Guidelines for the

CONTROL and MANAGEMENT of TUBERCULOSIS

Version II, 2011, Rarotonga, Cook Islands

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Executive Summary

Tuberculosis (TB) continues to be a public health issue of major significance around the world. 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.[1]

While a great deal of progress has been made in the fight against tuberculosis, the disease still poses a serious and even increasing problem in many low-income countries, affecting the health and social welfare of millions of people. Fighting tuberculosis is a challenge to all who are concerned about health and development.

World Health Organisation, Western Pacific Region comprises 36 countries and areas with a population of 1,641 million. The region contains 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.[2]

Reliable information from small island countries is often scarce. Therefore, little is known on the epidemiological situation of tuberculosis in these Pacific Island countries. Despite the limited information, available data indicate that tuberculosis is common and the treatment of the detected patients is very poor and inadequate.

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.

These guidelines contains a description of tuberculosis, its diagnosis, treatment, implementation of DOTS strategy, the organization and management of tuberculosis and essential services. This edition also addressed the challenges posed by HIV infection, drug-resistant tuberculosis, and provides a clear rationale for the cascade of treatment regimens if there is failure, relapse or return after default from the first course of treatment.

Therefore these guidelines have been developed to assist in the overall management and control of tuberculosis in the Cook Islands.

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1 International Union Against Tuberculosis and Lung Disease *"Management of Tuberculosis: A guide to essential s of good practice, sixth edition 2010"*

2 Secretariat of the Pacific community "*Guidelines for the Control of Tuberculosis in Cook Islands through DOTS strategy 1999*"

Glossary

AFB	-	acid-fast bacilli
AIDS	-	acquired immune-deficiency syndrome
ART	-	antiretroviral treatment
BCG	-	bacille Calmette-Guerin
BMU	-	basic management unit
CPT	-	cotrimoxazole preventive therapy
CTM	-	cotrimoxazole
DOT	-	directly observed treatment
DOTS	-	directly observed treatment short course
EPTB	-	extrapulmonary tuberculosis
FDC	-	fixed dose combination
HIV	-	human immuno-deficiency virus
IGRA	-	interferon-gamma release assay
IRIS	-	immune reconstitution inflammatory syndrome
MDR-TB	-	multidrug-resistant tuberculosis
NTP	-	national tuberculosis programme
PTB	-	pulmonary tuberculosis
TB	-	tuberculosis
WHO	-	world health organization
XDR-TB	-	extensively drug-resistant tuberculosis

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Introduction

Tuberculosis is a great problem in most low-income countries. It is the single most frequent cause of death from a single agent in individuals aged 15 to 49 years. In some countries, especially in sub-Saharan Africa, the human immunodeficiency virus (HIV) is the driving force in the overlapping epidemic with tuberculosis. Activities directed against tuberculosis and HIV as public health problems are the direct responsibility of government health authorities.

In recognition of the association between tuberculosis and HIV in setting where both are frequent, this revision of the [guidelines] contains more information about their interface than previous editions. In recognition of the development of drug-resistant tuberculosis, which may hinder the progress in tuberculosis control, the guidelines considers the implications of drug resistance that my result from treatment with inadequate anti-tuberculosis treatment regimens and expands the discussion on drug-resistant tuberculosis.

The target audience for this guidelines is the person responsible for the tasks at the basic management unit (BMU) of the NTP, often a nurse paramedical professional. While the guidelines itself may not necessarily find its way into the hands of all these individuals, the [aim] is to provide NTPs, and all those who work alongside them, with the basic information concerning the management of tuberculosis services, in the hope that this knowledge can be transferred, adapted to the local situation and provided in the local language to empower those whose responsibility it is to carry out this crucial task of organizing these services at the most basic management level...

In setting out to combat a problem such as tuberculosis, it is essential to have a clear concept of aims and priorities. The *aim* of the fight against tuberculosis are:

- *For a community*: to reduce the spread of tuberculosis micro-organisms and, by the means, to hasten the disappearance of this disease from society;
- *For individual patients:* to cure their disease, to quickly restore their capacity for activities of daily living and to preserve their position in their family and community.

Among the *priorities* of tuberculosis activities, the first is the appropriate *treatment and cure* of tuberculosis patients, especially those patients whoa re the most potent source of transmission of tuberculosis micro-organisms. Because tuberculosis is so frequent, may affect any part of the body and is such a serious disease, it must be a high priority for any practitioner who provides health care in low-income countries, and tuberculosis services must be incorporated into all health services...

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The general population must be mobilized to participate, including patients and community organizations, as well as groups of health professionals. It is important to make clear that tuberculosis is **curable**, that HIV infection can be prevented and treated and that there is no justification for discrimination or stigma.

Community participation is essential to encourage individuals with symptoms suggestive of tuberculosis to present themselves to the health services for diagnostic examination for both tuberculosis and HIV and to ensure that tuberculosis patients continue to take their treatment until they are cured.

While the majority of tuberculosis patients come from the general community, the disease is especially a problem for "high-risk" groups in the population. These groups (the poor, persons incarcerated in detentions centres, those with insecure housing, undocumented migrants and other marginalized groups) are often hard to reach with the usual public health services. They also contribute disproportionately to a cycle of poverty that frequently prevents economic development...

In many countries, non-governmental agencies provide tuberculosis services. They often work under difficult conditions in remote areas where they provide the only medical services available. Their activities should nevertheless always be undertaken in coordination with government offices and must follow the guidelines of the NTP. This especially applies to patients with multidrug-resistant tuberculosis, for whom services should be provided under the direction of the NTP, and not as separate projects by non-governmental organisations or private specialists.

Tuberculosis can only be conquered when all those affected by the disease are cared for by principles that follow the essentials of good practice. As the disease can affect virtually any organ of the body, patients may present at any location where health services are provided. While the ability to improve quality of tuberculosis services depends crucially on the good practice of the managers at the level of the basic management unit, any person providing health services must understand and be able to deliver high quality services for any tuberculosis patient that is encountered.

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National TB Programme

Framework of Cook Islands National TB Programme

Organisation of the Cook Islands health sector is the responsibility of the Ministry of Health. Within the Ministry, the National Tuberculosis Programme (NTP) is situated under the Director of Public Health, who answers to the Secretary of Health regarding all public health programmes.

The NTP office and DOTS Centre for the Cook Islands is based on Rarotonga. The DOTS Centre and NTP staff offices are located at the public health facility in Tupapa. However, TB patients receive diagnostic and treatment services at Rarotonga Hospital in Arorangi.

The NTP Manager, in conjunction with the NTP Coordinator, directly administers all TB services provided through the Cook Islands DOTS programme.

DOTS Programme staff

In Cook Islands, the DOTS treatment team consists of:

- an NTP Manager, based at the DOTS Centre, Tupapa, Rarotonga;
- an NTP Coordinator, also based at the DOTS Centre, Tupapa, Rarotonga;
- Clinical doctors and qualified health staff (i.e. nurse practitioners, public health nurses, inspectors etc) based at each hospital and health facility;
- Laboratory staff based at the Rarotonga laboratories; and
- Pharmacy staff.

[1] Secretariat of the Pacific community "*Guidelines for the Control of Tuberculosis in Cook Islands through DOTS strategy 1999*"

To provide a quality programme, each staff member completes a variety of important tasks as listed below:

NTP Manager

The NTP Manager is a trained medical doctor responsible for overseeing all policy, administrative, and clinical functions of the NTP relating to DOTS. These functions include:

- Liaising directly with the Permanent Secretary of Health 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 supporting the NTP;
    - defining the NTP strategy, including diagnosis and treatment policies, and preparation and updating of TB control guidelines;
    - detection of sputum smear-positive cases through direct and reliable AFB microscopy services;
    - regular and uninterrupted supply of anti-TB drugs through the pharmacy;
    - ongoing DOT during treatment of all identified TB patients;
    - recording of each patient's progress using the standardized reporting system.
- Ensuring adequate support of health staff, including doctors and nurse practitioners at outer island hospitals and clinics, relating to all aspects of the Cook Islands DOTS programme.
- Supervising the NTP Coordinator.
- In collaboration with the NTP Coordinator, monitoring ongoing TB patient treatment during supervisory visits to outer islands hospitals and health clinics.
- Confirming diagnosis and developing an individual treatment plan for each confirmed TB patient.
- Determining the required TB drug supply and working with the pharmacy to ensure that adequate stocks of anti-TB drugs are always available.
- Ensuring proper reporting of all Cook Islands TB cases through the National TB Register and Quarterly Reports on Case Findings and Treatment Outcomes
- Overseeing the development of educational and community awareness materials.
- Implementing recommendations made through specialist reports and regional initiatives regarding the DOTS programme.
- Representing the Cook Islands at regional and sub regional TB-related meetings.
- Providing reporting to the national CCM and technical advice to projects such as GFATM.

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NTP Coordinator

The NTP Coordinator is a qualified health professional with special training in DOTS programme provision. The NTP Coordinator manages the overall NTP and is responsible for the detailed operation of each component of the programme including care of all patients. The NTP Coordinator works under the supervision of the NTP Manager in performing the following tasks:

- Coordinating all TB case referrals to ensure:
    - ensuring all TB suspects referred to the TB Unit for diagnosis from the outer islands complete the diagnostic process;
    - verifying that collection, transport and documentation of all sputum samples follows recommended procedures;
    - checking that sputum samples are examined promptly by the laboratory;
    - ensuring that all smear-positive patients are hospitalized during the intensive phase of treatment.
- Assigning each diagnosed TB case a unique TB number and registering the case in the National TB Register
- Creating a master Treatment Card that includes patient details, exact dosage of medication (based on the NTP Manager's treatment plan) and the dates for each follow-up sputum examination during the course of treatment:
- When patients complete the diagnostic process at the hospital or when hospitalised patients are discharged from hospital to finish their treatment at the village level:
    - preparing a duplicate copy of the Treatment Card and transferring it to the health facility where ongoing treatment will be monitored;
    - checking with the relevant OI TB Coordinator that the health facility has an adequate supply of all drugs and sputum cups required for the remaining course of treatment (see Treatment kit).
- Supervising ongoing treatment of patients on Rarotonga including:
    - dispensing of TB medications;
    - direct supervision and recording of each treatment;
    - coordination of follow-up sputum examinations; and
    - referral to the NTP Manager for an end of treatment clinical exam.
- Working closely with the relevant doctor, or health staff, including the TB Coordinators from other islands:
    - to initiate TB treatment for each TB patient;
    - ensure all patients receive daily directly observed treatment (DOT);
    - ensure referral to the NTP Manager or appropriate medical officer for the end of treatment clinical exam.
- Providing and/or organizing ongoing training and supervision of all staff involved in delivering the NTP on the correct implementation of the DOTS programme

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NTP Coordinator continued..,

- Assisting the NTP Manager in the management of TB drugs.
- Communicating regularly with the relevant OI TB Coordinators to:
    - ensure sputum follow-up exams are conducted as scheduled;
    - receive monthly updates of Treatment Card and TB Register data for patients being monitored at the village level;
    - follow up on referrals and/or transfers;
    - discuss other related issues to ensure an efficient NTP.

- Using the standardised reporting system to record patient progress by:
    - formally updating master Treatment Cards and the National TB Register;
    - cross-referencing data on the TB Laboratory Register (kept at the Rarotonga hospital laboratory) with that on the National Tuberculosis Register (kept at the DOTS Centre) to ensure consistency and that suspects submit the correct number of specimens;
    - ensuring all diagnosed TB patients are registered and receiving appropriate treatment;
    - consolidating the National TB Register and TB Laboratory Register data to produce a data summary and prepare official quarterly reports on case findings and treatment outcomes for submission to the NTP Manager, SPC and WHO

- Conducting regular supervisory visits to OI hospitals, and community health centres throughout Cook Islands to monitor the efficiency of the DOTS programme and verify ongoing direct observation of treatment for each patient.
- Implementing TB control measures in the community including:
    - contact tracing to identify potential TB suspects;
    - use of prophylactic TB treatment when warranted; and
    - preparation and regular dissemination of educational and community awareness materials and activities.

Clinical Doctors

In Cook Islands, medical doctors treat patients at the two OPDs on Rarotonga and at the OI hospitals. These doctors work closely with the NTP Manager and NTP Coordinator to provide TB patients with quality diagnosis and treatment based on DOTS procedures.

In Cook Islands, clinical doctors:

- Perform clinical examinations on TB suspects.
- Confirm TB diagnosis
- Liaise with the NTP or TB Coordinator for sputum specimen collection including completion of the Laboratory Sputum Form for TB Investigation
- Develop an individual treatment plan, in collaboration with the NTP Manager, for each confirmed TB patient and organize initiation of TB treatment using the necessary DOTS process.
- Admit all sputum smear-positive patients and severely ill smear-negative and extra-pulmonary TB patients for inpatient treatment until they are well enough to continue treatment as outpatients
- Decide when hospitalised patients can return home to continue DOT as outpatients or home-based patients with home-delivered treatment
- Maintain regular communication with the laboratory technician and the NTP Manager, and TB Coordinators
- Work closely with the relevant TB coordinator to:
    - monitor TB treatment; and
    - assist with contract tracing in sputum positive households.
- Participate in regular meetings to discuss/review diagnoses of smear-negative and extra-pulmonary TB cases

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Qualified Health Staff

As an integral part of the treatment team, qualified health staff work directly with patients in hospitals and village health facilities. They are specifically trained in the DOTS programme to enable them to be involved in every aspect of TB patient identification and care.

Health staff use their skills to support the DOTS programme by being responsible for tasks that include:

- Identifying and referring TB suspects for diagnosis
- Collecting, labeling, registering and transferring the correct number of specimens for laboratory examination (3 specimens for diagnosis or 2 specimens for each follow-up), using the correct handling and storage procedures so that quality sputum arrives at the Rarotonga laboratory.
- Arranging transport for sputum samples and contacting laboratory staff and the NTP Coordinator to give details of the arrival of sputum samples in Rarotonga.
- Working with the NTP/TB Coordinator to arrange hospitalization for severely ill patients, and if necessary transportation and housing of village patients during their care at Rarotonga hospital.
- Working with the NTP Coordinator and/or the local TB Coordinator for all confirmed TB cases to:
    - supervise the use of the patient's treatment materials, including collection and distribution of medications;
    - directly observe (DOT) patients swallowing their medication 7 days per week;
    - update the patient's Treatment Card each time a TB drug is taken;
    - ensure the patient submits two sputum samples for each required follow-up examination.
- Regularly (on a monthly basis) reporting treatment to the relevant TB Coordinator for updating of the master treatment card.
- Maintaining regular contact with the NTP Coordinator to receive treatment reports for village patients who are away from home during treatment on Rarotonga, and then sharing those reports with family members to keep them informed of treatment progress.
- Attending regular training sessions through the NTP, to keep up to date with the Cook Islands NTP

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Laboratory staff

The laboratory diagnosis of active TB by sputum smear microscopy is crucial to the success of the TB programme in Cook Islands. Therefore, the quality of the service provided by laboratory staff has a major influence on the success of the national TB control programme. Laboratory staff work in a collaborative partnership with medical staff and use their skills to support the DOTS programme by being responsible for tasks such as the following:

- Prompt diagnosis of TB from sputum samples and other specimens using AFB staining techniques, ensuring specimens are reviewed within 7 days of the initial sample being taken.

- Diagnosis of both diagnostic and follow-up TB sputum samples to ensure the appropriate treatment plan can be prescribed for the patient.

- Communication with the referring doctor, chest physician and DOTS Centre for all SS+

- Participation by the national laboratory in ongoing internal and external laboratory quality assurance, as part of the PatLAB initiative including quarterly Blinded Slide Rechecking (BSR) with the Pacific Paramedical Training Centre (PPTC) in Wellington

- Adherence to international standards to ensure a safe laboratory working environment16.

- Ensuring laboratory supplies are adequate and ZN stain is of sufficient quality for diagnostic purposes.

- Ensuring the TB Laboratory Register is accurate and is regularly cross-checked with the National TB Register at the DOTS Centre.

- Monthly reporting of the TB Laboratory Register updates to the DOTS Centre to allow the information to be included in the quarterly reports to SPC and annual reports to WHO.

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Complementary TB control measures

Several preventative measures are followed in Cook Islands to control the spread of TB within the country. These measures include immunization, contact tracing and community awareness.

1.1 Early immunisation

It is compulsory for all infants to be vaccinated against TB (using BCG) at birth. Children with HIV-positive mothers should also be vaccinated if AIDS has been ruled out. All school children have their immunisation verified and updated as necessary, as do new immigrants

1.2 Contact tracing and prophylactic treatment

Tracing the close contacts of every identified infectious TB case, i.e. sputum smear positive cases (known as the index case) is important to stop active transmission in the community. Between 20—30% of all contacts will have TB infection, with 1% having TB disease. Once a patient is diagnosed as smear-positive, and is under treatment, the TB Coordinator from the DOTS Centre conducts household contact tracing to search for any potential carrier and/or to screen possible cross-infection cases.

The extent of contract tracing is based on the likelihood of transmission by the index case and is based on many factors including positive sputum microscopy, cavitations on a chest X-ray, presence of a cough, and behavioural and environmental factors. The patient is no longer infectious after TB DOTS treatment of 2–3 weeks. Any person identified during this investigation as a possible TB suspect is referred to the TB Clinic for an examination including diagnostic tests.

High priority is given to detecting children under 5 years of age who may have come in contact with active TB disease. As recommended by WHO, when active TB has been ruled out, any well child under the age of 5 years living in a household where a smear-positive case has been identified is given a prophylactic treatment of daily doses of Isoniazid for at least 6 months, to prevent the development of TB disease. This is especially important for breastfed children whose mothers are diagnosed as pulmonary TB sputum smear positive.

1.3 Early identification through community education and awareness activities

Based on advice from the DOTS Centre, ongoing community education initiatives are conducted to increase awareness of the disease and reduce the level of stigma associated with TB in the community.

As part of these initiatives, the NTP Coordinator, together with OI TB Coordinators and public health nurses, makes visits to groups within the community, e.g. schools and women‘s committees. As well, a range of TB awareness spots are aired on local television and radio. The goal of these measures is to increase case detection and early identification and treatment.

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Tuberculosis 101

What do we know about this disease?

Patients with tuberculosis can present themselves at any location where health services are provided. Therefore, all those who provide health services need to understand some basic information about this disease.

What is tuberculosis?

Tuberculosis is an infectious disease caused in most cases by a micro-organism called *Mycobacterium tuberculosis.* The micro-organisms usually enters the body by inhalation through the lungs. They spread from the initial location in the lungs to other parts of the body via the blood stream, the lymphatic system, the airways or by direct extension to the other organs.

- *Pulmonary tuberculosis* is the most frequent from of the disease, usually comprising over 80% of cases. It is the form of tuberculosis that can be contagious.
- *Extra-pulmonary tuberculosis* is tuberculosis affecting organs other than the lungs, most frequently pleura, lymph nodes, spine and other bones and joints, genito-urinary tract, nervous system, abdomen or virtually any organ. Tuberculosis may affect any part of the body, and may even become widely disseminated throughout the whole body.

How does tuberculosis develop?

Tuberculosis develops in the human body in two stages. The first stage occurs when an individual who is exposed to micro-organisms from an infectious case of tuberculosis becomes infected (*tuberculosis infection*), and the second is when the infected individual develops the disease (*tuberculosis*).

How are tuberculosis micro-organisms spread?

The likelihood that a patient with tuberculosis may infect another person is determined by the number of micro-organisms within the lungs and their ability to spread into the surrounding air. Patients with pulmonary tuberculosis in whom the micro-organisms are so numerous as to be detectable using a microscope to examine sputum specimens (*smear-positive cases)* are the most infectious cases.

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Those in whom micro-organisms cannot be detected directly under the microscope (*smear-negative cases*) are very much less infectious, and the severity of their disease is usually less than that of the smear-positive cases. *Extra-pulmonary cases* are almost never infectious, unless they have pulmonary tuberculosis as well.

The infectious tuberculosis patient expels micro-organisms into the air in tiny droplets when talking, coughing, laughing or sneezing. These small droplets dry rapidly, become "droplet nuclei" carrying the micro-organisms and may remain suspended in the air of a room for several hours. Any person entering the room may inhale these micro-organism. If the micro-organisms establish themselves in the lungs of the person who inhaled them and begin to multiply, *tuberculous infection* has occurred. Exposure to the micro-organisms is greatest among those in close and prolonged contact with an infectious case (i.e. those living in the same household with a smear-positive patient).

The micro-organisms are rapidly destroyed by exposure to sunlight and their concentration in the air is reduced by good ventilation. Except in the event of close and prolonged contact with an infectious case of tuberculosis, the chance of getting infected from a single contact with a tuberculosis patient is very small. Most individuals who become infected have no symptoms or evidence of illness in association with this infection.

What happens after infection?

Among those who do become infected, most (estimated at 90%) will never become ill with tuberculosis unless their immunity is compromised. The micro-organisms may remain dormant within the body for a long time.

Some individuals who have become infected subsequently develop disease (tuberculosis). They are most likely to develop disease in the months immediately following infection, but continue to experience a risk of developing tuberculosis throughout the remainder of their lives.

Tuberculosis infection does not prevent re-infection. Re-infection may occur and tuberculosis may develop even among tuberculosis patients who have been cured.

How does HIV affect tuberculosis?

Infection with HIV progressively leads to extensive destruction of the immune defense mechanisms of the body. As a result, those infected with HIV become ill with severe and often deadly infections to which persons without HIV infection would not usually be susceptible.

These conditions are called opportunistic infections. Tuberculosis is one such "infection" frequently affecting HIV-infected persons.

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The development of tuberculosis following tuberculous infection is usually prevented by the actions of the immune system; this explains why, in most people, only a relatively small proportion of those individuals who have been infected with tuberculosis micro-organisms go on to be come ill with the disease.

When the protection provided by the immune system is reduced by HIV infection, the tuberculosis micro-organisms (either from new infection, or dormant within the body of an individual who has been previously infected) may begin to multiply, causing tuberculosis. This means that the development of tuberculosis can be a warning sign indicating co-infection of HIV...

What is drug-resistant tuberculosis and how does it develop?

Large populations of tuberculosis micro-organisms always contain some micro-organisms that have spontaneously mutated to become resistant to a drug. Consequently, treatment with a single drug in a patient with a large population of micro-organisms kills those micro-organisms that are susceptible to the drug but allows those that are spontaneously resistant to the drug to multiply.

When the micro-organisms in a patient are resistant to all but one of the drugs that is given to the patient, the treatment has the same effect as if a single drug were being given alone. Resistance to drugs becomes clinically important when the patient has disease caused by a whole population of micro-organisms that are resistant to the drugs essential for treatment. Resistance always begins as a man-made problem, as it is the result of inadequate treatment somewhere along the chain of transmission.

For practical purposes, drug resistance in tuberculosis micro-organisms is divided into resistance in patients who have *never previously been treated for tuberculosis for as much as one month (new patients)*, and resistance in patients who have *previously been treated for tuberculosis for as much as one month (previously treated patients)*.

- In *new patients*, resistance occurs when a patient develops tuberculosis after being infected by another patient who has resistant micro-organisms
- In *previously treated patients*, resistance may have developed during the previous course of treatment with a single drug in patients with smear-positive pulmonary tuberculosis (sometimes referred to as monotherapy), or administration of powerful drugs to a patient harbouring tuberculosis micro-organisms resistant to all but one of the drugs given to the patient.

Micro-organisms with resistance to at least the two most important drugs, isoniazid and rifampicin, are termed *multidrug-resistant* (MDR). The majority of patients with this type of resistance cannot be treated effectively with regimens that use only first-line drugs.

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Unfortunately, in the last few years there has also emerged the problem of extensively drug-resistant tuberculosis (XDR-TB), which is defined as MDR-TB plus resistance to any fluoroquinolone and any of the second-line injectable drugs such as amikacin, kanamycin or capreomycin. Further consideration about the diagnosis and management of XDR-TB is outside the scope of this [guideline].

What is the significance of drug resistance for a tuberculosis programme?

The steady increase in multidrug-resistant tuberculosis in various part of the world over recent years is of great concern.

Although most patients with MDR-TB could be successfully treated with a combination of second-line drugs, the cost of some of these drugs is very high and adverse drug events are frequent, treatment takes a very long time and all drugs must be taken under direct observation.

In recent years an increasing number of countries have included treatment of multidrug-resistant tuberculosis in their National Tuberculosis Programmes (NTPs), since special external funding has been made available. To obtain his external funding, a proposal outlining how patients with MDR-TB will be managed must usually be approved by the Green Light Committee (GLC), a committee of experts in drug-resistant tuberculosis hosted by the world Health Organization (WHO)...

The NTP should set up an effective system for identifying multidrug-resistant cases and providing these few patients with second-line drugs. This is both to ensure cure of all tuberculosis cases and to reduce further spread of resistant strains, as long as the increased cost and workload of services for multidrug-resistant cases do not adversely affect the management of those patients without multidrug-resistant disease and thus produce even more cases of resistance...

The first priority should therefore always be to ensure an effective basic tuberculosis programme so that resistance is prevented. If an effective NTP is in place, treatment of multidrug-resistant patients will have an additional impact in controlling tuberculosis.

How is tuberculosis diagnosed?

Diagnosis is defined as "the process of determining health status and the factors responsible for producing it". In this instance, it means the process by which a health care worker decides that the patient has tuberculosis.

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When should tuberculosis be suspected?

The most frequent symptoms of pulmonary tuberculosis are:

- Persistent cough for 2 weeks or more: every patient presenting with this symptom should be designated a *tuberculosis suspect*;
- Sputum production, which may be blood-stained (haemoptysis), shortness of breath and chest pain;
- Loss of appetite and loss of weight, a general feeling of illness (malaise) and tiredness (fatigue), night sweats and fever.

Any patient presenting with any of these symptoms should be suspected of having tuberculosis. If the patient is, or was, in contact with a patient with infectious tuberculosis, such a person is even more likely to be suffering from tuberculosis.

Symptoms of extra-pulmonary tuberculosis depend on the organ involved. Chest pain from tuberculous pleurisy, enlarged lymph nodes and sharp angular deformity of the spine are some of the presenting symptoms or signs of extra-pulmonary tuberculosis.

Among whom is tuberculosis most likely to be found?

Tuberculosis cases are most frequently found among the following:

- Patients who present themselves on their own initiative at a health facility with symptoms suggesting tuberculosis;
- Those (especially children and young adults) living in the same household with smear-positive patients
- Those infected with HIV;
- Those found to have an abnormality that has the appearance of tuberculosis when a chest radiograph has been taken for clinical investigation of a sick patient.

Tuberculosis will be detected most efficiently where health care providers and community members are highly aware of the symptoms suggestive of tuberculosis.

How is a diagnosis of tuberculosis confirmed?

A diagnosis is proposed by the health care worker after considering the history given by the patient (the symptoms) and the evidence resulting from physical examination of the patient (the signs).

The process of diagnosis involves identifying the most likely condition to explain the symptoms and signs and listing other conditions that might explain the symptoms (the differential diagnosis). A variety of tests are conducted to confirm the diagnosis.

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What is the value of bacteriology?

Each individual suspected of having tuberculosis, regardless of HIV status, must have an examination of sputum to determine whether or not that individual has infectious tuberculosis. Sputum examination must be carried out before starting treatment. The examination consists of microscopic examination of a specimen of sputum that has been spread on a slide and stained by the Ziehl-Neelsen or fluorescence method (smear microscopy).

If micro-organisms (frequently referred to as acid-fast bacilli or AFB) are detected by this method, the patient is said to have smear-positive tuberculosis. Smear microscopy is currently the only means by which the diagnosis of tuberculosis can be confirmed in the majority of patients in most low-income settings.

It is also important to carry it out because it efficiently identifies those cases that are most infectious. Whenever tuberculosis is suspected, at least two specimens must be collected for examination by microscopy. Whenever possible, they should be obtained within 24 hours, as follows:

First specimen. During the patient's first visit, a specimen is collected on the spot; this specimen is obtained, after coughing and clearing the back of the throat, under the supervision of a health care worker, in a well-ventilated area, preferably in the open air. Obtaining a spot specimen implies that, before the patient leaves the health facility at the end of the consultation, a specimen has been obtained for submission to the laboratory.

Second specimen. The patient is then given a sputum container for collection of an early morning specimen before the second visit, which should be on the next working day.

One positive smear result is sufficient to register the patient as a sputum smear-positive patient and to start treatment. If the first spot specimen is positive and if the patient does not return for the second visit, a search must start immediately to find and enroll the patient on treatment, thus preventing further transmission of micro-organisms in the community and deterioration of the patient's condition.

It is reasonable to routinely examine only two specimens, rather than three. This , however, should be determined as policy by the authorities of the NTP and not decided individually.

Those patients whose sputum smears are negative but who are thought to have tuberculosis should be reviewed by a medical officer prior to commencing treatment. The Medical officer may wish to proceed in the following manner in order to determine whether or not the patient actually has tuberculosis, prior to commencing treatment. If chest radiography is available, it may be performed.

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If chest radiography is available, it may be performed. If the chest radiograph demonstrates shadows in the lung fields consistent with a pulmonary infectious disease, a course of broad spectrum antibiotics may be given. If the patient continues to show symptoms after completion of the antibiotics, a second series of two sputum smear examinations may be performed and, if still negative, the medical officer may choose to treat the patient for tuberculosis and record the patient as a case of smear-negative pulmonary tuberculosis.

The 'Trial of treatment', whereby the response of a patient to a short period to antituberculosis treatment is used to decide whether or not the patient has tuberculosis, is poor practice and should not be done.

Is X-ray useful?

Diagnosis by means of radiographic examination in patients suspected of tuberculosis presents a challenge. Abnormalities identified on a chest radiograph may be due to tuberculosis or to a variety of other conditions and the pattern o the radiograph is not specific for tuberculosis. Some individuals who have previously had tuberculosis that is now healed (and therefore does not require treatment) may have a chest radiograph that resembles tuberculosis requiring treatment. Chest radiographs may be helpful in those patients who are not sputum smear-positive, but they can only be read reliably by an experienced Medical Officer.

What about the tuberculin test?

A tuberculin skin test is sometimes used by health care workers to help in the diagnosis of tuberculosis. The response to the intradermal injection of tuberculin is read 48-72 hours later, requiring the patient to revisit the clinic after the injection as administered.

The interpretation of a test result is often very difficult, as a positive test may be caused by conditions other than tuberculosis and a negative test does not always rule out tuberculosis. Furthermore, tuberculin is not routinely available in many peripheral health institutions. It is expensive, has a very short shelf life, must be kept protected from light and heat, and requires some technical skill in administration and reading.

Thus, in most instances, health care workers are forced to work without this test. A significant reaction to the test indicates the presence of infection but cannot indicate whether or not the patient has the disease. Many patients with advanced immuno-suppression related to HIV will fail to react to the test even when they have the disease.

Interferon-gamma release assays (IGRAs) have recently been proposed as a possible solution to some of the problems encountered with the tuberculin skin test. They are more specific than the tuberculin skin test, particularly in people who have received BCG, and they require only one visit by the patient.

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However, like the tuberculin skin test, they cannot distinguish between infection and disease. The tests are costly, they require specific laboratory equipment and there is a need for a venous blood sample to be drawn. Currently, there is no evidence to support the use of IGRAs in routine practice.

How is tuberculosis diagnosed in children?

Diagnosis of tuberculosis in children is difficult. It is even more difficult in HIV-positive children or in infants (whose own HIV status cannot easily be confirmed even when their mothers are HIV-positive). Great care should be taken to rapidly identify serious forms of tuberculosis such as disseminated tuberculosis, tuberculous meningitis, spinal tuberculosis and tuberculosis in immunosuppressed children. These can be life-threatening conditions and they require prompt diagnosis and treatment if death or disability is to be avoided.

This is especially true in very small children (under 2 years of age), and particularly in children who have been in contact with smear-positive pulmonary tuberculosis patients.
In the majority of instances, however, childhood tuberculosis is a mild disease. Nevertheless, children with tuberculosis should be treated to prevent complications an to ensure that they do not subsequently develop tuberculosis from reactivation of their infection.

Only a very small proportion of children have tuberculosis that is smear-positive, and many children cannot produce sputum for examination. The points of most importance in determining a diagnosis in children, in order of priority, are:

- A history of contact with a case of infectious (sputum smear-positive) tuberculosis, particularly in the same household;
- An abnormal chest radiograph showing unilateral and sometimes bilateral lymphadenopathy and/or shadows in the lung field indicating infiltration.

In the absence of the above, it is less likely that the child has tuberculosis.

Any child under 5 years of age in contact with a smear-positive case who is not perfectly healthy must be carefully evaluated by a competent Medical Officer to decide if tuberculosis is present. If the child has signs or symptoms suggesting tuberculosis, it should be assumed that the child has tuberculosis, and the child should be given a full course of treatment. Those children under 5 years of age in contact with a smear-positive case of pulmonary tuberculosis who are perfectly healthy should be considered for preventive chemotherapy.

Who should be considered to be a case of tuberculosis?

Any person diagnosed with tuberculosis should be recorded as a case. Those who have tuberculosis micro-organisms visible on microscopic examinations of sputum should be

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recorded as *smear-positive.* All other cases should be recorded in such a way as to distinguish them from smear-positive cases (*as sputum smear-negative or as sputum smear-negative extrapulmonary cases).*

All those with a positive smear recorded in the laboratory register and for whom no record has been made in any tuberculosis register should be entered into the register and evaluated with all other patients even when they are given no antituberculosis treatment at all.

This includes all tuberculosis patients who never return after the sputum specimen has been examined, those who die before the start of treatment and all patients who start treatment for tuberculosis in hospital but cannot be traced after leaving the hospital.

How does HIV infection influence the diagnosis?

Tuberculosis is one of the most frequent opportunistic disease in HIV infected individuals in countries where both diseases are prevalent. Tuberculosis can occur at any stage during the course of HIV infection. In early HIV infection, when the immune defense mechanisms of the body are almost normal, tuberculosis presents with symptoms and signs that are similar to the symptoms and signs in an HIV-negative tuberculosis case, and a high proportion of cases in adults are smear-positive.

However, when HIV infection progresses and the immune defense mechanisms of the body weaken, the presentation of the case may be unusual, and extra-pulmonary forms are more frequent. In these cases, the clinical presentation may be quite different from what is expected and sputum smear examination may be more frequently negative.

It should be noted that individuals with advanced destruction of immune defense mechanisms may be symptom-free for some time, even though tuberculosis micro-organisms can be seen in their sputum. Some of these patients do not have chronic cough; some may present with non-specific symptoms, such as loss of weight and chronic fever; chest radiographs may have abnormal shadows in lung fields or intra-thoracic lymphadenopathy or they may be normal.

Although the appearance of tuberculosis varies according to the degree of destruction of the immune defense mechanisms in the body, positive smears still occur among those infected with HIV. Thus, sputum smear examination plays a vital role in the diagnosis of tuberculosis even in those countries where HIV infection is frequent. If the sputum examination is performed correctly, the majority of patients with pulmonary tuberculosis and HIV infection will be found to be smear-positive. Thus, the most contagious cases can be diagnosed rapidly.

Patients who are not sputum smear-positive must be offered treatment. However, other tests beyond the scope of this guidelines would be required to confirm their diagnosis. If

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these tests are not currently available, the diagnosis must be confirmed by a Medical Officer before treatment is initiated.

How do we know if a patient has drug-resistant tuberculosis?

The confirmation of the diagnosis of tuberculosis in most countries is based on sputum smear microscopy. To detect resistance and to exclude disease caused by other mycobacterium, other methods for species identification and drug susceptibility testing are needed. These methods are complex, slow and expensive, and are not widely available in most countries or are used only for specific patient groups (for example, those with a high risk of multidrug resistance).

In virtually all patients, even where drug susceptibility testing is available, treatment must be started without knowledge of the susceptibility of the micro-organisms to the drugs.

If drug resistance is already present, there is a possibility that the treatment might create more resistance. The recommendations put forward in this guidelines are developed specifically to prevent this from occurring. Changes to the recommendations may compromise their ability to reduce the possibility of promoting further resistance. However, when the recommendations are strictly followed, tuberculosis can be successfully treated in the vast majority of cases, without knowledge of the susceptibility patterns of individual patients and without promoting drug resistance.

The measurement of drug resistance is an important topic, but the details of how this is carried out are beyond the scope of this guidelines.

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Treatment (AntiTB drugs & regimens)

The main source of TB 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. Left untreated, 50% of patients with pulmonary TB will die within 5 years. If poorly treated, TB patients become chronic cases who live longer, spreading 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 essential to ensure that the patient completes the full course of treatment.

The treatment of TB consists of an initial intensive phase (which lasts from 2 to 3 months depending on TB type) using multiple drugs followed immediately by a 4–5 month continuation phase, using fewer drugs. Usually the level of bacteria in the sputum decreases rapidly in the first 2 weeks, with most active cases becoming non-infectious after 2–3 weeks of treatment.

Recommended anti-TB drugs

The following table (Table 1) lists the anti-TB drugs that are currently recommended and a suggested range of doses in mg/kg. An additional table detailing the dosage forms and strengths of these anti-TB drugs. Specific combinations and doses are detailed below.

Table 1: Essential anti-TB drugs and recommended daily doses

Anti-TB drugs (abbreviation)	Doses in mg/kg (range)	Contraindications
Isoniazid (H)	5 (4–6)	
Rifampicin (R)	10 (8–12)	
Pyrazinamide (Z)	25 (20–30)	
Streptomycin (S)	15 (12–18)	Streptomycin should not be given to pregnant women; for patients more than 50 years of age, 750 mg should be given.
Ethambutol (E)	15 (15–20)	Ethambutol should not be given to children under 6 years of age.

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. The symptoms of the most common adverse effects of anti-TB drugs.

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Treatment categories and regimens

There are currently several treatment regimens that are effective in curing different types of TB. However, to facilitate field operations and drug management, given conditions in the Pacific Islands, only three treatment regimens are recommended (Table 2). A treatment category, which includes a specific group of TB patients, corresponds to each treatment regimen. A fourth category – Chronic and MDR-TB Cases – is also listed in Table 2, but a definite treatment regimen has not been specified for this category as treatment drugs and doses must be carefully determined on an individual basis.

Treatment Category I includes new PTB sputum smear-positive cases 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 extra-pulmonary cases, which are both less severe types of the disease.

Table 2: Recommended treatment categories by type of patient, treatment regimen and phase

Treatment category	Type of patient	Intensive phase		Continuation phase	
		Drugs	Duration	Drugs	Duration
I	– New pulmonary smear-positive TB – New severe forms of both pulmonary smear-negative – And extra-pulmonary TB*	2HRZE **	2 months daily	4HR	4 months daily
II	Re-treatment of pulmonary smear-positive cases – Relapse – Treatment failure – Treatment after interruption (TAI)	2HRZES 1HRZE	3 months daily with S given only for the first 2 months	5HRE	5 months daily
III	Less severe forms of both pulmonary smear-negative and new extra-pulmonary TB	2HRZ	2 months daily	4HR	4 months daily
IV	Chronic and MDR-TB cases (still sputum-positive after supervised re-treatment)	Individualized treatment regimens, determined on a case-by-case basis, are prescribed by the clinician 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 drug indicates the duration in months of its administration.

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Treatment doses for adults and children

Whenever possible, to prevent drug resistance and improve patient compliance, FDCs of anti-TB drugs should be used. Examples of different FDCs for the three treatment categories, for children and adults. The following tables give examples of daily dosages for children and adults when loose drugs are used.

Treatment Category I for new case adults

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

Adult	Intensive phase (2 months daily)				Continuation phase (4 months daily)	
Patient weight (kg)	Rifampicin 300 mg	Isoniazid 300 mg	Pyrazinamide 500 mg	Ethambutol 400 mg	Rifampicin 300 mg	Isoniazid 300 mg
30–37	1	½	1 ½	1 ½	1	½
38–54	1 ½	1	2 ½	2	1 ½	1
55–70	2	1	3 ½	3	2	1
71–90	2 ½	1 ½	4	3 ½	2 ½	1 ½

Treatment Category I for new case children

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

Paediatric	Intensive phase (2 months daily)				Continuation phase (4 months daily)	
Patient weight (kg)	Rifampicin 150mg	Isoniazid 100mg	Pyrazinamide 500mg	Streptomycin 1g	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	1 ½	1	1 ½	0.50	1 ½	1
25–29	2	1 ½	1 ½	0.50	2	1 ½

*Doses may be calculated ad hoc by using syrup formulation

Note: Ethambutol as used with Category I and II adults is not included in paediatric therapy. It should not be given to children under 6 years of age.

Treatment Category II for re-treatment case adults

(relapses, failures, treatment after interruption/default)

Adult	Intensive phase (3 months daily)					Continuation phase (5 months daily)		
Patient weight (kg)	Rifampicin 300mg	Isoniazid 300mg	Pyrazinamide 500mg	Ethambutol 400mg	Streptomycin 1g*	Rifampicin 300mg	Isoniazid 300mg	Ethambutol 400mg
30-37	1	½	1 ½	1 ½	0.50	1	½	1 ½
38-54	1 ½	1	2 ½	2	0.75	1 ½	1	2
55-70	2	1	3 ½	3	1	2	1	3
71-90	2 ½	1 ½	4	3 ½	1	2 ½	1 ½	3 ½

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

Treatment Category III

(new pulmonary smear-negative – other than in Category I, new less severe forms of EPTB)

Adult	Intensive phase (2 months daily)			Continuation phase (4 months daily)	
Patient weight (kg)	Rifampicin 300 mg	Isoniazid 300 mg	Pyrazinamide 500 mg	Rifampicin 300 mg	Isoniazid 300 mg
30–37	1	½	1 ½	1	½
38–54	1 ½	1	2 ½	1 ½	1
55–70	2	1	3 ½	2	1
71–90	2 ½	1 ½	4	2 ½	1 ½

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Issues to consider in special situations

WHO recommends additional consideration when treating TB patients in any of the following special situations.

Pregnant women:
Before starting TB treatment, a woman should be asked whether she is pregnant. The four basic anti-TB drugs – isoniazid, rifampicin, pyrazinamide and ethambutol – are not teratogenic and are safe to use during pregnancy. The exceptions are streptomycin and other aminoglycosides, which are potentially ototoxic to the fetus (i.e. could damage hearing). These 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 the 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 anti-TB drugs are compatible with breastfeeding; a woman taking them can continue to breastfeed safely. Mother and baby should stay together, with the baby continuing to be breastfed in the normal way.
The baby should be given prophylactic isoniazid for at least 3 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 TB in children is difficult. The Mantoux tuberculin skin test (MST) can be used to aid the diagnostic process.
The following guidelines should be used at the clinician's discretion:
Children younger than 5 years - MST results - induration of 5mm or greater is considered positive
Children older than 5 years - Irrespective of BCG history, MST results with an induration of at least 10mm is considered positive

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 clinician to choose the better of the following two options to use 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.

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Issues to consider in special situations

WHO recommends additional consideration when treating TB patients in any of the following special situations.

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.

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 or excessive alcohol consumption. However, hepatotoxic reactions to anti-TB 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 this regimen, the total treatment duration is 8 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:

- SHRE/6 HR, or
- SHE/10 HE.

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

It is uncommon for a patient to contract TB and acute viral hepatitis at the same time10. However patients may develop acute viral hepatitis during the course of TB treatment. Clinical judgement is necessary. 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 3 months is the safest option.

If the hepatitis has resolved, the patient can then receive a continuation phase of 6 months isoniazid and rifampicin (3 SE/6 HR). If the hepatitis has not resolved, SE should be continued for a total of 12 months (12 SE).

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Issues to consider in special situations

WHO recommends additional consideration when treating TB patients in any of the following special situations.

Patients with renal failure

Isoniazid, rifampicin and pyrazinamide are either eliminated almost entirely by biliary excretion or metabolized 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 to prevent peripheral neuropathy.
Streptomycin and ethambutol are excreted by the kidney so should be avoided. 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 2 HRZ/6 HR.

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.

Patients with seizure disorders

Isoniazid (H) is associated with an increased risk of seizures in some people. In epileptics taking phenytoin concurrently with H, phenytoin will accumulate in the body. H has also been reported to significantly increase levels of carbamazepine when the two are used together. Pyridoxine 10 mg daily should be given to all epileptics taking H, to reduce the risk of seizures. Rifampicin also has serious interactions with anti-epileptic drugs, particularly carbamazepine, phenytoin, and sodium valproate. Serum drug levels should be closely monitored during TB treatment

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Treatment kit

A treatment kit should be made available for each confirmed TB patient to help ensure that:

- treatment is recorded properly,
- drug swallowing is observed by trained staff and
- TB drug supplies are available throughout the entire treatment duration

The treatment kit contains all the medications necessary to complete the intensive and continuation phases of the treatment. It also contains two sputum cups, the patient treatment card and patient information sheet

TB Treatment Kit

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

- medications for intensive and continuation phases
- sputum cups
- treatment card
- patient information sheet

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

Global Drug Facility

The Global Drug Facility (GDF) is a Stop TB Partnership initiative to improve access to high-quality TB drugs for national DOTS strategies. The GDF aims to resolve the problems faced by many developing countries, such as lack of resources, inadequate drug quality control, inefficient procurement of TB drugs, non-adherence to international recommendations and inadequate in-country management and monitoring of the TB drug supply.

The focus of GDF is to provide standardised TB drug treatment regimens, with an emphasis on FDCs, often supplied as TB drug treatment kits, to ensure adequate drugs are available for every TB patient for their entire treatment. It is envisaged the GDF will strengthen national DOTS strategies by improving the availability and quality of TB drugs and reducing the cost of those drugs, thereby preventing new strains of drug-resistant TB and ultimately improving outcomes for TB patients.

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Sputum smear examinations to monitor patient progress

Patients with sputum smear-positive pulmonary TB should be monitored routinely by sputum smear examination, to determine the response to TB treatment12. The usual method of follow-up for patients with sputum smear-negative pulmonary and extra-pulmonary TB is by clinical monitoring.

The intervals for diagnostic and follow-up sputum samples are summarized below

New cases sputum smear-positive (Category I)	Re-treatment 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.	At the end of 4 months ONLY if sputum at 3 months was still positive.
At the end of 5 months.	At the end of 7 months.

Results of all sputum examinations should be documented in the laboratory in the 'Laboratory Register' as well as entered, in a timely manner, in the TB Register at the DOTS Centre.

Treatment outcomes

When treatment is complete, TB patients are referred for final assessment to the DOTS Centre where they were originally diagnosed to determine the treatment outcome. The treatment outcome is based on a clinical assessment, sputum microscopy (for pulmonary TB cases still producing sputum) and frequently X-ray. Once decided on, the treatment outcome is subsequently recorded in the TB Register. Usually, the patient is assigned an outcome before stopping their anti-TB drugs. The types of treatment outcomes are outlined below.

TREATMENT OUTCOMES*

Cured
Patient who was smear-positive at diagnosis and became smear-negative at or 1 month before the completion of treatment, and 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 becomes smear-positive again at 5 months or more during treatment.

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

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

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

* 'Treatment outcomes' refers to the results of patients' treatment.

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Recording & Reporting

Regular recording and reporting of information is an integral part of each DOTS programme and enables monitoring of all levels of the programmes, i.e. from the success of TB treatment on an individual level to the overall success of the national DOTS programme.

Emerging issues such as MDR-TB can be detected and TB trends can be compared on a national, regional and global level.

The records and reports required in a DOTS programme are listed below:

- **National TB Register:** information on all patients receiving TB treatment in the country
- **Laboratory Register:** formal record of the number of TB suspects
- **Laboratory Specimen Form for TB Investigation:** enables patient tracking during microscopy diagnosis
- **Patient TB Treatment Card:** complete record of all TB treatment received by patient
- **TB Referral/Transfer Form:** formal documentation to ensure treatment continuity for patient transferring to another country

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[1] Secretariat of the Pacific community "*Guidelines for the Control of Tuberculosis in Cook Islands through DOTS strategy 1999*"

Infection control

The following are the key priorities of infection control to prevent airborne transmission of TB infection to other patients, staff and visitors:

- **Appoint Infection Control Officer to implement and monitor IC measures**

- **Ensure daily direct observation of all treatment**
  Keep record to verify
  Poor adherence to treatment will risk drug resistance and an untreatable infection

- **Patient placement**
  Advise patient of reasons for isolation
  Isolate the TB patient until considered non infectious
  Separate from immune-suppressed patients e.g. HIV patients
  The room should have natural ventilation and the door a "Stop Sign" to limit people going in and out of the room
  There are no special requirements for linen

- **Patient behaviour**
  Cough hygiene – advise patient to cough into a disposable tissue and provide a plastic bag for disposal
  Encourage daily outdoor activity
  Patient movement outside their room should be supervised and a surgical mask worn unless outdoors

- **Sputum collection**
  Sputum specimens should be collected in a private outdoor area with good natural ventilation (not in a toilet area)

- **Visitors**
  Visits by family or close friends should occur in an outdoor area especially young children

- **Staff protection**
  Staff entering the patients room should ideally wear an N-95 standard mask, these masks require a good face seal
  Surgical masks do not provide adequate protection
  Unvaccinated or immune-compromised staff should not be involved in the patient care

- **Staff education**
  Staff should be informed about the measures required to protect other patients, visitors and staff

Contact tracing

1. Introduction

The primary focus of all National Tuberculosis (TB) Programmes is to detect infectious cases early and to supervise their treatment with the aim of curing the patient and minimizing the extent to which the infection is transmitted.

A National TB Programme that is functioning effectively and uses the international recommended TB control strategy Directly Observed Treatment, Short-course (DOTS) is essential to underpin this objective.

Investigation of the closest contacts of a person with infectious TB is the next priority, as this process can identify a significant number of new cases of TB in an accessible group where high rates of recent infection are expected.

Despite recommendations to implement contact tracing activities, many National TB Programmes do not do so. In many cases the reasons relate to limited resources and a lack of trained staff.

Other issues that can make it more difficult to implement a contact tracing programme include difficulties in detecting active TB in the early stages (particularly in children), the imprecision of tuberculin (Mantoux) skin testing in detecting recent TB infection in a population vaccinated with Bacille Calmette-Guérin (BCG) and the extended duration of isoniazid preventive therapy.

2. Rationale

The World Health Organization (WHO), the International Union Against Tuberculosis and Lung Disease (IUATLD) and the International Standards for Tuberculosis Care (ISTC) recommend as a minimum:

- screening household and close contacts of smear positive pulmonary tuberculosis cases to detect new TB cases; and

- for children under five years of age and for all people with HIV without symptoms suggestive of TB, providing isoniazid preventive therapy (IPT).2 3 4 7

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1 Secretariat of the Pacific community *"Guidelines for tuberculosis contact tracing in Pacific Island countries and territories, 2010"*, *Richard Stapledon and Kerri Viney*

In addition, it is important to closely follow up contacts of patients with multidrug-resistant tuberculosis (MDR-TB) or extensively drug-resistant tuberculosis (XDR-TB) in order to prevent further spread of drug-resistant TB.

If resources exist in an effectively functioning and well-resourced DOTS programme, then screening can be more extensive to determine and treat other close contacts.
Part of the rationale for these recommendations is to detect additional cases of TB, as a way of preventing ongoing transmission of TB, both in the household and in the community.

In addition, young children living in the same household as a person with smear positive pulmonary TB are more susceptible to being infected with TB and subsequently developing severe forms of TB disease such as meningitis. Infected children under five years of age, in particular those in the first year of life, have a high risk of progression to TB disease.

The use of preventive therapy has been shown to be effective in significantly limiting the risk of future disease.8 People with HIV infection have a significantly higher risk of progressing from latent to active TB than those who are HIV negative, and isoniazid can decrease the risk of progression from latent to active TB by as much as 33%.

A systematic review of contact tracing activities in low and middle-income countries showed that when an average of 4.4 household contacts per index case were investigated, 4.5% of all evaluated household contacts had active TB.

The implication of this finding is that, to identify one case of active TB, contacts in approximately five households need to be screened. In the same study, latent TB infection was found in just over half (51.4%) of all contacts evaluated and the median number of contacts evaluated to find one case of latent TB was two.

The highest proportion of active TB was found in children under five years of age, which supports the recommendation to prioritize contact tracing in this age group (Table 1).
The results of this review suggest that contact tracing in low and middle-income countries is an important strategy to detect additional cases of TB.

Table 1: Yield of contact tracing by age group in low- and middle-income countries

Age group	TB* (%)	Latent TB infection^ (%)
< 5 years	8.5	30.4
5–14 years	6.0	47.9
All < 15 years	7.0	40.4
Adults (>15 years)	6.5	64.6

Notes
* Proportion of examined contacts with clinical and confirmed TB
^ Proportion of examined contacts with latent TB infection
Source: Morrison et al. 2008. Tuberculosis and latent tuberculosis infection in close contacts of people with pulmonary tuberculosis in low-income and middle-income countries: a systematic review and meta analysis. Lancet Infectious Diseases 8: 359–368

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3. Transmission of TB

Mycobacterium tuberculosis is an airborne pathogen that is transmitted from someone with infectious TB to susceptible contacts via shared air.11 When a person with infectious TB coughs or sneezes they expel tubercle bacilli in airborne droplet nuclei into the air, which can then be inhaled by those in close contact with the case.

The risk of acquiring TB infection is related to the intensity and duration of exposure to a person with infectious TB. Therefore, close contacts of people with infectious TB, particularly contacts who live in the same house, are at the highest risk of acquiring TB infection.

For this reason the focus of these guidelines is on screening household contacts of infectious TB cases although in some situations other contacts outside of the household may also be at risk of developing TB due to their exposure to the index case.

Each case needs to be assessed on an individual basis and contacts beyond the household may need to be screened if their contact was close and prolonged.

4. Assessing Infectiousness

In settings with limited resources, contact tracing is limited to highly infectious cases only. Cases with a high degree of infectiousness have one or more of the following:

- sputum smear positive pulmonary TB;
- symptoms suggestive of TB, with a cough;
- cavities on the chest x-ray (usually these people have a positive sputum smear as well); and/or
- laryngeal TB.

Contact tracing for less infectious cases (i.e. sputum smear negative pulmonary TB) is not recommended in settings with limited resources.

5. Definitions of Index Case and Contacts

The person who has infectious TB is called the index case. More specifically, for the purpose of these guidelines, an index case is a person with sputum smear positive pulmonary TB. This includes new and retreatment cases.

People identified as having been in close contact with an index case are called contacts. Within this category are two more specific groups:

- A household contact is someone who has lived in the same household as the index case during the infectious period, especially in the three months before treatment began.

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- A close contact is someone who has had close and prolonged contact with the index case during the infectious period. Close contacts may not live in the same household as the index case on a permanent basis but they have spent significant amounts of time with the index case during the infectious period.

  There is no precise amount of time used to define a close contact and the international literature contains little information on this point. To determine the threshold for du ration of exposure, consider the characteristics of the index case, the setting and the risk factors in the contact.

6. Decision to Initiate Contact Tracing

At a national level, the decision to initiate contact tracing is based first on the ability of the National TB Programme to undertake contact tracing activities in addition to the essential tasks of identifying TB cases and treating them successfully. Once this decision has been made, a decision to initiate contact tracing for any individual TB case is based on the level of infectiousness of the index TB case and the characteristics of the contacts.

If the index case is a child aged under 10 years, contact tracing is not recommended as children of this age rarely transmit TB. If, however, the child has sputum smear positive TB then contact tracing should be carried out.

A diagnosis of TB in a child usually indicates there has been transmission from an infectious adult; therefore the objective of contact tracing for index cases who are children may be to find the source of the child's infection.

This is sometimes referred to as a source case investigation and involves asking household and other close contacts if they have signs and symptoms of TB, in an attempt to find the person who may have infected the child.

7. Determining the Infectious Period

- It is important to determine the infectious period of the index case so that all contacts who may have been infected with TB can be identified.

- The infectious period should begin three months prior to the commencement of TB treatment. In some circumstances (i.e. prolonged infectiousness due to lack of Directly Observed Therapy (DOT), non-adherence or drug resistance), use an earlier start date.

- The infectious period ends three weeks after the initiation of TB treatment, if TB symptoms have improved.

8. Identification of Contacts

To identify household and other close contacts, interview the index case soon after diagnosis (within one week is recommended). Conduct the interview in hospital or the pa-

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tient's home depending on the context.

If resources permit and the patient agrees, staff might also visit the patient's home as a means of assessing the environment and potentially identifying additional contacts who may be at risk of acquiring TB.

Ideally, the person interviewing the index case should be familiar with the social and cultural context of the index case. Results of the interview should be accurately recorded on a standardized form.

During the interview, it is crucial to maintain confidentiality at all times, with respect to both the identity of the index case (if required) and the details of the contacts. The interview focuses on gaining the details of household contacts who have lived with the index case in the infectious period. In addition, if other non-household contacts have a similar level of exposure, these contacts may also be part of the contact tracing investigation.

9. Assigning Priorities to Contacts

The International Standards for TB Care state that priorities for contact investigation are determined by establishing the likelihood that a contact:

- has undiagnosed TB;
- is at high risk of developing TB if infected;
- is at risk of having severe TB if the disease develops; and
- is at high risk of having been infected by the index case2

Therefore, the highest-priority household contacts are:

- people with signs and symptoms suggestive of TB;
- children aged under five years;
- contacts with known or suspected immune-compromising conditions (in particular HIV infection, but certain other conditions are also a high priority); and
- contacts of patients with MDR or XDR-TB2 (Table 3).

Other household and/or close contacts can be screened, but have a lower priority than contacts in the four groups identified as highest priority. If resources do not permit any wider screening, these four groups remain the priority.

National TB Programme staff should evaluate contacts with symptoms suggestive of TB as a priority. An analysis of contact tracing studies in low and middle-income countries

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showed that 4.5% of household contacts of an infectious TB case also had active TB.9 Diagnosing and effectively treating active TB in close contacts of an index case should reduce ongoing transmission of TB, both in the household and in the wider community.

Children aged under five years are another priority group for contact tracing. They are prioritized because they are at substantially higher risk of more severe (and sometimes fatal) forms of TB disease as a result of recent TB infection.

People with immune-compromising conditions are also at greater risk of progressing from TB infection to TB disease.9 In particular, people with HIV have a significantly higher risk of progressing from latent TB infection to active TB disease.

HIV is the most powerful factor known to increase the risk of TB and people with HIV have approximately a 50% lifetime risk of developing active TB.9 Other groups with any condition that compromises immunity (e.g. cancer, diabetes mellitus) are another priority for contact tracing and should be screened as a matter of priority. In the Pacific context where HIV prevalence is low, other groups with immune-suppressing conditions (e.g. diabetes mellitus) can be part of routine contact tracing activities, if there are sufficient resources.

National TB Programme staff should closely evaluate contacts of patients with MDR- and or XDR-TB to determine if there are other additional cases of active TB that may also be drug resistant. Contact tracing for drug-resistant cases is the highest priority; in particular, index cases with XDR-TB represent an emergency for which contact tracing is of utmost urgency.

Table 3: International Standards for TB Care: Standards for public health: Standard 18

ISTC: Standard 18
All providers of care for patients with tuberculosis should ensure that persons (especially if symptoms suggestive of TB, children under 5 years of age, persons with HIV infection, and contacts to MDR/XDR) who are in close contact with patients who have infectious tuberculosis are evaluated and managed in line with international recommendations. The determination of priorities for contact investigation is based on the likelihood that a contact: 1. has undiagnosed TB 2. is at high risk of developing TB if infected 3. is at risk of having severe TB if the disease develops 4. is at high risk of having been infected by the index case.

Source: Tuberculosis Coalition for Technical Assistance. 2009. International standards for tuberculosis care.

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Table 3: Priorities in contact tracing: people at greatest risk of acquiring TB infection and developing TB disease

At greatest risk of acquiring TB infection
• Close contacts of smear positive pulmonary index cases • People with HIV infection • People who are highly exposed
At greatest risk of developing active TB
• Children < 5 years of age • People with HIV infection • People with other conditions that suppress immunity

Source: Tuberculosis Coalition for Technical Assistance. 2009. International standards for tuberculosis care.

10. Evaluation of Contacts

Ideally, all contacts will be identified and evaluation will commence within 14 days after diagnosis of the index case.

The scope of contact tracing will differ in different settings. In some Pacific Island countries and territories, tuberculin skin testing is used routinely, while in others this method is not available. Even within a country or territory, areas or provinces may vary in the methods used and resources that are available for contact tracing.

The local context will dictate whether and where to use tuberculin skin testing and other tests for latent TB infection (such as interferon gamma release assays). In addition, chest x-ray facilities may be available in some areas and not in others.

A minimum standard for contact tracing will occur in settings where the tuberculin skin test and/or chest x-ray are not available or it is not feasible to use them because staff are not trained to do so.

In these settings, contact tracing will rely on: identification of contacts; clinical assessment to determine if any contacts have TB; and offering isoniazid preventive treatment to the most susceptible contacts to prevent progression from TB infection to TB disease (once active TB has been excluded).

To apply the minimum standard for contact tracing, health programme staff should take the following steps:

- Carefully assess all household members for signs and symptoms suggestive of TB disease.
- To identify TB cases, use TB suspect criteria according to the National TB Programme protocol.

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- Refer TB suspects for further investigation in line with the National TB Programme TB suspect protocol. Collect sputum samples from TB suspects in line with the National TB Programme protocol. If resources permit, also take a chest x-ray.

- Where any contact is identified as having TB disease, register them with the National TB Programme and treat them with a standardized treatment regimen in accordance with National TB Programme treatment guidelines.

- Carefully assess children under five years of age and people who are HIV positive for any signs and symptoms suggestive of active TB. Once active TB has been excluded, recommend children under five years of age and people with HIV infection for isoniazid preventive therapy, once daily for six to nine months (Table 4). It is recommended that children receive isoniazid preventive therapy for six months, and people with HIV infection for six to nine months (depending on National TB Programme policy).2 4 Approximately 5 mg/kg/day of isoniazid (up to a maximum of 300 mg/day) is the correct dose. For more information on isoniazid dosages by weight of the patient, refer to Table 5.

- The principles of preventive treatment with isoniazid are as follows:
  - Directly observe all treatment.
  - Monitor the patient monthly to assess for adherence and monitor for side effects.
  - Follow up the patient to ensure that they complete the course of isoniazid preventive therapy.

- Diagnosing active TB in children is often difficult due to non-specific symptoms and the difficulty of confirming cases in the laboratory. Therefore, consider referral for urgent paediatric assessment (including a medical history, physical examination and chest x-ray) in all cases of children suspected of having TB.14

- If resources permit the use of chest x-rays in contacts, take chest x-rays for all children under five years of age irrespective of whether they have signs and symptoms of TB.

- For all contacts who have no signs and symptoms suggestive of TB, educate them on signs and symptoms of TB and the need to seek medical advice urgently should they develop these symptoms in the future.

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Table 4: International Standards for TB Care: Standards for public health: Standard 19

ISTC: Standard 19
Children < 5 years of age and persons of any age with HIV infection who are close contacts of an infectious index patient and who, after careful evaluation, do not have active tuberculosis should be treated for presumed latent TB infection with isoniazid.

Source: Tuberculosis Coalition for Technical Assistance. 2009. International standards for tuberculosis care.

In some Pacific Island countries and territories, tuberculin skin testing is used to assess close contacts for latent TB infection once active TB has been excluded. In these settings, health programme staff should take the following steps:

- Offer tuberculin skin testing to all HIV negative household and/ or close contacts of infectious TB cases who are five years of age and above and who have had active TB excluded.

- In general, do not administer tuberculin skin tests to contacts unless the National TB Programme can offer isoniazid preventive therapy to tuberculin skin test positive contacts and monitor this treatment.

- Any contact with a history of previous treatment for TB does not require a tuberculin skin test (as the result will likely be positive). Instead, check these contacts for signs and symptoms suggestive of TB

- In Pacific Island countries and territories where tuberculin skin testing is available there is no need to administer a tuberculin skin test to children and infants under five years of age who are close contacts of an infectious case. If it has been established that these children do not have active TB, give them six months of isoniazid preventive therapy, on the assumption that they have been infected by the index case

- Similarly there is no benefit in administering a tuberculin skin test to a contact with HIV infection who has no signs and symptoms suggestive of TB as the decision to treat with isoniazid preventive therapy will not be changed by the result of the tuberculin skin test (even if negative). In addition, tuberculin skin testing may be falsely negative in people with HIV infection

- For all other HIV negative household and close contacts aged five years of age and

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above with a tuberculin skin test ≥ 5 or ≥ 10 mm (irrespective of BCG status and dependent on local policy), consider giving six months of isoniazid preventive therapy (depending on National TB Programme policy), provided that TB disease has been excluded.

10.1 Interpreting the tuberculin skin test result

- Appendix 6 provides information on administering, measuring and reading the tuberculin skin test. Measure and read the tuberculin skin test between 48 and 72 hours after administration.

- A National TB Programme should be guided by its national policy to determine the cut-off for a positive tuberculin skin test (either ≥ 5 or ≥ 10 mm).2 Some Pacific Island countries and territories use the following cut-offs (irrespective of BCG status) to determine if a tuberculin skin test is positive:
  - ≥ 5mm – positive in immune-suppressed contacts (e.g. people with HIV, malnourished people, diabetics); and
  - ≥ 10mm – positive in all other contacts.

Over time, local epidemiology will inform the appropriate cut-off points for a positive tuberculin skin test. Consequently, it is important for National TB Programmes to collect information on results of tuberculin skin testing and subsequently to use this information to inform contact tracing policy.

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