

بِسْمِ اللّٰهِ الرَّحْمٰنِ الرَّحِیْمِ



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**SOP for Reporting and Maintaining Records for TB
Control Programme at Sub-national Level**

Contents

INTRODUCTION	4
PRIVACY AND CONFIDENTIALITY	4
OBJECTIVE OF THIS GUIDE	6
TARGET GROUP (Whom is this SOP for)	6
Documents used for Reporting and Maintaining records for TB control program at Sub-national level	6
1. TB Case Notification Form (Annex 1)	7
Case definitions for diagnosis and notifying TB	7
Anatomical site of disease	7
Bacteriological results	8
History of previous treatment and treatment outcome.....	8
HIV Testing	10
TREATMENT OF TB - DOTS	10
Documents used during diagnosis and treatment:.....	12
a. Sputum examination results for AFB (Annex 2).....	12
b. Tuberculosis Treatment Card (Annex 3.1 and 3.2)	12
c. Treatment Referral Letter for TB Cases (Annex 4).....	14
Documents used for Contact Investigation and Contacts	14
Contact Tracing Form in TB Treatment (Annex 3.1, page 4).....	15
TB Contact Investigation Form for Mass Screening (Annex 5).....	15
Registers.....	15
a. Confirmed TB Patients Register (Annex 6).....	15
b. TB Contact Register (Annex 7)	16
c. Chemoprophylaxis (CHP) Register (Annex 8).....	16
d. Sputum AFB Registers at laboratories (Annex 9).....	17
e. Anti-TB Drugs Stock Register (Annex 10).....	17
Monthly reporting to the NTP central at HPA	18
TB Monthly Reporting for Atoll Level (Annex 11)	18
TB Monthly Reporting for Respiratory Medicine Center (RMC) (Annex 12)	19
Further information and queries	21

ANNEX

01	TB Case Reporting Form	22
02	Sputum examination results for AFB	23
03	TB Treatment Chart.....	16
04	Treatment Referral Letter for TB Cases	17
05	TB Contact Investigation Form for Mass Screening	17
06	Confirmed TB Patients Register	15
07	TB Contact Register	16
08	Chemoprophylaxis (CHP) Register	32
09	Sputum AFB Registers at laboratories	33
10	Anti-TB Drugs Stock Register	34
11	TB Monthly Reporting for Atoll Level	35
12	TB Monthly Reporting for Respiratory Medicine Center (RMC)	37

INTRODUCTION

The government of Maldives is committed to preventing the spread of Tuberculosis (TB) in the country and recognizes the TB surveillance plays a central role in the response to the epidemic.

The national TB program consists of three levels.

1. At central level, the central NTP focal points at HPA, care providers at RMC in Male' and Reference Laboratory in IGMH
2. At atoll level, Atoll hospitals and Public Health Units
3. At island level, Island Health Centers

The roles and functions of institutions at the various levels are shown in *Figure 1* below.

The following chapters of this SOP describe the various documents used in the NTP, their purposes, when to use and how to use them.

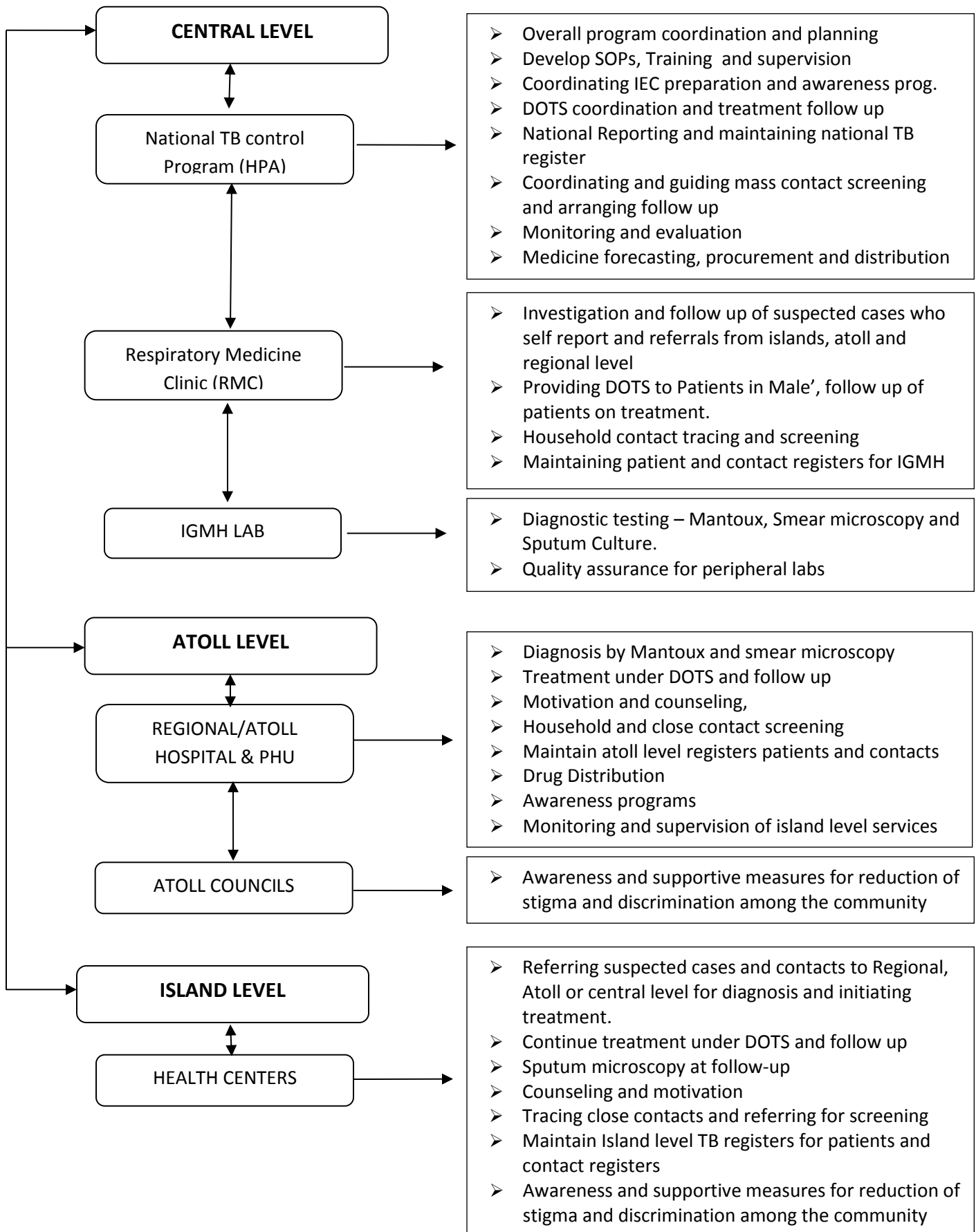
The forms and document formats are annexed separately, so that copies can be made from these directly for use in the relevant centers.

This SOP will be available in pdf format as well on Health Protection Agency and Ministry of Health website. Soft copies of the relevant registers and forms will also be provided to RMC and all atoll or regional level hospitals and NTP focal points at island health centers. If the institutions have not received it, please request for copies at the central NTP at HPA.

PRIVACY AND CONFIDENTIALITY

As Tuberculosis is still a disease with some social stigma, it is essential to be sensitive to patients and contacts privacy. Therefore all documents containing individual patient or contact names and any other identifying details, diagnosis and outcomes should be treated as **STRICLTY CONFIDENTIAL**. These documents should be accessible only to NTP personnel, treating clinicians, DOTS supervisors assigned by the program in consultation with the patient, and the patient and/or his/her guardian. These documents must not be shared with any other persons or parties without consent of the patient, except in the case of a public health threat or a medical or legal inquiry. Such documents requiring confidentiality are identified in this SOP.

Figure 1: National TB Control Program – Functions of institutions at various levels



OBJECTIVE OF THIS GUIDE

This SOP is prepared for health facilities for the purpose of documentation during diagnosis and treatment of patients with TB. The objective of the SOP is to describe the different documents used for reporting and maintaining records for the TB control programme at sub-national level and how to use them. The purpose of these documentation and reporting is for the following:

- Surveillance of TB
- Maintaining records of TB patients and their contacts for treatment and follow-up
- Reporting to higher levels for monitoring of the programme.

TARGET GROUP (Whom is this SOP for)

This SOP is to be used by all the health facilities where TB patients are diagnosed and treated, public as well as private, at all levels from island to central level. It includes records and documents required to be maintained by hospitals and clinics as well as public health units.

Documents used for Reporting and Maintaining records for TB control program at Sub-national level

The NTP uses the following forms and registers for the following purposes;

1. TB Case Notification Form for notification of suspected and confirmed TB patients to the NTP
2. Documents used during diagnosis and treatment
 - a. Sputum examination results for AFB
 - b. Tuberculosis Treatment Card
 - c. Tuberculosis Referral Form
3. Documents used for Contact Investigation
 - a. Contact tracing form (at the end of the TB treatment card)
 - b. TB contact investigation form for mass screenings
4. Registers for maintaining the following records:
 - a. Confirmed TB Patients Register
 - b. Contacts of TB Patients Register
 - c. Chemoprophylaxis (CHP) Register
 - d. Sputum AFB Registers at laboratories
 - e. Anti-TB Drugs Stock Register
5. Monthly reporting to the NTP central at HPA for monitoring and improving quality of the provision of DOTS and tracing where patients are receiving their treatment.
 - a. TB Monthly reporting form for Atoll Level
 - b. Monthly reporting form for Respiratory Medical Center

Described below are details of these forms and registers including when to use them, how to complete these documents and their formats. Formats of the document are annexed separately.

1. TB Case Notification Form (Annex 1)

All health Facilities in the country, both public and private, are required to notify or report **ALL SUSPECTED** and **CONFIRMED** TB cases to the National TB Control Programme as soon as the case is suspected. This form is used for notifying suspected and confirmed individual cases.

The most current WHO Treatment of Tuberculosis guidelines (currently Fourth Edition, 2010) should be used for the diagnosis and treatment of TB. According to this, the case definitions are as follows:

Case definitions for diagnosis and notifying TB

The following TB case definitions are to be used for the diagnosis, notification and registration of patients with TB, based on the level of certainty of the diagnosis and on whether or not laboratory confirmation is available.

Tuberculosis suspect: Any person who presents with symptoms or signs suggestive of TB. The most common symptom of pulmonary TB is a productive cough for more than 2 weeks,¹ which may be accompanied by other respiratory symptoms (shortness of breath, chest pains, haemoptysis) and/or constitutional symptoms (loss of appetite, weight loss, fever, night sweats, and fatigue).

Case of tuberculosis: A definite case of TB is a case that is confirmed by investigations OR one in which a health worker (clinician or other medical practitioner) has diagnosed TB and has decided to treat the patient with a full course of TB treatment.

Note: Any person given treatment for TB should be recorded as a case. Incomplete “trial” TB treatment should **not** be given as a method for diagnosis.

For Definite cases of TB, diagnosis should include the following:

- anatomical site of disease
- bacteriological results (smear status, culture, MDR or XDR where applicable)
- history of previous treatment (new case, relapse, default or re-treatment)
- HIV status of the patient

Details of this categorization are defined below:

Anatomical site of disease

In general, recommended treatment regimens are similar, irrespective of site, but definition may vary. Defining the site is important for recording and reporting purposes and to identify the more infectious patients – (those with pulmonary involvement who will be further subdivided by smear status) and to decide treatment duration.

Pulmonary tuberculosis (PTB) refers to a case of TB (defined above) involving the lung parenchyma. Miliary tuberculosis is classified as pulmonary TB because there are lesions in the lungs. Tuberculous intrathoracic lymphadenopathy (mediastinal and/or hilar) or tuberculous pleural effusion, without radiographic abnormalities in the lungs, constitutes a case of

extrapulmonary TB. A patient with both pulmonary and extrapulmonary TB should be classified as a case of pulmonary TB.

Extra pulmonary tuberculosis (EPTB) refers to a case of TB (defined above) involving organs other than the lungs, e.g. pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges. Diagnosis should be based on at least one specimen with confirmed *M. tuberculosis* or histological or strong clinical evidence consistent with active EPTB, followed by a decision by a clinician to treat with a full course of tuberculosis chemotherapy. The case definition of an EPTB case with several sites affected depends on the site representing the most severe form of disease.

Bacteriological results

Bacteriology refers to the smear status of pulmonary cases and the identification of *Mycobacterium tuberculosis* for any case by culture or newer methods. All patients suspected of having pulmonary TB should submit at least three sputum specimens for microscopic examination and the specimen should be collected in early morning as sputum collected at this time has the highest yield. Smear-positive cases are the most infectious and most likely to transmit their disease in their surroundings, they are the focus for infection control measures while it's also important to identify smear-negative cases, especially in persons living with HIV for whom mortality is higher than in smear-positive pulmonary TB cases.

For patients suspected of having EPTB, specimens should be obtained from the suspected sites of involvement. Where available, culture and histopathological examination should also be carried out. Additionally, a chest X-ray and examination of sputum may be useful, especially in persons with HIV infection.

History of previous treatment and treatment outcome

At the time of registration, each patient meeting the case definition is also classified according to whether or not he or she has previously received TB treatment and, if so, the outcome (if known). It is important to identify previously treated patients because they are at increased risk of drug resistance, including MDR-TB.

The distinctions between new and previously treated patients, and among the subgroups of previously treated patients, are also essential for monitoring the TB epidemic and programme performance.

New patients have never had treatment for TB, or have taken anti-TB drugs for less than 1 month. New patients may have positive or negative bacteriology and may have disease at any anatomical site.

Previously treated patients have received 1 month or more of anti-TB drugs in the past, may have positive or negative bacteriology and may have disease at any anatomical site.

Table 1: Registration group by outcome of most recent TB treatment

Registration Group (any site of disease)		Bacteriology	Outcome of most recent prior treatment
New		+ or -	-
Previously treated	Relapse	+	Cured Treatment completed
	Failure	+	Treatment failed
	Default	+	Defaulted
Transfer in: A patient who has been transferred from another TB treatment (DOTS) center to continue his/her treatment		+ or -	Still on treatment

Table 2: Treatment outcome

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

Treatment outcome should always be recorded when closing the file or when transferring the patient to another center

HIV Testing

WHO recommends determining HIV status of all TB patients This is critical for treatment decisions.

Follow VCT guideline for HIV testing.

HIV status could be either of the following:

- HIV negative
- HIV positive (person living with HIV= PLHIV0 including CD4 counts if available)
- AIDS

TREATMENT OF TB - DOTS


DOTS (Directly Observed Treatment, Short-course), is the World Health Organization recommended tuberculosis treatment strategy. Early diagnosis and complete treatment under DOTS is the most effective method of TB control.

Modern anti-TB treatment can cure virtually all patients. It is, however, very important that treatment be taken for the prescribed duration, which in every case is a minimum of 6 months. Because treatment is of such a long duration and patients feel better after a few weeks, treatment may often be interrupted. This is dangerous as it can lead to drug resistant TB.

Therefore, just providing anti-TB medication is not sufficient to ensure that patients are cured. The DOTS strategy ensures that TB patients are diagnosed and treated effectively till cure, by ensuring availability of the full course of drugs and a system for monitoring patient compliance to the treatment until the end of the treatment course.

Starting in 1994, DOTS was implemented to ensure TB patients are diagnosed and treated effectively till cured, by the year 2007; the entire country was covered by 100% DOTS coverage under the NTP programme.

Figure 2: Circular regarding DOTS and regulated sale of Tuberculosis drugs


 23-D2/2001/C-34

1422
 25

10
25

1

Documents used during diagnosis and treatment:

a. Sputum examination results for AFB (Annex 2)

This sheet will be completed by the laboratory technician and returned to the requesting person as soon as possible. In case the patient presents to an atoll or regional hospital, then this form will be sent to the medical doctor for further action. One form will be used to communicate the three smear results. However, if any sputum is positive, efforts will be done to inform the requesting clinician should be informed immediately even before all three results are available.

Whenever a TB patient's sputum examination is done, it is entered in the patient's treatment card, and also, a copy of this report is sent to National TB Programme.

Sputum examination results are **CONFIDENTIAL** documents.

b. Tuberculosis Treatment Card (Annex 3.1 and 3.2)

This is the most important document as it contains all the information related to the patient including his/her registration, diagnosis, treatment, referrals, follow up and outcome. This record should be **STRICTLY CONFIDENTIAL**. This card has four pages. As soon as a case is diagnosed, treatment card should be maintained and monitored a new card must be completed for every new registration. If a patient resumes treatment after having defaulted, a new card must be made. Information on page 1 of this card will preferably be completed by a medical doctor, where a doctor is available prior to starting treatment. A copy will be sent to the NTP so that a complete registration can be made in the TB Treatment Register. *Treatment schedule* tables on Page 2 can be completed by the DOTS provider. Page 3 is also for doctors' notes. At the end of the treatment (or when the file is closed earlier, in case of death, default or failure), the *Treatment outcome* table should be completed by the treating doctor, and a copy of the completed treatment card will be sent to the NTP at HPA for updating the TB Treatment Register and archiving.

The card contains a unique Patient Registration Number called the 'TB Number', that's allocated to every TB patient. The number is allocated by the NTP in HPA for all patients in the country. This implies that for every diagnosed TB patient, the NTP in HPA needs to be informed so that the patient can be registered and allocated a serial number.

The complete diagnosis, results of lab tests and X-rays and treatment details should be completed in the relevant sections.

The TB *Treatment schedule* on page 2 will help you to ensure that you give the patient the right TB drugs at the correct time. It is important for you to observe the patient take the TB drugs as scheduled and then mark it on the TB Treatment Card. This will also help the health facility to find out the default cases. Please write the names of the medicines given and planned treatment start dates, duration and end dates on the space provided here, so that the treatment plans are clear to anyone seeing this card.

DOTS Treatment Card – Patient Copy: A copy of the treatment schedule can be given to the DOTS supervisor to allow ticking of every supervised drug intake. Ticks should only be placed **after** treatment is taken. Please complete the treatment start dates, planned durations and end-dates, and names of medicines given to patient in each phase in this card. This is very important. The master card needs to be updated periodically (usually at least once a week) with all tick marks for drug intake, as well as for follow up sputum results and treatment outcome. This is attached in *Annex 3.2* as *DOTS Treatment Card – Patient Copy*.

Figure 2: How to mark DOTS treatment on the treatment card

Mark ✓ on the correct day on the TB Treatment Card each time after the patient has taken the TB drugs.

Day Mo nth	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
June								✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
July	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
August	✓	✓	✓																												

Mark the TB Treatment Card each time the patient takes the TB drugs.

Patient Movements

This schedule in the TB treatment card is to document details whenever a patient is referred to a different center for treatment. This is usually done when a patient changes his/her residence for a period (longer than 3 days). When referring a patient, along with the referral chit, a copy of the treatment card should be sent to the referral center where patient is referred to. The original is retained at the initial treatment center.

Doctors Notes and Recommendations

This section has a box for the doctor to document the detailed chest x-ray findings at diagnosis and follow up, and a box for noting risk factors and action taken to treat the patients' risk factors, and a box for noting adverse effects of medicines. The rest of the page is for any remarks and recommendations by the doctor, including and action taken for adverse events, any changes in treatment regime, any other medicines prescribed and any other advice. All treatments and

actions taken or recommended for control of other underlying risk factors and diseases also should be documented.

Contact Information for Contact Tracing

The last page (page 4) is to document the patient's contact investigation. This includes only minimum information of contacts of this patient that is required for identifying and tracing them.

Details of individual contacts, including their tests and results should be recorded in the Contact Register (see section 3 below), and not in this card.

c. Treatment Referral Letter for TB Cases (Annex 4)

Whenever a TB patient travels from any island within the duration of TB treatment, the health facility responsible for the patient's treatment should send this referral letter referring him / her to the next destination. The receiving island health facility should start the patient's treatment as soon as possible without interrupting treatment.

A copy of the patient's Treatment card should always be sent along with the referral letter, The patient's copy of the Treatment Card should be given to the patient, and a temporary DOTS supervisor from the patient's family or friends who will be traveling with him/her should be assigned and advised to give the medicines during travel, if the time to take medicine falls during travel time, and this should be documented.

If any referrals are done, a copy of the referral form should be sent to the national TB Control Programme at HPA.

This document is also **CONFIDENTIAL** and should only be accessed by those within the NTP and treating clinicians

Documents used for Contact Investigation and Contacts

Tuberculosis contacts are people who have close contact with patients with infectious TB. As they are at high risk for infection, TB contacts should be investigated systematically and actively for TB infection and disease. The TB contact investigation protocol should be used for this. This contributes to early identification of active TB, thus decreasing its severity, improving chances of complete cure and reducing transmission of mycobacterium tuberculosis to others.

Effective investigation may result in the detection of significant number of cases, which is important to prevent TB by treating them early and properly.

Contact investigation is required for all cases of TB who are infective, and for children diagnosed with TB to identify a source of infection and treat the person. Contact investigation is indicated for all patients diagnosed with:

1. Sputum positive TB
2. TB in a person living with HIV/AIDS

3. Children < 5 years (to identify source and treat)
4. Multi-drug resistant TB (MDR-TB or XDR-TB (proven or suspected))

According to the contact screening protocol, contact investigation should be commenced as soon as possible once the patient has been started on treatment and counseled, and is ready to cooperate

There are three documents used for contact investigation:

1. Contact tracing form (at the end of the TB treatment card)
2. TB contact Investigation form for mass screenings
3. TB contact register (described under Registers)

Contact Tracing Form in TB Treatment (Annex 3.1, page 4)

This is used for tracing contacts by interviewing the patient and notifying their contacts' addresses and phone numbers. (This is in the last page of the TB Treatment card)

TB Contact Investigation Form for Mass Screening (Annex 5)

This is to be used in the field for screening when a TB patient has a large number of contacts in an institution (eg: school, workplace, prison, home/shelter etc.) where mass screening is required. It can also be used for general mass screening activities in the field.

This form contains the significant clinical features and test results to be noted for diagnosis of the contact. A soft copy will be given to all atoll hospitals for easy sorting of contacts to prioritize follow up.

This document is **CONFIDENTIAL**, and should only be accessible to the persons directly in the NTP and to one person directly responsible for arranging mass screenings under an oath of confidentiality.

Registers

The following registers should be maintained at all health care facilities that provide treatment for patients with TB, including hospitals, health centers and clinics including RMC and any private or military medical clinics if they provide TB treatment.

a. Confirmed TB Patients Register (Annex 6)

This register is used for recording all TB patients who are **currently on treatment** in the Atoll or from the particular the Health Facility. All health care facilities (hospitals, health centers and

clinics including RMC) should maintain this register. Health facilities will maintain patients on treatment at the facility. Atoll hospital Public Health Units should maintain registers of all patients on treatment in the Atoll.

It is advisable to maintain this register in a bound book. A sample of details to be entered in the register is given in Annex 6. The NTP will also share electronic versions of the full TB register as MS Excel sheets with all atoll hospital PHUs. This could be completed and maintained at the atoll hospital, and sent to the NTP for updating when a new patient is registered. However, if this electronic register is maintained instead of a book, a file should be maintained with print-outs of this register. An update sheet should be printed out and filed whenever a new patient is entered, or a patient is transferred out.

This register should contain patient identifying details, full detailed diagnosis (as described under case definition in section 1), infective status (sputum +/-) and outcomes as described in section 1 above, including transfers.

A patient is entered into the register when a patient is started on treatment or transferred in for continuing treatment at the health facility or in the atoll (in case of atoll hospitals). When a patient completes treatment or reaches any of the outcomes, or is transferred out, patient will be removed from the register with the date and outcome noted.

This register should be **CONFIDENTIAL**, and accessible only to those directly in the NTP at the relevant center and central level.

b. TB Contact Register (Annex 7)

All contacts of TB patients and persons investigated in mass screenings should be entered in the TB contact register. This register contains all the relevant information of each contact and each person investigated for TB in mass screening activities.

This includes personal information for contacting, clinical details, test results, final outcome and follow up plans.

This register should be **CONFIDENTIAL**, and accessible only to those directly in the NTP at the relevant center and central level.

c. Chemoprophylaxis (CHP) Register (Annex 8)

The following categories of patients will need to be given prophylactic treatment:

- Newborns with a sputum positive mother.
- Close contacts under 5 years of age.
- Immune-compromised persons exposed to TB.
- Exposed patients who are unable to come for follow-up may also be considered for prophylaxis

A register should be maintained for contacts receiving chemoprophylaxis. This should contain contact details of all persons receiving chemoprophylaxis and their outcomes, including transfers.

This register should be **CONFIDENTIAL**, and accessible only to those directly in the NTP at the relevant center and central level.

d. Sputum AFB Registers at laboratories (Annex 9)

All laboratories that perform sputum AFB tests and any other tests for TB should maintain a specific register for these tests.

This register should be **CONFIDENTIAL**, and accessible only to those directly in the NTP at the relevant center and at central level.

e. Anti-TB Drugs Stock Register (Annex 10)

All facilities providing treatment for TB should maintain Anti-TB Drugs stock registers, which contain details of stocks received and dispatched, dates of expiry and buffer stocks.

Drugs should be used strictly in a “**First Expiry** – First Out” (FEFO) order, and **not** in a “First In – First Out” basis.

The central TB program at HPA should be notified in advance before drugs reach stock-out. Particularly if buffer stocks are utilized, the central program should be notified immediately.

Monthly reporting to the NTP central at HPA

All Atoll hospitals and RMC should report on a monthly basis to the NTP central at HPA for monitoring and improving quality of the provision of DOTS, and also for keeping track of where patients are receiving their treatment. The reporting forms for Atoll level and for RMC are slightly different.

TB Monthly Reporting for Atoll Level (Annex 11)

All the Atoll Hospitals will be required to send monthly reports to the National TB Control Programme in HPA using the TB Monthly Reporting Form on a monthly basis. Atoll hospitals are recommended to collect information from the islands belonging to the atoll to fill the report to be used both for atoll hospital and to report to HPA.

This form will give a summarized report of the TB status within the atoll. It will help atoll staff to keep track of patients who default and report such patients, which is important for preventing drug resistant TB. It also helps to plan the requirements of drugs, testing, training and other needs of the atoll for detection and treatment of TB.

The following are monitored by the monthly reporting from atolls:

TB Buffer Stock

As per the recommendation by TB Programme implementation assessment mission (2012), Buffer stock of TB drugs should be maintained at all Atoll hospitals. This is to maintain continuity of supply and easy access to anti-TB drugs in all atolls. This buffer stock is to be used when a positive diagnosis is made within the atoll, and when this buffer stock is used, it should be replaced as soon as possible (in addition to bringing drugs required for the patients).

TB Patients on Treatment

Most of the TB patients take their DOTS at the islands. After being diagnosed in Male' or at the Atoll hospital, they are referred to their island for continuing their DOTS treatment. This form will give a summary of number of patients currently on treatment within the atoll.

TB Patients who default or “miss treatment”

The treatment outcome “default” under NTP for reporting to WHO is ‘a patient who has not taken anti-TB drugs for 2 months or more consecutively after starting treatment’. The public health and clinical consequences of TB treatment default are severe. Relative to those who complete treatment, patients who default may continue to transmit TB to others and have high post-treatment mortality and rates of recurrent disease and drug resistant TB. Therefore it is important to detect near-defaulters without waiting for the defined 2 months and get them back on treatment by dealing with the systematic and socio-economic barriers to their DOTS treatment as early as possible.

Therefore for local monitoring purposes in *this form*, we have added *a new treatment outcome=“Missed treatment” if a patient has not taken anti-TB drugs for 3 or more*

consecutive days after starting treatment, or has missed receiving treatment intermittently more than 3 times for a period of 2 weeks.

If a patient has “**missed treatment**” as in the above definitions, every effort must be taken to trace the person and continue regular treatment. If patient cannot be traced within 1 week of the date of last treatment dose taken, **please report this patient to NTP immediately** by phone and fax or email without waiting to send as monthly report.

TB Monthly Reporting for Respiratory Medicine Center (RMC) (Annex 12)

Respiratory Medicine Clinic (RMC) will be required to send the TB Monthly case reporting form to National TB Control Program on a monthly basis.

Respiratory Medicine Clinic (RMC)

RMC is a specialized unit of the Internal Medicine department in Indira Gandhi Memorial Hospital (IGMH), Male’ which was established with the aim to manage tuberculosis.

The main services provided in RMC (IGMH) are:

- a. Treatment of TB patients with DOTS and follow up
- b. Chemoprophylaxis for TB contacts at high risk
- c. Investigation of treated patients coming to check sputum smear
- d. Investigation of TB suspects referred to the clinic
- e. Counseling and screening of close Contacts of TB patients for
- f. Screening for TB for medical check ups

RMC should also report to HPA on a monthly basis the following information:

TB Patients on Treatment

This form will give a summary of number of patients currently on treatment from RMC, number of patients with MDR TB, patients on second-line treatment.

Referral and Transfer

Many patients who are diagnosed in RMC are referred to a hospital or to another service delivery facility for continuing their treatment. RMC should note when they are transferred to another facility.

A national TB register is maintained centrally at the NTP for the entire country, the patient keeps his Patient Registration Number. The total number of patients in the country does not change even if the patient is referred from one center to another within the country. Transfer out may occur when the patient is transferred to the TB program of another country and continues treatment outside the country.

Default and “Missed treatment”

The definition for within country monitoring purposes will be as in section 5.a. described above.

Chemoprophylaxis

The number of patients on chemoprophylaxis should be reported to HPA.

TB contacts and screenings

Number of contacts identified, and screened (screening completed), and number to be followed-up should be reported to HPA monthly.

TB Medicine Stocks

TB drugs should be maintained at RMC. This is to maintain continuity of supply and easy access to anti-TB drugs. RMC should report monthly to HPA on the available drug stocks, and whether any medicines are running out of stock or expiring in the next 3 months.

Further information and queries

If you have any queries, or wish to clarify any information in this SOP, or wish to obtain further information, please contact:

The National TB Program (NTP),

Health Protection Agency,

Ministry of Health,

4th Floor, Roashanee Building,

Male', Maldives.

Telephone: 3014470, Fax: 3014484. Email: ntp.maldives@gmail.com

Website: <http://www.hpa.gov.mv>

This SOP and all forms will be available for download on the HPA website.

Health Protection Agency
 Republic Of Maldives
 Phone: 3014494 Fax: 3014484 email: ntp.maldives@gmail.com

TB Case Notification Form

This form is to be used to report newly infected TB case to Health Protection Agency

1. Name of the Facility

Name of Facility: _____	Date of Submission: ____/____/____ <i>DD MM YYYY</i>
Email/Telephone Number: _____	

2. Case Details

Case Classification: Suspect <input type="checkbox"/>	Probable <input type="checkbox"/>	Confirmed <input type="checkbox"/>
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3. Patient Information

Full Name: _____	Permanent Address: _____
Current Address: _____	Contact No : _____
Sex: Male <input type="checkbox"/> Female <input type="checkbox"/> Age (Years): ____	Type of TB: Pulmonary <input type="checkbox"/> Extra Pulmonary <input type="checkbox"/>
Date of Consultation: _____	Site : _____
Occupation: _____	

4. Classification of current diagnosis (Please tick)

5. Treatment Category

New <input type="checkbox"/> Relapse <input type="checkbox"/> Re-treatment <input type="checkbox"/> Failure <input type="checkbox"/>	Cat I and III <input type="checkbox"/> Cat II <input type="checkbox"/> 2nd line Drugs <input type="checkbox"/>
--	--

6. Details of Drugs (as prescribed)

--

7. Investigation Report

Sputum result

	Date	Result
1 st Sample		
2 nd Sample		
3 rd Sample		

X-Ray result

Date	Findings (+/-)

Reporter Details

Name:	Designation:	Signature:
-------	--------------	------------

Sputum Examination Result for AFB

SPUTUM EXAMINATION RESULT FOR AFB

Name of requesting Health Centre: _____ Date: _____

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

Permanent address: _____

Type of TB: Pulmonary Extra-pulmonary Site: _____Reason for examination Diagnosis Follow-up

For follow-up smears: Patient's register number _____

Laboratory Serial Number: _____

Visual appearance of sputum:	Mucopurulent	Blood-stained	Saliva
Specimen 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Specimen 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Specimen 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Microscopy Result (staining method: Ziehl-Neelsen)

Date	Specimen	Result*	Positive (grading)			
			3+	2+	1+	AFB#(1-9)
	A					
	B					

1-9 AFB grading column: write the exact numbers per 100 hpf

Date: _____

Signature _____

ANNEX 03

[NATIONAL TUBERCULOSIS CONTROL PROGRAMME
HEALTH PROTECTION AGENCY
MINISTRY OF HEALTH
TUBERCULOSIS TREATMENT CARD



TB NO.:	REGISTRATION DATE: DD/MM/YYYY	Treating Center:.....	Type of TB: <input type="checkbox"/> PTB - Sputum smear Positive (P+) <input type="checkbox"/> PTB - Sputum smear Negative (P-) <input type="checkbox"/> EP TB (site):								
Name:		Permanent Address:									
ID/PP. No:		Residential Address:									
Age: <input type="text"/> YY/MM Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female		Treatment Supervisor:									
		Supervisor Contact Address:									
Any TB Treatment before? <input type="checkbox"/> YES <input type="checkbox"/> NO		Last regimen (Rx category) <input type="text"/> Was full treatment completed? <input type="checkbox"/> YES <input type="checkbox"/> NO									
Previous TB No:	Treatment Completed/Cured/Stopped	Day	Month								
			Year								
Details on Patient Movements											
Referred to:											
Referred Date:											
Reference Chit No.:											
Registration Category	Treatment Category	Planned duration (mths)	Month	Results of sputum examination						Weight (kg)	
				Local Lab			Reference Lab				
				Date	Smear	Lab. No.	Smear	Cult	Sensitivity		
									Sens	Res.	
New	CAT I		0								
Relapse	CAT II		4 wks								
Treatment Failure	CAT III		2 mnth								
Returned Defaulter	OTHERS		4 mnth								
Transfer In			6 mnth								
Other			Rx End								

TREATMENT SCHEDULE: (place a tick (✓) for each date after giving drugs as DOTS)

1. Intensive Phase

Treatment Start Date: DD / MM / YYYY

Planned duration (mths): _____

Planned End Date: DD / MM / YYYY

Medicines: INH, RIF ETH, PRZ, _____

No. of Tabs

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

2. Continuation Phase

Treatment Start Date: DD / MM / YYYY

Planned duration (mths): _____

Planned End Date: DD / MM / YYYY

Medicines: INH, RIF _____

No. of Tabs

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

TREATMENT OUTCOME:

Diagnosis changed

Treatment stopped date:	DD	MM	YYYY
Outcome category	Please tick and write date (DD/MM/YYYY)		
Cured			
Completed treatment			
Treatment Failure			
Death			
Defaulted			
Transferred out			

Was treatment changed? YES NO

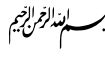
REMARKS

.....
.....
.....
.....

<p>STATUS AT START</p> <p>DATE</p> <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;"> <p>CAVITY</p> <p>INFLTRATION</p> <p>PLEURISY</p> <p>HILAR / MEDIAST GLANDS</p> </div> <table border="1" style="font-size: 8px; border-collapse: collapse;"> <tr><td>UZ</td><td></td><td style="text-align: center;">R</td><td></td><td style="text-align: center;">L</td></tr> <tr><td>MZ</td><td></td><td></td><td></td><td></td></tr> <tr><td>LZ</td><td></td><td></td><td></td><td></td></tr> <tr><td>UZ</td><td></td><td></td><td></td><td></td></tr> <tr><td>MZ</td><td></td><td></td><td></td><td></td></tr> <tr><td>LZ</td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td><td></td></tr> </table> </div> <p>DATE</p> <div style="text-align: center;"> </div> <p>FURTHER</p> <p>DATE</p> <div style="text-align: center;"> </div> <p>FURTHER</p> <p>DATE</p> <div style="text-align: center;"> </div> <p>FURTHER</p>	UZ		R		L	MZ					LZ					UZ					MZ					LZ															<p>RISK FACTORS – ACTION TAKEN</p> <p><input type="checkbox"/> Smoker <input type="checkbox"/> Quit Advice Given <input type="checkbox"/> <input type="checkbox"/> Referred for cessation</p> <p><input type="checkbox"/> Drug user <input type="checkbox"/> Referred for Rx or rehab.</p> <p><input type="checkbox"/> Alcohol user <input type="checkbox"/> Quit Advice Given <input type="checkbox"/> <input type="checkbox"/> Referred for cessation</p> <p><input type="checkbox"/> Diabetes <input type="checkbox"/> Referred for treatment <input type="checkbox"/> <input type="checkbox"/> Good control</p> <p><input type="checkbox"/> Other (specify) <input type="checkbox"/> Referred for treatment <input type="checkbox"/> Good control</p> <p>HIV test done <input type="checkbox"/> DO NOT write result here!</p> <p>ADVERSE EVENTS OF MEDICINES</p> <p><input type="checkbox"/> Fever</p> <p><input type="checkbox"/> Rash</p> <p><input type="checkbox"/> Joint pains</p> <p><input type="checkbox"/> Peripheral neuropathy</p> <p><input type="checkbox"/> Abdominal pain, discomfort or nausea</p> <p><input type="checkbox"/> Vomiting</p> <p><input type="checkbox"/> Loss of appetite</p> <p><input type="checkbox"/> Jaundice</p> <p><input type="checkbox"/> Elevated AST/ALT</p> <p><input type="checkbox"/> Blurred vision</p> <p><input type="checkbox"/> Altered hearing or tinnitus</p> <p><input type="checkbox"/> Dizziness</p> <p><input type="checkbox"/> Tingling or numbness around the mouth</p> <p><input type="checkbox"/> Bleeding tendency</p> <p><input type="checkbox"/> Other (specify):</p>	<p>DOCTOR'S NOTES AND RECOMMENDATIONS</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
UZ		R		L																																						
MZ																																										
LZ																																										
UZ																																										
MZ																																										
LZ																																										

CONTACT INFORMATION FOR CONTACT TRACING

NO.	NAME	RELATIONSHIP To PATIENT	AGE	ADDRESS	CONTACT NUMBER	CONTACT TRACING ACTION	
						Completed DATE DD/MM/YY	Cannot Trace (After Repeated Attempt) DD/MM/YY



ދިވެހިސަރުކާރުގެ ގެޒެޓްޔުގައި ބަޔާންކުރި ކަންކަމުގެ މަޢުލޫމާތު ލިބިދޭނެ ގޮތުގައި ސަލާމުގެ ބަދަލުގައި ސަރުކާރުގެ ގެޒެޓްޔުގައި ބަޔާންކުރި ކަންކަމުގެ މަޢުލޫމާތު ލިބިދޭނެ ގޮތުގައި ސަލާމުގެ ބަދަލުގައި

TREATMENT REFERRAL LETTER FOR T.B CASES

Dear Doctor / Hospital TB Focal point,

Please register the patient below in your hospital and provide DOTS treatment and testing as per protocol. A copy of the patient's Treatment card with all currently available information and treatment plans (4 pages), and the patients' copy for marking DOTS doses (1 page) are attached. If you need any clarification on patient's clinical details, please contact us (details below).

<p style="text-align: center;">----- ފަނޑުގަތުމުގެ ދުވަސް ދަށުން -----</p> <p style="text-align: center;">DURATION OF TREATMENT</p>	<p style="text-align: center;">----- ޖެނެރަލް ރެކިސްޓްރީ ނަންބަރު -----</p> <p style="text-align: center;">TB REGISTER NO</p>
<p style="text-align: center;">----- ސެކްސް : ----- ފަނޑުގަތުމުގެ ދުވަސް : -----</p> <p style="text-align: center;">SEX AGE</p>	<p style="text-align: center;">----- ފުލް ނެއުމް -----</p> <p style="text-align: center;">FULL NAME</p>
<p style="text-align: center;">----- ސުޕްޓަމް ރެޝަލްޓް -----</p> <p style="text-align: center;">SPUTUM RESULT</p>	<p style="text-align: center;">----- ޕްލިއުލްތިކަލް ޖަނުބަލާން ސަލާމް -----</p> <p style="text-align: center;">COMPLETE DIAGNOSIS</p>
<p style="text-align: center;">----- ޖިއާލީނުގެ ރިޞިޢަދުގެ ސަރަޙައްދު -----</p> <p style="text-align: center;">ADDRESS OF RESIDENCE IN ISLAND</p>	
<p style="text-align: center;">----- ފަނޑުގަތުމަށް ފޮނުވި ޖިއާލީނު -----</p> <p style="text-align: center;">ISLAND REFERRED TO</p>	
<p style="text-align: center;">----- ފަނޑުގަތުމުގެ މަޢުލޫމާތު ލިބިދޭނެ ގޮތުގައި ސަލާމުގެ ބަދަލުގައި -----</p> <p style="text-align: center;">DATE TREATMENT STARTED</p>	
<p style="text-align: center;">----- ފަނޑުގަތުމުގެ ފަޔާލާތު -----</p> <p style="text-align: center;">REMARKS</p>	

ދިވެހިސަރުކާރުގެ ގެޒެޓްޔުގައި ބަޔާންކުރި ތާރީޚު DATE OF ISSUE	މަޢުލޫމާތު AMOUNT	މަޢުލޫމާތު ލިބިދޭނެ ގޮތުގައި ސަލާމުގެ ބަދަލުގައި DOSAGE		ޖެނެރަލް ރެކިސްޓްރީ ނަންބަރު DRUGS
		ފްރީކްއެންސީ FREQUENCY	ސްޓްރެންތް (މި.ގްރޭމް) STRENGTH (MG)	

----- ފަނޑުގަތުމަށް ފޮނުވި ފެކުލްޓީ -----

FACILITY REFERRED FROM

----- ފަނޑުގަތުމަށް ފޮނުވި މަޢުލޫމާތު ލިބިދޭނެ ގޮތުގައި ސަލާމުގެ ބަދަލުގައި -----

NAME OF PERSON REFERRING

INFORMATION SHEET FOR SCREENING ACTIVE TB														
NO	NAME	ADDRESS	AGE	Weight	BCG Scar	Cough > 2 wks	Fever	Weight Loss	Shortness of Breath	Lymph node Enlargement	Fatigue	Family	Other Symptoms	Mantoux reading mm
1														
2														
3														
4														
5														
7														
8														
9														
10														

ANNEX 6

TB REGISTER FOR SPUTUM POSITIVE PULMONARY PATIENTS

NTB NO	NAME	AGE	GENDER	TYPE (P/NP or EP)	CLASSIFY (NEW,RELAPSE, DEFAULT,RE-TREATMENT)	PERMINET ADDRESS		REFFERE D FROM	DATE REGISTERED	STATUS	DISCHARGE DATE
						ADDRESS	ISLAND				

NTB NO National TB Register Number
P Pulmonary
NP New Pulmonary
EP Extra Pulmonary

TB CONTACT INVESTIGATION REGISTER

#	Patient No.	Date	Name	ID Card No.	Age (YY/MM)	Atoll	Island	Address	SYMPTOMS				BCG Scar Y/N	TEST RESULTS			OUTCOME	CONTACT TRACING ACTION	
									Cough >2 weeks Y/N	Fever Y/N	Wt. loss Y/N	Other TB symptoms Y/N		Date	MTX +/-	X-RAY +/-		SPUTUM +/-	Disch / LTBI / TB
1																			
2																			
3																			
4																			
5																			
6																			
7																			
8																			

Page 1

ANNEX 8

Chemoprophylaxis Register

ChP No:	Name	Age	Sex	INDEX case	Address	Island Address	Register Date	Status	Discharged Date

#	Laboratory No	Name	Age	Gender	ID No	Address	Date	Result
1							Sample 01	
							Sample 02	
							Sample 03	
2							Sample 01	
							Sample 02	
							Sample 03	
3							Sample 01	
							Sample 02	
							Sample 03	
4							Sample 01	
							Sample 02	
							Sample 03	
5							Sample 01	
							Sample 02	
							Sample 03	



Health Protection Agency

Republic Of Maldives

Phone: 3014494 Fax: 3014484 email: ntp.maldives@gmail.com

TB MONTHLY REPORTING FORM

Name of the Facility:

Reporting Period:/...../..... to/...../.....

TB BUFFER STOCK

DRUGS/COMMODITY	STOCK RECEIVED		DURING MONTH		BALANCE
	DATE RECEIVED	EXPIRY DATE	AMOUNT USED	EXPIRY DATE	
TB KITS					
MANTOUX					

TB PATIENTS CURRENTLY ON TREATMENT

TB PATIENT No	NAME	ADDRESS	ISLAND	TREATMENT STARTED	
				DATE	FACILITY

TB PATIENTS WHO DEFAULTED

TB PATIENT NO	NAME	ADDRESS AND ISLAND	DEFAULT DATE	REASON

Report prepared by:

Designation:

Date:

Signature:

INSTRUCTIONS

This entire form is to be completed by the Atoll hospital with relevant information collected from the islands in the Atoll.

- TB Buffer Stock is kept in every Atoll hospital for easy access to the drugs if any patient is been diagnosed within the Atolls.
- All TB patients currently on treatment in the Atoll (including island level) should be listed in this form.
- If any defaults are recorded in any island of the Atoll, it should be mentioned in this form with the relevant reason for the default.

(For monitoring purposes in this form, treatment outcome=“default” if a patient has not taken anti-TB drugs for 3 or more consecutive days after starting treatment, or has missed receiving treatment intermittently more than 3 times for a period of 2 weeks)

If a patient has defaulted as in the above definitions, every effort must be taken to trace the person and continue regular treatment. If patient cannot be traced within 1 week of the date of defaulting, **please report this patient to NTP immediately** by phone and fax or email without waiting to send as monthly report.

ANNEX 12

National TB Control Programme

Health Protection Agency
 Telephone: 3014494 Fax, 3014484



TB MONTHLY REPORTING FORM (RMC)

Name of the Facility: Respiratory Medicine Clinic

Reporting Period:/...../..... to/...../.....

COUNTS OF TB PATIENT	NP	EP	Under 5 years	5 Years & Above	Total
No of TB Patients on-treatment					
No of TB patients newly registered					
No of patients attending for DOTs treatment					
No of TB patients completed treatment					
No of defaults					
No of patients "Missed treatment"					
No of patients referred to other health facilities					
No of Patients on 2nd line Drug					
No of MDR TB patients					
No of patients on prophylaxis treatment					
No of patients newly started prophylaxis					
No of Contacts identified					
No of Contacts screened					
No of Contacts to be followed up					

Page 1

TB MEDICINES STOCK

DRUGS/COMMODITY	Stock received		During month		Balance
	Date received	Expiry date	Amount used	Expiry date	
TB Kits					
Mantoux					

Page 2