



MINISTRY OF
HEALTH

MANATŪ HAUORA

Directly Observed Therapy (DOT) for Tuberculosis

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This paper has been endorsed by the
Tuberculosis Working Group of the Ministry of Health.

This paper should be read in conjunction with Chapter 4
of the Ministry of Health publication
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Contents

| | |
|---|----|
| Introduction | 5 |
| Definition of DOT | 6 |
| Why use DOT? | 6 |
| How much is DOT used in New Zealand? | 7 |
| Which clients should be on DOT? | 7 |
| Using community DOT workers | 8 |
| Using health professionals | 8 |
| Incentives and enablers | 9 |
| Using DOT for chemoprophylaxis | 10 |
| An alternative to DOT | 11 |
| Appendix 1 – Establishing a community DOT worker programme | 12 |
| Attributes needed to be a DOT worker | 12 |
| Job description for a DOT worker | 13 |
| Administration | 14 |
| Training | 14 |
| Criteria for transferring clients to a community DOT worker | 16 |
| The role of the PHN | 16 |
| References | 18 |

Introduction

Detection and cure remains the cornerstone of TB control. Cure and the prevention of drug resistance is contingent upon patients' adhering to an appropriate anti-tuberculosis treatment regimen. Adherence is difficult for TB patients to maintain. People always need assistance and support to stay on anti-tuberculosis medication because:

- everyone finds it difficult to remember to take long courses of treatment without support
- the pills prescribed are sometimes hard to swallow
- large numbers of pills have to be taken, especially during the initiation phase of treatment
- there are sometimes unpleasant side effects from the medication
- abstinence or reduced intake of alcohol is necessary while on medication
- there may be difficulties filling prescriptions because not all pharmacies are aware that anti-tuberculosis medications are fully government subsidised
- stigma associated with TB often affects the patients.

Adherence is also difficult for health care providers to measure (Sumartojo 1993).

Directly observed therapy (DOT) ensures adherence. The Tuberculosis Working Group of the Ministry of Health strongly supports the use of DOT and urges all Medical Officers of Health to work with local medical practitioners to ensure that DOT is offered to all patients who are likely to benefit from it.

Definition of DOT

Directly observed therapy (DOT) means that a supervisor watches the client swallowing the medication for all doses over the course of treatment. This ensures that a TB client takes the correct drugs, the correct dose, and at the correct times. DOT may happen on an inpatient or outpatient basis. The DOT supervisor may be a health worker or a trained and supervised community member. There must be a clearly defined line of accountability between the TB control staff and the person administering DOT. It is important to ensure confidentiality and that DOT is acceptable to the patient (WHO 1997).

It is not DOT if an untrained family or community member administers the treatment to the patient.

Why use DOT?

The DOT strategy is actively promoted by the World Health Organization (WHO) for TB patients in an effort to control the global emergency of TB.

DOT produces superior treatment completion rates to those achieved by non-supervised interventions. Median treatment completion rates with DOT range from 78.6 percent to 91.0 percent (depending on the degree to which incentives and enablers are used), compared to 61.4 percent for non-supervised therapy (Chaulk and Kazandijan 1998). DOT also leads to reduced relapse rates and drug resistance rates (Weis et al 1994; Chinese Tuberculosis Control Collaboration 1996; Cao et al 1998).

The World Bank considers DOT to be one of the 'most cost-effective of all health interventions'. DOT is more cost-effective than self-administered treatment (Moore et al 1996; Floyd et al 1997).

Favourable reports of the use of DOT in the United States have been published in Texas (Weis et al 1996), Baltimore (Chaulk and Pope 1997), San Francisco (Schechter 1997), and New York City (Fujiwara et al 1997).

DOT is being successfully implemented in many other countries (WHO 2000).

Proponents of DOT argue that in the case of TB – a global pandemic of a drug-resistant disease with public health implications – it is the medical practitioner’s responsibility as much as the patient’s to ensure cure (Sbarbaro 1997).

How much is DOT used in New Zealand?

According to a Ministry of Health survey done for the Tuberculosis Working Group prior to a 1998 national TB workshop, the percentage of TB patients on DOT in New Zealand varied by district, ranging from 0 to 50 percent. In Auckland, where the largest number of cases are treated, 50 percent were managed with DOT in 1999.

Which clients should be on DOT?

As emphasised in section 4.3 of the Guidelines (Ministry of Health 1996), a decision to administer DOT should follow a careful assessment of the client by hospital and public health staff.

Universal DOT (that is, DOT for all TB clients) is not considered necessary in New Zealand because of low rates of drug resistance and apparently low relapse rates (though data on the latter are poor).

DOT is recommended for:

- all cases resistant to rifampicin
- all multidrug-resistant cases (resistant to INH and rifampicin)
- all relapses/reactivations
- all cases that clearly demonstrate an inability or unwillingness to self-medicate

- all cases that have been placed under closer supervision (for reasons listed in section 4.4 of the *Guidelines*) and who then need continued help with treatment.

People with tuberculosis should be considered for DOT when there is:

- extensive disease and/or a high degree of infectiousness
- weak or absent social support
- a complex treatment regimen.

Using community DOT workers

Extensive experience overseas has shown that trained and supervised community DOT workers can successfully provide DOT (Chaulk and Pope 1997; Schecter 1997; Fujiwara et al 1997).

Using community DOT workers may:

- help contain the costs of providing DOT
- facilitate communication and rapport with clients in some instances
- be more culturally or linguistically appropriate for TB clients
- help to develop a suitable workforce for other similar projects
- provide greater choice for clients over the settings in which DOT is provided.

See Appendix 1 for information on establishing a community DOT worker programme.

Using other health professionals

It may be appropriate to recruit and train other health professionals to administer DOT to some clients. Examples include:

- practice nurse
- pharmacist

- district nurse
- occupational health nurse
- school nurse
- dental nurse
- Plunket nurse
- District Health Boards staff.

Incentives and enablers

Measures other than DOT that have been shown to promote adherence include reminder cards, help by health workers, financial incentives, health education, and intensive supervision of staff in tuberculosis clinics (Volmink and Garner 1997). These interventions may be more appropriate in the first instance for a client who may need assistance with adherence to anti-tuberculosis medication.

Overseas experience has shown that using incentives and enablers (that is, to help the client overcome barriers) will increase adherence with DOT (Chaulk and Pope 1997; Schechter 1997; Fujiwara et al 1997). Increasing incentives is associated with improved adherence (Davidson et al 2000).

Examples of incentives include:

- money
- books
- vouchers
- lessons or courses
- celebration at the midpoint and end of treatment
- star chart or birthday party for a child.

Examples of enablers include:

- transport to clinic or DOT appointments
- taxi chits
- thinking creatively about convenient sites for DOT
- reducing stigma of the disease
- addressing psychological and cultural barriers.

Using DOT for chemoprophylaxis

Chemoprophylaxis for TB infection requires a long course of treatment in a well person. Adherence may be even more difficult to attain than in cases on full treatment for active disease. DOT has been shown to be cost effective for chemoprophylaxis in drug users at high risk of TB (Gourevitch et al 1998). It may be inappropriate to use DOT for everyone on chemoprophylaxis. However, using DOT for chemoprophylaxis should be considered if the client has risk factors for non-adherence and presents with one or more of the following:

- can be given DOT at the same time as a related case who is on full treatment by DOT in the same household or neighbourhood
- has recently converted their Mantoux test following exposure to an infectious case
- is under five years of age
- has risk factors for progression from infection to disease (see table 5.2 in the *Guidelines*)
- is a contact of a multidrug-resistant case.

Non-adherent cases on full treatment should have priority for DOT resources ahead of infected people requiring DOT chemoprophylaxis.

An alternative to DOT

If resources do not permit DOT for clients, electronic drug exposure monitoring (electronic lid monitors) may be useful to consider (Starr et al 1999). These devices record the time and date when medication container lids are removed. While this does not prove that the medication was ingested, research shows close correlation between lid removal and desired clinical response. For further information contact the author.

An alternative is to prescribe Vitamin B2 (riboflavine) with the anti-tuberculosis medication. Urine of people who have taken Vitamin B2 in the past 48 hours will fluorescence when illuminated against ultra violet light or torchlight (Jones 1967). Patients who take medication, which is blister packed with Vitamin B2 and who agree to random urine testing, can be inexpensively monitored.

Appendix 1

Establishing a community DOT worker programme

Material in this appendix is provided courtesy of Otara Health Inc and Auckland Public Health.

Attributes needed to be a community DOT worker

Suitable people may include ethnic community health workers, or a church minister, teacher or employer. They should:

- be fluent in speaking languages commonly spoken by TB clients; this is desirable but not essential
- recognise cultural differences
- be able to accept the client's beliefs and values and not try to change or influence them (for example, religion)
- have patience, tact, maturity, good judgement and honesty
- be flexible regarding times and settings to suit the client
- have the ability to communicate information and the skill to listen and answer relevant questions
- understand the client's and family's right to confidentiality and privacy
- recognise the limitation of their role and knowledge, and know when to ask for help
- be appropriately dressed
- be able to manage a workload and accurately record the work done
- be safe with children and young people
- give authority to obtain police clearance
- be able to attend training programmes and review meetings
- be physically fit, reliable and punctual

- have their own car and current driving licence
- know the community and be able to access clients or other key people
- have time to be present for the entire time needed for the client to swallow the medication
- feel comfortable working with people who have an infectious disease.

Job description for a DOT worker

The community DOT worker should:

- carry the correct medication for the client; administer the correct dose; see the medication being taken
- sign the drug sheet (held with the drugs)
- arrange the date for the next DOT
- contact the public health nurse (PHN) to give a weekly progress report – and at other times as necessary, for example to discuss side effects, advocacy, problems and queries
- let the PHN know if they are unavailable to give a DOT dose (in plenty of time for an alternative arrangement to be made)
- complete logs and timesheets neatly and punctually
- negotiate with the PHN before offering any incentives or rewards to clients
- arrive punctually for DOT appointments with clients
- follow up any client who does not attend promptly
- identify and document all adverse events promptly, and report them to the supervising PHN.

Administration

Administration will vary with each organisation but consider:

- a job description
- a person specification
- a contract
- remuneration
- clear lines of accountability
- performance appraisal
- administrative support
- a timesheet
- DOT visit logs and mileage claim records
- a confidentiality agreement.

Training

When developing a training course for community DOT workers, the following should be considered.

1. Background training in TB disease, chemotherapy and chemoprophylaxis.
2. Videos such as *TB: the forgotten plague* and *You can beat TB*.
3. Administering DOT. This includes:
 - how cases are allocated
 - selecting suitable clients for DOT workers
 - being sure who the supervising PHN is for each case
 - case loads
 - negotiating a written contract
 - documentation

- when to report non-adherence back to the PHN
 - when to arrange a three-way interview with the PHN
 - when and how to transfer a client back to the PHN
 - side effects to watch out for
 - occupational health risks such as TB.
4. Building relationships with the DOT client. This includes:
 - accepting their norms and environment and cultural differences
 - getting to know people and their habits
 - being patient and respectful
 - meeting the client with the PHN before starting DOT
 - meeting the client's family/whānau (or other people involved with the client)
 - remembering you are a visitor to the family/whānau
 - recognising that the client may have different time constraints
 - use of motivation and incentives
 - privacy.
 5. Role play.
 6. Getting practical field experience with PHNs before working alone.
 7. The legality of the administration of medicines. Community DOT workers do not prescribe or dispense medicines. They administer them in the same way as any family member might do for a child. There is no legal obstacle to this. Blister packs may facilitate the work.
 8. Two-step baseline Mantoux test before starting work.

A manual for training community DOT workers has been developed by Auckland Healthcare's Public Health Protection Communicable Disease Control team. Copies of this are available at a cost (contact Vivien Koberstein, Public Health Protection, Community Services, Auckland Healthcare, Private Bag 92 605, Symonds St, Auckland, ph 09 262 1855).

Criteria for transferring clients to a community DOT worker

- The client and DOT worker can communicate well.
- The client is stabilised on treatment, has had a period on DOT and has displayed no side effects (for at least a month).
- The client is willing to accept help with TB treatment.

The role of the PHN

The PHN is fully accountable for client care and remains the case manager who:

- has the primary key worker role and is accountable for resource utilisation and outcome
- assesses needs, and plans interventions
- co-ordinates, (for example, medical officer) as necessary and requests assistance from their colleagues to provide input
- monitors progress and achievement of goals
- modifies plans
- evaluates outcomes.

The PHN introduces the DOT worker to the client personally and discusses the following with the DOT worker:

- the client's history
- appointment times and places
- drugs and recordkeeping.

The handover phase needs to continue until the client, PHN and DOT worker are comfortable.

The PHN must receive and acknowledge weekly reports from the DOT worker (even if there is nothing unusual to report). The PHN continues to communicate relevant issues to the clinician responsible for the patient.

The PHN:

- can make a decision to resume responsibility for a DOT client if concerned about continuity/contracts/dynamics and so on
- must let the community DOT worker know of the alternative PHN who will act as case supervisor if they are away for any reason
- must advise their supervisor if the DOT worker fails to carry out any contracted duties
- conducts a monthly check for each DOT client to ensure that visits consistently take place. Frequent checks may be necessary if the client is on a complex or difficult regimen or when the DOT worker is inexperienced.

PHNs may need training if they have no experience in the supervision and monitoring of work delegated to non-health professionals. They must be aware that a non-health professional may not detect or report details of clinical significance, including drug side effects. This adds another dimension to case management. *The Health Service Assistant and the Registered Nurse* (Ministry of Health 1999) is a useful paper that addresses these issues.

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