GUIDELINES for the CONTROL of TUBERCULOSIS in WALLIS and FUTUNA through DOTS Strategy

Secretariat of the Pacific Community
Tuberculosis Control Section
Noumea, New Caledonia

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Part I

The WHO-recommended DOTS Strategy - A Regional Model

Part II
The Wallis and Futuna DOTS Strategy - A Country-specific Model

ACRONYMS AND ABBREVIATIONS

AFB	–	acid-fast bacilli
DOT	–	directly observed treatment
DOTS	–	directly observed treatment, short course
EPTB	–	extrapulmonary tuberculosis
FDC	–	fixed dose combination
kg	–	kilogram
mg	–	milligram
MDG	–	UN Millennium Development Goal
MDR-TB	–	multi-drug resistant tuberculosis
NTP	–	National Tuberculosis Programme
OPD	–	Outpatient Department
PICTs	–	Pacific Island Countries and Territories
PTB	–	pulmonary tuberculosis
S^+	–	smear-positive
S^-	–	smear-negative
SPC	–	Secretariat of the Pacific Community
TAI	–	treatment after interruption
TB	–	tuberculosis
WHO	–	World Health Organization
WPRO	–	Western Pacific Regional Office

DRUG ABBREVIATIONS

E	–	Ethambutol
H	–	Isoniazid
R	–	Rifampicin
S	–	Streptomycin
Z	–	Pyrazinamide

Overview of Tuberculosis as a Serious Public Health Threat

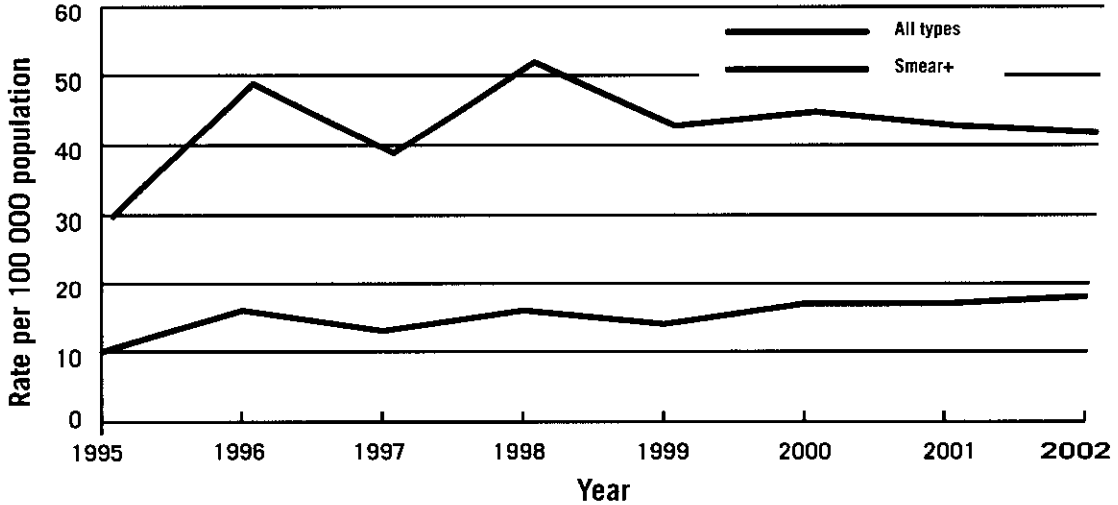
Statistics show that tuberculosis continues to be a serious and growing public health threat throughout the world:

- 2 billion people, nearly 1/3 of the total global population, are infected with the disease.
- Every day 5,000 people become sick with TB, and every year it causes 2 million people to die, including 250,000 children.
- It is the leading infectious killer among young women.
- Tuberculosis is also the leading cause of death among people who are HIV-positive, and as the number of HIV-AIDS cases increases, TB is likely to cause even more deaths. The high rate of TB/HIV-AIDS co-infection continues to increase the tuberculosis burden.
- When treatment of TB is not properly managed, the result can be development of multi-drug resistant (MDR) TB, which is prohibitively expensive to address, potentially incurable and all too often fatal.

Here in our own region, amongst the SPC Pacific Island countries and territories (PICTs), the magnitude is also alarming:

- Some 51% of the total population in the PICTs does not have access to correct TB treatment.
- 16,000 people are estimated to develop active tuberculosis each year and of those, only 6,000 are detected annually, leaving 10,000 potential sources of TB every year. **Each active TB case can infect an additional 10-20 people per year.**
- Amongst the PICTs, tuberculosis mainly affects young adults who are in their prime productive years. 80% of males and 85% of females with active TB are between the ages of 15-54 years, and among the women with active TB, more than 60% are between 15 and 34 years of age.
- As shown on graph I, the burden of tuberculosis in the Pacific has been on the rise since 1995.

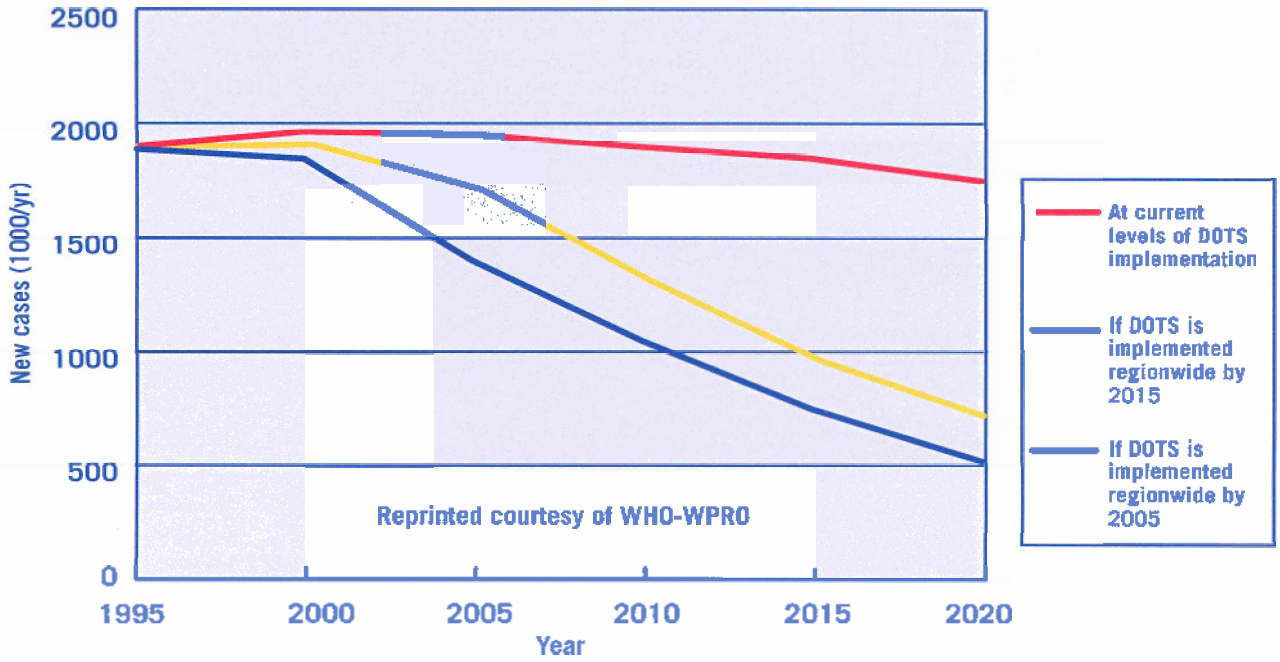
GRAPH I: **TB case notification trends in the Pacific Islands*, 1995-2002**
(Based on WHO-WPRO data)



* data does not include figures from Papua New Guinea

Clearly, tuberculosis among Pacific Island countries and territories is a serious and growing problem. It is a disease that spreads easily and can infect anyone. The good news is that there is a cure for TB. Today there are powerful drugs and a proven cost-effective strategy – **DOTS**[1] – that can successfully treat existing cases as well as prevent continued transmission of the disease. According to the WHO model shown on graph II, if all countries and territories in the region implement effective DOTS programmes by the end of 2005, the burden of TB will be reduced 50% by the year 2010. These efforts will also enable achievement of the UN Millennium Development Goal (MDG) - to halt and begin to reverse the incidence of TB by 2015. Conversely, partial or non-implementation of DOTS could lead to catastrophic results.

GRAPH II: **Projected TB cases in the region with different DOTS scenarios**



SPC recognizes the potential threat posed by tuberculosis in the region and has created the Tuberculosis Control Section to work in partnership with WHO, and related health organizations, to support DOTS amongst the PICTs. In addition to providing training and on-site technical assistance, the SPC Tuberculosis Control Section staff have prepared this manual, as one in a series of individualised practical guides offering assistance to countries/territories in their implementation of successful DOTS programmes.

Acknowledgement and Purpose

This document has been modified from "Guidelines for the Control of Tuberculosis through DOTS Strategy in Pacific Island Countries" with permission of the writing committee of WHO-WPRO (Dr Leopold Blanc, Dr Dong Il Ahn and Dr Carmine Diletto) to be applicable for Wallis and Futuna. Major country-specific additions to the original document, which detail the Wallis and Futuna DOTS strategy and which can be found in Part II of this publication, are:

[1] Directly observed treatment, short course (DOTS)

- Country Background
- Overview of the Wallis and Futuna Tuberculosis Program
- Operational Aspects of Case Detection, Diagnosis and Treatment
- Case Management, Monitoring and Assessment
- Patient Registration and Record Keeping.

The manual was prepared to assist the Wallis and Futuna Health Agency in its endeavour to combat tuberculosis. To this purpose, it has been organized in two parts:

Part I: The WHO-recommended DOTS Strategy - A Regional Model

This section summarizes the WHO Model as developed specifically for Pacific Island Countries in 1999 by the WHO Western Pacific Regional Office.

Part II: The Wallis and Futuna DOTS Strategy - A Country-specific Model

In this section the Wallis and Futuna country-specific DOTS strategy, which was developed based on the WHO Regional Model, is detailed.

We wish to especially acknowledge the WHO-WPRO writing committee who put the original document together, Ms. Mary Lamm for her role in adapting, writing and structuring this version of the text to meet individual country needs, the French and New Zealand Governments for financial assistance and the Secretariat of the Pacific Community for translation and for coordination of editing and printing.

Dr Janet O'Connor, Tuberculosis Specialist
Secretariat of the Pacific Community
Tuberculosis Control Section

SPC
tuberculosis
control
section
work together improve lives make a difference

FOREWORD by the Wallis and Futuna Head of Internal Medicine

This document owes its existence to the specialised tuberculosis treatment service that Dr. Janet O'Connor directs at the Secretariat of the Pacific Community. It covers guidelines for controlling tuberculosis through the DOTS Strategy, as adapted to the special conditions in the Territory of the Islands of Wallis and Futuna. In large part, it reflects the guidelines published for a certain number of other island groups that have been using the DOTS Programme for several years now, e.g. Samoa, the Cook Islands, Tonga.

The impressive increase in the number of tuberculosis cases identified on Wallis and Futuna over the past few years justified an in-depth reconsideration of how this disease was being treated.

Thanks to the efficient and intelligent collaboration of Dr. Janet O'Connor, we were able to rapidly review the disease, set up training for local staff, adapt organisation, and implement the DOTS Programme on Wallis and Futuna.

We would like to express our special acknowledgements to her for this, and to the Secretariat of the Pacific Community for the assistance provided to practitioners and the population of Wallis and Futuna in the health sector, among other areas.

Dr. Laurent Morisse
Head of the Internal Medicine Department, Sia Hospital
Responsible for the prevention of large-scale endemic diseases

FOREWORD by WHO Regional Director

Globally, every year, almost 9 million people develop tuberculosis and 3 million people die from the disease. More people are dying of tuberculosis today than ever before. Almost one third of the global total of infectious cases is detected in the Western Pacific Region, where the number of cases has almost doubled in the last decade to 900 000 cases.

About half a million people die from tuberculosis each year in the Region. The tuberculosis burden is even heavier in the small Pacific island countries, where, in 1998, the average notification rate in 17 of these countries was 73 per 100 000 population, which is much higher than the regional average.

If the control mechanisms are maintained at the current levels, it is projected that the number of tuberculosis cases and related deaths will increase considerably in the next few years. However, this trend can be reversed if the WHO recommended tuberculosis control strategy, the directly observed treatment short course (DOTS), is implemented. The DOTS strategy has been shown to be highly effective in all settings, even during conflicts. A full course of anti-TB drugs, sufficient to cure one patient, costs less than US$40, making the DOTS strategy one of the most cost-effective health interventions. Therefore, the potential to significantly reduce the size of the tuberculosis epidemic already exists, if governments are committed to providing continuous political and financial support.

Implementation of DOTS strategy is still much lower in the Pacific island countries than in the Region as a whole. Health staff in small countries and remote islands are isolated and lack the necessary information and tools to adequately address the problem of tuberculosis. Therefore these guidelines have been developed to facilitate the introduction and expansion of DOTS in such countries.

The guidelines have been produced in collaboration with professionals who have worked in Pacific island countries. Other international experts have also contributed. The guidelines will help national officers, physicians and health workers, as well as patients and community leaders, to implement DOTS effectively. The resulting improvement in tuberculosis care will lead to a reduction of tuberculosis cases and related deaths, reversing the current negative and alarming trend.

I am sure that this publication will be very helpful in curing tuberculosis patients in Pacific island countries, in facilititating their resumption of a more productive life and in reducing the suffering of their families and communities.

Dr Shigeru Omi
Regional Director
WHO Regional Office
for the Western Pacific

PREFACE

The World Health Organization's Western Pacific Region comprises 36 countries with a population of 1.648 billion. The region contains very large countries such as China and Japan, which together contribute to 83% of the total population, and small South Pacific countries, most with a population of less than 200,000.

Reliable information from small island countries is often scarce, and before the implementation of DOTS programs in the Pacific, little was known about the epidemiological situation of tuberculosis in these small Pacific Island countries. Despite limited information, the available data indicate that tuberculosis is common and that treatment of the detected patients is inadequate.

Each of the small Pacific Island countries has its own characteristics that need specific approaches in the implementation of the DOTS strategy. The available tuberculosis guidelines are often too complex and too difficult to adapt. Health managers and health workers of these small countries need to have operational guidelines that are practical and simple to assist them in implementing an effective tuberculosis control programme based on the WHO-recommended DOTS strategy.

The main objectives of the guidelines are to guide:

- the tuberculosis programme manager in the implementation of DOTS strategy and the control of tuberculosis
- health workers and community leaders in identifying and referring suspect cases
- health workers, patients and their families towards achieving a cure.

The guidelines have been tested in a variety of different situations in the field, and comments are welcomed and will help to improve future editions of this manual. Comments on Part I - the WHO regional model - can be sent to WHO Western Pacific Regional Office, Chronic Communicable Disease Unit. Any Comments on Part II - the Wallis and Futuna country-specific model - can be sent directly to the Secretariat of the Pacific Community (SPC), Tuberculosis Control Section.

It is acknowledged that the definitions used, the flow chart for the diagnosis of TB in adults in Figure 2, as well as the symptom-based approach to adverse effects of TB drugs in Annex 3, are from Treatment of Tuberculosis. Guidelines for National Programmes, *Second Edition 1997, WHO.*

Part I

The WHO-recommended DOTS Strategy - A Regional Model

Introduction

Based on the identified needs of Pacific Island countries regarding control of tuberculosis in the region, a model DOTS strategy was adapted by a team of tuberculosis specialists in 1999 for the World Health Organization (WHO), Regional Office for the Western Pacific. This WHO-recommended regional model is presented here in Part I of this manual, to highlight the general framework that was used in the preparation of the Wallis and Futuna country-specific strategy presented in Part II. Further, it is included to be used in future planning for the ongoing improvement of the Wallis and Futuna National Tuberculosis Programme.

A National Tuberculosis Programme (NTP)

The DOTS Framework: Objectives, Targets and Strategy

In the mid-1990s, the concept of DOTS (directly observed treatment, short course) was introduced into the Pacific as it had proven success in other parts of the world as a highly effective strategy for controlling tuberculosis. Since that time, several Pacific Island countries have streamlined the WHO-recommended DOTS strategy to meet their individual situations and have implemented DOTS programs. The fundamental DOTS framework common to all DOTS programs consists of the following objectives, targets and strategy.

■ General Objectives

- Reduce TB mortality and morbidity, and the transmission of the infection.
- Prevent the development of drug resistance.

■ Specific Targets

- Ensure that 100% of the population has access to DOTS.
- Detect 70% of the existing sputum smear-positive TB cases.
- Achieve a treatment success rate* of 85% of detected new sputum smear-positive TB cases.

** Treatment success rate is the sum of the percentage of cases "cured" and the percentage of "treatment completed". As a formula: Treatment Success Rate = % cured + % treatment completed. (Refer to page 10 for detailed Treatment Outcome Definitions and to page 42 for calculation instructions.)*

■ Strategy

To achieve these objectives and targets, the DOTS strategy should be adopted.

The DOTS strategy consists of the simultaneous implementation of the following five elements:

- government and political commitment to fund and sustain a NTP
- microscopy services for detecting sputum smear-positive cases
- regular and uninterrupted supply of anti-TB drugs
- direct observation of standardised short-course treatment (DOT) for sputum smear-positive cases
- standardized recording and reporting system to monitor patient progress.

All five components of DOTS should be in place before starting DOTS operations. First start DOTS in a demonstration and pilot area. *When the pilot centre has achieved 85% treatment success rate, then DOTS can be expanded to other areas.* The pilot centre will then function as a training centre for the new areas into which DOTS will be expanded.

Structure, Staff and Functions

Small countries do not have the usual three- or four-level administrative structures common in larger countries. Government, political and administrative functions are carried out by the Ministry of Health. The hospital is usually the only health service where diagnostic services are available. Therefore, the hospital together with the attached public health department, represents the reference centre where DOTS strategy can, realistically, be implemented. Only very basic health services are delivered at lower levels.

■ The Ministry of Health (administrative function)

The Ministry of Health has policy and administrative functions. A public health worker with expertise in tuberculosis control and administrative skills should be appointed to the Ministry as **National Tuberculosis Programme (NTP) Manager** with the following responsibilities:

- defining the national strategy, including diagnosis and treatment policies, preparation and updating of the tuberculosis control guidelines
- planning, implementing and evaluating the NTP activities, including preparation of budget and action plans
- ensuring that high priority is given to the NTP in the allocation of adequate financial, human and material resources
- coordinating with the laboratory to ensure that a sputum smear microscopy service is in place
- ensuring regular supply of anti-TB drugs, laboratory reagents and other materials
- supervising on a quarterly basis the DOTS Centres and ensuring adequate training of health workers
- consolidating and evaluating quarterly reports on notified cases and outcomes of treatment.

■ The DOTS Centre (clinical function and microscopy service)

Sputum microscopy service is available at this level, where the actual diagnosis of TB is made and the patient TB register is kept. This level is also the tuberculosis referral and reporting unit. The DOTS Centre should be located at the hospital. A public health worker trained in TB control and DOTS strategy should be appointed as **DOTS Coordinator.**

Responsibilities of the DOTS Coordinator are:

- ensuring that the diagnosis of pulmonary TB is based on sputum smear microscopy

- ensuring that daily Directly Observed Treatment (DOT) is applied for the sputum smear-positive cases

- keeping the Tuberculosis Register up to date, preparing and sending to the NTP manager the quarterly reports on notified cases and outcomes of treatment

- ensuring that the patients receive adequate information on the nature of the disease and its treatment

- supervising, training and motivating the health workers of the DOTS Centre as well as those operating at the village level.

FUNCTIONS OF A DOTS CENTRE:

➜ referral TB centre for diagnosis, mainly using microscope
➜ hospitalisation for smear-positive cases during intensive phase
➜ monitoring each patient's directly observed treatment (DOT)
➜ sputum examination follow-up
➜ maintaining and updating the Tuberculosis Register

■ Community or Village Level

This is the level where a primary health care facility may exist but without sputum microscopy service. Health staff at this level have the following responsibilities:

- identifying and referring TB suspects to the DOTS Centre for sputum smear examinations and other investigations; or, when appropriate, transferring the sputum container with necessary paperwork

- referring smear-positive patients for sputum and X-ray follow-up at the end of treatment

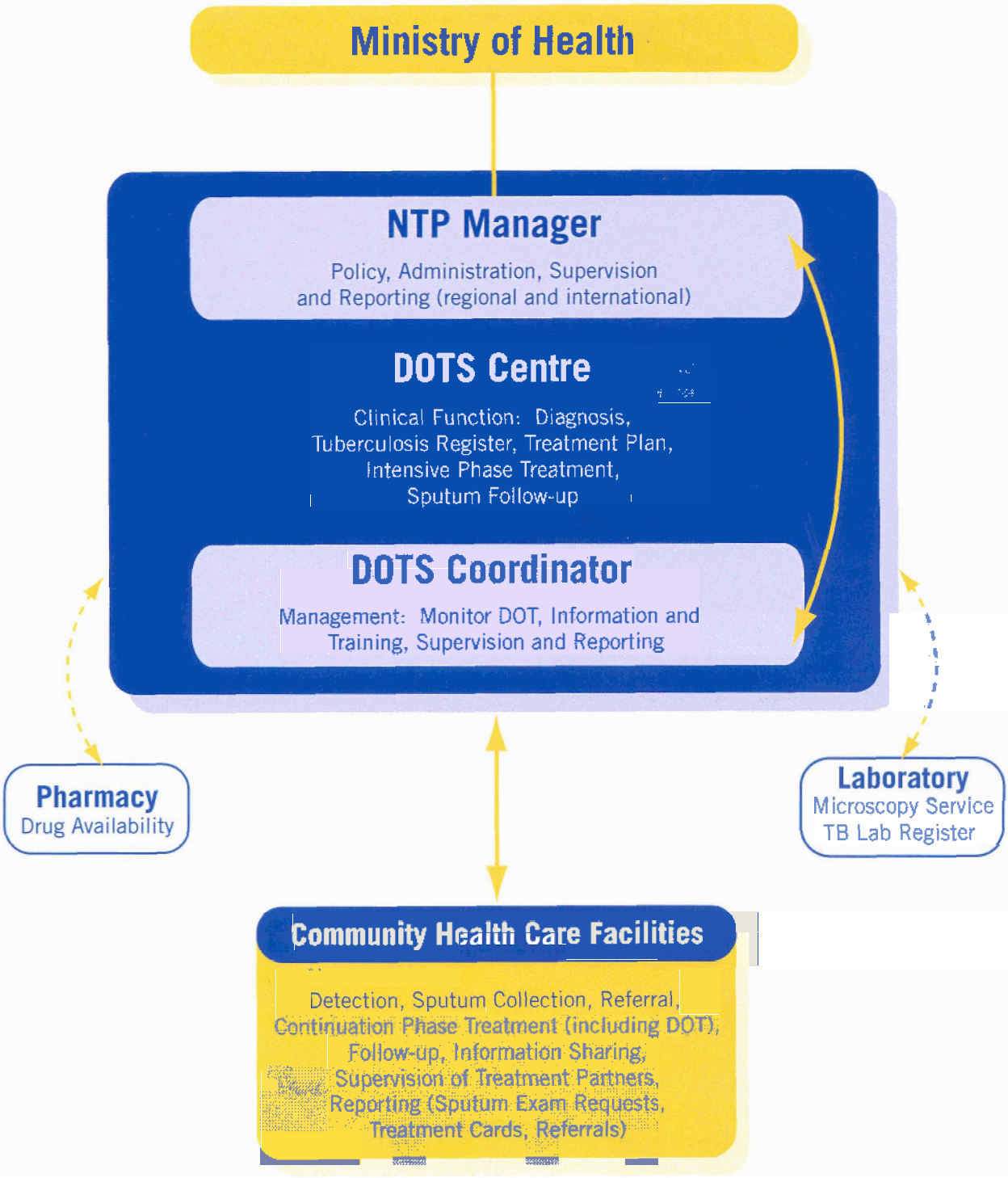
- providing daily direct observation of treatment (DOT) for pulmonary sputum smear-positive patients during the continuation phase and recording the intake of treatment on the patient treatment card

- delivering weekly medications for pulmonary sputum smear-negative and extrapulmonary cases and recording the intake of treatment on the patient treatment card

- tracing of the absentees and administering to the patient, his family and community basic TB information

- supervising community volunteers in charge of daily direct observation of treatment (DOT) and providing them with the weekly supply of anti-TB drugs.

FIGURE 1: MODEL NATIONAL TUBERCULOSIS PROGRAM (NTP) FRAMEWORK



Case Finding

The processes of finding cases and diagnosing tuberculosis are influenced by specific situations such as distance from a diagnostic service; difficult communication; and limited diagnostic tools.

Symptoms of Tuberculosis

It is most often the presenting symptoms of a patient that first alert medical staff to the possibility of tuberculosis. It is therefore essential that all levels of health care staff be made aware of these symptoms.

■ Pulmonary Tuberculosis (PTB)

The most important way of finding cases of pulmonary tuberculosis (PTB) is to identify suspect people. The most common symptom of PTB is a persistent cough lasting for three weeks or more, usually with expectoration. A person with this symptom is categorised as a suspect.

The persistent cough for three weeks or more may be accompanied by one or more of the following additional symptoms:

- ✔ expectoration
- ✔ weight loss
- ✔ coughing up sputum with blood
- ✔ fever
- ✔ tiredness
- ✔ night sweats
- ✔ chest pain
- ✔ shortness of breath
- ✔ loss of appetite

■ Extrapulmonary Tuberculosis (EPTB)

A person with extrapulmonary TB (EPTB) may have the following general symptoms: weight loss, fever and night sweats. Other symptoms and signs depend on the organs affected, for example: swelling, occasionally with pus drainage when lymph nodes are affected; pain and swelling when joints are involved; or headache, stiffness of the neck and drowsiness when there is TB meningitis (usually children). All these symptoms are only suggestive and are tools for the selection of EPTB suspect cases.

Identification and Referral of Suspect Cases

Health workers are responsible for identifying suspect cases encountered by health services. These suspect cases should be referred to the DOTS Centre for further investigation, including the collection of three sputum samples as: SPOT, Overnight and SPOT (see page 6). However, for suspect cases living in remote islands with regular domestic flights, the three sputum samples could be collected locally and then sent to the DOTS Centre by air. In this case the sputum should be sent in a hermetically sealed container within seven days after collection. The laboratory should be notified, and each sample should be clearly labelled and accompanied by a completed "Request for Sputum Examination" form. The DOTS Centre is usually located at the hospital where the diagnosis of TB is made, primarily using microscopy to examine the sputum samples.

The community at large, through its leaders, also has the responsibility of identifying and referring suspect cases to the nearest health facility or, in its absence, directly to the DOTS Centre.

Diagnosis

The definite diagnosis of tuberculosis depends on the diagnostic tools available. In small countries the diagnosis of pulmonary tuberculosis should be based mostly on the sputum smear examination and in a few cases on chest X-ray examination, as well as on physical examination by an experienced

clinician. Clinical examination by an experienced physician is even more important for the diagnosis of the extrapulmonary type of the disease, especially in children, since microbial culture and histological diagnosis are usually not available in small countries.

■ PULMONARY TUBERCULOSIS

The main tool for the diagnosis of pulmonary tuberculosis is the sputum smear examination by direct microscopy for acid-fast bacilli (AFB). Therefore, a person with suspected pulmonary TB should be referred to the DOTS centre for sputum examination. He/she should submit **three sputum samples** in the following way:

Sputum Collection for Diagnosis:
Day 1 (SPOT): this **first sample** is collected on the spot at the time of the consultation, under supervision of a health worker; also at this time, a sputum container is given to the suspect for collection of the second sputum sample, early the next morning.

Day 2 (Overnight): the suspect brings the **second sample**, collected early that morning, to the health facility.

Day 2 (SPOT): the **third sample** is collected on the spot under supervision when the suspect brings the second sample to the health facility.

Each of the sputum samples should be clearly labelled and accompanied by a completed "Request for Sputum Examination" form. At the laboratory, the results of each preliminary and each follow-up sputum examination are to be entered on the "Tuberculosis Laboratory Register".

According to the result of sputum smear examinations (see Fig. 2), pulmonary TB is classified as:
- pulmonary tuberculosis sputum smear-positive
- pulmonary tuberculosis sputum smear-negative.

■ EXTRAPULMONARY TUBERCULOSIS

A suspect of extrapulmonary TB should also be referred to the DOTS Centre. The diagnosis of extrapulmonary TB is made on strong clinical evidence of active tuberculosis and a decision by a physician to start anti-TB treatment. The decision must be based on thorough clinical assessment that is supported by radiological findings (e.g.: pleural or pericardial effusion, bone and joint TB, renal TB); biological abnormalities (e.g.: in pleural, peritoneal and cerebro-spinal fluid); positive tuberculin test (and, sometimes, identification of AFBs in tissue or fluids such as superficial abscess, lymphadenitis, or in urine).

TB CLASSIFICATIONS

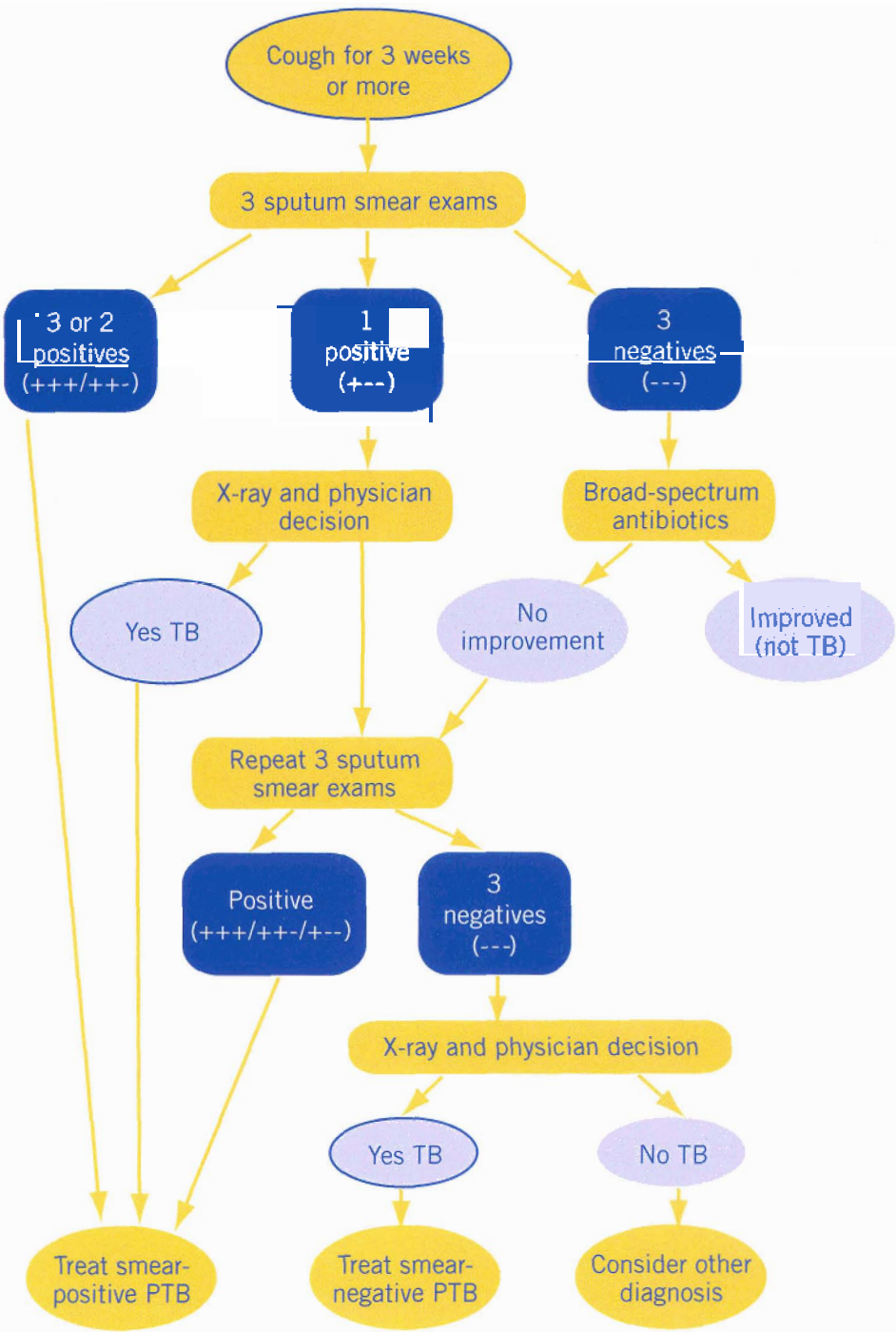
Pulmonary TB (PTB)	Extrapulmonary TB (EPTB)
→ Tuberculosis affecting the lungs: • Sputum smear-positive • Sputum smear-negative	→ Tuberculosis affecting organs other than the lungs

For the diagnosis of pulmonary tuberculosis follow the steps as indicated in Figure 2.

Notes:

- A patient with both pulmonary and extra-pulmonary TB is classified as having pulmonary tuberculosis. This classification provides the basis for prescribing the most effective treatment regimen.
- As soon as a diagnosis of tuberculosis is made, the patient must be registered on the "Tuberculosis Register" with their assigned TB registration number. The format of the Register provides a concise location for the documentation of each patient's laboratory and treatment results as an ongoing individualised record that allows ease in tracking at the local level and monitoring at the national level. (See page 37).

FIGURE 2: THE ROAD TOWARDS THE DIAGNOSIS OF ADULT PULMONARY TUBERCULOSIS



Case Definitions and Classification, Types of Patients and Treatment Outcomes

Tuberculosis is a global problem. In order to monitor control of the disease, it is essential that terms and definitions be used consistently when identifying, diagnosing, treating and reporting outcomes for tuberculosis patients.

The following boxes summarize the recommended definitions that should be used in all patient and programme documentation for recording, reporting and allocation of treatment.

Case Definitions* and Classification**

Pulmonary smear-positive
Minimum 2 out of 3 sputum smear-positive for AFB by microscopy.

OR

1 out of 3 sputum smear-positive with chest X-ray consistent with PTB and decision to treat made by a physician.

Pulmonary smear-negative
First set of 3 sputum smear-negative for AFB,

lack of clinical response despite 2 weeks of a broad-spectrum antibiotic,

second set of 3 sputum smears still negative, taken at least 2 weeks apart from the first set,

x-ray consistent with PTB and decision to treat made by a physician.

OR

Severely ill patient with 3 sputum smear-negative for AFB,

x-ray consistent with extensive PTB and decision to treat made by a physician.

Extrapulmonary tuberculosis
Strong clinical evidence of active extrapulmonary TB and a decision by a physician to start anti-TB treatment.

* "Case Definition" determines what constitutes a case of tuberculosis.
** "Classification" refers to the site affected and the result of the sputum examination.

Types of Patients*

New
A patient who has never been treated for TB or who has taken anti-tuberculosis drugs for less than 4 weeks.

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

Treatment failure
A previously sputum smear-positive patient who, while on treatment, remained or became again smear-positive five months or later after commencing treatment. It is also a patient who was initially smear-negative before starting treatment and became smear-positive after the second month of treatment.

Treatment after interruption (TAI) (default)
A patient who has taken at least 4 weeks of treatment but has subsequently interrupted treatment for 2 consecutive months or more, and returns to the health service with smear-positive sputum.

Transfer in
A patient who has been transferred into the reporting unit from another reporting unit in order to continue treatment.**

Other
All cases that do not fit the above definitions. This group also includes **chronic cases**, patients who are sputum-positive at the end of a re-treatment regimen.

* "Types" of patients refers to the history of previous treatment.

** In the Pacific Island setting, each country has only **one** reporting unit, which is where tuberculosis data is compiled and maintained at the national level in **one** national Tuberculosis Register. Therefore, to come from another reporting unit, a "transfer in" patient would have to be referred from a different country. Internal transfers between health facilities within the same Pacific Island country are not considered "transfer in" because they are already registered on the national Tuberculosis Register.

Treatment Outcomes*

Cured
Patient who was smear-positive at diagnosis and became smear-negative at, or one month before, the completion of treatment and on at least one previous occasion.

Treatment completed
Smear-positive patient who has completed treatment but without proof of cure as determined by smear examination or smear-negative patient who has completed treatment.

Treatment failure
Patient who remains or becomes again smear-positive at 5 months or later during treatment.

Died
Patient who dies for any reason during the course of TB treatment.

Treatment interrupted (default)
Patient whose treatment was interrupted for 2 consecutive months or more.

Transfer out
Patient who has been transferred to another reporting unit and for whom the treatment outcome is not known.

* "Treatment outcomes" refers to the result of the patient treatment.

Anti-TB Drugs, Treatment Categories and Regimens

Tuberculosis is a contagious disease caused by *Mycobacterium tuberculosis*. The main source of the infection is a person with TB of the lungs, usually a sputum smear-positive case, who coughs, sneezes or spits infectious droplets of the bacteria in the air. Anyone who breathes in infected droplets is at risk of acquiring the infection and later, 10% of those infected will develop the disease. Left untreated, a patient with TB of the lungs will infect between 10 and 15 persons a year. Without treatment, after five years, 50% of pulmonary patients will die. If poorly treated, TB patients become chronic cases that will live longer but spread the infection for a longer time with bacilli that are often resistant to one or more anti-TB drugs. Therefore, once the decision to start TB treatment has been made, it is absolutely necessary to ensure that the patient completes the full course of treatment.

The treatment of TB for new cases consists of an initial two-month intensive phase followed immediately by a four-month continuation phase. For retreatment cases, the intensive phase lasts three months and the continuation phase, five months.

Recommended Anti-TB Drugs

The following table provides a list of the anti-TB drugs that are currently recommended along with a suggested range of doses in mg/kg. An additional table detailing the dosage forms and strengths of these anti-TB drugs is given in Annex 1. Specific combinations and doses are detailed below and on page 13.

Anti-TB drugs are safe and most patients complete their treatment course without any significant side effects. However, a few patients do develop adverse effects to the drug taken. A symptom-based approach to the most common adverse effects of anti-TB drugs is given in Annex 3.

ESSENTIAL ANTI-TB DRUGS AND RECOMMENDED DAILY DOSES

Anti-TB drugs (abbreviation)	Doses in mg/kg (range)
Isoniazid (H)	5 (4-6)
Rifampicin (R)	10 (8-12)
Pyrazinamide (Z)	25 (20-30)
Streptomycin (S)*	15 (12-18)
Ethambutol (E)**	15 (15-20)

* Streptomycin should not be given to pregnant women; for patients more than 50 years of age, 750 mg should be given.
** Ethambutol should not be given to children under six years of age.

Treatment Categories and Regimens

There are currently several treatment regimens that are all effective in curing the different types of the disease. However, to facilitate field operations and drug management, given the specific situation of the Pacific Islands, *only three treatment regimens are recommended.* A treatment category, which includes a specific group of TB patients, corresponds to each treatment regimen.

Treatment category I includes the new PTB sputum smear-positive and other severe forms of the disease. For this reason, category I should be given the highest priority. Category III includes new PTB sputum smear-negative and extrapulmonary cases, both less severe types of the disease. Category III should be given the lowest priority.

TABLE 1: RECOMMENDED TREATMENT CATEGORIES BY TYPES OF PATIENT, TREATMENT REGIMES AND THEIR PHASES

TREATMENT CATEGORY	Types of Patient	Intensive phase		Continuation phase	
		Drugs	Duration	Drugs	Duration
I	• New pulmonary smear-positive • New pulmonary smear-negative, but severe (i.e. with extensive parenchymal involvement) • New cases of severe forms of extrapulmonary TB*	2HRZE**	2 months daily	4HR	4 months daily
II	Retreatment of pulmonary smear-positive cases • Relapse • Failure • Treatment after interruption (TAI)	2HRZES 1HRZE	3 months daily with S given only for the first two months	5HRE	5 months daily
III	• New pulmonary smear-negative (other than in category I) • New less severe forms of extrapulmonary TB	2HRZ	2 months daily	4HR	4 months daily
IV	Chronic and MDR-TB cases (still sputum-positive after supervised retreatment)	Individualised treatment regimes, determined on a case-by-case basis, are prescribed by the doctor based on the most recent WHO guidelines.			

* TB meningitis, pericarditis, peritonitis, bilateral or extensive pleurisy, miliary, spinal, intestinal and genitourinary disease.

** The number before the abbreviation of the drugs indicates the duration in months of their administration.

Treatment Doses for Adults and Children

Whenever possible, to prevent drug resistance and improve patient compliance, the fixed-dose combinations (FDCs) of anti-TB drugs should be used. Examples of different FDCs for the three treatment categories, for children and adults, are given in Annex 2. If loose drugs are used, examples of daily dosages for children and adults are given in the following tables.

■ TREATMENT CATEGORY I FOR NEW CASE ADULTS

(new pulmonary smear-positive, smear-negative with extensive parenchymal involvement, severe forms of extrapulmonary TB)

ADULT	INTENSIVE PHASE (2 months daily)				CONTINUATION PHASE (4 months daily)	
Weight (kg)	Rifampicin 300mg	Isoniazid 300mg	Pyrazinamide 500mg	Ethambutol 400mg	Rifampicin 300mg	Isoniazid 300mg
30-37	1	1/2	1 1/2	1 1/2	1	1/2
38-54	1 1/2	1	2 1/2	2	1 1/2	1
55-70	2	1	3 1/2	3	2	1
71-90	2 1/2	1 1/2	4	3 1/2	2 1/2	1 1/2

■ TREATMENT CATEGORY II FOR RETREATMENT CASE ADULTS

(relapses, failures, treatment after interruption/default)

ADULT	INTENSIVE PHASE (3 months daily)					CONTINUATION PHASE (5 months daily)		
Weight (kg)	Rifampicin 300mg	Isoniazid 300mg	Pyrazina-mide 500mg	Ethambutol 400mg	*Streptomy-cin 1g	Rifampicin 300mg	Isoniazid 300mg	Ethambutol 400mg
30-37	1	1/2	1 1/2	1 1/2	0.50	1	1/2	1 1/2
38-54	1 1/2	1	2 1/2	2	0.75	1 1/2	1	2
55-70	2	1	3 1/2	3	1	2	1	3
71-90	2 1/2	1 1/2	4	3 1/2	1	2 1/2	1 1/2	3 1/2

* Streptomycin is only given for the first 2 months of the intensive phase and 0.75g should be given to patients over 50 years of age

■ TREATMENT CATEGORY III

(new pulmonary smear-negative - other than in category I, new less severe forms of extrapulmonary TB)

ADULT	INTENSIVE PHASE (2 months daily)			CONTINUATION PHASE (4 months daily)	
Weight (kg)	Rifampicin 300mg	Isoniazid 300mg	Pyrazinamide 500mg	Rifampicin 300mg	Isoniazid 300mg
30-37	1	1/2	1 1/2	1	1/2
38-54	1 1/2	1	2 1/2	1 1/2	1
55-70	2	1	3 1/2	2	1
71-90	2 1/2	1 1/2	4	2 1/2	1 1/2

■ TREATMENT CATEGORY I FOR NEW CASE CHILDREN

(use the same doses for new case children Category III but without streptomycin)

PAEDIATRIC	INTENSIVE PHASE (2 months daily)				CONTINUATION PHASE (4 months daily)	
Weight (kg)	Rifampicin 150mg	Isoniazid 100mg	Pyrazinamide 500mg	Streptomycin 1g	Rifampicin 150mg	Isoniazid 100mg
Up to 7*	1/2	1/2	1/2	0.25	1/2	1/2
8-9	1/2	1/2	1/2	0.25	1/2	1/2
10-14	1	1/2	1	0.25	1	1/2
15-19	1	1	1	0.50	1	1
20-24	1 1/2	1	1 1/2	0.50	1 1/2	1
25-29	2	1 1/2	1 1/2	0.50	2	1 1/2

* Doses may be calculated ad hoc by using syrup formulation.

Operational Aspects of Case Management and Monitoring

The following regional model has been recommended by WHO; however, each Pacific Island country adapts the model to meet their own specific situation and needs. The country-specific adaptation for Wallis and Futuna can be found in Part II of this document.

New Sputum Smear-Positive Cases

Sputum smear-positive patients are hospitalised for the whole duration of the intensive phase of two months, at the end of which a sputum smear examination is conducted. Those patients who have become sputum smear-negative immediately start the four-month continuation phase of treatment, as an outpatient or from home.

For those who remain smear-positive, the intensive phase, as well as the hospitalisation stay, is prolonged for a third month. At the end of this extension, another sputum smear examination is conducted and recorded, but the patient starts the continuation phase irrespective of the result of this smear examination.

For all patients, an additional follow-up sputum examination is also conducted after the fifth month of treatment. If this sputum smear is still positive the patient is re-classified as a treatment failure, re-registered on the Tuberculosis Register, with a new TB number, and should start the retreatment (Category II) regimen afresh.

During the hospital stay, a health worker observes the patient swallowing their medications every day (DOT) and records the drug intake on the patient treatment card. The continuation phase is carried out through the health facility close to the patient's home with the treatment partner observing the daily intake of medications and completing the treatment card.

Retreatment Cases Sputum Smear-Positive: Relapse, Failure, Treatment after Interruption

Retreatment sputum smear-positive patients are also hospitalised for the intensive phase, which, in this category, is for three months duration and which culminates with a sputum smear examination. Those patients whose results are sputum smear-negative immediately begin the five-month continuation phase of their treatment. In the case of sputum smear-positive results, the intensive phase as well as the hospitalisation stay is extended to a fourth month. All patients also have an additional follow-up sputum examination after the seventh month of their treatment.

During the hospital stay, a health worker observes the patient swallowing the medications every day (DOT) and records the drug intake on the patient treatment card. The continuation phase is carried out at the health facility close to the patient's home and a treatment partner observes daily and then records the intake of the medications.

New Sputum Smear-Negative Pulmonary and Extrapulmonary Cases

These patients are treated at home as outpatients, except for those who are severely ill and require a short period in hospital. Their treatment, using a weekly supply of medications, is self-administered during both the intensive and continuation phases. However, the first dose of the weekly supply should be directly observed (DOT) by the treatment partner who will also monitor the entire treatment course.

Note: Any patient who is transferred to another location (locally, within the country or internationally) should have their records sent to the new location along with a completed "Referral and Transfer" form.

TABLE 2: SUMMARY OF THE MECHANISMS FOR DIRECTLY OBSERVED TREATMENT (DOT) ACCORDING TO THE DIFFERENT TREATMENT CATEGORIES AND TYPES OF PATIENT

Treatment categories and types of patient	Regimen	Routine sputum follow-ups (See page 17)	Drugs administration		Treatment partner
			Intensive phase	Continuation phase	Ambulatory/domiciliary
Category I **New cases: pulmonary smear-positive** **New cases: pulmonary smear-negative, but severe (i.e. with extensive parenchymal involvement)** **New cases: Extrapulmonary, but severe**	2HRZE/ 4HR	End of second month During the sixth month At the DOTS Centre	DOT daily as inpatient for 2 months If patient is smear-positive at the end of the second month, the intensive phase in the hospital is extended for 1 more month	DOT daily* (4 months) Outpatient: patient within 1 hour from the health facility Patient at home: patient > 1 hour from the health facility	Health worker for outpatients Outreach health worker or Community volunteer for home treatment under supervision of a health worker
Category II **Retreatment of pulmonary smear-positive cases** • **relapse** • **failure** • **treatment after interruption (default)**	2HRZES/ 1HRZE/ 5HRE	End of third month During the eighth month At the DOTS Centre	DOT daily as inpatient for 3 months If patient is smear-positive at the end of the third month, the intensive phase in the hospital is extended for one more month	DOT daily (5 months) Outpatient: patient within 1 hour Patient at home: patient living > 1 hour from the health facility	As above
Category III **New cases: pulmonary smear-negative (other than in Category I)** **New, less severe forms of extrapulmonary TB**	2HRZ/ 4HR	None as routine	Self-administered (6 months) with weekly drug supply The first dose of the weekly supply must be administered under direct observation Severely ill cases should be hospitalised for a short period Outpatient: patient living within 1 hour from the health facility Treatment at home: patient living > 1 hour away from the health facility		As above

* Treatment should be directly observed 5 days a week, but the patient needs to take medication every day (7days/week)

Treatment kit

A treatment kit is ideal in a set up where there are more than one hospital and more than one health centre. It is prepared for the patient upon discharge from the hospital or when treatment is to be supervised through a health centre outside the main DOTS centre. A treatment kit should be made available for each patient in order to encourage that:

- treatment recording is done properly
- drug swallowing is observed by a trained staff and
- TB drug supplies are available throughout the entire treatment duration.

The treatment kit contains all the medications necessary to complete the intensive and the continuation phase of the treatment. It also contains the patient treatment card, two sputum cups, and patient information sheet as well as an instruction sheet for the treatment partner.

Treatment Kit

The treatment kit is a box kept at the health facility that contains the following:

- ✔ medications for intensive and continuation phase
- ✔ treatment card
- ✔ sputum cups
- ✔ patient's information sheet
- ✔ instruction sheet for treatment partner

A treatment kit is prepared and allocated in the DOTS Centre for each patient who is diagnosed with tuberculosis. For hospitalised cases, the kit is given to hospital doctors or nurses. Patients who continue treatment in a health facility as outpatients or from home are provided with a treatment kit for the continuation phase. The kit is kept at the health facility under the responsibility of the health worker. However, if the patient lives very far from the health facility, community volunteers or outreach health workers may keep the kit. It will facilitate proper, easy case management from the first day of treatment until the patient is declared cured by a physician.

Treatment partner

The treatment partner is responsible for observing that patients swallow their medicines as prescribed. The treatment partner may be a health worker or a community volunteer (religious or government leader, a teacher or other influential community leader). Treatment partners are assigned to all TB patients, in particular smear-positive cases. If the treatment partner is a trained community member, he is supervised by and is accountable to the health worker.

If patients live less than one hour's travel from the DOTS Centre or health facility where they are taking the treatment, they may take the medications at the DOTS Centre or at the health facility. In this case, the treatment partner is a health worker of the DOTS Centre or of the health facility. *If patients live more than one hour away* from the DOTS Centre or health facility, the treatment may be delivered at the patient's home by an outreach health worker or, alternatively, by a trained community volunteer.

In the case of a community volunteer chosen as a treatment partner, the health worker will provide no more than a weekly supply of TB medications to the treatment partner (community volunteer). The treatment partner delivers the daily medications to the sputum smear-positive patients, observes the patients swallowing the drugs (DOT) and records this on the patient treatment card. For sputum smear-negative and extrapulmonary patients, the medications are delivered every week and the first dose of the weekly supply is supervised by the treatment partner.

Sputum Smear Examinations to Monitor Patient Progress and Cure

Sputum samples should be routinely examined for diagnosis and follow-up using the following intervals:

TABLE 3: DETAILS, INCLUDING TIMETABLE, FOR MONITORING PATIENT TREATMENT

SPUTUM SAMPLES and ACTIONS	Category I	Category II	Category III
Diagnosis using 3 initial samples: SPOT, Overnight, SPOT (see page 6)	Pre-diagnosis	Pre-diagnosis	Pre-diagnosis
1st Follow-up using 2 samples: Overnight, SPOT Collected at the end of the Intensive Phase. If negative, patient immediately starts continuation phase. If positive, patient continues intensive phase for 1 more month.	At end of 2nd month	At end of 3rd month	Not required
2nd Follow-up using 2 samples: Overnight, SPOT This follow-up is conducted **ONLY IF** the patient tested positive at the 1st Follow-up. After this second follow-up, all patients start the continuation phase of treatment, regardless of sputum results.	At end of 3rd month	At end of 4th month	Not required
3rd Follow-up using 2 samples: Overnight, SPOT Patients who are still positive at this follow-up are re-classified as treatment failure, re-registered, given a new TB number and start retreatment afresh, following the Category II regimen.	At end of 5th month or beginning of 6th month	At end of 7th month or beginning of 8th month	Not required
4th Follow-up using 2 samples: Overnight, SPOT Collected at the end of the Continuation Phase **ONLY FOR** those patients still producing sputum who do not yet have two consecutive sputum smear-negative results.	At end of 6 month treatment	At end of 8 month treatment	Not required
DRUG REGIME			
Intensive Phase	2HRZE	2HRZES 1HRZE	2HRZ
Continuation Phase	4HR	5HRE	4HR

Results of these examinations should be documented in the laboratory on the "Laboratory Register" as well as entered, in a timely manner, on the "Tuberculosis Register" at the DOTS Centre.

When treatment is complete, sputum smear-positive patients are referred for final assessment to the DOTS Centre where they were originally diagnosed.

Category III patients do not need routine sputum follow-ups during their course of treatment. However, if the patients do not improve or their situation deteriorates, they should be referred to the DOTS Centre where clinical and bacteriological examinations should be performed again.

Reporting of Case Findings and Treatment Outcomes

Regular reporting is an integral component of each DOTS programme to allow for monitoring of progress at all levels - local, national, regional and global. For this purpose, the following quarterly reports are recommended by WHO.

Quarterly Report on Tuberculosis Case-Finding

This report on case-finding provides a structured means for concise reporting of the numbers of new cases of tuberculosis which are identified each quarter. It is to be submitted to WHO at the beginning of the month directly following the end of the quarter being reported (i.e. in early April for the first quarter, which would include statistics for all of January, February and March). The statistics reported on this form can be used to calculate the notification rates for tuberculosis in a particular country, with a special focus on the rate for smear-positive cases. This rate is extremely important for monitoring tuberculosis trends at both the national and the regional levels, which becomes the basis for decision-making and policy development.

Quarterly Report on the Outcomes of Treatment of Pulmonary Tuberculosis Sputum Smear-Positive Patients

Monitoring of treatment outcomes is essential in determining the success of DOTS programmes and in identifying alarming trends, such as MDR-TB. This form is used to report the outcomes of tuberculosis treatment on a quarterly basis and from it, treatment success rates can be calculated, thus giving important information to DOTS programmes, governments and WHO. As with the report on case-finding, this report is to be submitted to WHO at the beginning of the month directly following the end of the quarter being reported. (Refer to page 41 for details)

Notes:

- For country-specific details on the completion and submission of these forms and on methods for calculating notification rates and treatment success rates, refer to pages 40 – 42 .
- It is strongly recommended that a copy of each report be kept in-country for internal monitoring purposes.

Part II

The Wallis and Futuna DOTS Strategy – A Country-specific Model

Country Background

The Territory of Wallis and Futuna comprises a group of three islands: Wallis, 96 sq. km; Futuna, 64 sq. km and Alofi, 51 sq. km. These islands are located more than 2000 km from New Caledonia.

The kingdom of Wallis is divided into three districts: the centre, Hahake, where the capital Mata'utu is located; the north, Hihifo; and the south, Mua. Futuna is divided into two kingdoms: Alo in the northeast, Singave in the southwest. The third island, Alofi, is uninhabited.

The population numbers about 15,000 inhabitants, nearly 5,000 of whom live on Futuna. It should be noted that there has been large-scale emigration of the population to New Caledonia, where about 18,000 Wallisians and Futunans live in the greater Noumea area.

The Territory's Health Department is organised into a Health Agency with the main hospital located on Wallis (Sia Hospital in Mata'utu), a large dispensary in Futuna (Kaleveleve Hospital), and several health centres, three on Wallis, i.e. one in each district, and two on Futuna, i.e. one in each of the two kingdoms. There are no private medical nor pharmaceutical practices on Wallis or Futuna.

The technical support centre is located in Sia Hospital on Wallis and offers a laboratory with a biologist and four technicians; x-ray equipment and two operators; and a two-room operating ward with a surgeon and anaesthesiologist, who run the 18-bed service, including 2 beds for intensive care. Sia Hospital also includes a maternity ward with a gynaecologist-obstetrician and two nationally accredited midwives; a 21-bed internal medicine ward; general and cardiovascular ultrasound equipment; a physical therapist; and, finally, a pharmacist who manages the Territory's entire supply of drugs, consumables, and medical accessories.

On Wallis, each health centre is an advanced medical centre with one or two doctors, one nurse, several health agents and health educators and a complete dental office.

On Futuna, the two dispensaries operate with daily nursing consultations and twice-weekly medical consultations. Kaleveleve Hospital covers most medical activity and operates with three doctors, a dentist, a mid-wife and a physical therapist. It is equipped with basic technical support capacities in terms of radiology and laboratory services, ultrasound and a pharmacy that carries all the same drugs as on Wallis.

Patients who cannot be cared for on Futuna due to the severity of their illnesses, inadequate diagnostic resources or the need for surgical treatment are sent to Wallis since there are quasi-daily flights between the two islands.

So, the populations of Wallis and Futuna have easy access to care. Furthermore, access to care is completely free of charge, both within the Territory and outside, including care for about 20 cases that need medical evacuation to New Caledonia each month, the cost of which is entirely underwritten by the French government through the Health Agency.

Overview of the Wallis and Futuna Tuberculosis Programme

Wallis and Futuna Adopts the DOTS Strategy

In recognition of the growing problem of tuberculosis in the region, the WHO Regional Committee for the Western Pacific adopted, in September 1999, a resolution which declared a regional "Tuberculosis crisis" and which urged member states to work together to solve the problem. Out of this initiative, the *Pacific Strategic Plan to Stop TB 2000* was developed. One of the main targets of this strategic plan was to, by 2002, "adopt DOTS as the primary tuberculosis control strategy in all countries and areas and territories".

As part of an SPC/WHO co-organised regional meeting (1st Stop TB Meeting in the Pacific Islands), SPC member countries, including Wallis and Futuna, met together in June 2000 to discuss the status of tuberculosis among Pacific Island countries, to review the regional strategic plan and targets and to decide what action to take. The end result of this meeting was endorsement of the regional recommendations as per the strategic plan.

In August 2002, after securing funding from the French government, the SPC Tuberculosis Specialist conducted an in-country tuberculosis evaluation. The results of this evaluation, as well as the fact that tuberculosis is endemic in Wallis and Futuna and that the number of identified cases is relatively high, justified implementation of controlled treatment using the DOTS strategy throughout the Territory. Following training of Health Agency staff, the Wallis and Futuna DOTS programme was launched during the final quarter of 2002.

The Wallis and Futuna National Tuberculosis Program (NTP) Framework

Organisation of the Territory's overall health sector results from a law giving the French national government responsibility for ensuring public health and hygiene. The Health Agency has a double mission: to provide diagnostic and curative medical care and to implement necessary health education and prevention measures.

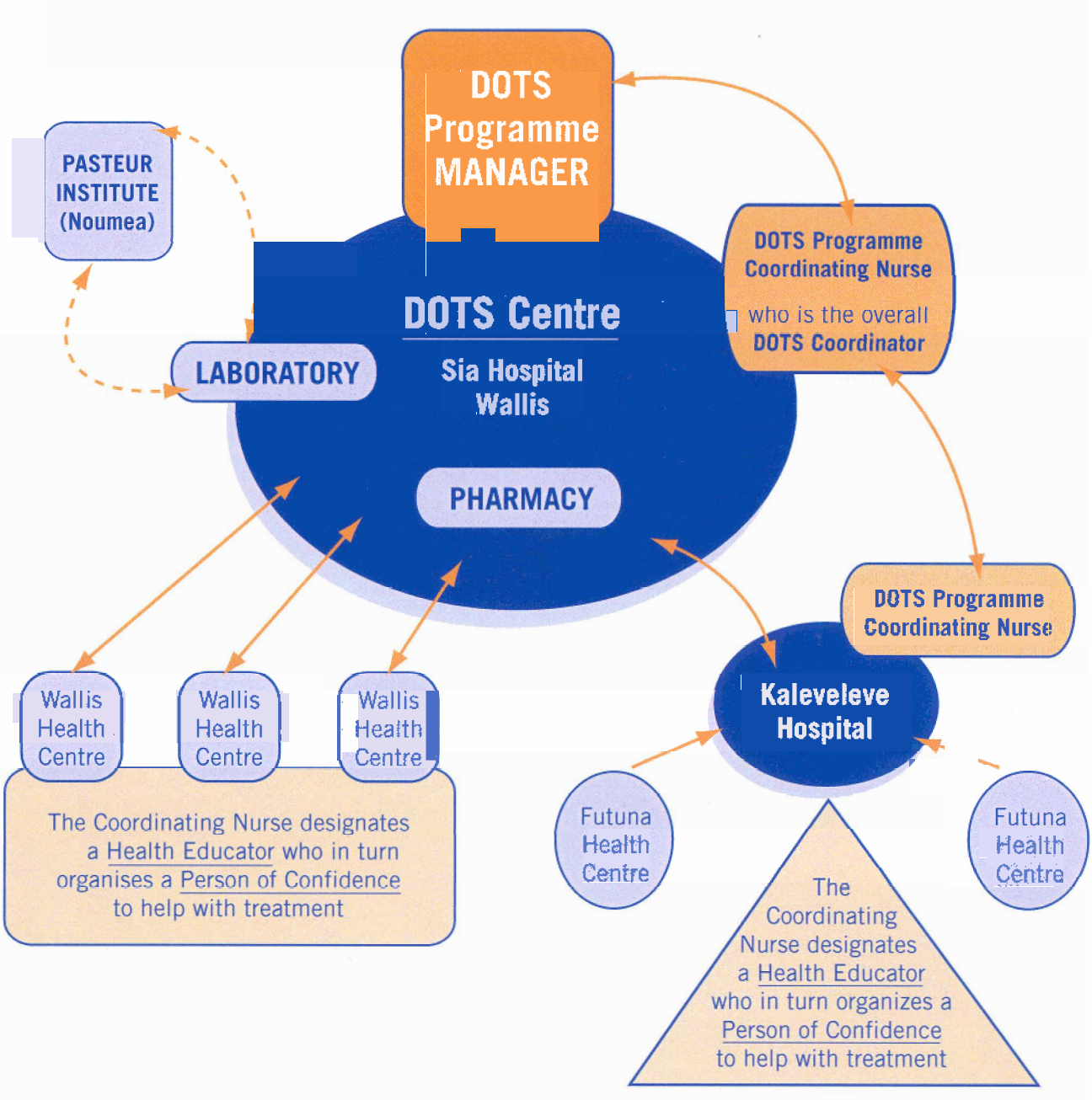
On Wallis, each of the three health centres meets the needs of the population of a single district, under the direction of a doctor who leads a care team of about eight people.

On Futuna, the two health centres are small dispensaries of Kaleveleve Hospital and operate with doctors from that hospital under the direction of Futuna's head doctor.

This is all coordinated by the Head of the Internal Medicine Department at Sia Hospital, who is also responsible for vector born, communicable and non-communicable diseases. Sia Hospital then, functions as the centralised technical support unit for the territory-wide Health Department, and doctors at each of the health centres refer cases to Sia Hospital if additional testing and specialised advice is needed

This same model is used for the National Tuberculosis Program, with Sia Hospital designated as the DOTS Centre - the central unit for management of all clinical functions of the Wallis and Futuna DOTS Programme. Figure 3 below gives a summary of this model as used for the Wallis and Futuna NTP.

Figure 3: Wallis and Futuna National Tuberculosis Programme (NTP) Flow Chart



■ STAFF

In Wallis and Futuna, the **DOTS Programme Manager** is responsible for overseeing all policy and administrative functions of the NTP including:

- ensuring that the DOTS strategy is in place and operating smoothly, especially in relation to:
  - continued government and political commitment to support the NTP
  - detection of sputum smear-positive cases through microscopy services at the laboratory (currently provided through Pasteur Institute in Noumea)
  - regular and uninterrupted supply of anti-TB drugs through the pharmacy
  - ongoing DOT during treatment of all identified tuberculosis patients
  - monitoring of each patient's progress using the standardized reporting system
- ensuring adequate support of health staff on all aspects of the Wallis and Futuna DOTS programme
- supervising all tuberculosis patients during the first two weeks of their intensive phase treatment, while hospitalised at Sia Hospital
- completing necessary paperwork (i.e. Tuberculosis Register) to track the progress of tuberculosis patients
- representing Wallis and Futuna at regional and sub-regional tuberculosis related meetings
- consolidating and evaluating quarterly reports on tuberculosis case findings and on treatment outcomes (refer to Annex 6, SPC/TUB Forms 06 and 07).

There are two **DOTS Programme Coordinating Nurses**, one based on each island. The coordinating nurse at Sia Hospital on Wallis is the overall **DOTS Coordinator**; however, the two coordinating nurses take each other's place so that there are no gaps in tracking the management and progress of each tuberculosis patient. **The Coordinating Nurses** are responsible for:

- creating a Treatment Card for each Koch's bacillus-positive patient during hospitalisation in the ward at Sia hospital
- transferring a copy of this Treatment Card to the original health centre, along with a completed Tuberculosis Referral/Transfer form, when the patient leaves hospital
- regularly verifying the Tuberculosis Registers in each of the secondary facilities (the health centres on Wallis, and Kaleveleve Hospital on Futuna) and recovering their data for inclusion in a quarterly report to the Manager
- comparing data on the Laboratory Register (kept at the laboratory) with that of the secondary facilities to ensure that it is consistent.

In addition, the overall **DOTS Coordinator** is also responsible for assembling the data from Wallis, Futuna and the laboratory so as to produce a synopsis and prepare the official quarterly reports for submission to the DOTS Manager, SPC and WHO.

As part of the treatment team, a **Health Educator** is appointed by the DOTS Coordinating Nurse on each island to:

- visually verify (DOT) that patients take their medication every day from Monday to Saturday during the Intensive Phase of treatment, and then one day a week during the Continuation Phase

- each week, distribute the remaining supply of medication to the Person of Confidence who will observe those treatment sessions

- complete the patient's Treatment Card for each treatment directly observed and for those treatments observed, and reported, by the assigned Person of Confidence.

The Health Educator is also responsible for "negotiating" this **Person of Confidence**, from the village or the family. The Person of Confidence:

- accompanies the patient to each health centre visit in order to pick up the correct doses of medication for administration during the week and:

  - visually verifies (DOT) that medication during the intensive phase is taken on Sundays, holidays and any additional days when the Health Educator missed seeing the patient

  - visually verifies (DOT) that medication during the continuation phase is taken six days per week

- documents each treatment observed and then reports back, during the weekly visit to the district health centre, so that the Health Educator can complete the Treatment Card.

■ FACILITIES (REFER TO PAGE 21, FIGURE 3)

Sia Hospital in Wallis operates as the **DOTS Centre** for the Territory. In this capacity, it is the central tuberculosis management, referral and reporting unit. It is also the location where the DOTS Programme Manager and the DOTS Programme Coordinator are based.

Both the **laboratory**, for sputum collection and documentation, and the **pharmacy**, for anti-TB medication distribution, are located at the DOTS Centre and operate as fundamental components of the NTP. At present, all sputum samples, including initial samples for diagnosis and repeat samples for follow-up examination, for all tuberculosis patients are transferred for analysis, once a week, from the DOTS Centre laboratory to the Pasteur Institute in Noumea (New Caledonia). It is planned that once an additional laboratory technician is added to the Wallis staff, that analysis of sputum samples will be completed locally in Wallis.

Once diagnosed, all patients in the Territory begin their tuberculosis treatment by being hospitalised at Sia Hospital where they receive the first two weeks of their intensive phase medications under the supervision of the DOTS Programme Manager.

Doctors at **Kaleveleve Hospital** in Futuna provide screening, diagnostic and follow-up services for all Futuna tuberculosis patients. Sputum samples are collected at Kaleveleve and sent by air to the DOTS Centre laboratory in Wallis for documentation and then transfer to Noumea. Other diagnostic procedures, including frontal thorax x-rays and skin tests are also carried out at Kaleveleve. Highly suspect cases are transferred to Sia Hospital on Wallis where actual diagnosis and treatment plans are finalised. Treatment of Futuna tuberculosis patients, except for the first two weeks of the intensive phase when all patients are

hospitalised at Sia Hospital, takes place on Futuna under the supervision of the Kaleveleve Hospital medical team.

The **district health centres** on Wallis are also integral parts of the NTP. Staff at these dispensaries provide initial detection and refer suspect cases for assessment and diagnosis to Sia Hospital. As well, on Wallis, once a patient returns from the two-week hospital stay at Sia Hospital, it is the district health centre staff who provide the actual direct supervision of treatment (DOT) and related record keeping.

Complementary Tuberculosis Control Measures

French law mandates that children be vaccinated against tuberculosis (using the BCG) before attending school or, at the latest, at six years of age. The effectiveness of these vaccinations is monitored up to the age of 15 through the use of skin testing. The skin test is also used as one of the diagnostic procedures for those suspected of having tuberculosis.

Once a case is diagnosed and the patient is under treatment, staff from the health centre conducts a family and neighbourhood contact investigation in order to search for any potential carrier and/or to screen possible cross-infection cases. Any person identified during this investigation as a possible TB suspect is referred to the doctor to take advantage of an examination including diagnostic tests. This procedure assists in controlling the spread of tuberculosis within the Territory.

Operational Aspects of Case Detection, Diagnosis and Treatment

Case Detection

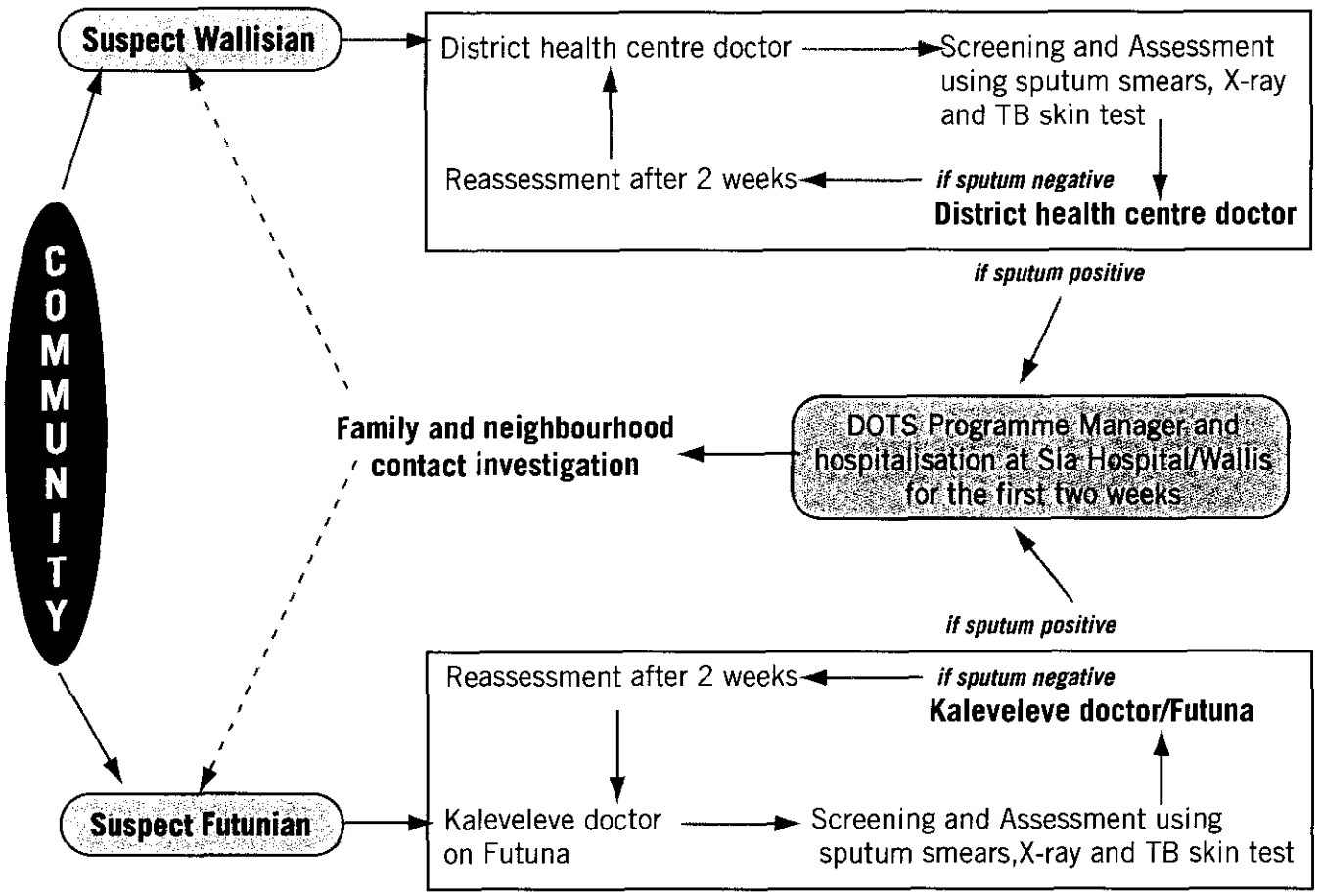
Identification of suspect cases of tuberculosis can occur at any level within the community. Doctors, nurses and paramedical staff, as well as community members-at-large, especially community leaders, can identify and refer persons with suspect symptoms to the nearest health centre. In this way, the entire community can help in the fight against tuberculosis.

Patients suspected of having tuberculosis are those with one or more of the following symptoms:

- a persistent cough for more than three weeks, in addition to pre-existing pathologies;
- an overall change in health with significant weight loss over a period of a few months;
- intense fatigue with night sweats;
- prolonged fever;
- functional pulmonary symptoms (i.e. sputum containing blood);
- close contact with a known TB patient identified recently.

Any patient presenting as a suspect case of tuberculosis should be referred directly and without delay to the district doctor for screening, assessment and diagnostic procedures. Figure 4 below summarises the Wallis and Futuna procedure for following patients suspected of having tuberculosis.

FIGURE 4: PROCEDURE FOR FOLLOWING PATIENTS SUSPECTED OF HAVING TUBERCULOSIS



Diagnosis

■ DIAGNOSTIC CLASSIFICATIONS

Tuberculosis patients are divided into various classification types based on previous case history and the result of diagnostic procedures, including sputum examinations. These classifications include:

- Pulmonary forms (PTB)
  - with positive sputum smears
  - with negative sputum smears but severe illness or
  - with negative sputum smears and mild illness.

Pulmonary tuberculosis affects the lungs and is the most common form of tuberculosis. (See Figure 2, page 7 for diagnostic detail.)

- Extrapulmonary forms (EPTB)
  - severe
  - less severe.

Extrapulmonary tuberculosis affects parts of the body other than the lungs and can include the lymph nodes, the joints, kidneys, etc.

• Retreatment (See definitions on page 9)

- due to interruption of initial treatment
- due to failure of initial treatment
- due to relapse.

Diagnosis of each class of tuberculosis is confirmed after clinical examination and the following additional tests:

✓ **Sputum bacteriological test:** This is conducted by paramedical personnel trained in the DOTS Programme. Three sputum samples are collected at either a health centre or the laboratory on Wallis or at Kaleveleve Hospital on Futuna. The samples include a **SPOT** (sample taken on the spot at the dispensary or the laboratory), an **Overnight** (early-morning sample collected the next morning during coughing efforts so as to avoid collected saliva) and, on the same day, another **SPOT** (sample taken at the dispensary or the laboratory when the patient drops off the overnight sample).

Sputum samples are carefully labelled and registered at the time of collection at the hospital or health centre. They are then taken/sent on the same day, along with a Laboratory Sputum Form for TB Investigation, to the DOTS Centre Laboratory at Sia Hospital, where they are formally recorded in the DOTS Laboratory Register before being sent to Noumea, within a week, for examination (see pages 27-28 for detail).

✓ **X-rays:** Frontal thorax x-rays are given to all pulmonary tuberculosis suspects. For extrapulmonary tuberculosis suspects, additional examinations are conducted based on the recommendation from the doctor regarding which organ appears to be involved.

✓ **10-unit tuberculin intracutaneous test**

✓ **Blood tests (NFS, VS, CRP)**

■ Treatment Categories

Interpretation of results from the additional diagnostic tests and consideration of the patient's history, makes it possible to classify the patient by tuberculosis type (pulmonary, extrapulmonary or retreatment), and then to assign each patient to a treatment category corresponding to the most appropriate treatment strategy to be used for the individual case. The treatment categories are as follows:

○ Category I Cases

New patients who are pulmonary smear-positive for acid-fast bacilli (AFB) as determined by direct microscopy

New cases that are pulmonary smear-negative but severely ill

New cases of severe extrapulmonary tuberculosis

○ Category II Cases

Pulmonary smear-positive patients who require retreatment due to:

- relapse
- interruption of treatment or
- failure of initial treatment.

○ Category III Cases

New patients with less severe forms of extrapulmonary tuberculosis

New patients who are pulmonary smear-negative with mild illness

■ Specific Diagnostic Procedures Used on Wallis and on Futuna

The following stages of the diagnostic process ensure thorough examination leading to accurate diagnosis:

PROCEDURE	WALLIS	FUTUNA
Step 1: **Screening and Evaluation**	Patients suspected of having tuberculosis undergo the following: • initial consultation with the district health centre doctor • sputum collection (3 samples) • relevant x-ray • a 10 unit tuberculin intra-cutaneous test and • blood tests (NFS, VS, CRP)	Patients suspected of having tuberculosis under go the following: • initial consultation with the doctor at Kaleveleve Hospital • sputum collection (3 samples) • relevant x-ray • a 10 unit tuberculin intra-cutaneous test and • blood tests (NFS, VS, CRP)
Step 2: **Sputum Sample Testing Using Acid-Fast Bacilli (AFB) Microscopy**	• Three sputum samples, SPOT, Overnight and SPOT, are taken by either the health centre's nurse or one of the health educators who have been trained in the DOTS strategy. • These samples are carefully labelled and registered, then delivered the same day to Sia Hospital, accompanied by a Laboratory Sputum Form for TB Investigation. • On arrival at Sia, the samples are recorded in the special DOTS Laboratory Register and then held at cool temperatures until the weekly transfer, by air in an ice chest, to Pasteur Institute in Noumea, where examination takes place. • Positive results are sent immediately, by e-mail, to the laboratory biologist in Wallis, who promptly enters the results in the Laboratory Register and notifies both the referring doctor and the DOTS Manager. The biologist is notified of negative results by regular mail.	• Three sputum samples, SPOT, Overnight and SPOT, are taken at Kaleveleve Hospital by either a nurse or one of the health educators who have been trained in the DOTS strategy. • These samples are carefully labelled and registered, then sent, that same day in an ice chest using the daily commuter flight, to Sia Hospital. • A Laboratory Sputum Form for TB Investigation is sent with the samples so that on arrival, details of the samples can also be recorded in the special DOTS Laboratory Register. As is done in Wallis, these samples are then held at cool temperatures until the weekly transfer, by air in an ice chest, to Pasteur Institute in Noumea, where examination takes place. • Positive results are sent immediately, by e-mail, to the laboratory biologist in Wallis, who promptly enters the results in the Laboratory Register and notifies both the referring Kaleveleve Hospital doctor and the DOTS Manager. The biologist is notified of negative results by regular mail.

PROCEDURE	WALLIS	FUTUNA
Step 3: **Diagnostic Decision**	• Between 4 and 7 days after the screening, once test results have been received, the patient returns to the health centre doctor to discuss the results, diagnosis, and stages of treatment, which starts at Sia Hospital.	• Between 4 and 7 days after the screening, once test results have been received, the patient again returns to the doctor at the Kaleveleve Hospital to discuss the results, diagnosis, and stages of treatment, which starts at Sia Hospital in Wallis.

In cases where no bacteriological proof is obtained, a broad-spectrum antibiotic treatment is prescribed and, after two weeks, a new set of three sputum samples is collected for bacteriological re-testing and a new frontal chest X-ray is taken.

Treatment

Once the screening and assessment are completed and a diagnosis of tuberculosis is confirmed, the DOTS Programme Manager develops an individual treatment plan for each tuberculosis patient from Wallis and from Futuna, assigns each patient a separate TB number and registers the patient in the Tuberculosis Register. For all treatment categories, patients follow a strict treatment regimen, which includes two phases: firstly, an **intensive phase** during which all patients are hospitalised for the first two weeks at Sia Hospital in Wallis, and secondly, a longer **continuation phase** which takes place back in the patient's community. The WHO recommended treatment doses for each treatment category, as presented on pages 12-13 in Part I of this manual, are prescribed as part of the treatment plan. Treatment procedures are as follows:

■ **TREATMENT PLAN FOR CATEGORY I PATIENTS** (as per page 26)

TREATMENT DETAILS	WALLIS	FUTUNA
INTENSIVE PHASE FOR CATEGORY I PATIENTS	• Treatment begins with a **two-week** period of hospitalisation at Sia Hospital, which is monitored by the ward staff and during which further testing is conducted to monitor treatment. For each patient the Coordinating Nurse prepares an individual Treatment Card which is used to record the daily directly observed treatment (DOT) when medication is given.	• Treatment begins with a **two-week** period of hospitalisation at Sia Hospital in Wallis, which is monitored by the ward staff and during which further testing is conducted to monitor treatment. For each patient the Coordinating Nurse prepares an individual Treatment Card which is used to record the daily directly observed treatment (DOT) when medication is given.
When and Where? What Occurs?	• At discharge, this Treatment Card is sent, along with a Tuberculosis Referral/Transfer Form and Liaison Sheet, to the doctor at the district health centre where the patient will be cared for during the rest of treatment	• At discharge, this Treatment Card is sent, along with a Tuberculosis Referral/Transfer Form and Liaison Sheet, to the doctor at Kaleveleve Hospital who takes charge of the remaining treatment.
Who Provides?	• When discharged, the patient returns home and is immediately taken into charge by the medical team at the district health centre. Treatment continues being directly observed (DOT) daily during the remainder of the **two-month intensive phase** and the Treatment Card is completed to record each daily-observed treatment. During this period of treatment, the assigned Health Educator completes DOT six days per week with the Person of Confidence covering Sundays and holidays.	• When discharged, the patient returns home to Futuna and is immediately taken into charge by the Kaleveleve medical team. Treatment continues being directly observed (DOT) daily during the remainder of the **two-month intensive phase** and the Treatment Card is completed to record each daily observed treatment. During this period of treatment, the assigned Health Educator completes DOT six days per week with the Person of Confidence covering Sundays and holidays.
	• **After two months,** the patient has a follow-up bacteriological examination consisting of an Overnight and a SPOT sample.	• **After two months,** the patient has a follow-up bacteriological examination consisting of an Overnight and a SPOT sample.

TREATMENT DETAILS	WALLIS	FUTUNA
CONTINUATION PHASE FOR CATEGORY I PATIENTS When and Where? What Occurs? Who Provides?	• During the **continuation phase of four months,** the Health Educator (one day per week) and the Person of Confidence (six days per week), continue daily supervised treatment (DOT), with the Health Educator being responsible for completing the Treatment Card. • During the **fifth month** of treatment, another bacteriological follow-up exam is carried out on two sputum samples (Overnight and SPOT). • At the **end of treatment**, if the patient has not already received two consecutive negative sputum results, a final sputum follow-up test (Overnight and SPOT) is completed.	• During the **continuation phase of four months,** the assigned Health Educator from the Kaleveleve medical team, and the designated Person of Confidence, continue daily supervised treatment (DOT) with the patient: once per week by the Health Educator and the remaining six days per week by the Person of Confidence. The Health Educator maintains responsibility for completing of the Treatment Card. • During the **fifth month** of treatment, another bacteriological follow-up exam is carried out on two sputum samples (Overnight and SPOT). • At the **end of treatment,** if the patient has not already received two consecutive negative sputum results, a final sputum follow-up test (Overnight and SPOT) is completed.

■ TREATMENT PLAN FOR CATEGORY II PATIENTS (as per page 26)

TREATMENT DETAILS	WALLIS	FUTUNA
INTENSIVE PHASE FOR CATEGORY II PATIENTS When and Where? What Occurs? Who Provides?	Treatment supervision for Category II patients follows the same format as for Category I except for the duration. In summary, treatment includes: • **a two week** period of hospitalisation at Sia Hospital • daily supervised treatment (DOT) and Treatment Card completion by the Coordinating Nurse • at discharge, sending of the Treatment Card, Tuberculosis Referral/Transfer Form and Liaison Sheet to the doctor at the district health centre where treatment will continue • when discharged, the patient returns home, is immediately taken into charge by the district health centre medical team and supervised treatment (DOT) continues daily during the remainder of the **three month intensive phase** with the Treatment Card being completed daily to record each observed treatment • follow-up bacteriological examination of Overnight and SPOT samples, **after three months** of treatment	Treatment supervision for Category II patients follows the same format as for Category I except for the duration. In summary, treatment includes: • a **two week** period of hospitalisation at Sia Hospital • daily supervised treatment (DOT) and Treatment Card completion by the Coordinating Nurse • at discharge, this Treatment Card, along with a Tuberculosis Referral/Transfer Form and Liaison Sheet, are given to the patient and e-mailed to the doctor at Kaleveleve Hospital who takes charge of the remaining treatment • when discharged, the patient returns home to Futuna, is immediately taken into charge by the Kaleveleve medical team and supervised treatment (DOT) continues daily during the remainder of the **three month intensive phase** with the Treatment Card completed daily to record each observed treatment • follow-up bacteriological examination of Overnight and SPOT samples, **after three months** of treatment
CONTINUATION PHASE FOR CATEGORY II PATIENTS When and Where? What Occurs? Who Provides?	• During the **continuation phase of five months**, the assigned Health Educator from the district health centre (one day per week), and the Person of Confidence (six days per week) provide observed treatment (DOT) daily, with the Health Educator being responsible for completing the Treatment Card. • During the **seventh month** of treatment, another bacteriological follow-up exam is carried out on Overnight and SPOT samples. • A final sputum follow-up test (Overnight and SPOT) is completed at the **end of treatment** for patients who have not yet received two consecutive negative results.	• During the **continuation phase of five months**, the assigned Health Educator from Kaleveleve Hospital (one day per week), along with the Person of Confidence (six days per week) provide observed treatment (DOT) daily, with the Health Educator being responsible for completing the Treatment Card. • During the **seventh month** of treatment, another bacteriological follow-up exam is carried out on Overnight and SPOT samples. • A final sputum follow-up test (Overnight and SPOT) is completed at the **end of treatment** for patients who have not yet received two consecutive negative results.

■ Treatment Plan for Category III Patients (as per page 26)

TREATMENT DETAILS	WALLIS	FUTUNA
INTENSIVE AND CONTINUATION PHASES FOR CATEGORY III PATIENTS When and Where? What Occurs? Who Provides?	• As with category I and II patients, category III patients start their treatment with a **two-week** hospitalisation at Sia Hospital during which they receive supervised treatment (DOT) daily from the DOTS Coordinating Nurse. • The remainder of the **two-month intensive phase** is supervised by the Health Educator from the district health centre who conducts DOT six days per week. The Person of Confidence covers the seventh day. • During the entire **four-month continuation phase**, the Health Educator completes DOT one day per week with the assigned Person of Confidence covering the remaining days.	• As with category I and II patients, category III patients start their treatment with a **two-week** hospitalisation at Sia Hospital in Wallis during which they receive supervised treatment (DOT) daily from the Coordinating Nurse. • The remainder of the **two-month intensive phase** is supervised in Futuna by a Health Educator from Kaleveleve Hospital who conducts DOT six days per week. The Person of Confidence covers the seventh day. • During the entire **four-month continuation phase**, the Health Educator completes DOT one day per week with the assigned Person of Confidence covering the remaining days.

Anti-TB Drug Availability

All the drugs required for TB treatment of the various categories are available at the Health Agency's pharmacy. The central pharmacy has an adequate stock and can easily receive new supplies by airmail from New Caledonia or metropolitan France. It is the responsibility of the pharmacist, in conjunction with the DOTS Programme Manager, to place the orders in a timely manner so that adequate stock is maintained.

All the health centres on Wallis and Kaleveleve Hospital on Futuna have stocks that allow them to easily begin several treatments and they can receive new supplies within the space of one day from Sia central pharmacy. This is not necessary for the two small dispensaries on Futuna as they do not dispense medication.

Case Management, Monitoring and Assessment

Wallis and Futuna is committed to the overall implementation of the DOTS Strategy which, as noted on pages 1-2, consists of five key elements. One of these elements requires DOTS programmes to use a "standardized recording and reporting system to monitor patient progress". Such a system has been implemented in the territory's programme so that, as described earlier, all staff and facilities have a part to play in the comprehensive management of each patient's diagnosis, treatment and follow-up. In summary, the monitoring system is made up of the following components:

- Patients exhibiting symptoms of tuberculosis are referred to a doctor for evaluation of their condition. During this assessment, diagnostic tests, including microscopic examination of sputum samples, are conducted. Strict transport procedures are followed to ensure that the quality of the sample is maintained.

- Documentation occurs at each step of the assessment process to ensure efficient tracking. (Refer to page 35-38 and figure 5.)

- All sputum smear-positive results are immediately communicated through the DOTS Laboratory to the referring doctor and the DOTS Programme Manager.

- Prompt follow up contact is made with the patient to discuss assessment results and to make a diagnosis.

- As soon as diagnosed, the patient is given a tuberculosis number and registered. Details of diagnostic results, treatment, follow-up and outcomes are all documented in a single section of the Tuberculosis Register so that individual progress can easily be verified.

- Each quarter, the numbers of cases diagnosed in that quarter are documented, verified by the DOTS Manager and sent in a formal report to SPC and WHO.

- For all patients, the initial two weeks of treatment takes place as inpatients at the DOTS Centre (Sia Hospital) in Wallis under direct daily supervision by the DOTS Manager and the DOTS Coordinator.

- Once discharged from inpatient care, the patient continues to be seen by health care staff six times per week during the remaining intensive phase and once per

week during the continuation phase. On all remaining days, it is the treatment partner who observes the patient taking their medication.

- For the entire treatment period, daily direct observation of drug swallowing (DOT) is recorded on the patient's individual Treatment Card. This increases the likelihood of successful treatment and decreases the risk level of default problems emerging.

- To monitor patient progress throughout treatment and to determine whether a patient has been "cured", follow-up sputum examinations are carried out based on the following schedule:

TABLE 4*: DETAILS, INCLUDING TIMETABLE, FOR MONITORING PATIENT TREATMENT IN WALLIS AND FUTUNA

SPUTUM SAMPLES and ACTIONS	Category I	Category II	Category III
1st Follow-up using 2 samples: Overnight, SPOT Collected at the end of the Intensive Phase. If negative, patient immediately starts continuation phase. If positive, patient continues intensive phase for 1 more month.	At end of 2nd month	At end of 3rd month	Not required
2nd Follow-up using 2 samples: Overnight, SPOT This follow-up is conducted **ONLY IF** the patient tested positive at the 1st Follow-up. After this follow-up, all patients start the continuation phase of treatment, regardless of sputum results.	At end of 3rd month	At end of 4th month	Not required
3rd Follow-up using 2 samples: Overnight, SPOT Patients who are still positive at this follow-up are re-classified as treatment failure, re-registered and given a new TB number and start retreatment afresh, following the Category II regimen.	At end of 5th month or beginning of 6th month	At end of 7th month or beginning of 8th month	Not required
4th Follow-up using 2 samples: Overnight, SPOT Collected at the end of the Continuation Phase **ONLY FOR** those patients still producing sputum who do not yet have two consecutive sputum smear-negative results.	At end of 6 month treatment	At end of 8 month treatment	Not required

* Wallis and Futuna has adopted the same sputum follow-up schedule as suggested in Part I of this manual.

- Details of each patient's progress are crosschecked by the DOTS Coordinator regularly, a minimum of once per quarter. Any identified discrepancies are addressed immediately.

- If a patient interrupts treatment to move to another location, it is very important to send a completed Tuberculosis Referral/Transfer Form, including detailed treatment status, to the new treating facility.

- When a patient completes treatment, the treatment outcome is documented, verified by the DOTS Manager and recorded on the formal quarterly report which is sent to SPC and WHO.

Given the continuity of monitoring that takes place with tuberculosis patients, there is a high likelihood that treatment will be successful.

Summary of Patient Registration and Record Keeping

A Sub-regional Tuberculosis Workshop on Data Management was organised by SPC and held in Noumea, New Caledonia from 29 September to 3 October, 2003. At that workshop, representatives met to revise existing record keeping forms based on country needs. It was a recommendation of the participants, including representatives from Wallis and Futuna, to adopt the new forms so that there could be standard reporting amongst the Pacific countries who work with the SPC Tuberculosis Control Section. These forms include:

Laboratory Sputum Form for TB Investigation (refer to Annex 6, SPC/TUB 01)

The Laboratory Sputum Form provides patient information necessary for tracking during sputum examinations, both diagnostic and follow-up. In Wallis and Futuna, whenever a sputum sample is collected, a Laboratory Sputum Form is completed and sent with the sample(s) to the Sia Hospital laboratory. There, necessary information is recorded in the Laboratory Register before the form is sent with the samples to the Pasteur Institute in Noumea, where testing occurs. Results are formally documented on this form by the lab staff and then entered on the Laboratory Register before the form is returned to the referring doctor.

In addition to giving important patient information and test results, the Laboratory Sputum Form can also be used for monitoring the efficiency of the laboratory service. This is possible because the dates recorded on the form demonstrate how quickly each stage of the process is completed, thus pinpointing where any breakdown may be occurring.

Laboratory Register

(refer to Annex 6, SPC/TUB 02)

The Laboratory Register is an important component of the national tuberculosis information system. For monitoring purposes, it provides a formal record of the numbers of tuberculosis suspects. It also allows for tracking the number of samples being examined for diagnosis (3 samples) and during follow-ups (2 samples for each). Accurate completion of this register also gives a detailed record of the results of each sputum examination for each patient. These results are critical in order to determine a specific diagnosis and to monitor treatment.

In Wallis and Futuna, there is one Laboratory Register that is kept at the Sia Hospital Laboratory. When sputum samples arrive at the lab, the laboratory secretary completes the first part of the register using information from the accompanying Laboratory Sputum Form for TB Investigation. As soon as they are received from Pasteur Institute in Noumea, test results are registered by the laboratory biologist. The biologist also notifies the DOTS Manager of all results so they can be cross-referenced on the Tuberculosis Register.

Regular cross checking, at least once per quarter, should be done between the Laboratory Register and the Tuberculosis Register to ensure compatibility of information on the two registers. Strict observation of laboratory codes regarding general safety and confidentiality should be enforced and maintained at all times.

■ Monthly Case Summary

Another important recommendation that was made at the Sub regional Tuberculosis Workshop on Data Management was for the laboratory staff to complete a Monthly Case Summary. This Case Summary data can be used to:

- monitor the quality of the testing being performed so that adequate supervision can be planned to ensure efficient testing practices
- make it easier to prepare the Quarterly Report on Tuberculosis Case-Finding since some monthly totals will already have been calculated.

At the end of each month, the following information should be tallied and, for ease, written directly on the Laboratory Register in a space created between the last name of the month being summarised and the first name of the next month. The data to be compiled includes:

Monthly Case Summary

Part 1: Number of Patients

Number of TB suspects whose sputum was examined for **diagnosis**_____

Number of these suspects diagnosed as smear-positive _____

Number of TB patients on treatment whose sputum was examined for **follow-up** _____

Number of these patients whose follow-up result was smear-positive_____

Part 2: Number of Specimens Submitted for Diagnosis

Number of TB suspects who submitted:

3 specimens _____
2 specimens _____
1 specimen _____

% of suspects who submitted 3 specimens for diagnosis _____

NOTE: **For Part 2, count only the number of specimens submitted for diagnosis. DO NOT include follow-ups.**

In quality DOTS programmes, the recommended target is for greater than 80% of suspects to have 3 specimens examined for diagnosis.

Part 3: Specimen Results

Total number of specimens tested_____

Number of specimens testing as:

3+ _____
2+ _____
1+ _____
scanty_____

In Wallis and Futuna, the Monthly Case Summary is completed by the laboratory secretary and verified by the DOTS Coordinating Nurse.

Tuberculosis Register

(refer to Annex 6, TUB 03)

All patients on TB treatment must be registered in the national Tuberculosis Register that is kept at all times at the DOTS Centre. In Wallis and Futuna, in addition to the hard copy, the Tuberculosis Register is also stored electronically. Once a patient is diagnosed, the DOTS Programme Manager assigns a TB number and registers the patient. The DOTS Manager is also responsible for regularly updating the register and ensuring that all data entered are accurate. On Futuna, a secondary Tuberculosis Register is kept at Kaleveleve Hospital and on Wallis, secondary Tuberculosis Registers are also kept at each district health centre for the patients being followed at those centres. It is the responsibility of the DOTS Coordinator to ensure, through cross-checking with the Health Educators, that the information from each of the secondary registers is consistent with the main national register. Also, on a regular basis, at least once per quarter, the DOTS Coordinator must crosscheck the Tuberculosis Register with the Laboratory Register to ensure that all cases are entered in the Tuberculosis Register and are being treated.

Patients who fail treatment under one category and need to be switched to another treatment category must be registered again under a new disease classification and treatment category and given a new TB number; e.g. a patient who fails CAT I because the sputum smear is still positive at the end of 5 months, must be re-registered as a treatment failure under CAT II, given a new TB number and reported as a retreatment case for that quarter.

In order to make quarterly reporting easier, it is suggested that a red line be drawn to separate each quarter. For the first quarter, the line should be drawn between the last case registered in March and the first case registered in April; for the second quarter, between the end of June and the beginning of July; for the third quarter, between September and October; and for the fourth quarter, between December and January.

Tuberculosis Treatment Card

(refer to annex 6, SPC/TUB 04)

An original/master copy of each Treatment Card should be made at the time of registration of a patient and kept at the DOTS Centre. These cards should be updated regularly during monitoring or supervisory visits to the health centres. One duplicate copy of the master Treatment Card should be made and given to the health centre (Health Educator) that administers the observed treatment (DOT) to the patient. In addition, a diary/notebook should be given to the Person of Confidence to keep track of treatment they observe at the patient's home. Treatment recording is divided into intensive phase (first 2 or 3 months depending on diagnostic category) on the front of the card, and continuation phase (last 4 or 5 months) on the back of the card.

All patient details should be completed, and disease classification and sputum results should be entered if the data is available. Treatment categories and prescribed doses must be indicated with a cross **(x)** *in the appropriate boxes. This is the responsibility of the DOTS Manager and takes place as soon as the patient arrives at hospital to begin treatment.*

Recording Treatment:

Daily treatment is entered in each box using a cross (x) when the swallowing of the drugs is directly observed (DOT). In Wallis and Futuna, DOT is completed as follows:

- During the two-week hospital stay at Sia Hospital, the DOTS Coordinator provides direct observation (DOT) daily and records it on the Treatment Card.

- During the remainder of the intensive phase of treatment, when treatment is supervised by a Health Educator from

either Kaleveleve Hospital on Futuna or one of the district health centres on Wallis, the Health Educator provides observed treatment (DOT) six days per week and completes the card. On the seventh day, the assigned Person of Confidence provides DOT and reports back to the Health Educator for completion of the card.

- During the continuation phase of treatment, the patient and the Person of Confidence come together to the treating health centre one day per week. At that time, the patient is given that day's treatment by the Health Educator, who directly observes the swallowing and marks the Treatment Card. The remaining 6 days of treatment are given to the Person of Confidence for supervised treatment the rest of the week. The Person of Confidence keeps their own record of each observed treatment (DOT) and reports it to the Health Educator during the next weekly health centre visit. At that time the Health Educator completes the Treatment Card based on the report from the Person of Confidence.

- On a monthly basis, the Coordinating Nurse should ensure that the master copy of the Treatment Card (held at Sia Hospital) is updated with the data already entered on the Health Educator's duplicate copy.

In cases when treatment is not directly observed, the following codes are used on the Treatment Card:

- A dash (—) is used for days when medication has been given but swallowing of the drugs has not been directly observed.

- A zero (**0**) is used if no medication was swallowed.

In order to alert the Health Educator and the patient to the date of the next required follow-up sputum examination, that exact date on the Treatment Card is outlined in red.

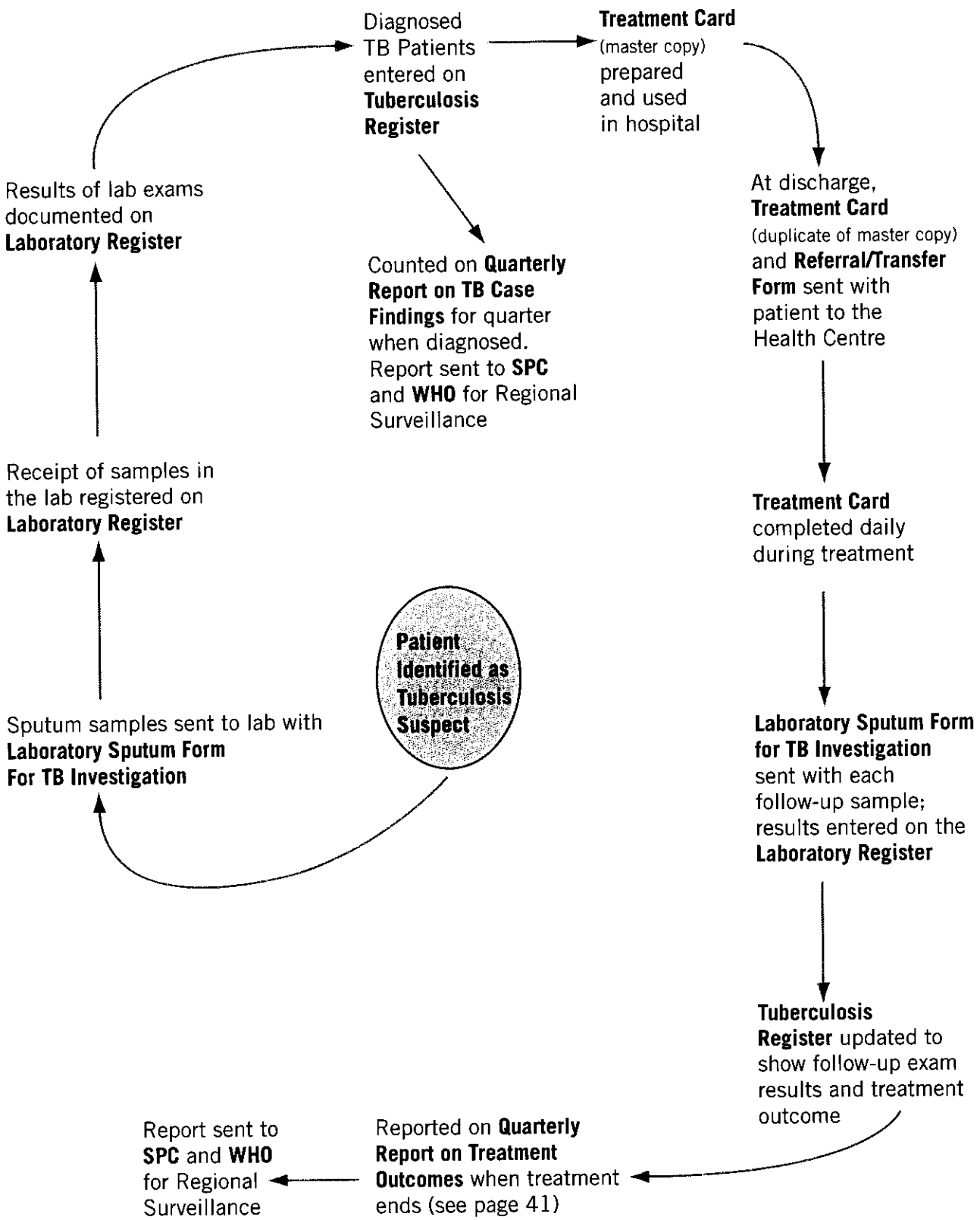
Tuberculosis Referral/Transfer Form

(refer to annex 6, SPC/TUB 05)

Referrals between health centres must be well defined and closely followed to prevent unnecessary treatment default. Likewise "transfer out" to another country, particularly for patients on treatment, should be clearly reported (to the physician abroad if such information is available or alternatively, through Embassies or Foreign Affairs' services) and well documented to ensure treatment continuity and completion.

The Tuberculosis Referral/Transfer Form is used for this purpose. When a patient ends the initial two-week hospital stay at Sia Hospital in Wallis, the DOTS Coordinator completes the Referral/Transfer Form and sends it, with the Treatment Card, to the appropriate district health centre for patients from Wallis; or to Kaleveleve Hospital for patients from Futuna. Likewise, if a patient leaves treatment in Wallis or Futuna to travel to another district or overseas, either temporarily or permanently, the Referral/Transfer Form is completed and forwarded to the new treating facility.

Figure 5: Summary of the Path of Patient Registration and Record Keeping for the DOTS Programme in Wallis and Futuna



Regional Reporting of Case Findings and Treatment Outcomes

In order to monitor trends at the national level for planning purposes and to aid in the surveillance of tuberculosis at the regional and global levels, the following quarterly reports are completed and submitted.

Quarterly Report on Tuberculosis Case-Finding (refer to Annex 6, TUB 06)

The Quarterly Report on Tuberculosis Case-Finding is used to document the numbers of tuberculosis cases registered in each quarter. It is based on information contained in the Tuberculosis Register that has been crosschecked with the Laboratory Register.

The report is completed by the DOTS Coordinator early in the first month following the end of the quarter being reported as follows:

Quarter	Includes All Tuberculosis Cases Registered Between...	Report Prepared and Submitted:
Quarter 1	1 January - 31 March	Early in April
Quarter 2	1 April - 30 June	Early in July
Quarter 3	1 July - 30 September	Early in October
Quarter 4	1 October - 31 December	Early in January

The report is divided into two sections: the top section for reporting totals of all cases, and the bottom section for reporting a detailed breakdown of new smear-positive cases by age group and gender. After completion of the report, it is the responsibility of the DOTS Coordinator to share the report with the DOTS Manager for approval and then to send one copy of the report to the Tuberculosis Control Section at SPC and a second copy to WHO.

Data reported in the Quarterly Report on Tuberculosis Case-Finding is then used to calculate the Wallis and Futuna notification rate. This is important both for national monitoring of the burden of TB and for making comparisons with regional and global rates.

Notification rates are calculated as follows:

The notification rate for all cases of TB =

- (total number "all types" TB) ÷ (total current country population) x 100,000

The notification rate for sputum smear-positive (S^+) cases =

- (total number S^+ cases) ÷ (total current country population) x 100,000

Quarterly Report on Treatment Outcomes (refer to Annex 6, SPC/TUB 07)

In order to measure the success of a DOTS Programme, the outcomes of treatment must be monitored closely. Recording these outcomes on the Quarterly Report form provides the formal documentation necessary for this monitoring at all levels.

The Quarterly Report on Treatment Outcomes is completed by the DOTS Coordinator to report the outcomes of treatment for all new sputum smear-positive, retreatment smear-positive, new sputum smear-negative and extrapulmonary TB cases, using the WHO definitions of "treatment outcomes" as presented on page 10. The Tuberculosis Register is again used to collect the necessary data for this report.

Reporting occurs early in the first month following the end of the quarter that is being reported (e.g. The report for the first quarter is submitted early in April). As a "treatment outcome" is assigned after treatment is completed, the numbers being reported are for TB patients who have already completed their treatment. Therefore, this Quarterly Report on Treatment Outcomes can only be done when every single patient in a given cohort quarter has completed their treatment. The report must be compiled and sent within the next two weeks following the end of that quarter.

The best way to determine who to include on each report is to refer to the Tuberculosis Register and to mark each quarter as a separate group (cohort) of patients, drawing a red line between each quarter as described on page 37. Then, monitor the cohort until the last of the patients finishes their treatment. Following is an example:

For the cohort of cases registered in Quarter 1, 2003 (1 January - 31 March)

- Category I patients (6 mo. treatment) will complete their treatment in Quarter 3
- Most Category II patients (8 mo. treatment) complete their treatment in Quarter 4
- Some other patients might end their treatment due to default in Quarter 2

Because Category II patients in the Quarter 1 cohort were the last to complete their treatment (in Quarter 4), treatment outcomes for ALL cases who were registered in Quarter 1, 2003 would be reported, on a separate SPC/TUB 07 form, in early Jan. 2004 (the first month following the end of treatment for the last of the patients in that cohort).

Once completed, the Quarterly Report on Treatment Outcomes is approved by the DOTS Manager and sent by the DOTS Coordinator to both the SPC Tuberculosis Control Section and WHO.

Data reported in the Quarterly Report on Treatment Outcomes is then used to calculate the Wallis and Futuna treatment success rate. This is important both for national monitoring of the success of the DOTS Programme and for determining if the regional target of an 85% success rate has been achieved.

The **treatment success rate** (in %) is calculated by adding the percentage of patients "cured" and the percentage of patients "treatment completed" in any sputum smear-positive subgroup as follows:

- For new smear-positive (S^+) cases:

  (% new S^+ patients "cured") + (% new S^+ patients "treatment completed")

- For retreatment smear-positive (S^+) cases:

  (% retreatment S^+ patients "cured") + (% retreatment S^+ patients "treatment completed")

- For total smear-positive (S^+) cases [sum of new S^+ and retreatment S^+ cases]:

  (% total S^+ patients "cured") + (% total S^+ patients "treatment completed")

For example:
If the treatment outcomes for 20 patients being reported for a given Cohort Quarter were:

Outcomes \ Patient Type	New Smear-positive		Retreatment Smear-positive		TOTAL Smear-positive*	
	No.	**%**	**No.**	**%**	**No.**	**%**
Cured	12	12/16 = **75%**	2	2/4 = **50%**	14	14/20 = **70%**
Treatment Completed	2	2/16 = **12.5%**	1	1/4 = **25%**	3	3/20 = **15%**
Treatment Failure	1	1/16 = 6.25%			1	1/20 = 5%
Died			1	1/4 = 25%	1	1/20 = 5%
Treatment Interrupted (default)	1	1/16 = 6.25%			1	1/20 = 5%
Transfer Out						
TOTAL	16		4		20	

* Includes both new and retreatment smear-positive cases

Then, using the above formulas:

➤ The treatment success rate for new smear-positive patients would be:

% new S^+ "cured" (75%) + % new S^+ "treatment completed" (12.5%) = 87.5%

➤ The treatment success rate for retreatment smear-positive patients would be:

50% + 25% = 75%

➤ The treatment success rate for total smear-positive patients would be:

70% + 15% = 85%

Similarly, **treatment completion rates** can be calculated to monitor outcomes for sputum smear-negative and extrapulmonary patients. This rate is also calculated as a percentage.

LIST OF ESSENTIAL ANTI-TUBERCULOSIS DRUGS FOR DAILY USE

WHO MODEL LIST OF ESSENTIAL DRUGS FROM DECEMBER 1997	
Drug	**Dosage forms and strengths**
Streptomycin	powder for injection, S 1g (as sulphate) in vial
Rifampicin	capsule or tablet, R 150 mg; R 300 mg
Isoniazid	tablet, H 100 mg; H 300 mg
Pyrazinamide	tablet, Z 400 mg, Z 500 mg
Ethambutol	tablet, E 100 mg; E 400 mg
Isoniazid + ethambutol	tablet, H 150 mg + E 400 mg
Rifampicin + isoniazid	tablet, R 150 mg + H 75 mg; R 300 mg + H 150 mg
Rifampicin + isoniazid + pyrazinamide	tablet, R 150 mg + H 75 mg + Z 400 mg

WHO Ad Hoc Committee Meeting on fixed dose combinations formulation from August 1998	
Drug	**Dosage forms and strengths**
Rifampicin + isoniazid	tablet, R 60 mg + H 30 mg *
Rifampicin + isoniazid + pyrazinamide	tablet, R 60 mg + H 30 mg + Z 150 mg *
Rifampicin + isoniazid + pyrazinamide + ethambutol	tablet, R 150 mg + H 75 mg + Z 400 mg + E 275 mg

* For paediatric use

E=Ethambutol, H=Isoniazid, R=Rifampicin, S=Streptomycin, Z=Pyrazinamide

STANDARDISED TREATMENT CATEGORIES USING DIFFERENT FIXED-DOSE COMBINATIONS (FDCs), FOR ADULTS AND CHILDREN

2 drugs-FDC for new, Category I case adults

(Use the same doses for new Category III case adults, but without ethambutol)

Adult	Intensive phase (2 months, daily)			Continuation phase (4 months, daily)
Weight (kg)	**RH** 150mg+75mg	**Z** 400mg	**E*** 400mg	**RH** 150mg+75mg
30-37	2	2	1 1/2	2
38-54	3	3	2	3
55-70	4	4	3	4
71-90	5	5	3 1/2	5

3 drugs-FDCs for new, Category I case adults

(Use the same doses for new Category III case adults, but without ethambutol)

Adult	Intensive phase (2 months, daily)		Continuation phase (4 months, daily)
Weight (kg)	**RHZ** 150mg+75mg+400mg	**E*** 400mg	**RH** 150mg+75mg
30-37	2	1 1/2	2
38-54	3	2	3
55-70	4	3	4
71-90	5	3 1/2	5

4 drugs FDCs for new, Category I case adults

Adult	Intensive phase (2 months, daily)	Continuation phase (4 months, daily)
Weight (kg)	**RHZE** 150mg+75mg+400mg+275mg	**RH** 150mg+75mg
30-37	2	2
38-54	3	3
55-70	4	4
71-90	5	5

4 drugs FDCs for retreatment case adults, Category II
(relapses, failures and treatment interruptions)

Adult	Intensive phase (3 months, daily)		Continuation phase (5 months, daily)	
Weight (kg)	**RHZE** 150mg+75mg+400mg +275mg	**S**** 1g	**RH** 150mg+75mg	**E*** 400mg
30-37	2	0.5	2	1 1/2
38-54	3	0.75	3	2
55-70	4	1g	4	3
71-90	5	1g	5	3 1/2

3 FDCs, tablets or packs of granules for new Category I case children
(Use the same doses for new Category III case children, but without streptomycin)

Paediatric	Intensive phase (2 months, daily)		Continuation phase (4 months, daily)
Weight (kg)	**RHZ** 60mg+30mg+150mg	**S**** 1g	**RH** 60mg+30mg
< 7	1	0.25	1
8-9	1 1/2	0.25	1 1/2
10-14	2	0.25	2
15-19	3	0.50	3
20-24	4	0.50	4
25-29	5	0.50	5

* Ethambutol should not be given to children under six years old.

** Streptomycin is given only for the first two months of the intensive phase.
For patients over the age of 50 years, 750 mg are given and streptomycin should not be given to pregnant women.

SYMPTOM-BASED APPROACH TO ADVERSE EFFECTS OF TB DRUGS

Adverse effects are classified as minor and major. In general, a patient who develops minor adverse effects should continue the same anti-TB treatment and may also receive symptomatic treatment. If a patient develops a major side effect, the treatment is stopped and the patient is referred to the hospital.

Side effects	Drugs probably responsible	Management
Minor		**Continue anti-TB drugs** **Check drug doses**
Anorexia, nausea, abdominal pain	**Rifampicin**	➤ Give drugs last thing at night
Joint pain	**Pyrazinamide**	➤ Aspirin
Burning sensation in the feet	**Isoniazid**	➤ Pyridoxine 100mg daily
Orange/red urine	**Rifampicin**	➤ Reassure the patient
Major		**Stop responsible drugs**
Itching of skin, skin rash	**Streptomycin**	➤ Stop anti-TB drugs
Deafness	**Streptomycin**	➤ Stop streptomycin and use ethambutol
Dizziness (vertigo and nystagmus)	**Streptomycin**	➤ Stop streptomycin and use ethambutol
Jaundice (other causes excluded)	Most anti-TB drugs (especially **isoniazid, pyrazinamide** and **rifampicin**)	➤ Stop anti-TB drugs
Vomiting and confusion (suspect drug-induced acute liver failure)	Most anti-TB drugs	➤ Stop anti-TB drugs. Urgent liver function test and prothrombin time
Visual impairment (other causes excluded)	**Ethambutol**	➤ Stop ethambutol
Shock, purpura, acute renal failure	**Rifampicin**	➤ Stop rifampicin

PATIENT INFORMATION SHEET*

(WHO/WPRO version)

1 Tuberculosis is a contagious disease caused by a germ. The infection is transmitted from a sick person that is sputum positive at the microscopic examination. The germs are spread in the air when a patient sneezes, coughs or spits. People in close contact can become infected when they breathe the air containing these germs.

2 Prevent the spreading of the germs by covering the mouth when coughing and sneezing, and by avoiding spitting in public places.

3 A patient taking regular treatment rapidly stops being infectious and is not a risk to others.

4 Tuberculosis is a curable disease if the patient takes the medicines regularly for 6 months. The number of pills will become much less after the first two months of treatment.

5 These medicines are safe and are the only means for curing the disease. However, sometimes they can cause minor problems such as sleepiness, nausea, abdominal discomfort, pain in the joints, and a burning sensation in the feet. These effects usually stop after a few days.

6 Rifampicin makes the urine red-orange but this does not cause problems.

7 To achieve the cure, the best way is to take the medicines under the direct observation of a treatment partner who could be a health worker or a responsible community leader.

8 If you were sputum positive at the microscopic examination, at the end of your treatment go back to your DOTS Centre for a final evaluation of your health status. *On this occasion bring your treatment card with you.*

** This annex was prepared by WHO/WPRO to support the regional model as presented in Part 1 of this manual. Individual countries may find that not all items relate to their particular setting; therefore, modification of the above points is recommended to reflect country specific needs and procedures.*

TREATMENT PARTNER INSTRUCTION SHEET*
(WHO/WPRO version)

(Community volunteers)

1 In agreement with your supervisor of the health centre, find a suitable means and place to receive the weekly supply of medicines for your patient.

2 In agreement with your patient find a convenient way and place where you can observe your patient swallow the medicines.

3 Make sure that the **sputum-positive patient** swallows the medicines in your presence every day for at least five days in a week. Give to the patient the medicines for the other two days.

4 If a patient is **sputum negative or extrapulmonary**, observe the patient swallow the first dose of the weekly supply. Give to him/her the supply of medications to be taken at home.

5 Record an **X** in the calendar of the treatment card each time that you observe the patient swallowing the medicines. Draw a horizontal line through the days to indicate the number of days' supply that is given to the patient for self-administration.

6 If the medicines cause minor problems such as sleepiness, nausea, abdominal discomfort, pain in the joints and a burning sensation in the feet, reassure the patient by telling him that the problems should stop in a few days.

7 If the symptoms persist, or the medicines cause major and more serious problems to your partner, refer him/her to the nearest health facility or to your supervisor.

8 If the patient fails to take the medicines, investigate the reasons, and inform your supervisor, if the patient does not resume his/her treatment.

9 If your patient was sputum positive at the microscopic examination and he/she has completed the treatment, refer him/her to the DOTS Centre for final evaluation. On this occasion give your patient the treatment card to bring to the DOTS Centre.

** This annex was prepared by WHO/WPRO to support the regional model as presented in Part I of this manual. Individual countries may find that not all items relate to their particular setting; therefore, modification of the above points is recommended to reflect country specific needs and procedures.*

The following records, registers and reports should be used to evaluate patients' progress and programme performance:

SPC/TUB 01** – ***Laboratory Sputum Form for TB Investigation
(accompanies sputum samples and is returned, with results, to the referring health facility);

SPC/TUB 02** – ***Laboratory Register
(stays at the laboratory where sputum smear is performed);

TUB 03 – ***Tuberculosis Register***
(stays at the DOTS Centre);

SPC/TUB 04** – ***Tuberculosis Treatment Card
(master copy kept at the DOTS Centre, one copy stays with the patient and another with the treating health facility);

SPC/TUB 05** – ***Tuberculosis Referral/Transfer Form
(stays at the health facility);

TUB 06 – ***Quarterly Report on Tuberculosis Case-Finding***
(stays at the DOTS Centre and is prepared by the DOTS co-ordinator; one copy is sent to the Tuberculosis Control Section at SPC and a second copy to WHO);

SPC/TUB 07** – ***Quarterly Report on Treatment Outcomes of Tuberculosis Patients Registered as a Cohort and Reported for the Quarter when the Last in the Cohort has Completed Treatment.
(Stays at the DOTS Centre and is prepared by the DOTS co-ordinator; one copy is sent to the Tuberculosis Control Section at SPC and a second copy to WHO).

** Initial forms (named TUB0_) for the Tuberculosis Information System were developed by WHO/WPRO for use in the Western Pacific Region. At the request of related SPC member countries, several of these forms were adapted by the SPC Tuberculosis Control Section to meet more specific local needs. These revised forms have been renamed using the system SPC/TUB0_ to reflect the changes, while still acknowledging WHO for their original work.*

SPC/TUB 01

Laboratory Sputum Form for TB Investigation

Name of patient: _____ Age: ___ Sex: M F

Complete Address: _____

_____ Tel: _____

Contact Person Name & Details (address, phone): _____

_____

Health unit: _____ Patient's TB No: _____

Reason for examination: Diagnosis ☐ Follow up ☐

Date of Sputum collection: ☐ _____
☐ _____
☐ _____

Requesting doctor: _____ Date of request: _____

Results (to be completed in the laboratory)

Lab Serial No: _____ Date received: _____

Specimen	Date of Examination	Visual Appearance (M, MP, B, P, S)*	Results**
1			
2			
3			

* M=mucoid, B=blood-stained, S=salivary, P=purulent, MP=muco-purulent

Date of report: _____ Examined by (signature): _____

** Grading system for results:
Neg No AFB seen in at least 100 fields
Scanty 1–9 AFB per 100 fields *(record the exact number of AFB seen)*
1+ 10–99 AFB per 100 fields
2+ 1–10 AFB per field in at least 50 fields
3+ >10 AFB per field in at least 20 fields

SPC/TUB 01

Laboratory Sputum Form for TB Investigation

Name of patient: _____ Age: ___ Sex: M F

Complete Address: _____

_____ Tel: _____

Contact Person Name & Details (address, phone): _____

_____

Health unit: _____ Patient's TB No: _____

Reason for examination: Diagnosis ☐ Follow up ☐

Date of Sputum collection: ☐ _____
☐ _____
☐ _____

Requesting doctor: _____ Date of request: _____

Results (to be completed in the laboratory)

Lab Serial No: _____ Date received: _____

Specimen	Date of Examination	Visual Appearance (M, MP, B, P, S)*	Results**
1			
2			
3			

* M=mucoid, B=blood-stained, S=salivary, P=purulent, MP=muco-purulent

Date of report: _____ Examined by (signature): _____

** Grading system for results:
Neg No AFB seen in at least 100 fields
Scanty 1–9 AFB per 100 fields *(record the exact number of AFB seen)*
1+ 10–99 AFB per 100 fields
2+ 1–10 AFB per field in at least 50 fields
3+ >10 AFB per field in at least 20 fields

TB LABORATORY REGISTER

Year:_____ **SPC/TUB 02**

TB No	Lab Serial No	Date of test	Date of specimen collection	Description of sputum*	Name and address of Patient	Sex M/F	Age	Name of treatment unit	Reason for exam: diagnosis/ follow-up	Result**	Remarks	Signature

Note: Use one block of 3 lines per patient

* S = salivary, P = purulent, M = mucoid, MP = muco-purulent, B = blood-stained

** Grading system:

Neg	No AFB seen in at least 100 fields
Scanty	1–9 AFB per 100 fields *(record the exact number of AFB seen)*
1+	10–99 AFB per 100 fields
2+	1–10 AFB per field in at least 50 fields
3+	>10 AFB per field in at least 20 fields

TUBERCULOSIS REGISTER

TUB 03

Date registered	Patient's TB No.	Name	Sex (M/F)	Age	Address	Name of treatment centre*	Treatment start date	Regimen**	Disease Classification P/EP	Type of patient***					
										new	relapse	failure	TAI (default)	transfer in	other

* Usually the name of the health facility where the patient is doing the continuation phase

** Write Cat. I or Cat. II or Cat. III

*** **new:** never previously treated for as much as 4 weeks
relapse: previously treated and declared cured, returns smear positive
failure: positive smear, 5 or more months after starting treatment, put on re-treatment
TAI (treatment after interruption): returns smear positive after interruption of 2 months or more
transfer in: registered and starts treatment in another DOTS Centre
other: patients that do not fit any of the previous definitions
(see page 9 "Types of Patients" for more detail)

Results of sputum-smear examinations and dates, according to the duration of treatment										Treatment outcome**** and date***** (according to the smear result at completion)						Name of the treatment partner	Remarks
Before treatment		End 2nd month		End 3rd month		During 6th month		During 8th month		Cured (negative)	Treatment completed	Treatment failure	Died	Treatment interrupted (defaulted)	Transfer out		
result	date	result	date	result	date	result	date	result	date								

**** **Cured:** negative smear at the last month of treatment and on one previous occasion
Died: *died for any reason during treatment*
Treatment completed: no proof of cure as determined by smear examination
Treatment interrupted (defaulted): *failed to collect medications for 2 months or more*
Treatment failure: positive smear at 5 months or later during treatment
Transfer out: *sent to another reporting unit for continuation of treatment*
(see page 10 "Treatment Outcomes" for more detail)

***** Write the date in the corresponding box

TUBERCULOSIS TREATMENT CARD

SPC/TUB 04

NAME: _____ TB No: _____

DOB (d/m/y): _____ Age: ____ Sex: M F

Address: _____

_____ Phone: _____

Contact person: _____

Island: _____ Village: _____

INTENSIVE PHASE: Date started _____

Treatment regimen and number of tablets*:

Adults	H (300mg)*	R (300mg)*	Z (500mg)*	E (400mg)*	S (1g)**
☐ Cat I (2HRZE)	☐	☐	☐	☐	
☐ Cat II (2HRZES/1HRZE)	☐	☐	☐	☐	☐
☐ Cat III (2HRZ)	☐	☐	☐		

Children	H (100mg)*	R (150mg)*	Z (500mg)*	S (1g)**
☐ Cat I (2HRZS)	☐	☐	☐	☐
☐ Cat III (2HRZ)	☐	☐	☐	

H= Isoniazid; R= Rifampicin; Z= Pyrazinamide; E= Ethambutol; S= Streptomycin

SPUTUM EXAMINATION RESULTS

Month	Date	Result	Weight	Date of next sputum exam
0				
2				
3				
4				
5				
6				
7				
8				

DISEASE CLASSIFICATION

Pulmonary smear-positive ☐

Pulmonary smear-negative ☐

Extrapulmonary ☐ Site: _____

TYPE OF PATIENT

NEW ☐ TREATMENT FAILURE ☐

RELAPSE ☐ TREATMENT AFTER INTERRUPTION ☐

TRANSFER IN ☐

OTHER ☐ (specify) _____

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

* Enter in the box the number of tablets to be administered daily.

** Enter in the box the daily dosage amount.

*** Enter a cross (x) on each day when medications were swallowed under direct observation. Draw a horizontal line (–) through the days to indicate when medications were swallowed but not directly observed. Enter a zero (0) for any day when no medication was taken (swallowed).

TUBERCULOSIS TREATMENT CARD

SPC/TUB 04 (cont.)

CONTINUATION PHASE: Date started _____

Treatment regimen and number of tablets:*

Adults	H (300mg)*	R (300mg)*	E (400mg)*
☐ Cat I and Cat III (4HR)	☐	☐	
☐ Cat II (5HRE)	☐	☐	☐

Children	H (100mg)*	R (150mg)*
☐ Cat I and Cat III (4HR)	☐	☐

REMARKS:

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

* Enter in the box the number of tablets to be administered daily.

*** Enter a cross (x) on each day when medications were swallowed under direct observation. Draw a horizontal line (—) through the days to indicate when medications were swallowed but not directly observed. Enter a zero (0) for any day when no medication was taken (swallowed).

Note: The number before the letter is the duration in months of the administration of the drugs; 2HRZES/1HRZE means 2 months with 5 drugs and 1 month with 4 drugs without S.

Treatment outcome: Cured ☐ Treatment completed ☐ Treatment failure ☐ Died ☐ Treatment interrupted ☐ Transferred out ☐

SPC/TUB 05

TUBERCULOSIS REFERRAL/TRANSFER FORM

Name of the referring/transferring unit: _____

Name of the unit to which the patient is referred: _____

Name of the patient: _____ Age: _____ Sex: _____

Address where the patient is going: _____

TB No: _____ Date treatment started: _____ Treatment regimen: _____

Drugs patient received: _____

TB classification: _____ Sputum examination results: _____

Reason for referral/transfer: _____

Remarks: _____

Printed name and signature: _____

Designation: _____ Date: _____

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

Name of the patient: _____ Age: _____ Sex: _____

Initial TB No: _____ Date treatment ended: _____

Treatment outcome:

Cured ☐ Treatment completed ☐ Died ☐ Transfer out ☐
Treatment failure ☐ Treatment interrupted (default) ☐

(Send treatment outcome to the DOTS Centre where the patient was originally registered)

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

Name of the patient: _____ TB No: _____

Age: _____ Sex: _____ Date referred/transferred: _____

The above patient reported at this health unit on the date: _____

Printed name and signature of the receiving officer: _____

Name of the health unit: _____ Date: _____

(Send this part back to the referring unit as soon as the patient has reported and registered)

QUARTERLY REPORT ON TUBERCULOSIS CASE-FINDING

Name of DOTS Centre _____	DOTS Coordinator _____
Patients registered in* _____ quarter of 20__	Signature _____ Date _____

ALL CASES REGISTERED IN THE QUARTER

PULMONARY					EXTRA-PULMONARY	TOTAL
SMEAR-POSITIVE				SMEAR-NEGATIVE		
New case	Relapse	Treatment failure	Treatment after interruption			

NEW SMEAR-POSITIVE CASES ONLY

Age group (years)	Female	Male	Total
0 – 14			
15 – 24			
25 – 34			
35 – 44			
45 – 54			
55 – 64			
65+			
Total			

Note: Use the Tuberculosis Register (TUB 03) to fill in this form;

* Write 1st or 2nd or 3rd or 4th to indicate the quarter of the year for which the report is made

1st: quarter comprises: January, February, and March;
2nd: April, May and June;
3rd: July, August and September;
4th: October, November and December.

QUARTERLY REPORT ON TREATMENT OUTCOMES OF TUBERCULOSIS PATIENTS REGISTERED AS A COHORT AND REPORTED FOR THE QUARTER WHEN THE LAST IN THE COHORT HAS COMPLETED TREATMENT

DOTS Centre: _____ DOTS Manager/Coordinator _____

Date of Report: _____ Signature: _____

Report for the cohort of TB cases registered in the ____ Quarter* of 20 ____

1. New Sputum smear-positive (S^+) cases: ***

Cured	Completed treatment	Failed	Died	Defaulted	TO**	Total

2. Retreatment Sputum smear-positive cases: ***

Retreatment	Cured	Completed treatment	Failed	Died	Defaulted	TO**	Total
Relapse							
Default							
Failure							
Total							

3. New Sputum smear-negative (S^-) cases: ***

Completed treatment	Failed	Died	Defaulted	TO**	Total

4. New Extra-Pulmonary TB (EPTB) cases: ***

Completed treatment	Failed	Died	Defaulted	TO**	Total

* Please complete a separate form for each cohort being reported.

** TO – transfer out

*** Take these numbers directly from the Tuberculosis Register (TUB 03)