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Papua New Guinea

National Tuberculosis Management Protocol



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NATIONAL TUBERCULOSIS MANAGEMENT PROTOCOL

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DEPARTMENT OF HEALTH
DISEASE CONTROL BRANCH
NATIONAL TB PROGRAM
PAPUA NEW GUINEA

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Foreword

Tuberculosis continues among the top 5 causes of deaths and hospital admissions in PNG over the years and is responsible for a lot of deaths and illnesses among our people. Whilst TB control activities have been expanded slowly due to a lot of challenges the occurrence of the HIV epidemic and the rapid rise of MDR TB have increased the burden of TB. Over the last 4 to 5 years TB control has been prioritised with resources committed by both the government and its developmental partners. A successful global fund round 6 grant application has improved the implementation of the Stop TB Strategy 2006 -2010. A lot of partnerships have been established and TB services have been decentralised to peripheral levels with communities being involved in the fight against TB. Curing a TB patient does not only restore an individual's wellbeing in the family and community, it also reduces the spread of TB in the community and thus contributes to disappearances of TB from society.

Strengthening the human resource capacity for TB control through training and supervision, expansion of quality DOTS with quality diagnosis and treatment, introduction and use of TB drugs in fixed dose combined (FDC) formulations under an active and innovative DOT program with improved supply chain management and a robust and active M & E system are ongoing activities for TB control. Activities to address the additional challenges of TB HIV and MDR TB are also ongoing. Improvements are seen in the TB indicators particularly improvements in case detection and treatment success rates as a result indicating that progress is made.

TB services are integrated in all public health service delivery and thus prioritising TB services is essential. Health workers need to be aware of the symptoms of TB and identify TB suspects / patients as early as possible. Early detection and treatment of TB in patients prevents further transmission in the community and good prognosis with fewer complications for the individual patients. Treatment must be initiated after quality and confirmed diagnosis. Sputum microscopy needs to be prioritised for a confirmed diagnosis of TB. Directly observed treatment (DOT) must be ensured and communities must be mobilized to participate. Proper management of TB is vital for curing patients and preventing complications and death, avoid development and transmission of drug resistance TB and getting rid of TB from the community. In our country where the HIV epidemic is prevalent, TB patients must be offered HIV test and care. This TB treatment guideline is an update from 2003 guideline to provide guidance to health workers to manage TB patients properly. Adherence to this guideline is vital for effective TB control and any changes in management of TB will be done through the National TB Program. This treatment protocol replaces all other TB treatment protocols in Papua New Guinea and is intended to be used throughout the country by all health care providers. All investigation and treatment for TB is free in all public health facilities and other government supported facilities in the country.

Most importantly, we all as health service providers, development partners, all people affected with TB, individuals and communities must be committed to TB control with our hearts. Without such a commitment we cannot make the fight against TB easier for the next generation. We control TB properly today so our children do not have to deal with the same problems for TB control or even worse the disasters we have created in our efforts to control TB.

Mr Pascoe Kase
Acting Secretary for Health

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The NTP partners, stakeholders and tireless hardworking and selfless health workers and treatment supporters in health facilities and communities throughout the country are the back bone for the elimination of TB in Papua New Guinea. Without them we cannot get rid of TB in Papua New Guinea.

Abbreviations

ACSM	Advocacy, Communication and Social Mobilization
AFB	Acid-fast bacillus
AIDS	Acquired immunodeficiency syndrome
AP	Aidpost
ART	Anti Retroviral Therapy
BCG	Bacillus Calmette-Guerin (vaccine)
BMU	Basic Management Unit
Cat	Treatment category
CNS	Central neurologic system
CPT	Cotrimoxazole Preventive Therapy
DC	Disease control
DOT	Directly observed treatment
DOTS	Directly observed treatment, short course , (TB Strategy)
E	Ethambutol
EPTB (EP)	Extra-pulmonary tuberculosis
ETH	Ethambutol
F	Female
FDC	Fixed dose combination
FEFO	First expiring, first out
H	Isoniazid
HC	Health center
HEO	Health extension officer
HIV	Human immunodeficiency virus
HPF	High power field (i.e. 100x10 magnification)
HSC	Health sub-centre
INH	Isoniazid
IPT	Isoniazid Preventive Therapy
IUATLD	International Union Against Tuberculosis and Lung Diseases
KNCV	Royal Netherlands Tuberculosis Association
M	Male
MDR	Multi drug resistant (i.e. resistant to at least isoniazid and rifampicin)
M & E	Monitoring and Evaluation
MO	Medical officer
NDOH	National Department of Health
NGO	Non-governmental organization
NTP	National Tuberculosis Programme
OIC	Officer-in-charge
PICT	Provider Initiated Counselling and Testing
PNG	Papua New Guinea
PTB	Pulmonary (lung) tuberculosis
PYZ	Pyrazinamide
R	Rifampicin
RIF	Rifampicin
S	Streptomycin
SMO	Specialist medical officer
STR	Streptomycin
TB	Tuberculosis
UC	Urban health center
VCT	Voluntary counselling and testing (for HIV/AIDS)
Z	Pyrazinamide

1 Introduction and Information on the National TB Program

1.1 Introduction

This guideline is prepared by the National TB program for all health workers for the management of TB patients. Early detection, diagnosis and treatment of TB results in good treatment outcomes. TB treatment is 6-8 months and thus requires selfless commitment and dedication and an indefinite love for other people. Poor management of TB results in death and creates multi drug resistant TB which is very hard and costly to treat with often poor outcomes.

Health workers managing TB patients need proper training in the diagnosis and treatment of TB and it is for this purpose that this guideline is produced as a guide to health workers. In producing this guideline, the National TB Program takes into consideration the emerging problems of TB/HIV and MDR TB as well as revisions made to TB management by the International Union Against TB and Lung Disease and World Health Organization. This guideline therefore replaces the 2003 TB protocol and the following are the major changes to TB management for PNG;

- *Only two sputum samples required for initial diagnosis of TB instead of 3*
- *Only 1 sputum sample required for follow up examination instead of 2*
- *Treatment is not extended at the end of intensive phase if the follow up sputum examination at the end of intensive phase is positive. Continuation phase is commenced regardless of whether sputum is positive or not.*

1.2. The National TB Program

The main roles for the different levels of TB control are summarised below.

A. National level(NTP)

- Support planning, coordination, monitoring and evaluation of TB control activities.
- Advise on and provide training of all personnel involved in tuberculosis work.
- Support supervision of all personnel involved in tuberculosis work.
- Advise on procurement and distribution of TB drugs and supplies.
- Prepare forms, registers, health education and teaching materials for TB
- Compile reports on case-finding and treatment with feedback to lower levels
- Monitor and prevent the development of drug resistance TB.
- Coordinate with partner agencies.
- Budget for implementation of the program.
- Promote TB/HIV Collaboration.

B. Provincial level

- Implement, coordinate and supervise tuberculosis control activities.
- Training of health centre, health sub-centre, urban clinic and aid post staff.
- Supervise health workers in case-finding and treatment of tuberculosis.
- Compile and send quarterly reports on case-finding and treatment to NTP.
- Involve health workers in educating patients and the community.
- Indent for and distribute TB supplies and supplies to health facilities
- Cooperate with the microscopy services, for examination of sputum
- Coordinate referral of TB patients from hospitals to peripheral centres.
- Advocate for DOTS.
- Promote and implement TB/HIV collaborative activities.

C. District and more peripheral levels

- Refer TB suspects/sputum samples /smears to diagnostic facilities with microscopy centres for investigation.
- Initiate TB treatment and ensuring that all TB Treatment is under DOT.
- Monitor TB treatment through follow up sputum examinations and reviews.
- Trace defaulters or irregular patients.
- Keep and updated TB treatment cards and district TB registers and submit quarterly reports on TB case-finding and treatment results to provincial level.
- Provide health education and advocacy to patients and to the community.
- Supervise peripheral health staff and treatment supporters in giving DOT.
- Implement TB/HIV collaborative activities.

1.3 Goal of Tuberculosis Control

- (a) To reduce the impact of tuberculosis (TB) as a public a public health problem
- (b) To limit the number of relapse cases to an acceptable minimum.
- (c) To prevent the occurrence of drug-resistance TB

1.4. Immediate Objectives

The immediate objectives of TB control in Papua New Guinea are:

1. To increase the cure rate of sputum smear positive tuberculosis to 85%;
2. To increase the detection of sputum smear positive tuberculosis
3. To cover 100% of the country's population with the DOTS strategy

1.4 Strategies of the National TB Control program

In order to achieve the above objectives, the main strategies are:

- Promote and sustain commitment of staff and resources for TB control services
- Promote early detection and quality diagnosis of sputum positive tuberculosis.
- Ensure effective chemotherapy to all diagnosed patients.
- Organize supervised treatment close to the patient.
- Adopt a standardized recording and reporting system.
- Monitor results of treatment and evaluate progress through cohort analysis.
- Offer HIV test to every TB patient and HIV/AIDS services accordingly.
- Avoid development and transmission of MDR TB as much as possible.
- Detect and treat MDR TB cases.
- Provide training and refresher courses for all staff involved in the TB control.
- Strengthen cooperation between the Government of Papua New Guinea and other partners involved in tuberculosis control.
- Fully integrate tuberculosis control in the primary health care services.

These strategies are adapted from the well proven and effective DOTS strategy.

The five components of the DOTS strategy

1. Sustained political commitment
2. Access to quality assured TB sputum microscopy
3. Standardized short course chemotherapy to all cases of TB under DOT
4. Uninterrupted supply of quality anti-TB drugs
5. Recording and reporting system with cohort analysis and evaluation of progress

2 Background TB Burden

2.1 Global TB Burden

Tuberculosis is a major cause of death and illness in the world. New TB infections are occurring every year with a global estimation of 9.4 million new TB cases annually with 1.3 million deaths. Furthermore about 1.4 million cases are co infected with HIV. The challenge of controlling TB is increased with the rise of MDR TB with a global estimation of 440 000 MDR TB cases occurring every year with only a smaller proportion of these cases being properly diagnosed and treated. The Western Pacific Region (WPRO) contributes about 31% of the global TB case burden with an estimated 1.9 million new TB cases and 28% of the global MDR TB burden with an estimated 120 000 cases annual. An estimated 45 000 TB HIV co infection cases and 260 000 TB deaths occur annually in WPRO. PNG and Cambodia have the highest of TB burden in the Western pacific Region with case notification rates of more than 200 per 100 000 population.

2.2 Tuberculosis burden in Papua New Guinea

PNG has an estimated prevalence of TB at 337 per 100 000 population and incidence of all forms of TB at 250 per 100 000 population based on WHO 2010 report. The incidence of infectious smear positive TB cases is estimated to be 108 per 100 000 population and TB mortality (excluding HIV) at 26 per 100 000 population. These may be underestimates based on under reported TB case notifications (2008). PNG remains one of the countries with highest TB burden WPRO.

The National TB Program has improved its data management and case reporting since 2008. In 2009, PNG reported 13 220 TB cases out of the estimated 17000 cases in the country which means the country detected 73% of the estimated cases. In 2010, the case notification rate for new smear positive and all TB cases (new & relapse) increased to 37 /100 000 and 208/100 000 population respectively (2010 notification data). However only 29% of pulmonary cases were smear positive while about 24% of all pulmonary cases had sputum not examined for TB. The treatment success rate for all new smear positive cases has improved from 41% in 2006 to 72% in 2010, however, the default rate has remained unchanged between 15 – 20% whilst the treatment completed rate for new smear positive cases varies between 13 and 30%. The cure rate for retreatment cases was 36% in 2010. Progress has been made in TB control however much more need to be done properly.

2.3 TB/HIV Burden

More people are believed to develop TB due to HIV infection. PNG has one of the highest HIV prevalence in the Western Pacific Region. WHO estimates 3.8 % HIV prevalence in adult incident TB cases in 2008 in PNG. HIV testing among TB patients was started scarcely in only few TB facilities. In 2010 out of a total of 15 813 TB patients only 2220 patients were tested for HIV with a positivity rate of 10.5% reported among those tested. TB/HIV collaborative activities need to be implemented and improved at all levels of the health care delivery system as the National Department of Health, partners and stakeholders scale up efforts to combat TB and HIV.

2.4 MDR TB Burden

The magnitude of MDR TB problem in PNG has be estimated only through modelling by WHO. In 2010 WHO estimates the MDR TB rate to be 1.9% among new TB cases and 13.8% among previously treated cases in PNG. An estimated 530 MDR TB cases occur yearly among new and relapse TB cases and 73 among incident acquired MDR TB cases with an estimated total of 603 cases each year. There is adequate evidence to suggest an occurrence of MDR TB in PNG. Specimens collected randomly from drug resistant TB suspects in three different settings (CPHL, IMR, Daru Hospital) for different surveys showed at least 40% MDR TB noted among MDR TB suspects with higher incidence of MDR TB among retreatment cases. A Drug Resistant Survey (DRS) is planned and when carried out should give a clearer picture of the magnitude of drug resistant TB problem in PNG.

3 General Information about Tuberculosis

3.1. WHAT IS TUBERCULOSIS?

Tuberculosis (TB) is an infectious disease, caused by a microorganism called *Mycobacterium tuberculosis*. The tuberculosis bacilli usually enter the body by inhalation through the lung and spread to other parts of the body through the blood system, the lymphatic system, or through direct extension to other organs. Most infections are caused by inhalation of droplets containing virulent human strains of the tubercle bacillus. Not all infected people will develop tuberculosis disease. Only about 10% will develop the disease, half of them shortly after infection, half of them later in their life. A strong immune system keeps TB bacilli dormant and prevents TB bacilli from multiplying and developing TB infection into TB disease; at the contrary, the HIV infected people are more at risk to develop TB disease once infected by *M. tuberculosis*.

People with TB infection do not have symptoms, do not feel sick, cannot spread TB and have a positive mantoux test. Almost any organ in the body can be affected, but *pulmonary tuberculosis* or PTB is the most frequent type and counts for more than 80% of all TB. *Extra-pulmonary tuberculosis* (EPTB) can involve sites such as glands, bones, brain, intestine, skin, genito-urinary system or almost any other part of the body.

3.2. WHICH TYPE OF TUBERCULOSIS IS IMPORTANT IN TB CONTROL?

Smear-positive pulmonary tuberculosis (P+ TB) is virtually the only form which is infectious. This is rarely found in children and therefore, with few exceptions, children do not transmit the disease. Smear-negative pulmonary tuberculosis (P-TB), but positive on culture only, are much less infectious than those found positive by microscopy and their outcome is also more favourable. The main source of infection is from adult patients with smear-positive tuberculosis of the lungs. They spread the bacilli by coughing, sneezing, singing, spitting etc without covering their mouths (droplet infection). An untreated infectious patient may infect up to 12 - 15 people per year. Those patients form the highest priority for the TB control programme. Active smear-negative pulmonary tuberculosis and extra-pulmonary tuberculosis (EPTB) are notified separately from those that are microscopically confirmed.

3.3. WHAT ARE THE COMMON SIGNS AND SYMPTOMS OF TUBERCULOSIS?

Tuberculosis should always be suspected if a patient presents with **cough for more than two to three weeks**, with or without sputum and or coughing of blood (hemoptysis). A tuberculosis patient may also have fever, chest pain, and shortness of breath, weight loss, night sweats and loss of appetite.

Sputum microscopy examination should always be done for a patient who has cough for 2 - 3 weeks or more even in the absence of any other symptoms. Symptoms and signs of extra-pulmonary tuberculosis usually depend on the site involved.

Examples: swelling of the lymph nodes, pain and swelling of joints, gibbus (loss of function of the lower limbs), headache, fever, neck stiffness and later mental confusion due to TB meningitis.

Chest X-ray may show various abnormalities or it may occasionally be normal. The diagnosis of extra pulmonary TB should always be confirmed by a trained clinician or medical officer.

4 Tuberculosis case-detection and diagnosis

4.1. WHAT IS A TUBERCULOSIS "CASE"?

The main objective of case-finding in tuberculosis control is to identify as early as possible the sources of infection in a community (i.e. those who spread infection with tubercle bacilli) and to treat and cure. **A patient whose sputum smear examination is positive for acid fast bacilli (AFB) and /or a patient with mycobacterium tuberculosis complex identified from a clinical specimen either by culture or a newer method such as X-pert is a tuberculosis "case" and should be registered and treated.** Any person given treatment for TB should be recorded as a TB case. **Incomplete "trial" treatment should not be given as a method of diagnosis.**

4.2. DIAGNOSIS OF TUBERCULOSIS

A. Role of Sputum Smear Microscopy

Diagnosis of tuberculosis rests on the identification of tubercle bacilli by sputum smear microscopy. **Direct sputum smear examination should be done for all pulmonary TB suspects, with a cough for more than 2-3 weeks.** Patients seen in health facilities with clinical symptoms suggestive of TB should also have sputum examined for TB before commencing on TB treatment. Health facilities without laboratory services should collect sputum from patients and send sputum samples or prepare smears and send smeared slides to microscopy centres. Careful packing and transportation is required. Referring patient to the health facility with laboratory is also recommended however care should be taken to avoid loss of patients in the process. When sending sputum, the specimen should reach the laboratory within 48 hours.

Two sputum samples are required for diagnosis of pulmonary TB. The first specimen can be taken on the spot when the patient is identified as a TB suspect and the second specimen can be taken early morning the next day.

The early morning sputum produces a higher yield of bacilli. Hence it is recommended to give a sputum container to TB suspects to collect early morning sputum and return it to the health facility. The flowchart in annex 1 illustrates the management of tuberculosis suspects. All sputum microscopy facilities must enrol in national external quality assurance.

B. Role of TB Culture and Drug Sensitivity Testing

TB culture is not done in PNG at the time of writing this guideline. All sputum cultures are now done in Queensland Mycobacterium Reference Laboratory. (QMRL), Australia.

1. Indications:

TB Culture and DST should be ordered by a doctor, but in general the following should be referred;

- Category I and II failures
- All patients with history of previous TB treatment (Relapse, Defaulters)
- Contacts of known MDR TB cases.

2. Procedure on specimen transport for TB culture

Sputum specimens for the above patients for DST/culture should be collected in hospitals or bigger facilities. Specimen (sputum) from patients requiring TB culture should reach CPHL within 48 hours after collection for better culture yield. The collection is same as that for sputum microscopy.

3. Result interpretation

TB bacilli is grown on special media which can be solid (Lowenstein Jensen media) or liquid (MGIT). The liquid media takes 2 weeks while the traditional solid LJ media takes 6-8 weeks. The culture basically provides the growth of bacilli which is then tested against the bacilli to see how well the drugs kill the bacilli or not. The TB bacilli is either sensitive or resistant to the different drugs (Rifampicin [R], Isoniazid [H], Streptomycin [S], Ethambutol [E], Pyrazinamide [Z], Kanamycin [Kn], Amikacin [Am], Capreomycin [Cm], Ofloxacin [Ofx] etc).

4. Quality Assurance

The fresher sputums yield better in culture so transportation within 48 hours is very important.

C.Role of X-ray in the diagnosis of tuberculosis

Tuberculosis should be diagnosed by sputum examination. PTB smear positive patients may have a chest x ray to help in assessing the extent in lung damage in complicated cases but not for diagnosis. Chest X ray is required for diagnosis of TB in sputum negative patients with persistent symptoms and extra pulmonary cases such as pleural effusion. Chest X-ray findings suggestive of PTB in patients whose sputum examinations are negative should always be supported by clinical findings and judgement. X-ray and clinical information are important in the diagnosis of pulmonary tuberculosis in small children and in miliary tuberculosis which are sputum negative, as well as in some forms of extra-pulmonary TB.

4.3. HOUSEHOLD CONTACTS

Children under 5 years and symptomatic household contacts of smear positive pulmonary TB patients should be screened for tuberculosis. Screening includes checking sputum in contacts with cough, careful history and clinical examination. Contacts diagnosed with TB should be registered and treated. Routine contact tracing is not recommended for PTB smear negative and extra pulmonary TB cases.

4.4 .DIAGNOSIS OF TB IN CHILDREN

Children are rarely sputum positive, so they are rarely infectious. Diagnosis of TB in children is difficult due to no sputum production in children but whenever sputum is produced smear should be examined for AFB. The following steps should be used in diagnosis of TB in children;

1. History - Symptoms, contact with TB patients/contacts
2. Clinical examination including growth assessment. Clinical findings should always be interpreted along with history and growth assessment and never in isolation.
3. Tuberculin Skin Test (Mantoux)
4. Chest X- Ray
5. Bacteriological and cyto-histological confirmation using sputum or other specimens
6. Use of TB score chart.

Based on findings from the above steps, the TB score chart can guide clinical officers to diagnose childhood TB. **A TB score of more than 7 in the absence of any other disease indicates likelihood of TB and the child should be commenced on TB treatment.** As the TB score chart is only a screening tool, HIV infection must be ruled out in those with TB score of more than seven before interpreting the TB score. A score chart is included in annex 2. Health workers should refer to the Manual on Management of childhood Tuberculosis for detailed instructions on the diagnosis and management of TB in children.

4.5 SUMMARY OF TECHNICAL POINTS OF CASE-FINDING AND DIAGNOSIS

Practical methods

The following case-finding methods lead to the detection of most smear-positive PTB cases;

1. Examination of symptomatic patients who present for consultation in health facilities.
2. Examination of TB suspects who have cough for more than 2 - 3 weeks.
3. The examination of symptomatic contacts of smear-positive cases.
4. The bacteriological examination of patients who for any reason have had a chest X-ray showing a possible tuberculous lesion.

Collecting sputum specimens procedures

1. For diagnosis two (2) sputum specimens should be collected. One on the spot when first contact with the patient and the second should be collected the next morning thus collecting a “spot” and “morning” sample. Hospitalized patients can give early morning specimens on two consecutive days.
2. Explain to patient reasons for the sputum examination. Fill sputum request form and label the sputum cup and not the lid.
3. Collect sputum in well ventilated room, preferably outdoors. Avoid contamination of the cup and if contaminated discard the specimen container and collect new specimen.
4. Send sputum to laboratory within 48 hours. Results should be ready within 24 to 72 hours and efforts should be done to communicate positive results as soon as possible. Any sputum collected for more than one week before examination is of limited value.

Diagnosis of tuberculosis

Sputum Microscopy:

A sputum smear-positive pulmonary TB case is diagnosed based on the presence of at least one acid fast bacillus (AFB+) in at least one sputum sample. A sputum smear-negative pulmonary TB case (P-TB) is diagnosed when all both sputum specimens are negative and radiographic abnormalities consistent with active pulmonary TB and no response to broad spectrum antibiotics (if HIV negative) plus decision is taken by a clinician.

Every pulmonary TB suspect should have sputum smear examination and not doing it is substandard care. Even in facilities where x-ray is readily available, all pulmonary TB patients should have a sputum examination. Diagnosis of extra-pulmonary TB (EPTB) should be based on one culture positive specimen, or histological or strong clinical evidence consistent with active extra-pulmonary tuberculosis, and a decision of a clinician to treat with a full course anti-tuberculosis chemotherapy.

External Quality Assurance on Sputum Microscopy

Laboratories providing sputum smear microscopy should participate in the national external quality assurance program.

Role of CPHL and Provincial laboratories

CPHL coordinates EQA for sputum smear microscopy throughout the country. Regional EQA coordinators are available to ensure facilities participate in EQA. CPHL also prepares and packs sputum samples sent for TB culture in QMRL. Once the culture facilities are available in PNG, CPHL will perform TB culture and drug sensitivity testing.

Other Newer Diagnostics

Newer diagnostic methods will be available in the near future to improve diagnosis of TB in terms of timing and diagnosis of drug resistance TB, including multi-drug resistance TB. Examples of this include Line Probe Assay and Gene-Expert.

5 TREATMENT OF TUBERCULOSIS

5.1 STARTING TREATMENT

Treatment of tuberculosis should be started as soon as possible after a firm diagnosis has been made. **There is no room for trial treatment.** TB Treatment is given to cure patients and alleviate suffering, preventing death from TB and its complications, reducing spread of TB in the community, preventing relapse and prevent development and transmission of drugs resistant TB.

For TB patients to be effectively treated, TB patients must be given the right drugs, in the right combinations, according to appropriate dosage, administered correctly and regularly for the appropriate duration of time.

The best way to ensure effective treatment is for them to be watched as they swallow TB drugs through **Directly Observed Treatment (DOT)**. TB can be effectively controlled in the community by diagnosing, treating and curing as many smear-positive patients as possible. All TB treatment must be given under DOT. The effect of TB treatment in pulmonary TB patients is monitored by follow up sputum examination. Effective treatment will have the following results:

1. rapid reduction of the number of TB bacilli, hence stop the transmission of the infection;
2. sterilization by killing all remaining bacilli, especially the persisters are very hard to kill;
3. minimal adverse side-effects to the patient;

Effective treatment for tuberculosis consists of two phases taking special combinations of drugs for a specific duration of time:

Intensive phase consist of 2-3 months taking combination of 4 -5 drugs daily with the aim of reducing rapidly and substantially the actively multiplying TB bacilli population. After two weeks of drug intake most virulent strains have been eliminated and the risk of transmission is reduced.

Continuation phase consist of 4-5 months taking combination of 2-3 different drugs, which is administered daily when using Fixed Dosed Combined TB drugs (FDC) . The aim is to eliminate the other mycobacterium populations and persistent TB bacilli.

5.2. TREATMENT CATEGORY FOR TB PATIENTS

A. Disease classification and type of patient

The appropriate categorisation and classification of a TB patient depends on the anatomical site of disease and type of patient and results of sputum examination.

(i) Type of TB Disease classification

Pulmonary TB (PTB) is TB disease affecting the lungs. **Extra pulmonary TB (EPTB)** is TB disease affecting organs other than lungs e.g., pleural cavity, lymph node, abdomen, bones and joints, meninges etc. Smear positive pulmonary TB is diagnosed when Acid Fast Bacilli are identified in a patient's sputum through microscopy. A patient who has both pulmonary TB and extra pulmonary TB is diagnosed as a pulmonary TB.

(ii) Type of Patient

A patient who has never taken anti TB treatment or has taken TB drugs for less than one month is a new case. Previously treated patients have received TB treatment for one month or more in the past.

Table 1. Definitions of type of patient

Type of Patient	Definition
New	A patient who has never taken TB treatment before or who has taken TB treatment for less than 1 month.
Relapse	A patient who was successfully treated for TB before (cured/completed) and now diagnosed with bacteriologically (smear or culture) positive TB.
Treatment after Failure	A patient who is restarted on treatment after failing previous treatment (i.e. during treatment or end of treatment) and is (smear or culture) positive TB.
Treatment after Default	A patient who has taken TB treatment for more than one month, and has interrupted treatment for more than two consecutive months and now returns to treatment with bacteriologically (culture or smear) positive TB.
Transfer In	A patient who has been transferred from another BMU / tuberculosis register to continue the ongoing treatment
Others	All cases that do not fit any of the above definitions. Other cases include: -all previously treatment cases regardless of type (PTB or extra pulmonary TB) but now have extra pulmonary TB or PTB with sputum negative.

Note: Although smear-negative pulmonary and extra-pulmonary cases may also be relapses, failures or chronic cases, this should be a very rare event, supported by pathological or bacteriological evidence.

B. Treatment Category, TB drugs and Regimen of Treatment

Standard Regimen for all new TB cases (Category I)

All new TB patients receive category I treatment which requires 6 months (2 months intensive phase & 4 months continuation phase). FDC drugs containing rifampicin, isoniazid, pyrazinamide and ethambutol are given daily for the two months intensive phase. In the next 4 months of continuation phase only two drugs, rifampicin and isoniazid in FDC combination are given daily.

Standard Regimen for previously treated TB cases (Category II)

All retreated TB patients receive category II treatment which requires 8 months (3 months intensive phase and 5 months continuation phase) treatment. The first 2 months of intensive phase consist of treatment with oral FDC drugs four drugs rifampicin, Isoniazid, pyrazinamide, ethambutol and streptomycin injection. The 3rd month of intensive phase consist of only the FDC containing the 4 drugs rifampicin, isoniazid, pyrazinamide and ethambutol. Streptomycin injection is only given in the first 2 months of intensive phase and is stopped strictly after 56 doses. All drugs are given daily in the intensive phase. In the next 5 months or continuation phase treatment 3 drugs namely rifampicin, isoniazid and ethambutol are given. Continuation phase treatment is also given daily with FDC drugs.

All TB drugs are now available in fixed dosed combination (FDC) in PNG. All TB patients regardless of type of patient or TB disease classification must be given TB drugs in FDC formulations. FDC drugs must be administered daily both in intensive and continuation phase. No patient should be started on TB treatment on loose drug formulations unless indicated in cases of adverse effects etc.

MDR TB cases receive an MDR treatment regimen. A guideline for the programmatic management of drug resistance TB in Papua New Guinea is now available for management of DR /MDR TB cases. See chapter 7 for procedures in diagnosis and management of drug resistant TB.

Table 2 Categories of Treatment and their Regimens

Treatment category	Type of patient	Drug Regimen and duration			
		Intensive Phase		Continuation Phase	
		Drugs	Duration	Drugs	Duration
Category I	All new patients -New PTB + -New PTB - -New EPTB	Rifampicin (R)	2 months	Rifampicin	4 months
		Isoniazid (H) Pyrazinamide (Z) Ethambutol (E)		Isoniazid	
		<i>Drug Regimen code: 2 (RHZE)/4(HR) - in FDC given daily</i>			
Category II	All retreatment cases -Relapse -Treatment after Default -Treatment after Failure -Others	Streptomycin (S)	2 months	Rifampicin	5 months
		Rifampicin	3 months	Isoniazid	
		Isoniazid		Ethambutol	
		Pyrazinamide Ethambutol			
		<i>Drug Regimen: 2(RHZES)/1(RHZE)/5(HRE) - in FDC daily</i>			
Category IV	Failure or MDR TB	Second line drugs as per DR/ MDR TB guideline			

Please note that intensive phase is not extended regardless of a positive smear at the end of intensive phase.

5.3. DOSAGE AND FREQUENCY OF THE DRUG REGIMEN

Dosage is determined based on the weight of the patient and should be adjusted if the patient changes to a new weight band as shown in annex 4.

Fixed dose combination (FDC) drugs must be given to all TB patients to prevent drug resistance. All TB drugs in fixed dosed combinations (FDC) will be taken daily in both the intensive phase and continuation phase of treatment.

5.4 SPECIAL SITUATIONS

Table 3. Recommendations for special situations when deciding TB treatment.

Special Situation	Recommended regimen
Meningitis	Ethambutol does not pass through the blood brain barrier therefore it should be replaced with streptomycin, for instance, Cat I : 2(HRZ)S/4(HR)
Pregnancy	Streptomycin should not be given in pregnancy as it causes foetal deafness.
Breast feeding	Mother should be given normal TB treatment. Isoniazid prophylaxis given to baby. BCG after prophylaxis period if not yet immunized.
TB/HIV	Same regimen as a non HIV TB patient.
Oral contraceptive pills	Higher dose of estrogen (50mcg) or other forms of contraception
Liver disorder	Patients with hepatitis virus carriage, history of acute hepatitis, excessive alcohol can receive usual regimen.

5.5 REGISTRATION

A TB treatment card (TB01) is completed with information of the patient's diagnosis and treatment and updated during the treatment. It is kept at the registering centre and a copy can be made for the treatment supporter. All diagnosed TB patients are registered and are allocated a unique TB registration number. This number is also entered on the patient treatment card.

5.6. HEALTH EDUCATION

Patient health education should include;

- Information on TB disease- What is Tuberculosis, how TB spreads, how to prevent spread
- TB treatment information – TB is curable, details of treatment and its duration
- Importance of directly observed treatment and regularity of treatment

5.7. TREATMENT ADMINISTRATION AND ADHERENCE

5.7.1 Directly Observed Treatment (DOT)

All TB treatment should be given under DOT for both the intensive and continuation phases.

DOT means not making patients wait in a queue BUT actually watching the patient swallow the drugs and then recording the treatment in the treatment card.

The following ways of supervising treatment are considered (in order of priority):

1. The patient goes daily to health facility and swallows his drugs in front of the health worker.
2. The patient is supervised daily by a treatment supporter trained in DOT in the community.
3. The patient is hospitalized for the intensive phase.

Patients attend monthly for follow up on treatment, sputum collection at the required time and continuous health education. Community TB treatment supporters can also be non-health care workers who can be trained and supervised by the health facility and preferably should be selected by patients or to their convenience. Family members are not recommended treatment supporters.

5.7.2 Ensuring continuation of treatment

When a TB patient is referred or transferred to another facility a referral or transfer form should be filled and sent with the patient. Whether a patient is transferred or referred or travels temporarily the patient should be supplied treatment for the duration of travel and information should be given.

5.7.3 Management of patients who interrupted treatment

Retrieval action is taken within 24 -48 hours if a TB patient misses a dose for more than 24 hours or a treatment supporter or self administered patient fails to collect drugs. The treatment centre should identify early defaulters and take action. Priority is given to smear positive PTB. Treatment is continued and prolonged to make up for missed doses if the duration of default is less than 2 months. However, a patient is regarded as a treatment defaulter after he misses treatment for more than two consecutive months.

5.8 ADVERSE EFFECTS OF ANTI TB DRUGS

Minor side effects can be treated at the health facilities however treatment should be stopped and patient should be referred to a trained clinician or hospital if major side effects occur.

Table 4 Common side effects of anti TB drugs

Side Effects	Drugs responsible	Management
Minor side effects		
Anorexia, nausea, vomiting, Abdominal pain (and no jaundice)	Bulk of Drugs Pyrazinamide, Rifampicin	Take drugs with food, divided dose or before sleeping
Joint pain	Pyrazinamide	Aspirin / Indomethacin

Burning sensation in the feet, tingling	Isoniazid	Pyridoxin 100 mg daily (when better reduce to 25 mg/day)
Confusion, sleep disturbance	Isoniazid	Pyridoxin 25 mg/day
Orange/red urine	Rifampicin	Reassurance
Itching, rash without blisters	Any drug (or skin disease)	Phenegan, promethazin
Major side effects		
Deafness	Streptomycin	Stop streptomycin
Dizziness, vertigo, nystagmus	Streptomycin	Stop streptomycin
Jaundice (other causes excluded), hepatitis	All drugs but commonly isoniazid. Also rifampicin and Pyrazinamide	Stop anti-TB drugs, start same regimen after two weeks or refer.
Confusion	Most anti-TB drugs	Stop anti-TB drugs, refer
Difficulty with vision	Ethambutol	Stop ethambutol, refer
Shock, purpura, acute renal failure	Rifampicin	Stop rifampicin, refer

5.9 PREVENTIVE THERAPY AND IMMUNISATION

The following contacts of TB patients are given isoniazid prophylaxis 5-10mg/kg for 6 months;

- Children aged less than 5 years after exclude active TB disease
- Other children or adults living with HIV after excluding active TB

All children contacts of TB patients under 2 years of age are given BCG if unimmunised. Isoniazid Preventive therapy should be completed first before BCG if both are required.

5.10 MONITORING TREATMENT

5.10.1 Sputum follow up

Three different follow up sputum examinations for AFB are done during TB treatment to evaluate treatment of smear positive PTB. **Only one sputum sample is required during each follow up unless it is positive at 5 or 6 month.** In this case sputum is repeated and only if positive also the patient is declared a "failure "case. The following is the schedule for follow up sputum.

Table 5. New Smear Positive Pulmonary TB cases

No.	Normal schedule	Action if sputum is positive
Follow up		
1st	End of intensive phase	Begin continuation phase. Do not extend treatment.
2nd	End of 5 months treatment	Repeat sputum examination. If positive declare as failure. Re- register and commence standard treatment for previously treated cases (i.e. category II treatment). Do not extend treatment.
3rd	End of treatment	Repeat sputum examination. If positive declare a failure. Re- register and commence standard treatment for previously treated cases (i.e. category II treatment). Do not extend treatment.

Table 6 Retreatment smear positive PTB cases

No. Follow up	Normal schedule	Action if smear is positive
1st	End of intensive phase (3 months)	Begin continuation phase of treatment. Do not extend treatment.
2 nd	End of 5 months treatment	Repeat sputum. If repeat sputum is positive, declare failure. Send for DST.
3 rd	End of treatment (8 months)	Repeat sputum. If repeat sputum is positive, declare failure. Send for DST.

Intensive phase of treatment is only for 2 months for all new cases and 3 months for all retreatment cases whether patients convert to smear negative or remains smear positive at the end of intensive phase. If sputum is found positive on two occasions at 5 months or later, then the patient is declared “failure”. The patient is registered as “treatment after failure”, and is commenced on standard regimen for previously treated cases (i.e. category II treatment) under strict DOT and /or referred for investigation (DST) for MDR TB. **See annex 4 & 5 flow charts for new and retreatment cases.**

5.10.2 Smear negative PTB – and EPTB cases

Monitoring of the treatment of P-TB and EPTB is done by clinical assessment, weight and eventually x-ray. New PTB - cases have sputum examination at the end of the 2 month intensive phase however both PTB- and EPTB cases sputum should be checked in case of suspicion of failure. If a smear negative PTB case becomes sputum smear positive at end of intensive phase, then the patient is declared treatment failure and is registered and restarted on standard regimen for previously treated cases (i.e category II) as Others.

5.11 RECORDING TREATMENT OUTCOMES

Every registered patient is evaluated at the end of treatment or when closing the file for another reason. The following table shows the possible outcomes for TB patients.

Table 7. Possible Treatment Outcomes

Treatment Outcome	Definition
Cure	A sputum smear positive patient who is sputum smear negative in the last month of treatment and on at least one previous follow up examination. Only applicable to patients who were smear positive initially.
Treatment Completed	Patient who has completed treatment but who does not meet the criteria to be classified as a cure or failure.
Treatment Failure	Patient who is sputum smear positive at 5 month or later during treatment. Also applies to sputum smear negative patient who become sputum smear positive at 2 months.
Died	Patient who dies for any reason during the course of treatment.
Defaulted	Patient whose treatment was interrupted for 2 consecutive months or more.
Transfer out	A patient who has been transferred to another recording and reporting unit (BMU) and for whom the treatment outcome is not known.
Treatment Success	The sum of cured and completed treatment. Mostly used to assess treatment outcome for smear or culture positive patients.

The treatment outcome should be recorded on the back of the TB treatment card and register.

6 TREATMENT OF TUBERCULOSIS IN CHILDREN

6.1 NEW TREATMENT GUIDELINES FOR CHILDHOOD TB IN PNG

The following are the major changes to TB treatment for children compared to those in the 8th edition of the *Standard Treatment Manual for Common Illnesses of Children, 2005*:

Categories of treatment: The childhood TB patients are categorized into category I and category II.

Use of fixed dose combination (FDC) drugs: Depending on the weight of the patient, adult formulations (with four-drug, three-drug and two-drug combination non-dispersible tablets) or pediatric formulations (with three-drug and two-drug combination dispersible tablets) are used.

Treatment duration: Treatment duration for *new* cases is 6 months, except in specific cases like TB meningitis, TB spine, TB abdomen, TB pericarditis and TB lymphadenitis, where the health providers can extend the continuation phase by three more months (similar to the “special situations” listed in the 2005 STM).

Frequency of treatment: In the new protocol, the frequency of treatment in both the intensive phase and the continuation phase is daily.

Anti-Tuberculosis drug doses for Paediatric age group of <12 years old

The pharmacokinetics of anti-tuberculosis drugs is such that children generally need higher doses (per kg body weight) than adults do to achieve effective serum concentration.

Table 8 Anti TB drug dosages.

Anti-TB Drug	Paediatric daily doses	Adult daily doses
Rifampicin	15 mg/kg	10 mg/kg
Isoniazid	10 mg/kg	5 mg/kg
Pyrazinamide	35 mg/kg	25 mg/kg
Ethambutol	20 mg/kg	15 mg/kg
Streptomycin	25 mg/kg	15 mg/kg

The risk of developing optic neuritis (eye damage) from Ethambutol in children is very small, thus four drugs are now used in all new cases of paediatric TB. It is important to be aware that eye problems are possible and to check all children for visual problems during their treatment course.

6.2 CATEGORIES OF TREATMENT FOR CHILDHOOD TB WITH WEIGHT BANDS AND CLASSIFICATIONS

Category I:

(a) all new cases (*patient who has definitely never taken anti-TB drugs or who has taken anti-TB drugs for less than one month including both SS-ve and SS +ve paediatric PTB patients*), including severe forms (*Seriously ill cases include children with symptomatic TB meningitis, military TB, pulmonary TB with severe respiratory signs, bone and joint TB, spinal TB, TB abdomen (ascites or severe abdominal distension), or severe malnutrition (wasting)*), and

(b) Children who have failed to complete a full course of treatment previously (i.e. defaulted from treatment) but are not seriously ill meaning they are clinically well, based on signs and symptoms.

Category II:

For most re-treatment cases: *relapse, treatment after default, treatment after failure, others*. However, those children who have failed to complete a full course of treatment previously (i.e. defaulted from treatment) but are not seriously ill should receive Category I.

Single drug formulations of Rifampicin and Isoniazid should no longer be used, except in special cases such as drug reactions or for prophylaxis. **Streptomycin should only be used for category II re-treatment cases.** If a patient fails to respond in spite of directly observed treatment (DOT) with first-line drugs, the possibility of resistance arises thus such cases should be refer to major centres urgently. When it is unclear if a re-treatment case has taken a full course of treatment previously or has defaulted, the patient should be treated as a Category II patient and referred to a paediatrician.

A. For children in the weight band of 3kgs – 10.9kgs (using pediatric formulations)

Table 9. Category I regimen (for all new cases, and non-seriously ill defaulters)

Intensive Phase: (RHZ)HE for 2 months, daily			
Weight bands (in kg)	RHZ (Dispersible tabs)	Additional INAH	Ethambutol tabs
	60mg:30mg:150mg	100mg Tab	100mg
3 – 5.9	1 tab	¼ tab	1 tab
6 – 10.9	2 tabs	½ tab	1½ tab
Continuation Phase: (RH) for 4 months, daily (except in severe cases like TB meningitis and TB spine where this phase should be of 7 months)			
Rifampicin: Isoniazid (RH) (60mg:60mg)			
3 – 5.9	1 tab		
6 – 10.9	2 tabs		

Category II regimen (for all re-treatment cases, except for non-seriously ill defaulters)

Intensive Phase: (RHZ)HES for 2 months, and (RHZ)E for the following 1 month, daily				
Weight bands (in kgs)	Rif:INAH:PZA (Dispersible tabs)	Additional INAH	Ethambutol tabs	Streptomycin injections (first 2 months only)
	60mg:30mg:150mg	100mg Tab	100mg	
3 – 5.9	1 tab	¼ tab	1 tab	100mg
6 – 10.9	2 tabs	½ tab	1½ tab	200mg
Continuation Phase: (RH)E for 5 months, daily				
Rifampicin: Isoniazid (60mg:60mg)			Ethambutol 100mg	
3 – 5.9	1 tab		1 tab	
6 – 10.9	2 tabs		1 ½ tabs	

B. For children in the weight bands of 11-30.9kgs, use adult kits with additional INAH

Table 10. Category I regimen (for all new cases, and non-seriously ill defaulters)

Intensive Phase: (RHZE)H for 2 months		
Weight bands (in kgs)	Rif: INAH:PZA: E tab	Additional INAH 100mg tab
	150mg: 75mg: 400mg: 275mg	
11 – 15.9	1 tab	1 tab
16 – 20.9	2 tabs	1 tab
21-30.9	2 tabs	2 tabs
Continuation Phase: (RH) for 4 months, daily (except in severe cases like TB meningitis and TB spine where this phase should be of 7 months)		
Rif: INAH (150mg:75mg)		Additional INAH 100mg tab
11 – 15.9	1 tab	1 tab
16 – 20.9	2 tabs	1 tab
21 – 30.9	2 tabs	2 tabs

Category II regimen (for all re-treatment cases, except for non-seriously ill defaulters)

Intensive Phase: (RHZE)HS for 2 months, and (RHZE)H for following 1 month, daily			
Weight bands (in kgs)	Rif: INAH: PZA: E tabs 150mg: 75mg: 400mg: 275mg	Additional INAH 100mg tab	Streptomycin injections (for first 2 months only)
11 – 15.9	1 tab	1 tab	250mg
16 – 20.9	2 tabs	1 tab	400mg
21-30.9	2 tabs	2 tabs	500mg
Continuation Phase: (RHZ)H for 5 months, daily			
	Rif: INAH: E tab 150mg:75mg:275mg	Additional INAH 100mg tab	
11 – 15.9	1 tab	1 tab	
16 – 20.9	2 tabs	1 tab	
21 – 30.9	2 tabs	2 tabs	

C. For children in the weight bands of 31kg and more, use adult kits as follows

Table 11. Category I regimen (for all new cases, and non-seriously ill defaulters)

Intensive Phase: (RHZE) for 2 months	
Weight bands (in kgs)	Rif: INAH:PZA: E tab (150mg: 75mg: 400mg: 275mg)
30 – 39	2 tabs
40 – 54	3 tabs
Continuation Phase: (RH) for 4 months, daily (except in severe cases like TB meningitis and TB spine where this phase should be for 7 months)	
Weight bands (kg)	Rif: INAH (150mg:75mg)
30 – 39	2 tabs
40 – 54	3 tabs

Category II regimen (for all re-treatment cases, except for non-seriously ill defaulters)

Intensive Phase: (RHZE)S for 2 months, and (RHZE) for the following 1 month, daily		
Weight (kg)	RHZE (150mg: 75mg: 400mg: 75mg)	Streptomycin (first 2 months only)
30 – 39	2 tabs	500 mg
40 – 54	3 tabs	750 mg
Continuation Phase: (RH)E for 5 months, daily		
Weight (kg)	Rif: INAH: E tabs (150mg:75mg: 275mg)	
30 – 39	2 tabs	
40 – 54	3 tabs	

6.3 ISONIAZID PREVENTIVE THERAPY IN CHILDREN (IPT)

Give Isoniazid Preventive Therapy to children who have a family or household member known to be a sputum positive TB patient, and who is:

- less than 5 years old, and not symptomatic for TB
- HIV-infected, irrespective of age, and not symptomatic for TB

The doses of IPT are listed in table 12. Studies have shown that 6 months of IPT may be protective for two years. If such children are symptomatic for TB i.e., have chronic cough, fever, weight loss, malnutrition, enlarged lymph nodes or prolonged pneumonia, a pediatrician should fully evaluate them to exclude active TB disease. If the child has TB, then s/he should receive full anti-TB treatment. Never give IPT to children who are symptomatic for TB without a proper evaluation.

IPT is effective in preventing TB infection for children with HIV. However it is essential that TB infection, if present, is diagnosed and a full treatment course given. IPT for children with HIV may need to be given for 6 to 9 months, and should be given with Septrin (cotrimoxazole). Antiretroviral therapy in children with HIV improves immune function and also reduces the risk of TB infection. Consult pediatricians on the management of all children with suspected HIV and TB.

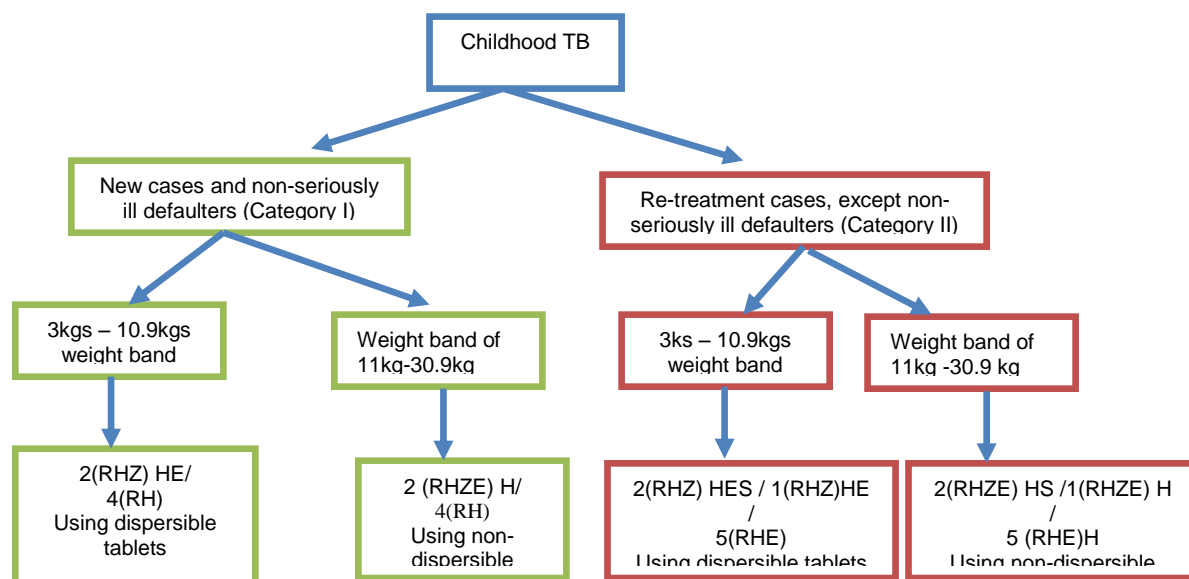
Weight	H (100mg) tabs
3 - 5.9 kg	½ tab
6 - 10.9 kg	1 tab
11 - 15.9 kg	1½ tab
16 - 20.9 kg	2 tab
21 - 30.9 kg	3 tab
31 - 45.9 kg	3 tab

6.4 OTHER IMPORTANT MANAGEMENT ISSUES OF CHILDHOOD TB

Some other important management issues are as follows:

- 1. Nutritional status:** For management of malnutrition refer to PNG Standard Treatment Manual, 2005 (“Blue Book”, page 60-68 or see 9th edition), WHO Pocketbook of Hospital Care for Children (Chapter 7), Paediatrics for Doctors in PNG (pg 210-220)
- Always ensure provider-initiated testing and counselling (PITC) for HIV .
- Manage other illnesses like pneumonia, anaemia, etc as per the Standard Treatment Manual.
- Always screen contacts like family and friends, by inquiring about history of cough. If any adult has history of cough, use the diagnostic algorithm for adult TB for diagnosis.
- Record and report all TB cases to the Provincial TB Office using BMU quarterly reports.

FIGURE 1. SUMMARY OF TREATMENT CATEGORIES AND REGIMENS



Note: For children with weights above 30.9kg, use adult kits, without additional Isoniazid.

7 DRUG RESISTANT TB/MDR TB AND INFECTION CONTROL

7.1 MANAGEMENT OF DR TB

Drug Resistant TB (DR TB) is TB that is resistant to TB drugs. Resistance can be developed to one or more TB drugs as in single drug resistance where only one drug is resistant, poly drug resistance where more than one drug is resistant or extensive drug resistant where second line drugs are also resistant. **Multi Drug Resistant TB (MDR TB)** is a form of poly drug resistant TB that is resistant to both rifampicin and isoniazid which are considered the two most powerful anti TB drugs. **MDR TB and other drug resistant TB results from poor management of susceptible TB and thus the primary way to prevent MDR TB or any other drug resistant TB is to ensure that all TB patients with susceptible TB must be diagnosed and treated properly with the right drug regimen for the appropriate duration.** Ensuring all TB patients complete TB treatment under supervision (DOT) is the most effective way to ensure normal TB patients are successfully treated and that drug resistant strains of TB are not created. MDR TB patients will be diagnosed and managed from designated hospitals by trained physicians and clinicians under the direction of the PNG PMDT core team. A separate guideline for the programmatic management is available. This chapter outlines only the basic diagnostic and management procedures for DR TB.

1. Case finding - DR TB Suspects

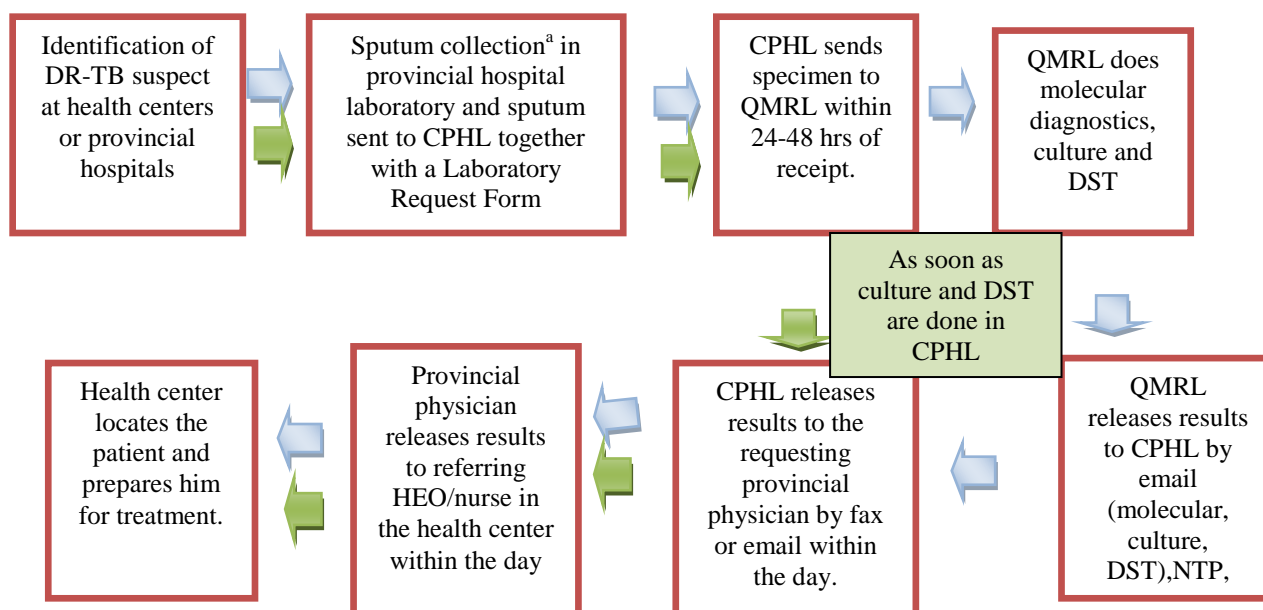
The following patients are considered at risk for drug resistant TB and must be referred or screened.

- Retreatment cases - treatment failure cases, relapse, return after default or others.
- DOT non-converters (Cat 1 and II). These should be patients who are smear positive at 5th month of treatment or at the end of treatment under a supervised treatment regimen.
- Symptomatic contacts of known DR-TB patients
- TB/HIV coinfecting

2. Case finding procedures

(i). The current flow of procedures shown in blue arrow is interim arrangement pending the upgrade of CPHL and in green arrow is long-term routine for culture and DST in CPHL.

Figure 2 . Flow of specimens from health facilities in PNG to release of results from QMRL



^a Sputum may be collected in the health center and then brought to the provincial hospital by ambulance, by boat or by air. A health center staff may also bring the sputum when he attends meeting in the provincial hospital.

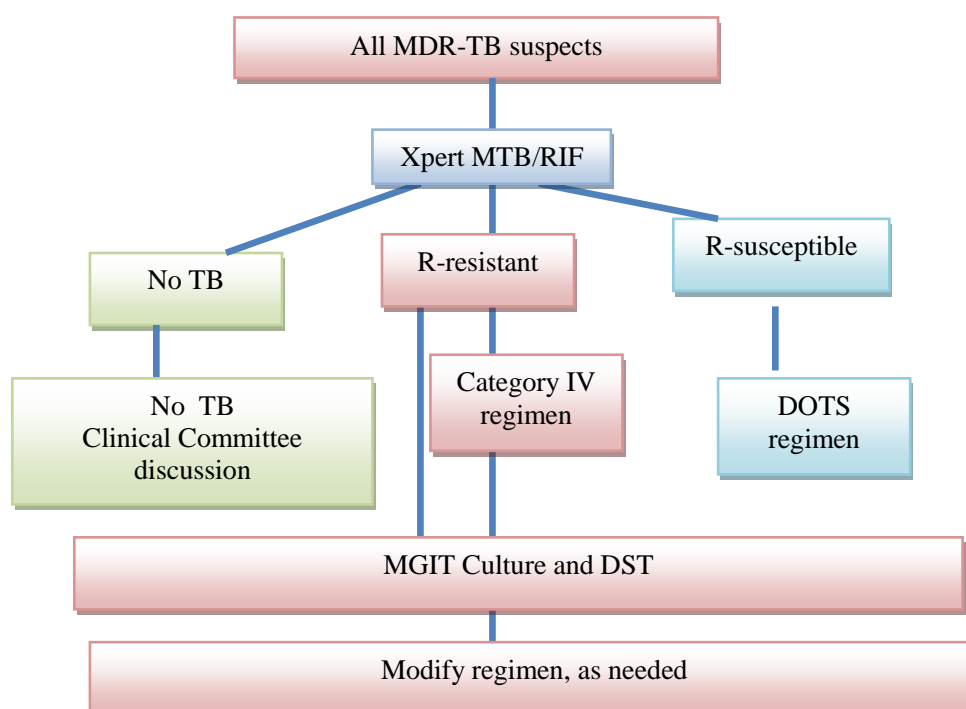
(ii). Gene -Xpert MTB/RIF will be used as the initial diagnostic test in individuals suspected of having MDR-TB or HIV-associated TB when it is available in the main regional centres. All health facilities should send sputum sample for DR TB suspects to the nearest provincial hospital laboratory for shipment to their respective Gene Xpert location.

Table 13. Zoning mechanism for Xpert MTB/RIF covering the 4 regions in PNG

GeneXpert location	Region	Province
CPHL	Southern Highlands	NCD, Central Prov., Milne Bay, Oro, Gulf EHP, WHP, SHP, Chimbu, Enga
Daru Hosp. (Lab)		Western Province
Lae (future)	Momase Region	
Madang – IMR	Momase Region	Madang, Morobe, East Sepik, Sandaun
Kokopo (Lab)	New Guinea Islands Region	ENBP, WNBP, New Ireland (Kavieng), Manus, Bougainville (ABG)

- Despite a 99% negative predictive value (NPV) of Xpert in both low- and high-prevalence of R-resistance, **R-susceptible** cases still need to have culture and DST to detect H-mono, and poly- -resistance (H-, HE-, HS-, HES- resistance)
- Considering the low positive predictive value (PPV) of the test in areas with low R-resistance, there is a need to do culture and DST in order to avoid unnecessary toxicity to those falsely identified to be **R-resistant**, plus detect resistance to drugs other than R.
- While waiting for the culture and DST results, R-susceptible cases will be assumed drug-susceptible and will be started on DOTS, while R-resistant cases will be assumed MDR and will be started on the standard Category IV treatment. Cases that turn out otherwise in the culture and DST will have regimen adjusted.

Figure 3. Case finding algorithm using Xpert MTB/RIF



3. Treatment and case holding for category IV (MDR TB / DR TB) patients

(i) MDR-TB model of care and delivery of treatment:

The model of care will be mainly ambulatory consisting of a short hospitalization phase followed by an ambulatory phase. Hospitalization for 2 months is recommended but if the patient converts earlier, he may be discharged as long as there are no uncontrolled or serious adverse reactions. The nurse or the Health Extension Officer (HEO) at the health facility does the daily DOT, ticks the Treatment Card, and continues to manage the patient. The injectable after hospitalization can be completed at the health center (hospital) otherwise this is given on an out-patient basis. After the injectable phase, community Health workers (CHWs) may be assigned as DOT partners as long as they have satisfactorily completed PMDT training for volunteers. Treatment supporters (village volunteers) may supervise patients from remote or hard-to-reach areas as long as they have been trained. DOT partners are supervised by the health facility staff.

Infection control measures must be in place and followed in all facilities involved in the management of drug resistant TB patients.

(ii) Patients eligible for Category IV/MDR TB treatment will be

- a) Category II failures (MDR-TB suspects)
- b) Xpert MTB/RIF positive with R-resistance,
- c) Confirmed Cases of MDR.

(iii) Treatment Regimen

Patients are started on a **standardized regimen** consisting of the following:

Intensive phase: Pyrazinamide (Z) Kanamycin (Km) Levofloxacin (Lfx) Ethionamide (Eto) and Cycloserine (Cs)

Continuation phase: Z Lfx Eto Cs

- Capreomycin (Cm) is used in Km-resistant cases.
- PAS may be used in case Cs cannot be tolerated.

Dosages: Dosage is based on weight. See MDR TB guideline for details.

Z and Lfx should be given once a day as the peaks attained may be beneficial. However, Eto, Cs and PAS may be given in split doses to reduce adverse effects. To further help patients adjust to the toxic effects of Eto, Cs and PAS, drug ramping or dose escalation over a period of 1-2 weeks is recommended until full dose is reached (see MDR TB guidelines).

Duration: The duration of the injectable is at least 8 months, with at least 4 months past culture-conversion prior to discontinuation. The total duration of the regimen is at least 20 months with at least 18 months past culture conversion.

(iv). For MDR-TB/HIV co infected

Initiate anti-retroviral treatment regardless of CD₄ count and as soon as anti-TB treatment is tolerated, ideally in 2 weeks and no later than 8 weeks from the start of anti-TB treatment.

(v). Supervised therapy

- Because DR-TB treatment may represent the last therapeutic option, each dose whether given once or twice daily is directly observed all throughout the treatment and a Treatment Card is marked for each observed dose.
- Supervised therapy is recommended to be delivered by trained health care workers. Alternatively, trained community members based on selection criteria, can serve as effective

DOT workers with adequate training, supervision and support from the health facility staff. Family members are not recommended to provide DOT but encouraged to provide support.

(vi). Initial evaluation and follow-up:

- Sputum smear and culture are done at baseline and monthly while on treatment.
- Other examinations are performed prior to the start of treatment (baseline) and during treatment to detect reactions to therapy.

(vii). Management of adverse reactions

Adverse reactions to treatment are managed promptly. Mild reactions may be treated in the health facility while moderate-severe ones are managed in the provincial hospitals. See PMDT guideline for Common adverse reactions, suspected agents and management strategies.

A guideline for the programmatic management of drug resistant TB (PMDT) in PNG was developed and is now available to provide guidelines for standards for DR-TB case diagnosis, management, registering, monitoring and reporting the treatment outcomes of patients with DR-TB. MDR TB or other drug resistant TB suspects identified in routine TB care facilities must be referred to hospitals / designated MDR TB centres for diagnosis and initiation of treatment.

See PMDT guidelines for the management of mono- and poly-resistant cases, cases documented or suspected to have XDR-TB, MDR TB in special conditions, Extra pulmonary DR TB for other detail aspects of drug resistant TB management.

7.2 INFECTION CONTROL

The basic principles of TB infection control covered in this guideline can be applied to all other airborne infectious diseases. In any health facility, when a smear positive TB patient enters, he/she breathes out or coughs out infectious bacilli containing droplets called aerosols. These are small droplet nuclei bacilli at its core and usually invisible to the naked eye. The droplet nuclei remain suspended in the air even after the patient leaves the room and may settle slowly. When another non-infected person enters or is in the same room and breathes the same aerosols, he or she is likely to get TB infection. Other patients and health workers who are exposed to the same room air as a smear positive TB patient are at higher risk of TB infection. Sunlight quickly kills TB bacilli, so a room where there is plenty of natural light will have faster killing of TB bacilli by the sunlight.

The following are methods of air-borne infection control in health facilities;

1. Patient triage and organization of patient flow
2. Ensuring ventilation in rooms
3. Patient education and cough etiquette
4. Sputum collection and management of hazardous bio-medical waste
5. Take measures to decrease personal occupational risk as a health worker

1. Patient triage and organization of patient flow

Triage is the prioritization of patients. To reduce chances of TB transmission, it is advisable to quickly attend to likely smear positive patients and reduce the time spent by them in the health facility. Have separate waiting areas for patients with cough and do not let them mingle freely with immuno-compromised patients such as HIV positive patients or with children. The infectiousness of TB cases depends on smear positivity. Patients who are not yet identified as smear positive TB, but are coughing pose the largest risk in terms of TB transmission. It is expected that one smear positive

TB case can spread the infection to 10 to 15 patients per year on an average. On an average one-tenths of household contacts of a smear positive patient gets infected.

Identify people who have cough and separate them from others to the extent possible. Provide instructions in the health facility and waiting areas for people who have cough to move to the front of the queue. Coughers may be spreading TB, and everyone is susceptible. Use of signage can be helpful. Please prepare bio-hazard sign for areas where TB patients are examined and preferably keep these areas as 'No thoroughfare' areas.

Smear positive patients who have been on DOT regimens for 2 weeks or more are likely to be less infectious or may have been rendered smear negative by the treatment. So the largest risk is posed by unidentified smear positive patients. If possible have a separate waiting area for coughing patients. Wherever smear status is known, smear positive patients can be asked to wear a well fitted face mask (The same could be provided at registration area to coughing patients).

In HIV care facilities coughing patients should be investigated for TB. TB suspects (coughing patients) and TB patients should be given a mask while in the facility or have a separate entrance and should be prioritized in terms of all other treatments. They should not stay longer in the HIV facilities.

2. Ensuring ventilation in health facility rooms

All health facility rooms are to be designed in such a way that there is good movement of air in all rooms which are accessible to smear positive TB patients. The warm tropical climate in our country facilitates having rooms with good cross ventilation and use of natural air-flow and sunlight. Good movement of air in all rooms helps the infection containing aerosols to disseminate quickly from the ambient air. Aerosols can remain for hours in poorly ventilated rooms, whereas they get diluted quickly in well ventilated rooms, maybe in a matter of seconds. It is expected that about 25 to 40% of the surface area of a room should be devoted to window/ door space, and that windows/ doors face each other and are in line with usual wind direction in the locality so as to allow good and effective cross-ventilation. Cross ventilation is to be ensured to allow rapid removal of infectious particles. Stand-alone ceiling or table fans are to be used only if there are vents/ windows for rapid replacement of ambient air. Systems which re-circulate ambient air without effective filtration and cleaning of air and dust are to be discouraged. Fans must not be used in closed rooms with no cross-ventilation as they may keep aerosols suspended for longer without allowing them to settle. Most commercially available air conditioners re-circulate ambient air with very little filtration and therefore are most likely not effective in dilution of infectious aerosols.

Some health facilities may use mechanical ventilation systems – these may consists of one of the following:

1. Exhaust fans – A fan which sucks air out of the room is installed at a window
2. Local filter units for specific rooms or isolated areas
3. Central ventilation mechanisms with air handling units and HEPA filters

A mechanical ventilation unit usually consists of;

- a) A fan or a motorized unit which helps to suck air out of the room
- b) An air filter at the point of exhaust
- c) Sometimes, a germicidal irradiation mechanism such as UV lights

To improve ventilation and decrease risk in your facility, you can take following steps:

1. Check that all windows and doors can be opened and are easy to keep open. This might include, for example, oiling hinges, obtaining an appropriate rod to open a skylight and keeping it available and installing a hook to hold a window open.

2. Check that doors allow some airflow, even when closed. Doors on examination and treatment rooms can be trimmed to increase air flow below them even when closed.
3. Check that all exhaust fans and air conditioners are in good working order and clean. Clean dirty fans, and repair or replace broken fans. To check that fans with a grille are working, hold a tissue or piece of paper against the grille. If the fan is working, the tissue or paper should be pulled against the grille. Keep exhaust fans on. If there is an air conditioner, check that its filter is kept clean.
4. Place fans in windows to blow room air to the outdoors. Window fans should be placed in locations so they add to natural ventilation currents. However, check where the fan will be blowing the air: it should not blow into a patient waiting area or hall where people would breathe that air.
6. Keep doors, windows and skylights open as much as possible. Allow air to blow into and out of the building.

3. Patient education and cough etiquette

All patient waiting areas should have posters instructing patients to cover their mouth and nose with an handkerchief or their sleeves when coughing or sneezing. Patients must not cover their mouth or nose with bare hands. Pamphlets can be given to patients and relatives on the need for cough etiquette and disinfection of fomites used at home. Hand washing with soap is also to be practiced.

4. Sputum collection and management of hazardous bio-medical waste

Sputum collection is an activity which can be carried out with nil or negligible risk. However omitting to take certain precautions could increase risk of TB transmission at time of sputum collection and during handling of sputum in labs. At all times, follow the precautions below:

- a. Encourage patients to cough out to bring sputum in open well ventilated, sunny areas. Do not use poorly ventilated, closed or poorly lit closed rooms or corridors
- b. Never stand in front of a coughing patient. When observing a patients sputum collection, stand behind the patient.
- c. Stand upstream of wind-direction when patient is coughing to bring out sputum. Keep good cross ventilation in the rooms.

Keep doors and windows open and allow in natural air and light. Use 5% phenol or 5% hypochlorite to mop the working surfaces before and after work. Fill 5% phenol or 5% hypochlorite into used sputum cups and keep for few hours before discarding. Handle all biological fluids as potentially infectious and follow guidelines at all times. Disinfect spills as per given SOPs. Wash hands with germicidal soap before and after work.

5. Take measures to decrease personal occupational risk as a health worker

Always follow recommended infection control procedures in your work in the health facility. Be aware of possible signs and symptoms of TB in yourself. If one or more of these develop, report promptly for assessment and care. If you are diagnosed with TB, start treatment promptly and adhere to treatment until it is completed. Common symptoms of TB include;

- a. **Cough for more than 2 weeks duration**
- b. Fever and/ or night sweats
- c. Weight loss and malaise
- d. Blood in sputum

Health workers should decrease their risk factors for TB disease to the extent possible eg. by stopping smoking, or following treatment for diabetes, knowing their HIV status or getting retested periodically etc. If a health worker is HIV-infected, he/she may decrease his/her risk of developing TB by taking CPT, ART and IPT if appropriate. Health workers who have positive HIV status should not work in TB facilities.

8 TUBERCULOSIS AND HIV

8.1 TUBERCULOSIS AND HIV CO INFECTION

HIV infection leads to a profound destruction of cellular immunity. As a result, those infected become ill from severe and often deadly opportunistic diseases and are thus said to have AIDS. TB is a common opportunistic disease often resulting in death in HIV infected persons. Because containment of tuberculosis infection in an individual is dependent on the integrity of cellular immunity, HIV infection has emerged as the strongest known risk factor to developing TB. HIV infection may thus increase tuberculosis morbidity in three ways:

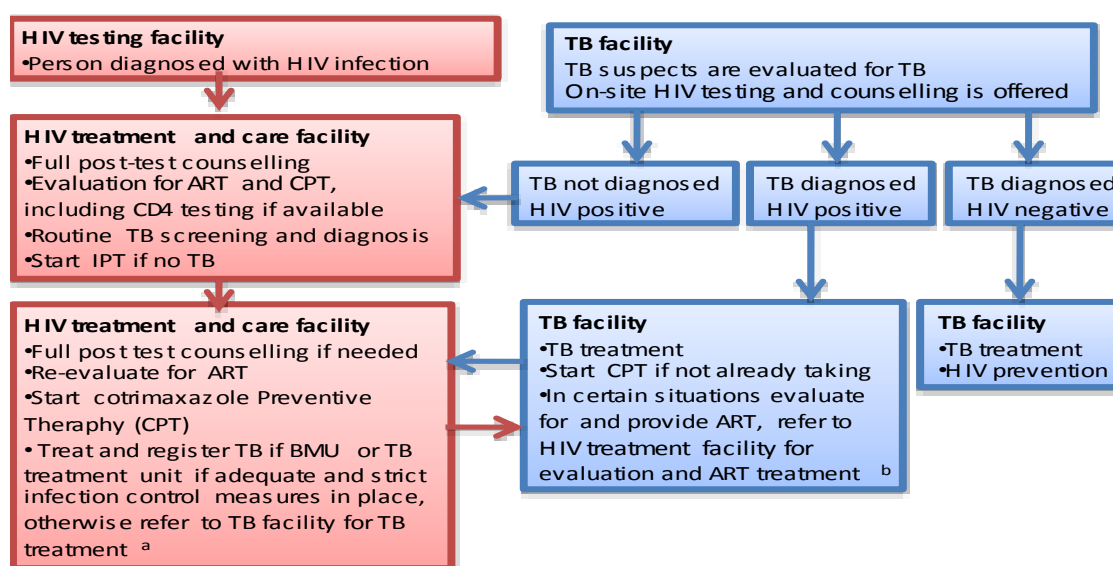
- (1) Reactivating pre-existing tuberculosis infection in persons
- (2) By new infection with TB and direct progression to TB disease.
- (3) By spread from highly infectious HIV infected sputum positive cases to the community

8.2 HIV AND TB DIAGNOSIS AND TREATMENT

All TB suspects and patients should be offered Provider Initiated Counselling and Testing (PICT) for HIV as part of routine management for TB diagnosis and treatment. HIV positive patients may be referred for further indebt counselling and care to HIV care, treatment and support services.

All people living with HIV (PLWHIV) should be screened for TB. All HIV TB co infected patients identifies in HIV care and treatment centres should be commenced on TB treatment immediately. It is recommended that HIV care and treatment facilities who have the capacity to diagnose and manage TB patients **with adequate infection control measures in place** should become basic management units (BMU) for TB where they should initiate TB treatment, register their TB patients and submit quarterly reports or become TB treatment centres where they can be supplied the full course of TB treatment for them to supervise. This will ensure easy access to TB treatment for patients accessing HIV care and reduce defaults in patients taking both TB and HIV treatment.

Figure 4: Flow diagram for HIV and TB diagnosis and treatment



- a. TB treatment can be provided at the TB facility nearest to the patient's home or at the ART treatment facility, depending on the needs of the patient
b. ART treatment will be provided at the ART treatment facility. However for patients with MDR or XDR TB, ART should be provided at the TB treatment facility.

Figure adopted from WHO Revised Framework to address TB/HIV co infection in the Western Pacific Region, 2008.

8.3 CLINICAL PICTURE

TB may present at any stage of HIV infection although the risk of developing TB increases with worsening immune status. TB may present with the classical symptoms of fever, night sweats, productive cough (haemoptysis), shortness of breath, and weight loss occurring over weeks to months. However the clinical presentation of TB in HIV infection may be influenced by the degree of immunosuppressant (table 1). With normal or moderately reduced CD4 counts ($>200\text{cells}/\text{mm}^3$) the presentation is more typical. With increasing immunosuppressant ($\text{CD4} < 200\text{ cells}/\text{mm}^3$) the clinical presentation becomes less typical.

People living with HIV infection are more likely to present with extra-pulmonary TB (EPTB) or smear negative TB than TB patients who are HIV negative. Although TB/HIV co-infection may present in other forms, the majority of cases are bacteriologically positive and therefore sputum smear and culture remains the first diagnostic test. No chest x-ray pattern that is absolutely typical of pulmonary TB in HIV infection (table 14).

Table 14: The presentation of pulmonary TB may differ in early and late HIV infection

Features of pulmonary TB	Stage of HIV infection	
	Early	Late
Clinical picture	Often resembles post-primary pulmonary TB	Often resembles primary pulmonary TB
Sputum smear	Often positive	May be negative
Chest x-ray	Often cavities	Often infiltrates with no cavities (may be normal)

Figure modified from: TB/HIV: a clinical manual 2nd edition. Geneva, WHO 2004

Figure 5. Algorithm for TB screening for ambulatory people living with HIV infection

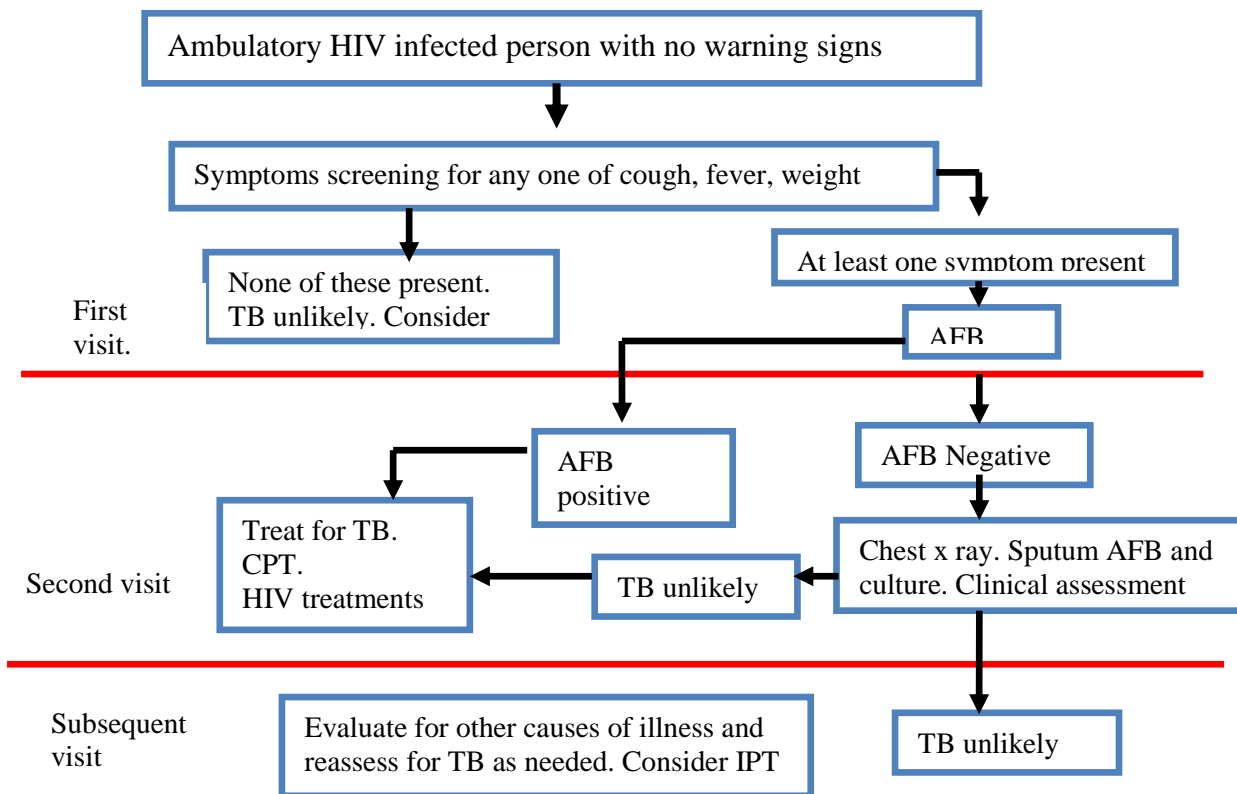


Figure adopted from WHO Revised Framework to address TB/HIV co infection in the Western Pacific Region, 2008.

8.4 MANAGEMENT AND PREVENTIVE THERAPY IN TB HIV COINFECTION

8.4.1. Management of TB/HIV co infection

- TB treatment and cotrimoxazole preventative therapy (CPT) are commenced first.
- ART is commenced 2 to 8 weeks after commencing TB treatment depending on the progression of HIV disease.
- TB/HIV patients are treated using the same TB treatment categories as non-HIV infection.
- Treatment should be administered under DOT at all times.

8.4.2. Cotrimoxazole preventative therapy

Cotrimoxazole (two single strength tablets or one double-strength tablet per day - 160mg trimethoprim/800mg sulfamethoxazole) should be provided to all HIV-infected TB patients at the time of diagnosis and should be continued as per the HIV care and treatment guideline.

8.4.3 Isoniazid Prophylaxis Therapy (IPT)

HIV positive patients who do not have active TB disease should be commenced on Isoniazid preventive prophylaxis 10mg/kg daily for 6 months. PLWHs who do not have cough, night sweats and weight loss should be given IPT. Isoniazid prophylaxis in HIV positive patients should be repeated every two years. **Active TB should be excluded before Isoniazid prophylaxis.**

8.4.4 Prevention of HIV transmission in Health care facilities

- High safety standards, sterilization and disinfection procedures must be maintained.
- One needle is used for one injection for one patient only. Dispose used needles properly.
- HIV patients without TB should not be admitted in a TB ward.
- TB suspects and smear-positive TB patients should not be admitted in a HIV ward.
- HIV/TB co-infected patients can be admitted in a TB ward.

8.4.5 TB/HIV Collaboration

The recommended activities for TB /HIV collaboration focuses on establishing mechanisms of collaboration between TB and HIV programs at all levels, decreasing the burden of TB in People living with HIV (PLWHIV) through intensified case finding, INH preventive therapy & infection control and decreasing the burden of HIV in TB patients through PICT, prevention methods, CPT preventive therapy, HIV treatment and care and support for TB/HIV co infected patients. Guidelines for PICT and TB/HIV collaborative activities are now in place to guide health workers in the respective activities.

9 ROLE OF ACSM IN TB CONTROL

9.1 DEFINITION OF KEY TERMS:

Advocacy, Communication, Social Mobilisation

ACSM strategies have the potential to improve case detection and treatment adherence, reduce stigma and discrimination, empower people with TB and mobilise political commitment. The framework for ACSM in the context of PNG is based on the 'ACSM 10 Year Framework for Action' (WHO and Stop TB Partnership, 2006). Under this framework ACSM is defined as follows;

Advocacy is the act or process of supporting a cause or issue. It means engaging in dialogues with governments, politicians, international funding agencies/institutions, with multilateral agencies and other similar individuals and groups.

Commonly we term these people 'decision makers' meaning they are in a position to influence the behaviour of others and in this context they are in a position to contribute to TB control.

Communication is the process people use to exchange information about TB. This could make use of some form of media or channels of communication. In the context of programme communication, this is related to creating awareness and empowering people to take action.

The main forms of TB communication that Health Workers will need to be familiar with in PNG include posters which correct common misconceptions, TB fact brochures, flipcharts, information cards, newsletters, comic books or even balloons and temporary tattoos (often used for awareness events). These materials are developed to have an impact or influence on people's behaviour.

Social Mobilization is a process that engages people to take action towards the achievement of a goal for the common good. The 'common good' may be defined situationally in terms of the impact that is generated through a given action. Social mobilization can aim at mustering national and local support for health promotion through an open process that gives ownership to the community.

Social mobilisation can help ensure that TB services and care are devolved to a village level. Social mobilisation has the power to bring together community members and other stakeholders to strengthen community participation for sustainability and self-reliance around TB.

9.2. THE ROLE OF ACSM IN THE NATIONAL TB PROGRAM

ACSM is a critical part of the NTP as it helps increase the demand for TB care. For this reason ACSM must always go hand in hand with health system strengthening. The following outcomes can be achieved through ACSM:

- Improvement in case detection and treatment adherence.
- Reduction in stigma and discrimination towards patients.
- Empowerment of people affected by TB.
- Mobilization of political commitment and resources for TB.

As you develop ACSM strategies more people will know about TB. As more people know about symptoms and where to access treatment their health seeking practices will improve. This means a likely increase in people coming to clinics as TB suspects and most probably the number of people being diagnosed as having TB. Since one of the core messages in TB awareness campaigns is 'TB is curable', it is important that we do in fact have the capacity to cure this new influx of patients. ACSM without health system strengthening can be seen as doing a disservice to patients.

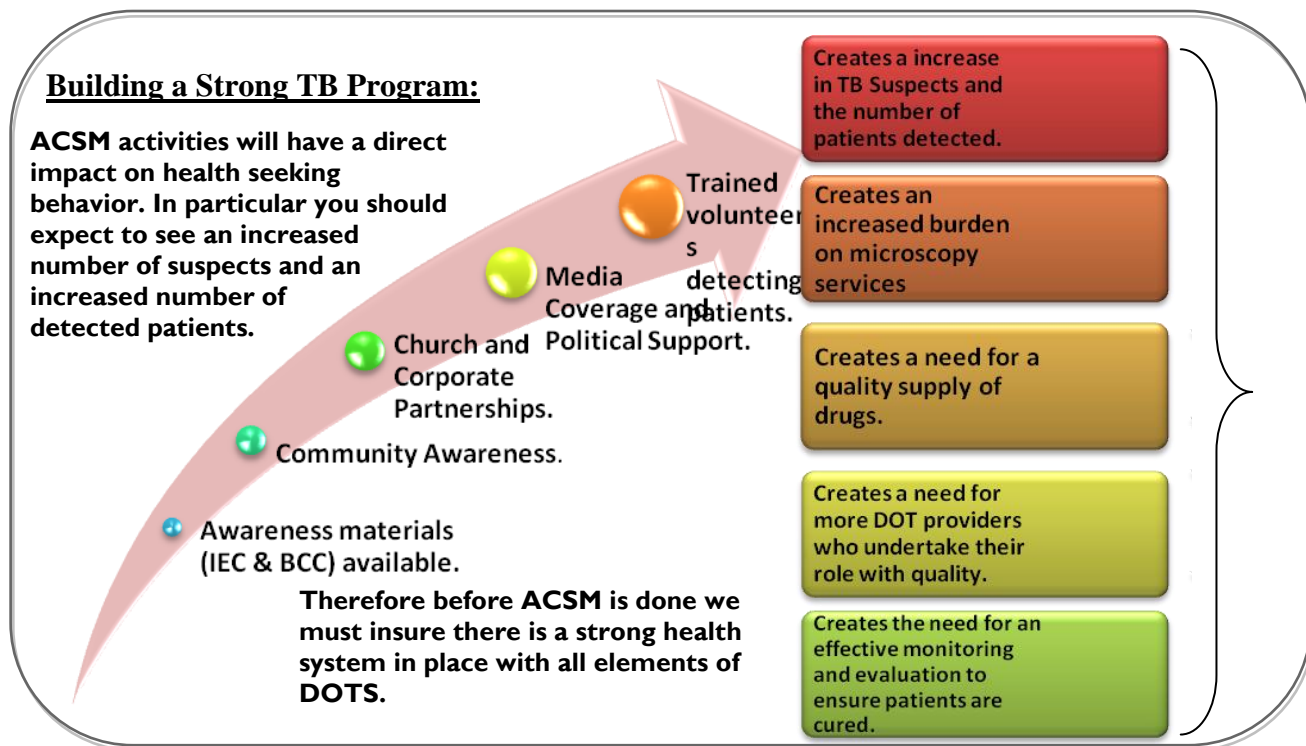


Figure 6. ACSM for TB control – How ACSM correlates with technical aspects of TB control.

9.3 AWARENESS EVENTS: -Key Awareness Dates:

- World TB Day (Every March 24):
- World AIDS Day (Every December 1):
- PNG Independence Day (Every September 16)
- Local Cultural festivals (normally between August and November)
- Thematic events that link into TB such as World Health Day, events to celebrate human rights, child rights or the Millennium Development Goals.

9.4 HOW TO ADVOCATE TO DECISION MAKERS

Decision makers can be politicians right through to LLG Ward members. They may be Church leaders, village leaders, NGO stakeholders, Corporate leaders or even sports stars and local celebrities. These people have the ability to influence the behaviour of others to varying extents.

When meeting with decision makers it can be good to consider the following:

- Know what you want to achieve and make your targets as specific as possible.
- Identify a realistic decision maker/group of decision makers that can help you achieve this.
- Identify a realistic and appropriate way of reaching your identified decision maker.
- Make sure there is more than just talk – make sure you reached a solid outcome.
- Maintain partnerships –Progress of the program and their contribution to this progress.

9.5 MOBILISATION AND TRAINING TREATMENT SUPPORTERS

What is a volunteer Treatment Supporter?

A volunteer treatment supporter is a person who observes a TB patient taking their medication every day. The person must be trained in basic TB knowledge and care, but they do not need to have any formal background in health. They must be supervised by the TB nurse. They can be;

- Ex- TB Patients.
- Priests or members of the local church, or village or community leaders.
- Work mates or supervisors.
- Retired nurses or health workers.
- Members of women’s groups or other social organisations within the community.

Table 15. Qualities of an ideal treatment supporter

Ideal characteristics	Why this is important:
Be literate	So that they are capable of filling out a patient treatment record card.
Be un-related to the patient.	In PNG data has shown that patients who have a non-family member support them through their treatment are more likely to be cured than if a family member were to assist them. This may be because when a patient is treated by a family member the process of observation may be less accountable or more relaxed.
Live close by the patient.	The intention of DOT is localise TB treatment to the community and make it accessible to the patient daily. The treatment supporter should live within an easy walking distance of the patient.
Be motivated to cure patient/s for non-monetary gain.	These people should be involved with the program because of a personal passion to save the lives of people in their community and contribute to the fight against TB in PNG. There is no incentive program by the NTP.
Be a person who the patient both respects and feels comfortable with.	It is important that the patient feels comfortable taking medication from the treatment supporter. Yet at the same time there should be a healthy level of respect between patient and supporter to help reinforce the necessity of daily treatment intake when at times the patient may not be willing.

What are the objectives of training volunteer treatment supporters?

1. Have basic knowledge of TB covering simple epidemiology, detection, diagnosis and treatment.
2. Be able to provide community-based DOT to a TB patient.
3. Be able to accurately mark Treatment Cards for patients they are observing.
4. Know the side effects and adverse reactions to the TB drugs and respond accordingly.
5. Be able to identify and advise the patient on the scheduled sputum follow ups.
6. Understand why patients default and provide moral support to patients to prevent default.
7. Identify other TB suspects in their community and refer them to health centres.
8. Provide community awareness on TB as necessary.

9.6 OTHER ACSM AREAS OF FOCUS

TB Support Groups and Community Based Organizations:

A TB support Group is comprised of trained TB treatment supporters. Groups meet on a regular basis and support each other in order to address TB in their communities. Support Group Members are known to local clinic staff as they will frequently refer TB suspects to the clinic and in turn the clinic staff will refer diagnosed patients back to their Support Group members for daily DOT.

Corporate partnerships:

These partnerships include the adoption of a Workplace TB Policy which aims to

- a) Save lives by protecting the company's most valuable asset - their people,
- b) to create awareness and share information about TB among staff and the general community and
- c) to foster a positive work environment, free from fear of discrimination or dismissal on the basis of having TB. Workplace partnerships also look at the sustainable means by which companies can contribute to the long term sustainability of the program and TB control.

Church Partnerships:

Many villages in PNG are highly inaccessible and sometimes the only support or infrastructure in place is the church networks thus partnerships with churches is important for providing DOT.

10 MANAGEMENT ASPECTS OF TB CONTROL PROGRAM

10.1 Human Resource Development

10.1.1 Health Care Workers

Health workers trained or orientated in TB management should manage TB patients. Treatment can be supervised by all other health workers and community volunteers.

10.1.2 Training

Training for TB is done in a week long intensive training, refresher training or on the job training. Trainings for TB management include training for health workers for clinical management, coordinators and laboratory microscopists. PICT training is provided by the National HIV Program. TB programs can liaise with their HIV program at the provincial level for the PICT training.

10.1.3 Supervision

Supervisory visits are carried out regularly at all levels preferably quarterly. TB coordinators and technical staff from the national, provincial and district level carry out supervision to the respective levels to provide technical guidance and support, validate records, registers and reports, ensure and coordinate effective delivery of TB control activities. A supervisory checklist is used as a tool.

10.2. Supplies for TB

All basic management units (BMU) for TB compile and submit quarter BMU reports to NTP which also include a request for drugs and supplies. All TB drugs and supplies are supplied quarterly based on consumption to the provinces. Drugs and supplies for TB include;

- Drugs for TB treatment, isoniazid for IPT, cotrimoxazole for CPT
- Other supplies for treatment such as needles, syringes, sterile water for injection etc.
- Supply for TB diagnosis such as sputum cups, laboratory reagent/kits, slides etc
- Forms and registers

10.2. 1 TB Drugs (FDC)

TB drugs are now available in fixed dosed combination (FDC) formulations for both adults and paediatric which makes TB treatment more effective and efficient. FDC are made up of 2 to 4 drugs combined in one tablet. These come in FDC kits simplifying forecasting, ordering and distribution and completely ensuring full course of treatment available. When ordering TB drugs a buffer stock for three months is included in the calculation. The following formula is used when ordering drugs and supplies for TB;

A + B – C = D whereby

A = quantity used last quarter (eg. Number of Cat I kits used based on number of new cases)

B = **A**. This is for buffer stock and the number is same as A.

C = stock left at the end of the quarter.

D= amount to order for the next quarter.

10.2.2 Storage

All TB drugs and supplies are stored in a safe and secured room under appropriate conditions. Drugs are checked regularly for expiry dates. A stock register is maintained and updated whenever drugs and other materials are received or dispensed. A stock (bin) card is maintained for each drug and is updated every time drugs are received or dispensed.

10.2.3 Laboratory consumables

Adequate supply of sputum containers and slides are needed for sputum microscopy. Laboratories need good quality binocular microscope, regular supply of slides and reagents.

10.3. DOCUMENTATION

10.3.1 Forms, Records and registers

The following documents are used in the tuberculosis control program;

- TB treatment cards (TB01) – contains information on patient's particulars, diagnosis and treatment details, results of diagnosis. Treatment calendar etc
- Patient Record book –patient's identification card with information on TB treatment
- TB Register (TB08) – register of TB patients with information on patient's particulars, diagnosis and treatment details, results of investigations, follow up and outcome.
- TB suspect register – register of all TB suspects with patient information and details of sputum examination and results and actions taken
- TB Referral Register – Register of patients that are diagnosed in a diagnostic facility but referred to BMUs for registration and continuation of treatment.
- TB Laboratory Register –registers sputums and results of investigations eg. AFB detected
- Request Form for sputum Examination – contains patient's information and purpose for investigation and accompanies samples for investigation and returned with results.
- Request Form for culture and sensitivity testing (TB06) -This form should be filled and should accompany the specimen for culture and sensitivity.
- Referral or transfer forms – contains information on patient's particulars, diagnosis and treatment results and accompanies patients transferring or referring to another facility

11 MONITORING AND EVALUATION FOR TB CONTROL PROGRAM

1. Recording & Reporting

1.2 Reporting of TB Detection and Treatment Activities

Basic Management Unit (BMU) quarterly Report

A BMU quarterly report contains the following reports from different cohorts;

- Quarterly report on TB case registration (TB 07) – This contains case detection information for all patients identified in the quarter that just ended.
- Quarterly report on sputum conversion – This report is filled in for the new smear positive patients registered in the previous quarter i.e. the quarter that ended 3 months ago.
- Quarterly report on TB treatment outcome (TB08) - This report is for the cohort analysis of the treatment results for the cohort of patients registered one year ago
- Quarterly order form for TB drugs – Based on consumption from the last quarter.
- Quarterly order form for laboratory supplies – Based on consumption from the last quarter
- Yearly report on program management – Filled in once on an annual basis

The above reports should be compiled at the end of every quarter using information from different cohorts as indicated using source documents such as the TB register, TB treatment card, Laboratory register etc. BMU reports are filled in triplicate whereby the BMU keeps one, the provincial TB office keeps one and submits the 3rd one to the NTP unit.

1.2 Recording and reporting for Category IV (MDR TB)

The reporting and information system for MDR TB is an extension of the basic TB DOTS information system. The forms and registers are also standardized as follows;

- ❖ *Category IV Treatment Card* - Contains all information about the patient's diagnosis and treatment and is completed once a patient is commenced on MDR TB treatment.
- ❖ *Category IV Register* - List of all patients started on Cat IV/MDR treatment.
- ❖ *Request for sputum examination* - Form accompanies the sputum sample of the patient both for diagnosis and treatment follow-up for smear, culture and DST. Request for DST must contain the patient's registration type.
- ❖ *Laboratory Register for culture and DST* - Registers are separate for smear and culture in culture centres while DST centres will have forms with an additional column for DST results. Compare regularly with the Category IV Register to ensure that all detected MDR cases are started in treatment.
- ❖ *Quarterly report in MDR-TB detection and category IV treatment start* - Used to assess the no. of MDR-TB cases detected and the no. of MDR-TB cases started on treatment. The no. of XDR-TB cases should be added, if applicable, e.g., DST to FQs and second-line injectables is done. Number detected may not be the same as the no. started on treatment considering the delay between diagnosis and start of treatment.
- ❖ *Six-month interim outcome assessment of confirmed MDR-TB cases* - Includes all cases entered in the Category IV Register.
- ❖ *Annual report of treatment result of confirmed MDR-TB patients starting category IV treatment* - Shows the final result of treatment by year of treatment start. Patients are classified according to previous anti-TB drug use (none, first-line, SLD, or both) Source documents: Treatment Card and Category IV Register. Due 24 months after last day of the cohort, and 36 months after last day of the cohort, e.g., for cohort of Jan 1-Dec 31, 2008, report is due on Jan 1 2011 and Jan 1 2012

2. MONITORING AND EVALUATION FOR TB CONTROL

2.1. Monitoring of TB Case Detection and Treatment Activities

Monitoring TB control activities is important to assess success and identify areas that need improvement. The National TB Program monitors the following indicators

1. TB case detection indicators

A. Monitoring done by NTP level

- i. Proportion of TB cases detected who were sputum smear positive as an indicator related to quality of diagnosis.
- ii. Proportion of new smear positive cases (also all TB cases) detected among estimated total in the country, province etc

B. Monitoring done at health facility level

- i. Proportion of TB suspects tested who were **13 years** and over among all adult outpatients
- ii. Proportion of TB suspects tested who were sputum smear positive

2. TB Treatment Outcome indicators

i. Sputum conversion Rate

This indicator refer to conversion of sputum positive TB to sputum negative TB and is measured as the proportion of new sputum smear positive cases converted at 2 or 3 months.

ii. TB Treatment Outcome

This indicator refers to treatment outcomes for new smear positive cases, smear positive retreatment cases and all other TB patients (cohort) registered in a particular quarter. Treatment Outcome indicators are measure as a proportion of new smear positive cases (also other respective TB cases as well as among all TB cases) with the following treatment outcomes;

- Cure
- Treatment Completed
- Treatment Failure
- Died
- Default
- Transfer Out
- Treatment success Rate (proportion cured plus completed)

The most important treatment outcome is the cure rate for smear positive patients. The desire cure rate for PNG is more than 85%.

2.2 MONITORING AND EVALUATION OF CATEGORY IV (MDR TB)

MDR TB Indicators

A minimum set of indicators are monitored for the programmatic management of MDR TB to assess programme performance, case detection and treatment outcomes and are group into;

1. Case Detection

Early detection of drug resistance will ensure adequate treatment and prevent further resistant. Four indicators are monitored to assess case detection activities for MDR TB as follows;

1. TB patients with results for isoniazid and rifampicin
2. Confirmed MDR TB detected among TB patients tested for isoniazid and rifampicin DST
3. Confirmed MDR TB tested for susceptibility to fluroquinolone and second line injectable

4. Delay in diagnosis of MDR TB - between date of MDR TB suspected and date for DST for Isoniazid and rifampicin.

The period of assessment is 6 calendar months and is measured three months after the end of the 6 month period. The data is from the basic TB register, MDR TB suspect register, lab. register.

2. Enrolment on MDR TB treatment indicators

- I. MDR TB cases (suspected or confirmed) enrolled on MDR TB treatment, aggregated by (i) all cases, (ii) cases aged <15years, and (iii) females
- II. Confirmed MDR TB cases enrolled on MDR TB treatment regimen, aggregated by (i) all cases, (ii) cases with HIV on ART, and (iii) cases with HIV but not known to be HIV
- III. Confirmed XDR TB cases enrolled on XDR TB treatment
- IV. Delay in start of MDR TB treatment –duration of time between confirmation of MDR TB and start of MDR TB treatment. Delay is zero if treatment was started prior to confirmation. Period of assessment is 6 calendar months and are measured in the month following the end of the six month period. Data is from the MDR TB treatment register and the lab. register for culture/ DST

3. Interim Results at 6th month.

Interim results are assessed for culture conversion and deaths at 6 months for early indicators for success of treatment as final treatment outcomes will be ready in 2 to 3 years. These are;

1. MDR TB cases on MDR TB treatment regimen with negative culture by 6 months
2. MDR TB cases on MDR TB treatment regimen who died by 6 months
3. MDR TB cases on MDR TB treatment regimen who defaulted by 6 months
4. Patients on MDR TB treatment regimen found not to have MDR TB
5. Patients on XDR TB treatment regimen found not to have XDR TB.

Defaulting, change of regimens to XDR TB or susceptible TB treatment are also evaluated. The period of assessment is 3 calendar months where all patients registered and treatment during the assessment period is included. Indicators are measured 9 months after end of quarter of assessment.

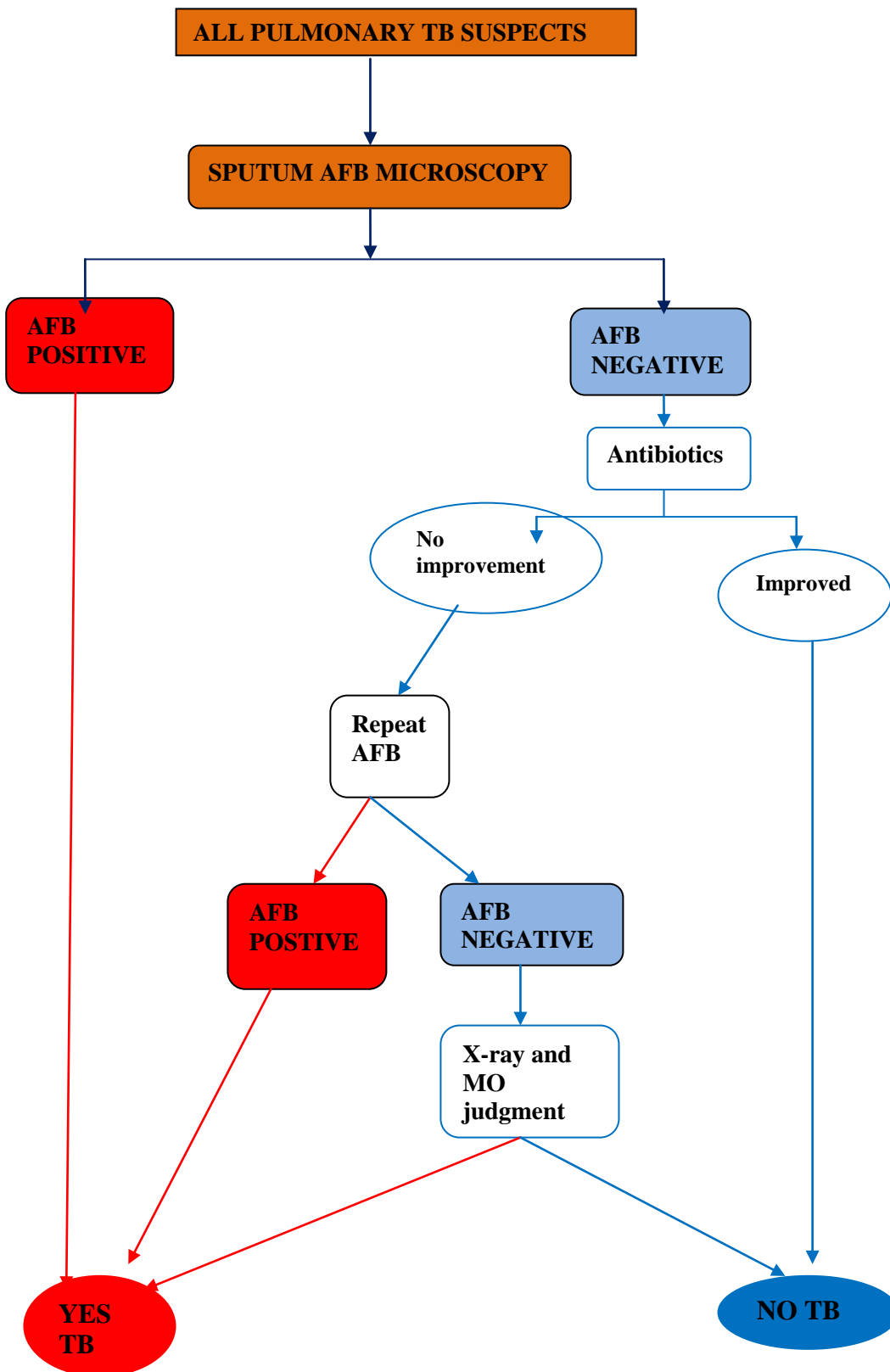
4. Final treatment outcome

All confirmed MDR TB cases on MDR TB treatment regimen will have the following outcomes,

1. Cured
2. Completed
3. Died
4. Failed
5. Defaulted
6. MDR TB cases on MDR TB treatment regimen with no outcome assigned

The period of assessment is 12 calendar months (annual cohort) and the indicators are measured 24 months after the end of the year of assessment. All data can be extracted from the MDR TB treatment register.

Annex 1: Flow chart for standard Management for PTB Suspects



Annex 2 - Paediatric TB Score Chart

Feature	0	1	2	3	4	Score
LENGTH OF ILLNESS	< 2	2-4		> 4		
NUTRITION STATUS (% OF WEIGHT FOR AGE)	>80	60-80		< 60		
FAMILY HISTORY OF TB	None	Verbal family history		Proven sputum +ve history		
SIGNIFICANT MANTOUX (.....MM)				Yes		
LYMPH NODES: LARGE, PAINLESS, FIRM, SOFT SINUS IN NECK/ AXILLA				Yes		
NIGHT SWEATS, UNEXPLAINED FEVER			Yes			
ANGLE DEFORMITY OF SPINE					Yes	
MALNUTRITION, NOT IMPROVING AFTER 4 WEEKS				Yes		
JOINT SWELLING, FIRM, NON-FLUID, NON-TRAUMATIC				Yes		
UNEXPLAINED ABDOMINAL MASS, ASCITES				Yes		
COMA FOR MORE THAN 48 HOURS (with or without convulsions) Send to hospital if possible				Yes		
					TOTAL	

Notes:

To identify TB among children, score if the feature (sign or symptom) is present

A score of 7 or more is indicative of TB

Please note that the TB score chart is only a screening tool and not a diagnostic tool for TB

**ANNEX 3: RECOMMENDED TREATMENT REGIMENS AND DOSAGES
USE OF FIXED DOSED COMBINED DRUGS FOR ADULTS**

Category I for all new TB cases

Regimen		Initial Phase (2 months)	Continuation Phase (4 months)
Patient's Weight		2 (HRZE)	4 (HR)
		Daily – 56 total doses	Daily – 112 total doses
		Drugs per adult FDC tablet (Isoniazid[H] 75mg + Rifampicin[R] 150mg + Pyrazinamide[Z] 400mg + ethambutol[E] 275mg)	(Isoniazid [H] 75mg + Rifampicin [R] 150mg)
	30 -39 kg	2	2
	40-54kg	3	3
		4	4
		5	5

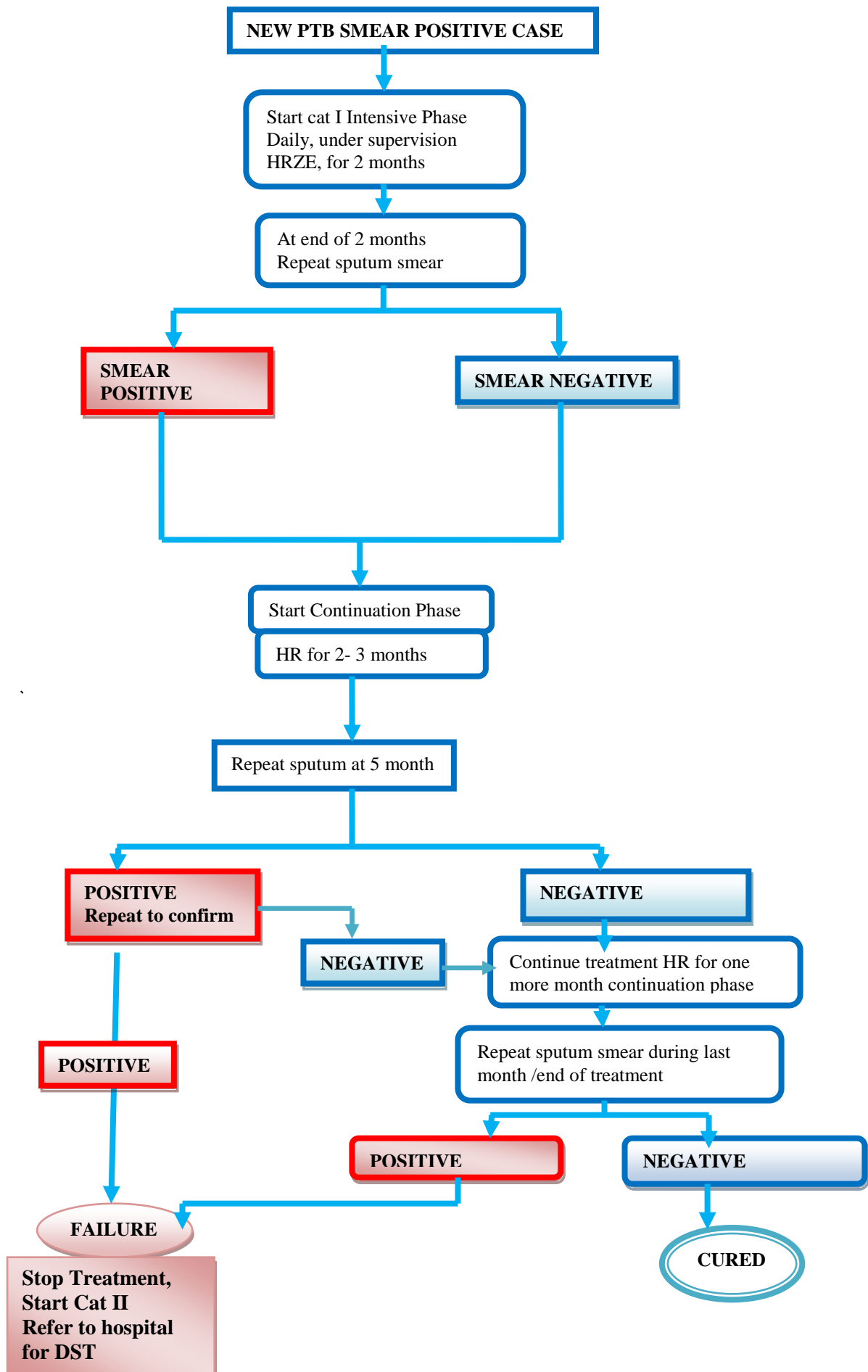
Category II regimen for all retreatment cases

Regimen		Initial Phase (3 months)	Continuation Phase (4 months)	
Patient's Weight		2 (HRZE)S/1(HRZE)	5 (HRE)	
		Daily – 84 total doses of HRZE plus 56 doses of S	Daily – 140 total doses	
		Drugs per adult FDC tablet (Isoniazid[H] 75mg + Rifampicin[R] 150mg + Pyrazinamide[Z] 400mg + ethambutol[E] 275mg)	Streptomycin (vials, IM) 2 months	(Isoniazid [H] 75mg + Rifampicin [R] 150mg + Ethambutol 275mg)
	30 -39 kg	2	0.5mg	2
	40-54kg	3	0.75mg	3
		4	4	
		5	5	

Please note:

- Number of tablets should be changed when a patient's weight increases to the next weight range
- Continuation phase is administered daily.
- Streptomycin is only for the first 2 months and should be stopped after 56 doses.
- * 750mg of streptomycin for patients aged over 60 years even though they weigh over 55kg.
- All treatment should be given under DOT.
- When using Kits, drug boxes used made up for each individual based on their weight.
- See chapter on paediatric TB for paediatric doses.

Annex 4: Flow Chart for management of New Smear Positive Cases



Annex 5 – Flow Chart for management of retreatment smear positive cases

