** _____
Signature over Printed Name

The completed form (with results) should be sent to the treatment unit, for recording.
A separate Result Form for Culture, DST and LPA will be issued.

C. Form 2b. NTP Laboratory Result Form for HIV testing of TB Patients

This form will be used in DOTS facilities offering PICT. If the patient consents to HIV testing, standard recording forms of the NEC will be accomplished by the health worker who offered PICT. The NTP Laboratory Result Form for HIV testing is accomplished by the medical technologist who conducts the testing. It is accomplished as follows *(See **Form 2b** below)*:

1. Write the name of the DOTS facility.
2. Write the initials of the patient. (Note: The complete patient name and data are to be supplied in the NEC forms).
3. Write the date the test was requested (mm/dd/yy).
4. Write the age in completed years and sex (**M** or **F**) of the patient.
5. Write the laboratory serial number. This will be from the HIV testing logbook to be maintained by the medical technologist.
6. Fill-in the following data in the HIV result portion:
   a. Testing method used;
   b. Kit/Reagent used;
   c. Lot no. of testing kit;
   d. Result, whether **reactive** or **non-reactive.**
7. Write the date the test was performed (mm/dd/yy).
8. Write the date the test was released (mm/dd/yy).
9. Write the printed name of the medical technologist who did the testing.
   Affix the signature above the name.

Form 2b. NTP Laboratory Result Form for HIV Screening of TB Patients

Name of DOTS Facility: _____

Patient Name/ Initials: _____ **Date Requested:** _____

Age: _____ **Sex:** [ ] M [ ] F **Laboratory Serial Number:** _____

HIV Result (Screening)			
Method Used	Kit/ Reagent Used	Lot No.	Results

Date Performed: _____ **Date Released:** _____

Medical Technologist: _____
Signature over Printed Name

D. Form 3. NTP Laboratory Register (Microscopy and Xpert MTB/RIF)

All patients undergoing DSSM and Xpert MTB/RIF testing will be recorded in the NTP Laboratory Register for Microscopy and MTB/RIF. Information for the Laboratory Register will come from Form 2a, NTP Laboratory Request Form. This register will be maintained by the medical technologist or microscopist/Xpert MTB/RIF technician at the microscopy center or Xpert MTB/RIF site.

Accomplish the Laboratory Register as follows: (See Form 3 on the next page).

Indicate the year in the right upper hand corner of every page.

Column 1: Write the Laboratory Serial no. This number will be assigned by the MT/ microscopist/Xpert operator sequentially beginning with 0001 every start of the year.

Column 2: Write the date when the specimen was received at the laboratory (mm/dd/ yy).

Column 3: Write the name of patient. Family name first, all in capital letters, then the first name and the middle name.

Column 4: Write the age of the patient in years (as of the last completed year). If less than 1 year old, write the age in months (as of last completed month).

Column 5: Write F for female and M for male.

Column 6: Write the complete address of the patient. Include where he/she can be contacted (telephone or cellphone).

Column 7: Write the name of the collection unit (ie, the DOTS facility that requested the tests).

Column 8: Indicate the history of previous treatment, whether New (**N**) or Retreatment (**R**). If retreatment and for Xpert MTB/RIF testing, write the registration group (i.e., relapse, TAF, TALF, PTOU, other).

Column 9: Indicate the reason for the examination by putting a check mark (✓) under the diagnosis column if for diagnosis or by writing the TB case number if for follow-up. If for other reasons (e.g., certification of non-infectiousness or after treatment interruption), consider as “Follow-up” and specify reason(s) under “Remarks”.

Column 10: Write the date when the examination was done on the upper row. In the lower row, indicate the reading. *(See **Table No. 7 - Standard DSSM** and **Table No. 8 - Xpert MTB/RIF Readings** on page 25).*

For DSSM, please see above under section Form 2a, NTP Laboratory Request Form.

Column 11: Write any other pertinent information. For DSSM, write the visual appearance of the specimen (whether **salivary, muco-purulent, blood-stained,** etc.) and the final laboratory diagnosis (whether **positive** or **negative**). Use red ink for positive results.

Column 12: The medical technologist or microscopist/Xpert MTB/RIF technician affixes his/her signature.

At the bottom of each page, summarize the results.

For DSSM count the total number of cases examined for diagnosis, the number of positive result among those examined for diagnosis and the number of cases examined for follow-up.

For Xpert MTB/RIF, count the number of cases examined, the number with MTB detected (positive), the number with Rifampicin resistance and the number with indeterminate/ invalid/error result according to registration group.

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Form 3. NTP Laboratory Register (Microscopy and Xpert MTB/RIF)

Lab. Serial No.	Date Specimen Received (MM/DD/YY)	Name (SURNAME/ First Name/ Middle Name)	Age	Sex (M/F)	Address & Contact Number	Name of Collection Unit	History of Treatment (N/R)	Reason for Examination		Date of Examination/Result			Remarks	Signature of MT/Mx/ Lab. Tech.
							if for Xpert, write Registration Group	Diagnosis	Follow-up (TB Case No.)	Smear Microscopy 1st	Smear Microscopy 2nd	Xpert MTB/RIF		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)		(10)			(11)	(12)

DSSM		
No. of Examined (for diagnosis)	No. with Positive Examination Results	No. of Follow-up Cases Examined

Xpert MTB/RIF				
History of Treatment/ Reg. Group	No. of Examined	No. of MTB Detected	No. with Rif Resistance	No. of Indeterminate/ Invalid/ Error
New				
Relapse				
Other Retreatment				

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E. Form 4. TB Treatment/ IPT Card

This form is used for all TB patients that are initiated on treatment or patients given IPT. It is accomplished and maintained by the health worker at the DOTS facility.

Accomplish the TB Treatment/IPT Card as follows *(See **Form 4** on page 73)*:

For the front page,

1. Write the TB Case number or the IPT number. This a sequential number that will be determined once the patient is registered in Form 6a. Drug-susceptible TB Register or Form 9. IPT Register.

   For TB cases, the case number will follow the format: __ __ - __ __ __ - __ __
   (year – assigned facility number – patient number starting at 001 every year).

   For IPT, the IPT number will follow the format: __ __ - __ __ __
   (year – patient number starting at 001 every year).

2. Write the date (mm/dd/yy) the case was registered. Specify if Transfer In or Late Registration beside the date.

3. Write the region and the province.

4. Write the name of the DOTS facility.

5. Write the name of the patient, family name first, all in capital letters, then the first name and the middle name.

6. Write the date of birth (mm/dd/yy), age in years since last birthday (if less than 1 year, in completed months), and sex (M or F). Write the height (in centimeters).

7. Indicate if the BCG scar is present, absent or if doubtful, by putting a check mark (✓) in the appropriate space.

8. Write the complete address of the patient and contact numbers (telephone or cellphone).

9. Indicate with a check mark (✓) the source of the patient (i.e., from whom or where patient was referred). The source of the patient may be:

   Public Health Center – all "walk-in" patients for consultation in health centers with no referrals or not referred by the Barangay Health Stations.

   Other government facilities – include government hospitals, government workplaces, public schools, jails and prisons, government-operated residential homes and other government facilities.

   Private – include all private health care facilities (hospitals/clinics), NGO clinics and private physicians/practitioners

   Community – referred by community-based organizations, Community Health Teams and TB Task Forces

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Note: The verification of source would be through a duly accomplished referral form/letter from the referring facility, practitioner or community worker.

10. Write other patient details:
    - Occupation
    - PhilHealth number when applicable (if dependent, write **dependent** beside the PhilHealth number of the member)
    - Contact person (spouse, parent, children or other household member), and contact number of the contact person.

11. Write the first name and age (in years or completed months if less than 1 year) of all household contacts, regardless of age. Once the contact has been evaluated, indicate the date of evaluation (mm/dd/yy) under the column "screened".

12. Diagnostic tests: Write the date (mm/dd/yy) and result of all diagnostic tests done on the patient (i.e., TST, CXR, DSSM, Xpert MTB/RIF, others). Indicate the test reading for DSSM and Xpert MTB/RIF based on Tables No. 7 and No. 8 on page 25. If a test is not done, indicate as **ND**.

    For DSSM, if positive, write the higher rating among the 2 specimens in red ink. Write 0 if negative.

    If HIV testing was done, indicate by putting a check mark (✓) before **YES** under PICT (no need to write date/result). If HIV testing was not done and for areas not doing PICT, put a check mark (✓) before **NO**.

13. Indicate the diagnosis, whether TB disease, infection or exposure.

14. Indicate if there was a history of intake of anti-TB drugs by putting a check mark (✓) before **YES** or **NO.** If **YES**, indicate when drugs were taken (at least the year) and check the duration of intake, whether less than 1 month or more than 1 month.

    Put a check mark (✓) to indicate drugs previously taken.

15. Indicate the classification of the patient by bacteriological status (whether bacteriologically-confirmed or clinically-diagnosed), by anatomical site (whether pulmonary or extra-pulmonary, specify site), by registration group (New, Relapse, TALF, Treatment after Failure, PTOU, other) and transfer-in if referred from another facility.

    Leave this section blank if patient is for IPT only.

16. Encircle the appropriate treatment regimen and corresponding registration group. Leave this section blank if the patient is for IPT.

17. Indicate the date (mm/dd/yy) treatment or IPT was started. Specify if Transfer In or Late Registration beside the date.

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18. Indicate the last day of drug intake as the date (mm/dd/yy) of treatment outcome. Indicate with a check mark (✓) the treatment outcome. For patients transferred to another facility for continuation of treatment, get the final outcome from the receiving facility and indicate that as the treatment outcome. If this is not obtained (i.e., no feedback from receiving facility), assign "not evaluated" as the outcome.

19. During each monthly visit, write the date (mm/dd/yy) and indicate the weight of the patient.

    For children, indicate the corresponding clinical signs and symptoms present. Write a check mark (✓) if present and O if absent. If "unimproved general well-being" and "side effects" are present, specify the findings using the legend below the card.

20. For children using syrup preparations, indicate the dosage (in ml) of TB drugs during each visit.

For the back page,

1. Write the full name and designation of the treatment partner.

2. Record the daily intake as follows:

   - Write the corresponding months for the intensive and continuation phase.
   - Place the initials of the treatment partner on each box corresponding to the day of intake.
   - If the drugs were given for self-administered treatment, write a bracket and horizontal line on dates drugs were given.
   - If intake was missed for that day, encircle the box corresponding to the day the dose was missed..

3. Indicate the total number of doses given for each month.

4. Indicate the cumulative doses given (i.e., total number of doses for the month added to all previous doses in the treatment phase) each month.

5. In the remarks, write other pertinent information during treatment (e.g., reasons for interruption and interventions done).

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Form 4. TB Treatment/ IPT Card

TB CASE No./ IPT No.: **DATE OF REGISTRATION:** MM/DD/YY **REGION & PROVINCE/ CITY:** **NAME OF DOTS FACILITY:**

NAME OF PATIENT (SURNAME/ First Name/ Middle Name)**:**

Date of Birth (MM/DD/YY)**:** _____/_____/_____ **Age:** _____ years _____ mos. **Sex:** **Height:** _____ cm.

BCG Scar: [ ]Yes [ ]No [ ]Doubtful

COMPLETE ADDRESS & CONTACT NO.:

SOURCE OF PATIENT:
[ ] Public Health Center [ ] Community
[ ] Other Government Facilities/ Hospitals
[ ] Private Hospitals/ Clinics/ Physicians/ NGOs

Other Patient Details:
Occupation: _____
Philhealth No.: _____
Contact Person: _____
Contact No.: _____

HOUSEHOLD MEMBERS:

First Name	Age	Date Screened

DIAGNOSTIC TESTS:
1. Tuberculin Skin Testing (TST): 2. CXR Findings:
Result: _____mm _____
Date read: _____/_____/_____ Date of exam: _____/_____/_____
3. Other exam: _____ TBDC : _____
Date of exam: _____/_____/_____
4. XPERT MTB/RIF Result: _____ Date Collected:___/ ____/ ____
5. DSSM Results:

Month	Due Date	Date Examined	Result
0			
2			
3			
4			
5			
6			
>7			

6. PICT done? [ ]Yes [ ]No

HISTORY OF ANTI-TB DRUG INTAKE: [ ] No [ ] Yes When:
Duration: [ ] less than 1 mo. [ ] 1 mo. or more
Drugs taken: [ ]H [ ]R [ ]Z [ ]E [ ]S

BACTERIOLOGICAL STATUS:
[ ] Bacteriologically Confirmed
[ ] Clinically Diagnosed

ANATOMICAL SITE:
[ ] Pulmonary [ ] Extra-pulmonary
specify: _____

REGISTRATION GROUP:
[ ] New [ ] TALF
[ ] Relapse [ ] PTOU
[ ] Treatment After Failure [ ] Other
[ ] Transfer-in

TB DISEASE TREATMENT REGIMEN (encircle)

I. 2HRZE*/4HR
1. PTB, New-bacteriologically confirmed
2. PTB, New-clinically diagnosed
3. EPTB, New

Ia. 2HRZE*/10HR
1. EPTB, New-CNS/bones or joint

*For children <4 weeks, change E to S

II. 2HRZES/1HRZE/5HRE
1. Relapse
2. Treatment After Failure
3. TALF
4. Previous Treatment Outcome Unknown

IIa. 2HRZES/1HRZE/9HRE
1. EPTB, Retx-CNS/bones or joint

DATE TREATMENT/ IPT STARTED: MM/DD/YY

DIAGNOSIS: [ ] TB DISEASE
[ ] TB INFECTION, for IPT (for children below 5 yo)
[ ] TB EXPOSURE, for IPT (for children below 5 yo)

TREATMENT OUTCOME: **Date of Last Intake** (MM/DD/YY) _____
[ ] CURED [ ] FAILED
[ ] TREATMENT COMPLETED [ ] LOST TO FOLLOW-UP, specify reason: _____
[ ] DIED, specify cause of death:_____ [ ] NOT EVALUATED [ ] EXCLUDED FROM COHORT

CLINICAL EXAMINATION BEFORE AND DURING TREATMENT: [/] if present, [O] if absent, [--] if not applicable or write specific sign or symptoms

Date Examined/Results	Initial ___/___/___	1 ___/___/___	2 ___/___/___	3 ___/___/___	4 ___/___/___	5 ___/___/___	6 ___/___/___	7 ___/___/___	8 ___/___/___	9 ___/___/___	10 ___/___/___
Weight in Kg.											
Unexplained fever >2 wks											
Unexplained cough/ wheezing >2wks											
Unimproved general well being*											
Poor appetite											
Positive PE findings for Extra-pulmonary TB											
Side Effects**											

* 1-Fatigue, 2-reduced playfulness, 3-lethargy ** 1-itchiness, 2-skin rashes, 3-vomiting, 4-abdominal pain, 5-joint pains, 6-numbness, 7-yellowing of sclerae and skin, 8-visual disturbance, 9-hearing disturbance, 10-others

DRUGS: Dosages and Preparations (for children)

Isoniazid [H] 10mg/kg *(200mg/5ml)*	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml
Rifampicin [R] 15mg/kg *(200mg/5ml)*	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml
Pyrazinamide [Z] 30mg/kg *(250mg/5ml)*	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml
Ethambutol [E] 20mg/kg *(400mg tab)*	_____tab	_____tab	_____tab	_____tab	_____tab	_____tab	_____tab	_____tab	_____tab	_____tab	_____tab	_____tab
Streptomycin [S] 15mg/kg *(1g/vial)*	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml	_____ml

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Name of Treatment Partner: _____ Designation of Treatment Partner: _____

Drug Intake (Intensive Phase/6 months IPT): initials if supervised by treatment partner, [--] if self-administered, 0 if absent

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Doses given for this month	Total doses given

Drug Intake (Continuation Phase): initials if supervised by treatment partner, [--] if self-administered, 0 if absent

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Doses given for this month	Total doses given

Remarks: _____
_____
_____

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Mga Paalala Patungkol sa IPT

1. Ang Isoniazid Preventive Therapy (IPT) ay para sa mga bata mula 0-4 taong gulang na maaring magkasakit ng TB. Kailangang inumin ang isoniazid araw-araw sa loob ng 6 na buwan upang maiwasan ang sakit na TB.
2. Ang Isoniazid ay hindi bitamina kaya hindi ito para sa lahat ng bata.
3. Kailangang ibalik ang bata sa DOTS Center sa itinakdang araw upang masuri ng doktor at makasiguro na epektibo ang gamutan.
4. Ipasuri ang mga kasama sa bahay na may ubo na 2 linggo o mahigit pa para maiwasan ang posibleng pagkahawa.

Form 5. NTP Identification Card

[ ] TB Disease

TB Case No.							

[ ] IPT

IPT No.

Certification:

This certifies that _____, bearer of this NTP ID card, has complied with the required treatment, supervised by _____ (name of DOTS facility).

Issued this ____th day of _____, 20___.

_____
Physician
Signature over Printed Name

Mga Paalala Patungkol sa Sakit na TB

1. Ang sakit na TB ay nakakahawa pero nagagamot.
2. Mas malaki ang posibilidad ng paggaling kung araw-araw ang pag-inom ng gamot.
3. Kailangang magpasuri ng plema sa itinakdang araw ng health worker upang malaman kung tuloy-tuloy and paggaling.
4. Kapag magaling ka na, higit kang makatutulong sa pamilya at ka-barangay.

Name of DOTS Facility: _____

Name of Patient: _____

Address: _____

Treatment Partner/s: _____

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[ ] Isoniazid Preventive Therapy

[ ] Disease Anatomical Site
[ ] Pulmonary
[ ] Extra-pulmonary
Specify: _____

Treatment Regimen:

_____

Date Treatment Started (mm/dd/yy):

_____

Registration Group:
[ ] New
[ ] Relapse
[ ] Treatment After Failure
[ ] TALF
[ ] PTOU
[ ] Other
[ ] Transfer-in

DSSM Results & Weight:							
Schedule	0	Mo. 2	Mo. 3	Mo. 4	Mo. 5	Mo. 6	Mo. >7
Date Examined (MM/DD/YY)							
Result							
Weight (kg)							

Drug Intake (Intensive Phase/6 months IPT): initials if supervised by treatment partner, [--] if self-administered, 0 if absent

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Doses given for this month	Total doses given

Drug Intake (Continuation Phase): initials if supervised by treatment partner, [--] if self-administered, 0 if absent

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Doses given for this month	Total doses given

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F. Form 5. NTP ID Card

The NTP ID Card is accomplished in duplicate, one for the patient and one for the treatment partner, upon start of treatment. It is updated by the designated treatment partner.

Accomplish the NTP ID Card as follows *(See **Form 5** on pages 75-76).*

1. Indicate with a check mark (✓) whether the patient is undergoing TB treatment or IPT. Write the corresponding TB case number or IPT number (same procedure as in **Form 4. TB Treatment/ IPT Card.**

2. Write the name of the DOTS facility, name of the patient, address of the patient and name of designated treatment partner.

3. Complete the following data using the same procedures as that in **Form 4. TB Treatment/ IPT Card** *(See **Section E** on page 70),*

    - Type of treatment (IPT or Disease) and site of TB disease (pulmonary or extra-pulmonary)
    - Date (mm/dd/yy) treatment started
    - Registration group
    - Sputum follow-up examination dates (mm/dd/yy) and results; weight of patient
    - Record of drug intake and number of doses given (monthly and cumulative)

4. Upon completion of treatment, accomplish the certification at the back of the ID card. Affix the signature of the DOTS physician.

G. Form 6a. Drug-susceptible TB Register

All patients given Category I/Ia and II/IIa regimens will be recorded in the Drug-susceptible TB Register. Drug-resistant TB (DRTB) cases will be recorded in a separate register, Form 6b. DR-TB Register.

Information for the Drug-susceptible TB Register will come from Form 4. TB Treatment/ IPT Card. This register will be maintained by health workers at the DOTS facility.

Accomplish the Drug-susceptible TB Register as follows *(See **Form 6a** on page 79):*

At the upper right hand corner, indicate the month and year per page of the register.

Column 1: Write the date (mm/dd/yy) when the patient is registered in the DOTS facility. Specify if Transfer In or Late Registration beside the date.

Column 2: Write the TB Case number using the following format (year - assigned facility no. - patient no.).

Column 3: Write the full name of the patient. Family name first, all in capital letters, then the first name and the middle name.

Column 4: Write the date (mm/dd/yy) of birth.

Column 5: Write the age of the patient in years (as of the last birthday). If less than 1 year old, write the age in months (as of last completed month).

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Column 6: Write **F** for female and **M** for male.

Column 7: Write the complete address of the patient. Include where he/she can be contacted (telephone or cellphone).

Column 8: Indicate with a check mark (✓) the source of the patient following guidelines above in Form 4. TB Treatment/ IPT Card.

Column 9: Indicate the site of the disease by writing **P** for pulmonary and **EP** for extra-pulmonary. If EP, write the specific site below EP.

Column 10: Indicate the classification by bacteriological status by writing **BC** for bacteriologically-confirmed and **CD** for clinically-diagnosed.

Column 11: Indicate the registration group by putting a check mark (✓) under the appropriate column. Patients that are transferred from another DOTS facility will be indicated as "Transfer-in" and their assigned registration group from the referring facility. Please note that these cases should **NOT** be reported anymore in the case finding and case holding quarterly reports *(See **Form 6a** on the next page)* since they will be reported by the referring facility.

Column 12: Indicate the treatment regimen by writing **I, Ia, II or IIa**.

Column 13: Write the date (mm/dd/yy) treatment was started. For transferred-in patients and patients registered late, this should still reflect the date when TB drugs were first taken in the facility.

Column 14: Write the date (mm/dd/yy) and results of DSSM and Xpert MTB/RIF, including follow-up DSSM results. The date is written in the upper space and the result is written in the lower space. *(See **Tables No. 7 and No. 8** on page 25).*

Column 15: Indicate the treatment outcome by putting the date (mm/dd/yy) of last drug intake in the appropriate column.

For patients transferred to another facility for continuation of treatment, get the final outcome from the receiving facility and indicate that as the treatment outcome. If this is not obtained (i.e., no feedback from receiving facility), indicate not evaluated.

For patients that are shifted to a DR-TB regimen during treatment, write across the outcome columns: "DR-TB- excluded from cohort".

Column 16: For TB patients eligible for PICT (i.e., aged 15 year old and above), indicate if PICT was done by writing **Y** for yes and **N** for No. If done, indicate date (mm/dd/yy) of testing and the result (whether P for positive or N for negative).

For patients not eligible for PICT (i.e., less than 15 years old), write **NA** or a dash **(-)** under this column.

Column 17: Write other pertinent information about the patient (e.g., CXR result, PhilHealth number, TBDC result).

H. Form 6b. DR-TB Register

For DOTS facilities providing treatment for DRTB cases, all patients given DRTB treatment will be recorded in the Form 6b. DR-TB Register *(See **Form 6b** on page 82).*

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Form 6a. Drug-susceptible Register

Date of Registration (MM/DD/YY)	TB Case No.	Name (SURNAME/ First Name/ Middle Name)	Date of Birth (MM/DD/YY)	Age	Sex (M/F)	Address & Contact Number	Source of Patient				Anatomical Site (P/ EP)	Bacteriological Status (BC/ CD)	Registration Group						Transfer-in	Treatment Regimen (I/ II)
							Public Health Center	Other Public Facilities	Private	Community			New	Relapse	Treatment After Failure	TALF	PTOU	Other		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)				(9)	(10)	(11)							(12)

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Month & Year: ____________________

Date Started Treatment (MM/DD/YY)	Sputum Examination (Date Examined/ Result)								Treatment Outcome (Indicate Date of Last Intake)						PICT		Remarks (CXR result, PhilHealth member, TBDC result, CPT/ART, etc.)
	Before Treatment		Mo. 2	Mo. 3	Mo. 4	Mo. 5	Mo. 6	Mo. >7	Cured	Completed	Died	Failed	Lost to Follow-up	Not Evaluated	Done? (Y/ N/ NA)	Date (MM/DD/YY) / Result	
	DSSM	Xpert															
(13)	(14)								(15)						(16)		(17)

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Form 6b. Drug-resistant TB Register

Treatment Facility: _____

(1) DR-TB Registration Number (TC-YY-NNNN)	(2) Screening Date (MM/DD/YY) / (3) Treatment Start Date (MM/DD/YY)	(4) Full Name (SURNAME, First, Middle)	(5) Age / (6) Sex (M/F)	(7) Permanent Address (House No., Street, Barangay, City/ Municipality, Province & Region)	(8) Site of Disease (P/ EP & specify) / (9) History of TB Treatment (N/R-FLD/R-SLD)	(10) Registration Group (see legend below) / (11) Risk Factor/s (see legend below)	(12) Drug Susceptibility Testing: Date Collected (MM/DD/YY)	H	R	E	S	Z	Ofx	Lfx	Km	Am	Cm	Date Released (MM/DD/YY)	(13) Bacteriologic Status at Start of Treatment (see legend below)	(14) Regimen at Start of Treatment (Initials)

R (in red)- Resistant, S- Susceptible, ND- Not Done

Registration Group:
N- New
R- Relapse
Add "-TI" and date of transfer if Transferred-in
O- Other
TAF- Treatment After Failure
TALF- Treatment After Lost to Ff-up
PTOU- Previous Treatment Outcome Unknown

Risk Factor/s:
None
C- Contact of a confirmed/ suspected DRTB case with CXR findings/ symptoms suggestive of TB
NC- Non-converter of Category I or Category II treatment
H- PLHIV with signs and symptoms suggestive of TB

Bacteriologic Status:
BC RR/ MDR- Bacteriologically-confirmed RR-/ MDR-TB
BC XDR- Bacteriologically-confirmed XDR-TB
CD MDR- Clinically-diagnosed MDR-TB
OD- Other DR-TB (Mono-, Poly-)

Anti-TB Drugs:
H- Isoniazid
R- Rifampicin
E- Ethambutol
Z- Pyrazinamide
S- Streptomycin
Km- Kanamycin
Am- Amikacin
Cm- Capreomycin
Ofx- Ofloxacin
Lfx- Levofloxacin
Mfx- Moxifloxacin
Pto- Prothionamide
Cs- Cycloserine
PAS- PASER

Summary: Total No. of Patients Registered ____ No. of Patients Transferred-in ___ No. of Bacteriologically-confirmed RR-/MDR-TB ____ No. of Bacteriologically-confirmed XDR-TB ____ No. of Clinically-diagnosed MDR-TB ____ No. of Other DR-TB ____

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Form 6b. Drug-resistant TB Register

Region: _____ Quarter & Year: ______________________________

(15) Direct Sputum Smear Microscopy (S), TB Culture (C) and Xpert MTB/RIF (X) (Results/ Date Examined MM/DD/YY)																																							(16) Treatment Outcome (Date & Reason)	(17) Name of Treatment Site/ Partner	(19) Post-Treatment Follow-up (Results/ Date)				(20) HIV Status (see legend below)	(21) Remarks
S	B		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36		(18) Date Decentralized (MM/DD/YY)	1	2	3	4		
S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/	S/			S/	S/	S/	S/		
X	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C			C	C	C	C		

DSSM:
0 — 1+ (in red)
+n (in red) — 2+ (in red)
3+ (in red)

TBC:
0
MTb (in red)
ND- not done

Xpert MTB/RIF:
RR (in red)- MTb detected, Rif-resistance detected
T (in red)- MTb detected, Rif-resistance not detected
TI (in red)- MTb detected, Rif-resistance indeterminate
N- MTb not detected
I- Invalid/ no result/ error
ND- not done

HIV Status:
N- Negative
P- Positive
P ART- Positive on ART
P CPT- Positive on CPT

No. of Culture Negative at 6th month of Treatment ___

No. of Cured ___ No. of Completed Treatment ___ No. of Failed ___ No. of Died ___ No. of Lost to Follow-up ___

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I. Form 7. NTP Referral Form

The NTP Referral Form will be used by DOTS facilities as well as other health facilities and providers engaged in DOTS to refer to other DOTS facilities for services. It will be accomplished by the health workers in the referring facility and brought by the patient to the receiving facility. The receiving facility will accomplish the feedback form and resend to the referring facility.

All referral should be accompanied by copies of supporting documents, such as: previous or current treatment card or ID card, results of DSSM, CXR or other diagnostic tests, certification of diagnosis from previous physician (e.g., for EPTB), etc.

Accomplish the NTP Referral Form as follows *(See **Form 7** on the next page).*

For the upper portion, this will be accomplished by the referring facility as follows,

1. Indicate the TB case number if patient is currently on treatment.
2. Write the name of the facility referred to and the date (mm/dd/yy) of referral.
3. Write the name of the referring unit.
4. Write the telephone number, fax number including area code and e-mail address of the referring unit (as applicable).
5. Write the complete address of the referring unit, including the ZIP code.
6. Write the full name of the patient, family name first, all in capital letters, then the first name and the middle name.
7. Write the age in years (or, completed months if less than 1 year old), the sex (**M** or **F**) and weight in kilograms.
8. Write the patient's complete address and contact numbers (telephone or cellphone number). If patient is going to transfer residence, write here the new address/ contact numbers.
9. Indicate the reason for referral by putting a check mark (✓) in the appropriate box/ es. For reasons not cited here, check "others" and specify the reason, current regimen and duration of intake if possible.
10. Write the details of previous TB treatment history, including the date (mm/dd/yy) treatment was started, facility where patient was treated, anti-TB drugs taken and duration, and outcome of treatment. *(See **Chapter 3 Section 1** on page 34).*
11. Write the name of the referring DOTS staff and affix the signature.
12. Write the cellphone/telephone number and/or e-mail address of the DOTS staff.
13. Write the designation of the DOTS staff (e.g, physician, nurse, midwife).

For the lower portion, this will be accomplished by the receiving facility as follows,

14. Write the name and address of the referring unit.
15. Write the name of the receiving unit, the date (mm/dd/yy) referral was received and the telephone/fax number, including the area code.
16. Write the complete address of the receiving unit.
17. Write the full name of the patient, family name first, all in capital letters, then the first name and the middle name.
18. Write the name and designation of the receiving DOTS staff, affix the signature. Write also the telephone or cellphone number, including the area code, of the staff.
19. Indicate the action taken on the patient by placing a check mark (✓) on the appropriate box. Indicate the date (mm/dd/yy), result or number and reason as required, according to action taken.
20. Write any other pertinent information about the referral in the remarks.

    The bottom portion should be cut-off and sent back to the referring facility. If sending back is not possible, the receiving facility should give feedback through other means (e.g., SMS, e-mail, through the local NTP coordinator, etc.).

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Form 7. NTP Referral Form

TB Case Number

To: _____ **Date Referred**: _____

Please accommodate the patient bearing this referral form. Kindly inform the Referring DOTS Staff as soon as patient has been evaluated by calling, sending SMS/email or sending back the Return Slip below.

(To be accomplished by Referring Unit)

Name of Referring Unit	**Telephone No.**	**Fax No.**	**E-mail Add.**

Complete Address of Referring Unit

Name of Patient (SURNAME/ Given Name/ Middle Name)	**Age**	**Sex**	**Weight (kg)**

Complete Address of Patient	**Contact No. of Patient**

Reason for Referral:

[ ] For DSSM

[ ] For registration and treatment

[ ] For continuation of treatment

[ ] For IPT (children 0-4 y/o)

[ ] For evaluation of Presumptive DRTB *(Write history below)*

- ○ Relapse
- ○ Treatment After Failure
- ○ Treatment After Lost to Follow-up
- ○ Previous Treatment Outcome Unknown
- ○ HH Contact of DRTB Case
- ○ Non-converter of Cat I or II
- ○ PLHIV with TB symptoms
- ○ Other

[ ] Others, specify _____

History of TB Treatment

Date Treatment Started	Name of Treatment Unit	Anti-TB Drugs Taken and Duration	Outcome

Name of Referring DOTS Staff	**Signature**	**Cellphone No./Email Add.**	**Designation**

Please attach copy of: 1. NTP Treatment Card/s of Previous Treatment/s, 2. Latest DSSM results, 3. Other laboratory results (CXR, TBDC, blood chem.)

Return Slip

Name of Referring Unit: _____

Address of Referring Unit: _____

(To be accomplished by Receiving Unit)

Name of Receiving Unit	**Date Received**	**Contact No.**

Complete Address of Receiving Unit

Name of Patient

Name of Receiving DOTS Staff	**Signature**	**Cellphone No./ Email Add.**	**Designation**

Action Taken:

[ ] DSSM performed, write date ____/ ____/ ____ and results _____

[ ] Patient started/ resumed treatment and registered: TB Case No._____ Date Registered ____/ ____/ ____

[ ] Evaluated as Presumptive DR-TB, Xpert test performed write date ____/ ____/ ____ and results _____

[ ] Not enrolled, specify reasons/s _____

[ ] Others, specify _____

Remarks:

_____

J. Form 8. Hospital TB Referral Logbook

The Hospital TB Referral Logbook will be used in all hospitals implementing DOTS either as DOTS providing hospital or DOTS referring hospital. It shall be maintained by the hospital's TB team. All patients, whether from the inpatient or outpatient department, referred to the hospital TB team will be registered in this logbook.

The hospital referral logbook is accomplished as follows *(See **Form 8** on page 87)*:

Column 1: Write the date (mm/dd/yy) when the patient was received/seen by the TB clinic.

Column 2: Write the referral number. This is a sequential numbering of referrals that start at 001 every year, (e.g., 14-001 for the 1st patient in 2014).

Column 3: Write the full name of patient. Family name first, all in capital letters, then the first name and the middle name.

Column 4: Write the age of the patient in years (as of the last birthday). If less than 1 year old, write the age in months (as of last completed month).

Column 5: Write **F** for female and **M** for male.

Column 6: Write the complete address of the patient.

Column 7: Write the contact number (telephone or cellphone number including area code).

Column 8: Write **TB** if patient was diagnosed to have TB disease and **Pr** if patient is a presumptive TB. If patient was initially a presumptive TB but was later diagnosed to be active TB, update the entry by crossing out Pr and adding TB below.

Column 9: If TB, write **P** if pulmonary or **EP** if extra-pulmonary on the top row. At the bottom row, write **BC** for bacteriologically-confirmed or **CD** for clinically-diagnosed. If not TB, leave this column blank.

Column 10: If TB, indicate the registration group (whether **New, Relapse, TALF, TAF, PTOU, other**). If not TB, leave blank.

Column 11: If TB, indicate the treatment regimen by writing **I, Ia, II, or IIa.** If not TB, leave blank.

Column 12: If TB, write **Y** if patient is already registered in another DOTS facility at the time of referral. Write **N** if not.

Column 13: Write the source of (internal) referral as follows,

O for OPD
W for wards or inpatient
WI for walk-in
Specify if others (e.g., ER, pharmacy, radiology, HMOs, etc.)

Column 14: If TB, write **Y** if the patient was started treatment while in the wards/inpatient. Otherwise, write **N.**

Column 15: If TB, write the TB case number if the patient was registered in the hospital DOTS clinic. If not, leave blank.

Column 16: Write **Y** if the patient was referred to another facility and **N** if not. If referred, indicate the date (mm/dd/yy) of referral.

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Column 17: Write other actions taken as follows,

PMDT if referred to PMDT facilities.
TH if referred to a treatment hub.
R if not registered nor referred to other DOTS facilities.
TBDC if referred to a TBDC.
Specify if other actions were taken.

Column 18: Indicate the reason for referring as follows,

D for DSSM.
X for Xpert MTB/RIF.
I for IPT.
R for registration and treatment.
T for transfer.
Specify other reasons.

Column 19: If referred, write the name and complete address of the facility referred to (i.e., receiving facility).

Column 20: Write the contact number, including area code, of the receiving facility.

Column 21: Indicate the outcome of the referral by writing **accepted** or **lost**. If accepted, write the date (mm/dd/yy) patient was received at the facility. Patients with no feedback of the referral at the end of the next quarter will be classified as "lost."

Column 22: Indicate the mode used to find out the outcome of the referral as follows,

R if the return slip was brought back by patient or family.
XT if cross-checked with the TB register of the receiving DOTS facility.
XE if cross-checked with the ITIS.
C if the receiving facility called or was called (e.g., by land or mobile phone).
E if informed via email.
S if informed via text message.
F if the return slip was faxed.
P if return slip was mailed back via postage.

Column 23: Write other pertinent information about the patient (e.g., TBDC recommendations, reasons for refusing DOTS referral, if patient died at the hospital, etc.)

Summary Table 1*:* This table should contain the number of patients referred **EXCLUDING** those that have been registered in other DOTS facilities at the time of reporting (i.e., **Y** in column 12).

For each page, summarize by counting and writing the total number of referrals and the number of referrals from the ward (count **W** in column 13) segregated into confirmed and presumptive TB (see column 8). Count and write also the number of confirmed TB registered in the hospital (column 15) and the number of confirmed TB cases not registered and not referred (count the number of confirmed cases with **N** in column 15 and **N** in column 16.)

Summary Table 2*:* For each page, summarize by counting the total number of confirmed TB cases referred to other DOTS facilities (see column 8 – **TB** and column 16 – **Y**). Among these, write the total number of accepted and the total number of lost referrals (column 21).

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Form 8. Hospital TB Referral Logbook

Date Received by TB Clinic (MM/DD/YY)	Referral No.	Patient Information						Classification of TB		Treatment Regimen	Registered in another DOTS Facility? (Y/ N)*	Source of Referral (see legend below)
		Name (SURNAME/ First Name/ Middle Name)	Age	Sex (M/ F)	Complete Address (No., St., Brgy, Municipality/ City, Province)	Contact No.	Write "**TB**" if disease; "**Pr**" if presumptive	Anatomical Site (P/ EP) / Bacteriological Status (BC/ CD)	Registration Group			
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)

(24) Summary Table 1	*Confirmed TB*	*Presumptive TB*
1. Total no. of referrals		
2. No. of referrals from Wards		
3. No. of confirmed TB registered		
4. No. of confirmed TB not registered and not referred		

* (12) Registered in another DOTS facility: if "Y", do not include this patient in the summary table (24).

Legend (13)
O- OPD
W- Ward
WI- Walk-in
Others, specify- ER, pharmacy, radiology, HMOs, pay, etc.)

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Action/s Taken				Reason for Referring (see legend below)	Receiving DOTS Facility Information		Outcome of Referral (Accepted, Date/ Lost)	Mode of Knowing Outcome of Referral (see legend below)	Remarks (TBDC recommendations; reason for refusing DOTS/ referral; patient died at the hospital, etc.)
Started Treatment at the Ward? (Y/ N)	Registered at the Hosp. TB Clinic? (write TB Case No.)	Referred to a DOTS Facility? (Y, write date/ N)	Others (see legend below)		Name & Complete Address of Receiving DOTS Facility	Contact No.			
(14)	(15)	(16)	(17)	(18)	(19)	(20)	(21)	(22)	(23)

Legend (17)
PMDT- referred to a PMDT facility
TH- referred to a Treatment Hub
R- not registered nor referred to other DOTS facilities
TBDC- referred to TBDC
O - Other actions taken, specify

Legend (18)
D- for DSSM
I- for IPT
R- for registration & treatment
T- for Trans-out
O- Others, specify

(25) Summary Table 2	*Confirmed TB*
1. No. referred to other DOTS facilities	
2. Outcome of external referrals	
No. and % accepted	
No. and % lost	

Legend (22)
R- return slip brought by patient/relative
XT- cross-checking w/ TB Reg. of receiving DOTS
XE- cross-checking with ITIS of the city
C- calling receiving DOTS facility
E - Email
S - text message
F - Fax
P - Postage

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K. Form 9. IPT Register

All patients given IPT (whether children or PLHIV) will be recorded in the IPT Register. Information for this Register will come from **Form 4. TB Treatment/IPT Card**. This register will be maintained by health workers at the DOTS facility.

Accomplish the IPT Register as follows *(See **Form 9** on the next page)*:

Column 1: Write the date (mm/dd/yy) when the patient was evaluated at the DOTS facility

Column 2: Write the IPT number using the following format (year - patient no. starting at 001 every year).

Column 3: Write the full name of the patient, family name first, all in capital letters, then the first name and the middle name.

Column 4: Write the age of the patient in years (as of the last birthday). If less than 1 year old, write the age in months (as of last completed month).

Column 5: Write **F** for female and **M** for male.

Column 6: Write the complete address of the patient. Include where he/she can be contacted (telephone or cellphone, including the area code).

Column 7: Write **E** for TB exposure or **I** for TB infection.

Column 8: Write the date (mm/dd/yy) when the patient is started on IPT.

Column 9: Indicate the outcome of IPT by putting the date (mm/dd/yy) of last drug intake in the appropriate column.

Column 10: Write other pertinent information about the patient.

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Form 9. IPT Register

Month & Year: _____

Date Evaluated (MM/DD/YY)	IPT No.	Name (SURNAME/ First Name/ Middle Name)	Age	Sex (M/F)	Address & Contact Number	Exposure or Infection? (E/ I)	Date IPT Started (MM/DD/YY)	Outcome (Indicate Date MM/DD/YY of Last Intake)					Remarks
								Completed	Died	Failed	Lost to Follow-up	Not Evaluated	
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)			(9)			(10)

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V. PROCEDURES FOR REPORTING

The NTP reporting forms are to be accomplished quarterly by all DOTS facilities or TB laboratories and submitted to the next higher level (i.e., provincial or city health offices). All reports should be reviewed and approved by the DOTS facility physician before submission.

The reports will be consolidated and analyzed by the PHOs/CHOs and submitted to the ROs. The ROs will, likewise, analyze and consolidate the reports. The laboratory reports **(Reports 1 and 2)** will be submitted to NTRL while the rest **(Reports 3a, 3b, 4, 5a, 5b, 5c and 6)** will be submitted to NTP.

This section describes the different reporting forms.

A. Report 1. Quarterly Report on TB Microscopy and GX Laboratory Examinations

The Quarterly Report on TB Microscopy and Xpert MTB/RIF Laboratory Examinations will be accomplished by the medical technologist or microscopist/Xpert technician in the microscopy center and Xpert MTB/RIF sites. Data source for Report 1 will be **Form 3. NTP Laboratory Register (Microscopy and Xpert MTB/RIF)**. The ROs will submit this report to the National TB Reference Laboratory (NTRL).

Accomplish the Report 1 as follows: *(See **Report 1** on the next page)*

1. Count the number of patients examined **for diagnosis** with DSSM. For patients examined with Xpert MTB/RIF, segregate according to registration group- i.e., new, relapse or other retreatment cases (TAF, TALF and PTOU).

2. Among those patients in #1, indicate how many had a positive DSSM or Xpert MTB/RIF result. For Xpert MTB/RIF, positive means “MTB detected” regardless of Rifampicin resistance (i.e., RR, T and TI)

3. For DSSM only, indicate the positivity rate which is number with positive exam (#2) divided by number examined for diagnosis (#1) in percentage.

4. For Xpert MTB/RIF only, among those with positive exam or “MTB detected”, indicate how many were resistant to Rifampicin or (Rifampicin resistance detected).

5. Indicate the number of cases where Rifampicin resistance where not detected.

6. Indicate the number of cases with indeterminate Rifampicin resistance.

7. Indicate the number of cases with error/invalid results.

8. Indicate the number of cases with MTB undetected.

9. Indicate the number of follow-up DSSM examinations done for the quarter.

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Report 1. Quarterly Report on TB Microscopy and GX Laboratory Examinations

(Source of Data: Form 3. NTP Laboratory Register – Microscopy and GX)

Name of RO: _____ Report for the period: ____ Quarter of _____

Name of Province/ City: _____ Date Reported: _____

Name of DOTS Facility: _____ Prepared by: _____

Population of Catchment Area: _____ Designation: _____

For Province/ City and Regional Level:

Total no. of TMLs that submitted report	
Total no. of TMLs	

A. Case Finding:

Laboratory Activities	DSSM	Xpert		
		New	Relapse	Previously Treated (except Relapse)
1. No. examined				
2. No. with positive examination result*				
3. Positivity Rate**				
4. No. with Rifampicin resistance				
5. No. with Rifampicin resistance not detected				
6. No. with Rifampicin resistance indeterminate				
7. No. with error/ invalid result				
8. No. with MTB not detected				

*For Xpert, all MTB positive result

**Positivity Rate = #2 / #1

B. Treatment Follow-up (DSSM only):

9. No. of follow-up cases examined	

B. Report 2. Quarterly Report on EQA for TB Microscopy

The Quarterly Report on EQA for TB Microscopy will be accomplished by the validator (medical technologist) at the provincial or city Quality Assurance center. Data source for this report will be the EQA reports being accomplished also by the provincial or city validators. The RO will submit this report to the NTRL.

Accomplish Report 2 as follows: *(See **Report 2** on the next page)*

1. Indicate the total number of TMLs (**A**) in the catchment area that are part of the TB Laboratory network (i.e., using a TB Laboratory Register). Segregate by private or public ownership and get the total.

2. Among those in (**A**), indicate how many participated in EQA (**B**) for the quarter being reported. Segregate by private or public ownership and get the total. Percentage is computed by (**B**) divided by (**A**).

3. Indicate the number of TMLs that have less than 5% major errors on EQA (**C**) including those that have no major errors. Segregate by private or public ownership and get the total. For the percentage, divide (**C**) by the total number of TMLs (**A**).

4. Indicate the number of TMLs with major errors, regardless of percentage of major errors (**D**).

5. Among those with major errors (**D**), indicate how many were given feedback and discussed corrective actions (**E**). Compute the percentage given feedback (i.e., (**E**) divided by (**D**)).

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Report 2. Quarterly Report on External Quality Assessment for TB Microscopy

(Source of Data: Quality Assurance Center Records)

Name of RO: _____ Report for: _____ Quarter of _____

Name of Province/ City: _____ Date Reported: _____

Name of QA Center: _____ Prepared by: _____

Population of Catchment Area: _____ Designation: _____

TB Microscopy Laboratory		Public	Private	Total
No. of TB Microscopy Laboratories (TMLs)	(A)			
TML participating in EQA	(B)			
	(B/A) x 100	%	%	%
TML with <5% major errors	(C)			
	(C/A) x 100	%	%	%

EQA: On-site Evaluation		Number
TMLs with major error/s	(D)	
Feedback done by the QAC Team to discuss corrective actions	(E)	
	(E/D) x 100	%

C. Report 3a. Quarterly Report on Case Finding of Drug-susceptible TB Cases and IPT

The Quarterly Report on Case Finding will be accomplished by the nurse at the DOTS facility. Data source for this report will be **Form 6a. Drug-susceptible TB Register** and **Form 9. IPT Register.**

Accomplish **Report 3a** as follows: *(See **Report 3a** on the next page)*

1. For Tables A and B: Count the number of TB cases by anatomic site (column 9 in DS TB Register), by bacteriologic status (column 10), and by registration group (column 11). Segregate by sex (column 6).

   For the registration group, all other retreatment cases aside from Relapse (i.e., TALF, Treatment after Failure, PTOU and Other) are included under "Previously Treated".

2. For Table C: Count all New and Relapse cases, regardless of anatomic site and bacteriologic status, and segregate by age group (column 5) and sex (column 6). The total number of new relapse cases from Tables A and B should equal Table C.

3. For Table D: Count the source of patient (column 8) ONLY for new and relapse cases. The total number of new relapse cases from Tables A and B should equal Table D.

4. For Table E: Count the number of pulmonary and extra-pulmonary TB cases (column 9) that are less than 15 years old (column 5). This will include all registration groups and bacteriologic status.

5. For Table F: Count the total number of TB patients aged 15 years old and above who are eligible for HIV testing (i.e., with either a **Y** or **N** in column 16). Among these patients, count how many were actually tested (**Y** in column 16) and how many were subsequently confirmed to be **positive** for HIV.

   If there are TB-HIV co-infected patients being given ART or CPT at the DOTS facility, indicate the number also.

6. For Table G: Count the number of children less than 5 years old and PLHIV that were initiated on IPT for the quarter.

D. Report 3b. Quarterly Report on DR-TB Cases

The Quarterly report on DR-TB cases will be accomplished by the nurse in DOTS facilities providing PMDT services. Data source for this report will be **Form 6b. DR-TB Register.** *(See **Report 3b** on page 98).*

This report will be submitted by DOTS facilities with PMDT services to the PHOs/CHOs.

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Report 3a. Quarterly report on Case Finding of Drug Susceptible TB Cases and IPT

(Source of Data: Form 6a. Drug-susceptible TB Register and Form 9. IPT Register)

Name of RHO: _____ Report for: _____ Quarter of _____

Name of Province/ City: _____ Date Reported: _____

Municipality: _____ Prepared by: _____

Name of DOTS Facility: _____ Designation: _____

Population of Catchment Area: _____

For Province/ City and Regional Level:

Total no. of DOTS Facilities that submitted report	
Total no. of DOTS Facilities	

A. Bacteriologically-confirmed TB Cases Registered During the Quarter by Registration Group and Sex

Classification	New		Relapse		Previously Treated (except Relapse)		Total	
	M	F	M	F	M	F	M	F
Pulmonary								
Extra-pulmonary								
Subtotal								
Total								

B. Clinically-diagnosed TB Cases Registered During the Quarter by Registration Group and Sex

Classification	New		Relapse		Previously Treated (except Relapse)		Total	
	M	F	M	F	M	F	M	F
Pulmonary								
Extra-pulmonary								
Subtotal								
Total								

C. All New and Relapse TB Cases (All Forms) by Age and Sex

	0-4		5-14		15-24		25-34		35-44		45-54		55-64		>=65		Total	
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
New																		
Relapse																		
Subtotal																		
Total																		

D. Source of All New and Relapse TB Cases (All Forms)

Number of All New and Relapse TB Cases (All Forms)	Source of Patient			
	Public Health Center	Other Public Facilities	Private	Community

E. TB in Children

Total TB cases less than 15 years old	Number
Pulmonary	
Extra-pulmonary	

F. HIV Status Among 15 Years Old and Above

Number of TB Cases registered for the quarter (15 years old and above)	No. of cases tested or with known HIV status during the quarter	No. of TB cases confirmed positive for HIV	Among HIV positive, number given	
			ART	CPT

G. Individuals Given IPT

	Number given IPT
Children age 0-4 (without HIV)	
PLHIV	

Report 3b. Quarterly Report on All DR-TB Cases

(Source of Data: Form 1. Presumptive TB Masterlist and Form 6b. DR-TB Register)

Name of RO: _____ Report for: _____ Quarter of _____

Name of Province/ City: _____ Date Reported: _____

Municipality: _____ Prepared by: _____

Name of DOTS Facility: _____ Designation: _____

Population of Catchment Area: _____

For Province/ City and Regional Level:

Total no. of DOTS Facilities that submitted report	
Total no. of DOTS Facilities	

A. All Presumptive DR-TB identified during the quarter:

Classification	New	Relapse	Previously Treated (except Relapse)	Total
Number of All Presumptive DR- TB Screened				
Number of All Presumptive DR-TB Tested				
Number of All Confirmed RR-TB				

B. All DR-TB cases registered during the quarter:

Classification of DR-TB Case	New	Relapse	Previously Treated (except Relapse)	Total
All Bacteriologically-confirmed RR-/ MDR-TB				
All Bacteriologically-confirmed XDR-TB				
All Clinically-diagnosed MDR-TB				
Other Drug-resistant TB cases				
Total				

C. Breakdown of New and Relapse Bacteriologically-confirmed RR / MDRTB and XDRTB Cases Registered During the Quarter by Age, Group and Sex

	0-4		5-14		15-24		25-34		35-44		45-54		55-64		>=65		Total	
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
New																		
Relapse																		
Subtotal																		
Total																		

D. HIV Status Among 15 Years Old and Above

Number of DR-TB Cases registered for the quarter (15 years old and above)	No. of cases tested or with known HIV status during the quarter	No. of DR-TB cases confirmed positive for HIV	Among HIV positive, number given	
			ART	CPT

E. Report 4. Quarterly Report on Drug and Supply Inventory and Requirement

The Quarterly Report on Drug and Supply Inventory and Requirement will be accomplished by the designated health worker (nurse or midwife) in the DOTS facility. At the provincial, City and RO level, it will be accomplished by the NTP nurse in coordination with the supply officer. This report will be the basis for the quarterly allocation of TB drugs to the DOTS facilities. *(See **Report 4** on the next page).*

Data source for this report will be **Report 3a. Quarterly Report on Case Finding of Drug-susceptible TB and IPT for Data** on the number of TB cases treated and given IPT and **Report 1. Quarterly Report on TB Microscopy and Xpert MTB/RIF Laboratory Examinations** for data on the number patients undergoing laboratory examinations and the stock cards and inventory reports for the current stocks of drugs and supplies.

Computations related to this table are to be discussed in **Chapter 6. Management of TB Drugs and Laboratory Supplies.** In addition to data on drug inventory and requisition, DOTS facilities will indicate in the form if they experienced stock-outs in Category I drugs for adults anytime during the quarter.

F. Report 5a. Quarterly Report on Treatment Outcome of Drug-susceptible TB Cases

The Quarterly Report on Treatment Outcome of Drug-susceptible TB cases will be accomplished by the nurse in the DOTS facility. Data source for this report will be **Form 6a. Drug-susceptible TB Register** and **Form 9. IPT Register.** The treatment outcomes of registered TB patients will be reported after one year, as follows:

Table No. 25 - Summary of Reporting Period and Corresponding Cohorts, Treatment Outcomes of Registered TB Patients

Reporting Period	Cohort of Patients to be Reported
1st quarter of current year (e.g., April 2013)	1st quarter of previous year (e.g., Jan-Mar 2012)
2nd quarter of current year (e.g., July 2013)	2nd quarter of previous year (e.g., Apr-Jun 2012)
3rd quarter of current year (e.g., October 2013)	3rd quarter of previous year (e.g., July-Sep 2012)
4th quarter of current year (e.g., Jan 2014)	4th quarter of previous year (e.g., Oct-Dec 2012)

Accomplish **Report 5a** as follows: *(See **Report 5a** on page 102)*

1. For Table A, B and C: Indicate in the first column the number of cases that were registered the previous year (Refer to **Report 3a** submitted last year for the same cohort). New and Relapse cases should be disaggregated according to bacteriologic confirmation (Table A and B) while all previously treated patients (TALF, Treatment after Failure, PTOU and Other) are included in 1 cohort regardless of bacteriologic status (Table C).

   For each cohort, count the number of cases corresponding to each treatment outcome (column 11). Get the total number of patients that have been assigned an outcome and reflect this in the last column of each table.

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Report 4. Quarterly report on drug and supply inventory and requirement

(Data Source: Stock Inventory Records and Program Reports)

Name of RO: _____ Report for: _____ Quarter of _____

Name of Province/ City: _____ Date Reported: _____

Municipality: _____ Prepared by: _____

Name of DOTS Facility: _____ Designation: _____

Population of Catchment Area: _____

For Province/ City and Regional Level:

Total no. of DOTS Facilities that submitted report	
Total no. of DOTS Facilities	

A. Quarterly Drug Inventory and Requirements

Treatment Regimen	Category 1 TB Kits (Adult)	Category 2 TB Kits (Adult)	Category 1 TB Kits (Children)	Category 2 TB Kits (Children)
New cases				
Retreatment cases				
Total Stocks Required in a quarter (A)				
Total Stocks Required in a quarter, with buffer (B = Ax2)				
Stock on hand (C)				
Total kits to request (D = B-C)				

For DOTS Facilities:

Did your facility experience stock-outs of Cat 1 anytime during this quarter? [ ] Yes [ ] No

For Province/ City and Regional Level:

No. of DOTS Facilities with stock-outs of Cat 1 in this quarter	
Total no. of DOTS Facilities	

B. Annual Inventory and Requirements for Laboratory Supplies (DSSM)

	Sputum cups (in pieces)	Glass slides (in pieces)	Immersion oil (in bottles)	Staining Kit (in bottles)
Presumptive TB with DSSM done in past year (A)				
Number of follow-up DSSM done in past year (B)				
Total laboratory supplies required in a year (C)	= (AX2) + B	= (AX2) + B	= [(AX2) + B] / 600	= [(AX2) + B] / 125
Total laboratory supplies required in a year, with buffer (D = Cx2)				
Stock on Hand (E)				
Total quantity of supplies to request (F = D-E)				

C. Quarterly Inventory and Requirements for Laboratory Supplies (Xpert MTB/RIF)

	Xpert Cartridge	Conical Tubes/ Sputum Cups (in pieces)
Number of Xpert MTB/RIF ran in past quarter (A)		
Total laboratory supplies required in a quarter, with buffer (B = Ax2)		
Stock on Hand (C)		
Total quantity of supplies to request (D= B-C)		

Report 5a. Quarterly report on Treatment Outcome of Drug Susceptible TB Cases

(Data Source: Form 6a. Drug-susceptible TB Register)

Name of RO: _____ Cohort for cases registered in: _____ Quarter of _____

Name of Province/ City: _____ Date Reported: _____

Municipality: _____ Prepared by: _____

Name of DOTS Facility: _____ Designation: _____

Population of Catchment Area: _____

For Province/ City and Regional Level:

Total no. of DOTS Facilities that submitted report	
Total no. of DOTS Facilities	

A. Bacteriologically-confirmed New and Relapse TB Cases

Total Number of TB Cases		Cured	Completed	Died	Failed	Lost to Follow-up	Not Evaluated	Total
	New							
	Relapse							

Note: Exclude from the cohort the cases found to be drug resistant at any time during treatment.

Number of cases excluded from the cohort = _____

B. Clinically-diagnosed New and Relapse TB Cases

Total Number of TB Cases Registered		Completed	Died	Failed	Lost to Follow-up	Not Evaluated	Total
	New						
	Relapse						

Note: Exclude from the cohort the cases found to be drug resistant at any time during treatment.

Number of cases excluded from the cohort = _____

C. Previously Treated Cases (except Relapse)

Total Number of TB Cases Registered		Cured	Completed	Died	Failed	Lost to Follow-up	Not Evaluated	Total
	Retreatment (excluding Relapse)							

Note: Exclude from the cohort the cases found to be drug resistant at any time during treatment.

Number of cases excluded from the cohort = _____

D. Other Cohorts

Total Number of TB Cases Registered		Cured	Completed	Died	Failed	Lost to Follow-up	Not Evaluated	Total
	PLHIV cases (all registration groups)							
	Children Given IPT							

Note for PLHIV: Exclude from the cohort the cases found to be drug resistant at any time during treatment.

Number of cases excluded from the cohort = _____

Number of patients that have been excluded from the cohort because they were shifted to a DRTB regimen should be indicated under each table. Transferred Out cases with unknown outcomes as of the reporting period are classified under **not evaluated**

2. For Table D: Under PLHIV cases, do the same procedure above for all TB patients who are co-infected with HIV. This cohort will include all TB-HIV coinfected patients regardless of bacteriologic status and registration group. Note that these patients have already been counted under tables A, B and C above.

   For the outcome of children given IPT, count the number of children given IPT during the same reporting period 1 year ago from **Form 9. IPT Register.** Count the number of cases corresponding to each treatment outcome.

G. Report 5b. Quarterly Report on Interim Treatment Outcome of DR-TB Cases

The Quarterly report on Interim Treatment Outcome of DR-TB cases will be accomplished by the nurse in DOTS facilities with PMDT services. Data source for this report will be Form 6b. DR TB Register *(See **Report 5b** on page 104)*. The Interim Treatment outcomes of registered DR-TB patients will be reported after 9-11 months of registration as follows:

Table No. 26 - Summary of Reporting Period and Corresponding Cohorts, Interim Treatment Outcomes of Registered DR-TB Patients

Reporting Period	Cohort of Patients to be Reported
1st quarter of current year (e.g., April 2013)	2nd quarter of previous year (e.g., Apr-Jun 2012)
2nd quarter of current year (e.g., July 2013)	3nd quarter of previous year (e.g., July-Sept 2012)
3rd quarter of current year (e.g., October 2013)	4rd quarter of previous year (e.g., October-December 2012)
4th quarter of current year (e.g., January 2014)	1th quarter of previous year (e.g., Jan-Mar 2013)

H. Report 5c. Annual Report on the Treatment Outcome of DR-TB Cases

The Annual Report on Treatment Outcome of DR-TB cases will be accomplished by the nurse in DOTS facilities with PMDT services at the end of the calendar year. Data source for this report will be **Form 6b. DR-TB Register** *(See **Report 5c** on page 105)*.

Two reports will be submitted every January to cover the outcomes of DR-TB patients registered who have completed 2-3 years of treatment. An example of annual reporting for treatment outcome of DR-TB is as follows:

Table No. 27 - Summary of Reporting Period and Cohort of Patients to be Reported

Reporting Period	Cohort of Patients to be Reported
January 2014	1. Patients registered in 2010 (36th month) 2. Patients registered in 2011 (24th month)

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Report 5b. Quarterly Report on Interim Treatment Outcome of DR-TB Cases

(Source of Data: Form 6b. DR-TB Register)

Name of RO: _____ Cohort for cases registered in: _____ Quarter of _____

Name of Province/ City: _____ Date Reported: _____

Municipality: _____ Prepared by: _____

Name of DOTS Facility: _____ Designation: _____

Population of Catchment Area: _____

For Province/ City and Regional Level:

Total no. of DOTS Facilities that submitted report	
Total no. of DOTS Facilities	

All DR–TB Cases Registered During the Quarter

Total Number of DR-TB Cases Registered	Classification of DR-TB	Still on Treatment: Bacteriological result at 6th month			No Longer on Treatment			Total
		Negative	Positive	Not Evaluated	Failed	Died	Lost to Follow- up	
	All Bacteriologically-confirmed RR-/ MDR-TB							
	All Bacteriologically-confirmed XDR-TB							
	All Clinically-diagnosed MDR-TB							
	Other Drug-resistant TB cases							
	Total							

Report 5c. Annual Report on the Treatment Outcome of DR-TB Cases

(Source of Data: Form 6b. DR-TB Register)

Name of RO: _____ Cohort for cases registered in: Year _____

Name of Province/ City: _____ [ ]24th month [ ]36th month

Municipality: _____ Date Reported: _____

Name of DOTS Facility: _____ Prepared by: _____

Population of Catchment Area: _____ Designation: _____

For Province/ City and Regional Level:

Total no. of DOTS Facilities that submitted report	
Total no. of DOTS Facilities	

All DR – TB Cases Registered During the Calendar Year

Total Number of DR-TB Cases Registered	Classification of DR-TB	Treatment Outcomes					Not Evaluated	Still Ongoing*	Total
		Cured	Completed	Died	Failed	Lost to Follow-up			
	All Bacteriologically-confirmed RR-/ MDR-TB								
	All Bacteriologically-confirmed XDR-TB								
	All Clinically-diagnosed MDR-TB								
	Other Drug-resistant TB cases								
	Total								

* Patients that are still on treatment at the time of this reporting.

I. Report 6. Quarterly Report of Hospital TB Referrals

The Quarterly Report on Hospital TB Referrals will be accomplished by the nurse of the hospital TB team. Data source for this report will be **Form 8. Hospital TB Referral Logbook**.

Accomplish **Report 6** as follows: *(See **Report 6** on page 108)*

1. Indicate the total number of referrals to the TB clinic for the period. This includes both confirmed TB cases and presumptive TB cases.

2. Among the referrals, indicate how many were referred from the inpatient department/ wards (column 13).

3. Determine the number of TB cases admitted to the hospital for the period using the hospital discharge census.

4. Compute the intra-hospital referral rate for wards by dividing the number of referrals from the ward (#2) by the total number of TB admissions (#3).

5. Indicate the number of bacteriologically-confirmed TB cases referred to the TB clinic **BC** in column 9).

6. Determine the number of presumptive TB that were confirmed bacteriologically (i.e., positive DSSM, Xpert MTB/RIF or Culture result in the hospital laboratory using **Form 3. NTP Laboratory Register (Microscopy and GX**).

7. Compute the laboratory referral rate by dividing the number of bacteriologically-confirmed referrals (#5) by the total number of bacteriologically-confirmed TB diagnosed in the laboratory (#6).

8. Indicate the number of referrals that were later confirmed as TB cases (TB in column 8).

9. Among the confirmed TB cases, indicate the number of new and relapse cases (column 10).

10. Among the confirmed TB cases, indicate the number referred to other DOTS facilities (column 16).

11. Among the confirmed TB cases, indicate the number registered by the hospital (column 15).

12. Among the confirmed TB cases, indicate the number who were initiated treatment at the ward (column 14).

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Data for numbers 13-15 will be obtained from referrals made in the previous quarter, not the current reporting period (e.g., for the **2nd Quarter Report**, refer to cases referred during the 1st quarter).

13. Indicate the number of confirmed TB cases (column 8) that were referred to other DOTS facilities (column 16).

14. Indicate the number of referred TB cases that were accepted and registered at the other DOTS facility (column 21 and 12).

15. Compute the external referral acceptance rate by dividing the number accepted and registered in other DOTS facilities (#14) with the number of referrals to other DOTS facilities (#13).

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Report 6. Quarterly Report of Hospital TB Referrals

(Data Source: Form 8. Hospital TB Referral Logbook and Hospital Records)

Name of RO: _____ Report for: _____ Quarter of _____

Name of Hospital: _____ Date Reported: _____

Location: _____ Prepared by: _____

Category: [ ] TDPH [ ] TDRH Designation: _____

A. Patients referred during this reporting period:

	Indicators	No.	%
1	Total no. of referrals (Presumptive TB/ TB patients) to hospital TB team		
2	Total no. of referrals from the wards		
3	No. of TB patients admitted at the ward (Source: Hospital Discharge Census)		
4	Intrahospital referral rate (ward) [No. 2/No.3 x 100]		
5	No. of bacteriologically confirmed cases referred to the hospital TB team		
6	No. of bacteriologically confirmed cases detected by laboratory (Source: Hospital Laboratory Register)		
7	Laboratory referral rate [No. 5/No. 6 x 100]		
8	"Internal referrals" that were confirmed as TB cases (by TB clinic)		
9	No. of TB cases, all forms		
10	TB cases referred to peripheral DOTS facilities (external referral)		[=10/8]
11	TB cases registered by TDPH (managed by the TB clinic)		[=11/8]
12	No. of TB cases started treatment at the ward		

B. Referral outcome of patients referred during the quarter prior to this reporting period:

	Indicators	No.	%
13	Total no. of TB cases referred to peripheral DOTS facilities during the quarter prior to this reporting period		
14	No. accepted and registered (with TB case number) at the peripheral DOTS facility		
15	External referral acceptance rate [No. 14/No. 13 x 100]		

CHAPTER 6

Management of Anti - TB Drugs and Diagnostic Supplies

I. INTRODUCTION

Anti-TB drugs, laboratory and other medical supplies are key elements of the National TB Control Program (NTP). An uninterrupted supply of diagnostic supplies and drugs is necessary for the sustained provision of quality TB diagnostic and treatment services in all service delivery facilities. It promotes better patient care, improves the public health services' credibility, and increases the patients' trust and participation in the program. This can translate to better treatment success and reduced TB deaths, and contribute to better overall health in the family and community. TB drugs represent a major out-of-pocket expense for a patient and the family. The high cost of anti-TB drugs for the poor is a major barrier that limits access to treatment and cure.

This Chapter provides general information on the proper management of TB drugs and diagnostic supplies particularly at the peripheral level. It aims to guide program managers, particularly the focal persons at the primary level (DOTS facility) on how best to ensure an uninterrupted supply of drugs and diagnostic supplies through better supply management practices.

II. OBJECTIVE

To ensure continuous supply of quality TB drugs and diagnostic supplies at all DOTS facilities nationwide

III. DEFINITION of TERMS

A. Supply chain management cycle – A systems-based process consisting of product selection, quantification and procurement, inventory management (distribution and storage), and rational use. The cycle is guided by the national policy and legal framework that defines the goals for the management of drugs and diagnostic supplies and supports the continuous availability of these commodities and their appropriate use. It is supported by management systems that include planning, financial management, logistics information management system, organization and infrastructure, human resources, training, monitoring and evaluation, and quality monitoring of the commodities and the logistics process *(See **Figure No. 9** on page 111).*[31]

B. Product Selection – The process of establishing a limited list of essential anti-TB drugs to be procured based on the treatment guidelines and national formulary. Selection is guided by inputs from clinicians and laboratory staff as well as by information on the types of TB to be tested for and treated at different levels of health facilities.

C. Quantification – The process of estimating the quantity and cost of the products required to ensure an uninterrupted supply. It is an ongoing process of monitoring, reviewing, and updating forecast data and assumptions, and recalculating the total supply requirements and costs.

D. Procurement - The process of acquiring commodities either through purchase or donation via international, regional, or local sources of supply.

E. Inventory Management (Distribution and Storage) – The process by which the products procured are received, assessed, and stored until they are distributed to the next level from the central warehouse to the regional and provincial warehouses, down to the DOTS facilities where they are dispensed to patients.

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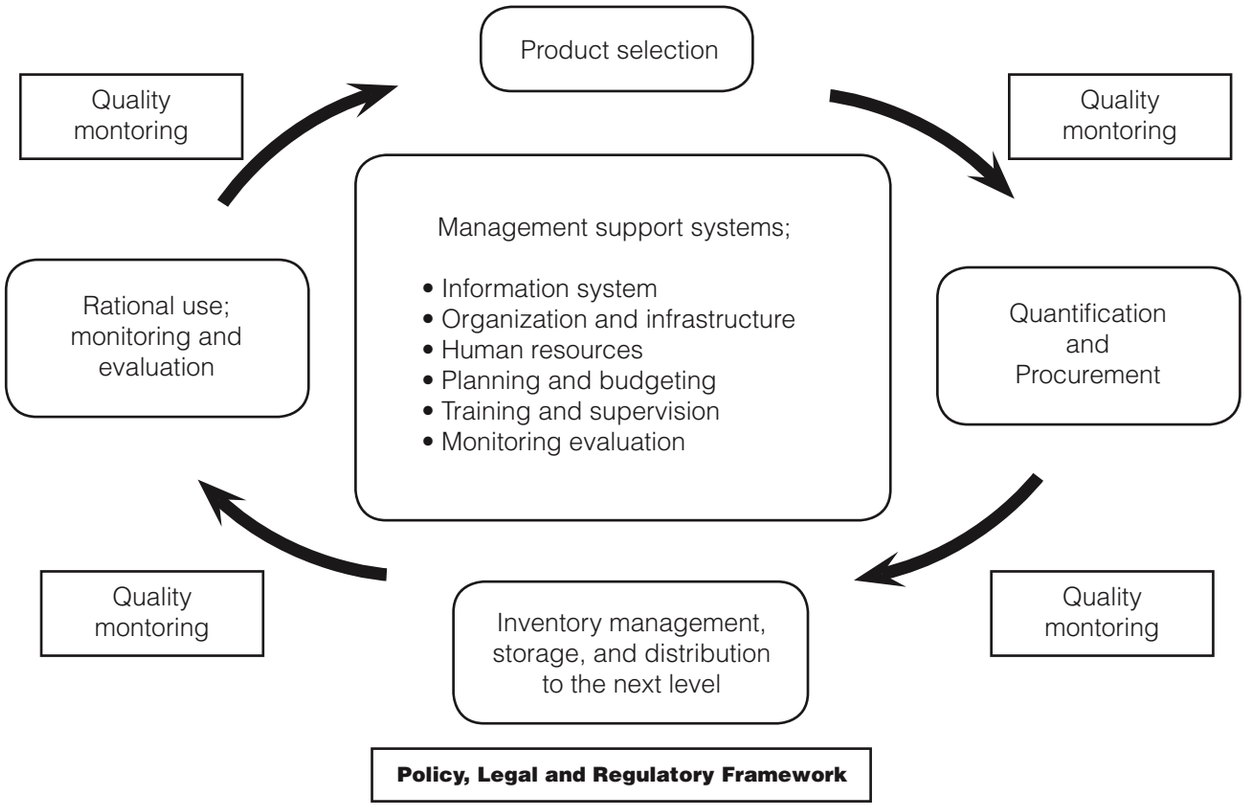
F. Rational use of medicines and diagnostic supplies – refers to the appropriate, safe, and effective use of TB drugs and diagnostic supplies based on program guidelines.

G. Quality monitoring – refers to the continuous monitoring of the quality of the commodities and the logistics process for suitability, effectiveness, and efficiency.

Figure No. 9 - Policy, Legal and Regulatory Framework of the Supply Chain Management Cycle



IV. POLICIES

A. The overall management of all TB drug supplies and diagnostic supplies, and the development and dissemination of corresponding policies and guidelines shall be the responsibility of the NTP with the support of the MMD, the NTRL/RITM, ROs and the LGUs. *(See **Table 28** on page 112).*

B. The local government units shall ensure that NTP policies and guidelines for NTP supplies management are implemented properly at their level. They shall also actively participate in the monitoring and evaluation of the implementation of these policies and guidelines.

C. NTP shall ensure that drugs selected for the use of the program is in accordance to international guidelines (e.g., WHO), are indicated in the national standard guidelines (i.e., NTP-MOP), registered with the Philippines FDA and included in the national formulary. Standardized fixed dose combination (FDC) of anti-TB drugs shall be used under the NTP whenever appropriate. The NTP, with the support of NTRL and FDA, shall ensure the quality of anti-TB drugs and laboratory supplies used in the program.

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D. Quantification and ordering shall be based on utilization rate, projected increase of cases due to strengthened case finding and provision of buffer stocks. Buffer stocks equivalent to 100% annual requirement should be maintained.

E. Procurement of TB drugs and diagnostic supplies at the national and local government level shall follow the "Government Procurement Reform Act" or RA 9184 and the DOH policies, guidelines, and standards for the procurement of TB drugs and laboratory supplies.

F. Medicines and supplies shall be stored under appropriate conditions and accounted for through proper recording and reporting. Stock status should be reflected in the National Online Stock Inventory Reporting System (NOSIRS).

G. The ROs, PHOs and CHOs shall ensure that drugs and diagnostic supplies are promptly distributed to the next level. The DOH central office shall deliver the NTP commodities to the ROs. ROs shall deliver the NTP commodities to the PHOs/CHOs. PHOs and CHOs shall ensure the prompt delivery of the NTP commodities to RHUs/HCs and all other DOTS facilities. Drugs for DOH retained hospitals within NCR will come from MMD, while for those outside of NCR, drugs will come from the ROs.

H. The use of medicines shall be guided by the presence of appropriate indications for treatment based on the NTP standards for diagnosis of TB, and the absence of contraindications to their use.

I. Disposal of expired and damaged drugs and diagnostic supplies shall follow the government rules and regulations.

J. LGUs shall be responsible for the reproduction of all official NTP forms to ensure availability and adequacy in all RHUs/DOTS facilities including jails and prisons.

K. LGUs shall set aside funds for the emergency procurement of sufficient quantities of TB drugs and diagnostic supplies in times of impending shortage to ensure continuous availability of NTP commodities at their service delivery points.

Table No. 28 - Management Component and Responsible Units for Managing NTP Commodities

Component	Responsible Unit
Selection	IDPCD - NTP
Procurement	National level for national procurement LGU for local procurement
Distribution	Allocation: IDPCD - NTP, RO, PHO and CHO Distribution: MMD, RO warehouse, and PHO/CHO warehouse
Storage	MMD, RO, PHO warehouses RHU/HC
Use	DOTS facilities (RHU/HC, hospitals, etc.)

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VI. PROCEDURES

Management of TB commodities in DOTS facilities will be based on the following procedures[33, 34, 35]:

A. Calculation of Anti-TB Drugs and Diagnostic Supplies

1. Estimate the number of patients you expect to test and treat for the order period. The number of patients treated in the previous quarter can be used to guide your estimate. Alternatively, you can use the number of patients treated in the same quarter last year to guide your estimate. Consider special activities (intensified case finding, health promotion activities, etc.) that may result into more patients diagnosed and requiring treatment.

2. Calculate buffer stock quantity equivalent to one quarter. For DSSM laboratory supplies, calculation of annual needs may be done. *(See **Tables 24-26** on pages 61, 99, and 103).*

3. Fill-up Order Request Form and submit to PHO/CHO.

Table No. 29 - Matrix for Computation of Quarterly Drug Requirements[36]

Treatment Regimen	TB Kits for Category 1	TB Kits for Category 2
New cases registered in previous quarter		
Retreatment cases registered in previous quarter		
Total stocks required in a quarter (A)	Expected number of cases this quarter*	Expected number of cases this quarter*
Total stocks required in a quarter, with buffer (B)	= A x 2	= A X 2
Stock on hand (C)		
Total kits to request	= B - C	= B - C

**The expected number of cases for the coming quarter can be based on the number of cases in the previous quarter. Another way is to base this on the number of cases in the same quarter of the previous year. Both methods can be used to come up with a good estimation. Also consider planned intensified case finding and other activities that may increase the number of cases.*

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Table No. 30 - Matrix for Computation of the Annual Requirement of Laboratory Supplies for DSSM

	Sputum cups/ glass slides (in pieces)	Immersion oil (in bottle)	Staining Kit (in bottles)
Presumptive TB with DSSM done in past year (A)			
Number of follow-up DSSM done in past year (B)			
Total laboratory supplies required in a year (C)	= (A X 2) + B	$= \frac{(A \times 2) + B}{600}$	$= \frac{(A \times 2) + B}{125}$
Total laboratory supplies required in a year, with buffer (D)	= C X 2	= C X 2	= C X 2
Stock on Hand (E)			
Total quantity of supplies to request**	= D - E	= D - E	=D - E

Assumptions: 1 staining kit (500 ml. bottle) is good for 125 tests/slides based on 4 ml per test
1 immersion oil (30ml bottle) is good for 600 tests/slides based on 0.05ml per test

***Note: May divide the total quantity to request by the number of pieces per unit of packaging (e.g., Sputum cups = 1,000 pieces/pack; Glass slides= 72 pieces/box)*

Table No. 31 - Matrix for Computation of Quarterly Requirements of Laboratory Supplies for Xpert MTB/RIF

	50ml Conical Tubes and Xpert Cartridge (In pieces)	Conical Tubes/Sputum Cups (In pieces)
Number of Xpert MTB/RIF run in past quarter (A)		
Total laboratory supplies required in a quarter, with buffer (B)	= A X 2	= A X 2
Stock on Hand (C)		
Total quantity of supplies to request***	= B - C	= B - C

**** Note: May divide the total quantity to request by the number of pieces per unit of packaging (e.g., conical tubes = 25 pieces/pack; sputum cups = 1,000 pcs/pack)*

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B. Receiving Supplies of Medicines and Diagnostic Supplies

The point person (e.g., PHN) for drug management shall perform the following procedures when receiving medicines and supplies delivered to the facility.

1. Obtain the supply receipt forms accompanying the delivery.

2. Check for the following: quantities for each item listed, check medicine labels for name, strength, and dosage form, inspect for damages, and note the expiry dates.

3. Record discrepancies noted and send feedback to the distributing unit.

4. Record the quantity of good items and quantity that are missing or damaged on the receipt form.

5. Sign the receipt form. If possible, have a fellow health worker verify and sign too for the quantities received.

6. Keep a copy of, and file the delivery receipt form, for your records.

7. Encode data into NOSIRS.

C. Storage of Drugs and Diagnostic Supplies

1. Maintain clean storeroom with regular cleaning, prohibit food consumption where stocks are kept, remove spoiled products and clean affected areas immediately. Perform regular inspections to check for signs of theft, pest, water damage, or deterioration due to high humidity.

2. Organize TB kits so labels can be easily read (product name, expiry date).

3. Promote air circulation in the storage room – high ceilings with vents; if feasible, install air conditioner, an exhaust fan, or a window or air vents. Allow more space between shelves. Leave adequate space (about 10-15 cm) between the walls and the shelves or stack of medicines for better circulation. Monitor and record daily the temperature in the storage area.

4. Keep medicine containers closed to avoid exposure to humid air. Light sensitive products must be kept in their original packaging and stored in closed cupboard or in a shady corner.

5. Store medicines and supplies under recommended storage temperatures (i.e., PPD and BCG at 2-8C; Xpert MTB/RIF cartridge below 28^0C)

6. Store medicines only on shelves or pallets, never on the floor. Do not store medicines near the ceiling where temperatures are higher. Do not stack containers too high to avoid crushing the lower ones.

7. Practice “First Expiring, First Out” (FEFO) to avoid expired medicines and wastage. Remove all expired or damaged items from the usable stocks and place in a clearly marked area for such items. Maintain records of expired or damaged medicines.

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8. Return excess medicines to the provincial/city NTP coordinator for redistribution. Record all items that were returned.

9. Access to the storage area must be restricted and those authorized to handle supplies shall be accountable for their actions. Fit doors with security locks, and install bars on storeroom windows. Maintain inventory records for accountability.

D. Maintaining Records for TB Drugs and Diagnostic Supplies

The facility shall maintain proper records for drugs and supplies to facilitate monitoring of available stocks and consumption.

1. Maintain and update drugs and diagnostic supplies stock records – to track supplies ordered, delivered, consumed, or loaned to another treatment facility; expiry dates; and as a reference for next order of anti-TB drugs.

2. Perform physical inventory or counting of stock items regularly to monitor stock levels. Compare the physical counts to quantities written on the stock records or stock cards.

3. Encode and update data regularly into NOSIRS.

E. Rational Use of Anti-TB Drugs and Diagnostic Supplies

Preparing and administering treatment to patients is the focus of all health care activities in the facility. Treatment must be based on the NTP's guidelines for treatment regimens and administration and should be recorded on patients' treatment cards and on the TB register. Refer to case finding and case holding chapters on the rational use of laboratory supplies and drugs.

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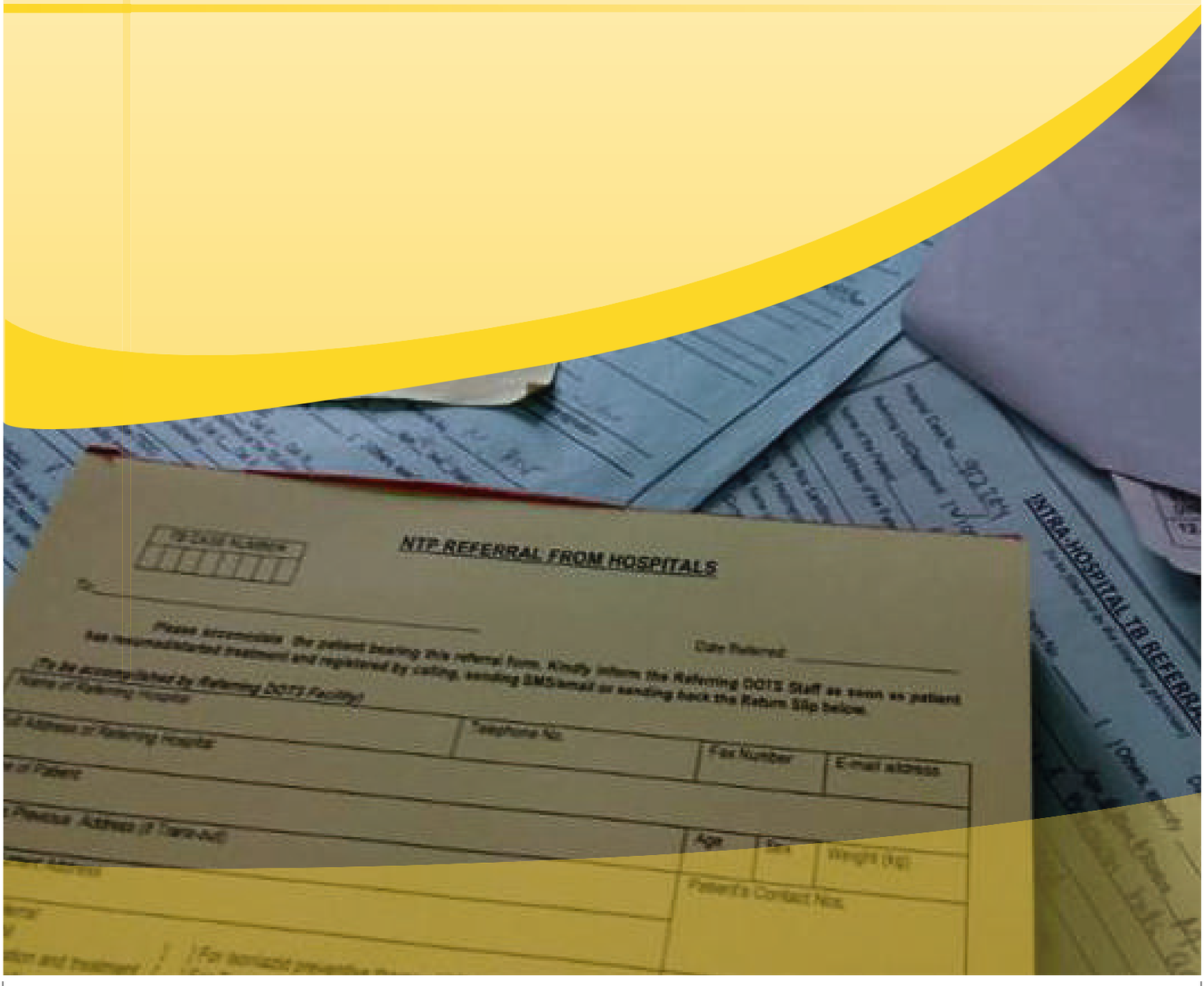
7

CHAPTER

TB-DOTS Referral System



I. INTRODUCTION

Nationwide, many health facilities or practitioners are providing TB care services such as diagnosis, treatment and counselling to TB patients or presumptive TB. These are the following:

- Public health facilities such as the health centers, rural health units, MDR-TB treatment centers, satellite treatment centers, treatment hubs,
- Other public facilities such as public hospitals and laboratories, jails and prisons, school clinics and military hospitals
- Private health facilities such as private clinics, private hospitals, diagnostic centers, pharmacies and NGOs, and
- Community groups such as the barangay workers, community health teams, TB Task Forces and many others.

Presumptive TB and TB patients consult this wide array of health care providers as shown by the 2007 National TB Prevalence Survey and the 2008 National Demographic Health Survey. In the past years, many of them had been engaged by NTP to participate in TB control under different initiatives.

Due to different health needs of the presumptive TB and TB patients and the varying capacities of the health care providers, patients are being referred to other health facilities for transfer of service or co-management. Specifically, these could be due to any of the following major reasons:

Table No. 32 - Major Reasons for Referrals

Major Reasons	Examples
For TB diagnosis	• A drug store/CXR facility refers presumptive TB to RHU for evaluation. • An RHU refers a presumptive extra-pulmonary/complicated TB cases to a hospital.
For registration and initiation of treatment	• A private clinic or hospital refers a confirmed TB case for registration to health center. • PMDT facility refers Rifampicin-susceptible TB to DOTS facilities.
For continuation of treatment	• A DOTS facility refers patient to another DOTS facility. • A PMDT treatment facility refers to a DOTS facility for decentralization • A jail/prison refers a discharged inmate to RHU.
For management of serious side effects and complications	• A health center refers a TB patient with liver disease to hospital. • PMDT treatment facility refers MDR-TB case under treatment for serious drug adverse reaction to a hospital.
For screening for MDR-TB	• A health center refers presumptive DR-TB to PMDT treatment facility.
For screening of TB among PLHIV	• A treatment hub refers a presumptive TB for rapid diagnostic test.

Different NTP initiatives had shown the feasibility and effectiveness of the referral process such as the public-private mix DOTS, enhanced hospital TB-DOTS and the community referral

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system. Controlling TB requires early diagnosis and prompt treatment of TB patients; hence, there must be a systematic process of referral between and among these health facilities and providers.

II. OBJECTIVE

To ensure that various diagnostic, treatment and information needs of presumptive / confirmed TB cases are promptly and appropriately addressed through an effective two-way referral system between health facilities that will:

a. Reduce the delay in the diagnosis and treatment of a TB case;
b. Ensure continuity and compliance to treatment;
c. Reduce out-of-pocket costs to patients;
d. Ensure that the TB patient is registered and notified to NTP.

III. DEFINITION of TERMS

A. Referral process – Set of processes for systematically referring a patient from a health care provider to another health facility to address his/her needs and for knowing the outcome of referral.

B. Referring facility – A facility that refers or transfers patient to another health facility for various reasons.

C. Receiving facility – A facility that provides the requested health service/s of the referring facility.

D. Referral feedback – Process of informing the referring facility of the outcome of the referral.

E. Internal referral system – A system of referral within a hospital or clinics (e.g., a multi-specialty or polyclinic). This involves referral from the wards, outpatient department or other departments to the hospital TB team.

F. External referral system – Process of referral from one health facility to another facility or institution (eg. hospital to health center, jail to prison, jail/prison to health center).

IV. POLICIES

A. Patients shall have the right to know the reason/s for referral and to participate in the choice of facilities where s/he will be referred.

B. Health care providers have the responsibility of ensuring prompt and appropriate response to patient's health needs by immediate referral for services that can be provided by other health providers/facilities.

C. A two-way functional referral must be observed by ensuring that a receiving facility provides feedback to the referring facility

D. It is a shared responsibility of the referring and receiving facilities to exert all efforts of ensuring that a referred patient is not lost during the referral process.

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E. All referring facilities / providers must use the standard NTP referral form **(Form 7. NTP Referral Form)**.

F. All hospitals shall maintain a hospital TB referral logbook.

G. Patients who were not referred in accordance to NTP policies and procedures shall be accommodated and evaluated accordingly.

V. PROCEDURES

A. Hospital Internal Referral System

In some health facilities, like hospitals and big clinics where there are many service units, there is a need to establish an internal TB referral system. All TB cases identified by the OPD, wards and other units of the hospitals or sections of the clinics must be referred to the hospital/ clinic TB team or point person.

1. Referring staff (e.g., attending physician, nurse on duty) fills-up an intra-hospital referral form with the pertinent documents attached and send this to the hospital TB team or point person.

2. Hospital TB team evaluates the patient , fills-up the reply form, and records the patient in the hospital TB Referral Logbook.

3. Patient may be provided with NTP drugs while at the hospital. Drugs may come from the health center where the patient resides or from the hospital TB team.

B. External TB Referral System

1. Explain to the patient why he/she will be referred.

2. Identify the DOTS/health facility where he will be referred using the national or local DOTS facility directory or the list of hospitals/diagnostic centers and mutually agree with the patient where s/he will be referred.

3. Fill-out **Form 7. NTP Referral Form,** and attach the following, depending on the purpose of the referral:

   a. For diagnosis: request for laboratory examination or CXR examination
   b. For initiation/continuation of treatment: **Form 5. NTP ID Card** and results of diagnostics
   c. For MDR-TB screening: results of DSSM, CXR, ID card and copy of previous **Form 4. TB Treatment/IPT Card** if available.

4. Discuss the referral process with the patient and emphasize the importance of giving a feedback to the referring unit.

5. For hospitals, list the patient to be referred in **Form 8. Hospital TB Referral Logbook** or write under remarks in **Form 6a. Drug-susceptible TB Register** or **Form 1.**

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Presumptive TB Masterlist. If patient was given treatment at the ward, fill-up **Form 5. NTP ID Card**. Upon discharge, refer patient to a DOTS facility and give at least one or two-week supply of anti-TB drugs.

6. If possible, inform the receiving facility.

7. Receiving facility gives feedback to referring facility through the reply slip of the referral form, telephone call, SMS, email or other modalities. If the patient was registered, provide the TB case number in the reply.

8. Once the feedback is received, referring facility staff update the records (i.e., **Form 8. Hospital TB Referral Logbook, Form 1. Presumptive TB Masterlist** or **Form 6a. Drug-susceptible TB Register**, as applicable).

9. If the patient had not gone to the facility within five days, exert efforts to retrieve the patient through the help of barangay health workers, local officials or community groups. Ensuring successful referral is a shared responsibility of the referring and receiving health facility.

C. Referring Presumptive DR-TB

1. The following are considered presumptive DR-TB:

   a. All re-treatment cases including non-converter of Category II
   b. New TB cases who are:
      i. Contacts of confirmed DR-TB cases
      ii. Non-converter of Category I
   c. People living with HIV (PLHIV) with signs and symptoms of TB

2. Fill-out **Form 7. NTP Referral Form** and attach copies of pertinent supporting documents: old treatment card/s, DSSM result, CXR (plates and results).

3. Record the details of the referral in **Form 1. Presumptive TB Masterlist** and/or **Form 8. Hospital TB Referral Logbook** *(See Procedures for Recording Hospital Referrals on page 85).*

4. Contact the DOTS facility with PMDT services where the patient is to be referred for proper coordination (i.e., confirm the availability of the service requested and its requirements) and thereby minimize inconvenience for the patient.

5. The receiving facility shall acknowledge the referral through a return slip, SMS, phone call, facsimile or mail. Record the outcome of the referral in **Form 1. Presumptive TB Masterlist** and/or **Form 8. Hospital TB Referral Logbook**.

D. Handling TB Patients Previously Managed Outside DOTS facility and not Referred According to NTP Policies and Procedures

There are many patients who go to DOTS facilities with history of taking anti-TB drugs for few weeks or months either with a private clinic, hospital or other health facility not implementing NTP procedures. Either they are walk-ins or with a referral letter or note that is not the NTP referral form. Handle them as follows:

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1. Get a detailed clinical history following the same procedures as with any presumptive TB.

2. Secure copies of supporting documents of TB diagnosis, evidence of disease activity or history of treatment. Verify each, if necessary and, with the patient's consent, contact the attending physician and/or health care facility. Note them accordingly on the remarks section of the presumptive TB masterlist.

3. Assess the patient's willingness and commitment to continue treatment under a DOTS program.

4. Do DSSM, if not done or done by a non-NTP recognized TB microscopy unit. Record in **Form 3. NTP Laboratory Register** as a new presumptive TB. If with DSSM results from an NTP-recognized diagnostic facility, follow the schedule for follow-up smears according to appropriate treatment category.

5. The DOTS physician shall exercise best clinical judgement on deciding whether to continue, modify, restart or discontinue treatment. Register if patient will restart or continue treatment. *(Note: Even if the physician decides to continue treatment, patient should not be registered as "Transfer in." Assign a registration group to the patient based on NTP policies.)*

6. Provide the necessary treatment based on the evaluation of the patient and NTP policies.

7. Provide a feedback to the previous attending physician or facility of the patient.

E. Modes of Knowing the Outcome of Referral

1. Receiving the NTP referral reply slip that has been brought back to the referring facility by patient/relative or TB coordinator/health center staff, or faxed, mailed or e-mailed by the receiving health facility.

2. Talking with the receiving health facility through telephone call.

3. Following up through SMS or by texting the patient or health facility.

4. Reviewing the electronic TB register or TB case register.

F. Strengthening and Sustaining the TB DOTS Referral System

1. Ensure that the patient understands the reason for the referral and the importance of going to the receiving facility.

2. Provide an enabler to TB patients who had been diagnosed, had gone to the health center, and had given feedback. This could be in kind such as rice, grocery item, callcards, etc. that can be sourced out from partners or LGUs.

3. Avail of the PhilHealth outpatient benefit package and share an amount to the referring TB care providers.

4. Provide motivations and incentives to referring health workers and facilities. This may be a yearly recognition through giving of plaques or certificates, recommending them to join an inter-local area visit or participating in scientific conferences, providing load or other in-kind incentives.

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8

CHAPTER

Advocacy, Communication and Social Mobilization

I. INTRODUCTION

Advocacy, Communication and Social Mobilization (ACSM) is an essential tool in increasing both demand for TB services and the supply of services, the two important pillars in achieving TB control program. targets. It can be used to identify and address TB control challenges in the following critical areas: a) advocate for support from policy and decision makers and other influential people at the national and local levels; b) improve interpersonal communication and counselling (IPC/C) skills of health workers and community health volunteers so vital information would be communicated well to target clients; c) combat stigma and discrimination among patients, their relatives, people surrounding them, and even among health workers; and d) empower community action for advocacy and education so that presumptive TB would be motivated to seek consultation and undergo sputum examination, and so that TB patients would be motivated to initiate, continue, and complete treatment and submit for confirmatory sputum examination.

This Chapter presents the principles and basic activities in ACSM. The detailed procedural aspects of advocacy, communication and social mobilization are discussed in the "The Health Promotion Handbook: A Guide to Doing Advocacy, Communication and Social Activities in the TB Control Program in Communities."[37]

II. OBJECTIVES

ACSM aims to improve TB case detection and treatment success through the following:

- Mobilize political and multi-sectoral commitment and sustain adequate resources for TB;
- Increase awareness and knowledge about the disease as well as the DOTS services available;
- Minimize TB stigma and discrimination through behaviour change communication (BCC); and
- Empower people affected by TB.

III. DEFINITION OF TERMS

A. Advocacy – Activities designed to place TB control high on the political and development agenda, foster political will, increase financial and other resources on a sustainable basis, and hold authorities accountable to ensure that pledges are fulfilled and results achieved.[37]

B. Communication – The process people use to exchange information about TB.

C. Social Mobilization – The process of bringing together all feasible and practical inter-sectoral allies to raise awareness of and demand for a particular program, to assist in the delivery of resources and services, and to strengthen community participation for sustainability and self-reliance.

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D. **Behavior Change Communication (BCC)** – The process of developing tailored messages and approaches utilizing various channels of communication. Its three components are IEC, IPC/C, and Community Mobilization.

E. **Information, Education, and Communication (IEC)** – Attempts to change and/or reinforce a set of behaviours in a targeted segment of audience on a specific problem in a predefined period of time.

F. **Interpersonal Communication and Counselling (IPC/C)** – Face-to-face, verbal and non-verbal exchange of information or feelings between two or more people.37 In the TB program, this refers to intense communication process between the health provider and the patient for the latter to complete the DOTS treatment.

G. **Community Mobilization** – The process of building the capacity of individuals, groups, or organizations designed to plan, implement, and evaluate specific set of activities on a participatory and sustained manner to achieve a certain set of goals, through their own initiative or through stimulation by others.

H. **Cough to Cure Pathway** – A six-stage framework developed by the STOP TB Partnership to analyze the barriers that prevent the patient from completing the DOTS regimen.

I. **Community-based Organizations (CBOs)** – A group of individuals made up of and generally operated by the community residents themselves organized with a common objective of achieving a set of goals. In most cases, CBOs are assisted by other groups such as government agencies, non-government organizations (NGOs), and faith-based organizations.

J. **Community Health Team (CHT) Mobilization Campaign** – DOH's strategy to ensure that all populations and individuals are periodically visited and attended by health workers to link them to social service providers, provide critical social and health services when needed, and deliver key health messages.

K. **Barangay Health Worker (BHW)** – An individual who voluntarily renders primary health care services in a community after having been accredited to function as such by the local health board in accordance with the guidelines promulgated by DOH.

IV. POLICIES

A. The Local Health Board of all LGUs shall include ACSM activities in their provincial, city or municipal health plan.

B. The DOTS facility staff and stakeholders shall advocate with local political leaders to increase funding for TB programs and institute policy changes to support the implementation environment.

C. The DOTS facility health staff shall ensure the provision of accurate, reliable and up-to-date information to all clients and patients that will motivate them to seek care and complete treatment.

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D. ACSM activities must be customized according to specific needs of a community but communication messages delivered must be consistent with the messages developed by the National TB Control Program and National Center for Health Promotion of the DOH.

E. The DOTS facility health staff shall involve the community in TB program implementation through social mobilization activities, mainly organizing and sustaining existing community-based organizations or groups.

F. All BHWs, CHTs and CBOs must refer presumptive TB identified in the community and ensure that these patients go to the DOTS facility.

V. PROCEDURES

A. Advocating for Increased Funding and Policy Support from LCEs

1. Ensure that the TB subplan in the annual provincial, city or municipal health plan is properly prepared and included in the LGU budget.

2. Advocate, together with support groups and public-private sector collaborating groups such as the Multisectoral Alliance for TB Control or the TB Provincial Coordinating Council, for adequate and sustained support for the TB program.

3. Regularly convene meetings of the public-private sector collaborating groups for update and planning.

B. Advocating for Greater Public Support and De-stigmatization of TB

1. Hold regular meetings with media and civic groups for increased coverage of TB campaigns and activities.

2. Examples of key advocacy messages[35] are as follows:

   a. TB control is a national priority.

   b. TB is a public health problem. It is the 6th leading cause of illness in the Philippines.

   c. TB is everyone's concern.

   d. TB affects the most economically productive age group, resulting in enormous economic losses.

   e. DOTS is the most cost-effective strategy to control TB.

C. Communicating with TB Patients

1. Conduct health education sessions for both patient and his/her family. Emphasize the following key points:

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a. Importance of regular drug intake;

b. Effect of irregular drug intake;

c. Side-effects of taking anti-TB drugs;

d. Necessity of DSSM follow-up;

e. Importance of treatment compliance; and

f. Importance of family and treatment partner support.

2. Conduct regular consultation meetings with patient and treatment partner.

3. Continuously disseminate key TB communication messages. Localized key messages are encouraged but should be in-line and consistent with the NTP Communication Plan developed by the NTP and NCHP of the DOH. The current NTP Communication Plan has the following key messages:

   a. *Maling kaalaman ang magpapalala sa TB.*

   b. *Anim na buwang gamutan para gumaling. Kaya mo 'yan! Kapag tumigil bago makumpleto ang anim na buwan ay maaaring humaba ang buwan ng gamutan hanggang dalawang taon.*

   c. *Huwag bibitiw sa DOTS para mapuksa ang TB sa katawan. Bawat araw na kumpleto ang pag-inom sa gamot, paganda nang paganda ang pakiramdam mo. Kapag bumitiw, ang anim na buwan ay maaaring maging dalawang taong gamutan.*

   d. *Pagkatapos ng dalawang linggong gamutan, hindi na nakahahawa ang TB. Pero dapat tapusin ang anim na buwang gamutan para todo-todong gumaling.*

   e. *Ekspertong kaalaman. Dekalidad na serbisyo. May nagmamalasakit pang treatment partner na sinisigurong nasusunod ang tamang paggamot.*

   f. *Sa TB-DOTS, ang mga mahal sa buhay ay natututukan sa tamang paggamot.*

   g. *Kung may kakilala kang may TB, dapat silang kumbinsihin na mag-DOTS – ang nag-iisang paraan para gumaling siya nang husto. Naprotektahan mo pa ang sarili mo.*

D. Social Mobilization

1. Communicate the need for CBOs and other volunteers, such as the CHTs and BHWs, to become TB educators, advocates, and treatment partners.

2. Identify CBOs in the locality. Coordinate with the Provincial/City/Municipal Development Council and local NGOs and/or FBOs in identifying CBOs.

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3. Seek assistance of NGOs as Technical Assistance Providers (TAPs) in the formation, strengthening and sustaining of CBOs/CHTs. Prepare a Memorandum of Agreement or Understanding to formalize the partnership and define the TA provider's role.

4. Conduct regular monitoring and supervisory dialogues with the CBOs and TAPs.

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CHAPTER 9

DOTS Certification and PhilHealth Accreditation

I. INTRODUCTION

Certification and accreditation are processes which ensure that a DOTS facility is capable of providing quality DOTS services to presumptive TB and TB patients. Certification aims to standardize the provision of DOTS by institutionalizing a set of standards and criteria for a quality-assured DOTS facility. Compliance with these standards and criteria provides the platform for PhilHealth Accreditation.

DOH Administative Order 2006-0026 "Implementing Guidelines in the Conduct of the National TB Control Program – Directly Observed Treatment Short-Course (NTP-DOTS) Certification" established the guidelines and procedures in the conduct of NTP-DOTS Certification among public and private DOTS facilities, specifically for assessing the quality of TB-DOTS implementation. In 2013, the DOTS Certification process was revised to decentralize the issuance of DOTS certificate to the regions, in consonance with the reconstitution of the National and Regional Coordinating Committees for NTP (NCC-NTP/RCC-NTP) through AO 2006-0026-A.

The Philippine Health Insurance Corporation or PhilHealth is the government agency that is primarily responsible in providing Filipinos the mechanism to gain financial access to health services. Facilities like TB DOTS Centers must be accredited before they can participate as providers of benefit packages. This is to ensure that delivery of health care services to its members and their dependents are of quality necessary to achieve the desired health outcomes and member satisfaction. PhilHealth Circular 17 s. 2003, "Accreditation of TB DOTS facilities", and Circular 8 s. 2006, "Amendment to Accreditation of TB DOTS facilities", laid down the guidelines and standards for accreditation of TB DOTS facilities. In 2012, PhilHealth issued Circular 54, s 2012 "Provider Engagement through Accreditation and Contracting for Health Services" which revised the accreditation guidelines for all health facilities including TB DOTS Centers.

II. OBJECTIVE

To ensure that DOTS facilities are providing sustainable quality services

III. DEFINITION of TERMS

A. Accreditation – A process wherein qualifications and capabilities of a health facility are verified in accordance with the quality, standards and procedures for a DOTS facility set by PhilHealth in consultation with stakeholders for the purpose of conferring upon them the privilege of participating as providers of TB DOTS Benefit Package.

B. Automatic accreditation – Accreditation given to any institutional health care provider that is licensed or certified by DOH or other certifying body duly recognized by PhilHealth and has the opportunity to be accredited through basic participation.

C. Certification – Refers to the process wherein the Regional Coordinating Committee (RCC-NTP) assesses and evaluates a DOTS facility, either public or private, if it has met the standards for quality DOTS implementation.

D. Certified – A certification decision that results when a health facility demonstrates acceptable compliance with the core standards for initial certification and / or re-certification

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E. Not certified – A certification decision that results when an applicant TB-DOTS facility consistently fails to demonstrate compliance with the core standards for initial and / or recertification, when certification is withdrawn for other reasons or when the health facility voluntarily withdraws from the certification process.

F. Re-certification - Pertains to the process wherein the DOTS facility is re-issued a DOH certificate upon expiration of the certification or 3 years after it was issued.

IV. POLICIES

A. Policies on DOTS Certification

1. The DOH, through the RCC-NTP, shall be the lead agency in the TB-DOTS certification process. The RCC-NTP shall be responsible for certifying TB-DOTS centers/facilities in both public and private sectors.

2. A health facility that provides TB DOTS services and assumes ownership and transparency for its operations is eligible for certification.

3. A DOTS facility shall be awarded certification if it meets the following set of core standards prescribed by NTP:

    a. The TB DOTS center is easily located and patients have convenient and safe access to the center.
    b. The TB DOTS center provides for the privacy and comfort of its patients and staff.
    c. The TB DOTS center provides for the safety of its patients and staff.
    d. All patients undergo a comprehensive assessment to facilitate the planning and delivery of treatment.
    e. All patients have continuous access to accurate and reliable TB diagnostic tests.
    f. A care plan is developed and followed for all patients
    g. Patients have continuous access to safe and effective anti-TB medications throughout the duration of their treatment.
    h. Policies and procedures for providing care to patients are developed, disseminated, implemented and monitored for effectiveness
    i. Policies and procedures for managing patient information are developed, disseminated, implemented and monitored for effectiveness and
    j. The TB DOTS center has an adequate number of qualified personnel skilled in providing DOTS services.

4. The length of certification award has an effectivity of 3 years.

B. Policies on PhilHealth Accreditation

1. DOTS facilities which are eligible for accreditation include, but are not limited to, the following: LGU health units, hospital-based clinics, HMO, factory clinics, church-based clinics and school-based clinics.

2. TB DOTS package providers duly certified by DOH are qualified for automatic accreditation (PhilHealth Circular 54 s. 2012). TB DOTS clinics that are not certified shall undergo pre-accreditation survey to ensure that they comply with the standards .

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3. PhilHealth shall provide the benefit package for qualified adult and child TB patients from any accredited DOTS facility. The package shall include the following:follow-up sputum smear examination/s, consultation services and anti-TB drugs for the entire treatment cycle.

4. The health care provider shall determine the PhilHealth's member eligibility and compliance with the requirements for availment as prescribed by PhilHealth.

5. The DOH recommends the following allocation scheme for the TB DOTS benefit package: 25% for consultation services of the referring physician during the treatment course, 35% for the health facility staff including the treatment partner who had a role in the delivery of services to the patient, 40% for operational costs involved in providing quality care for TB patients.

   When applicable, payment for TB Diagnostic Committee and quality assurance for sputum microscopy, expenses for training of staff, cost of additional laboratory supplies and drugs will be included in the operational costs. In cases when there is no referring physician, the 25% shall be allocated for operational cost.

6. Accredited TB DOTS facilities may continuously participate as provider until such participation is withdrawn or terminated based on the rules set by PhilHealth. However, they are required to submit the following requirements on or before January 31 of every year:

   a. Updated DOH Certificate
   b. Performance Commitment
   c. Latest Audited Financial Statement (for private facilities only)
   d. Proof of payment of the participation fee, and
   e. Updated business permit (for private facilities only)

7. Failure to submit the above requirements by the end of February shall cause denial of claims starting March 1 (based on treatment start date). If the requirements are submitted after February, the health care institution shall apply for re-accreditation.

8. If the certificate of the TB DOTS provider expires within the year, the facility is given 60 days within which to submit the updated certificate. Failure to submit within 60 days shall cause denial of claims beginning on the 61st day and onwards (based on treatment start date) until it submits the certificate.

V. PROCEDURES

A. Procedures on Certification

The following steps are based on the **Implementing Guidelines on the Flow of the DOTS Certification Process.**

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Table No. 33 - Certification Procedures

Cycle	Procedure	Concerned Agency
Self -Assessment	1) Filling-up of "Self-assessment Form (SAF)" 2) Request for technical support from the Technical Assistance (TA) team from the province/city composed of the Provincial/ City NTP Coordinators, DOH representatives and private/NGO representatives 3) SAF is accomplished and ready for use by the certifying team upon their visit	Head of DOTS center/facility
Application	1) Submission of a written "Letter of Intention on Certification (LOIC)" to the RO	Head of DOTS center/facility
Certification	1) On-site validation of the health facility by the certifying team 2) Reporting of the certifying team's findings, rating and over-all decision to the DOTS facility utilizing the "Summary Report on DOTS Certification" and reporting of the same to RCC-NTP 3) Approval/Disapproval for certification 4) Application for PhilHealth accreditation in case of approval 5) Notification of TA team in case of disapproval 6) Re-application for certification in case of disapproval 7) Joint monitoring of facility after 3 consecutive failure to qualify for certification	Certifying team Certifying team Certifying team Head of DOTS center/facility RO/Prov/City Coordinator RO Coordinator Head of DOTS center/facility NCC-NTP, RCC-NTP, RO/Prov./City Coordinators
Registration and Issuance	1) Registration of the facility into the official registry 2) Issuance of "Certificate of Quality Service on DOTS"	RCC-NTP RCC-NTP
Follow-up	1) Yearly monitoring of certified TB-DOTS centers/facilities 2) Renewal of certification after 3 years	RO/Prov./City NTP Coordinators, TA team Head of DOTS center/facility

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A summary of the roles of different implementing agencies in the DOTS certification process is found below:

Table No. 34 - Roles and Responsibilities of Implementing Agencies in DOTS Certification

Agency	Roles and Responsibilities
NCC-NTP	• Receive and consolidate reports on the number of DOTS facilities certified by respective RCC-NTP in each region • Serve as an oversight body in resolving issues and concerns beyond the jurisdiction of RCC-NTP. • Conduct joint-monitoring of TB-DOTS centers/facilities with concerned parties as needed.
RCC-NTP	• Oversee the certification process at the regional level. • Identify and designate the members of the certifying team. • Review and approve the final results of assessment by the certifying team. • Mediate concerns should the certifying team fail to come up with a concrete decision on the approval for certification. • Issue the "Certificate of Quality Service on DOTS", duly signed by the Chair and Co-chair of RCC-NTP and affixed with the committee's dry seal. • Update the status of DOTS certification to facilitate PhilHealth accreditation. • Maintain an official registry of all certified DOTS facilities in the region and submit a quarterly report of the number of facilities certified to NCC-NTP. • Recommend/designate a representative from the private sector and appoint a substitute in the absence or unavailability thereof. • Conduct joint-monitoring of TB-DOTS centers/facilities with concerned parties as needed.
Certifying Team	• Validate the findings of the facility on-site based on the accomplished Self-Assessment Form (SAF). • Recommend to the RCC-NTP whether the facility shall be given approval for DOTS certification or shall be recommended for re-assessment. • Prepare a written report detailing the team's findings, rating per standard and the team's overall decision; and submit a copy to the health facility and RCC-NTP.
Technical Assistance (TA) Team	• Provides technical assistance to the DOTS facility prior to application and in case of re-assessment.
RO Coordinator	• Facilitate all the requirements for certification. • Coordinate with the members of certifying team regarding the schedule of actual certification visits. • Notify PhilHealth regarding the DOTS certification status of the facility and assist the facility in applying for PhilHealth accreditation. • Ensure that feedback of the results of the certification process is provided to the TA team of the facility needing re-assessment. • Monitor all DOTS certified facilities together with provincial TA team.

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DOH Representatives	• Facilitate the submission of all pertinent documents to the province/ city, RO and vice-versa, within the set time frame. • Assist the facility by providing adequate and appropriate technical support to the DOTS facility and ensure that the SAF is properly filled-up. • Provide technical assistance as needed.
Provincial / City Coordinators	• Provide technical assistance as needed and serve as the head of the TA team • Assist the facility by providing adequate and appropriate technical support to the DOTS facility and ensure that the SAF is properly filled-up. • Ensure the proper completion of the SAF prior to submission to RO for certification.
Representative of the Private Sector or Local Coalition	• Participate as a member of the certifying team after being duly trained. • Provide technical assistance as needed.
DOTS facility	• Conduct self-assessment • Comply with certification standards • Apply for certification

B. Procedures in Applying for Accreditation as PhilHealth DOTS Facility

(See Annex E on page 160)

1. Secure an application form for accreditation from any PhilHealth office or download from the PhilHealth website: www.philhealth.gov.ph

2. Prepare the following documents:

   a. Performance Commitment – duly signed by Local Chief Executive/owner and head of the facility/Medical Director/Chief of Hospital;

   b. Provider Data Record;

   c. Participation fee;

   d. Electronic copies in JPEG format of recent photos of the facility both the interior and outside surroundings;

   e. Statement of Intent (if applicable- this is for Health Care Institutions that submitted their application during the 4th quarter of the year). The statement of intent gives the TB DOTS facility a prerogative to choose the preferred start date of their accreditation;

   f. Updated TB DOTS Certificate;

   g. Location Map;

   h. Updated business permit (for private HCIs only);

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3. Submit to the PhilHealth regional office or Local Health Insurance Office the complete documents and pay the accreditation fee;

4. Upon approval of application, PhilHealth shall issue a certificate of accreditation and letter of approval which will be sent to the facility;

5. For any concerns regarding accreditation, the facility may inquire at the nearest PhilHealth Regional Office or Local Health Insurance Office in their area.

C. Procedures on PhilHealth Claims Processing *(See Annex E on page 160)*

1. Claims shall be filed within 60 calendar days after completion of prescribed treatment

2. The following documents must be submitted in filing claims:

   - Claim Form 1
   - Claim Form 2
   - Copy of NTP treatment card
   - Other documents required by PhilHealth

3. TB DOTS claims should have the correct ICD 10 Codes and Package Codes

4. Claims shall be processed based on the existing guidelines of PhilHealth.

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CHAPTER 10

Monitoring, Supervision and Evaluation

I. INTRODUCTION

Monitoring, Supervision and Evaluation (MSE) is a collective set of activities that informs the manager whether program activities are being implemented as planned to attain the set objectives. In all these activities, accurate and timely data and information is very important. Indicators from the NTP are used for the analysis of performance using routinely collected data.

It is the role of the DOTS facility staff, especially the physician and nurse, to monitor program performance and supervise the other health workers including Barangay Health Workers and treatment partners. Periodic evaluation must also be done.

The ROs and PHOs/CHOs NTP coordinators will also provide technical supervision over the DOTS facilities in their areas.

II. OBJECTIVES

The objectives of MSE are to:

- Ensure adherence of program implementers to NTP policies and guidelines.
- Monitor progress of program implementation, identify gaps and provide basis for decision making to improve implementation.
- Ensure that the program targets of 90% case detection rate for all forms and 90% treatment success rate for all forms are reached and maintained.

III. DEFINITION OF TERMS

A. Monitoring – Regular, systematic and purposeful observation of program performance to determine whether activities are implemented as planned and according to schedule. It also involves giving feedback to implementers, program managers, donors and beneficiaries of the program.38

B. Supervision – The process of overseeing the performance and progress of a person or group. It aims to increase efficiency of health workers by developing their knowledge and skills, improving work attitude, and increasing their motivation.

C. Evaluation - The careful collection of information about program, or some of its aspects, with particular focus on its effectiveness and impact over time.

IV. POLICIES

A. The RO NTP coordinators shall serve as technical assistance providers for the PHO/CHO NTP coordinators. The provincial or city NTP coordinators shall serve as NTP supervisors for all DOTS facilities. The DOTS facility physicians shall serve as NTP supervisors for the health staff of the facility while the Public Health Nurse serves as supervisors for midwives. Midwives shall supervise community volunteers.

B. Monitoring, supervision and evaluation activities should be integrated in the annual workplans of the health facility and should contain the list of areas/facilities to be visited, objectives of the visit, timelines, expected outputs and feedback mechanisms

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C. Conduct of monitoring and supervisory visits should be done on a quarterly basis. Areas may be prioritized for monitoring based on TB program performance and other needs. Whenever feasible, NTP monitoring in DOTS facilities shall be integrated with monitoring of other health programs.

D. Qualitative and quantitative data from routine NTP reports shall be analyzed and used to identify and address problems in program implementation.

E. Key program indicators will be used to monitor and evaluate TB program performance at all levels.

F. Local Government Units shall support monitoring, supervision and evaluation activities.

V. PROCEDURES

A. Monitoring and Supervision

1. Inform the facilities and health workers beforehand of the planned monitoring to ensure that the data and the key personnel will be available at that time.

2. Monitoring and supervision may be done through any of the following methods:

   a. Record and report review can be done at the office or during monitoring visits. The usual NTP records for review are **Form 1. Presumptive TB Masterlist, Form 3. NTP Laboratory Register** and **Form 6a. Drug-susceptible TB Register, Form 4. TB treatment/IPT Card**, **Quarterly Reports and Stock Inventory Cards.**

      i. Compare and verify that the information in the records and reports are complete, accurate and consistent. Specifically, compare the information in **Form 3. Laboratory Register, Form 4. TB Treatment/IPT Card** and **Form 6a. Drug-susceptible TB Register**

      ii. Verify if the classification of the patient, registration group, the category of treatment and the treatment outcome are correct

      iii. Check **Form 4. TB Treatment/IPT Card** if drug intake is complete and if sputum follow-up is done on time.

   b. Direct observation – Routine tasks that can be observed include sputum collection, storage of specimens, patient flows, provision of treatment and counselling, storage and inventory of drugs, waste disposal practices and infection control practices.

      i. Observe if the DOTS facility staff are giving correct and relevant information to patients and doing DOT correctly.

      ii. Observe how the staff instructs patients on sputum collection.

   c. Interviews of health workers and patients - to collect information about health worker's views about program performance, activities and problems and about patients' knowledge on TB causation, transmission, and treatment.

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3. The standard monitoring form and supervisory checklist *(See **Table No. 35** on the next page)* can be used for all DOTS facilities. This could be expanded for specific facilities (e.g., hospitals, jails and prisons).

4. Practice supportive supervision by being tactful, diplomatic and facilitative.

5. Provide feedback to the facility and personnel monitored and supervised. Discuss the findings with the concerned staff and agree on appropriate actions.

6. Prepare a formal report of the monitoring and supervisions conducted. Give a copy of the report to the DOTS facility or personnel visited and to the next higher level.

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Table No. 35 - Standard Monitoring and Supervision Tool

Date:_____ Region:_____ Province/City:_____
DOTS Facility: _____ Address: _____
Monitoring Team: _____

Part 1. Program Indicators

Indicator	Previous Period _____	Current Reporting Period _____	Remarks
OUTCOME INDICATORS			
1. Case Notification Rate (all forms)			
2. TB Case Detection Rate (all forms)			
3. Notification of MDR-TB			
4. Treatment Success Rate (all forms)			
5. Cure Rate (NSP)			
6. Treatment Success Rate of MDR-TB			
7. Percent of bacteriologically-confirmed MDR-TB cases with negative culture after 6 months of treatment (interim outcome)			
SERVICE INDICATORS			
8. Total number of presumptive TB examined			
9. Percent contribution from non-NTP care providers			
10. Number of children with TB detected and given treatment and those given IPT			
TB-HIV COLLABORATION			
11. Percentage of TB cases in category A and B areas with HIV counselling and testing among aged 15 years old and above			
12. Percentage of DR-TB cases provided with HIV counseling and testing among 15 years old and above			
LABORATORY AND LOGISTICS			
13. TMLs within EQA standards (Y/ N)			
14. No stockouts of anti-TB drugs and laboratory supplies in the last 12 months (Y/ N)			

Part 2. Records and Reports (Data Quality Assessment)

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Records	Available	Complete	Remarks
Form 1. Presumptive TB Masterlist			
Form 2a. NTP Laboratory Request Form			
Form 3. NTP Laboratory Register (Microscopy and GX)			
Form 4. TB treatment/IPT card			
Form 5. NTP ID card			
Form 6a. Drug-susceptible TB Register			
Form 6b. DR-TB Register			
Form 7. NTP referral form			
Form 8. Hospital TB referral logbook			
Reports	**Available**	**Complete**	**Remarks**
Report 1. Quarterly Report on TB Microscopy and GX Laboratory Examinations			
Report 2. Quarterly report on EQA for TB Microscopy			
Report 3a. Quarterly report on Case Finding of Drug-susceptible TB Cases and IPT			
Report 3b. Quarterly Report on DR-TB Cases			
Report 4. Quarterly report on drug and supply inventory and requirement			
Report 5a. Quarterly report on Treatment Outcome of Drug-susceptible TB Cases			
Report 5b. Quarterly Report on Treatment Interim Outcome of DR-TB Cases			
Report 5c. Annual Report on the Treatment Outcome of DR-TB Cases			
Report 6. Quarterly report of hospital TB referrals			
Data Accuracy: Check for accuracy by reviewing Form 4. Tb Treatment/ IPT Card			
	YES	**NO**	
1. Classification of TB Cases			
2. Category of Treatment			
3. Treatment Outcome			

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Part 3. Laboratory
Observe/ask for the following:

Indicator	Findings		Remarks
	Previous Period (_____)	Reporting period (_____)	
1. No. of trained medical technologists			
2. No. of trained microscopists			
3. No. of informal laboratory workers			
4. Functional microscope			
5. EQA performance			
a. % of minor errors			
b. % of major errors			
6. Laboratory Turnaround time (receipt of specimen to issuance of result)			
7. Program turnaround time (collection of specimen to start of treatment)			

Part 4. Health Facility and Logistics (Drugs and Supplies)
Observe the health facility and inspect the availability of supplies and commodities.

Health Facility	Observation	Remarks
1. Facilities for handwashing available (with continuous water supply)		
2. Work areas (clinic and laboratory) are clean and orderly.		
3. Suitable sputum collection area.		
4. Appropriate storage of anti-TB drugs and laboratory supplies		
5. Proper segregation and disposal of waste		
6. Adequate and well-ventilated waiting area		
7. Availability of infection control policy and plan at the facility		
Drugs and Supplies	**Availability**	**Remarks**
1. Adequate Laboratory Supplies • Sputum Cups • Glass slides • Staining kits • Immersion oil • Alcohol lamp • Sterile gloves • PPD solution		

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2. Adequate stocks of Anti-TB drugs • Category 1 kits • Category 2 kits • SDF: Isoniazid (Tab and syrup) • SDF: Rifampicin • SDF: Pyrazinamide • SDF: Ethambutol • Second-line drugs		
3. Personal Protective Equipment (respirators or masks)		
4. Drug and supply inventory/stock cards updated		

Part 5. Health Staff Interview

Determine if the health staff can give key messages about tuberculosis:

Question	Response	Remarks
1. What is tuberculosis/ MDR-TB?		
2. How is TB/ MDR-TB transmitted/spread?		
3. How is TB treated?		
4. Why is there a need to refer for DR-TB screening?		
5. Why is it important to have a treatment partner?		
6. How do you monitor a patient's response to treatment?		

Part 6. Patient Interview

Determine if the patient was educated/counselled appropriately:

Question	Response	Remarks
1. What is tuberculosis/ MDR-TB?		
2. How is TB/ MDR-TB transmitted/spread?		
3. How is TB treated?		
4. Why is it important to have a treatment partner?		
5. How will you know if you are getting well?		
6. What are your suggestions to make the services of the DOTS facility better?		

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Part 7. Supervisory Checklist
Observe or Interview the health staff regarding the following:

Procedure to Observe (Question)	Observation/ Response	Remarks
1. Identifying presumptive TB (How do you identify presumptive TB?)		
2. Collecting sputum specimens (Describe how you instruct patients to collect sputum specimens for diagnosis)		
3. Deciding on treatment based on results of diagnostic tests (What do you tell patients after a positive/negative DSSM result?)		
4. Referring patients for DR-TB screening (Who are the patients considered presumptive MDR-TB cases?)		
5. Initiating treatment (What are the key messages when initiating treatment for TB?)		
6. Explaining DOT (How is DOT done?)		
7. Monitoring response to treatment (How do you monitor response of patient to treatment?)		
8. Managing Adverse Drug Reactions (What are the common ADRs your patients encounter and how do you address them?)		
9. Assigning and explaining treatment outcomes (Define the different treatment outcomes. What will you advise a patient who has completed treatment?)		

B. Evaluation

1. All NTP Quarterly reports will be reviewed and analyzed by the DOTS facility physician prior to submission to the PHO/CHO. Together with the DOTS facility staff, the physician will analyze the program indicators to track the progress of program implementation towards the set goals and objectives *(See **Section VI,** **Program Indicators** below).*

2. Quarterly reports will be collected, consolidated and analyzed by the PHO/CHO, RO and NTP *(See **Table 24** on page 61)*. At all levels, identified problems and recommended actions will be given as feedback.

3. Program Implementation Reviews (PIR) will be conducted on a semi-annual or annual basis to evaluate performance. General steps in the conduct of the PIR are:

    a. Plan for the PIR by deciding what program elements to evaluate, what data collection tools and methods to use and by preparing the necessary logistics.

    b. Collect the necessary data prior to the actual PIR.

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c. Analyze and interpret the TB data collected. Report and explain the results of the analysis.

d. Discuss strategic directions that will address the program implementation gaps.

e. Prepare the PIR report and disseminate.

4. Analyze the core program indicators (CDR, CR, TSR) from the LGU scorecard.

Table No. 36 - Flow of NTP Reporting and Timelines

Level	Functions	Timeline for Submission
DOTS Facility	Data collection, analysis and submission to next higher level	1st week of the month following end of quarter
PHO/CHO	Data collection, analysis, consolidation, feedback and submission	2nd week of the month following end of quarter
RO	Data collection, analysis, consolidation, feedback and submission	3rd week of the month following end of quarter
DOH-NTP	Data collection, analysis, consolidation, feedback and submission	1st month of the following quarter

VI. PROGRAM INDICATORS

The program indicators measure the progress of implementation towards the set goals and objectives. They will be determined at least quarterly at all levels. Some indicators (i.e., case detection rates) are more applicable at provincial/regional/national levels rather than Barangay or Municipal levels. The next table summarizes the main program indicators, the definition and calculation, and the data sources.[40]

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Table No. 37 - Program Indicators and Definitions

Indicator	Definition/Calculation	Data Source
1. Case Notification Rate (all forms)	Number of Notified TB, all forms, for every 100,000 population Numerator = Number of Notified TB, all forms Denominator = population divided by 100,000 Note: "Notified TB, all forms" include new and relapse, (whether bacteriologically-confirmed or clinically-diagnosed) who were detected, registered and reported to the NTP	Report 3a. Quarterly report on Case Finding of Drug-susceptible TB Cases and IPT
2. TB Case Detection Rate (all forms)	Percentage of TB cases (all forms) detected and treated out of the estimated incident cases of TB (all forms) Numerator= Number of TB, all forms detected Denominator = Total number of TB,all forms estimated to occur each year based on the global TB report (i.e., population x incidence rate of TB, all forms)	Report 3a. Quarterly report on Case Finding of Drug-susceptible TB Cases and IPT
3. Notification rate of MDR-TB	Proportion of MDR-TB cases registered out of the estimated MDR-TB cases among notified TB cases Numerator = Number of registered bacteriologically-confirmed drug-resistant TB (RR/MDR-TB) cases Denominator = estimated MDR cases among the new and retreatmentTB cases	Report 3b. Quarterly Report on DR-TB Cases

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4. Treatment Success Rate (all forms)	Percentage of TB, all forms that are successfully treated Numerator = Number of TB, all forms, that are cured and completed treatment Denominator = Total number of TB, all forms, registered during a specified period	Report 5a. Quarterly report on Treatment Outcome of Drug-susceptible TB Cases
5. Cure Rate (New Bacteriologically-confirmed)	Percentage of TB, new bacteriologically-confirmed, that are cured Numerator = Number of new bacteriologically-confirmed TB cases cured Denominator = Total number of new bacteriologically-confirmed TB cases registered during a specified period	Report 5a. Quarterly report on Treatment Outcome of Drug-susceptible TB Cases
6. Treatment Success Rate of MDR-TB	Percentage of MDR-TB that are successfully treated Numerator = Number of registered bacteriologically-confirmed drug-resistant TB cases (RR/MDR-TB) cured and completed treatment Denominator = Number of registered bacteriologically-confirmed drug-resistant TB cases (RR/MDR-TB) during a specified period	Report 5c. Annual Report on the Treatment Outcome of DR-TB Cases
7. Percent of bacteriologically-confirmed MDR-TB cases with negative culture after 6 months of treatment (interim outcome)	Percentage of bacteriologically-confirmed MDR-TB cases with negative culture after 6 months Numerator: Number of bacteriologically-confirmed MDR-TB cases with negative culture after 6 months of MDR-TB treatment Denominator: Total number of bacteriologically-confirmed MDR-TB cases	Report 5b. Quarterly Report on Treatment Interim Outcome of DR-TB Cases

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8. Total number of presumptive TB examined	Absolute number of presumptive TB examined during the reporting period	Report 1. Quarterly Report on TB Microscopy and GX Laboratory Examinations
9. Percent contribution from non-NTP care providers	Percentage of notified TB cases contributed by non-NTP care providers Numerator = Number of notified TB cases, all forms, referred/managed by all non-NTP care providers (e.g., other government, private, or community-based providers, etc.) Denominator = Total number of notified TB cases, all forms	Report 3a. Quarterly report on Case Finding of Drug-susceptible TB Cases and IPT
10. Number of children with TB detected and given treatment and those given IPT	Absolute number of children with TB detected and given treatment plus those given IPT	Report 3a. Quarterly report on Case Finding of Drug-susceptible TB Cases and IPT
11. Percentage of TB cases in Category A and B areas with HIV counseling and testing aged 15 years old and above	Percentage of registered TB cases in Category A and B areas that underwent HIV counseling and testing Numerator = Number of registered TB cases in category A and B areas provided with HIV counseling and testing 15 years old and above Denominator = Total number of registered TB cases in category A and B areas 15 years old and above	Report 3a. Quarterly Report on Case Finding of Drug-susceptible TB Cases and IPT
12. Percentage of DR-TB cases provided with HIV counseling and testing aged 15 years old and above	Percentage of registered DR-TB cases that underwent HIV counseling and testing Numerator = Number of registered DR-TB cases provided with HIV counseling and testing 15 years old and above Denominator = Total number of registered DR-TB cases 15 years old and above	Report 3b. Quarterly Report on DR-TB Cases

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13. Percent of TMLs within EQA standards	Percentage of TMLs with less than 5% major errors Numerator = Number of TMLs who have less than 5% major errors (adequate performance) Denominator = All TMLs providing TB laboratory services within the NTP laboratory network	Report 2. Quarterly Report on EQA for TB Microscopy
14. Percent of DOTS/ Laboratory facilities with no stock-outs of anti-TB drugs and laboratory supplies in the last 6 months	Percentage of DOTS facilities with no stock-outs of anti-TB drugs and laboratory supplies in the past 6 months Numerator = Number of DOTS and laboratory facilities with no stock-outs of 1st line and 2nd line anti-TB drugs and lab supplies in the past 2 quarters Denominator = total number of DOTS and Lab facilities	Report 4. Quarterly Report on drug and supply inventory and requirement

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Annexes

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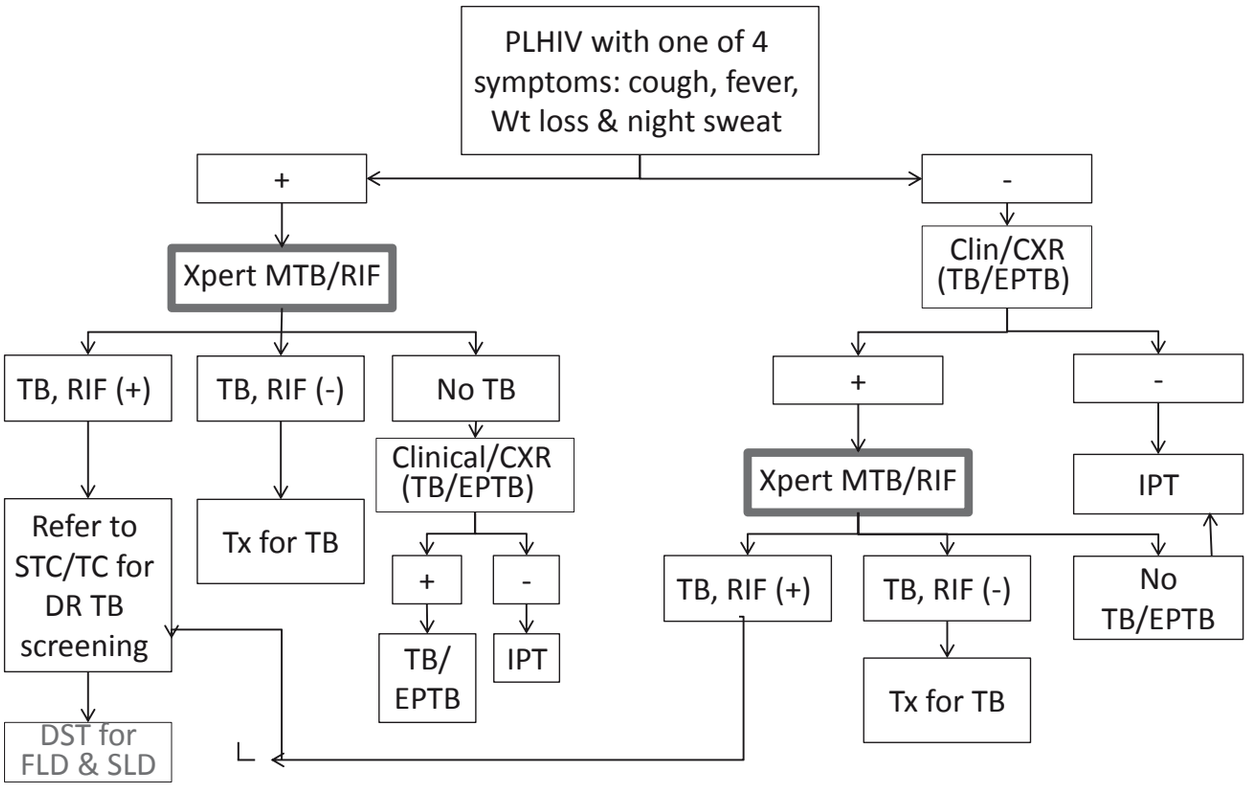
ANNEX A. Diagnostic Algorithm for PLHIV



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ANNEX B. Reporting Form for Adverse Drug Reactions (Food and Drug Administration)

SUSPECTED ADVERSE REACTIONS FORM v 5 (4/2012)
"Saving Lives Through Vigilant Reporting"
****FIELDS MUST BE COMPLETED.***

For FDA use only ***All reports are confidential.***
AER No. 2012-0001
Date received: _____

PATIENT'S PARTICULARS

***Patient's Name or Initials**_____ *** Sex:** ☐ **Male** ☐ **Female** **Weight** _____**Kg** **Height (cm)** _____

Address or Contact Number: _____ ***Age**_____ **Date of Birth (mm/dd/yr)**_____

Medical History/Admitting Diagnosis: _____ **Ethnic group:** ☐ **Filipino** ☐ **Chinese** ☐ **Caucasian**

Any Known Allergy: ☐ **No** ☐**Yes, Specify:**_____ **Pregnancy Status:** ___ **No**

Hospital/facility , if admitted:_____ ___ **Yes (1st, 2nd, 3rd trimester)**

*DETAILS OF THE ADVERSE REACTION

Date of onset:_____; ____**am,** ____**pm**

Do you consider the reaction to be serious? ☐ **Yes**, if yes indicate why: ☐ **No**

Describe the reaction, including pertinent laboratory data:

- ☐ Patient died due to reaction
- ☐ Involved or prolonged in-patient hospitalization
- ☐ Life threatening
- ☐ Involved persistent or significant disability
- ☐ Congenital anomaly in the newborn
- ☐ Other outcome, please give details:

Can this be due to Medication Error? ☐ **No**
☐ **Yes**, if yes, which type:

___Prescribing
___Transcription
___Dispensing
___Administration

Can the adverse reaction be due to :

1. **Product quality defect** ___**No** ___**Yes, Specify, encircle:** color change ; caking; powdering ; counterfeit; odor change; defective container; contaminants; separation of components; undissolved suspension/powder
2. **Therapeutic failure:** ___**No** ___**Yes, Specify, encircle:** antimicrobial resistance, drug interaction, poor compliance, counterfeit, expired; improper storage; under-dosing, inappropriate medication; inappropriate route of administration; excipients/preservatives

*Suspected drug product(s) Indicate brand name	Daily Dose	Route	Date started	Date stopped	Reason (s) for using the product (Indication)	Manufacturer and Batch/Lot #

List all other drug/s taken at the same time and/ or 3 months before. If none, check box. ☐ ***No Other drug/s taken***

Brand name of the drug	Daily Dose	Route	Date started	Date stopped	Reason/s for using the drug	Manufacturer and Batch & Lot No.

*MANAGEMENT OF ADVERSE REACTION

Was treatment given? ☐ **No** ☐ **Yes** (If yes, please specify): _____

Outcome:
☐ Recovered (Date of recovery):_____ ☐ Unrecovered **Other diseases**: _____liver _____renal _____HPN
☐ Fatal (Date of death):_____ ☐ Unknown _____ Diabetes _____CVS ____Endocrine ____Cancer

Sequela/e: (any permanent complications or injuries as a result of the ADR) **Re-challenge?** ☐ **Yes Result**_____
☐ **Yes (Please specify)**_____ ☐ **No** ☐ **Unknown** ☐ **No**

* REPORTER'S PARTICULARS

***Printed Name of Reporter:** _____
Signature of reporter: _____
Date reported (mm/dd/yr): _____

***Contact no:**_____
Email address: _____
***Profession**: __MD ___ RPh ___RN___Patient ___Dentist ___other
***Facility:** ___Clinic ____Trial site _____Other

FDA Food and Drug Administration PHILIPPINES

National Pharmacovigilance Center
"Saving Lives Through Vigilant Reporting"
Send completed form to: ADR Unit, FDA, Civic Drive, Filinvest Estate, Alabang, Muntinlupa ,1781.
Or fax to: (02) 807-85-11, c/o The ADR Unit. **Send sample, if any, of suspect drug for analysis.**
Website: www.fda.gov.ph

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ANNEX C. Philippine Priority Areas for HIV Intervention

Category A+	Category B+	ROTC
Parañaque City Muntinlupa City Taguig City Pasay City Makati City Mandaluyong City Marikina City Quezon City Caloocan City Navotas City Las Piñas City Manila city Pasig City San Juan City Malabon City Valenzuela City Pateros Angeles City Davao City Cebu City Mandaue City Bacoor, Cavite Puerto Princesa City Zamboanga City Cagayan de Oro City Baguio City	Olongapo City Antipolo City, Rizal Dasmariñas City, Cavite Batangas City, Batangas Cainta, Rizal Imus, Cavite Lipa City, Batangas Iloilo City Bacolod City, Negros Occidental Lapu-Lapu City, Cebu Talisay, Cebu General Santos City Butuan City Danao City San Fernando,Pampganga Mabalacat,Pampanga San Jose del Monte, Bulacan Meycauayan, Bulacan Sta. Rosa, Laguna	All other cities and municipalities

Source Department of Health. Memorandum from National Epidemiology Center: Philippines Priority Area for HIV Intervention (PAHI). March 5, 2012

Table 2. Number of Most At-Risk Population in each Priority Category and the Rest of the Country

Area Category	MSM	IDU	FSW	Male Clients of FSM
A (22 areas)	119,733	4,989	36,290	199,558
NCR	95,908	1,126	20,117	159,850
Cities of Cebu, Mandaue, & Danao	10,144	3,528	3,213	16,906
Davao City	11,105	148	1,763	18,508
Angeles City	2,576	34	11,197	4,294
B (18 areas)	56,383	2,497	11,625	87,976
C (30 area)	49,048	654	9,161	81,813
Rest of the Country	454,365	8,467	32,099	779,868
Combined A & B (40 areas)	176,116	7,446	47,915	287,534
Combined A, B & C (70 areas)	225,164	8,111	57,076	360,347

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Assessment checklist for healthcare facilities and other congregate settings (WHO)

ANNEX D. Assessment Checklist for TB Infection Control

a) Services visited, TB case load, workload, responsible staff:

_____

_____

Comments (progress after previous assessment?):

_____

_____

b) TB Infection Control measures implemented

TB Infection Control measures	Yes	No	Comments
Managerial			
Responsibilities for TB IC			ICC, IPT, ICN? Terms of reference available
Health facility design, and use			Occupancy? Patient flow? Outdoor areas? Sitting arrangements? Other characteristics
Surveillance and assessment of TB among staff			Realized and current activities? Written context specific policies, waste management policy and lab biosafety
Training in IC-TB			How often? How many staff? Register?
Communication (IEC)			Realized and current activities?
Monitoriung and evaluation			Which indicators are used?
Operational research			Research agenda?
Administrative			
Triage			How is this performed? Questionnaire?
Separation / Isolation			Areas?
Cough etiquette			Poster? Face masks? Written policy on sputum disposal?
Expedient service delivery			Waiting time, DSSM and culture-around time, and hospital stay reviewed? Standard times set for the facility?
Prevention & care package for staff			Periodic TB screening? Workplace policy?
Environment			

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Natural and/or mechanical			Provide sketch. Check airflow (with smoke, vaneometer), Calculate ACH
Fans			Maintenance, placement?
UVGI			Provide Sketh. LAst maintenance check? UVGI design and installation adequate for the space?
Personal protective equipment			
Pesperators			Type? Average usage? Stocks? Storage? Signage?
Fit testing			How is it organized? Frequency of fit test

1) Function, use and utilization of room assessed for ACH

_____

_____

2) Sketch room. Include main room, anteroom, hallway, UV lights fans, windows, furniture and airflow direction:

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3) Make a flowchart of the patient flow through the facility:

d) Summary of the facility assessment

Strengths	Weaknesses
Priority problems	
1.	
2.	
3.	
4.	
5.	
Agreed solution and recommendations between evaluator(s) and staff/management	
Recommendation / Medium/High Priority / Responsible / Estimated Budget	
Name, date and signature	
Next assessment:	

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ANNEX E. Revised Guidelines for the PhilHealth Outpatient Anti-TB DOTS Benefit Package

Republic of the Philippines
PHILIPPINE HEALTH INSURANCE CORPORATION
Citystate Centre Building, 709 Shaw Boulevard, Pasig City
Healthline 441-7444 www.philhealth.gov.ph

PHILHEALTH CIRCULAR

NO. 014, s2014

TO : ACCREDITED HEALTH CARE INSTITUTIONS AND PROFESSIONALS, TB – DOTS CLINICS, PHILHEALTH MEMBERS, PHILHEALTH LOCAL HEALTH INSURANCE OFFICES, REGIONAL OFFICES, CENTRAL OFFICE AND ALL OTHER CONCERNED

SUBJECT : REVISED GUIDELINES FOR THE PHILHEALTH OUTPATIENT ANTI-TUBERCULOSIS DIRECTLY OBSERVED TREATMENT SHORT-COURSE (DOTS) BENEFIT PACKAGE

UNCONTROLLED COPY Date: 6/23/14 DC:

I. BACKGROUND

PhilHealth constantly develops its benefit packages to effectively respond to the needs of its members. Mindful of PhilHealth members afflicted with Tuberculosis (TB), the PhilHealth Board approved Resolution Nos. 485 and 490 of 2002 which established the case rate benefit for out-patient TB-DOTS package amounting to 4,000 pesos for "consultation, anti-tuberculosis medicines and necessary diagnostic services".

Subsequently, PhilHealth issued Circular No. 17 s-2003 which provided the guidelines for the accreditation of Directly Observed Therapy Short Course (DOTS) facilities as well as Circular No. 19, s-2003 that implemented the TB-DOTS Package to include new cases, pediatric and extra-pulmonary TB. Although treated under DOTS and on out-patient basis, retreatment cases are not yet covered in the said Package.

The Philippine Plan Against Tuberculosis 2010-2016 was crafted to fine tune strategic directions with a view to sustain the gains of the TB control program and achieve Millennium Development Goals (MDG) for TB. The goal is to reduce TB prevalence and mortality rates by half compared to 1990 figures. Targets were marked at 85% case detection rate and at least 90% treatment success rate.

To achieve these targets, the NTP addressed some problems that hamper access to diagnosis and treatment of TB in the DOTS facilities. Criteria for management of sputum negative TB were modified in cases when there are no TB Diagnostic Committee (TBDC) (DOH Memorandum No. 2011-0218, dated July 19, 2011). The TBDC recommendation should not be a cause of delay in initiating treatment. In the said memorandum, DOH emphasized that ALL forms of TB should be given treatment. Also, to improve case finding, diagnosis by Direct Sputum Smear Microscopy

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(DSSM) shall only require submission of 2 samples, as stated in DOH Memorandum No. 2013-0021, dated January 9, 2013. The NTP Manual of Procedures was likewise revised to ensure that the processes in DOTS implementation support the objectives and strategies in the Philippine Plan of Action to Control Tuberculosis (PhilPACT). In light of the said modifications, the guidelines to PhilHealth TB-DOTS benefit package should be likewise updated to reflect the overall national objectives and standards of TB control.

Furthermore, the National Health Insurance Act of 2013 strengthens the role of PhilHealth in providing means for the members to have financial access to health care and for the healthcare providers to improve their health services. The law prohibits charging additional fees to indigent patients. It also prescribes that PhilHealth reimbursements to public health facilities be retained by the individual facility and be spent on operating expenses of the facility as well as improvement of its services, while professional fees shall be pooled and distributed among the facility's health personnel. Such measures are reflected in this revised TB DOTS package, such that public and private facilities have means to sustain the delivery of TB DOTS services, leading to better TB control.

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Date: 6/23/14
DC:

II. OBJECTIVES

This circular is issued with the following objectives:

1. To expand the benefit to cover other TB cases that are sensitive to first line anti-TB drugs.
2. To align the PhilHealth TB DOTS Package with the current policies and guidelines for TB control
3. To strengthen the financial mechanism as leverage for better performance of providers leading to desired health outcomes and sustained TB control.

III. GENERAL GUIDELINES

1. To avail of this package, accredited TB DOTS facilities shall comply with the prescribed guidelines of the NTP on diagnosis, treatment and reporting for TB.
2. PhilHealth TB DOTS Package shall cover TB cases that are susceptible to 1st line anti-TB drugs.
3. It shall cover for diagnostic exams, consultation services, drugs, health education and counseling during TB DOTS treatment.
4. PhilHealth TB DOTS Package shall cover both children and adults, with the following **registration groups** (whether bacteriologically confirmed or clinically diagnosed, pulmonary or extra-pulmonary):

    a. New

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b. Retreatment

1) Relapse

2) Treatment After Failure

3) Treatment After Lost to Follow-up (Return After Default)

4) Previous Treatment Outcome Unknown

5. The following cases are excluded:

a. In-patient admissions

b. Drug resistant TB

c. Latent TB Infection

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6. HIV patients that are under treatment for 1st line drug sensitive TB and on anti-retro viral drugs may avail of TB DOTS Package in accredited TB DOTS Centers and Out-patient HIV/AIDS Treatment (OHAT) Package in accredited HIV treatment hubs at the same time. Claims shall be filed separately.

7. The TB DOTS package shall be a fixed case rate of four thousand pesos (Php 4,000.00) and to be given to health care institution in two separate payments.

a. The first payment of two thousand five hundred pesos (Php 2,500.00) shall be given after the intensive phase (Package Code 89221).

b. The second payment of one thousand five hundred pesos (Php 1,500.00) shall be given after the continuation (maintenance) phase (Package Code 89222).

8. Payment for referring physicians and other expenses for some services done outside the facility (e.g. chest x-ray) shall be settled by the facility.

IV. PROVIDER ACCREDITATION

1. Accreditation of TB-DOTS providers shall be in accordance with the policy on Provider Engagement through Accreditation and Contracting of Health Services as stated in PhilHealth Circular (PC) 54 s-2012 and subsequent issuances.

2. The Health Care Institution shall submit the following requirements upon its application for initial accreditation:

a. Performance Commitment, duly signed by both the owner or local chief executive and the head of the facility (e.g. MHO, CHO, PHO, medical director, chief of hospital, etc.);

b. Properly accomplished provider data record;

c. Proof of payment of accreditation fee (Php 1,000.00);

d. Electronic copies of photos (in jpg format) of the internal and external areas of the facilities;

e. Statement of intent for those applying in the last quarter of the current year as attached in PhilHealth Circular 11, s-2013;

f. Updated DOH-PhilCAT Certificate;

g. Location map;

3. As provided in Section VI.C of PhilHealth Circular 54, s-2012, accredited TB DOTS Package Providers may continuously participate in the National Health Insurance Program (NHIP) until such participation is withdrawn or terminated. To ensure this, TB DOTS Facilities shall submit annually (on or before January 31st)the following:

a. Signed performance commitment;

b. Updated DOH-PhilCAT TB DOTS Certificate (if not submitted, the facility shall be subjected to pre-accreditation survey);

c. Latest Financial Statement/Report for private facilities;

d. Proof of payment of accreditation fee (Php 1,000.00).

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Date: 9/23/14
DC:

4. In line with All Case Rates Policy stated in PhilHealth Circular 31, s-2013 Section VI.B that professional services must be provided by accredited health care professionals, PhilHealth shall accredit TB DOTS physicians who provide consultation services in the TB DOTS facility.

a. PhilHealth shall require that TB DOTS physician/s be accredited with PhilHealth for TB DOTS facilities applying for initial and re-accreditation in 2014.

b. Currently accredited TB DOTS facilities shall have their physicians accredited by July 31, 2014.

c. It shall be a requirement for all continuous, initial and re-accreditation in 2015.

5. Accreditation of TB DOTS physician/s shall be according to the provisions of PhilHealth Circular 10, s-2014. They shall submit to the nearest PhilHealth Local Health Insurance Office or Regional Office the following requirements for initial application:

a. Properly accomplished Provider Data Record for professionals;

b. Signed Performance Commitment;

c. Updated PRC License or its equivalent;

d. Two (2) pieces of 1x1 photo;

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e. Proof of payment of premium contribution; and

f. Certificate of completed residency training or specialty board certificate if applicable.

V. BENEFIT DELIVERY AND CLAIMS FILING

1. The payment shall be payable to the accredited TB DOTS facility.
2. Claims with the following treatment outcomes shall be paid:
   a. Cured
   b. Treatment completed
   c. Died
   d. Treatment failed
3. Claims with the following treatment outcomes shall be denied:
   a. Lost to follow-up
   b. Not evaluated
4. Claims of TB cases that were initially treated with 1st line anti-TB drugs but were diagnosed to have Drug Resistant TB anytime during treatment even before being declared as treatment failed in the 5th month shall be paid.
5. TB DOTS Facilities must comply with the referral mechanisms prescribed by NTP. In cases when the patient is referred to another facility, the referring facility shall file the claim. Claims from receiving facility shall be denied.
6. Availing of this package shall have no corresponding deduction in the 45-days benefit limit per calendar year.
7. No Balance Billing policy as prescribed in PhilHealth Circular 03, s-2014 shall apply.
8. The following package codes shall be used for each treatment phase:

Treatment Phase	Package Code	Description
Intensive Phase	89221	Directly observed treatment short course; intensive phase
Continuation Phase	89222	Directly observed treatment short course; continuation (maintenance) phase

9. The ICD 10 Codes listed in Annex 2 shall be used for this Package.

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10. For easier verification of eligibility status, all TB DOTS Facilities must have a PhilHealth Enhanced HCI Portal. Policies and guidelines of which are stated in PhilHealth Circular 02, s-2014.

11. Since there will be separate claims for each treatment phase, the following shall be considered dates of admission and discharge:

Admission Date	Discharge Date	Anti-TB Treatment Phase being claimed	Package Code
First day of intensive phase (treatment start date)	Last day of intensive phase	Intensive Phase	89221
First day of continuation (maintenance) phase	Last day of continuation (maintenance) phase	Continuation (maintenance) Phase	89222

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12. PhilHealth members and their dependents are eligible to avail of the package if premium contributions are paid for at least three months within the six months prior to admission dates of each treatment phase.

13. For claims filing, the following documents must be submitted to PhilHealth within 60 calendar days after the last day of each treatment phase:

    a. PhilHealth Benefit Eligibility Form (PBEF) OR

    Other documents required by PhilHealth as proof of eligibility such as Member Data Record (MDR), proof of premium payment for individually paying program members, overseas workers program members and PhilHealth ID cards (for sponsored, lifetime members) and other secondary documents as enumerated in the PBEF or listed in PhilHealth Circulars 50, s-2012 and PC 1, s-2013 in cases when PBEF is not available.

    b. PhilHealth Claim Form 1 (CF1) duly filled up by the member and/or employer

    It shall no longer be required if PBEF affirmed the eligibility of patient to avail of PhilHealth benefits upon the start of treatment date.

    c. PhilHealth Claim Form 2 (CF2) - instructions and sample form of which are attached as Annex 3 and Annex 4 respectively.

    d. Copy of patient's completed NTP treatment card

14. Submission of the NTP Treatment Card prior to starting the treatment is no longer required. Also, the TBDC Recommendation Form is not a requirement anymore for sputum negative/clinically diagnosed patients.

15. Claims with incomplete requirements and/or discrepancy/ies in the entries shall be returned to the facility or sender (RTS) for compliance within 60 days from the receipt of notice. Failure to

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comply shall cause denial of claim. However, as stated in PhiHealth Circular 09, s-2014, it shall only be allowed for claims with admission dates on or before June 30, 2014. Afterwards, PhilHealth shall no longer return these claims to the facility but would already deny the claims. The facility must ensure that all requirements are attached, all forms are properly accomplished and there are no discrepancies in the entries before submitting the claims.

16. TB DOTS facilities and physicians shall ensure that their PhilHealth accreditation is updated. Both must be accredited at the start of the treatment. If there is a gap in their accreditation during the course of patient's treatment, claims may still be paid provided that they are accredited on start of treatment. Claims with treatment start date when either of them are not accredited shall be denied starting August 31, 2014.

VI. ALLOCATION OF TB DOTS PACKAGE PAYMENT

1. Public TB DOTS facilities shall maintain a trust fund for reimbursements received from PhilHealth. This trust account shall be created through appropriate administrative issuances such as ordinances or resolutions from Sangguniang Panlungsod/Bayan/Lalawigan for LGU-owned facilities and executive committee resolutions or administrative memoranda for TB DOTS facilities in the government hospitals/infirmaries/other institutions. In cases when there is one trust fund for several PhilHealth benefits, a separate ledger shall be kept for TB DOTS package payment.

2. All TB DOTS facilities shall allocate reimbursement for TB DOTS Package based on their existing policies and procedures.

3. Should the TB DOTS facilities not have any policy on allocation of TB DOTS payment prior to the effectivity of this circular, they shall follow the following guidelines prescribed by DOH in the latest NTP Manual of Procedures:

    a. Forty percent (40%) for the facility fee.

    b. Twenty five percent (25%) for the referring physicians to cover for consultation services during the course of treatment. Should there be no referring physician, this portion shall also be allotted as facility fee.

    c. Thirty five percent (35%) for the services of the staff of the TB DOTS facility.

4. The facility fee shall be used for operational costs and for contingency to augment the supply of anti TB drugs and reagents; acquire equipment such as microscope, IT equipment and software; and support for TB Diagnostic Committee, advocacy activities and training of staff. This may also be used for referral fees of warranted diagnostic services that are not available in the facility and quality assurance of sputum microscopy.

5. The fee for services of the health facility staff shall be pooled and distributed among health personnel who were involved in the delivery of health services for TB including the DOTS physicians, nurses, midwives, medical technologist or sputum microscopist, barangay health workers and treatment partners.

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6. Guidelines on the distribution of TB-DOTS payment for the services of the facility staff shall be set by each facility after thorough consultation among its governing body and the health staff. The guidelines shall be approved by the head of the organization (i.e. local chief executive in LGU owned TB DOTS clinic). The allocation should take into consideration the expertise, skills and time that each health care worker allotted in ensuring that the patient received quality care leading to cure or completion of TB treatment.

VII. MONITORING AND EVALUATION

1. Monitoring and evaluation (M and E) of the delivery and utilization of the benefit package shall be based on the M and E framework of PhilHealth.

2. Public DOTS facilities shall furnish PhilHealth copies of their issuances creating the trust fund and guidelines on allocation within a year after their initial accreditation through their respective PhilHealth Regional Offices.

3. The facility is required to maintain a minimum set of information on each patient such as NTP treatment card and TB registry that shall be readily available to PhilHealth during monitoring and evaluation.

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VIII. EFFECTIVITY

This Circular shall take effect 15 days after its publication in a newspaper of general circulation. New and retreatment cases with intensive treatment starting that date should follow the guidelines of this circular.

IX. REPEALING CLAUSE

All other existing issuances and provisions of previous issuances inconsistent with this circular are hereby repealed and/or amended.

X. ANNEXES

1. Annex 1 – Definition of Terms
2. Annex 2 – ICD-10 Codes for TB
3. Annex 3 – Instructions How to Accomplish Claim Form 2 for TB DOTS Package
4. Annex 4 – Sample Claim Form 2

ALEXANDER A. PADILLA
President and CEO

Date signed: 6/13/14

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ANNEX 1 - DEFINITION OF TERMS

1. **Presumptive TB case** – any person whether adult or child, with signs and/or symptoms suggestive of TB (pulmonary or extra-pulmonary, or those with chest x-ray findings suggestive of active TB.

2. **TB infection or latent TB infection (LTBI)** – a condition in which an individual has no signs and symptoms presumptive of TB or radiologic or laboratory evidence, but has a positive Tuberculin skin test (TST) reaction.

3. **TB disease** – a presumptive TB who after clinical and diagnostic evaluation, is confirmed to have TB.

4. **Classification of TB Disease** – Classification based on the 5th Edition of Manual of Procedures for the National TB Control Program
   A. **Classification based on bacteriological status:**
      i. **Bacteriologically confirmed** - A TB patient from whom a biological specimen is positive by smear microscopy, culture or rapid diagnostic tests (such as Xpert MTB/RIF).
      ii. **Clinically diagnosed** – A TB patient who does not fulfill the criteria for bacteriological confirmation but has been diagnosed with active TB by a clinician or other medical practitioner who has decided to give the patient a full course of TB treatment. This definition includes cases diagnosed on the basis of x-ray abnormalities or suggestive histology, and extrapulmonary cases without laboratory confirmation.

   B. **Classification of TB Disease based on anatomical site:**
      i. **Pulmonary TB (PTB)** - refers to a case of tuberculosis involving the lung parenchyma. A patient with both pulmonary and extrapulmonary TB should be classified as a case of pulmonary TB.
      ii. **Extrapulmonary TB (EPTB)** - refers to a case of tuberculosis involving organs other than the lungs (e.g. larynx, pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges).

   C. **Classification of TB disease based on history of previous TB treatment**
      i. **New case** – a patient who has never had treatment for TB or who has taken anti-TB drugs for less than one (<1) month. Isoniazid preventive therapy or other preventive regimens are not considered as previous TB treatment.
      ii. **Retreatment case** – a patient who has been previously treated with anti-TB drugs for at least 1 month in the past.

5. **TB Disease Registration Group** – classification of TB cases based on history of previous treatment in addition to anatomical site and bacteriologic confirmation. It is necessary in order to determine the correct treatment regimen.

Registration Group	Definition of Terms
New	A patient who has never had treatment for TB or who has taken anti-TB drugs for less than one (<1) month.

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Registration Group		Definition of Terms
Retreatment	Relapse	A patient previously treated for TB, who has been declared cured or treatment completed in their most recent treatment episode, and is presently diagnosed with bacteriologically-confirmed or clinically-diagnosed TB.
	Treatment After Failure	A patient who has been previously treated for TB and whose treatment failed at the end of their most recent course This includes: A patient whose sputum smear or culture positive at 5 months or later during treatment A clinically diagnosed patient for whom sputum examination cannot be done and who does not show clinical improvement anytime during treatment
	Treatment After Lost to Follow-up (TALF)	A patient who was previously treated for TB but was lost to follow-up for two months or more in their most recent course of treatment and is currently diagnosed with either bacteriologically-confirmed or clinically-diagnosed TB.
	Previous Treatment Outcome unknown (PTOU)	Patients who have been previously treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented.
Transfer-in		A patient who has been registered in a DOTS facility adopting NTP policies and is transferred to another DOTS facility with proper referral slip to continue the current treatment regimen.
Other		Patients that do not fit into any of the registration group listed above.

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6. **Treatment Outcome** – result of treatment based on completion of treatment regimen, results of follow-up sputum smear microscopy and clinical improvement.

The following are the identified outcomes for drug susceptible TB cases.

Outcome	Definition
Cured	A patient with bacteriologically- confirmed TB at the beginning of treatment and who was smear – or culture – negative in the last month of treatment and on at least one previous occasion in the continuation (maintenance) phase.

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Outcome	Definition
Treatment completed	A patient who completes treatment without evidence of failure but with no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because tests were not done or because results are unavailable. This group includes: • A bacteriologically confirmed patient who has completed treatment but without direct sputum smear microscopy (DSSM) follow-up in the last month of treatment and on at least one previous occasion • A clinically diagnosed patient who has completed treatment
Treatment failed	A patient whose sputum smear or culture is positive at 5 months or later during treatment. A clinically diagnosed patient (child or EPTB) for whom sputum examination cannot be done and who does not show clinical improvement anytime during treatment
Died	A patient who dies for any reason during the course of treatment.
Lost to follow-up	A patient whose treatment was interrupted for 2 consecutive months or more.
Not Evaluated	A patient for who no treatment outcome is assigned. This includes cases transferred to another DOTS facility and who treatment outcome is unknown.

Note: According to NTP Manual of Procedures, a patient who is diagnosed to have Drug Resistant TB anytime during treatment (i.e. before being declared treatment failed in the 5th month) shall be excluded from the cohort and is not assigned an outcome if they started on second line drug regimen. However, if treatment with a second-line drug regimen is not possible, the patient is kept in the main TB cohort and assing an outcome from among those listed above.

7. **Referring physicians** – private practicing physicians who are not staff of the TB DOTS providing facility but participate in the delivery of TB DOTS services by referring their patients to TB DOTS facilities for treatment and still conducting regular check-ups to these referred patients until they are able to finish treatment. They are trained and certified by DOH and/or Philippine Coalition Against Tuberculosis (PhilCAT) as TB DOTS referring physicians.

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ANNEX 2 - ICD 10 CODES for TB Cases

Anatomical Site	Diagnostic Criteria	Definition of Terms		ICD 10 Code/s
Pulmonary (PTB)	Bacterio-logically confirmed	Smear-positive	A patient with at least one (1) sputum specimen positive for AFB, with or without radiographic abnormalities consistent with active TB	A 15.0
		Culture-positive	A patient with positive sputum culture for MTB complex, with or without radiographic abnormalities consistent with active TB	A 15.1 *Note: if confirmed by both culture and smear, the code should be A15.0*
		Rapid Diag-nostic test-positive	A patient with sputum positive for MTB complex using rapid diagnostic modalities such as Xpert MTB/RIF, with or without radiographic abnormalities consistent with active TB	A 15.0
	Clinically diagnosed	A patient with two (2) sputum specimens negative for AFB or MTB or with smear not done due to specified conditions but with radiographic abnormalities consistent with active TB; **and** there has been no response to a course of empiric antibiotics and/or symptomatic medications; **and** who has been decided (either by the TBDC and/or physician) to have TB disease activity requiring a full course of anti-TB chemotherapy **OR** A child (less than 15 years old) with two (2) sputum specimens negative for AFB or with smear not done, who fulfills three (3) of the five (5) criteria for disease activity namely: signs and symptoms suggestive of TB; exposure to an active TB case; positive tuberculin test; abnormal chest radiograph suggestive of TB; and other laboratory findings suggestive of tuberculosis **and** who has been decided (either by the physician and/or TBDC) to have Tb disease requiring a full course of anti-TB chemotherapy **OR** A patient with laboratory or strong clinical evidence for HIV/AIDS with two (2)	A16.0 *(if smear or MTB culture was done but negative)* A16.1 *(if smear or culture was not done)* For cases of clinically diagnosed PTB resulting from HIV, the following codes shall be used: B20.0, A16.0 *(if smear or culture negative)* B20.0, A16.1 *(if smear or culture*

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Anatomical Site	Diagnostic Criteria	Definition of Terms	ICD 10 Code/s
		sputum specimens negative for AFB or MTB or with smear not done due to specified conditions but who, regardless of radiographic results, has been decided (either by physician and/or TBDC) to have TB disease activity requiring a full course of anti-TB chemotherapy.	*was not done)* B20.0, A16.2 (*without mention of smear or culture confirmation)*
Extra-pulmonary (EPTB)	Bacterio-logically confirmed	A patient with a smear/culture/new diagnostic test from a biological specimen in an extra-pulmonary site (i.e., organs other than the lungs) positive for AFB or MTB complex	A15.4 – A15.6, A15.8 *Note: 4th character of ICD 10 Code depends on the site*
	Clinically diagnosed	A patient with histological and/or clinical or radiologic evidence consistent with active extra-pulmonary TB and there is a decision by a physician to treat the patient with anti-TB drugs	A16.3 – A16.6, A16.8, A17 – A19

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ANNEX 3 – INSTRUCTIONS HOW TO ACCOMPLISH CLAIM FORM 2 (CF2) FOR TB DOTS PACKAGE

Claim Form 2 shall be accomplished using capital letters and by checking the appropriate boxes. All items should be marked legibly by using ballpen only.

All dates should be filled out in MM-DD-YYY format.

CF 2 Part/Item	Description	Instruction
Part I	PhilHealth Accredited Number Name of Health Care Institution Address	Write the PhilHealth Accreditation Number, name of HCI and the address on the space provided
Part II, item 1	Name of Patient	Write the complete name of the patient in this format: Last Name, First Name, Name Extension (if any), Middle Name
Part II, item 2	Referred by another HCI	Write "not applicable" *The referring facility will file the claim.*
Part II, item 3	Confinement period	
	Date Admitted	for intensive phase (89221) write the start date of intensive phase for continuation phase (89222) write the start date of continuation phase
	Date Discharged	for intensive phase (89221) write the date of the last day of intensive phase for continuation phase (89222) write the date of the last day of continuation phase
Part II. item 4	Patient Disposition	For intensive phase (89221) WRITE N/A For continuation phase (89222) WRITE the treatment outcome e.g. Cured, Failed, Died on the space below "Patient Disposition" WRITE DRTB if the patient was diagnosed to have DRTB during the course of treatment prior to being declared as treatment failed.
Part II, item 5	Type of Accommodation	Leave it blank
Part II, item 6	Admission Diagnosis/es	Write the diagnosis upon start of treatment including the classification based on bacteriological status, anatomical site the history of previous treatment, registration group of patient and whether sputum negative or

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CF 2 Part/Item	Description	Instruction
		positive e.g. Pulmonary TB, new, bacteriologically confirmed (sputum positive)
Part II, item 7	Discharge Diagnosis	Write the diagnosis after complete of treatment including the classification based on bacteriological status, anatomical site the history of previous treatment, registration group of patient AND the treatment outcome e.g. Pulmonary TB, new, bacteriologically confirmed (sputum positive), cured
	ICD-10 Code/s	Write the appropriate ICD-10 Code/s (see Annex 2 for the list of ICD-10 Code/s
	Related Procedures	Write the applicable treatment phase Intensive phase Continuation phase
	RVS Code	Write corresponding package code For intensive phase - 89221 For continuation phase - 89222
	Date of procedures	Write the dates when the treatment phase were started
Part II, item 8 d	Special consideration TB DOTS Package	Tick the appropriate box Intensive phase OR Maintenance phase (Continuation phase) AND WRITE the patient's Registration Group e.g. New, Relapse etc on the space beside the "Maintenance Phase" AND WRITE the Category of Treatment e.g. Category I, Ia, etc. on the space beside the "Maintenance Phase"
Part II, item 9	PhilHealth Benefits	Write the appropriate package codes 89221 for intensive phase 89222 for continuation phase
Part II, item 10	Professional Fees	Write the accreditation number and the name of TB DOTS Physician on the spaces provided

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CF 2 Part/Item	Description	Instruction
		Affix the signature of the TB DOTS Physician over his/her name Write the date of the space provided
	Details	IF patient has NO co-pay or out-of pocket expense for professional fee/s: Tick No co-pay on top of PhilHealth Benefit
		IF patient HAS co-pay or out-of pocket expense for professional fee/s: Tick With co-pay on top of PhilHealth Benefit and write the amount of co-payment
Part III Section A	Certification of Consumption of Benefits	IF patient did not have any co-payment/out of pocket expenses related to TB treatment such as payment for medicines, laboratory, professional fee: Tick first box (PhilHealth benefit is enough to cover HCI and PF charges) Accomplish the table: • No entries for total health care institution fees and total professional fees • Write Php 4,000 on the Total Actual Charges
		IF there is co-payment from the patient: Tick second box(with co-pay on top of PhilHealth Benefit) then accomplish Tables a and b Table a: • Put amount of actual charges for HCI fee and professional fees • Put amount after deduction of discount if there is any, if none leave blank • Put amount of PhilHealth Benefits ▪ Total professional fees (PF) includes professional fee of facility staff and professional fee of referring physician (if applicable ▪ Total HCI fees is the remaining amount (from Php 4,000) after total PF have been deduction • Amount after PhilHealth Deduction shall be: *If no discount:* Total actual charges – PhilHealth benefit *If with discount:* Amount after application of discount –PhilHealth benefit Accomplish this both for HCI fee and PF • Tick the applicable box/es on the payer/s of remaining balance (may have several payers) Table b: • *If patient did not purchase medicine and/or paid for laboratory exams outside the facility,* tick None • *If patient paid for medicine and/or paid for laboratory exams outside the*

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CF 2 Part/Item	Description	Instruction
		facility, tick the boxes and write the amount.
Part III Section B	Consent to Access Patient Record/s	Print the name of the patient and affix his/her signature over the name Write the date when this was signed Should the patient is unable to sign, tick the appropriate boxes
Part IV	Certification of Health Care Institution	Print the name of the authorized person to fill-up the claim and his/her designation. Affix his/her signature above the name. Write the date when he/she signed the form. This person must review and verify all the entries before affixing his/her signature.

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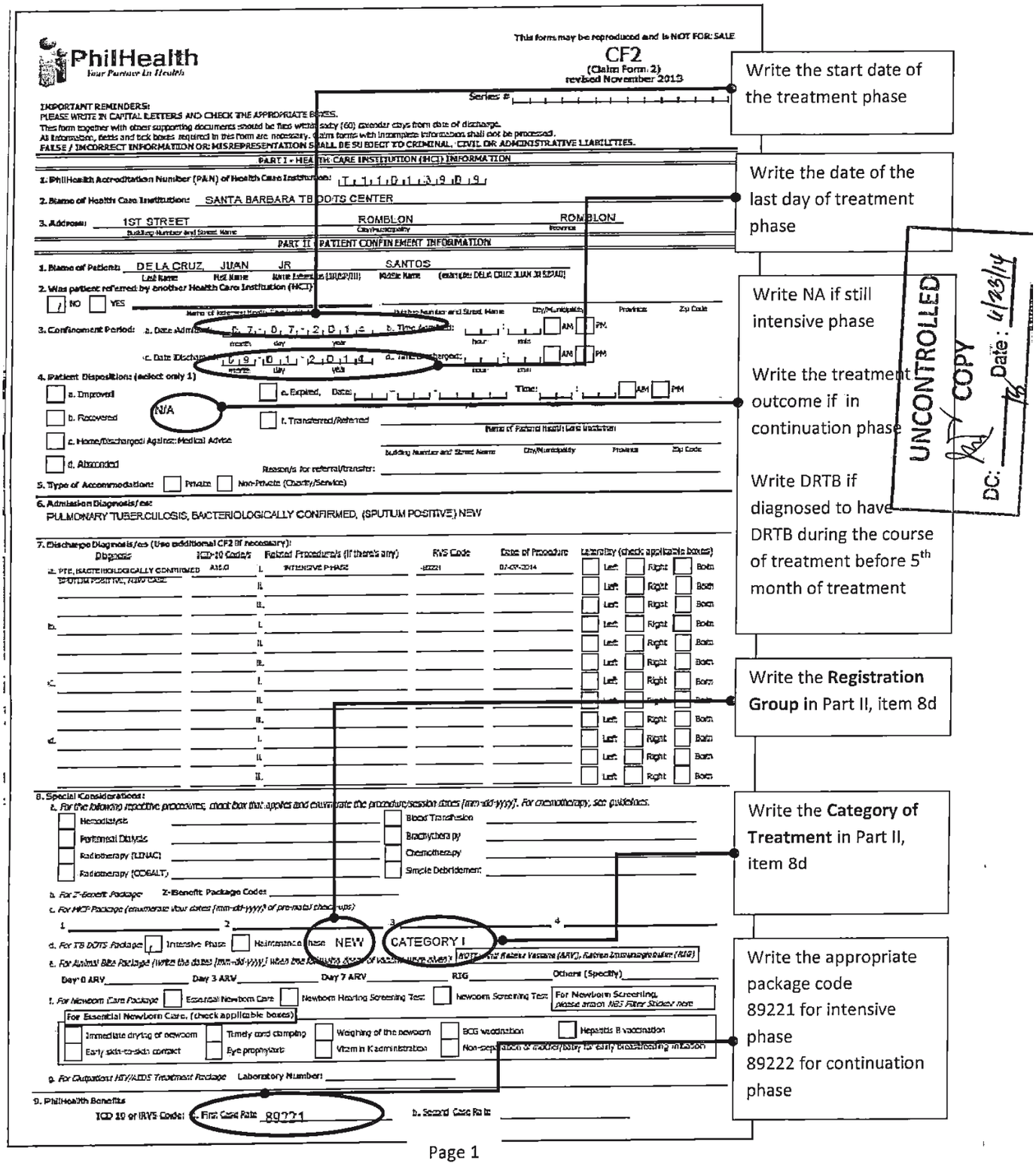
ANNEX 4 - SAMPLE CLAIM FORM 2



PhilHealth
Your Partner in Health

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CF2
(Claim Form 2)
revised November 2013

Series #

IMPORTANT REMINDERS:
PLEASE WRITE IN CAPITAL LETTERS AND CHECK THE APPROPRIATE BOXES.
This form together with other supporting documents should be filed within sixty (60) calendar days from date of discharge.
All information, items and tick boxes required in this form are necessary. Claim forms with incomplete information shall not be processed.
FALSE / INCORRECT INFORMATION OR MISREPRESENTATION SHALL BE SUBJECT TO CRIMINAL, CIVIL OR ADMINISTRATIVE LIABILITIES.

PART I - HEALTH CARE INSTITUTION (HCI) INFORMATION

1. PhilHealth Accreditation Number (PAN) of Health Care Institution: 1 1 1 0 1 3 0 9
2. Name of Health Care Institution: SANTA BARBARA TB DOTS CENTER
3. Address: 1ST STREET (Building Number and Street Name) ROMBLON (City/Municipality) ROMBLON (Province)

PART II - PATIENT CONFINEMENT INFORMATION

1. Name of Patient: DE LA CRUZ (Last Name) JUAN (First Name) JR (Name Extension) SANTOS (Middle Name) (example: DELA CRUZ JUAN JR SEGUNDO)
2. Was patient referred by another Health Care Institution (HCI)? [/] NO [ ] YES
Name of Referring Health Care Institution | Building Number and Street Name | City/Municipality | Province | Zip Code
3. Confinement Period: a. Date Admitted: 0 7 / 0 7 / 2 0 1 4 (month / day / year) b. Time Admitted: : [ ] AM [ ] PM (hour / min)
c. Date Discharged: 0 9 / 0 1 / 2 0 1 4 (month / day / year) d. Time Discharged: : [ ] AM [ ] PM (hour / min)
4. Patient Disposition: (select only 1)
[ ] a. Improved [ ] e. Expired, Date: Time: [ ] AM [ ] PM
[ ] b. Recovered N/A [ ] f. Transferred/Referred: Name of Referral Health Care Institution
[ ] c. Home/Discharged Against Medical Advice: Building Number and Street Name | City/Municipality | Province | Zip Code
[ ] d. Absconded Reason/s for referral/transfer:
5. Type of Accommodation: [ ] Private [ ] Non-Private (Charity/Service)
6. Admission Diagnosis/es: PULMONARY TUBERCULOSIS, BACTERIOLOGICALLY CONFIRMED, (SPUTUM POSITIVE) NEW
7. Discharge Diagnosis/es (Use additional CF2 if necessary):

Diagnosis	ICD-10 Code/s	Related Procedure/s (if there's any)	RVS Code	Date of Procedure	Laterality (check applicable boxes)
a. PTB, BACTERIOLOGICALLY CONFIRMED SPUTUM POSITIVE, NEW CASE	A15.0	I. INTENSIVE PHASE	89221	07-09-2014	I. Left Right Both
		II.			II. Left Right Both
		III.			III. Left Right Both
b.		I.			I. Left Right Both
		II.			II. Left Right Both
		III.			III. Left Right Both
c.		I.			I. Left Right Both
		II.			II. Left Right Both
		III.			III. Left Right Both
d.		I.			I. Left Right Both
		II.			II. Left Right Both
		III.			III. Left Right Both

8. Special Consideration/s:
a. For the following repetitive procedures, shade box that applies and enumerate the procedure/session dates (mm-dd-yyyy). For chemotherapy, see guidelines.
[ ] Hemodialysis [ ] Blood Transfusion
[ ] Peritoneal Dialysis [ ] Brachytherapy
[ ] Radiotherapy (LINAC) [ ] Chemotherapy
[ ] Radiotherapy (COBALT) [ ] Simple Debridement
b. For Z-Benefit Package Z-Benefit Package Codes:
c. For HCP Package (enumerate four dates [mm-dd-yyyy] of pre-natal check-ups) 1 2 3 4
d. For TB DOTS Package [/] Intensive Phase [ ] Maintenance Phase NEW CATEGORY I
e. For Animal Bite Package (write the dates [mm-dd-yyyy] when the following doses of vaccine were given) [ ] Anti-Rabies Vaccine (ARV) [ ] Rabies Immunoglobulin (RIG)
Day 0 ARV Day 3 ARV Day 7 ARV RIG Others (Specify)
f. For Newborn Care Package [ ] Essential Newborn Care [ ] Newborn Hearing Screening Test [ ] Newborn Screening Test For Newborn Screening, please attach NBS Filter Sticker here
For Essential Newborn Care: (check applicable boxes)
[ ] Immediate drying of newborn [ ] Timely cord clamping [ ] Weighing of the newborn [ ] BCG vaccination [ ] Hepatitis B vaccination
[ ] Early skin-to-skin contact [ ] Eye prophylaxis [ ] Vitamin K administration [ ] Non-separation of mother/baby for early breastfeeding initiation
g. For Outpatient HIV/AIDS Treatment Package Laboratory Number:
9. PhilHealth Benefits
ICD 10 or RVS Code: a. First Case Rate 89221 b. Second Case Rate

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Write the start date of the treatment phase

Write the date of the last day of treatment phase

Write NA if still intensive phase

Write the treatment outcome if in continuation phase

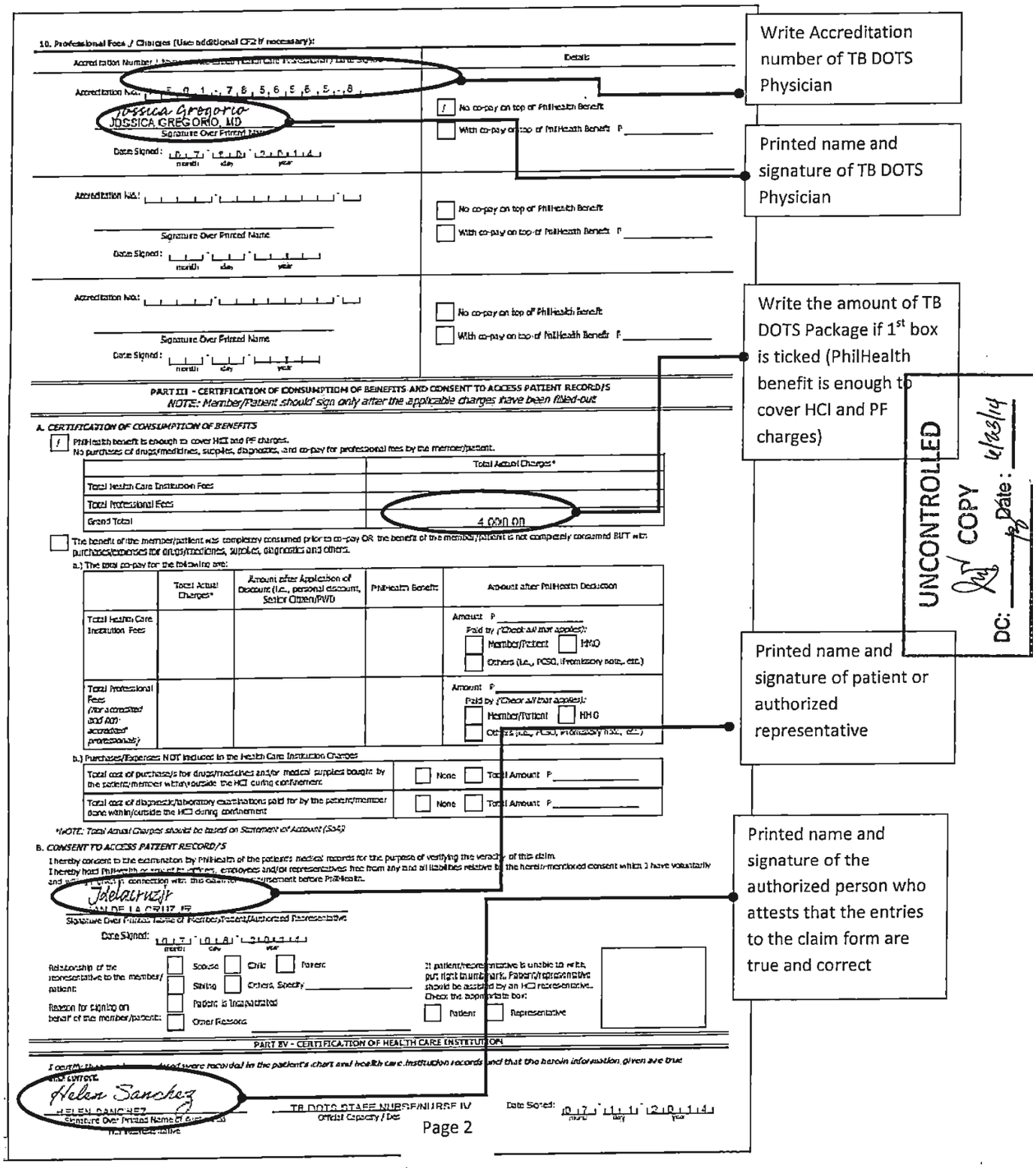
Write DRTB if diagnosed to have DRTB during the course of treatment before 5th month of treatment

Write the **Registration Group** in Part II, item 8d

Write the **Category of Treatment** in Part II, item 8d

Write the appropriate package code
89221 for intensive phase
89222 for continuation phase

Page 1



10. Professional Fees / Charges (Use additional CF2 if necessary):

Accreditation Number / Name of Accredited Health Care Professional / Date Signed

Accreditation No.: 0 1 - 7 8 5 6 5 5 5 - 8

Jessica Gregorio
JESSICA GREGORIO, MD
Signature Over Printed Name

Date Signed: 10 / 7 / 2014 (month / day / year)

Details

[/] No co-pay on top of PhilHealth Benefit

[ ] With co-pay on top of PhilHealth Benefit P _____

Accreditation No.: _____

Signature Over Printed Name

Date Signed: ___ / ___ / ____ (month / day / year)

[ ] No co-pay on top of PhilHealth Benefit

[ ] With co-pay on top of PhilHealth Benefit P _____

Accreditation No.: _____

Signature Over Printed Name

Date Signed: ___ / ___ / ____ (month / day / year)

[ ] No co-pay on top of PhilHealth Benefit

[ ] With co-pay on top of PhilHealth Benefit P _____

PART III - CERTIFICATION OF CONSUMPTION OF BENEFITS AND CONSENT TO ACCESS PATIENT RECORD/S

NOTE: Member/Patient should sign only after the applicable charges have been filled-out

A. *CERTIFICATION OF CONSUMPTION OF BENEFITS*

[/] PhilHealth benefit is enough to cover HCI and PF charges.
No purchases of drugs/medicines, supplies, diagnostics, and co-pay for professional fees by the member/patient.

	Total Actual Charges*
Total Health Care Institution Fees	
Total Professional Fees	
Grand Total	4 000 00

[ ] The benefit of the member/patient was completely consumed prior to co-pay OR the benefit of the member/patient is not completely consumed BUT with purchases/expenses for drugs/medicines, supplies, diagnostics and others.

a.) The total co-pay for the following are:

	Total Actual Charges*	Amount after Application of Discount (i.e., personal discount, Senior Citizen/PWD	PhilHealth Benefit	Amount after PhilHealth Deduction
Total Health Care Institution Fees				Amount P _____ Paid by (Check all that applies): [ ] Member/Patient [ ] HMO [ ] Others (i.e., PCSO, Promissory note, etc.)
Total Professional Fees (for accredited and non-accredited professionals)				Amount P _____ Paid by (Check all that applies): [ ] Member/Patient [ ] HMO [ ] Others (i.e., PCSO, Promissory note, etc.)

b.) Purchases/Expenses NOT included in the Health Care Institution Charges

Total cost of purchase/s for drugs/medicines and/or medical supplies bought by the patient/member within/outside the HCI during confinement	[ ] None	[ ] Total Amount P _____
Total cost of diagnostic/laboratory examinations paid for by the patient/member done within/outside the HCI during confinement	[ ] None	[ ] Total Amount P _____

**NOTE: Total Actual Charges should be based on Statement of Account (SOA)*

B. *CONSENT TO ACCESS PATIENT RECORD/S*

I hereby consent to the examination by PhilHealth of the patient's medical records for the purpose of verifying the veracity of this claim.
I hereby hold PhilHealth or any of its officers, employees and/or representatives free from any and all liabilities relative to the herein-mentioned consent which I have voluntarily and willingly executed in connection with this claim for reimbursement before PhilHealth.

Jdelacruz jr
JOLDE LA CRUZ JR
Signature Over Printed Name of Member/Patient/Authorized Representative

Date Signed: 10 / 7 / 10 / 8 / 2014 (month / day / year)

Relationship of the representative to the member/patient: [ ] Spouse [ ] Child [ ] Parent [ ] Sibling [ ] Others, Specify _____

Reason for signing on behalf of the member/patient: [ ] Patient is Incapacitated [ ] Other Reasons _____

If patient/representative is unable to write, put right thumbmark. Patient/representative should be assisted by an HCI representative. Check the appropriate box: [ ] Patient [ ] Representative

PART IV - CERTIFICATION OF HEALTH CARE INSTITUTION

I certify that the above-listed were recorded in the patient's chart and health care institution records and that the herein information given are true and correct.

Helen Sanchez
HELEN SANCHEZ
Signature Over Printed Name of Authorized Representative

TB DOTS STAFF NURSE/NURSE IV
Official Capacity / Designation

Date Signed: 10 / 7 / 10 / 1 / 2014 (month / day / year)

UNCONTROLLED COPY
DC: _____ by _____ Date: 4/23/14

Write Accreditation number of TB DOTS Physician

Printed name and signature of TB DOTS Physician

Write the amount of TB DOTS Package if 1st box is ticked (PhilHealth benefit is enough to cover HCI and PF charges)

Printed name and signature of patient or authorized representative

Printed name and signature of the authorized person who attests that the entries to the claim form are true and correct

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