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The directly observed therapy revisited

A close look at DOT

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DOTS, the Directly Observed Treatment, Short-course, is "the most effective strategy available for controlling the TB epidemic today" (WHO). The element of DOTS that gave the strategy its name, namely the so-called Directly Observed Therapy DOT, has evoked partly passionate discussions. DOT means that a member or representative of the health system observes each drug intake of the TB patient, at least for the initial two months of treatment. Since patients' non-adherence to treatment is common, supervision of treatment is essential. DOT, developed in the 1960ies1, is seen to address the problem of patient non-adherence to treatment. Good adherence to treatment prevents the development of drug resistance. This article tries to give a balanced view of the different advantages and disadvantages of the various forms of DOT.

Clearly, the patient needs support and prompting in terms of treatment adherence. However, rigid forms of supervision may be an intolerable burden for the patient. It may mean high expenditures for transportation costs, having to stop work, losing privacy and confidentiality, and a loss of self-worth. Rigid supervision can also demand a lot from the health facility personnel. What kind of supervision is appropriate and feasible in different circumstances is not clear. To our knowledge, there are only three studies that properly compare in a randomised controlled trial the treatment success rate of various forms of DOT (2-4). Those who are critical of strict DOT can cite studies (2,3) and those who believe strict DOT is essential can also cite studies (5-9). The following article looks at four ways of supervision of applying DOT :

DOT 1 - Health facility-based DOT: The patient comes to the health facility for each drug intake (except during the weekend or non-working days) and takes the drugs in the presence of a health worker.

DOT 2 - Community-based DOT: A community health worker or person in the community trained and supervised by the health system observes drug intake of the patient. The community health worker goes to the patient's house or the patient goes to the community health worker's house.

DOT 3 - Family DOT: The patient takes the drugs at home and is being supervised by a family member who has officially been tasked to observe the patient's drug intake.

DOT 4 - Self-administered treatment with once-a-week DOT in the health facility: the patient goes to the health facility for DOT once a week only and takes the drugs at home on the other days.

Different degrees of treatment supervision

This overview attempts to present the many aspects that need to be considered when a TB programme decides what kind of supervision should be used. Advantages and disadvantages of the different ways of DOT are presented.

	DOT 1: Health facility-based, from Monday to Friday or Saturday	DOT 2: By community health worker. Weekly DOT in health facility.	DOT 3: By family member. Weekly DOT in health facility.	DOT 4: Self-administered treatment. Weekly DOT in health facility.
Effect on completion of treatment?	No direct effect visible (1,2)	Hard to say (2,3,4)	Better than self-administered treatment (5, 6, 7)	Good results in some places (8)
Assurance of drug intake (while patient is on treatment)?	Excellent if staff works well	Good if community health worker works well	Average or good, depending on family	Average
Monitoring of side effects?	Excellent if staff works well	Excellent if community health worker works well	Good if family member works well	Detected within 7 days
Detection of non-adherence?	Excellent if staff works well	Excellent if community health worker works well	Detected within 7 days	Detected within 7 days
Prevention of drug resistance?	No trial evidence but evidence from country comparisons suggests DOTS (and thus DOT?) crucial (9-11) Strong rational for DOT 1			

Danger of spread of TB / MDR-TB?	High	Quite low	Quite low	Low
Burden for the health facility staff?	Major	Major for community health worker	Minor	Minor
Burden for the patient?	Major	Potentially considerable if stigma is a problem	Small	Small
Attractive for patient?	Unattractive for a considerable proportion (2, 12)	Unattractive for a smaller proportion	Yes, but not in chaotic families	Yes
Attractive for private sector?	No; even impossible?	No	Feasible	Feasible

References: (Table): 1 Zwarenstein et al (1998) Lancet, 352: 1340-3. 2 Walley et al (2001) Lancet, 357: 664-9. 3 Wilkinson et al (1996) Am J Public Health, 86:1094-7. 4 Volmink et al (2000) Lancet, 355: 1345-50. 5 Kamolratanakul et al (1999) Transactions Roy Soc Trop Med Hyg, 93: 552-7. 6 Becx-Bleumink et al (1999) Int J Tuberc Lung Dis, 3 (12): 1066-72. 7 Manders et al (2001) Int J Tuberc Lung Dis, 5 (9): 838-42. 8 Bayer et al (1998) Am J Public Health, 88(7): 1052-8. 9 Chaisson et al (1999) Int J Tuberc Lung Dis, 3 (1): 1-3. 10 Kenyon et al (1999) Int J Tuberc Lung Dis, 3 (1): 4-11. 11 Dosso et al (1999) Int J Tuberc Lung Dis, 3 (9): 805-9. 12 Lönnroth et al (2001) Soc Sci Med, 52(6): 935-48.

The table attempts to show the effects of the four presented forms of DOT on various indicators of the success of a TB programme. Considering these various indicators suggests that each form of DOT has its advantages and disadvantages, which might be illustrated also by some case studies from Manila, Philippines:

The deterring effect of health facility-based DOT

Rosa, a mother of four, undergoes a chest X-ray; the result is 'positive for TB'. Even though Rosa has no symptoms, the private doctor gives her a prescription for non-generic quadruple anti-TB treatment. She consults me. I explain the unreliability of X-ray and suggest she get sputum examination at the

local health centre. Her reaction to this is: "I don't want to go there because when you get treatment there, then you have to go to the health centre every day. I know this through a friend who is treated there."

The limitations of family DOT

Juan, 18 years old and jobless, is from a broken family: his mother and siblings live somewhere else. He has smear-positive TB and family DOT is assigned to him: his grandmother is the "treatment partner". His last follow-up sputum examination is positive. The health centre staff was told that his drug intake was regular. When we interview him after the end of his treatment, he again affirms to have taken treatment regularly. A contradicting comment of his nearby aunt prompts us to ask again, and the truth comes out: His intake of rifampicin was quite regular, but the intake of all the other drugs was highly irregular. His grandmother comments that she was unable to convince her grandchild to take the medication regularly.

We also interviewed Juan fifteen days after treatment start and 2½ months after treatment start. On both occasions the importance of regular drug intake was emphasised and the irregular drug intake was not detected.

It is likely that his erratic drug intake resulted in drug resistance. Health facility-based DOT would possibly have resulted in him defaulting from treatment. But it would most likely have prevented the development of drug resistance.

The limits of DOTS

Lito, 41 years old, develops symptoms of TB. His cousin, with whom he shared a simple house, had died of TB some time ago in spite of treatment. Lito ignores the symptoms. Later on, he moves to another place, now living with his brothers. There he starts a six-month treatment at the local health centre. However, with one exception, all his follow-up sputum examinations are smear-positive.

He finishes seven months of treatment. Some months later he is extremely thin and too weak to stand up. Around 1½ hours travel from his place there is a DOTS-Plus project. However, some months ago, a double disaster struck Lito and his brothers: Their slum area including their house burned down. And in the same month, the eldest brother lost his job when a local factory had to close down. Now, only one brother has a poorly paid job. This extreme poverty makes it highly unlikely that Lito can use the DOTS-Plus project.

Health facility-DOT and privacy

Milo has TB but does not disclose it to his wife. When being asked by his wife about his daily going to the health centre, Milo gives evasive answers. The wife suspects that Milo is in love with a lady of the health centre. She goes to the health centre to face 'the problem'. With astonishment and displeasure she finds out that her husband has TB. The consequence is that she kicks him out of their house.

For every setting, the probable benefit of strict DOT needs to be balanced with the probable burden of strict DOT. In each local setting the potential advantages and disadvantages of the various forms of supervision should be carefully assessed. Feasibility and acceptability - for the patient and for the health facility staff - must be given due weight. Then it can be decided what kind of supervision is appropriate. Different patients may have different modes of DOT. For instance, for those patients working, health facility-based DOT is often not feasible while for those living in broken families, family DOT may not be applicable. It is crucial that the results of each of the chosen options are evaluated.

Flexible approaches to DOT, integrating behavioural knowledge, cost considerations, and practicality may improve completion rates and program effectiveness10. One big advantage of health facility-based DOT is the avoidance of development of drug resistance since monotherapy cannot occur under health facility-based DOT. Thus, abandoning health facility-based DOT should only be done when there is strong evidence that less strict forms of supervision still result in high treatment adherence.

It can be argued that whatever the form of DOT, the non-negotiable minimal requirements are:

a) Health-facility based treatment intake once a week with careful assessment of problems such as side effects and non-regular or incorrect intake of medication.

b) Immediately visiting the patient by the health facility staff should the patient not appear on the due date in the health facility ('tracing of defaulters').

c) If treatment intake is not always in the health facility: officially assign a "treatment partner" (community health worker or family member) to the patient. One may also argue that in any case, it is good to assign a family "treatment partner/supervisor".

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