

Directly Observed Treatment, Short-course).<sup>10</sup> The DOTS strategy consists of a five point policy package: political commitment, sputum smear microscopy for diagnosis of infectious patients, standardised short course (that is, rifampicin based) chemotherapy, secure drug supply, and a recording and reporting system. The DOTS strategy represents the basic minimum necessary for control of tuberculosis. Implementing the strategy requires flexibility, with adaptation to a broad range of contexts and community needs.<sup>11</sup>

WHO recommends "standardised short-course chemotherapy ... under proper case management conditions," with the aim of adherence, completion of treatment, and therefore tuberculosis cure and prevention of drug resistance. These refer to a range of measures, including DOT, aimed at promoting treatment adherence and completion. These include placing the patient at the centre of activities for the control of tuberculosis, ensuring confidentiality and consideration of patients' needs, organising tuberculosis services so that the patient has treatment as close to home as possible, considering incentives, identifying potential problems, keeping accurate address records, and taking measures to deal with defaulters.

The long experience of promoting adherence to treatment of tuberculosis can inform the development of the concept of concordance. An agreement between a patient with tuberculosis and the healthcare provider reinforces their mutual contribution and responsibility to achieve successful treatment. Concordance is therefore a key step at the start of the dynamic process of supporting a patient with tuberculosis throughout treatment. The Bangladesh Rural Advancement Committee approach provides a good example of concordance. After signing a written agreement, the patient is supported by a community health worker throughout the full course of treatment, and the programme achieves a high cure rate (at least 85%).<sup>12</sup>

An enhanced concept of concordance embraces the initial agreement between patient and healthcare

provider, and also measures for ongoing support for patients to enable them to complete treatment. This is relevant to successful outcomes of treatment of communicable and non-communicable disease.

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## Directly observed treatment for tuberculosis

*Less faith, more science would be helpful*

Drugs cure tuberculosis. So why does the disease remain in the top 10 causes of global mortality, with 1.8 million deaths a year?<sup>1</sup> Most deaths are in low and middle income countries, where a major challenge is to ensure that drugs are available and people complete the long treatment. The World Health Organization has been tackling the global problem of inadequate tuberculosis control for some years and launched a new programme of integrated care in 1994, called directly observed treatment, short course (DOTS).<sup>2</sup> By using a six month course of drugs, including rifampicin, WHO has mobilised money, people, and systems in countries to tackle the global problem with good progress.<sup>3</sup> Its strategy is divided into five key aspects: political commitment, access to sputum microscopy, short course chemotherapy using

direct observation of treatment, an uninterrupted supply of drugs, and a recording and reporting system.

There is little argument that resources, drugs, political support, and active management of programmes help improve control of tuberculosis. However, debate continues over whether direct observation of patients taking their treatment by health workers (or their delegates) is essential for successful control. It seems to have arisen out of special programmes in the United States, where direct observation of treatment was part of multifaceted strategies and special studies in Africa.<sup>4</sup> It was at the core of WHO's strategy at launch in 1995, with the director general saying that direct observation by a health worker was the biggest health breakthrough this decade. Direct observation remains core to the current

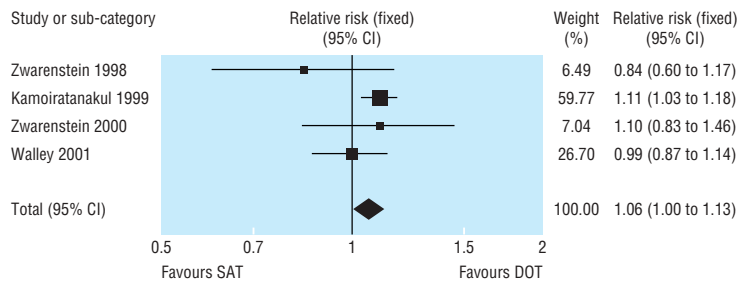
WHO strategy: recently published guidelines say that the key treatment principle of direct observation of treatment remains the same, whichever method of implementation is chosen.<sup>5</sup> The problem with this global policy is that there are currently four carefully conducted trials in Thailand, South Africa, and Pakistan, and these studies show little or no advantage of direct observation over self treatment at home in relation to cure (figure).<sup>6</sup> What is more, these studies were carried out in settings with relatively low cure rates—exactly where better control of tuberculosis is needed.

What are the implications for global policy with these research results? We think that WHO and others should reflect on the mismatch between this research evidence and its own beliefs, expressed individually or as consensus statements.<sup>5 7 8</sup> Other data are of course important, and this reflection needs also to consider that direct observation costs more than other methods,<sup>9</sup> is paternalistic towards patients, and it can take health workers away from other essential tasks. Some health services may be of such poor quality that patients would prefer not to attend, so potentially direct observation could reduce adherence.

Enthusiasts make the world go round, but there is a belief among specialists in tuberculosis that it is unethical not to provide direct observation. This attitude stifles debate and good research into alternatives to direct observation is replaced by semantics. For example, specialists state that “direct observation of treatment is more than a mechanical procedure of dropping medicine into a patient’s mouth; it is a human bond between a patient and the health worker, to transmit a recognition of the value of treatment success.”<sup>7</sup> What would be more helpful is to look at all the strategies to promote adherence. For example, we know that defaulter retrieval action seems to work in some settings;<sup>10</sup> so why not try defaulter actions for self treating patients who do not visit the clinic once a month? What about some good research on staff support and supervision, health education, or various forms of prepackaging? What about peer assisted treatment support? We need a variety of methods to help patients complete their treatment, as well as exploring the circumstances where direct observation will be useful.

The energy going into insisting that direct observation is essential and non-negotiable has its own opportunity costs. We believe that there are good arguments for dropping the insistence on direct observation and turning the passion into credible

Review: Directly observed therapy for treating tuberculosis  
 Comparison: 01 Any directly observed therapy (DOT) vs self administration  
 Outcome: 02 Cure plus treatment completion



Total events: 663 (Treatment), 488 (Control)

Test for heterogeneity:  $\chi^2=4.25$ ,  $df=3$ ,  $P=0.24$ ,  $I^2=29.4\%$

Test for overall effect:  $Z=1.80$ ,  $P=0.07$

Results of four trials of direct observation over self treatment in tuberculosis

methods for developing, evaluating, and promoting sustainable measures to improve adherence.

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## The patient’s perspective on medicines in mental illness

*Drug treatment is only a part of what the patient needs*

Worldwide 40 antipsychotic preparations are available and twice as many antidepressants. As a patient with a recurrent depressive disorder myself it would be comforting to think that choice of treatment is based on a concordance between the patient’s wishes and the doctor’s advice. In

reality it will reflect the many factors that affect their relationship—medical attitudes; the way information is presented; the capacity of patients to understand this information and to relate it to their condition; health service, social, and commercial pressures. Not surprisingly, Cochrane reviews of interventions to improve

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