

Guidelines for Tuberculosis Control in New Zealand 2010

Chapter 4: Adherence to Treatment and
Directly Observed Therapy

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Summary

Tuberculosis (TB) control requires a high level of adherence to the treatment regimen. If adherence is poor, drug resistance, prolonged infectiousness or reactivation may develop. Healthcare staff must support patients and enable them to adhere to the full course of treatment.

This chapter discusses the different levels of supervision for treatment, including the use of directly observed therapy (DOT). It is primarily intended for public health nurses and clinicians with TB patients.

Clinical and public health services providing treatment and follow-up for TB must provide:

- a free service
- free TB medications
- good case management
- appointment reminders and follow up of non-attendance
- a comfortable clinic environment with minimal waiting times
- clear advice about side effects
- clear communication, including written and oral health education materials
- interpreters and culturally appropriate workers, if required.

TB programmes need to use multiple strategies to ensure patient adherence to the treatment regimen. The most successful programmes combine outreach workers, supervised therapy, thorough case management, excellent patient–provider communication, and additional assistance or incentives to patients if required. In the case of treatment for LTBI, shorter courses of medication offer the possibility of improved completion of therapy.

Public health offices should ensure that information on DOT is carefully completed on the EpiSurv Case Report form.

1 Adherence

1.1 Introduction

Adherence refers to the extent to which a patient follows the instructions given for prescribed treatment.¹ Adherence is critical for successful TB control. Patients who do not adhere to their treatment regimen remain infectious longer, take longer to complete treatment and are more likely to relapse or develop drug resistance than patients who do adhere.

Low adherence with any prescribed treatment is common, with typical adherence rates estimated to be about 50%.¹ A meta-analysis of interventions to improve adherence with long-term medication found that almost all the effective interventions were complex, including drug combinations, information, counselling, reminders, self-monitoring, reinforcement, family therapy, and other forms of additional supervision or attention.¹

1.2 Adherence and tuberculosis medication

Patients need support to adhere to a course of TB medication because:

- it is difficult to remember to take long courses of treatment
- the pills prescribed are sometimes hard to swallow
- large numbers of pills have to be taken
- the medication can have unpleasant side effects
- patients must abstain from or reduce their intake of alcohol
- stigma and negative attitudes associated with TB can affect the patient's acceptance of diagnosis and willingness to adhere to treatment
- medication for other conditions may result in a very large total number of tablets and interactions may compound difficulties
- the patient usually feels better long before the treatment has been completed.

These factors are also relevant in the treatment of latent tuberculosis infection (LTBI), where the patient does not even feel unwell before starting treatment (see Chapter 8).

Factors influencing adherence include:

- the accessibility and responsiveness of the health service (health care factors)
- the nature of the treatment (treatment factors)
- stigma and cross-cultural concepts of TB (cultural factors)
- the existence of more pressing personal problems (patient factors).

A New Zealand study of older people found that the public health nurse, resourced to deliver a patient-centred model of care, is a key support during TB treatment.²

2 Assessing Adherence

Risk factors for non-adherence must be formally assessed for each patient at the beginning of treatment to determine the optimal level of supervision.

2.1 Risk factors for non-adherence

Recognised risk factors for non-adherence to the treatment regimen include:

- homelessness
- a history of TB
- substance abuse
- denial of diagnosis
- living alone
- patients believing that they are likely to have poor adherence.^{3,4}

It is difficult for health care workers to predict a patient's adherence with accuracy. Demographic variables such as age, gender and ethnicity do not predict adherence.

2.2 Determining the initial level of supervision

The optimal level of supervision is influenced by patient factors, clinical factors such as drug resistance and the presence of side effects, and social factors (see Table 2.1).

Table 2.1: Recommended level of supervision

Risk factor	Level of supervision
Intermittent regimens (thrice-weekly doses) Resistance to rifampicin or multi-drug resistance (resistance to isoniazid and rifampicin) and other cases of multiple drug resistance All relapses and re-activations Inability or unwillingness to self-medicate (eg, substance abuse, denial of diagnosis, homelessness, intellectual limitations) Consistent failure to comply with ward or outpatient clinic requests Poor adherence during close supervision Extensive disease and high infectiousness	Directly observed therapy
Weak or absent social support Psychiatric illness Troublesome drug side effects Complex treatment regimen Record of previous non-adherence with regard to treatment for other diseases	Close supervision: consider directly observed therapy
None of the above risk factors	Self-administered treatment

3 Monitoring Adherence

All patients on TB medication must be systematically monitored for adherence to their treatment regimen.

3.1 Methods for monitoring adherence

Monitoring methods include patient interviews, pill counts and, rarely, urine assays.

Record-keeping sheets help public health nurses to record pill counts and detect adherence problems (see Appendix 1).

3.2 Levels of supervision and treatment contracts

3.2.1 Levels of supervision

There are three levels of treatment supervision. Treatment may be delivered as:

- self-administered treatment
- treatment under close supervision
- DOT.

A process for determining the level of supervision is shown in Figure 3.1.

The type of treatment and the required level of supervision may change during the course of treatment.

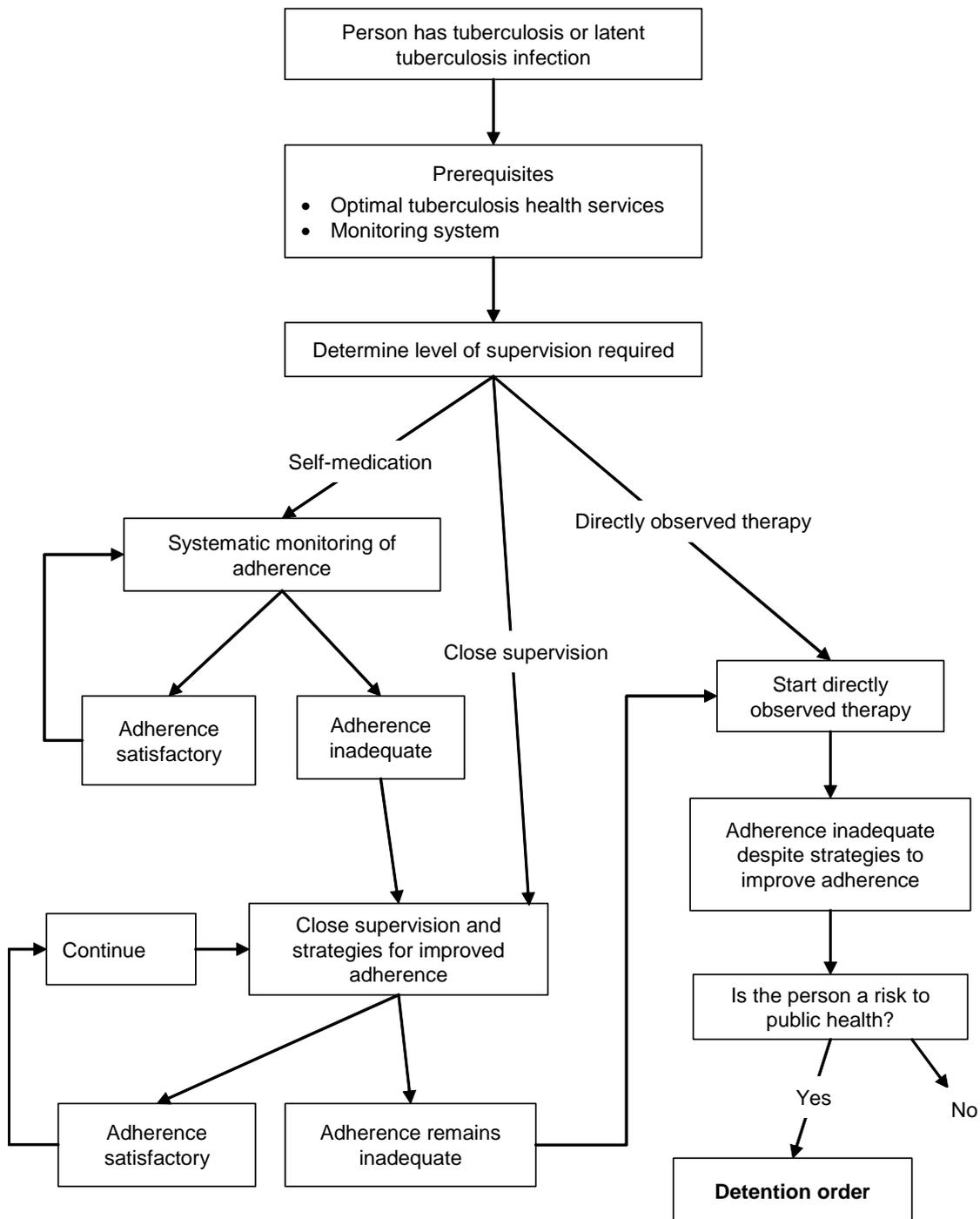
3.2.2 Treatment contracts

Treatment contracts can be used at all levels of supervision, if the patient's adherence is doubtful. A treatment contract includes:

- the time and place for delivery of supplies of medication (or delivery of DOT)
- the patient's agreement to contact the case worker if plans change
- the patient's intention to attend all appointments.

After the patient has dated and signed the treatment contract, the public health nurse or medical officer of health should date and countersign the contract.

Figure 3.1: Flow diagram for determining level of supervision



3.3 Self-administered treatment

Self-administered treatment is possible if there are no risk factors and regular monitoring confirms good adherence. The patient self-administers medications daily with oversight by a public health nurse. Table 3.1 shows the routine requirements for monitoring when there are no concerns about adherence.

Table 3.1: Routine activities for monitoring adherence

Clinical activities	Public health activities	Clinical and public health activities
Monitoring of: <ul style="list-style-type: none">• clinic non-attendance• adherence (physician assessment)• rate of clinical response to medication	Regular assessment of patient by public health nurse, which includes: <ul style="list-style-type: none">• discussing progress and problems, including side effects and adherence• making monthly pill counts or syrup volume checks• checking medications are dispensed as prescribed• monitoring changes to risk factors for non-adherence	Good communication among case workers, clinicians and patient Rapid communication if concerns about adherence Regular case review meetings between clinical and public health services

3.4 Close supervision

Under close supervision, the patient self-administers medications daily, but has frequent, usually weekly, visits from an outreach worker, generally a public health nurse. The worker explores and tries to alleviate barriers to adherence.

Trigger points that might lead to closer supervision (or DOT) include:

- the patient did not attend one clinic visit
- the patient was not present for one pre-arranged public health nurse visit
- the public health nurse or hospital staff were concerned about adherence
- pill counts indicate consistent missing doses (more than 15%).

4 Directly Observed Therapy (DOT)

4.1 Definition

The WHO DOTS strategy stands for Directly Observed Therapy, Short Course. This includes a comprehensive strategy for tuberculosis which is relevant for developing countries.

DOT, as discussed here, describes the process where a trained supervisor watches the patient swallowing the medication for all doses during the course of treatment. It is one component of the DOTS strategy.

The DOT supervisor may be a health worker or a trained and supervised community member. DOT may be given daily or intermittently. Chapters 3 and 8 outline accepted regimens. WHO recommends that intermittent regimens should be thrice weekly rather than twice weekly as the consequences of missed doses are likely to be less serious.⁵

4.2 Directly observed therapy rates in New Zealand

Universal DOT is not required in New Zealand, which has high rates of treatment completion and low rates of drug resistance and relapse.^{6,7,8}

In New Zealand, about 32% of notified TB cases received DOT in 2002–07.

Only people who received DOT for the whole duration of their treatment are classified on the EpiSurv case report form as having received DOT. An additional question has now been added: 'Did the case receive DOT throughout the intensive phase of treatment'.⁹

Public health services need to ensure that information on DOT use is collected and entered on EpiSurv.

4.3 Effectiveness of directly observed therapy

Some literature shows that DOT produces superior treatment completion rates to those achieved by non-supervised interventions. DOT also leads to decreased relapse and drug-resistance rates.^{10,11,12} However, randomised trial evidence for the effectiveness of DOT is limited,^{13,14,15} and DOT may not always lead to better treatment outcomes than self-administered treatment.^{16,17,18}

4.4 Adherence to treatment of latent tuberculosis infection

Treatment for LTBI requires a long course of treatment in a well person. Adherence is even more difficult than in cases on full treatment for active TB disease. No one strategy has been found to be successful for improving adherence to treatment for LTBI.¹⁹ It has been found that shorter courses of treatment for LTBI are associated with better adherence.²⁰ Offering the patient the choice of medication regimen for LTBI is also associated with better adherence.²¹

DOT is associated with higher completion rates of LTBI treatment.^{22,23} It should be considered if the client has risk factors for non-adherence and one or more of the following apply:

- Full DOT treatment of TB disease is being given at the same time to a person in the same household or neighbourhood.
- The patient is aged under five years.
- There are risk factors for progression from infection to disease (see Chapter 8).
- The patient is a contact of a multi-drug-resistant (MDR-TB) TB case and treatment has been recommended.

DOT should *always* be used for intermittent regimens (thrice-weekly doses).

5 Practical Problems During DOT

5.1 Temporary inability to give DOT

Self-administration of thrice-weekly treatment is *not acceptable* and can be authorised only by a medical officer of health or a clinical TB specialist and only in exceptional circumstances.

If a patient is going overseas and cannot be given DOT, he or she must change to daily treatment. If the patient is travelling around New Zealand, he or she should try to continue DOT through another public health office; if this is not possible, daily treatment should be prescribed.

5.2 Missed DOT doses

There are no published data (for daily or intermittent regimens) on how much treatment a person can miss and still be cured, but the medical officer of health should be advised if the patient misses:

- more than one DOT dose per month (for intermittent treatment)
- more than one DOT dose per week (for daily treatment).

If the patient misses a dose, the medical officer of health should meet the patient to discuss any obstacles to adherence to the DOT regimen. If adherence cannot be achieved in a patient who poses a risk of infection to others, the patient may need to be detained under section 16 of the Tuberculosis Act 1948.

Any missed doses of DOT must be added on to the end of treatment.

5.3 Non-traditional DOT workers

Community DOT workers are people without formal healthcare training. Community DOT workers need training and supervision in the provision of DOT.

In some circumstances health professionals from outside the public health workforce can be recruited to administer DOT.

In either situation, the public health nurse remains the case manager with overall responsibility for DOT, and close communication is essential.

6 Detention Order

6.1 Section 16 of the Tuberculosis Act 1948

If all attempts to enable a patient to adhere to their treatment regimen fail, the local medical officer of health may seek a three-month detention order under section 16 of the Tuberculosis Act 1948.

A detention order is only applicable where it is necessary to isolate an infectious pulmonary (or laryngeal) TB patient who is posing a risk to others (ie, if a patient is non-adherent but does not pose an infectious risk to others, a detention order is not applicable).

6.2 When may a detention order be sought

It is important to involve the medical officer of health as soon as it is apparent that a detention order may be necessary.

Before seeking a detention order, ensure that every effort has been made to ensure that barriers to adherence have been minimised and there is good communication. This may include using cultural advisors, other health workers, or any other people who can engage with the patient.

The Ministry of Health has produced a guide for medical officers of health, explaining the protocol for detaining patients: *A Guide to Section 16 of the Tuberculosis Act 1948*.²⁴ The guide outlines the legal implications and steps to follow when considering whether and how to detain a patient.

7 Optimising Tuberculosis Health Services to Improve Adherence

7.1 Code of Health and Disability Services Consumers' Rights

The Code of Health and Disability Services Consumers' Rights (the Code of Rights) describes a series of rights for all users of health services in New Zealand (including the right to be treated with respect, to effective communication, to full information and to confidentiality). These rights are part of best clinical practice.

7.2 Free services

The local medical officer of health can write an order (a letter) under section 9 of the Tuberculosis Act 1948 requiring a person suspected or known to have TB to undergo compulsory investigation and treatment, if patients refuse to do so voluntarily. The District Health Board is then obliged to provide free TB diagnosis and treatment to these patients (including to non-resident patients ineligible for publicly funded health care who do not have health insurance).

The services are free in accordance with the Minister of Health's gazetted notice *2003 Direction of the Minister of Health regarding eligibility for publicly-funded health and disability services in New Zealand*.²⁵

7.3 Medications

Anti-TB medication is free to all patients, regardless of their eligibility for publicly-funded health care.

Blister packs are recommended to aid adherence.

7.4 Case management

Ideally, a designated physician and a single case worker (usually a public health nurse) will communicate regularly with the patient and each other.

Patient reminders should be issued for follow-up of non-attendance at clinics. A copy of the appointment should be sent to the public health service, as the public health staff may know about changes affecting the patient's ability to attend.

7.5 Clinic visits

The case worker should ensure that the clients are reminded and supported to attend all clinic visits.

7.6 Advice about side effects

Clients need clear instructions (written and oral) about the potential side effects of medication, and what they need to do and who to contact should these occur.

A poor understanding of side effects has been reported in regard to treatment of LTBI.^{26,27}

7.7 Language

Effective communication, given in a form, language and manner that the patient understands, is one of the rights in the Code of Rights. At the first contact with the health service, any patient whose first language is not English should be assessed to establish whether or not an interpreter is needed. If there is any doubt, an interpreter should be used.

When an interpreter is needed, a professional interpreter (ie, an interpreter with specialised training) should be used whenever possible. In general, untrained interpreters (eg, family members or friends) should not be used except in emergency situations, as this compromises the patient's confidentiality and there is a risk of miscommunication.

A telephone interpreting service can sometimes be used.

Tips for communicating through an interpreter

- Speak slowly and clearly, using one or two sentences at a time.
- Focus your attention on the patient, not the interpreter.
- Use simple English — try to avoid medical terms and colloquialisms.
- Avoid conversation with the interpreter in front of the client. If this cannot be avoided, try to include the client or explain what is happening.

Source: Ministry of Health (2001).²⁸

Ensure that written information is available in the patient's language to complement verbal information.

7.8 'Incentives and enablers': measures that help a patient to overcome barriers and improve adherence

Incentives and enablers can increase adherence with DOT.^{29–33} These can include:

- discussions of barriers and attempts to overcome them
- more intensive supervision
- text message reminders
- additional information sessions
- assistance with transport, food, phone top-ups, or other goods
- monetary incentives.

Appendix 1: Sample medication record for patients on self medication

Place sticky label here
 CLIENT NAME / NHI /
 DATE OF BIRTH / ADDRESS

Medication record for patients on self medication

Medicine name: _____

A	B	C	D	E	F	G	H	I	J	K	L
Date	No. of days since last visit	Prescribed dose	No. of tabs in a dose	No. of tabs left last visit	No. of doses left last visit (E/D)	No. of tabs today <u>plus</u> no. dispensed today	No. of doses present today (G/D) <u>plus</u> no. dispensed today	Expected doses today (F-B)	Doses missed (H-I)	Percentage of doses missed (J/B%)	PHN/PHA initials

Comments: _____

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