GUIDELINES for the CONTROL of TUBERCULOSIS in NIUE through DOTS STRATEGY

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

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TABLE OF CONTENTS

Acronyms and Abbreviations vi
Introductory Statement, Purpose, Structure and Acknowledgements vii-ix
Foreword by the Niue Director of Health x
Foreword by the WHO Regional Director xi
Preface xiii

Part I

1.0 The WHO-recommended DOTS Strategy — A Regional Model

1.1 Introduction 1

1.2 A National Tuberculosis Programme (NTP) 1

1.2.1 The DOTS Framework: Objectives, Targets and Strategy 1
1.2.1.1 General Objectives
1.2.1.2 Specific Targets
1.2.1.3 Strategy
1.2.2 Structure, Staff and Functions 2
1.2.2.1 The Ministry of Health (administrative function)
1.2.2.2 The DOTS Centre (clinical function and microscopy service)
1.2.2.3 Community or Village Level
Figure 1: Model National Tuberculosis Programme (NTP) Framework 4

1.3 Case Finding 5

1.3.1 Symptoms of Tuberculosis 5
1.3.1.1 Pulmonary Tuberculosis (PTB)
1.3.1.2 Extrapulmonary Tuberculosis (EPTB)
1.3.2 Identification and Referral of Suspect Cases 5
1.3.3 Diagnosis 5
1.3.3.1 Pulmonary Tuberculosis
1.3.3.2 Extrapulmonary Tuberculosis
Figure 2: The Road towards the Diagnosis of Adult Pulmonary Tuberculosis 7

1.4 Case Definitions and Classification, Types of Patients and Treatment Outcomes 8

1.4.1 Case Definitions and Classification 8
1.4.2 Types of Patients 9
1.4.3 Treatment Outcomes 10

1.5 Anti-TB Drugs, Treatment Categories and Regimens 11

1.5.1 Recommended Anti-TB Drugs 11
1.5.2 Treatment Categories and Regimens 11
Table 1: Recommended Treatment Categories 12
1.5.3 Treatment Doses for Adults and Children 12
1.5.3.1 Treatment Category I for new case adults
1.5.3.2 Treatment Category II for retreatment case adults
1.5.3.3 Treatment Category III
1.5.3.4 Treatment Category I for new case children
1.5.4 Issues to Consider in Special Situations 14

1.6 Operational Aspects of Case Management and Monitoring 16

1.6.1 New Sputum Smear-positive Cases 16
1.6.2 Retreatment Cases Sputum Smear-positive: Relapse, Failure, Treatment after Interruption 16
1.6.3 New Sputum Smear-negative Pulmonary and Extrapulmonary Cases 16
Table 2: Summary of the Mechanisms for Directly Observed Treatment (DOT) 17
1.6.4 Treatment Kit 18
1.6.5 Treatment Partner 18
1.6.6 Sputum Smear Examinations to Monitor Patient Progress and Cure 19

1.7 Reporting of Case Findings and Treatment Outcomes 20

1.7.1 Quarterly Report on Tuberculosis Case-Finding 20
1.7.2 Quarterly Report on The Outcomes of Treatment of Pulmonary Tuberculosis Sputum Smear-positive Patients 20

Part II

The Niue DOTS Strategy — A Country-specific Model 2.0

2.1 Country Background 21

2.2 Overview of the Niue Tuberculosis Programme 22

2.2.1 Niue Adopts the DOTS Strategy 22

2.2.2 The Niue National Tuberculosis Programme (NTP) Framework 22

Figure 3: The Niue National Tuberculosis Programme (NTP) Flow Chart 23

2.2.2.1 DOTS Programme Staff

NTP Manager

DOTS Coordinator

Doctors

Nursing Staff

2.2.2.2 DOTS Programme Facilities

2.2.3 Complementary Tuberculosis Control Measures 28

2.3 Operational Aspects of Case Detection, Diagnosis and Treatment 28

2.3.1 Case Detection 28

Figure 4: Procedure for Following Patients Suspected of Having Tuberculosis 29

2.3.2 Diagnosis 29

2.3.2.1 Diagnostic Classifications

2.3.2.2 Treatment Categories

Category I Cases

Category II Cases

Category III Cases

2.3.2.3 Summary of Specific TB Screening and Diagnostic Procedures Used in Niue

2.3.3 Treatment 34

2.3.3.1 Treatment Plan for Category I Patients

2.3.3.2 Treatment Plan for Category II Patients

2.3.3.3 Treatment Plan for Category III Patients

2.4 Anti-TB Drug Availability 45

2.5 Case Management, Monitoring and Assessment 45

Table 3: Details, including Timetable, for Monitoring Patient Treatment in Niue 46

Table 4: Timetable and Purpose of Monitoring and Supervisory Visits 47

2.6 Summary of Patient Registration and Record Keeping 48

2.6.1 Laboratory Sputum Form for TB Investigation 48

2.6.2 TB Laboratory Register 48

2.6.2.1 Monthly Case Summary

2.6.3 Tuberculosis Register 50

2.6.4 Tuberculosis Treatment Card 50

2.6.5 Tuberculosis Referral/Transfer Form 51

Figure 5: Summary of the Path of Patient Registration and Record Keeping 52

2.7 Regional Reporting of Case Findings and Treatment Outcomes 53

2.7.1 Directions for Completing the Quarterly Report on Tuberculosis Case-Finding 53

2.7.2 Directions for Completing the Quarterly Report on Treatment Outcomes 54

2.8 Ongoing Quality Assurance of Microscopy Services 56

2.8.1 Quality Control 56

2.8.2 External Quality Assessment 56

2.8.3 Drug Resistance Surveillance 57

Annex 1 List of Essential Anti-Tuberculosis Drugs for Daily Use 60

Annex 2 Standardised Treatment Categories Using Different Fixed-Dose Combinations (FDCs), for Adults and Children 61

Annex 3 Symptom-Based Approach to Adverse Effects of TB Drugs 63

Annex 4 Patient Information Sheet 64

Annex 5 Treatment Partner Instruction Sheet 65

Annex 6 Tuberculosis Information System-SPC/TUB Programme Forms #1 - 7 66

ACRONYMS AND ABBREVIATIONS

AFB	–	acid-fast bacilli
AIDS	–	acquired immunodeficiency syndrome
BCG	–	Bacille Calmette-Guerin
CCM	–	Country Coordinating Mechanism
DOT	–	directly observed treatment
DOTS	–	directly observed treatment, short course
DRS	–	drug resistance surveillance
EPTB	–	extrapulmonary tuberculosis
EQA	–	external quality assessment
FDC	–	fixed-dose combination
GFATM	–	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	–	human immunodeficiency virus
IMVS	–	Institute of Medical and Veterinary Science (Adelaide, Australia)
kg	–	kilogram
MDG	–	UN Millennium Development Goal
MDR-TB	–	multidrug-resistant tuberculosis
mg	–	milligram
MOH	–	Ministry of Health
NTP	–	National Tuberculosis Programme
OPD	–	outpatient department
PATLAB	–	Pacific TB Laboratory Initiative
PICTs	–	Pacific Island countries and territories
PPTC	–	Pacific Paramedical Training College (Wellington, New Zealand)
PTB	–	pulmonary tuberculosis
PTRL	–	Pacific TB Reference Laboratory
QC	–	quality control
S^+	–	smear-positive
S^-	–	smear-negative
SPC	–	Secretariat of the Pacific Community
TAI	–	treatment after interruption
TB	–	tuberculosis
TST	–	tuberculin skin test
WHO	–	World Health Organization
WPRO	–	Regional Office for the Western Pacific, WHO
UN	–	United Nations

DRUG ABBREVIATIONS

E	–	ethambutol
H	–	isoniazid
R	–	rifampicin
S	–	streptomycin
Z	–	pyrazinamide

INTRODUCTORY STATEMENT

Tuberculosis is a serious public health threat

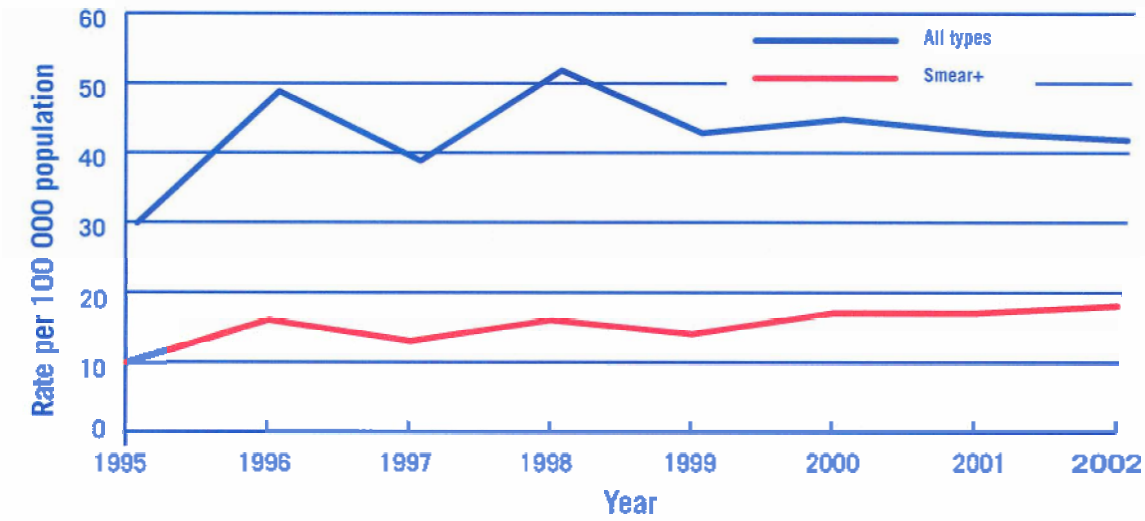
Statistics show that tuberculosis continues to be a serious and growing public health threat throughout the world.

- Two billion people, nearly one-third of the total global population, are infected with the disease.
- Every day, 5000 people become sick with tuberculosis (TB), and every year the disease causes two million people to die, including 250,000 children.
- Tuberculosis 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 the development of multidrug-resistant tuberculosis (MDR-TB), which is prohibitively expensive to address, potentially incurable and all too often fatal.

Here in our own region among the SPC Pacific Island countries and territories (PICTs), the magnitude of the tuberculosis problem 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 6000 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.**
- Among 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 and 54 years.
  - 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.

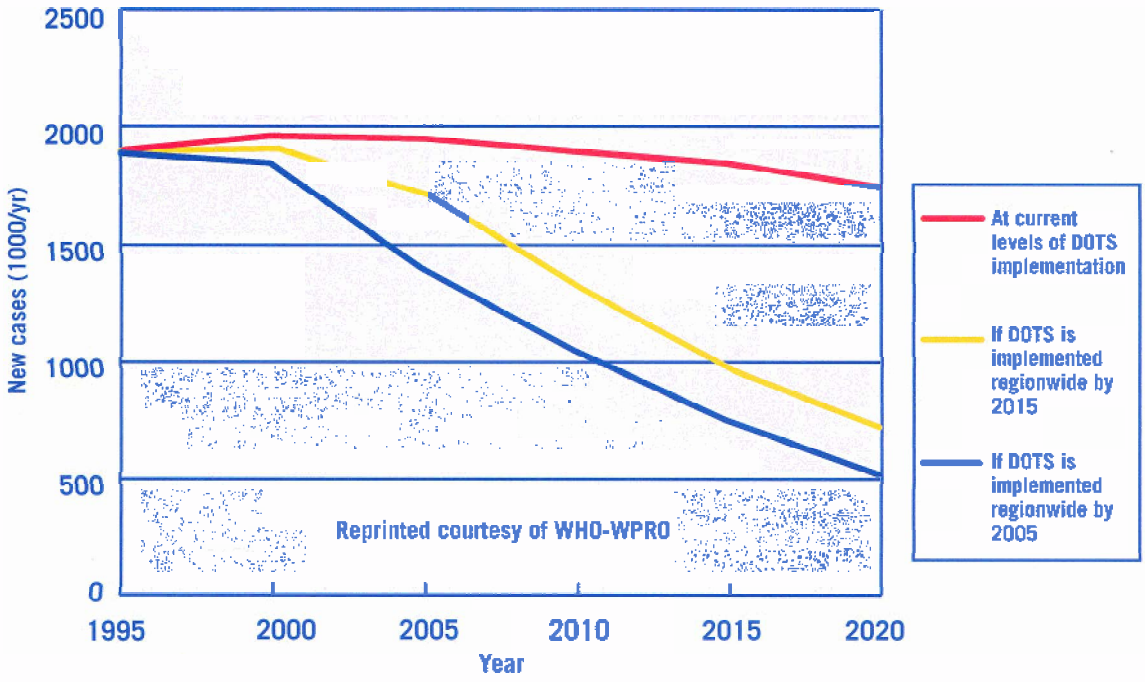
Graph I: **TB case notification trends in the Pacific Islands*, 1995–2002**
Based on data from the WHO Regional Office for the Western Pacific (WHO-WPRO)



*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 were to implement effective DOTS programmes before the end of 2005, the burden of TB would be reduced by 50% by 2010. These efforts would also help to achieve the UN Millennium Development Goal (MDG) for tuberculosis, which is 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 recognises 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 organisations, to support the DOTS strategy among 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 and territories in their implementation of successful DOTS programmes.

Purpose and Structure

This document has been modified from Guidelines for the Control of Tuberculosis through DOTS Strategy in Pacific Island Countries (WHO 1999) with permission of the writing committee of WHO-WPRO (Dr Leopold Blanc, Dr Dong Il Ahn and Dr Carmine Diletto) to be applicable for Niue. Major country-specific additions to the original document, which detail the Niue DOTS strategy and which can be found in Part 2 of this publication, are:

- Country Background
- Overview of the Niue Tuberculosis Programme
  Operational Aspects of Case Detection, Diagnosis and Treatment
- Case Management, Monitoring and Assessment
- Patient Registration and Record Keeping

[1] *directly observed treatment, short course (DOTS)*

The manual was prepared to assist the Niue Ministry of Health in its endeavour to combat tuberculosis. To this purpose, it has been organised in two parts:

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

This section summarises the WHO Model for DOTS, as developed specifically for Pacific Island countries in 1999 by the WHO Regional Office for the Western Pacific.

Part II: The Niue DOTS Strategy — A Country-specific Model

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

Acknowledgements

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 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 differen

FOREWORD by the Niue Director of Health

Niue is among the top six countries in the Pacific with a high tuberculosis burden.

The DOTS programme was introduced to Niue in March 2002, but was adopted only in principle; the intention was to conduct a formal training of health workers towards the end of 2002. This training did not take place, however, because of competing national commitments. We subsequently concluded that the training was not necessary because Niue's health system and infrastructure is not complicated. It includes only two levels: the hospital (the only health facility that provides all health services) and the community.

In light of the above, we decided, with the support and advice of the TB Specialist at the Secretariat of the Pacific Community, to develop a DOTS national guidelines manual. This document will ensure that the DOTS programme is standardised and effectively managed, and serves as a useful reference tool.

As Director, I fully support the development of these guidelines, and trust they will assist all health workers, patients and the community in their effort to fight tuberculosis in Niue.

It is my pleasure, therefore, to endorse this important document.

Dr H. H. Paka
Director of Health
Health Department
Niue

FOREWORD by the 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.

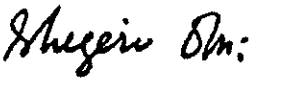
About half a million people die from tuberculosis each year in the Region. The tuberculosis burden is even heavier in the small Pacific island countries, where, in 1998, the average notification rate in 17 of these countries was 73 per 100 000 population, which is much higher than the regional average.

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 programmes in the Pacific, little was known about the epidemiological situation of tuberculosis in these small Pacific Island countries. Despite limited information, the available data indicates that tuberculosis is common, and that treatment of 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 Regional Office for the Western Pacific, Tuberculosis Programme, Chronic Communicable Disease Unit. Comments on Part II — the Niue 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

1.0 The WHO-recommended DOTS Strategy — A Regional Model

1.1 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, Regional Office for the Western Pacific (WHO-WPRO). 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 Niue country-specific strategy presented in Part II. Further, it is included to be used in future planning for the ongoing improvement of the Niue National Tuberculosis Programme.

1.2 A National Tuberculosis Programme (NTP)

1.2.1 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 because of its 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 programmes. The fundamental DOTS framework common to all DOTS programmes consists of the following objectives, targets and strategy.

1.2.1.1 General Objectives

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

1.2.1.2 Specific Targets

- Ensure that 100% of the population has access to DOTS.
- Detect 70% of 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 cases "treatment completed". The rate can be represented by the formula: Treatment success rate = % cured + % treatment completed (Refer to Section 1.4.3 for detailed Treatment Outcome Definitions and to Section 2.7.2 for calculation instructions.)*

1.2.1.3 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 an NTP
- reliable microscopy services for detecting sputum smear-positive cases
- regular and uninterrupted supply of anti-tuberculosis (anti-TB) drugs
- direct observation of standardised short-course treatment (DOT) for sputum smear-positive cases
- standardised recording and reporting system to monitor patient progress and to assess treatment outcomes

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 an 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.

1.2.2 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 (MOH). 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.

1.2.2.1 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 reliable sputum smear microscopy service is in place
- ensuring a 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

1.2.2.2 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
- ➜ maintaining and updating the Tuberculosis Register

1.2.2.3 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

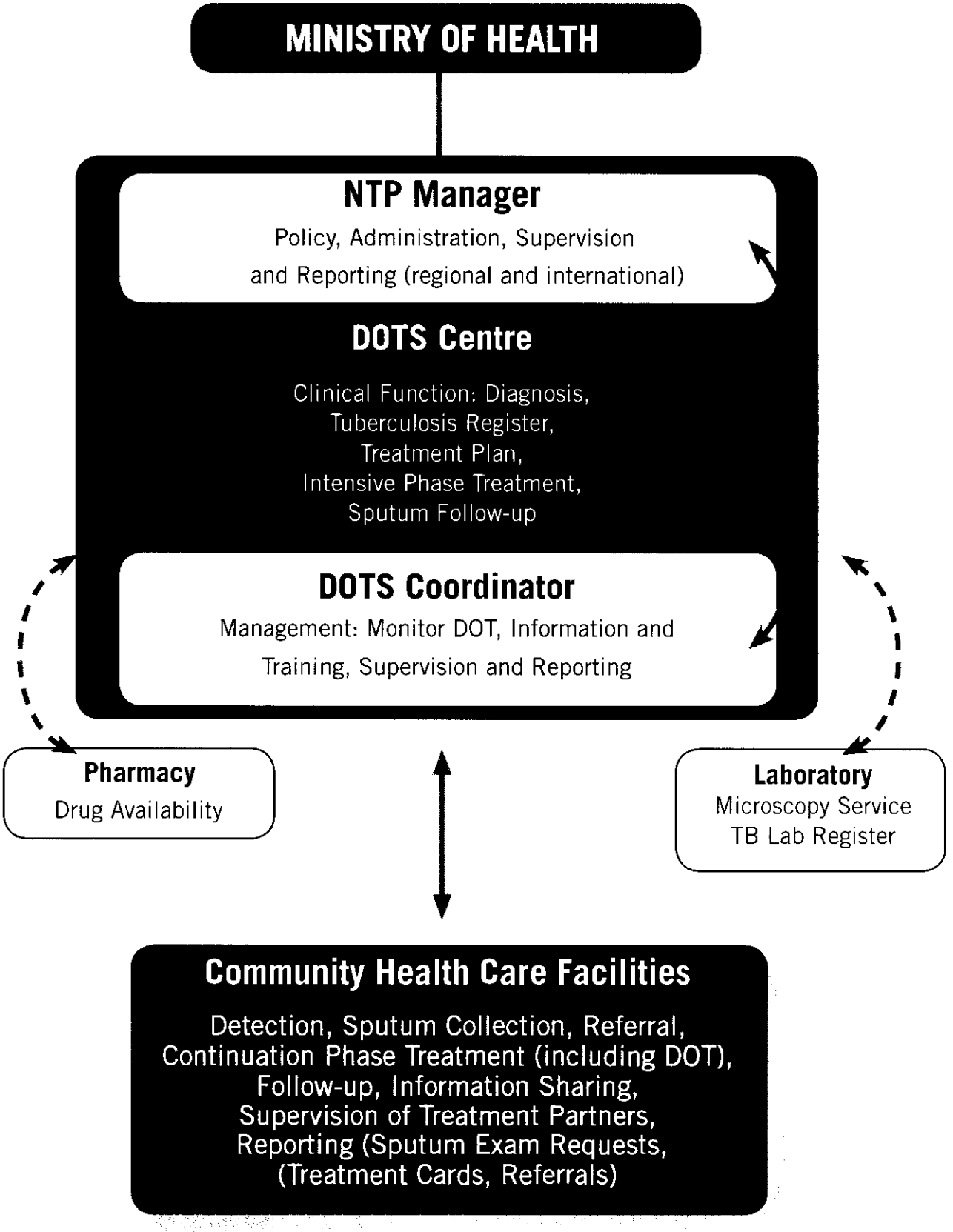
- providing daily direct observation of treatment (DOT) for pulmonary sputum smear-positive patients during the Continua-tion Phase and recording the intake of treatment on the patient treatment card

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

- tracing of absentees and administering basic TB information to the patients, their Family and community

- 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 Programme (NTP) Framework



1.3 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.

1.3.1. 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.

1.3.1.1 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 (sputum). 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

1.3.1.2 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, and may include, 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.

1.3.2 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 Section 1.3.3.1). 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 such cases 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 a responsibility to identify and refer suspect cases to the nearest health facility or, in its absence, directly to the DOTS Centre.

1.3.3 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.

1.3.3.1 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)** The **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 in the Tuberculosis Laboratory Register.

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

- pulmonary tuberculosis sputum smear-positive; or
- pulmonary tuberculosis sputum smear-negative.

1.3.3.2 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 AFB in tissue or fluids such as superficial abscess, lymphadenitis, or in urine).

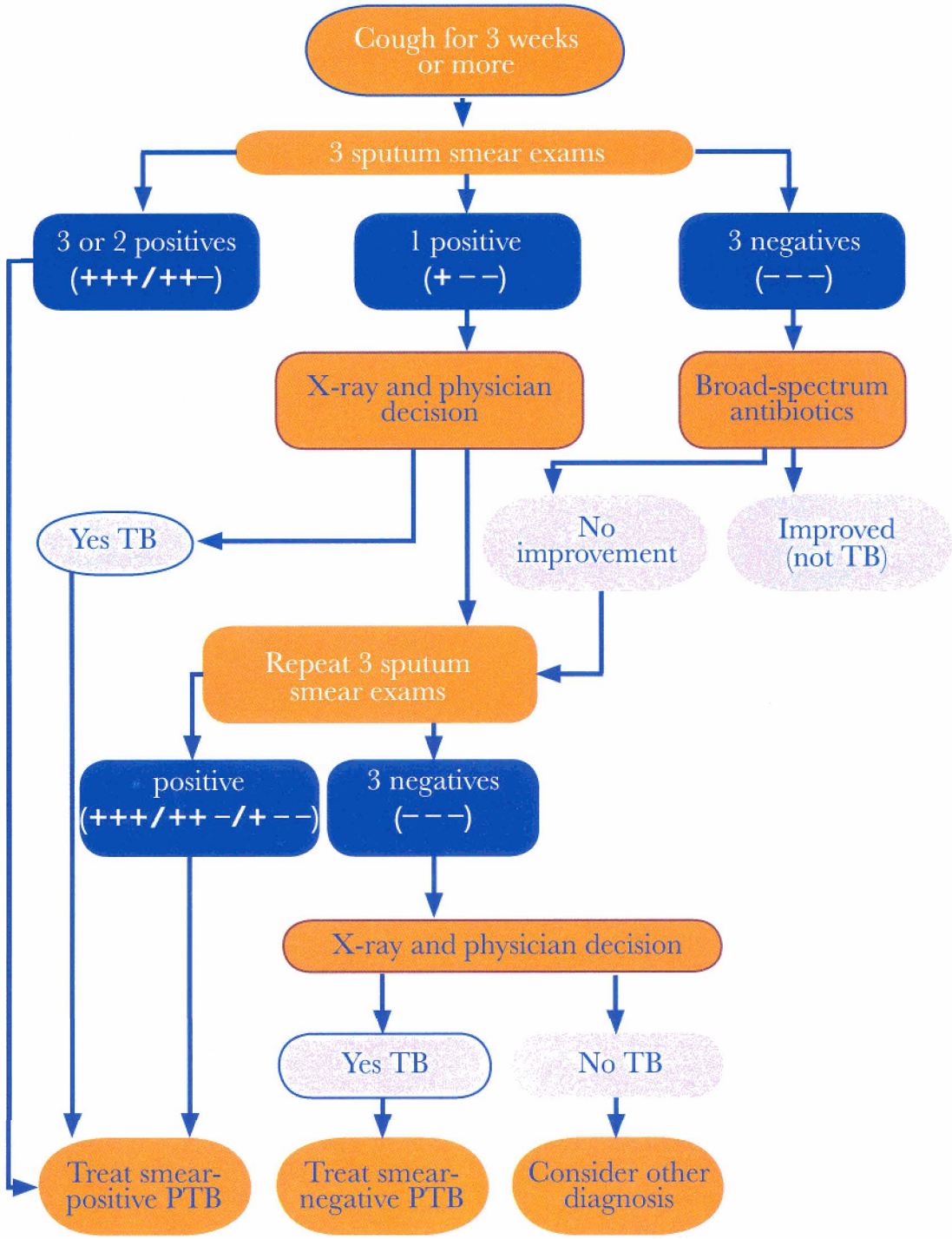
TB CLASSIFICATIONS	
Pulmonary TB (PTB)	**Extrapulmonary TB (EPTB)**
➢ **Tuberculosis affecting the lungs:** • **Sputum smear-positive** • **Sputum smear-positive**	➢ **Tuberculosis affecting organs other than the lungs**

For the diagnosis of pulmonary tuberculosis follow the steps as indicated in Figure 2 (see next page).

NOTES:

- A patient diagnosed with both pulmonary and extrapulmonary 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 in 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 Section 2.6.3**).

Figure 2: The Road towards the Diagnosis of Adult Pulmonary Tuberculosis



Case Definitions and Classification, Types of Patients and Treatment Outcomes 1.4

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

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

1.4.1. Case Definitions* And Classification**

Pulmonary smear-positive

- Minimum two out of three sputum smear-positive for AFB by microscopy

OR

- One out of three sputum smear-positive **and** chest X-ray consistent with PTB **and** decision to treat made by a physician

OR

- One out of three sputum smear-positive **and** at least one sputum that is culture-positive for AFB

Pulmonary smear-negative

Either: a patient who fulfils all the following criteria:
- first set of three sputum smear-negative for AFB;
- lack of clinical response despite two weeks of a broad-spectrum antibiotic;
- second set of three sputum smears still negative, taken at least two weeks apart from the first set;
- X-ray consistent with PTB; **and**
- decision by a physician to treat with a full curative course of anti-TB chemotherapy;

Or: a patient who fulfils all the following criteria:
- severely ill;
- set of three sputum smear-negative for AFB;
- X-ray consistent with extensive PTB (interstitial or miliary); **and**
- decision by a physician to treat with a full curative course of anti-TB chemotherapy;

Or: a patient whose initial set of three sputum smears was negative, who had sputum sent for culture initially, and whose subsequent sputum culture result is positive.

Extrapulmonary tuberculosis

One culture-positive specimen from an extrapulmonary site, **or** histological **or** strong clinical evidence of active extrapulmonary TB **and** a decision by a physician to treat with a full course of anti-TB therapy.

* "Case Definition" determines what constitutes a case of tuberculosis.

** "Classification" refers to the site affected and the result of the sputum examination.

1.4.2 TYPES OF PATIENTS*

New

A patient who has never been treated for TB or who has taken antituberculosis drugs for less than four weeks.

Relapse

A patient previously treated for TB who had been declared "cured" or "treatment completed" after one full course of TB chemotherapy, and who is again diagnosed with bacteriologically positive (smear or culture) tuberculosis.

Treatment failure

A previously sputum smear-positive patient who, while on treatment, remained or again became 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 four weeks of treatment but has subsequently interrupted treatment for two 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 in the national Tuberculosis Register.

1.4.3 TREATMENT OUTCOMES*

Cured

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

Treatment completed

Smear-positive patient who has completed all treatment but without the smear results at the end of treatment as proof of cure **or** smear-negative patient who has completed treatment.

Treatment failure

Patient who remains or again becomes smear-positive at five 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 two 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.

** The words in italics have been inserted by SPC.

1.5 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 into 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 who 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.

1.5.1 Recommended Anti-TB Drugs

The following table is a list of the antituberculosis 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, in Sections 1.5.2 and 1.5.3.

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, 750mg should be given.

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

1.5.2 Treatment Categories and Regimens

There are currently several treatment regimens that are all effective in curing the different types of tuberculosis. However, to facilitate field operations and drug management, given the specific situation of the Pacific Islands, *only three treatment regimens are recommended (see Table 1).* A treatment category, which includes a specific group of TB patients, corresponds to each treatment regimen. While a fourth category — chronic and MDR-TB cases — has also been listed in Table 1, a definite treatment regimen has not been specified for this category because treatment drugs and doses must be carefully determined on an individual basis.

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.

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 2 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.

1.5.3 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.

1.5.3.1 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	½	1½	1½	1	½
38–54	1½	1	2½	2	1½	1
55–70	2	1	3½	3	2	1
71–90	2½	1½	4	3½	2½	1½

1.5.3.2 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	Pyrazinamide 500mg	Ethambutol 400mg	*Streptomycin 1g	Rifampicin 300mg	Isoniazid 300mg	Ethambutol 400mg
30-37	1	½	1½	1½	0.50	1	½	1½
38-54	1½	1	2½	2	0.75	1½	1	2
55-70	2	1	3½	3	1	2	1	3
71-90	2½	1½	4	3½	1	2½	1½	3½

*Streptomycin is only given for the first 2 months of the Intensive Phase; 0.75g should be given to patients over 50 years of age.

1.5.3.3 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	½	1½	1	½
38–54	1½	1	2½	1½	1
55–70	2	1	3 ½	2	1
71–90	2½	1½	4	2½	1½

1.5.3.4 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	Streptomycin1g	Rifampicin 150mg	Isoniazid 100mg
Up to 7 *	½	½	½	0.25	½	½
8-9	½	½	½	0.25	½	½
10-14	1	½	1	0.25	1	½
15-19	1	1	1	0.50	1	1
20-24	1½	1	1½	0.50	1½	1
25-29	2	1½	1½	0.50	2	1½

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

PLEASE NOTE: *Ethambutol as used with Category I and II adults is not included in paediatric therapy. It should not be given to children under six years of age.*

1.5.4 Issues to Consider in Special Situations

WHO recommends[2] additional consideration when treating tuberculosis patients in any of the following special situations described below.

Pregnant women

Before starting TB treatment, a woman should be asked whether she is pregnant. Most antituberculosis drugs are safe for use in pregnancy. The exception is **streptomycin**, which is ototoxic to the foetus (i.e. it could damage hearing). It **should not be used** during pregnancy.

A pregnant woman should be advised that successful treatment of TB with the recommended standardised regimen is important for the successful outcome of her pregnancy.

Breastfeeding mothers

A breastfeeding woman who has TB **should receive a full course of TB treatment.** Timely and properly applied chemotherapy is the best way to prevent transmission of the infection to her baby. All antituberculosis drugs are compatible with breastfeeding; a woman taking them can safely continue to breastfeed. Mother and baby should stay together and the baby should continue to be breastfed in the normal way.

The baby should be given prophylactic isoniazid for at least three months beyond the time the mother is considered to be non-infectious. BCG vaccination of the newborn should be postponed until the end of isoniazid prophylaxis.

Children

Diagnosis of tuberculosis in children is difficult. To aid the diagnostic process, the following guidelines could be used at the doctor's discretion.

To diagnose **TB infection without active TB**, look for:

- tuberculin skin test results ≥ 10 mm (if no prior BCG); **or**
- tuberculin skin test results ≥ 15 mm (if prior BCG).

NOTE:

Skin test results should be interpreted with caution due to their non-specificity.

To diagnose **active TB disease,** look for:

- positive AFB in sputum or gastric aspirate; **or** two or more of the following:
  - history of contact with an active TB case (S^+)
  - cough for more than two weeks
  - weight loss/loss of appetite
  - reactive tuberculin skin test (TST) as described above
  - positive X-ray findings compatible with TB

When treating children less than six years of age, **ethambutol should not be used**. The recommended paediatric treatment regimen and doses can be found in Section 1.5.3 or in Annex 2.

Women using oral contraception

Rifampicin interacts with oral contraceptive medications, creating a risk of decreased protection against pregnancy. A woman receiving oral contraception should consult with her doctor to choose whichever of the following two options is best for her situation, so that it can be used for the duration of her TB treatment with rifampicin:

- switching to an oral contraceptive pill with a higher dose of oestrogen (50 µg); **or**
- changing to another form of contraception.

Patients with liver disorders

Isoniazid, rifampicin and pyrazinamide are all associated with hepatitis. Of the three drugs, rifampicin is least likely to cause hepatocellular (severe liver) damage, although it is associated with cholestatic jaundice. Of the three agents, **pyrazinamide is the most hepatotoxic.**

[2] *WHO 2003. Treatment of Tuberculosis: Guidelines for National Programmes. 3rd edn. Geneva: WHO. 108 p. (document WHO/CDS/TB 2003.313)*

Patients with the following conditions can receive the usual short-course chemotherapy regimens provided there is no clinical evidence of chronic liver disease: hepatitis virus carriage, a past history of acute hepatitis, excessive alcohol consumption. However, **hepatotoxic reactions** to antituberculosis drugs may be more common among these patients and **should** therefore **be anticipated.**

Patients with established chronic liver disease

Patients with liver disease **should not receive pyrazinamide**. Isoniazid plus rifampicin, plus one or two non-hepatotoxic drugs such as streptomycin and ethambutol, can be used for a total treatment duration of eight months. An alternative regimen is SHE in the Intensive Phase, followed by HE in the Continuation Phase, with a total treatment duration of 12 months. Therefore, recommended regimens are:

- 2SHRE/6HR; **or**
- 2SHE/10HE.

Patients with acute hepatitis (e.g. acute viral hepatitis)

Uncommonly, a patient has TB and concurrently has acute hepatitis unrelated to TB or TB treatment. **Clinical judgement is necessary in such instances.** In some cases, it is possible to defer TB treatment until the acute hepatitis has resolved. In other cases, when it is necessary to treat TB during acute hepatitis, the combination of SE for three months is the safest option.

- **If** the **hepatitis has resolved**, the patient can then receive a Continuation Phase of six months isoniazid and rifampicin (**3SE/6HR**).

- **If** the **hepatitis has not resolved**, SE should be continued for a total of 12 months (**12SE**).

Patients with renal failure

Isoniazid, rifampicin and pyrazinamide are either eliminated almost entirely by biliary excretion or are metabolised into non-toxic compounds. These drugs can therefore be given in normal dosage to patients with renal failure. Patients with severe renal failure should receive pyridoxine with isoniazid in order to prevent peripheral neuropathy.

Streptomycin and ethambutol are excreted by the kidney, so they **should be avoided in patients with renal failure**. However, if facilities are available to monitor renal function closely, streptomycin and ethambutol may be given in *reduced* doses. Thioacetazone is partially excreted in the urine; however, since the margin between a therapeutic dose and a toxic dose is too narrow, patients in renal failure **should not receive thioacetazone.**

The **safest regimen** for patients with renal failure is **2HRZ/6HR**.

Patients with HIV infection

Generally, TB treatment is the same for HIV-infected as for non-HIV-infected TB patients, with the exception that **thioacetazone is contraindicated in those who are HIV-infected**. Streptomycin remains a useful drug in countries able to ensure the use of sterile needles and syringes. Deaths during treatment (partly due to TB itself and partly due to other HIV-related diseases) are more frequent in HIV-infected patients, particularly in the advanced stages of immunodeficiency. If a pregnant woman is known to be HIV-positive, the availability of antiviral treatment to prevent mother-to-child transmission should be considered.

Operational Aspects of Case Management and Monitoring 1.6

The following regional model has been recommended by WHO; however, each Pacific Island country adapts the model to meet its own specific situation and needs. The country-specific adaptation for Niue can be found in Part 2 of this document.

1.6.1 New Sputum Smear-positive Cases (Category I)

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 one more month (to a total of three months). 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, reregistered in 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 nurse or treatment partner observing the daily intake of medications and completing the treatment card.

1.6.2 Retreatment Cases Sputum Smear-positive: Relapse, Failure, Treatment after Interruption (Category II)

Retreatment sputum smear-positive patients are also hospitalised for the Intensive Phase, which, in Category II, is for three months duration, culminating 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 for one more month (to a total of four months). 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 and records the daily intake of the medications.

1.6.3 New Sputum Smear-negative Pulmonary and Extrapulmonary Cases

New sputum smear-negative pulmonary and extrapulmonary patients are treated at home as outpatients, unless they 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 nurse or 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 Section 1.6.6)	Drugs administration		Treatment partner Ambulatory / domiciliary
			Intensive Phase	Continuation Phase	
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) <u>Outpatient:</u> patient living within 1 hour of the health facility <u>Patient at home:</u> patient living more than 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 1 more month	DOT daily (5 months) <u>Outpatient:</u> patient living within 1 hour of the health facility <u>Patient at home:</u> patient living more than 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 <u>Outpatient:</u> patient living within 1 hour of the health facility <u>Treatment at home:</u> patient living more than 1 hour from the health facility		As above

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

1.6.4 Treatment Kit

A treatment kit is ideal in a set-up where there are more than one hospital and more than one health centre. The kit 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 to ensure 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.

Treatment Kit

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

- ✔ medications for Intensive and Continuation Phases
- ✔ treatment card
- ✔ two sputum cups
- ✔ patient's information sheet
- ✔ instruction sheet for treatment partner

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.

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. In such cases, 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. Use of the kit will facilitate proper, easy case management from the first day of treatment until the patient is declared cured by a physician.

1.6.5 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 (a religious or government leader, a teacher or other influential community leader). Treatment partners are assigned to all TB patients, in particular to smear-positive cases. If the treatment partner is a trained community member, he or she 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, a nurse aide or, alternatively, by a trained community volunteer.

In the case of a community volunteer being 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.

1.6.6 Sputum Smear Examinations to Monitor Patient Progress and Cure

Sputum samples should be routinely examined for diagnosis and follow-up using the intervals given in Table 2 (Section 1.6.3) and summarised below.

New cases sputum smear-positive (Category I)	Retreatment cases sputum smear-positive (Category II)
End of the 2 month period of the Intensive Phase.	End of the 3 month period of the Intensive Phase.
At the end of 3 months ONLY if sputum at 2 months was still positive. During the 6th month.	At the end of 4 months ONLY if sputum at 3 months was still positive. During the 8th month.

Results of all sputum examinations should be documented at the lab in the TB Laboratory Register; as well as entered, in a timely manner, in 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 a patient does 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 1.7

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.

1.7.1 Quarterly Report on Tuberculosis Case-Finding

The Quarterly Report on Case-Finding provides a structured means for concise reporting of the numbers of new cases of tuberculosis that are identified each quarter. The report is to be submitted to WHO and SPC 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.

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

Regular monitoring of treatment outcomes is essential in determining the success of DOTS programmes and in identifying alarming trends, such as MDR-TB. Therefore, the outcomes of tuberculosis treatment are reported on a quarterly basis. From the report, 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 and SPC at the beginning of the month directly following the end of the quarter being reported (refer to Section 2.7.2 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 Sections 2.7.1 and 2.7.2.
- It is strongly recommended that a copy of each report be kept in-country for internal monitoring purposes.

Part II

2.0 The Niue DOTS Strategy — A Country-specific Model

2.1 Country Background

"Rock of Polynesia" is the historical name given to Niue, the largest single coral atoll in the Pacific, with a land area of 259 square kilometres. Niue is situated in the centre of a triangle formed by Tonga to the southwest, Samoa to the northwest and the Cook Islands to the east.

The world's smallest self-governing state, Niue has continued to maintain close political ties with New Zealand since gaining free association status in 1974. A Niuean citizen enjoys free citizenship rights in New Zealand, a factor that explains why more than 20,000 Niueans reside in New Zealand today, and only a handful remain in Niue.

According to the 2004 mid-year estimate for Niue, the island population is 1593, which yields a population density of six persons per square kilometre. 33% of the population is below 15 years of age, and 54% is between 15 and 59 years of age. Life expectancy at birth for both males and females is 70.1 years and the infant mortality rate is 2.9%. Approximately 35% of the total population resides in Alofi, the capital village. The balance of the population is dispersed among the remaining 12 villages on the island.

Between the 1991 and 1997 censuses, the net migration rate was −2.4%, and the annual population growth rate was −1.2%, showing a declining trend in population. Just five years later, at the time of the last census in September 2001, with the crude birth rate at 1.9%, the crude death rate at 0.8% and the net migration rate changing to −4.9%, the annual population growth rate decreased even further into negative figures, to an annual rate of −3.8%. This clearly indicates that more people are leaving the country now than ever before.

During the five-year period between 1997 and 2001, Niue reported three cases of tuberculosis. One of these cases was reported in 1998 giving a notification rate, for all types of TB, of 48/100,000. Then, in 1999, when two cases were identified, the notification rate escalated to 111/100,000 for all types of TB and to 56/100,000 for sputum smear-positive cases. While no cases were reported in either 2000 or 2001, two cases were again identified in 2002 causing the notification rates to return to very high levels; with 118/100,000 for all types of TB and 59/100,000 for sputum smear-positive cases. These rates recorded in Niue are much higher than the rates ever recorded by neighbouring countries Tonga and Samoa, which averaged 20/100,000 for the same period.

In January 2004, Cyclone Heta devastated Niue causing massive destruction, including the loss of the island's hospital, Lord Liverpool Hospital. This hospital was the key facility offering health services to all Niueans. In addition to having provided diagnostic and treatment services through both outpatient and inpatient care, the Lord Liverpool Hospital had also housed the National Tuberculosis Programme's DOTS Centre, pharmacy and laboratory for sputum microscopy. At the time of the writing of this manual, thanks to funding from New Zealand, Niue was in the process of rebuilding the hospital with the plan to return to the same level of care that was provided prior to the cyclone. Further, it was projected that the infrastructure of health care services provided through the Ministry of Health would also remain the same. As a result, these DOTS guidelines are being written based on the planned return to the pre-cyclone health services infrastructure and facilities rather than on the current short-term transition period.

Overview of the Niue Tuberculosis Programme 2.2

2.2.1 Niue Adopts the DOTS Strategy

In August 1998, SPC started Phase I of the then newly created SPC Tuberculosis Control Project (now named the SPC Tuberculosis Control Section) by employing a Tuberculosis Specialist to head the project. As part of this first phase, the TB Specialist carried out in-country tuberculosis evaluations in a number of PICTs including Niue's main neighbours. It was clearly demonstrated in the results of these Phase I evaluations that TB was an escalating concern in several countries in the region. This concern coupled with a trend towards increased international mobility led officials to acknowledge the very high risk of intra-regional transmission of the disease.

One year later, in September 1999, in recognition of the growing problem of tuberculosis in the entire region, the WHO Regional Committee for the Western Pacific adopted a resolution that declared a regional "tuberculosis crisis" and 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 the strategic plan was to "adopt DOTS as the primary tuberculosis control strategy in all countries and areas and territories" by 2002. To help meet this target, the SPC TB Specialist, as part of Phase I of the TB Control Project, worked closely with several countries to implement the DOTS strategy.

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

In 2001, Phase II of the SPC Tuberculosis Control Project was implemented, allowing for expansion of the number of countries working directly with SPC on their implementation of the DOTS strategy. Niue was targeted as one of the expansion countries and, following an in-country TB evaluation by the TB Specialist early in 2002, the Niue Ministry of Health agreed in principle to adopt the DOTS strategy in order to control the disease. Once the strategy was adopted and the first DOTS training for health staff in Niue was conducted by the SPC TB Specialist, Niue's National Tuberculosis Programme was under way.

Since that time, Niue has continued to support TB initiatives and to participate in related regional activities such as the Sub Regional Tuberculosis Workshop on Data Management held at SPC from 29 September to 3 October 2003 and the joint venture submission as a recipient of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). In addition, in March 2004, Niue sent two representatives to the 2nd Stop TB Meeting in the Pacific Islands. This regional meeting was again co-sponsored by SPC and WHO and held in Noumea, New Caledonia, to follow up on progress made in DOTS implementation; to review and finalise national action plans through the year 2005; to discuss technical issues; and to strengthen collaboration between countries and international partners in tuberculosis control.

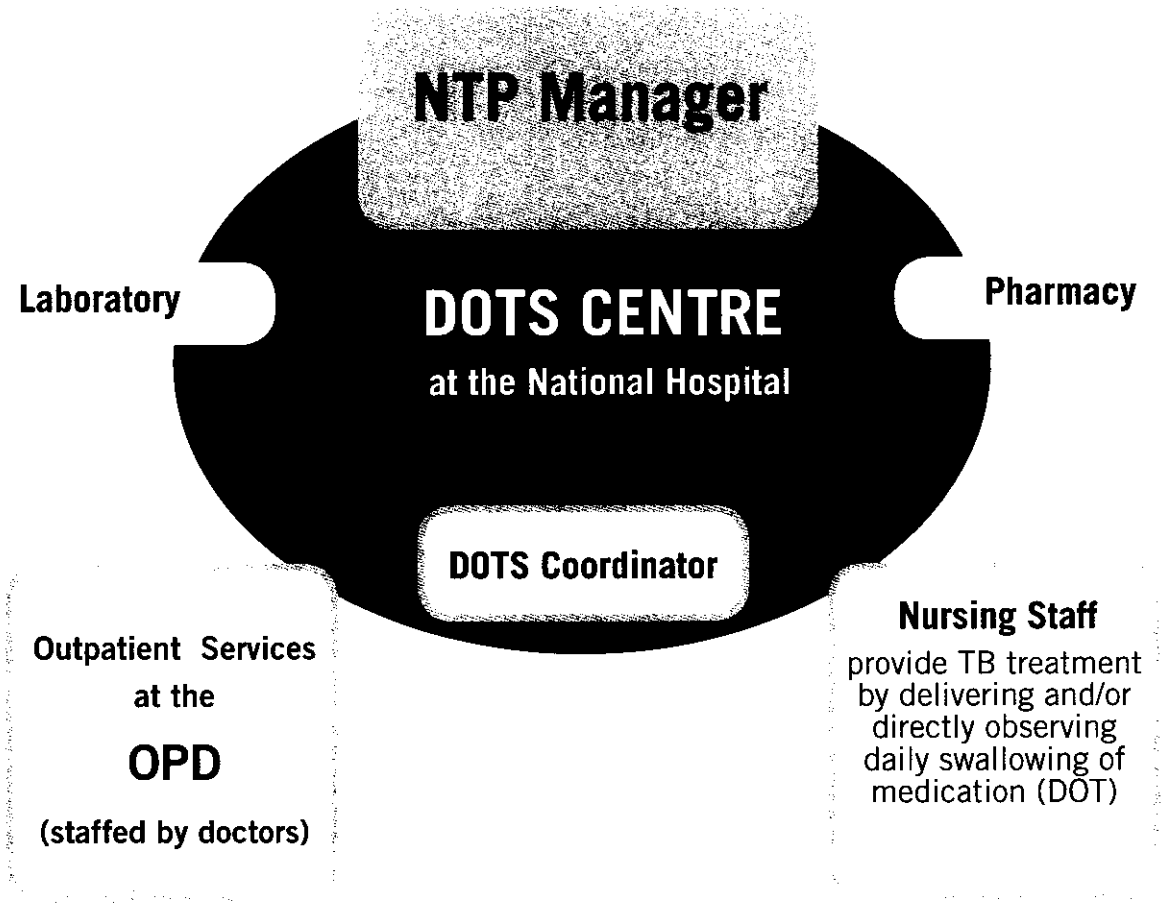
2.2.2 The Niue National Tuberculosis Programme (NTP) Framework

Organisation of the Niue health sector is mandated by government as part of the Ministry of Health. Within the Ministry, the National Tuberculosis Programme is under the Director of Public Health who answers to the Secretary to Government regarding all public health programmes.

In the Niue health sector there is one central unit for management of all clinical functions, the National Hospital. Unlike most other Pacific Island countries, in Niue there are no outer islands. Further, with the small size of the island of Niue, all patients can access the National Hospital directly so there is no need for a network of village-level health facilities. Patients follow a fairly simple process of first being seen through outpatient services at the outpatient department (OPD) and then, if requiring additional testing and/or specialised care, they are referred to inpatient services.

The same referral model is used for tuberculosis services, with the NTP office and DOTS Centre both based at the National Hospital. Patients in need of diagnostic (including laboratory) or treatment services for tuberculosis are first seen at the OPD. Then, the DOTS Coordinator, in conjunction with the NTP Manager, arranges and oversees the necessary diagnostic tests and/or treatment procedures. In this way, programme consistency is more likely since the NTP Manager, together with the DOTS Coordinator, directly administers all tuberculosis services provided through the Niue DOTS Programme. Figure 3 (below) shows a summary of this model.

Figure 3: The Niue National Tuberculosis Programme (NTP) Flow Chart



2.2.2.1 DOTS Programme Staff

In Niue, the DOTS treatment team consists of:

- an NTP Manager
- a DOTS Coordinator
- Doctors
- Nursing Staff

To provide a quality programme, each staff member completes a variety of important tasks, some of which are listed below.

NTP Manager

The **NTP Manager** is responsible for overseeing all policy, administrative, and clinical functions of the NTP, such as to:

- liaise directly with the Secretary to Government on national TB policy and budgetary issues to ensure 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 direct microscopy services at the laboratory
  - regular and uninterrupted supply of anti-TB drugs through the pharmacy
  - ongoing DOT during treatment of all identified tuberculosis patients
  - recording of each patient's progress using the standardised reporting system
- ensure adequate support of health staff, including doctors, on all aspects of the Niue DOTS Programme
- supervise the DOTS Coordinator
- when necessary, in collaboration with the DOTS Coordinator, monitor ongoing TB patient treatment
- ensure proper reporting of all Niue TB cases through the Tuberculosis Register and the Quarterly Reports on Case Findings and on Treatment Outcomes (refer to Annex 6, SPC/ TUB Forms 03, 06 and 07)
- arrange representation of Niue at regional and sub regional tuberculosis related meetings
- implement recommendations made through specialist reports and through regional initiatives regarding the DOTS programme
- through membership on the national Country Coordinating Mechanism (CCM), ensure that, for tuberculosis, the programme, finance and reporting requirements of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) are met within agreed timelines
- perform additional tasks as the need arises

DOTS Coordinator

The **DOTS Coordinator** is a qualified nurse with special training in DOTS programme provision. In conjunction with the NTP Manager, the DOTS Coordinator manages the overall NTP and is responsible for the detailed operation of each component of the programme including care of all patients. To be successful, the DOTS Coordinator is responsible for many tasks, such as to:

- coordinate, with the doctor and laboratory technician, all TB case referrals, including to:
  - verify that collection, transport, and documentation of all sputum samples follows recommended procedures
  - check that sputum is examined within 7 days of collection of the first sample
  - ensure that all smear-positive patients are hospitalised during the Intensive Phase of treatment
- work closely with the NTP Manager, doctors and nursing staff to initiate TB treatment by:
  - tracing each diagnosed TB patient, assigning each a unique TB number and then registering each patient in the Tuberculosis Register
  - creating a master Treatment Card which includes patient details, exact dosage of medication and the dates for each follow-up sputum examination during the course of treatment:

DOTS Coordinator (cont.)

- for each Category I or II patient as soon as they are admitted to the hospital for inpatient care and
- for each Category III patient as soon as they are diagnosed

- training ward and community nurses on supervision and recording of TB treatment
- when necessary, assisting nursing staff to organise hospital admission, including transportation if required
- for patients who are discharged from hospital to finish their treatment from home:

  - preparing a duplicate copy of the Treatment Card, for use with any patient who will receive their daily medications at home (The original master copy of the Treatment Card must remain at the DOTS Centre at all times. It should never be carried to the patient's home.)
  - preparing and storing a Treatment Kit (see Section 1.6.4) for each patient to ensure that all medications and treatment supplies are available for the duration of treatment
  - supervising, if needed, the ongoing treatment for patients to include: dispensing of TB medications, direct supervision and recording of each treatment, coordination of follow-up sputum examinations and referral to the doctor for an end of treatment clinical exam

- in collaboration with the NTP Manager, determine required TB drug supply and work with pharmacy staff to ensure that adequate stocks of anti-TB medication and laboratory materials, including reagents, are always available

- regularly communicate with health staff to:
  - encourage increased case detection
  - ensure sputum follow-up exams are conducted according to schedule
  - receive monthly updates of Treatment Card data for any patients being monitored from home
  - follow up on referrals and/or transfers
  - discuss other related issues in order to ensure an efficient NTP

- use the standardised reporting system to record patient progress by:
  - on a monthly basis, updating master Treatment Cards and the Tuberculosis Register
  - regularly (at least quarterly) cross-referencing data in the TB Laboratory Register (kept at the laboratory) with data in the Tuberculosis Register (kept at the DOTS Centre), to ensure that:
    - it is consistent
    - each suspect submits three sputum specimens for diagnosis and two for each follow-up, and
    - all sputum-positive cases are registered and receiving appropriate treatment
  - consolidating Tuberculosis Register and TB Laboratory Register data so as to produce a data summary and prepare the official quarterly reports for submission to the NTP Manager, SPC and WHO

- provide and/or organise ongoing training and supervision of Ministry of Health staff and any volunteers who are involved in the DOTS programme

- conduct regular supervisory visits to the hospital and to each patient's home in order to monitor efficiency of the DOTS programme and to verify ongoing direct observation of treatment for each patient (see Table 4 in Section 2.5)

- implement tuberculosis control measures in the community to include:
  - contact tracing to identify potential tuberculosis suspects
  - use of prophylactic TB treatment when warranted (see Section 2.2.3)
  - preparation and regular dissemination of educational and community awareness materials and activities

- perform additional tasks as the need arises

Doctors

In Niue, **Doctors** work directly with TB suspects and diagnosed TB patients at both the OPD and inpatient sections of the hospital. Whenever possible, they collaborate closely with the NTP Manager and DOTS Coordinator to provide TB patients with high-quality care based on DOTS programme procedures.

For TB patients, the doctors:

- perform clinical examination of TB suspects
- liaise with the DOTS Coordinator for sputum specimen collection
- confirm tuberculosis diagnosis based on the flow chart shown in Figure 2
- expedite case referral when necessary
- maintain regular communication with the laboratory technician and the DOTS Coordinator regarding diagnostic and follow-up sputum exams/results
- collaborate with the DOTS Coordinator for initiation of TB treatment using the necessary DOTS process
- develop an individual treatment plan for each confirmed TB patient
- admit to hospital
  - all sputum smear-positive patients for inpatient treatment during the entire Intensive Phase
  - severely ill sputum smear-negative and extrapulmonary TB patients for inpatient treatment until well enough to continue treatment as outpatients
- decide when hospitalised patients can return home to continue directly observed treatment as outpatients
- work closely with the DOTS Coordinator throughout the patient's treatment to
  - ensure the hospitalisation period goes smoothly
  - monitor the full course of TB treatment
  - organise appropriate contact tracing in sputum-positive households
- convene regular meetings to discuss/review diagnosis of smear-negative and extrapulmonary tuberculosis cases
- perform additional tasks as the need arises

Nursing Staff

As an integral part of the treatment team, Nursing Staff, who work directly with patients at the outpatient and inpatient sections of the hospital as well as in patient's homes, receive specific training in DOTS. This ensures that nurses can be involved, whenever necessary, in every aspect of TB patient identification, diagnosis and care.

Nursing staff use their skills to support the DOTS programme by being responsible for tasks such as to:

- identify and refer TB suspects for diagnosis (refer to Section 2.3.1)
- when necessary, collect, label, register and transfer the correct number of sputum specimens for laboratory examination (3 specimens for diagnosis or 2 specimens for each follow-up), using correct handling procedures so that quality sputum arrives at the laboratory NO LATER THAN 7 DAYS AFTER COLLECTION OF THE FIRST SAMPLE (see Section 2.3.2)
- work with the DOTS Coordinator to arrange hospital admission and, if necessary, transportation for patients to start the Intensive Phase of treatment
- during Intensive Phase hospitalisation of TB patients, nursing staff:
  - distribute daily medications
  - directly observe each treatment (DOT), 7/7 days per week
  - complete the patient's Treatment Card on a daily basis
  - collect the two end of phase sputum samples (Overnight and SPOT) for follow-up exam and send it to the laboratory
  - arrange any additional medical procedures as ordered by the doctor, NTP Manager or DOTS Coordinator

- for patients who have been discharged from hospital and approved to finish their treatment from home, nursing staff, in conjunction with the DOTS Coordinator:
  - supervise the use of the patient's Treatment Kit, including distribution of medications
  - directly observe (DOT) that patients swallow their medication every day, 7 days per week
  - complete the patient's Treatment Card for each treatment directly observed
  - monitor the patient's treatment schedule via the Treatment Card and ensure that the patient submits two sputum samples (Overnight and SPOT) for each required follow-up examination
  - regularly (on a monthly basis) report treatment to the DOTS Coordinator for updating of the master Treatment Card
  - refer the patient to the doctor for an end of treatment clinical exam
- communicate regularly with the DOTS Coordinator to ensure quality case management
- with the DOTS Coordinator, conduct community awareness activities to increase case detection
- perform additional tasks as the need arises

2.2.2.2 DOTS Programme Facilities (refer to Figure 3)

In Niue, the **DOTS Centre** is located at the National Hospital in the capital village of Alofi. Both the NTP Manager and the DOTS Coordinator are based at the DOTS Centre which is designated as the central tuberculosis management, referral and reporting unit.

All administrative and managerial functions of the NTP, as well as direct treatment for patients, during both inpatient and outpatient care, are coordinated through the DOTS Centre, where the Tuberculosis Register is kept. As well, both laboratory and pharmacy functions are provided through the DOTS Centre.

The TB Section of the **National Laboratory**, where sputum examination, documentation and, at times, collection takes place and the **pharmacy**, where anti-TB medication is stored and distributed, operate as fundamental components of the NTP. To assist the DOTS programme, laboratory technicians based at the laboratory are specifically trained and supervised to be responsible for:

- sputum examinations using AFB microscopy
- related recording in the TB Laboratory Register, which is kept at the lab
- reporting of results to referring doctors and the DOTS Coordinator
- ongoing quality assurance of the microscopy services (see Section 2.8)

Since there is only one key health facility in Niue, that being the National Hospital, community health staff, doctors and nurses making village rounds have a critical role in the identification of tuberculosis suspects and in the follow-up of any patients who may be defaulting on their treatment. Ongoing community awareness and education as well as observation for symptoms of tuberculosis contribute towards increased case detection and treatment success rates. All levels of clinical and public health staff therefore work together to identify TB suspects and refer them for assessment, diagnosis and treatment.

2.2.3 Complementary Tuberculosis Control Measures

Several preventative measures are recommended to be followed in Niue in order to control the spread of tuberculosis within the country. These measures include:

➢ **Early immunisation**

It is compulsory for all infants to be vaccinated against tuberculosis (using the BCG) at birth. Children with HIV-positive mothers should also be vaccinated, if AIDS in the child has been ruled out.

➢ **Contact tracing and prophylactic treatment**

Once a patient is diagnosed as smear-positive, and is under treatment, staff from the DOTS Centre should organise household contact tracing 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 for appropriate examination. Further, as recommended by WHO[3], when active TB has been ruled out, any well child under the age of five years living in a household where a smear-positive case has been identified should be given a prophylactic treatment of daily doses of isoniazid for at least 6 months, with regular follow-up. This is especially important for breastfed children whose mothers are diagnosed with sputum smear-positive tuberculosis.

➢ **Early identification through community education and awareness activities**

Based on advice from the DOTS Centre, ongoing community education initiatives should be conducted in order to increase awareness of tuberculosis and reduce the level of stigma surrounding the disease. The goal of this measure is to increase overall case detection, and early identification and treatment of each case.

Operational Aspects of Case Detection, Diagnosis and Treatment 2.3

2.3.1. 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 people with suspect symptoms to the nearest health facility. 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
- blood-stained sputum
- close contact with a known TB patient identified recently

Any patient presenting as a tuberculosis suspect should be referred directly and without delay for screening, assessment and diagnostic procedures by one of the doctors at:

➢ **the National Hospital OPD**

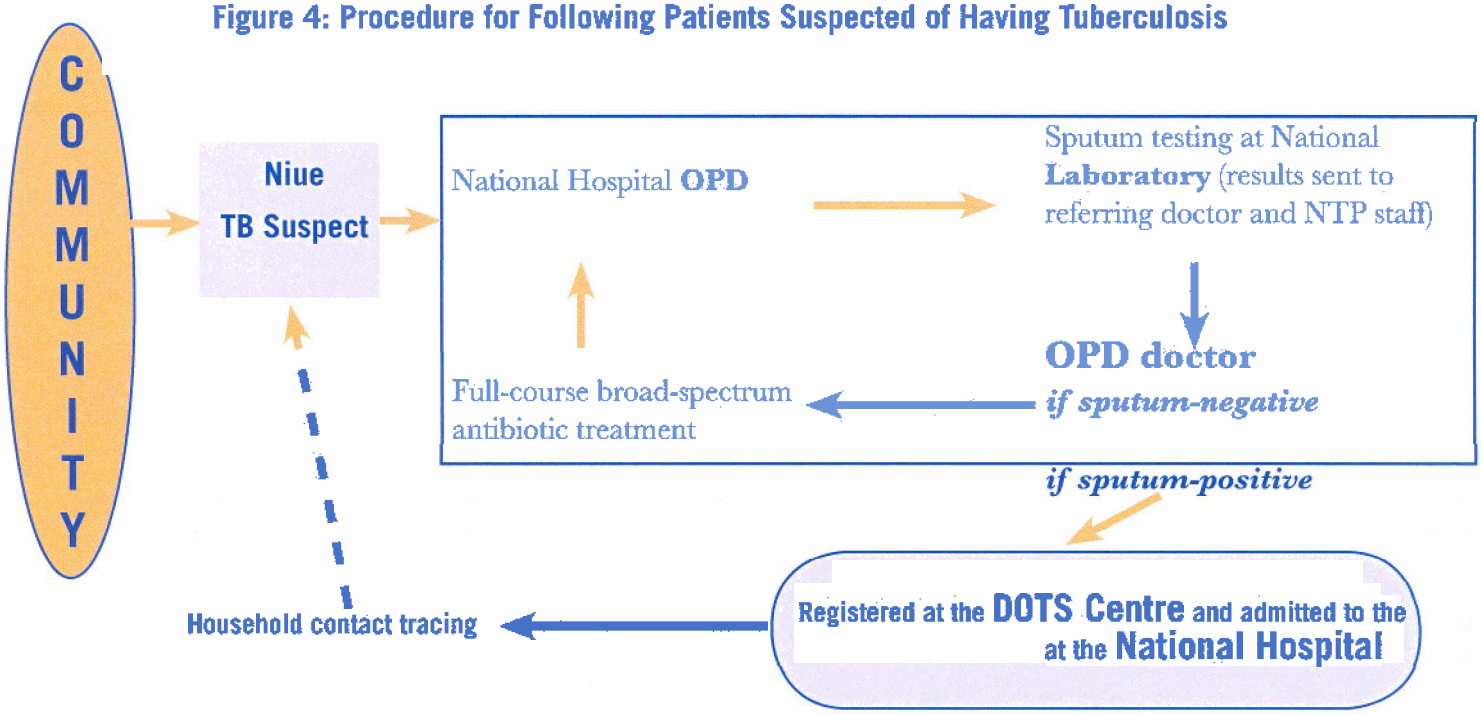
If suspected cases are not reliable or cannot make the trip to the doctor, the DOTS Coordinator or a nurse trained in sputum collection should collect the three sputum specimens required (refer to Section 2.3.2) and ensure that they reach the National Laboratory **NO LATER THAN 7 DAYS AFTER COLLECTION OF THE FIRST SAMPLE.**

To meet this timeline, sputum should be collected as close to the date of delivery as possible.

Figure 4 summarises the Niue procedure for following patients suspected of having tuberculosis.

[3] *WHO 2003. Treatment of Tuberculosis: Guidelines for National Programmes. 3rd edn. Geneva: WHO. 108 p. (document WHO/CDS/TB 2003.313)*

Figure 4: Procedure for Following Patients Suspected of Having Tuberculosis



2.3.2. Diagnosis

2.3.2.1 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**
  (pulmonary tuberculosis, 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, for diagnostic detail.)

- **Extrapulmonary forms**
  (extrapulmonary tuberculosis, EPTB)
  - severe or
  - less severe

Extrapulmonary tuberculosis affects parts of the body other than the lungs, including the pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and/or bones, meninges, kidneys etc.

- **Retreatment**
  (see definitions in Section 1.4.2)
  - due to relapse
  - due to interruption of initial treatment (default)
  - due to failure of initial treatment

Diagnosis of each class of tuberculosis is confirmed after clinical examination and one or more of the following additional tests.

✔ **Sputum bacteriological test** — This test is conducted by medical staff trained in DOTS procedures. Three sputum samples are collected at the OPD, the National Laboratory or, if required, at the patient's home. The three samples include:

1 SPOT — sample taken on the spot at the health facility, while under supervision

2 Overnight — early morning sample self-collected at home the next morning, during coughing efforts so as to avoid collecting saliva

3 SPOT — sample taken at the health facility the same day the patient collects and drops off their overnight sample

Since tuberculosis is a contagious disease, extra caution must be used when collecting the sputum sample. The next procedures should be carefully followed during collection:

- Show the patient how to give a good sputum sample by taking a deep breath and coughing hard from deep in the lungs.
- If at all possible, have the patient give the sample while outdoors. If this is not possible, be sure that the patient is in an open, well ventilated room.
- Stand behind or face away from the patient during their coughing efforts.
- If the sputum container becomes contaminated on the outside, safely discard it and start again.
- Tightly close the lid of the container as soon as the procedure is completed.
- Wash your hands well with soap and water and/ or if possible, rinse with alcohol.

Sputum samples are carefully labelled and registered at the time of collection at the hospital or alternative collection site. They are then delivered as soon as possible, so as to reach the National Laboratory **within 7 days of collection of the first sample.** A completed Laboratory Sputum Form for TB Investigation accompanies each patient's sputum samples. On arrival at the National Laboratory, each sample is recorded in the DOTS TB Laboratory Register before being promptly evaluated by the laboratory technician (see Sections 2.3.2.3 and 2.6 for detail).

✔ **X-rays** — Chest X-rays are ordered for pulmonary tuberculosis suspects when additional information is needed to confirm a diagnosis. For extrapulmonary tuberculosis suspects, additional examinations, which may include X-rays, are conducted based on a recommendation from the doctor regarding which organ appears to be involved.

✔ **Blood tests** If additional diagnostic information is necessary, relevant blood tests may be recommended by the doctor.

2.3.2.2 Treatment Categories

Interpretation of results from the 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 described below.

❍ **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 (default) 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.

2.3.2.3 Summary of Specific TB Screening and Diagnostic Procedures Used in Niue

Careful completion of the following stages of the diagnostic process ensures thorough examination leading to accurate diagnosis:

TB Screening and Diagnostic Procedures in Niue	
STEP 1 Visit to health facility for screening and evaluation	• Sick patients visit the National Hospital OPD, where they have: ➢ an initial consultation with the doctor • Patients identified by the doctor as TB suspects (see Sections 1.3.2 and 2.3.1) then undergo: ➢ collection of 3 sputum samples ➢ if necessary, other diagnostic tests including relevant X-rays (as shown in Figure 2) and/or blood tests **(NOTE: To misdiagnose a patient, placing them in the wrong category, is both a waste of resources and a detriment to the credibility of the programme.)**
STEP 2: Sputum sample testing using Acid-Fast Bacilli (AFB) Microscopy and laboratory registration	• The designated nursing staff or a laboratory technician, trained in the DOTS strategy and supervised by the DOTS Coordinator, collects the **three** sputum samples as: ➢ **SPOT** ➢ **Overnight** ➢ **SPOT** (see Sections 1.3.3.1 and 2.3.2.1 for details) • The samples are: ➢ carefully labelled, on the side of the container **not** the lid, to show the sequence of collection (i.e. #1 SPOT, #2 Overnight, #3 SPOT) ➢ registered on a Laboratory Sputum Form for TB Investigation ➢ then kept at cool temperatures until delivered to the laboratory

TB Screening and Diagnostic Procedures in Niue (continued)

STEP 2 continued:

- **Within 7 days of collection of the FIRST sample**, the nursing staff delivers the samples, with a completed Laboratory Sputum Form for TB Investigation for each patient, to the National Laboratory at the National Hospital.

- On arrival, the laboratory technician:

  - checks the sample's labels

    and

  - the completed Laboratory Sputum Form for TB Investigation for each patient

- The samples are then:

  - recorded in the DOTS TB Laboratory Register

    and

  - **promptly** examined by the laboratory technician

- Results are **immediately** entered in the DOTS TB Laboratory Register

- The laboratory technician then reports the results to the:

  - referring doctor

    and

  - the NTP Manager/DOTS Coordinator so that prompt treatment can be started

TB Screening and Diagnostic Procedures in Niue (continued)

STEP 3:

Diagnostic decision and pre-treatment management

For all tuberculosis cases, a doctor, using the procedure in Figure 2, makes the final diagnosis and classifies TB patients as:

- **Pulmonary smear-positive** (new or retreatment)
- **Pulmonary smear-negative** (mildly or severely ill)
- **Extrapulmonary** (mildly or severely ill)

Based on the definitions in Section 1.4.1:

- Patients confirmed as **smear-positive** cases are:
  - immediately traced by the DOTS Coordinator and
  - referred to the National Hospital to be admitted for supervised treatment (refer to Sections 2.3.3.1 and 2.3.3.2 for details)

- Patients with **smear-negative** results:
  - can be given a full course of broad-spectrum antibiotics

    ! IMPORTANT ! 3 sputum specimens MUST be examined at the National Laboratory BEFORE any course of antibiotics is started.

  - if there is no improvement after the antibiotic treatment, a second set of 3 sputum samples is examined (repeat step 2 on previous page)
  - *if results are still negative and the patient is still sick, he/she should be further evaluated* at the hospital

- Patients confirmed with **pulmonary smear-negative** or **extrapulmonary TB** who are **severely ill** are:
  - immediately traced by the DOTS Coordinator **and**
  - referred to the National Hospital to be admitted for supervised treatment, until released by the doctor (refer to Section 2.3.3.1 for details)

- Patients confirmed with **pulmonary smear-negative** or **extrapulmonary TB** who are **mildly ill** can be:
  - treated as outpatients through the DOTS Centre, under direct supervision of the DOTS Coordinator or a qualified nurse specially trained in DOTS procedures (refer to Section 2.3.3.3 for details)

2.3.3. Treatment

Once screening and assessment are completed and a diagnosis of tuberculosis is confirmed, the:

- doctor
  - **assigns each patient to a treatment category** (I, II, or III as defined in Section 2.3.2.2) and
  - **develops an individual treatment plan** for each tuberculosis patient;

and the

- DOTS Coordinator:
  - **assigns each patient a unique TB number;** and
  - **registers the patient in the Tuberculosis Register** which is kept at the DOTS Centre.

In all three treatment categories:

- patients follow a strict treatment regimen, which includes two phases:
  - firstly, the **Intensive Phase** and
  - secondly, the longer **Continuation Phase**
- during both phases, patients must take daily medications

> **In Niue, the drugs and treatment doses prescribed as part of the treatment plan are those recommended by WHO and presented in Section 1.5 of Part 1 of this manual.**

Following are the detailed treatment procedures to use with each of the three treatment categories, during both Intensive and Continuation Phases.

2.3.3.1 Treatment Plan for all new Pulmonary Smear-Positive Cases: as well as new, Severely Ill, Pulmonary Smear-Negative and Extrapulmonary Cases. (Category I patients as defined in Section 2.3.2.2)

INTENSIVE PHASE for CATEGORY I PATIENTS

(all new pulmonary smear-positive and severely ill pulmonary smear negative or extrapulmonary cases)

Length of Intensive Phase

- **2 months** (may be extended to 3 months based on first sputum follow-up results)

Drug treatment

- **Daily** doses of four medications — **HRZE** — for the entire **Intensive Phase**

When and where treated

- It is compulsory for all **smear-positive (S^+) patients** in Niue, to be **hospitalised** in the Medical Ward at the National Hospital **during the entire Intensive Phase (2–3 months).**

  NOTE: *Only under exceptional circumstances,* ***when approved by the treating doctor in consultation with NTP staff,*** *can some patients be permitted to take the medications of the Intensive Phase as an outpatient or from home.*

- **Severely ill** smear-negative (S^-) or extrapulmonary (EPTB) patients are also **hospitalised** in the Medical Ward at the National Hospital **until released by the treating doctor.**

  - If approved for discharge, patients continue daily supervised Intensive Phase treatment from home as **outpatients.**

Hospital admission procedure

- When the patient arrives at hospital, the **DOTS Coordinator:**

  - prepares a master Treatment Card to be kept at the DOTS Centre
  - delivers a duplicate copy of it to the nurse in charge of the Medical Ward at the hospital

INTENSIVE PHASE for CATEGORY I PATIENTS (continued)

Treatment supervision

- The **nurse** in the ward (during hospitalisation), or the **DOTS Coordinator** (for S^- or EPTB patients, when approved for treatment from home):
  - observes daily swallowing of medications **(7 days per week)**
  - records each treatment on the Treatment Card
  - arranges any further testing required to ensure high-quality care

Sputum follow-up exams

- After two months of treatment, two sputum samples – an Overnight and a SPOT – are sent for **follow-up bacteriological examination**.
  - **If results are negative**, the patient is discharged to start the Continuation Phase of treatment as an outpatient.
  - **If results are positive**, the patient remains at hospital for an additional month of Intensive Phase treatment as an inpatient (to a total of three months).
    - At the end of this third month, another sputum follow-up (Overnight and SPOT) exam is done.
      - Regardless of the results of this exam, the patient is discharged to start the Continuation Phase of treatment.

Hospital discharge procedures

- When the patient is discharged from hospital inpatient care to start the Continuation Phase of treatment, the **nurse** in charge of the Medical Ward notifies the **DOTS Coordinator** who:
  - makes a duplicate copy of the patient's **Treatment Card** for use during daily outpatient treatment (the master copy always remains at the DOTS Centre)
  - verifies that the patient's **Treatment Kit** will cover the duration of treatment (see Section 1.6.4) Each kit is then stored at the hospital for use during the remaining treatment
  - if Continuation Phase treatment will be supervised by a nurse other than the DOTS Coordinator, the DOTS Coordinator orients and supervises the assigned nurse on use of the Treatment Card and Treatment Kit

CONTINUATION PHASE for CATEGORY I PATIENTS

Length of Continuation Phase

- **4 months**

Drug treatment

- **Daily** doses reduced to two medications — **HR** — for the **entire Continuation Phase**

  (all necessary medication is included in the **Treatment Kit**, stored by the DOTS Coordinator at the DOTS Centre/hospital)

When and where treated

- During the Continuation Phase, **all Category I patients**, who have been discharged from hospital by the doctor, can be treated from home as **outpatients**
- Supervision of daily treatment takes place through the DOTS Centre located at the National Hospital
- Patients receive their medication daily:
  - at the DOTS Centre (for patients who can make the daily trip), or
  - at home (for remaining patients)

Treatment supervision

Patients MUST continue to take their medication every day, being supervised for the entire phase as follows:

- The **DOTS Coordinator** or the approved **nurse** meets with the patient to develop a schedule and location for the daily patient visits, preferably to cover **all 7 days of the week**.
- Based on the agreed schedule, each day either the **DOTS Coordinator** or the designated **nurse**:
  - **dispenses** the medication from the Treatment Kit to the patient
  - **supervises** the patient swallowing their medication
  - **completes** the Treatment Card (a copy of which has been included in the Treatment Kit)

CONTINUATION PHASE for CATEGORY I PATIENTS (continued)

Sputum follow-up exams

- During the fifth month of treatment, another bacteriological follow-up exam is carried out on two sputum samples (Overnight and SPOT)

> ***NOTE: If the results of this exam are still positive, Category I treatment is stopped and the patient is classified as treatment failure. The patient then IMMEDIATELY:***
>
> - ***is given a new TB number***
> - ***is reregistered in the TB Register under Category II***
> - ***starts retreatment following the Category II regimen***

- At the end of the 6 month treatment, if the patient has not already received two consecutive negative sputum results, a final sputum follow-up test (Overnight and SPOT) is completed.

End of treatment procedures

- On completion of treatment and based on sputum exam results, the patient is:
  - assigned a treatment outcome (refer to Section 1.4.3) which is documented in the Tuberculosis Register
    - Patients diagnosed as smear-positive who became smear-negative at, or one month before, the completion of treatment and who also tested smear-negative on at least one previous occasion, are documented as **cured.**
    - Patients diagnosed as smear-positive who have completed all treatment but without the smear results at the end of treatment as proof of cure are documented as **treatment completed.**
    - Patients diagnosed as smear-negative who have completed all treatment are document as **treatment completed.**
  - discharged from care

2.3.3.2 Treatment Plan for all Smear-Positive Retreatment Cases; due to Relapse, Treatment Failure or Interrupted Treatment/Default (Category II patients as defined in Section 2.3.2.2)

INTENSIVE PHASE for CATEGORY II PATIENTS
(pulmonary smear-positive retreatment cases due to relapse, treatment failure or interruption/default)

Treatment for Category II patients follows the same format as for Category I except for duration and drug regimen. In summary, treatment includes:

Length of Intensive Phase

- **3 months** (may be extended to 4 months based on first sputum follow-up results)

Drug treatment

- **Daily** doses of:
  - five medications — **HRZES** — for **two months** followed by
  - four medications — **HRZE** — for **one month**

When and where treated

- Compulsory **hospitalisation** as an inpatient in the Medical Ward at the National Hospital **for the entire 3-4 month Intensive Phase**

> ***NOTE:*** *Only under exceptional circumstances,* ***when approved by the treating doctor in consultation with NTP staff****, can some patients be permitted to take the medications of the Intensive Phase as an outpatient or from home.*

Hospital admission procedure

- When the patient arrives at hospital, the **DOTS Coordinator**:
  - prepares a master Treatment Card to be kept at the DOTS Centre
  - delivers a duplicate copy of it to the nurse in charge of the Medical Ward at the hospital

INTENSIVE PHASE for CATEGORY II PATIENTS (continued)

Treatment supervision

- The **nurse** in the ward:
  - observes daily swallowing of medications **(7 days per week)**
  - records each treatment on the Treatment Card
  - arranges any further testing required to ensure high-quality care

Sputum follow-up exams

- **Follow-up bacteriological examination** of two sputum samples (Overnight and SPOT), after three months of treatment
  - **If results are negative**, the patient starts the Continuation Phase as an outpatient
  - **If results are positive**, Intensive Phase treatment and hospitalisation are extended for one more month (to a total of four months), followed by an additional sputum follow-up exam

Hospital discharge procedures

- At the end of inpatient care, the **nurse** from the ward must notify the **DOTS Coordinator** so that formal arrangements can be made for the remaining treatment.
- When the patient is discharged, their master Treatment Card remains at the DOTS Centre and the **DOTS Coordinator**:
  - makes a duplicate copy of the **Treatment Card** for use during daily outpatient treatment
  - verifies that the **Treatment Kit** will cover the duration of treatment (see Section 1.6.4) Each kit must be stored at the hospital for use during the remaining treatment.
  - if Continuation Phase treatment will be supervised by a nurse other than the DOTS Coordinator, the DOTS Coordinator orients and supervises the assigned nurse on use of the Treatment Card and Treatment Kit

CONTINUATION PHASE for CATEGORY II PATIENTS

Length of Continuation Phase

- **5 months**

Drug treatment

- **Daily** doses reduced to three medications — **HRE** — for the **entire Continuation Phase**

  (all necessary medication is included in the **Treatment Kit,** stored by the DOTS Coordinator at the DOTS Centre/hospital)

When and where treated

- During the Continuation Phase, once discharged from hospital by the doctor, **all Category II patients** can be treated from home as **outpatients**.
- Supervision of treatment takes place from the DOTS Centre located at the National Hospital under supervision of the **DOTS Coordinator**.
- Patients receive their medication daily:
  - at the DOTS Centre (for patients who can make the daily trip), or
  - at home (for remaining patients)

Treatment supervision

- As with Category I patients, Category II patients MUST continue to take their medications every day **(7 days per week)**, under direct supervision of the **DOTS Coordinator** or a designated nurse.
- The **coordinator** or **nurse**:
  - **develops** their schedule of daily patient visits
  - **dispenses** the medication from the Treatment Kit to the patient
  - **supervises** the patient swallowing their medication
  - **completes** the Treatment Card (a copy of which has been included in the Treatment Kit)

CONTINUATION PHASE for CATEGORY II PATIENTS (continued)

Sputum follow-up exams

- During the seventh month of treatment, a bacteriological follow-up exam of two sputum samples (Overnight and SPOT) is carried out.
- A final sputum follow-up test on two samples (Overnight and SPOT) is completed at the end of the 8 month treatment for patients not yet having two consecutive negative results.

End of treatment procedures

- On completion of treatment and based on sputum exam results, the patient is:
  - assigned a treatment outcome (refer to Section 1.4.3) which is documented in the Tuberculosis Register
    - Patients diagnosed as smear-positive who became smear-negative at, or one month before, the completion of treatment and who also tested smear-negative on at least one previous occasion, are documented as **cured**.
    - Patients diagnosed as smear-positive who have completed all treatment but without the smear results at the end of treatment as proof of cure are documented as **treatment completed.**
  - discharged from care

2.3.3.3 Treatment Plan for new Pulmonary Smear-Negative and Extrapulmonary Cases who are Mildly Ill

(Category III patients as defined in Section 2.3.2.2)

INTENSIVE and CONTINUATION PHASES for CATEGORY III PATIENTS
(mildly ill new pulmonary smear-negative or extrapulmonary cases)

Treatment duration and drugs

- **Daily** doses of three medications — **HRZ** — during the **2 month Intensive Phase**

followed by

- **Daily** doses of two medications — **HR** — during the **4 month Continuation Phase**

When and where treated

- After diagnosis, which occurs at the National Hospital:
  - the **DOTS Coordinator** arranges treatment with the referring doctor and prepares:
    - an individualised **Treatment Card** for the patient
    - a personalised **Treatment Kit**. This kit must be stored at the DOTS Centre/ OPD where treatment is monitored
  - the **patient**:
    - returns home
    - receives medication under direct supervision of the **DOTS Coordinator** or an assigned **nurse**

! REMINDER !: *Medication must be taken* **DAILY** *during the entire six-month treatment.*

INTENSIVE and CONTINUATION PHASES for CATEGORY III PATIENTS (continued)

Treatment supervision

If facilities and resources permit, it is very strongly recommended that the DOTS Coordinator, or an assigned nurse:

- **dispenses** the medication from the Treatment Kit to the patient **all 7 days of the week**
- **supervises** the patient swallowing their medication
- **completes** the Treatment Card throughout the entire 6 month treatment

If case loads are extremely high, the following alternative could be followed during a limited period when there is a shortage of staff:

- The DOTS Coordinator or assigned nurse, supervises the patient swallowing their daily medication **at least 5 days per week**.
- On the 5th day, the patient is given medication to cover the 2 remaining days of the weekly treatment.
- The patient self administers their treatment on these 2 remaining days.
- It is very important that during the next supervised visit, the patient report to the DOTS Coordinator or the assigned nurse whether or not they swallowed all medication for the 2 self-administered days so that the Treatment Card can be correctly completed.

> ***NOTE: If this alternative is necessary, the coordinator or nurse should identify and train additional community volunteers as treatment partners (see Section 1.6.5) to help provide the strongly recommended daily observed treatment.***

Sputum follow-up exams

- Sputum follow-up exams are not required for Category III patients.

End of treatment procedures

- On completion of the **6 month treatment**, the patient is:
  - assigned a treatment outcome (refer to Section 1.4.3) which is documented in the Tuberculosis Register
  - discharged from care

2.4 Anti-TB Drug Availability

The NTP Manager in conjunction with the DOTS Coordinator ensures that all drugs required for TB treatment of patients in each of the diagnostic categories are available through the central pharmacy located at the National Hospital. **The pharmacy should maintain adequate stock so as to be able to easily dispense necessary supplies to the DOTS Centre or the Medical Ward at the hospital on an as-needed basis.** It is the responsibility of the DOTS Coordinator, in conjunction with the pharmacist, to monitor stock levels and use-by dates and to place orders in a timely manner so that adequate stock is maintained. In addition, laboratory stock, including reagents, must also be monitored to ensure adequate supply.

In Niue, all tuberculosis patients start their treatment by being registered through the DOTS Centre. After any inpatient care, when a patient is discharged from the ward at the hospital to continue their treatment from home, he or she is allocated a Treatment Kit containing all necessary medications for the entire duration of the treatment (refer to Section 1.6.4). This Treatment Kit is then held at the DOTS Centre/ National Hospital, where the patient is treated, so that dispensing of medications can be directly supervised and treatment progress monitored.

2.5 Case Management, Monitoring and Assessment

Niue is committed to the overall implementation of the DOTS Strategy which, as noted in Section 1.2.1.3, consists of five key elements. One of these elements requires DOTS programmes to use a "standardised recording and reporting system to monitor patient progress". Such a system has been implemented in the country'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 the hospital's OPD for evaluation of their condition. During this assessment, diagnostic tests, including microscopic examination of sputum samples, are conducted. Strict collection and delivery 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 Section 2.6 and Figure 5.)

- All sputum smear-positive results are immediately reported by the laboratory technician at the National Laboratory to both:
  - the referring doctor **and**
  - the DOTS Coordinator

- 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 TB 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 be easily verified.

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

- For Category I and II patients, the Intensive Phase of treatment takes place as inpatients at the National Hospital under direct daily supervision by a nurse in the Medical Ward.

- Once discharged from inpatient care, the patient continues to be seen by the DOTS Coordinator, or a designated nurse, seven days per week (at least five days per week for Category III patients) for the duration of treatment.

- 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 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 schedule in Table 3.

Table 3: Details, including Timetable, for Monitoring Patient Treatment in Niue

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 reclassified as treatment failure, reregistered 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 have not yet had two consecutive sputum smear-negative results.	At end of 6-month treatment	At end of 8-month treatment	Not required

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

- Both patient treatment and DOTS programme efficiency are also monitored by NTP and/or Ministry of Health staff during supervisory visits. This ensures that treatment is supervised, Treatment Cards are up to date and the overall DOTS operation is running smoothly. Supervisory/monitoring visits take place as outlined on the next page in Table 4.

- If a patient interrupts treatment to move to another location, a completed Tuberculosis Referral/Transfer form, including detailed treatment status, is sent to the new treating facility.

- When a patient completes treatment, the treatment outcome is documented, verified by the NTP Manager/DOTS Coordinator and recorded, along with outcomes for the remaining patients in the cohort, on the formal quarterly report. This report is then 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.

Table 4: Timetable and Purpose of Monitoring and Supervisory Visits

LOCATION	FREQUENCY AND PURPOSE OF SUPERVISORY CONTACTS
Niue (all villages)	➢ The **DOTS Coordinator** should make weekly monitoring and supervisory visits to: ▪ the Medical Ward at the National Hospital ▪ the laboratory ▪ the central pharmacy ▪ patient's homes (for patients taking or receiving treatment in their homes) ➢ During these regular visits, the **DOTS Coordinator** meets with clinical doctors, health staff, laboratory and pharmacy staff and, when necessary, sees individual patients in order to: **With patients:** ▪ share necessary information and offer support ▪ check that daily treatment doses are taken and recorded ▪ evaluate progress ▪ monitor any problems ▪ follow up on any defaulters or patients failing their treatment **With doctors, health staff, laboratory and/or pharmacy staff:** ▪ review DOTS programme procedures used for case detection, screening, diagnosis and treatment in order to confirm programme compliance ▪ collect necessary data ▪ ensure that the overall DOTS operation is running smoothly ▪ monitor any problems ▪ update Treatment Cards ▪ monitor and cross-reference the TB Laboratory Register with the Tuberculosis Register ▪ deliver supplies ▪ ensure adequate stock of anti-TB drugs ▪ as needed, provide ongoing training and supervision to Ministry of Health staff involved in the DOTS programme ➢ The **DOTS Coordinator** also directly supervises the work of any designated nurse and/or treatment partner assigned to observe and monitor a TB patient's treatment. ➢ During regularly scheduled visits to monitor public health services, **the NTP Manager** can, when requested, follow up on any DOTS-related matters.

Summary of Patient Registration and Record Keeping 2.6

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 the workshop, representatives met to revise existing record-keeping forms based on country needs. It was a recommendation of the participants, including representatives from Niue, to adopt the new forms so that there could be standard reporting among the PICTs that work with the SPC Tuberculosis Control Section. These forms are described below.

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

The Laboratory Sputum Form for TB Investigation provides patient information necessary for tracking during sputum examinations, both diagnostic and follow-up. In Niue, whenever a patient's sputum samples are collected, a Laboratory Sputum Form is completed by the referring doctor or DOTS Coordinator and sent with the samples to the laboratory at the National Hospital. There, necessary information is recorded in the TB Laboratory Register before slides are prepared and testing occurs. Results are formally documented on the Sputum Form by the laboratory staff and then entered in the TB Laboratory Register before notification is given to the referring doctor and the DOTS Coordinator. In cases of smear-positive results, the referring doctor and the DOTS Coordinator are immediately notified by telephone so as to prevent any delay in starting treatment.

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 internal breakdown may be occurring.

2.6.2. TB Laboratory Register (refer to Annex 6, SPC/TUB 02)

The TB 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 (three samples) and during follow-ups (two samples for each). Further, accurate completion of this register gives a detailed record of the results of each sputum examination for each patient. These results are critical indicators for determining a specific diagnosis and for monitoring treatment.

When sputum samples arrive at the laboratory, the lab technician completes the first part of the register using information from the accompanying Laboratory Sputum Form for TB Investigation. Then, as soon as they are known, test results are registered by the lab technician, who also notifies the DOTS Coordinator of all results so they can be cross-referenced in the Tuberculosis Register.

Regular cross-checking by the DOTS Coordinator should be done between the TB Laboratory Register and the Tuberculosis Register to ensure compatibility of information in the two registers.

Strict observation of laboratory codes regarding general safety and confidentiality should be enforced and maintained at all times.

2.6.2.1 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; and
- make it easier to prepare the Quarterly Report on Case-Finding, since some monthly totals will already have been calculated.

At the end of each month, the monthly case summary data should be tallied and, for ease, written directly in the TB Laboratory Register in a space created between the last patient name in the month being summarised and the first patient name of the next month. In Niue, this Monthly Case Summary is completed by a TB lab technician and verified by the laboratory supervisor and/or DOTS Coordinator.

The data to be compiled is shown on the following summary sheet.

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 _____

2.6.3. Tuberculosis Register (refer to Annex 6, TUB 03)

All patients on TB treatment must be registered in the Tuberculosis Register that is kept at all times at the DOTS Centre. Once a patient is diagnosed, the DOTS Coordinator assigns a TB number and registers the patient. The DOTS Coordinator is also responsible for regularly updating the register and ensuring that all data entered is accurate.

Also, on a regular basis the DOTS Coordinator must cross-check the Tuberculosis Register with the TB Laboratory Register to ensure that all tuberculosis cases are entered in the TB 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 CATEGORY I because the sputum smear is still positive at the end of five months, must be reregistered as a treatment failure under CATEGORY 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.

2.6.4. Tuberculosis Treatment Card (refer to Annex 6, SPC/TUB 04)

At the time of each patient's registration in the DOTS programme, the DOTS Coordinator creates an original master copy of the Treatment Card for the individual patient. This master copy is kept at all times at the DOTS Centre and is used to document directly observed treatment (DOT) for the duration of the patient's care. During treatment, master and duplicate copies of the Treatment Card are used as follows:

- During Intensive Phase hospitalisation at the National Hospital, daily treatments are recorded by the ward nurse on a duplicate copy of the master Treatment Card. This duplicate copy is kept in the Medical Ward.
- During any Continuation Phase treatment conducted by the DOTS Coordinator through the DOTS Centre, daily treatments are recorded directly on the master copy at the DOTS Centre.
- For any patient who has their treatment monitored by a designated nurse under supervision of the DOTS Coordinator, and administered through the DOTS Centre, one duplicate copy of the master Treatment Card is made by the DOTS Coordinator. This duplicate is included in the Treatment Kit that is used by the nurse who will directly administer, in consultation with the DOTS Coordinator, the observed treatment (DOT) to the patient. The duplicate Treatment Card stays with the Treatment Kit at the DOTS Centre/ hospital where treatment is being administered. It is the responsibility of the assigned nurse to record each daily treatment that they personally observe, as well as any treatment that was observed and reported by a treatment partner. For this reason it is compulsory for any treatment partner, who helps monitor TB treatment from home, to report each observation for inclusion on the Treatment Card.

The designated nurse who directly observes each treatment must report regularly to the DOTS Coordinator so that the master copy of the patient's Treatment Card can be updated to show ALL treatment. This reporting can take place during regular supervisory or monitoring visits.

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 Coordinator and takes place as soon as the patient arrives at hospital to begin treatment (for Category I and II cases), or as soon as diagnosed (for Category III cases).

Recording Treatment

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.

Daily treatment is entered in each box using a tick (✔) when the swallowing of the drugs is directly observed (DOT). In Niue, DOT is completed as described below.

- During Intensive Phase inpatient treatment at the National Hospital, the nurse in the ward provides direct observation (DOT) daily and records it on the duplicate copy of the Treatment Card.
- During the Continuation Phase of treatment, the patient is seen daily by either the DOTS Coordinator, an assigned nurse trained in DOTS or by a treatment partner working under supervision of the Coordinator. During the visit, which takes place either at the DOTS Centre/ National Hospital or at the patient's home, medication is dispensed and swallowing is directly observed. The DOTS Coordinator or the nurse completes the Treatment Card for each directly observed treatment. Any treatment partner who helps deliver treatment keeps their own record of each observed treatment and reports it to the DOTS Coordinator or nurse during the next visit to the DOTS Centre/National Hospital. At that time the coordinator/nurse completes the Treatment Card based on the report from the treatment partner.
- On a **monthly basis**, the DOTS Coordinator should ensure that the master copy of the Treatment Card (held at the DOTS Centre) is updated with any data from the duplicate Treatment Card that was compiled as a result of home based treatment.

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 supervising DOTS Coordinator or nurse 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.

2.6.5. Tuberculosis Referral/Transfer Form (refer to Annex 6, SPC/TUB 05)

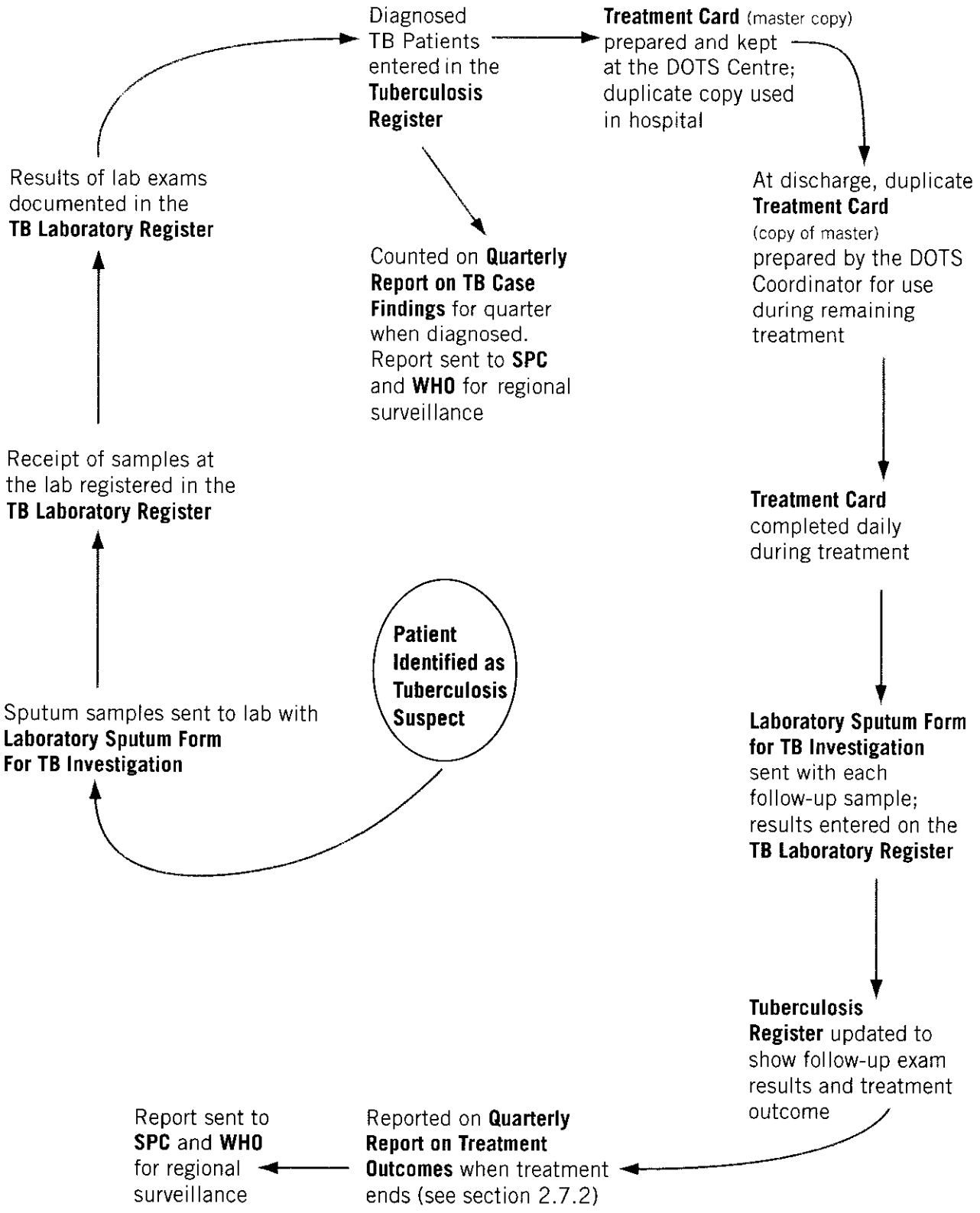
Referrals of patients who move from one DOTS Centre to another must be well defined and closely followed to prevent unnecessary treatment default. Therefore, "transfer out" to another country, particularly for patients on treatment, should be clearly reported (to the physician abroad if such information is available, or alternatively, through embassies or foreign affairs services) and well documented to ensure treatment continuity and completion.

If a patient leaves treatment in Niue to travel overseas, either temporarily or permanently, the Referral/ Transfer Form is completed and forwarded to the new treating facility. Two additional copies of the Referral/Transfer Form are distributed as follows:

- one is kept by the DOTS Coordinator at the DOTS Centre; and
- one is sent to the NTP Manager.

The bottom two sections of the Referral/Transfer Form are to be completed by the new DOTS Centre and returned to the referring DOTS Centre as directed on the form.

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



2.7 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 regional and global levels, the following quarterly reports are completed and submitted.

2.7.1 Directions for Completing the 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 cross-checked with the TB 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:
1	1 January – 31 March	Early in April
2	1 April – 30 June	Early in July
3	1 July – 30 September	Early in October
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 NTP Manager for approval and then to send one copy of the report to the SPC Tuberculosis Control Section, with a second copy to WHO.

Data reported in the Quarterly Report on Tuberculosis Case-Finding is then used to calculate the Niue 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:

Notification rate **for all types of TB** =

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

Notification rate **for sputum smear-positive (S^+) cases** =

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

2.7.2 Directions for Completing the 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 in Section 1.4.3. 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 can only be done when every single patient in a given quarter's cohort has completed their treatment. The report must be compiled and sent within the two weeks following the end of that quarter.

The best way to determine who to include in 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 above at the end of Section 2.6.3. 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, 2005 (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, 2005 would be reported, on a separate SPC/TUB 07 form for Quarter 4, and submitted in early January 2006 (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 NTP 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 Niue 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 (see Section 1.4.3 for definitions of "cured" and "treatment completed"):

- **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=**75.00%**	2	2/4=**50%**	14	14/20=**70%**
Treatment Completed	2	2/16=**12.50%**	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. These rates are also calculated as percentages.

Ongoing Quality Assurance of Microscopy Services 2.8

Given that examination of sputum samples by direct microscopy is the key to diagnosing tuberculosis in DOTS programmes, it is essential that NTP staff — both administrative and technical — engage in ongoing quality assurance practices. This is necessary in order to ensure the effectiveness and reliability of microscopy services. The main quality assurance practices recommended by WHO and SPC are divided into three areas: quality control (QC), external quality assessment (EQA) and drug resistance surveillance (DRS). For a detailed explanation of these three practices, refer to the 2003 WHO-WPRO Stop TB publication: *Quality Assurance of Sputum Microscopy in DOTS Programmes: Guidelines for Pacific Island Countries.*

2.8.1 Quality Control

WHO-WPRO defines quality control (QC) as "a systematic internal monitoring of working practices, technical procedures, equipment and materials, including quality of stains"[4]. It is a process based on international standards and performed internally on a regular basis. QC is the responsibility of all laboratory workers.

In Niue, a laboratory staff member is designated to organise the internal monitoring of quality. This includes working closely with the lab staff, who are responsible for adhering to all standard operating procedures. The laboratory supervisor directly performs the supervisory/evaluation visits to assess the quality of lab practices. These visits take place as needed depending on the situation. During QC monitoring in Niue, the following general categories are assessed:

- staffing — knowledge, skills and training, workload
- work environment and procedures
- lab equipment — cleaning, metrology (standardisation and control of parameters)
- lab materials — slides, reagents and stains (including stock management and recording of reception and opening), hoods, etc.
- safety practices
- sample collection, transport and handling procedures
- slide preparation (i.e. staining) and reading
- recording results (Laboratory Sputum Form for TB Investigation and TB Laboratory Register)
- data collection, analysis and reporting

A specific checklist to be used in Niue to evaluate laboratory status is in the process of being developed. It will be based on recommendations made in the WHO Quality Assurance Manual and will be included in the Laboratory Standard Operating Procedures Manual.

2.8.2 External Quality Assessment

External quality assessment (EQA) is a structured process used to evaluate laboratory performance, especially in relation to reliability of sputum smear results. In partnership with an external reference laboratory, the level of quality achieved in the National Laboratory is monitored using three main practices: on-site supervisory assessments, panel testing and blinded rechecking of slides. EQA offers a positive, cooperative way of ensuring ongoing improvements to existing microscopy services.

As part of the Pacific TB Laboratory Initiative (PATLAB), Niue has been identified to work directly with the Wellington, New Zealand, based Pacific TB Reference Laboratory (PTRL). This lab, the Pacific Paramedical Training College (PPTC), works in partnership with the Niue Laboratory staff to provide the following forms of EQA.

- **Panel testing**

  On a regular basis, the PPTC sends 5 10 unstained smears to be stained and evaluated by the Niue Laboratory staff. Once completed, these slides are then returned to New Zealand for analysis. Based on the results of this exercise, the PPTC provides feedback to the

[4] *WHO 2003. Quality Assurance of Sputum Microscopy in DOTS Programmes: Guidelines for Pacific Island Countries. WHO-WPRO. 46 p*

laboratory staff and addresses any problems that have been identified regarding staining procedures and/or the accuracy of scoring the slides. Through this process the quality of AFB microscopy at the lab can be monitored and improved.

- **Blinded rechecking**

While panel testing contributes towards quality assessment, blinded rechecking is recognised as the most effective means of monitoring the performance of diagnostic tuberculosis laboratories. It provides an opportunity for laboratory staff to receive feedback on the:

- scoring of smears
- performance of the stain
- size of the smear
- quality of the specimen
- source of any errors

Because these factors greatly affect reliability of AFB microscopy results, staff efficiency and lab effectiveness are enhanced through practising blinded rechecking.

Currently, in Niue, because of the low number of tuberculosis patients, all* slides examined using AFB microscopy undergo blinded rechecking. On a six monthly basis, the NTP Manager gathers and packs the slides according to the methods described in the Laboratory Standard Operating Procedures Manual. Once properly packaged, they are sent to the PPTC in New Zealand for evaluation. The PPTC staff then report back to the Niue NTP staff to share the results of the evaluation and to recommend strategies for improving laboratory practices. Should any of the rechecked slides be found to contain major errors, they are returned to the Niue Laboratory so that staff can review the corrected scoring first hand.

* *In future, should there be an increase in the tuberculosis burden in Niue, the process of blinded rechecking may change to be in line with other higher burden countries. Then, instead of rechecking every slide, a set number of slides would be randomly selected by the NTP Manager and/or the DOTS Coordinator to be sent to the PPTC, as recommended by WHO in their quality assurance (QAS) guidelines.*

In addition to the regularly scheduled panel testing and blinded rechecking offered through the PPTC, Niue Laboratory staff also receive practical support through the following EQA services.

- **On-site assessment**

When possible, assessment visits are conducted by external consultants, who also provide informal on-site training when necessary. These visits provide an opportunity for laboratory staff to raise questions and concerns and to receive important feedback that can contribute to the overall improvement of laboratory practices.

If, due to financial constraints, these visits can not be conducted as often as necessary, staff can use email, telephone or fax to discuss their questions and/or concerns.

- **Technical advice**

Whenever necessary, the Niue Laboratory staff can contact SPC or WHO to request technical advice and/or assistance. Both organisations are available to offer a variety of assistance in order to support the ongoing operation of a quality DOTS programme in Niue.

2.8.3 Drug Resistance Surveillance (DRS)

If a DOTS programme fails to identify, or to properly treat, one or more tuberculosis patients, the potentially catastrophic result could be the emergence of multidrug-resistant tuberculosis (MDR-TB). Drug resistance surveillance is a procedure used to monitor the prevalence of MDR-TB so that any cases are identified early, and treated appropriately

without delay. As with EQA, a partner reference laboratory is used in order to offer technical support for implementation of DRS in Niue and, when necessary, to provide actual drug-resistant strain testing of sputum.

The PATLAB initiative has designated the Institute of Medical and Veterinary Science (IMVS) in Adelaide, South Australia, as Niue's PTRL for drug resistance surveillance. IMVS and the Niue Laboratory will work together using the following procedure.

- Drug resistance susceptibility testing will be performed by the IMVS in Adelaide **only** on those sputum specimens found to remain positive at the end of the 5th month of treatment (in Category I) or at the end of the 7th month of treatment (in Category II) or on other specimens as recommended by a doctor.

- The relevant specimens are packed according to IMVS regulations and sent, by the Niue Laboratory staff, to IMVS in Adelaide.

- Results of the testing are returned to Niue so that prompt action can be taken.

Annex 1	List of Essential Anti-Tuberculosis Drugs for Daily Use	60
Annex 2	Standardised Treatment Categories Using Different Fixed-Dose Combinations (FDCs) for Adults and Children	61
Annex 3	Symptom-Based Approach to Adverse Effects of TB Drugs	63
Annex 4	Patient Information Sheet	64
Annex 5	Treatment Partner Instruction Sheet	65
Annex 6	Tuberculosis Information System	66

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 150mg; R 300mg
Isoniazid	tablet, H 100mg; H 300mg
Pyrazinamide	tablet, Z 400mg, Z 500mg
Ethambutol	tablet, E 100mg; E 400mg
Isoniazid + ethambutol	tablet, H 150mg + E 400mg
Rifampicin + isoniazid	tablet, R 150mg + H 75mg; R 300mg + H 150mg
Rifampicin + isoniazid+ pyrazinamide	tablet, R 150mg + H 75mg + Z 400mg

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

* For paediatric use

E = ethambutol, H = isoniazid, R = rifampicin, S = streptomycin, Z = pyrazinamide

ANNEX 2

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

Two-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)	**RH** 150mg+75mg	**Z** 400mg	**E*** 400mg	**RH** 150mg+75mg
30–37	2	2	1½	2
38–54	3	3	2	3
55–70	4	4	3	4
71–90	5	5	3½	5

Three-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	1½	2
38–54	3	2	3
55–70	4	3	4
71–90	5	3½	5

Four-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

Four-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	0.50	2	1½
38–54	3	0.75	3	2
55–70	4	1g	4	3
71–90	5	1g	5	3½

Three-drugs 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	1½	0.25	1½
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, 750mg are given. Streptomycin should not be given to pregnant women.

ANNEX 3

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 six 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 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.*

ANNEX 5

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 swallowing the first dose of the weekly supply. Give to the patient the remaining six days 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 or her 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 or 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 treatment.

9 If your patient was sputum-positive at the microscopic examination and has completed the treatment, refer him or 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.*

TUBERCULOSIS INFORMATION SYSTEM

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** ***TB 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 duplicate copy stays at the treating health facility)

SPC/TUB 05** ***Tuberculosis Referral/Transfer Form
(one copy stays at the referring health facility, one copy is sent to the new health facility and one copy is sent to the DOTS Coordinator)

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

** Initial forms (named TUB 0_) 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/TUB 0_ 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 section 1.4.2 "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 section 1.4.3 "Treatment Outcomes" for more detail)

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

TUB 03 (cont.)

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) or a tick (✓) 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) or a tick (✓) 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)

TUB 06

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.

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

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 (S^+) 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)