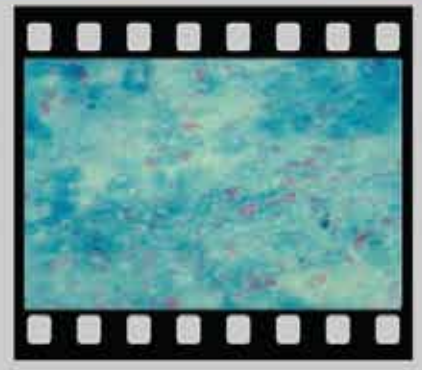
MINISTRY of Health

Shaping Fiji's Health

Tuberculosis Guideline

Clinical diagnosis and management of tuberculosis, and measures for its prevention and control



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DISCLAIMER

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While every effort has been made to ensure that this document is correct and in accordance with current evidence based and clinical practices, the dynamic nature requires that users exercises in all cases independent professional judgement and understand the individual clinical scenario.

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PREFACE

This is the third edition of the technical guide for tuberculosis control in Fiji. The first edition was printed in 1996 and the second in 2004. This edition updates previous editions to current data, health system and practice, as well as treatment and programme recommendations.

The contents of this guide have been developed with reference to the World Health Organisation's Stop TB Department, Australian Respiratory Council and the IUATLD recommendations.

The main objectives of this guideline are:

- To describe global, regional and local TB burden and the strategy for effective TB control;
- To describe standardized treatment regimens according to TB case definitions;
- To demonstrate monitoring and evaluation principles for individual patients and the Programme;
- To provide information on special and emerging situations in TB control

This guideline is aimed primarily at TB clinicians, medical physicians, paediatricians, civil society organizations, but clinical and public health teachers, and students in medical and nursing will also find it helpful.

FOREWORD

There will be a warm welcome to this third edition of the TB guidelines. The first and second editions were printed in 1996 and 2004 respectively, and have been most valuable and extensively used.

The synthesis of this revised version is based on the distressing epidemiology of TB globally and regionally. Further, it was recognized that new diagnostic and therapeutic methods have been discovered, a number of public health challenges have emerged to hinder TB control efforts, and innovative support from civil society institutions have been proved successful in most TB endemic territories.

With the global explosion of HIV, and in some countries much ill-informed and chaotic treatment practices, the world is threatened with an uncontrollable epidemic of TB and MDR-TB. The only way to prevent this is to ensure that the concepts and principles outlined in this guideline are universally applied, both in the public and private sector.

If and when the guidelines contained in this manual are followed, it will then be possible to reach the overall aim of the National Tuberculosis Programme, which is to reduce morbidity, mortality and disease transmission due to TB.

We must therefore make every necessary effort to ensure that this vital objective is indeed achieved. Time is not on our side and the need is urgent. This Guideline must have the widest possible distribution.

Dr Neil Sharma
Minister of Health, Fiji

ABBREVIATIONS

ACSM	Advocacy Communication Social Mobilization
AFB	Acid Fast Bacilli
AIDS	Acquired lmmuno Deficiency Syndrome
ART	Anti-retroviral therapy
BCG	Bacillus Calmette Guerin (TB vaccine)
CSO	Civil Society Organization
DOT	Directly Observed Treatment
DOTS	Directly Observed Treatment Short course
DST	Drug Susceptibility Testing
EPTB	Extra pulmonary tuberculosis
EQA	External Quality Assessment
FDC	Fixed Dose Combination
FPBS	Fiji Pharmaceutical & Biomedical Services
HCW	Health care worker
HIV	Human Immunodeficiency Virus
IPT	Isoniazid preventative therapy
ISTC	International Standards for Tuberculosis Care
IUATLD	International Union against Tuberculosis and Lung Disease
MDR-TB	Multidrug Resistant Tuberculosis
MO	Medical Officer
MOH	Ministry of Health
NGO	Non-Government Organisation
NTP	National Tuberculosis Programme (Fiji)
OCP	Oral contraceptive pill
PAL	Practical Approach to Lung Health
PICT	Pacific Island Countries and Territories
PLWHA	Person living with HIV & AIDS
PTB	Pulmonary Tuberculosis
QMRL	Queenland Mycobacteria Reference Laboratory
SLT	Senior Laboratory Technician
TB	Tuberculosis
TBCO	TB Control Officer
WHO	World Health Organization
XDR-TB	Extensively drug-resistant Tuberculosis

Anti-TB Medicines:

E	Ethambutol
H	Isoniazid
R	Rifampicin
S	Streptomycin
Z	Pyrazinamide

INTRODUCTION

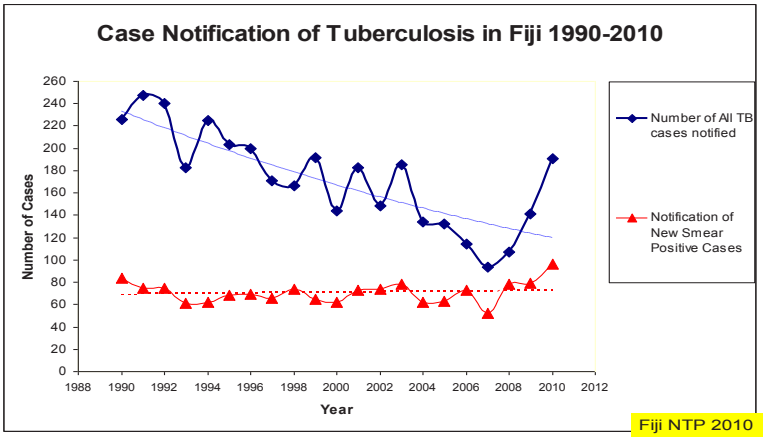
Tuberculosis epidemiology

Globally TB incidence rates are falling in five of WHO's six regions with the exception in the South-East Asia Region, where the incidence rate is stable. If these trends are sustained, the MDG target[1] will be achieved. Between 1995 and 2009, a total of 41 million TB patients were successfully treated in DOTS programmes, and up to 6 million lives were saved including 2 million among women and children.

In 2008, the Pacific had 8% fewer TB cases than 2007 notified to National TB Programmes. Excluding Papua New Guinea (PNG), 1,459 TB cases were notified, a notification rate of 48 per 100,000 of the total population. The numbers and rates of TB cases notified in individual countries and territories varied significantly, ranging from zero in Niue to 387 in Solomon Islands to 13,984 in PNG.

The TB case notification rate continues to decline in Fiji. The case detection and treatment success rates are now above or close to the internationally recommended targets of 70% and 85%, at 95% and 81% respectively. Reasons for a low treatment success rate are varied but can include: an interrupted TB drug supply, limited access to TB clinic services, poorly functioning or non-effective directly observed therapy (DOT), and costs associated with TB treatment. In addition, the rate of death in TB patients and defaulters influences the treatment success rate.

Figure 1. Trend of TB case notification 1990-2010

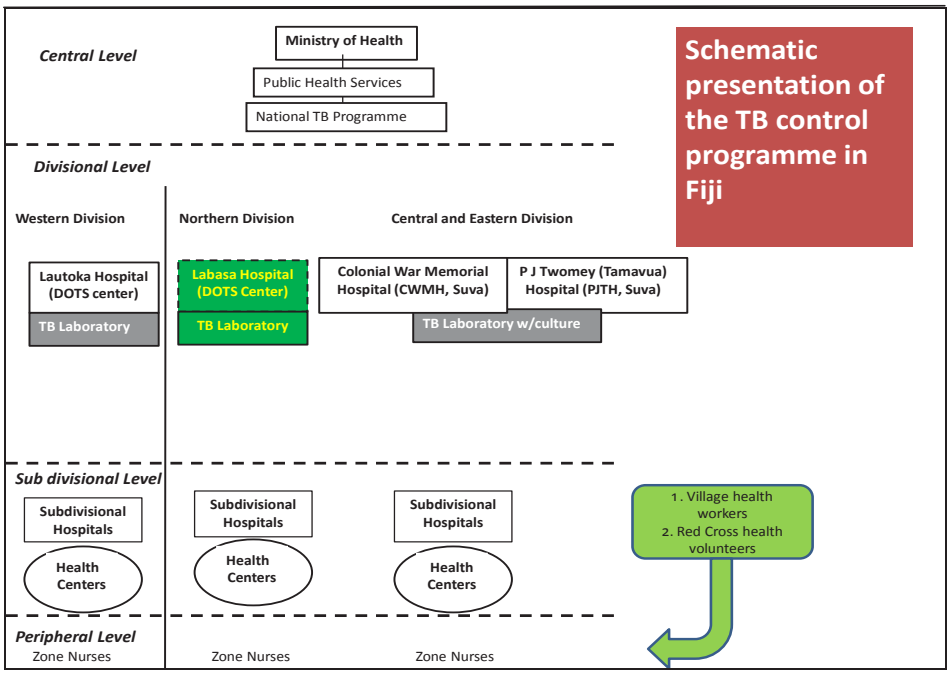


[1] TB incidence is predicted be decrease in 2015 compared to 1990 levels

Structure of the National Tuberculosis Programme

Currently there are three (3) DOTS centres in Fiji which are located in Labasa, Lautoka and Tamavua-Twomey hospitals that take charge of TB control activities in the North, West and Central/East respectively. The Fiji National Tuberculosis Programme (NTP) was established in late 1940s and adopted the DOTS strategy in 1997.

Figure 2. Fiji NTP Structure



Objectives of the National Tuberculosis Programme

- To reduce the impact of tuberculosis until it is no longer a public health problem
- To limit the number of re-treatment case to an acceptable minimum (10%)
- To effectively address emerging issues in TB control such as MDR-TB, TB/HIV co-infection, TB among children and TB in high risk populations
- To address TB care and control in high risk populations
- To engage all health care providers

Targets of the National Tuberculosis Programme

- To maintain the treatment success rate (of smear positive cases) at >85%
- To increase case detection rate of smear positive TB up to >70%

Strategies of the National Tuberculosis Programme

- To pursue high quality DOTS in all Divisions;
- To introduce Fixed Dose Combinations (FDCs) for first-line TB drugs;
- To formalize Public-Private Mix for TB care and control through an improved referral system;
- To empower people with TB and communities;
- To increase case finding activities at rural communities through mobilization of community health care workers and volunteers;
- To improve supervised treatment during the continuation phase close to the patient through mobilization of health care workers and volunteers.

To implement this strategy the TB control programme envisages to:

- Be fully integrated in the general health care structure, including at the periphery;
- Be effective nation-wide, reaching rural and urban populations;
- Be permanent; and
- adapted to the needs of the people. TB services should be as close to the community as possible for both diagnostic and treatment services.

The Ministry of Health in Fiji has followed the principles of the WHO recommended DOTS strategy successfully since 1997.

The five elements of the DOTS strategy are:

- Sustained political commitment
- For case detection access to quality assured TB sputum microscopy
- Standardised short course chemotherapy for all cases of diagnosed TB under proper case management conditions, including direct observation of treatment
- Uninterrupted supply of quality anti-TB drugs for the duration of treatment for each patient
- Recording and reporting system enabling outcome assessment of every patient as well as of the overall programme performance

TB PROGRAM ELEMENTS

1.1. Detecting and diagnosing people with tuberculosis

The major strategy for detecting tuberculosis in Fiji is to ensure that all people with symptoms of TB are identified as TB suspects and appropriately investigated. For this to be achieved the following public health interventions must be applied:

- Community awareness of symptoms that should lead them to seek health care;
- Community awareness of appropriate health care workers to attend;
- Knowledge of the symptoms of TB among ALL health care workers including village health workers, volunteers, and traditional healers.
- Capacity of health care workers to collect and dispatch sputum specimens (or slides) of TB suspects to the nearest microscopy center;
- Laboratory capacity for high quality sputum microscopy and culture.

The implementation of this strategy for detecting and diagnosing people with tuberculosis should be integrated with the implementation of the Practical Approach to Lung Health (PAL).

1.1.1. TB suspects

Any person who with symptoms or signs suggestive of TB should be investigated for tuberculosis. The most common symptom of pulmonary TB is a **productive cough for more than 2 weeks**, which may be accompanied by

- other respiratory symptoms including shortness of breath, chest pains, coughing up blood (haemoptysis) and/or
- constitutional symptoms including loss of appetite, weight loss, fever, night sweats, and fatigue.

TB Suspect: Cough >2weeks, breathlessness, chest pain, haemoptysis, fever, night sweats, and fatigue.

1.1.2. Investigation of TB suspects

Patients who are TB suspects should be investigated for TB. Those who live near a DOTS centre should be referred for appropriate care and follow up. However, those who would take more than one day to travel to the DOTS centre, who are too sick to travel, or cannot afford to travel should have the initial investigations performed at the hospital or health centre nearest to where they live.

Two sputum specimens should be collected, using the method decribed below. One is collected immediately (spot), when the patient is first seen. The second specimen should be collected the following morning. If this is not feasible, then the patient should be asked to wait at the health facility, and produce a second specimen one or two hours after the first specimen.

Sputum specimens:
1. Spot (collected immediately during first consultation)
2. Early morning sample (collected the following morning)

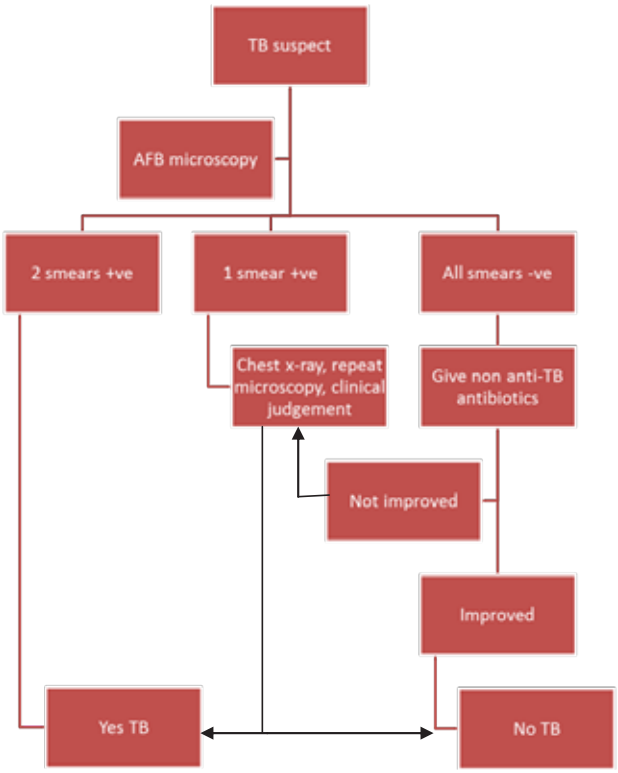
These specimens should be transported to the nearest DOTS or microscopy centre for slide preparation and examination. The responsible DOTS centre should then transfer the original sputum specimen to the DOTS centre in Suva (at Tamavua-Twomey Hospital) for culture. The cost of sputum transport should be borne by the NTP. Fo interior mainland or remote island settings it is advisable to transport fixed slides after performing slide preparation.

The sputum specimen should reach the DOTS centre within two days of collection. When this is not possible, then sputum should be sent to the nearest facility where preparation and fixation of slides could be done and and later sent to the DOTS centre for staining and microscopy. **In these circumstances it will not be possible to perform TB culture.**

TB suspects whose sputum microscopy is negative should be referred to the nearest Health Centre or sub-divisional hospital (if initially seen at a more peripheral level). They should receive a course of simple antibiotics. If the symptoms do not resolve with this treatment they should be referred to the nearest DOTS centre with x-ray facilities where they can be investigated for smear negative TB.

nearest DOTS centre with x-ray facilities where they can be investigated for smear negative TB.

Figure 3. Diagnostic algorithm for a suspected case of Pulmonary TB



1.1.2.1. Standard procedures for sputum collection, processing, transport

- Fill in the form "Request for sputum examination" (Tub 3 - See Appendix 3). Write the registration number and name of the patient on the form and on the side of the sputum cup.
- Demonstrate to the patient how a good sputum specimen is produced by taking a deep breath and coughing deeply.
- Find an outdoor location, away from others, for the patient to expectorate sputum into the sputum container. For children, the use of nebulizers may help in stimulating the airways in order to obtain a good sputum sample.
- Ask the patient to screw the lid onto the container before returning it you.
- Make sure that the lid on the container is firmly close. Place the container inside a plastic bag. Wash your hands.

- When two specimens have been collected, send both the specimens together with the request form to the laboratory as soon as possible. If it cannot be despatched immediately store in a fridge if one is available or a cool place if there is no fridge.
- The specimen should be sent to the nearest DOTS centre within two days.

1.1.2.2 Laboratory services

The details of laboratory procedures are beyond the scope of this guide and should be dealt with in a separate Manual of Laboratory Procedures.

a) Microscopy

All health care technical staff should be trained to fix sputum smears on microscopy slides and transport them to the nearest DOTS microscopy centre. All three DOTS microscopy centres should:

- Perform AFB microscopy
- Provide a written report on all AFB microscopy results (positive and negative) to the referring HCW.
- Enter the results of all AFB microscopy performed on TB suspects onto standard Laboratory register on a daily basis.
- Send replacement sputum containers and request forms to each site that submits sputum specimens for examination on a quarterly schedule.

b) Sputum culture

Sputum culture remains the gold standard procedure to diagnose TB however it takes 6-8 weeks to obtain results hence clinical dependency on microscopy yield to determine earliest and appropriate intervention. TB culture is only performed at the Central-Eastern DOTS centre (at Tamavua-Twomey Hospital). At least one (1) diagnostic sputum specimen of all the TB suspects should be sent to Daulako Mycobacterium Laboratory (at Tamavua-Twomey Hospital) for culture.

c) Drug Susceptibility Testing (DST)

Drug susceptibility testing is not yet routinely available in Fiji but plans are underway to carry out advance TB diagnostic tests (such as DST & GeneXpert) in the year 2012. However, specimens can be referred to the Queensland Mycobacterial Reference Laboratory in Brisbane for DST. This should be done for:

- Those who come from areas with high endemicity of MDR-TB
- Re-treatment cases and their contacts
- Cases that remain smear positive after 3 months of TB chemotherapy
- Cases that have been contacts of patients with known MDR-TB

d) Xpert MTB/RIF

The Xpert MTB/RIF test offers a potential solution for improving TB diagnosis. A single Xpert MTB/RIF test is able to confirm active disease among both smear positive and negative TB patients whilst concurrently testing for **rifampicin** resistance, thus identifying patients who need second-line drug treatment. AFB microscopy remains to be the first line mode of TB diagnosis considering the cost and time factor for Xpert MTB/RIF and culture respectively.

Sputum samples eligible for Xpert MTB/RIF test:

- All diagnostic smear positive sputum samples to ascertain TB disease and to rule out rifampicin resistance
- Diagnostic smear negative sputum samples as decided by the clinician
- For patients with abnormal chest X-ray or as decided by clinician

e) Quality assurance

i) Quality Assurance for microscopy

All three DOTS centers and microscopy units of Divisional hospitals participate in External Quality Assurance (EQA). This is achieved by sending selected AFB slides to the Senior Lab Technician (SLT) who is based at the Daulako Mycobacteria Laboratory in Tamavua-Twomey hospital for viewing. The NTP office sends selected slides from the Dauloka Mycobacteriance Laboratory at the Tamavua-Twomey hospital to QMRL on a quarterly rota for EQA purposes.

Panel testing: Ten(10) prepared slides are sent by QMRL to all labs that perform microscopy in Fiji annually. Lab technologists from the four microscopy centers[2] who receive prepared slides read and send their findings to the laboratory scientists at QMRL for verification of results reported. Findings at all stages for EQA are exchanged among the respective officers to ascertain quality of microscopy services in Fiji.

ii) Quality Assurance for culture

Daulako Mycobacterial Laboratory (based at Tamavua-Twomey Hospital) performs culture for diagnostic purposes on all specimens (sputum & body fluids) received from referring clinicians. Plans are underway to implement quality assurance for culture procedures conducted at National level in collaboration with QMRL.

[2]All three DOTS centers & CWM hospital laboratory

1.1.2.3 Other investigations

a) Radiology

Tuberculosis should be diagnosed whenever possible by clinical evaluation and sputum examination. Chest X-ray examination is valuable for sputum smear negative cases. Chest X-ray findings suggestive of pulmonary TB in patients with a sputum smear negative result should always be supported by physical examination findings and a clinician should decide on the diagnosis.

X-ray may be helpful in assessing the extent of lung damage in complicated cases. It is also important in the diagnosis of tuberculosis in children and extra-pulmonary TB.

b) Tuberculin skin test

Tuberculin skin test (TST or Mantoux test) detects tuberculosis **infection only**. TST is **not** a test to diagnose active TB disease.

This is relevant to support the decision to give isoniazid for treatment of **latent** tuberculosis infection (Isoniazid Preventative Therapy). It has **no role** in the initial investigation of patients with suspected pulmonary tuberculosis.

1.1.3 Case definitions and classification

A case of tuberculosis. A patient who is AFB smear positive and/or AFB culture positive or in whom the medical officer has diagnosed TB and has decided to treat with a full course of treatment. It should be noted that current techniques do not allow non-tuberculous mycobacteria to be distinguished from *M. tuberculosis* in Fiji. Hence, this case definition may overestimate the burden of TB. However, these cases will be identified as non-tuberculous if they do not respond to treatment and specimens are referred to QMRL for DST. Cases of tuberculosis are further classified according to the **anatomical site** of disease, **bacteriological status** and the **history of previous treatment**.

This classification is important for:

- Selecting appropriate treatment regimens
- Patient registration and notification, which is relevant to analysis of treatment outcomes and evaluation of program performance

a) Anatomical site of disease

Pulmonary tuberculosis refers to a case of TB involving the lung parenchyma (including miliary tuberculosis). All other cases where the lung parenchyma is not involved (include intrathoracic lymphadenopathy and pleural effusions) are classified as extra-pulmonary tuberculosis (EPTB).

Diagnosis should be based on history and examination findings, histological evaluation or strong clinical evidence consistent with active EPTB, followed by a decision by a clinician to treat with a full course of tuberculosis chemotherapy.

b) Bacteriological classification

A case of pulmonary TB is classified as **smear positive** if one or more sputum specimens collected at the start of treatment are positive for AFBs on microscopy. A case of pulmonary TB is classified as **smear negative** if at least two sputum specimens collected at the start of treatment are negative for AFBs on microscopy AND either:

- sputum culture is positive for *M. tuberculosis*, or
- decision by a clinician to treat with a full course of anti-TB therapy
- radiographic abnormalities consistent with active pulmonary TB
- no improvement in response to a course of broad-spectrum antibiotics (excluding anti-TB drugs and fluoroquinolones and aminoglycosides).

c) History of previous treatment

At the time of registration each patient meeting the case definition is classified according to whether or not he or she has previously received TB treatment and, if so, the outcome.

The following definitions are used:

New. These are patients who have never had any treatment for TB or who have taken anti-TB drugs for not more than a month.

Relapse. A patient previously treated for TB who has been declared cured or treatment completed, and is diagnosed with bacteriological positive (smear or culture) TB.

Treatment after default. A patient who returns to treatment, positive bacteriologically, following interruption of treatment for 2 months or more.

Treatment after failure. A patient who is started on a re-treatment regimen after having failed previous treatment.

Transfer in. A patient who has been transferred from another TB register to continue treatment.

1.1.4 TB in children

The risk of TB in children is exposure to an active case of (smear positive) tuberculosis in the household.

Symptoms of TB in children include

- Unexplained **weight loss** or failure to grow normally (failure to thrive)
- Unexplained **fever**, especially when it last for more than two weeks
- Chronic **cough**

Signs of TB include

- Fast and shallow breathing (as in Pleural effusion)
- Enlarged non-tender lymph nodes, especially in the neck
- Signs of meningitis (with spinal fluid containing mostly lymphocytes, low glucose and elevated protein)
- Abdominal swelling with or without palpable lumps
- Progressive swelling or deformity in a bone or joint (including the spine)

The diagnosis of intrathoracic (i.e. pulmonary, pleural, and mediastinal or hilar lymph node) tuberculosis in symptomatic children with negative sputum smears should be based on the finding of chest radiographic abnormalities consistent with tuberculosis and either a history of exposure to an infectious case or evidence of tuberculosis infection (positive tuberculin skin test). Sputum specimens should be obtained (by expectoration, gastric washings, or induced sputum) for AFB microscopy and culture.

1.1.5 Active case finding (screening) in high risk groups

At present there is no formal programme of active case finding by x-ray screening in Fiji. However, operational research projects to establish the role of active case finding in high risk groups are being planned by the NTP. A necessary pre-condition for active case finding is the availability of an x-ray facility that is accessible to the population in whom screening is to be undertaken.

1.1.5.1 Contact screening

All care providers for patients with Tuberculosis should ensure that persons (especially if symptoms suggestive of TB, children <5years of age, persons with HIV infection, and contacts to MDR/XDR-TB) who are in close contact with patients who have infectious TB are screened and attended to accordingly.

The key objectives of screening are to assess if the contact:

- has undiagnosed TB
- is at high risk of developing TB if infected.
- is at high risk of having been infected by the index case

Priorities in contact screening	
Higher risk of acquiring TB infection	**Higher risk of developing TB disease**
Close contacts of smear positive PTB	Children <5years of age
People with HIV infection	People with HIV infection
People who are highly exposed to smear +ve PTB	People with other conditions that suppress immunity (Diabetics, those malignant disorders etc)

a) Adult contacts

- Assess all household members for signs and symptoms suggestive of TB disease using criteria in Page 11,(1.1.1)
- If signs & symptoms are present refer TB suspects for proper work up: Sputum examination +/- chest x-ray (if resources permit)
- Tuberculin skin testing (Mantoux test) could be used to determine the presence of latent TB infection (LTBI) if a contact is cleared from clinical and investigation assessments stated above. A positive TST varies among contacts: i) >5mm induration for immune-suppressed contacts (eg PLWHA, malnourished, diabetics); ii) >10mm indurated for all other contacts
- Once active TB is excluded, Isoniazid(INH) preventive therapy may be given to contacts with presumed or diagnosed with LTBI based on clinical and TST results. Recommended regimen:

-INH 5mg/kg (max 300mg) daily for six months administered under DOT strategy with Pyridoxine (vitamin B6) 10-20mg/day .

Screening methodology: Clinical assessment for TB related symptoms; chest x-ray; and sputum smear microscopy. TST may help in establishing previous exposure (+infection) with *M. tuberculosis*

b) Children contacts (<5years old)

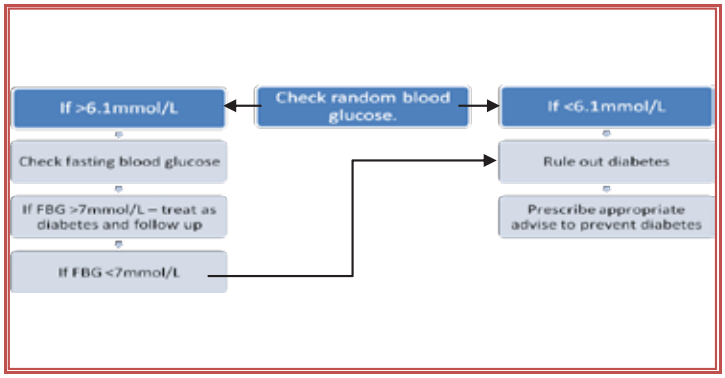
At this stage targeted treatment of latent tuberculosis infection in Fiji is only recommended for children aged <5 years who are household contacts of patients with smear positive pulmonary tuberculosis. These children should be seen as soon as possible after the index (smear positive) case is diagnosed. They should have a chest x-ray and clinical review to exclude active TB. As TB may progress rapidly in young children it is recommended that **ALL** such children (in whom active TB is excluded) are commenced.

Isoniazid preventative therapy.
The dose of isoniazid is 5mg/kg daily for at least 6 (maximum 9) months.

c) TB screening among Diabetics and vice versa

Type 2 diabetes involving chronic high blood sugar, is associated with altered immune response to TB. This leads to patients with diabetes and TB take longer to respond to anti-TB treatment. Patients with active tuberculosis and Type 2 diabetes are more likely to have multi-drug resistant TB. The Fiji NTP promotes screening for diabetes for all registered TB cases and vice versa. This is achieved through a robust collaborative initiative with the NCD unit of MOH, Divisional and sub-divisional hospitals.**(Standard TB screening procedures must be applied to known cases of diabetes depending on resources available at the respective levels of care.)** On the other hand, all confirmed TB patients **must be screened** for diabetes on the day of enlistment at a DOTS centre. The following assessment protocol should be applied:

- If known diabetic – ensure proper control of blood glucose with diet and prescribed medications
- If unknown diabetic:



d) TB Screening among PLWHA

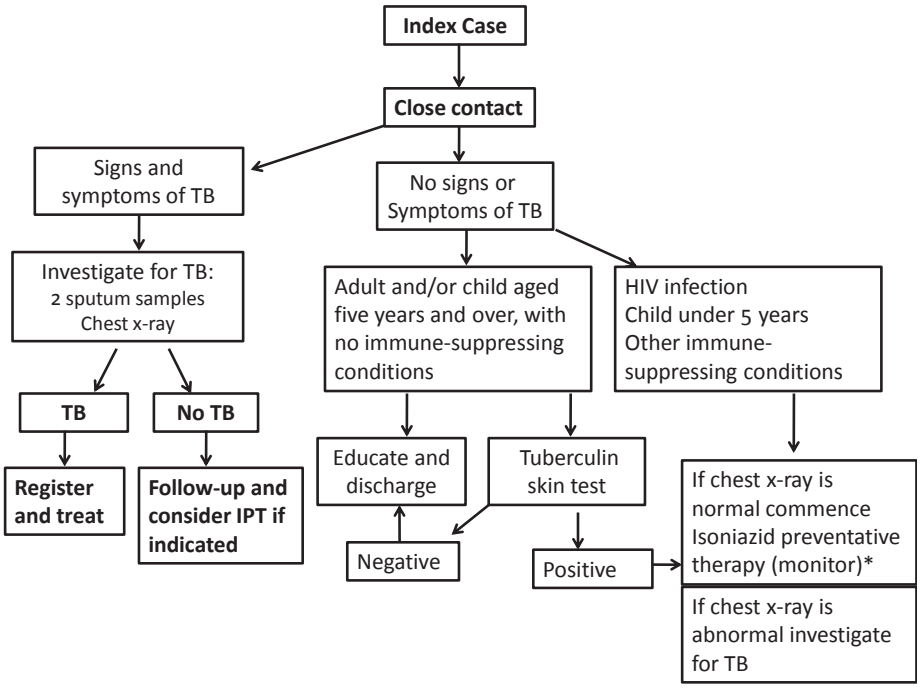
People living with **HIV infection** who are also **infected with TB** are at greater risk of developing **active TB**. The clinical features of TB in people with HIV infection may be atypical. Extrapulmonary and disseminated TB disease are common among PLWHA. PLWHA should be thoroughly screened for active TB disease before considering the administration of Isoniazid preventative therapy (IPT). Standard screening techniques above **[1.1.5.1 (a)]** apply.

e) TB screening in Prisons & Correctional Facilities

All Prisons & Correctional facilities should designate a person or a working group with experience in infection control, occupational health and building design to be responsible for the TB infection-control program. These persons should have the capacity and authority to develop, implement, enforce, and evaluate TB infection-control policies in collaboration with NTP. The detail of TB control in Correctional facilities is beyond the scope of this Guideline. Standard screening protocol **[as in 1.1.5.1 (a)]** is used to identify persons who have active TB disease or latent TB infection:

- All correctional facility employees and inmates who have suspected or confirmed TB disease should be identified promptly, and the case(s) or suspected case(s) should be reported to the nearest Public health facility or DOTS center.
- Employees and long-term inmates infected with *M*. tuberculosis (i.e., those who have positive skin-test results) should be identified and evaluated for Isoniazid preventive therapy.

Figure 4.Contact screening procedure



1.1.11 The role of Civil Society & Private health care providers in case finding

The NTP promotes the participation of community/faith based, civil society organizations and private health care facilities[3] to support national efforts to scale up TB case detection.

a) Community/faith based, civil society groups and private health care facilities should:

- Follow national guidelines to detect TB
- Refer all TB suspects to the nearest DOTS center or public health facility for diagnosis and treatment
- Report on programme activities using MOH systems
- Neither possess nor sell anti-TB medicines
- Communicate promptly with the NTP regarding defaulters and absentees

b) The NTP should:

- Take overall responsibility to work up suspects referred from community/faith based, civil society organizations and private health care facilities, to confirm or rule out TB and to design and apply the appropriate treatment regimen
- Supply anti-TB medicines supplies free of charge to civil society organizations and private health care facilities with adequate shelf life and establish a reliable system for re-supply (in events where the patient opts for care by private health care provider or CSO rep
- Supply reporting and recording formats to community/faith based, civil society organizations and private health care facilities
- In collaboration with community/faith based, civil society organizations and private health care facilities carry out ACSM[4] activities that aim to improve attitude, behaviour and practice to control TB in Fiji
- Monitor and report on community based DOT activities on a quarterly and annual basis.
- Lead and provide capacity development opportunities for communities on TB –DOT care.

[3] Privately administered health centers & pharmacy outlets

[4] Advocacy Communication Social Mobilization

1.2 TREATMENT OF PEOPLE WITH TUBERCULOSIS

1.2.1 Registering the case and initiating treatment

All patients diagnosed with tuberculosis must be registered by the Divisional TB control officer right after diagnosis and at the start of treatment. A unique registration number is assigned for each new patient. Details of the registration procedure are enclosed in the TB register (Appendix 5).

A treatment card is completed and a TB identity card is given to the patient upon registration. In the event the diagnosis of TB is made at a regional or peripheral location, the patient is transfered to the nearest DOTS center for commencement of intensive phase of treatment.

1.2.2 Recommended regimens

NTP now uses Fixed Dose Combination (GDF Kits-antiTB medicines) for intensive and continuation phase of treatment. Regimens are available for adults and children and for new patient and re-treatment cases. The regimens below are based on FDC preparations. For adults these are available in patient kits which should be supplied for individual patients. Paediatric preparations are available upon request from FPBS.

1.2.2.1 New cases

a) Adults and children > 30kg Table 1. Standard regimen: 2RHZE/4RH

Treatment phase	Essential anti-TB medicine	Dosage (mg/kg)
Intensive	Rifampicin (R)	10
	Isoniazid (H)	5
	Pyrazinamide (Z)	25
	Ethambutol (E)	15
Continuation	Rifampicin (R)	10
	Isoniazid (H)	5

b) Children < 30 kg

Regimen: 2RHZ/4RH or 2RHZE/4RH

Table 2. Children between 5kg and 20kg (without ethambutol)

	Intensive Phase (2 months)		Continuation phase (4 months)	
Weight	R 30 H 30 Z 150	R 60 H 60	R 60 H 30	R 60 H 60
5 to 7 kg	1	1	1	1
8 to 14 kg	2	1	2	1
15 to 20 kg	3	2	3	2

Table 3. Children between 5kg and 20kg (with ethambutol)

	Intensive Phase (2 months)			Continuation phase (4 months)	
Weight	R 30 H 30 Z 150	R 60 H 60	E 100	R 60 H 30	R 60 H 60
5 to 7 kg	1	1	1	1	1
8 to 14 kg	2	1	2	2	1
15 to 20 kg	3	2	3	3	2

Table 4. Children between 21kg and 30kg without ethambutol

	Intensive Phase (2 months)			Continuation phase (4 months)	
Weight	R 150 H 75	R 60 H 60	Z	R 150 H 75	R 60 H 60
5 to 7 kg	2	2	2	2	2

Table 5. Children between 21kg and 30kg with ethambutol

	Intensive Phase (2 months)		Continuation phase (4 months)	
Weight	R 150 H 75 Z 400 E 275	R 60 H 60	R 150 H 75	R 60 H 60
21 to 30 kg	2	2	2	2

1.2.2.2 Re-treatment cases

All re-treatment patients should have cultures sent to the QMRL in Brisbane for DST. While awaiting the results of DST, re-treatment patients who have defaulted or relapsed after their first treatment regimen should be started on the **standard re-treatment regimen**. The treatment regimen should be adjusted on the basis of DST when results are available.

Table 6. Standard re-treatment regimen: 2RHZES/1RHZE/5RHE

Treatment phase	Intensive phase (2months)	Intensive phase (1month)	Continuation phase (5months)
Regimen*	Rifampicin Isoniazid Pyrazinamide Ethambutol **Streptomycin**	Rifampicin Isoniazid Pyrazinamide Ethambutol	Rifamipicin (5) Isoniazid (5) Ethambutol (5)

For doses refer to 3.2.2.1 above.

- **If the organism is confirmed as fully-susceptible** to the standard first-line drugs then the re-treatment regimen should be continued.
- Streptomycin is ceased after two months, the other intensive phase therapy (rifampicin, isoniazid, pyrazinamide and ethambutol) is continued for a third month.
- The standard continuation phase (rifampicin,isoniazid & ethambutol) then begins and continues for five months. This regimen totals at least 8 months. **Streptomycin should not be used in children, in pregnant women or people with renal failure.**

1.2.2.3 MDR-TB

Fiji has never encountered a case of MDR-TB. However, the NTP has the capacity to recognise and diagnose MDR-TB, should it occur. If MDR-TB is suspected, on the basis of treatment failure, or confirmed on DST then consultation with an expert (through WHO) in the management of MDR-TB is advised. The patient should be placed in a **single room with respiratory isolation precautions** in one of the three(3) DOTS centers. **Usually, it is safest to withhold second-line drugs until susceptibility is confirmed on DST. Emperical regimens of second line drugs will be used for the MDR-TB patients based on the DST results.**

1.2.2.4 Regimens for extra-pulmonary tuberculosis

The regimens described above are given for all forms of tuberculosis except that the continuation phase should be extended to 10-12 months (or directed by the TBCO) in patients with miliary, meningeal, and bone or osteo-articular tuberculosis. Patients with tuberculous pericarditis or tuberculous meningitis should receive **prednisone for the first 10 – 12 weeks of therapy. The dose should start at 50 mg daily (1 mg/kg/day in children) and taper of this period.**

1.2.2.5 Regimens for patients with liver disease or renal failure

Standard TB treatment can be administered to patients with mild abnormalities of liver function. However, expert consultation is recommended before embarking on treatment of TB in patients with severe underlying liver disease. For patients with renal failure or severely impaired renal function it is recommended that **ethambutol and pyrazinamide are given only three times per week (in the standard doses).** This means that, during the intensive phase, the regimen described above is given three days per week and on the remaining four days per week, the four drug FDC is replaced by rifampicin 150 / isoniazid 75 FDC.

1.2.3 Ensuring adherence

Every dose of chemotherapy taken by a patient with tuberculosis should be directly observed by an appointed DOT supervisor. At present this is being achieved during the intensive phase by keeping all patients in hospital throughout this phase. It is not generally being achieved during the continuation phase. The implementation of strategies to ensure direct observation of therapy during the intensive phase is a high priority. This should be accompanied by implementation of strategies to enable direct observation of treatment in the community during the intensive phase.

1.2.3.1 Strategies for direct observation of therapy (DOT) in the community

All patients who do not otherwise need to be hospitalised for medical reasons can be treated in the community, **in either or both the intensive phase and the continuation phase**. Patients who do NOT adhere to DOT will need to be hospitalised for supervised treatment. A range of alternative strategies will be required to enable DOT in the community. These may include:

- Requiring patients to attend a nearest health or DOTS centre for treatment
- Arranging for zone nurses to visit patients at home on a fortnightly basis to supervise implementation of DOT.
- Arranging for DOT to be administered by peripheral health centres or nursing stations.
- Arranging for DOT to be administered by trained community based volunteers from civil society (such as Red Cross), village health workers or faith based organisations.
- Arranging for DOT to be administered by traditional healers in the village dispensary.
- Identifying other appropriate, independent and trustworthy individuals who can deliver DOT in the village setting.

The Divisional TBCO should identify the appropriate DOT supervisor, in consultation with local health staff and other civic leaders, at the time of commencing therapy or prior to discharge from hospital. The Divisional TBCO will need to ensure that the designated TB supervisor receives:

- Motivation and instruction about DOT
- Advice about how to report non-adherence
- Advice on adverse effects and how to report them
- Treatment cards
- The appropriate medication supply (kits) for the patient
- A contact number for assistance

During the continuation phase, daily regimens should be used, to implement DOT. Where DOT supervision is undertaken by non-health system staff, the Zone nurse responsible should make a fortnightly visit to supervise the DOT process and more importantly to obtain regular update regarding patient's progress.

1.2.3.2 Defaulter tracing

- The peripheral health staff (particularly zone nurses) should organise the tracing of patients who are reported by their DOT supervisors to have missed more than one dose during the intensive phase or more than one week of treatment during the continuation phase.
- The Divisional TBCO and the Divisional Medical Officer should be made aware of all such cases. Priority must always be given to smear positive TB patients.
- If the patient is absent for more than two months, he or she is declared a **defaulter** and his/her sputum must be investigated again. Such patients should be re-admitted to hospital to undergo **re-treatment** regimen.

1.2.3.3 Clinical monitoring of treatment

- Patients should have regular medical monitoring planned by the responsible TB medical officer.
- This should include medical examination, particularly on biochemical assays for liver, kidney and hematological functions, at the DOTS centre at least at the end of the intensive phase and at the end of treatment.
- The patients should bring his/her treatment card to all these appointments.

1.2.3.4 Bacteriological monitoring of patients

Sputum smear examinations should be performed:

- at the end of the intensive phase, that is, **two** months for new patients and **three** months for the standard, non-MDR, re-treatment regimen;
- at the end of three months if they were smear positive at the two month examination;
- one month before the end of treatment, that is, five months for new patients and seven months for the standard, non-MDR, re-treatment regimen. (This only applies patients who were smear positive at the start of treatment).
- Patients with positive sputum smears at the end of three months or one month before the end of treatment should have specimens sent for culture and DST.

1.2.4 Adverse events (side-effects) & drug interactions

- Patients with HIV infection, alcohol dependency, malnutrition, diabetes, chronic liver disease or renal failure as well as pregnant or breastfeeding women should receive pyridoxine (vitamin B6) throughout their course of treatment to prevent peripheral neuropathy.
- Patients taking the oral contraceptive pill (OCP) should be advised to use alternative means of contraception during TB treatment as rifampicin makes the OCP unreliable.
- Patients should be warned that their urine will turn orange and advised that they should not be alarmed.
- Patients should be informed of the more common or serious side effects of treatment at the time they commence on treatment.

Table 7. Symptom based approach to side effects of anti-TB drugs.

SIDE EFFECT	ANTI-TB DRUG RESPONSIBLE	MANAGEMENT
Minor		**Continue anti-TB drugs, check doses**
Anorexia, nausea, abdominal pain	R, Z	Give drugs with small meals or last thing at night.
Joint pains	Z	Aspirin
Burning sensation in feet, Orange/red urine	H, R	Pyridoxine 100mg daily Reassurance
Major		**Stop responsible drug(s)**
Itching, skin rash	H, R, Z, S	Stop anti-TB
Deafness, no wax on auroscopy	S	Stop S, use E
Dizziness (vertigo & nystagmus)	S	Stop S, use E
Jaundice (other causes excluded)	H, Z, R	Stop anti-TB drugs
Confusion (acute liver failure if jaundice is present)	Most anti-TB drugs	Stop anti-TB drugs, urgent LFTs & PTTK
Visual impairment (other causes excluded)	E	Stop E
Shock, purpura, acute renal failure	R	Stop R

1.2.5 Co-management of HIV and active TB disease

1.2.5.1 HIV pre-test counselling should be offered to all newly diagnosed cases of TB by a health care worker trained in provider intitiated counselling & testing (approved by PSH) who is responsible for their care. HIV testing must be aligned with the new HIV Decree in Fiji.

1.2.5.2 Standard TB treatment regimens should be implemented without delay for all patients with HIV infection who are diagnosed with tuberculosis. Daily therapy should be administered throughout both intensive and continuation phases. TB treatment should be observed daily for HIV infected TB patients either at DOTS centres or if this is not feasible by zone nurses in both the intensive and continuation phase of treatment.

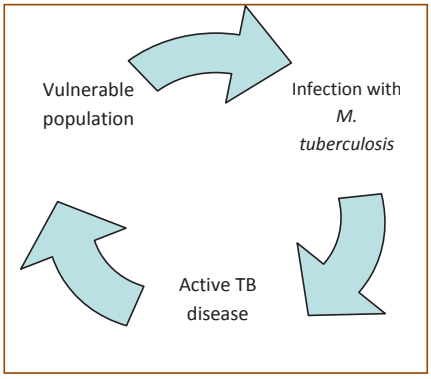
1.2.5.3 Co-trimoxazole preventive therapy should be provided to all HIV-infected TB patients at the time of diagnosis and should be available at both TB and HIV care facilities.

1.2.5.4 All TB patients with a positive HIV test should be discussed with HIV care facilities for appropriate anti-retroviral therapy (ART). ART should be commenced as soon as possible and within eight weeks of commencing TB treatment. The administration of ART must follow standardised national HIV guidelines.

Adverse drug effects are common in HIV-positive TB patients, and some toxicities are common to both ART, co-trimoxazole and TB drugs. Careful monitoring for adverse events is important.
All adverse drug reactions must be reported by the responsible health worker and shared with FPBS

1.3 PREVENTING TUBERCULOSIS

The prevention of TB involves the protection of the population vulnerable from infection and suppressing the development of active disease among those already infected with *M. tuberculosis.*



1.3.1 Infection control

The goal of infection control activities is to **minimise the risk of TB transmission.** The principles outlined in the "MOH-Infection Control Manual for Health facilities" should be applied at all times. With respect to TB, as a matter of priority, all patients diagnosed with or suspected of having TB must be separated from other patients, placed in adequately ventilated areas, educated on cough etiquette and respiratory hygiene, and assessed for risk for TB transmission.

- All patients with TB or suspected TB should be categorised as having a high, medium, low or negligible risk for transmission of TB. This will guide isolation requirements for the TB patient or suspect.
- All care should be taken to minimise the exposure of non-infected patients (in particular, those who are immunocompromised) to TB. Patients living with HIV or with strong clinical evidence of HIV infection, or with other forms of immunosuppression, should be physically **separated** from those with suspected or confirmed infectious TB.
- To minimise the spread of droplet nuclei, patients with or suspected of having TB, should be educated in cough etiquette and respiratory hygiene that is, in the need to cover their nose and mouth using a piece of cloth, tissue or surgical mask when sneezing and or coughing. The cloth, tissue or a surgical mask should be disposed of as infectious waste.

1.3.1.1 Isolation

Each DOTS centre or hospital caring for patients with tuberculosis should have well ventilated rooms suitable for housing patients with TB. Airborne precautions should be implemented when these rooms are occupied.

DOTS centers should also have a few isolation rooms with acceptable standards for housing the following patients:

- People suspected of having infectious drug resistant TB. These are all re-treatment or treatment failure cases. They should be accommodated in a single room until MDR-TB is excluded by DST.
- People with confirmed MDR-TB or XDR-TB. They should remain in a single room until sputum is culture negative.
  While patients are in isolation (they are considered infectious).
- Contact with visitors should be minimised (or appropriate infection control measures adhered to),
- Visitors who are less than 5 years of age or those who are immuno-suppressed (eg HIV) should be discouraged from visiting patients in the isolation room
- Patients should wear surgical masks (not N95 masks) to reduce the risk of transmission when they are not in isolation rooms eg during transportation.
- Mothers with infectious TB should wear surgical masks if/when caring for their infants eg breastfeeding.

1.3.1.2 Use of N95 masks

Personal protective equipment should be used by health workers and visitors in situations where there is an increased risk of transmission to reduce the risk of infection or re-infection with TB. These situations include:

- Those entering the isolation rooms described above;
- HCWs performing or attending aerosol-generating procedures associated with high risk of TB transmission (e.g. bronchoscopy, intubation, sputum induction procedures, aspiration of respiratory secretions, and autopsy or lung surgery)

N95 masks are recommended for this purpose. HCWs should be trained in the use of N95 masks and educated on managing stigma which may arise as a result of using N95 masks.

1.3.1.3 Natural ventilation

Simple natural ventilation may be effective in reducing the risk of transmission. This should be optimized in DOTS center by maximizing the size of the opening of windows and locating them on opposing walls.

1.3.2 BCG vaccination

BCG vaccination is included in the Expanded programme of Immunisation. In Fiji BCG vaccination is given at birth. The dosage is 0.05ml of BCG vaccination injected intradermally on the upper aspect of the right arm (at the point of insertion of the deltoid muscle into the humerus). BCG vaccination after infancy is not recommended.

1.3.3 Preventative chemotherapy

The following group of persons should be properly examined for the presence of active TB disease. Once active TB is ruled out, Isoniazid preventative treatment (IPT) should be instituted for at least 9 months:

a) People living with HIV/AIDS

Patients with **HIV infection** who are also **infected with TB** are at great risk of developing **active TB**. The clinical features of TB in people with HIV infection may be atypical. Extrapulmonary and disseminated TB disease is common among PLWHA.

PLWHA should be evaluated for the presence of TB and, if this is not present, should receive isoniazid preventive therapy

If active TB is excluded, they should be screened for latent tuberculosis infection by Mantoux test. The Mantoux test should be performed by a HCW experienced in performing this test. Patients with HIV infection who have a Mantoux test ≥ 5mm in diametre should be considered to have latent tuberculosis infection and should be prescribed a six month course of Isonazid 300 mg daily (5mg/kg up to a maximum of 300mg daily in children) together with vitamin B6 (pyridoxine) 25 mg daily. They should be reviewed on a monthly schedule to ensure proper adherence to prescribed treatment.

b) All children contacts (<5yrs old): Refer to Page 19. Management of latent TB infection in children.

1.4 Monitoring & evaluation

1.4.1 Cohort analysis

Evaluation of treatment outcome in new pulmonary smear-positive patients is used as a major indicator of programme quality and performance. Outcomes in other patients (re-treatment, pulmonary smear-negative, extra-pulmonary) are analysed in separate cohorts. Each registered patient should have his/her outcome recorded in the register as soon as treatment course is completed. The following treatment outcome definitions should be used for sputum smear-positive patients.

Table 8. Treatment outcome definitions

Outcome	Definition
Cured	A patient whose sputum smear was positive at the beginning of the treatment but who was smear-negative in the last month of treatment and on at least one previous occasion.
Treatment completed	A patient who completed treatment but who does not have a negative sputum smear result in the last month of treatment and on at least one previous occasion.
Treatment failure	A patient whose sputum smear is positive (and culture positive) at 5 months or later during treatment. Also included in this definition are patients found to harbour a multidrug-resistant (MDR) strain at any point of time during the treatment, whether they are smear-negative or positive.
Died	A patient who dies for any reason during the course of TB treatment.
Default	A patient whose treatment was interrupted for 2 consecutive months or more.
Transfer out	A patient who has been transferred to another recording and reporting (DOTS) unit and whose treatment outcome is unknown.
Treatment success	A sum of cured and completed treatment.

These treatment outcomes should be determined by the Divisional TBCO in charge. This will allow the National TB Office to perform cohort analysis on a quarterly and annual basis.

1.4.2 Recording and reporting system

1.4.2.1 TB patient register

The TB patient register is kept at the:

- Divisional DOTS centers – should contain register of all patients covered under the respective Divisional DOTS center.
- Sub-divisional hospitals – should contain register of all patients covered under the respective sub-divisional hospital.
- Primary health care centers (Health centers) – should contain register of all patients covered under the respective primary health care center.

1.4.2.2 Laboratory registers

Laboratory aspects of tuberculosis management are beyond the scope of this Guide. However, each laboratory performing TB microscopy (in the three DOTS centres) should keep a laboratory register. The technologist in charge of the laboratory is responsible for maintaining this register up-to-date on a daily basis.

1.4.2.3 Treatment cards

The treatment card contains all the information about the patient. Two copies of a treatment card will be completed for each patient, as well as a patient's identification card. One copy of the treatment card is retained at the DOTS centre responsible for the patient.

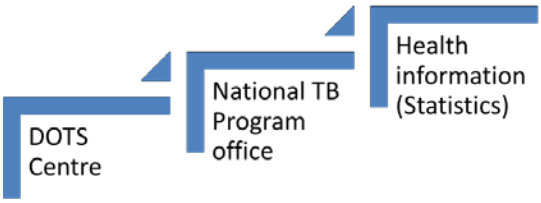
The second copy of the treatment card is sent to the health facility/person (TB liaison officer) responsible for delivering supervised treatment to the patient. The person administering treatment (either in hospital or in the community) must record the patient's daily intake of prescribed drugs according to that patient's treatment schedule on this treatment card. Each administered dose should be signed for (with initials). The Treatment card, domiciallery form and Patient identification card can be found in the enclosed Appendices.

1.4.2.4 Reporting mechanisms

a) DOTS centres should report the following on a quarterly (within the first month of new quarter) and annuall schedule to the National TB Programme Office in Suva on:
   - TB Case Notification: number (age/gender distribution, classification)
   - TB-HIV coinfection & MDR-TB
   - Treatment outcome (highlighting those cured, treatment completed, died, failures, defaulters, & transfers)

b) The National TB Programme reports to Health Information Unit at the MOH quarterly & annually on:

- TB Case Notification - number & rate (age & gender distribution, classification & type of TB case)
- TB-HIV coinfection & MDF-TB + TB -Diabetes co-infection
- Number and proportion of children (0 - 13 years) screened for TB and starting TB prophylaxis.
- Treatment outcome (highlighting those cured, treatment completed, died, failures, defaulters, & transfers)



1.4.3 Managing anti-TB drug supply

The FPBS work in partnership with the NTP in determining the required supply of anti-TB drugs on an annual basis. Procurement and distribution of anti-TB drugs to DOTS centres and Divisional hospital pharmacies are solely the responsibility of the FPBS. Divisional hospitals also possess anti-TB drugs, and advise their respective DOTS centres of a newly diagnosed case of TB before or when commencing treatment. DOTS centres are responsible for the dispensing and recording of appropriate supply of anti-TB drugs on a case by case basis to Sub-divisional or peripheral level.

1.5 PROGRAMME SUPERVISION

1.5.1 National supervision

The NTP office at Tamavua-Twomey hospital in Suva provides technical and programmatic oversight of all TB control activities in Fiji. This is done through:

- conduct of quarterly supervisory visits to the three(3) DOTS centres
- standardising operating procedures
- provision of technical support to other TB stakeholders .ie. FRCS, FNA, FNU, NRL, HIU and FPBS.
- liaison to donor and technical partners .ie. WHO, GFATM, GMU-MOH, SPC

1.5.2 Divisional supervision

The three(3) DOTS centres are located in Lautoka (Tagimoucia unit), Labasa and Tamavua-Twomey hospitals. They provide and conduct:

- Divisional TB control services
- Supervision of sub-divisional health centres (TB patient – health care provider-health service) and to community settings where TB patient is under DOT care by community health worker.
- Report to NTP head office on quarterly & annual basis

1.5.3 Sub-divisional supervision

The sixteen (16) sub-divisional hospitals in Fiji are in charge of the following TB control activities:

- Supervision of identified health centres and communities
- Provide complementary TB services particularly on suspect referral, contact screening and continuum of care for patients undergoing continuation phase of treatment
- Report on quarterly & annual basis to their respective DOTS centers (indicator elements pertaining to TB case notification, and treatment outcome)

1.5.4 Laboratory supervision and EQA

Daulako Mycobacterium laboratory (at Tamavua-Twomey hosp.) offers the following services:

- Supervises and provides EQA for all three(3) divisional hospital laboratories
- Offer technical support to staff of the three(3) divisional laboratories

- Organises capacity building programmes planned for divisional technicians related to TB microscopy and culture
- Collaborates with QMRL (Queensland) on the conduct of DST for MDR-TB suspects

Divisional laboratories play a pivotal role in:

- Supervising and conducting EQA for sub-divisional laboratories
- Offering technical support to all sub-divisional labs
- Providing quarterly and annual reports to Daulako Mycobacterium laboratory on TB (cases, TB cases tested for HIV, TB-HIV coinfected, smear negative-culture positive, smear positive-culture positive, smear positive-culture negative)
- Providing capacity building opportunities to sub-divisional laboratory staff.

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APPENDICES

Tub 1	Referral/transfer forms
Tub 2	Laboratory Register
Tub 3	Laboratory (AFB microscopy) request form
Tub 4	AFB Microscopy Register
Tub 5	TB Register
Tub 6	TB Patient ID Card
Tub 7	TB Contact Register
Tub 8	TB Treatment Card
Tub 9	HIV testing Consent form
Tub 10	Pharmacy form
Tub 11	Domicilliary Treatment Supervision form
Tub 12	Treatment Completion form
Tub 13	Quarterly Report on Sputum Conversion
Tub 14	Quarterly Report on TB case registration
Tub 15	Quarterly Report on Treatment Outcome

Appendix

Tuberculosis Referral/Transfer Form

TUB 1

Ministry of Health
Fiji National Tuberculosis Programme

TUBERCULOSIS REFERRAL/TRANSFER FORM

Name: _____ Phone: _____
Address: _____
Koro dina: _____ Tikina: _____ Yasana: _____
DOB: _____ Sex: _____ Age: _____ Ethnicity: _____
Contact person: _____ Phone: _____

TUBERCULOSIS PATIENT TRANSFER

TB REG No.: _____ OPF No.: _____ Date Treatment started: _____
Transferred From: _____
To: _____
Diagnosis: ☐ PTB Smear Pos. ☐ PTB Smear Neg. ☐ EPTB _____
Treatment: ☐ SCC (new case) ☐ Re-treatment (relapse, failure, default)
☐ RIF/ INH ☐ ETH ☐ PZA ☐ STREP
☐ 150/100mg ☐ 100mg ☐ 500mg
☐ 300/150mg ☐ 400mg ☐ 400mg inj. _____ g
Remarks: _____
Date of Transfer: _____ Signed: _____

TUBERCULOSIS SUSPECT REFERRAL

Referred From: _____
To: _____
☐ Cough for more than 2 weeks
Other symptoms: _____
Sputum specimen No.: _____ Date produced: _____
Remarks: _____
Date: _____ Signed: _____

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TUBERCULOSIS TRANSFER/ REFERRAL ACKNOWLEDGEMENT

The patient/suspect: _____ Address: _____
1. Who was transferred to _____ reported/ did not report for treatment
2. Who was referred to _____
Has been diagnosed with ☐ PTB smear pos. ☐ PTB smear neg. ☐ EPTB
Tuberculosis treatment will be started at: _____ on date _____
☐ Has NOT been diagnosed with tuberculosis
Date: _____ Signed: _____

TUB 2a

Ministry of Health
Fiji National Tuberculosis Programme

LABORATORY REQUEST FOR SPUTUM EXAMINATION

Name:	Other Name:	DOB	Gender	Ethnicity	Ward	Hosp. No.

MO I/Charge	Facility:	Clinical Note:	Specimen Collection Date:

☐ 1st Specimen ☐ 2nd Specimen ☐ 3rd Specimen ☐ Follow-up: _____

☐ **AFB Microscopy** ☐ **TB Culture** ☐ **Drug Susceptibility Test**

Received:

Signature:

REMARKS:

Note: This form is to be used for Tuberculosis diagnosis only.

TUB 2b

Ministry of Health
Fiji National Tuberculosis Programme

LABORATORY REPORT OF TB EXAMINATION

Name	Other Name	DOB	Gender	Ethnicity	Ward	Hosp. No.	Lab Reg. No.

MO I/Charge	Facility:	Specimen Collection Date:
Brief Clinical Note (Diagnosis):		Received:

REPORT

AFB MICROSCOPY		CULTURE	DRUG SUSCEPTIBILITY TEST	
Actual No.			DRUGS	SENSITIVITY
1+			Streptomycin	
2+			Isoniazid	
3+			Rifampicin	
Negative/ No AFB Seen			Ethambutol	
			Pyrazinamide	

Examined by:	Date Reported	Officer In-charge

TUB 3

Ministry of Health
Fiji National Tuberculosis Programme

LABORATORY REGISTER FOR AFB MICROSCOPY

LAB REG. No.	DATE	TB REG. No./ Hosp. No.[1]	NAME	SEX	DOB	PATIENT'S ADDRESS	REFERRAL CENTRE[2]	OFFICER[3]

[1] Note TB REG. No. if patient is registered TB case, otherwise note hospital no.
[2] Where patient/specimen is referred from.
[3] Person sending specimen.

TUB 3

Ministry of Health
Fiji National Tuberculosis Programme

LABORATORY REGISTER FOR AFB MICROSCOPY

YEAR:

NATURE OF SPECIMEN[4]	CLINICAL NOTE	REASON FOR DIAGNOSIS[5] (D or F)	SMEAR RESULT[6]			CULTURE DONE (Y/N)	DST SENT (Y/N)	HIV TEST DONE (Y/N)	REMARKS
			1	2	3				

[4] Macroscopic appearance of specimen.

[5] Write D for Diagnosis or F for Follow-up

[6] Indicate result with (N) No AFB, Positive as 3+ 2+ 1+ or actual number (mark positives with red pen) with dates of respective results in the space below.

TUB 4

Ministry of Health
Fiji National Tuberculosis Programme

LABORATORY REGISTER FOR TB CULTURE

Lab Serial No.	TB Reg. No./Hosp. No.	Specimen	Patient's Name	Sex (M/F)	Age	Referral Health Facility	Clinician	Date Specimen Collected	Date Specimen Inoculated

TUB 4

Ministry of Health
Fiji National Tuberculosis Programme

Reason for Examination[1] (D or F)	Result of Culture[2] (Weeks)						Result of Confirmatory Test for MTB (pos /neg)	Date Reported	Culture Sent for DST (Y/N)	Sensitivity Test[3]					Date DST Result Reported	Signature	Comments
	3	4	5	6	7	8				R	H	E	S	Z			

[1] Write D for Diagnosis or F for Follow-up; [2] Outcome of culture reported as follows; [3] Indicate sensitivity with (I) intermediate (S) sensitive (R) resistant

No growth reported	0
Fewer than 10 colonies	Write the number of colonies
10 – 100 colonies	+
More than 100 colonies	++
Innumerable or confluent growth	+++

TUB 5

Ministry of Health
Fiji National Tuberculosis Programme

TUBERCULOSIS REGISTER

LABORATORY RESULTS														Treatment Result [8]		HIV Test Done (Y/N) [9]	Remarks
Start of Treatment								End of 2nd or 3rd Month[7]		End of 5th Month[7]		End of Treatment					
Date	Smear	Culture	Drug Sensitivity Test[6]					Date	Smear	Date	Smear	Date	Smear	Date	Result		
			R	H	E	Z	S										

[6] Enter S (Sensitive) or R (Resistant), [7]A smear at the end of 3rd and 5th months are only done for those who failed to convert, [8] Cured (C), Treatment Completed (TC), Treatment Failure (F), Died from whatever cause (M), Defaulted or lost to follow-up (D), Transferred Out (O)
[9] HIV test conducted. Enter Y (Yes) N (No)

TUB 5

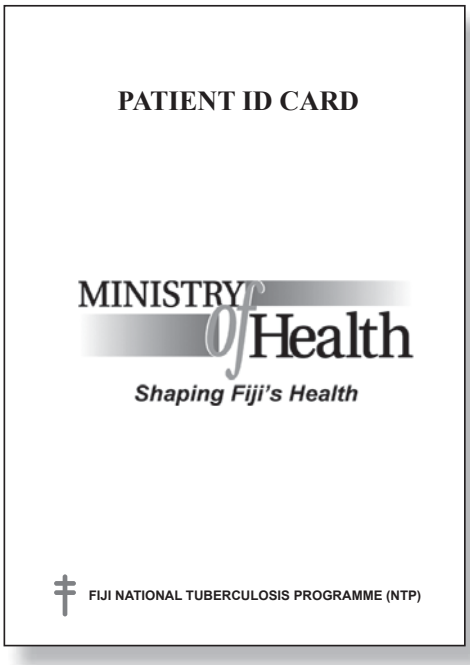
Ministry of Health
Fiji National Tuberculosis Programme

TUBERCULOSIS REGISTER

TB Reg. No.	Date of Reg.[1]	Name	Sex [2]	DOB	Address	Treatment Centre	Treatment Regimen[3]	Disease Class[4]	Type of Patient[5]

[1] Date when the patient was entered into the sub divisional register, [2] Male (M), Female (F), [3] HRZE or HRZES, [4] Smear positive pulmonary TB (PTB+), smear negative pulmonary TB (PTB-), Extra - pulmonary TB (EPTB), [5] Enter the correct code: New (N), Relapse (R), Treatment After Failure (F), Treatment After Default (D), Transfer in (I), Others (O).

Patient ID Card



PATIENT IDENTITY CARD

Name: _____ Sex : M ☐ F ☐

OPF No. /NHN _____ TB Reg. No. _____

Address: _____

DOB _____ Phone: _____

Treatment Centre: _____

Date Treatment Started: _____ Completed _____

REMINDER:
Remember that:

1. If you miss taking your medicine (even 3 doses in a month) **DRUG RESISTANCE** can develop.
2. This is bad for you and your community.
3. If you stop you will become ill within months or a year.
4. Medicines **MUST NOT** be shared with family and friends.
5. If you find it difficult taking your medicine regularly, DISCUSS with health workers.
6. Seek support from your treatment supervisor, family or friends.
7. If you change your address please notify your nurse or doctor, **AS SOON AS POSSIBLE**
8. If you feel unwell when you take your medicine, see your nurse or doctor.
9. Visit your doctor at least once a month for review.

Possible Side Effects of Anti-TB Medicines:

No appetite	Orange/red urine
Abdominal pain	Skin rash
Nausea	Dizziness
Tingling/numbness around the mouth	Ringing in the ears

PLEASE SEE YOUR DOCTOR AS SOON AS POSSIBLE IF YOU HAVE ANY OF THE ABOVE

DISEASE CLASSIFICATION

PULMONARY ☐ EXTRA-PULMONARY ☐
SMEAR POS. ☐ SITE: _____
SMEAR NEG. ☐

TYPE OF PATIENT

NEW ☐ TREATMENT AFTER FAILURE ☐
TRANSFER IN ☐ TREATMENT AFTER DEFAULT ☐
RELAPSE ☐ OTHER ☐

TREATMENT REGIMEN

PHASE		INTENSIVE PHASE	CONTINUATION
RIF	150/300 mg	☐	☐
INH	100/150 mg	☐	☐
ETH	100/400 mg	☐	☐
PZA	400/500 mg	☐	
STREP	_____mg	☐	

APPOINTMENT DATES

Doctor's Visit Dates: _____

Drug Collection Dates: _____

Final Review Dates: _____

TUB 7

Ministry of Health
Fiji National Tuberculosis Programme

REGISTER OF TB CONTACTS

Year_____ Facility_____

Name of Index Cases	TB Register No.	Name of Contact [1]	Sex	Age	Address of Contact	SCREENING			Prophylaxis[3]	Remarks/Relationship to Index Case
						Date	Method	Result		

[1] List all contacts consecutively under the name of the index case. [2]Enter method of screening: Symptom Screening (Sym), Tuberculin Skin test (TST), Chest x-ray(CXR) or sputum smear examination (SSE). [3]Prophylaxis Regimen: 9H or 6HR

Ministry of Health
Fiji National Tuberculosis Programme

TUB 8

TUBERCULOSIS TREATMENT CARD

Name[1]: _____ Phone: _____
Address: _____ Occupation:[22] _____
Koro dina _____ Tikina _____ Yasana _____
Contact Person: _____ Phone: _____
Sex:[6] _____ Date of Birth[5]: _____ Ethnicity[7]: _____
Paediatric Cases[9] (<15 years) Yes ☐ No ☐ Country of Birth[8]: _____
History of TB contact: Yes ☐ No ☐
Previous diagnosis of TB[4]: Yes ☐ No ☐ If yes, year of diagnosis: _____

TB Register No.[3]: _____
OPF No. _____ NHN _____
Station: _____
Date registered[2]: _____
Division: _____

DISEASE CLASSIFICATION/ SITE OF TB DISEASE [11]

PULMONARY ☐ EXTRA PULM ☐ SITE _____
Sputum date collected[12] _____
Smear: Positive ☐ Negative ☐

(INTENSIVE PHASE) DRUG REGIMEN[29] Weight: (DOTS) START: _____kg.

☐ RHZE 150/75/400/275mg _____ TABS OD ☐ RIFAMPICIN SUSP[N] _____ ml OD
☐ RIF/INH 150/100 mg _____ TABS OD ☐ ISONIAZIDE SUSP[N] _____ ml OD
☐ RIF/INH 300/150 mg _____ TABS OD
DOTS Therapy Stopped/Not Started[38]: ☐ Died ☐ Others _____ Date Stopped _____
DOTS Therapy Extended[39] NO ☐ YES ☐ Duration _____ months.

TYPE OF PATIENT [28]

New ☐ Transfer in ☐ Relapse ☐
Defaulter ☐ Treatment Failure ☐ Others ☐

Status at TB Diagnosis[10]: ☐ Dead ☐ Alive

INTENSIVE PHASE (DOTS) **START DATE [27]** _____

Day / Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Laboratory Results			
																																Date	Lab No.	Smear	Culture

ENTER X on day of supervised drug administration or DC when drugs are collected. DRAW A LINE to include number of days supply given. TICK appropriate box after the drugs have been taken by the patient.

[13]Sputum Culture Not Done ☐ Neg. ☐ Pos. ☐ Date: _____ Reference Lab _____ [14]Smear/Pathology/Cytology of Tissue/Other body Fluids . Done? Yes ☐ No ☐
[16]CXR: Normal ☐ Abnormal ☐ Cavity: Yes ☐ No ☐
[17]Skin Test (TST) Date _____ Pos. ☐ Neg. ☐ Not done ☐ [15]Culture of Tissue/Other Body Fluids, Done? Yes ☐ No ☐
[18]Primary reason evaluated for TB: _____ TB Symptom Onset Date _____
[19]TB Symptoms: Cough ☐ Coughing of blood ☐ Chest pain ☐ Loss of appetite ☐ Loss of weight ☐ Fatigue ☐

NOTE: SUPERSCRIPT NUMBERS CORRESPOND TO EPIANYWHERE DATA INFO

TUB 8

Ministry of Health
Fiji National Tuberculosis Programme

CONTINUATION PHASE (DOT) **START DATE**:_____ **WEIGHT: START**_____**kg ; END** _____ **kg**

Day / Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Laboratory Results			
																																Date	Lab No.	Smear	Cult

ENTER X on day of supervised drug administration or DC when drugs are collected.
DRAW A LINE to include number of days supply given.
TICK appropriate box after the drugs have been taken by the patient
NOTE: SUPERSCRIPT NUMBERS CORRESPOND TO EPIANYWHERE DATA INFO

Drug regimen: ☐ HR ☐ HRE
(DOT) Others_____

[20]HIV Testing at TB Diagnosis: NO ☐ YES ☐ [21]Homeless within past year NO ☐ YES ☐
[23]Illegal drug use within past year: NO ☐ YES ☐ INJ ☐ NON-INJ ☐[24]
[25]Weekly Alcohol Use within past year: NO ☐ YES ☐ Not Known ☐
[26]TB Risk Factors: Diabetes Pos ☐ Neg ☐ Others: Missed contact 2 years or less ☐ Contact with TB Disease ☐ Others ☐ _____
[30]Genotype Testing Done: NO ☐ YES ☐ Isolate submitted for genotype testing: NO ☐ YES ☐ Date isolate received at genotyping laboratory:_____
[31]Drug Susceptibility Testing done: NO ☐ YES ☐ Date: _____ If yes, genotyping accession number for episode:_____
Enter specimen type: ☐ Sputum or Anatomic Code: ☐ Pulmonary ☐ Extrapulmonary_____
[32]Drug Susceptibility Results: Sensitive to: _____ Resistant to: _____ [39]Reason standard therapy regimen extended:_____
[33]If MDR, is the case Green Light Committee Approved: NO ☐ YES ☐ [40]Local Health Provider Available NO ☐ YES ☐
[34]Sputum Smear Conversion: Date 1st sputum smear negative:_____ Date 2nd sputum smear negative:_____
[35]Sputum Culture Conversion: Date 1st sputum culture negative_____ [41]Directly Observed Therapy (DOT): NO ☐ YES ☐ No. of weeks _____
[36]Transfer/ Moved: Did the patient move/ transfer during TB Therapy? NO ☐ YES ☐ [42]Treatment Outcome:
Out of Division: Specify: ☐WD ☐CE ☐ND ☐Out of Country; _____ ☐ CURED ☐ TREATMENT COMPLETED ☐ DIED
[38]Reason DOT therapy stopped/ Never started:_____[37] Date stopped:_____ ☐ DEFAULTED ☐ TRANSFERRED OUT ☐ FAILED
Was TB death registered in the registration system of: NO ☐ YES ☐ Date: _____

Consent Form (HIV/AIDS and TB)

TUB 9

Ministry of Health
Fiji National Tuberculosis Programme

CONSENT FORM
HIV/AIDS and TB

_____
(Name of Facility)

Name: _____ DOB: _____ Sex: F/ M

Contact Home: _____Work: _____NHN_____

Address: _____

Occupation:_____ Marital Status: _____

History of presenting complaint:

_____

_____

_____

COUNSELLING AND TESTING ☐ **PICT** ☐ **VCCT**

Explanation of the signs/ symptoms of TB and HIV/AIDS

- ☐ Officer provides knowledge on HIV/AIDS and TB
- ☐ Assess client's knowledge on HIV/AIDS and TB
  - What is the difference between HIV/AIDS and TB
  - What are some of the signs and symptoms of HIV/AIDS and TB
  - What are some of the ways to protect oneself from getting HIV/AIDS and TB
- ☐ Client understands the risks associated with HIV/AIDS and TB
- ☐ Client knows what to do if result is positive or negative

I, _____ agree/disagree to be tested for HIV/AIDS.

Signature: _____ Date: _____

Counsellor: _____ _____

(Name) (Signature)

Pharmacy Form

TUB 10

Ministry of Health
Fiji National Tuberculosis Programme

PHARMACY FORM

ANTI TUBERCULOSIS MEDICATION

TO:	**FOR:**(RECIPIENT OF TB MEDICATION)
NAME:	PATIENTS FULL NAME :
DESIGNATION:	ADDRESS:
ADDRESS:	SEX:
FACILITY:	DOB:

TB MEDICATION: ☐ **INTENSIVE PHASE** ☐ **CONTINUATION PHASE**

Name & Strength	**Dosage**	**Quantity Supplied**	**Comments**
☐ RHZE 150/75/400/275 mg	_____ tabs OD	_____	_____
☐ Rif/Inh 150/100 mg	_____ tabs OD	_____	_____
☐ Rif/Inh 300/150 mg	_____ tabs OD	_____	_____
☐ Rifampicin Suspension __	_____ ml OD	_____	_____
☐ Isoniazide Suspension __	_____ ml OD	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

STATUS OF SUPPLY: Balance_____ **Final/ Last Supply(Y/N)** _____

SIGNATURE (PHARMACIST IN CHARGE) _____DATE SENT_____

DATE TAKEN BY PATIENT (FILLED BY ZONE NURSE): _____

Cut and send back to the pharmacist.

ACKNOWLEDGEMENT LETTER

Pharmacist _____ Date received _____

Facility _____

Patient's Name/ Recipient: _____

Drugs Supplied	**Quantity**
1) _____	_____
2) _____	_____
3) _____	_____

Receiver's Name_____ Signature_____

Facility _____

TUB 11

Ministry of Health
Fiji National Tuberculosis Programme

DOMICILLARY SUPERVISION FORM

YEAR: _____

Name: _____ Phone: _____	Supervisor: _____
Address: _____	Position: _____
Koro dina: _____ Tikina: _____ Yasana: _____	Address: _____
DOB: _____ Sex: _____ Age: _____ Ethnicity: _____	Phone: _____
Contact person: _____ Phone: _____	Facility: _____

INTENSIVE / CONTINUATION PHASE MEDICATIONS (DOT)

☐ Rifampicin/ Isoniazid Combination ☐ 300/150mg ☐ 150/100mg ☐ Ethambutol ☐ Pyrazinamide ☐ 400mg ☐ 400/500mg ☐ Streptomycin

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

Remarks:

Zone nurse home visit dates (once every 2 weeks)**:**_____

Treatment Completion Form

TUB 12

Ministry of Health
Fiji National Tuberculosis Programme

TREATMENT COMPLETION FORM

(To be completed by a Medical Officer)

NAME: _____ DOB: _____ SEX: _____

ADDRESS: _____

HOSPITAL NO/NHN: _____

TB REGISTER NO.: _____

DIAGNOSIS: _____

INTENSIVE PHASE STARTED IN: _____ (FACILITY) INCLUSIVE DATES: _____

CONTINUATION PHASE STARTED IN: _____ (FACILITY) DATE STARTED: _____

DURATION OF CONTINUATION PHASE: _____ DATE COMPLETED: _____

*Pharmacist to fill-up Patient's name and details.

SUBMITTED BY: _____

FACILITY: _____

SIGNATURE: _____ DATE SUBMITTED: _____

CC TO:
1. DIVISIONAL TB CONTROL OFFICER - White
2. SDMO - Yellow
3. MO HEALTH CENTRE - Pink
4. BOOK COPY - Green

THANK YOU FOR YOUR COOPERATION TOWARDS OUR GOAL OF A TB FREE FIJI.

Ministry of Health
Fiji National Tuberculosis Programme

TUB 13

QUARTERLY REPORT ON SPUTUM SMEAR MICROSCOPY CONVERSION

Name of Division: _____ Facility: _____ Name: _____ Signature: _____	_____ *quarter of year* _____ Date of completion of this form: _____

Number of **new** sputum smear microscopy positive cases registered in quarter recorded above[2]	Sputum smear microscopy not done at either 2 or 3 months	Sputum smear microscopy conversion at:	
		2 months	3 months
Total converted at 2 or 3 months:			

Number of sputum smear microscopy positive **retreatment** cases registered in quarter recorded above[2]	Sputum smear microscopy not done at either 2 or 3 months	Sputum smear microscopy conversion at:	
		2 months	3 months
Total converted at 2 or 3 months:			

1 Quarter: This form applies to patients registered (recorded in the TB Register) in the quarter that ended 3 months ago. For example, if completing this form at the beginning of the 3rd quarter, record data on patients registered in the 1st quarter.

2 This number should match the number of new sputum smear microscopy positive cases in Block 1, Column 1, first row of the Quarterly Report on TB Case Registration previously completed for patients registered in this quarter.

White Copy - **NTP OFFICE** Yellow Copy - **DOTS CENTRE**

TUB 14

Ministry of Health
Fiji National Tuberculosis Programme

QUARTERLY REPORT ON TB CASE REGISTRATION

Name of Division: _____ Unit: _____	**Patients registered during**[1] _____ **quarter of year** _____
Name of TB Coordinator: _____ Signature: _____	Date of completion of this form: _____

Block 1: All TB cases registered during the quarter[2]

Pulmonary sputum smear positive				Pulmonary sputum smear negative	Pulmonary smear not done / not available	Extrapulmonary	Other previously treated[3]	Total
New cases	Previously treated							
	Relapses	After failure	After default					

Block 2. Breakdown of TB cases by sex and age group

	New	0 – 4	5 – 4	15 – 24	25 – 34	35 – 44	45 – 54	55 – 64	≥ 65	Total
New Smear positive	M									
	F									
Pulmonary smear negative/not done/ not available	M									
	F									
Extrapulmonary	M									
	F									
Total										

Block 3: Laboratory activity - direct smear[4]

No. of TB suspects examined for diagnosis by sputum smear microscopy	No. of TB suspects with sputum smear microscopy positive result

Block 4: Quarterly report on TB/HIV activities

	No. tested for HIV before or during TB treatment[5]	No. HIV positive
New sputum smear microscopy positive TB		
All TB cases except new smear positive, 'transferred in' and chronic cases[6]		

1 Registration period is based on date of registration of cases in the TB register, following the start of treatment.
Q1: 1 January-31 March; Q2:1 April -30 June; Q3: 1 July-30 September ; Q4:1 October-31 December.
2 In areas routinely using culture, a quarterly report on TB case registration for unit using culture should be used. 'Transferred in' and chronic cases are excluded.
3 Other previously treated cases include pulmonary cases with unknown result of previous treatment, sputum smear negative pulmonary cases and extra-pulmonary cases previously treated. 'Transferred in' and chronic cases are excluded.
4 Data collected from the TB laboratory register related to activity performed in the unit during the quarter.
5 Documented evidence of HIV tests (and results) performed in any recognized facility before or during TB treatment should be reported here.
6 Includes smear negative, smear not done, extra-pulmonary cases and all previously treated cases.

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Quarterly Report on TB Treatment Outcomes and TB/HIV Activities

Ministry of Health
Fiji National Tuberculosis Programme

TUB 15

QUARTERLY REPORT ON TB TREATMENT OUTCOMES AND TB/HIV ACTIVITIES

Name of Division: _____

Name of TB Coordinator: _____ Signature: _____

Patients registered during[1]
_____quarter of year_____
Date of completion of this form:
_____

Block 1: Quarterly report on TB treatment outcomes

Type of case	Total number of patients registered during quarter*	Treatment outcomes						Total number evaluated for outcomes (sum of Columns 1 to 6)
		Cured (1)	Treatment completed (2)	Died (3)	Treatment failure[2] (4)	Default (5)	Transfer out (6)	
Sputum smear positive								
Sputum smear neg and not done								
Extrapulmonary								
Relapses								
Treatment after failure								
Treatment after default								
Other previously treated[3]								

** These numbers are transferred from the Quarterly Report on TB Case Registration for the above quarter. Of these patients, _____ (number) were excluded from evaluation for the following reasons: "Not TB": Other reasons:_____*

Block 2: Quarterly report on TB/HIV activities (same quarter analysed as Block 1)[4]

	No. tested for HIV[6]	No. HIV positive (a)	No. on CPT[6]	No. on ART[6]
New sputum smear microscopy pos. TB				
All TB cases except new smear positive, 'transferred in' and chronic cases 5				

Block 3: Quarterly report on TB treatment outcomes of HIV-positive patients

Type of case	Total number of HIV positive TB patients Block 2, Column (a)*	Treatment outcomes						Total number evaluated for outcomes: (sum of Columns 1 to 6)
		Cured (1)	Completed (2)	Died (3)	Failure[7] (4)	Default (5)	Transfer out (6)	
New sputum smear microscopy pos. TB								
All TB cases except new smear positive, 'transferred in' and chronic cases[5]								

** Of these patients, _____ (number) were excluded from evaluation for the following reasons:*

1. Quarter: This form applies to patients registered (recorded in the Divisional Tuberculosis Register) in the quarter that ended 12 months ago. For example, if completing this form at the beginning of the 3rd quarter, record data on patients registered in the 2nd quarter of the previous year.
2. Include patients switched to Cat. 4 because sputum sample taken at start of treatment turned out to be MDRTB.
3. Include pulmonary cases with unknown result of previous treatment, sputum smear-negative pulmonary cases and extrapulmonary cases previously treated.
4. Documented evidence of HIV tests (and results) performed in any recognized facility during or before TB treatment should be reported here.
5. Includes smear negative, smear not done, extrapulmonary cases and all previously treated cases.
6. Includes TB patients tested for HIV before and during TB treatment, continuing on CPT or ART started before TB diagnosis and those started on CPT or ART during TB treatment (till last day of TB treatment).
7. Include patients switched to Cat. 4 because sputum sample taken at start of treatment turned out to be MDRTB.

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