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Costs and cost-effectiveness of different DOT strategies for the treatment of tuberculosis in Pakistan

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An economic study was conducted alongside a clinical trial at three sites in Pakistan to establish the costs and effectiveness of different strategies for implementing directly observed treatment (DOT) for tuberculosis. Patients were randomly allocated to one of three arms: DOTS with direct observation by health workers (at health centres or by community health workers); DOTS with direct observation by family members; and DOTS without direct observation. The clinical trial found no statistically significant difference in cure rate for the different arms.

The economic study collected data on the full range of health service costs and patient costs of the different treatment arms. Data were also disaggregated by gender, rural and urban patients, by treatment site and by economic categories, to investigate the costs of the different strategies, their cost-effectiveness and the impact that they might have on patient compliance with treatment.

The study found that direct observation by health centre-based health workers was the least cost-effective of the strategies tested (US$310 per case cured). This is an interesting result, as this is the model recommended by the World Health Organization and International Union against Tuberculosis and Lung Disease. Attending health centres daily during the first 2 months generated high patient costs (direct and in terms of time lost), yet cure rates for this group fell below those of the non-observed group (58%, compared with 62%). One factor suggested by this study is that the high costs of attending may be deterring patients, and in particular, economically active patients who have most to lose from the time taken by direct observation.

Without stronger evidence of benefits, it is hard to justify the costs to health services and patients that this type of direct observation imposes. The self-administered group came out as most cost-effective ($164 per case cured). The community health worker sub-group achieved the highest cure rates (67%), with a cost per case only slightly higher than the self-administered group ($172 per case cured). This approach should be investigated further, along with other approaches to improving patient compliance.

Key words: DOT, tuberculosis, direct observation, patient compliance, costing study, cost-effectiveness analysis, Pakistan

Introduction

Tuberculosis (TB) remains the most common cause of adult deaths in developing countries. Numbers of cases are continuing to grow, due to population growth, HIV and, in some circumstances, inadequate treatment. There is therefore considerable interest in improving the performance of health services in treating TB, and in particular in increasing patient compliance. Non-compliance rates are often high, and can lead to relapse and the development of drug-resistant strains, which are harder and more expensive to treat.

The current model of treatment recommended by the World Health Organization (WHO) and the International Union against Tuberculosis and Lung Disease (IUATLD) is the DOTS (directly observed treatment, short-course) strategy. The DOTS model includes strengthening diagnosis, treatment, outcome monitoring, drug supplies and direct observation of treatment. There has been little evidence to date, however, of the additional benefit provided by the direct observation of treatment (DOT) component. A study in South Africa (Zwarenstein et al. 2000) found some benefit from DOT using lay health workers, but the result was not statistically significant. A Thai study (Kamolratanakul et al. 1999) found DOT to be effective, but they had adapted the model, using DOT by family members, supported by a once-weekly home visit from health workers.

A recent review of DOT and treatment adherence (Volminck et al. 2000) emphasizes the importance of a wide array of interventions to promote adherence – such as reminder letters, financial incentives and increased supervision by staff. They observe that factors such as the quality of interaction between patients and supervisors may be more relevant than

the DOT itself, and recommend that WHO make explicit both the mixture of inputs which are required to improve adherence and the additional resources which successful implementation of DOT usually requires.

The details of the clinical trial in Pakistan are published elsewhere (see Walley et al. 2001). However, the overall conclusion – which is surprising – is that the directly observed element made little difference to cure rates. Cure rates rose from 26 to 60% in the trial group as a whole, with no statistically significant difference between the different arms and with similar results from the three sites. This raises some important questions for the implementation of the DOT strategy in this and other countries.

This paper takes a social perspective, focusing on the costs to the health service and to patients of the different treatment strategies. These can be used to shed light on a number of important questions:

(1) What are the costs to patients of the different treatment strategies? What proportion can be attributed to the directly observed element? To what extent may these costs account for (poor) compliance levels?
(2) What are the total (patient and health service) costs of the different treatment strategies?
(3) What is the overall cost-effectiveness of the different strategies, looking at total costs and cure rates?

Methods

Strategies compared

In order to assess the effectiveness of different DOT strategies, a randomized controlled trial was carried out in three trial sites (Rawalpindi, Gujranwala and Sahiwal) in the Punjab, Pakistan, with three arms. All three received a strengthened service (i.e. the other components of DOTS), but one group had their treatment supervised by health workers, a second by family members and a third were unsupervised. Within the arm supervised by health workers, patients were divided into two sub-groups: those living within 2 km of the nearest health centre were supervised by health workers based in those centres, while more distant patients visited their local community health worker (CHW), commonly a Lady Health Worker (LHW). The health worker DOT followed the WHO guidelines, adapted to the Pakistan context. In contrast, family member DOT is not recommended by WHO, but was included as a possible alternative when access to health workers is poor. The self-administered group is the current practice in Pakistan and was included as a control.

The treatment takes 8 months. The 'intensive phase', during which observation of treatment is recommended, covers the first 2 months. Three visits to a diagnostic centre are required during the first 2 months, for initial diagnosis, sputum smears and follow-up. During the remaining 6 months, a further two visits should be made for sputum examination and clinical assessment. During this second phase, all treatment groups visit their local health facility every 2 weeks to collect their drugs.

The main difference between the arms is the number of daily visits required for direct observation of treatment during the first 2 months. Patients allocated to the health facility group made an additional 40 visits during this period to their local health facility to be watched taking their drugs, while the CHW group visited their village health worker an additional 53 times, and family member patients had 53 meetings with the family member chosen to supervise their drug taking.

Costing

Patients

From the total of 497 patients in the trial (all adult), 337 (68%) were found and interviewed after the completion of the trial. Of these, 194 were from rural areas and 143 from urban. Forty-six belonged to the health facility group, 73 to the CHW group, 107 to the family member group and 111 were unsupervised. The proportion found and interviewed from each of the three trial sites ranged from 66–69%. Forty-eight per cent were male and 52% female.

Patient costs were collected using a standardized questionnaire. Data collected included travel and transportation costs, service charges, miscellaneous out-of-pocket expenses and the opportunity costs of travelling to health facilities and receiving treatment. Service charges (though at a subsidized rate) were levied at two of the three diagnostic centres run by NGOs; treatment was free at the government-run TB Centre. Fees are added in to the totals for patient costs, in order to illustrate the real costs to patients. They are omitted from the final cost-effectiveness ratios in order to avoid double-counting with health service costs (the fees are contributing to the service costs of the NGOs). Data on the cost of family escorts were also collected (these are particularly relevant for women).

In order to value the time lost during travel and treatment, focus group discussions were held among patients arriving at the TB Centre, Rawalpindi, and for different occupational groups. Average losses (in Pakistan Rupees) were calculated for each of the six main occupation groups: unskilled daily labourers; skilled daily labourers; farmers; household women; self-employed traders; and the unemployed. An average opportunity cost of Rs.11 per hour was used to value time lost for travel, waiting, treatment, observation of drug taking, etc. This was a conservative estimate, based on the assumption that a full day's labour would not be lost. If attending treatment meant losing the opportunity to work for the full day (e.g. for day labourers), the opportunity costs would be much higher (estimated average daily cost of Rs.100).

Escorts often accompany the TB patients on their visit to the diagnostic and treatment centres. This is more commonly the case with female patients. Based on the interviews with patients, gender-specific data were collected on the frequency of use of escorts. This was then used to calculate the direct and opportunity costs that they incur. It was assumed that the time and transport costs they face are the same as for patients.

Health service costs

Data on health service costs were collected from the three trial sites (Rawalpindi, Gujranwala and Sahiwal). These included:

- the costs of clinical assessment at the diagnostic centres (including laboratory investigations and diagnostic procedures, health education, record keeping, etc.);
- contacts at the treatment centre for drug collection (for urban patients);
- cost of outpatient visits to basic health units and rural health centres (for rural patients to collect drugs);
- the TB drug regimen;
- supervision of patients by their designated supervisors;
- costs of strengthening the programme (a one-off start-up cost of setting up the TB DOTS programme).

For the diagnostic centres, expenditure data for 1997–8 were used to estimate costs. To derive unit costs, cost centres were set up for the various components of the programme (such as clinical assessment, radiological investigations, laboratory investigations, health education, record keeping and TB drugs). Administrative or overhead costs were allocated to them on the basis of the payroll costs of the service centres. Two other allocation methods were tested: one using the proportion of the budget allocated to the cost centre; the other using number of persons employed in that department. The first method was found to be weighted in favour of departments with high expenditure (e.g. with large drugs budgets); the second was found to favour departments with a large number of support staff (such as clinical assessment). The payroll method was found to be the most proportionate.

Annual building rent (based on the size of facility and market rental values) was added to reflect the capital costs of the programme. Similarly, a depreciation charge of 10% of the value of fixed assets was added to reflect the economic costs of equipment (using an estimated useful lifetime of 10 years for most equipment, such as X-ray machines). Drugs and supplies budgets were linked to number of patient visits to produce average costs per TB patient.

At the district level, budget data for 1997–8 were used as the basis for calculating average costs per outpatient visit to peripheral units – the basic health units (BHU) and rural health centres (RHC). Budgets are usually consumed, so this was thought to be a good proxy for expenditure. Costs of administration and supervision at the district level were included, as well as funds allocated directly to the peripheral centres. Based on interviews with officials, it was understood that on average RHCs consumed three times the budget of a BHU. This ratio was therefore used to allocate supervision and administrative costs. Drugs costs were taken from the annual budget for medicines. These costs were then linked to numbers of patients visiting the health centres (taken from the health management information system) to produce unit costs.

Drugs costs were estimated at Rs.2000 per patient in the provincial plan (PC-1). This was cross-checked against a retail market survey, which came out with the figure of Rs.1915 for a complete course of adult patients. As this was close, the figure of Rs.2000 was used.

To calculate the costs of community health workers, two sources were used: (1) the PC-1, issued by the government, which details the costs of LHWs; and (2) interviews with government officials to establish overall costs of employing LHWs, and what proportion might be attributed to this programme. A monthly cost for work on the programme was calculated, including salary, supervision costs, driver costs and petrol for travel. Interviews were carried out to assess the time taken by CHWs and LHWs for patient visits and the average number of patient visits per day (1997–8). From this, a daily rate for LHW services was calculated, as well as a cost per patient visit.

The costs of strengthening the programme were taken from provincial plans for implementation of community-based DOTS TB care in three of the four provinces (Northwest Frontier, Punjab and Sindh; figures not available for Balochistan). They include programme management, supervision and monitoring costs; health education; training; and investments in laboratory materials and salaries. Although these are start-up costs for the programme (i.e. non-recurrent in theory), it was decided to include them as they will be necessary in most cases and should contribute to the higher cure rate achieved. Overall costs were divided by the number of patients treated, to gain an average cost per patient across the different sites.

Although from a decision-maker's point of view, marginal cost information is preferable, this information was not available in this study, and so average cost figures are used throughout. As programme size, organization and/or utilization changes, these unit cost figures will of course be altered.

The smaller items are reported in Pakistan Rupees (Rs), while the main results are reported in US dollars ($). They are converted from Pakistan Rupees at the exchange rate prevailing at the time of the trial, which was roughly Rs.50: US$1 (1997–8), and rounded up or down to the nearest dollar.

Using the cure rates data from the clinical trial (which used the WHO/IUATLD definition of cure – sputum negative at 7 or 8 months, and on at least one previous occasion), we have calculated a cost per patient cured for the different arms.

Results

Patient and family costs

Patient costs varied by site and rural/urban status. Generally, costs increased with distance, as you would expect, so that visits to diagnostic centres were more costly than treatment centres, etc. Average figures for distance, time and direct costs incurred per visit are presented in Table 1. Note that the service charges are based on two sites only, as there were no charges made at the government centre at Rawalpindi.

Table 1. Average distances, times and costs per visit for TB trial patients

	Mean	Median
Distances – average distance from home to the:		
Diagnostic centre	15 km	12 km
Treatment centre	6 km	4 km
CHW/LHW	2 km	1 km
Family supervisor	0 km	0 km
Time – average time spent in travel to and from:		
Diagnostic centre	136 minutes	120 minutes
Treatment centre	76 minutes	60 minutes
CHW/LHW	19 minutes	20 minutes
Family supervisor	0 minutes	0 minutes
Costs – travel, to and from:		
Diagnostic centre	18 Rs.	16 Rs.
Treatment centre	8 Rs.	6 Rs.
CHW/LHW	2 Rs.	1 Rs.
Family supervisor	0 Rs.	0 Rs.
Costs – misc. out of pocket expenses:		
Diagnostic centre	33 Rs.	10 Rs.
Treatment centre	13 Rs.	0 Rs.
CHW/LHW/Family supervisor	0 Rs.	0 Rs.
Costs – service charges at diagnostic centre (apply in two sites only; averaged over three):		
Clinical assessment	29 Rs.	20 Rs.
Lab. Investigation: ESR	12 Rs.	0 Rs.
Lab. Investigation: Sputum microscopy	35 Rs.	0 Rs.
Lab. Investigation: X-ray/MMR	90 Rs.	0 Rs.
Pharmacy	21 Rs.	0 Rs.

An urban patient incurred direct costs of Rs.32 per visit to the diagnostic centre (either for diagnosis/treatment, or drug collection). Added to this was Rs.38 in opportunity costs for diagnosis/treatment (based on the valuation of Rs.11 per hour), and Rs.18 in opportunity costs of drug collection. A rural patient incurred direct costs of Rs.63 per visit to the diagnostic centre and Rs.13 per visit to the treatment centre. Their average opportunity costs were Rs.59 for visits to the diagnostic centre and Rs.17 for visits to the treatment centre.

All patients make five visits to the diagnostic centres, and 17 to treatment centres to collect drugs. The health centre group had an additional 40 visits to their treatment centre for DOT; while CHW and family supervision patients had 53 additional visits for DOT. The average costs of visiting the CHW for an urban patient was Rs.5 (i.e. Rs.265 total), while rural patients incurred Rs.2 per visit (Rs.106 total). These reflected opportunity costs only: no direct costs were incurred. For family member patients, no additional costs (direct or opportunity) were thought to have been incurred. Table 2 shows total patient costs, by treatment arm. The differences in total patient costs are attributable to the DOT element.

A patient follow-up survey (with a 67% response rate) carried out as part of this trial sheds some light on compliance issues (see Table 3).

Table 2. Total patient costs, by treatment arms

	Unsupervised/family member DOT (US$)	Health facility DOT (US$)	Community health worker DOT (US$)
Patient direct costs of visits to diagnostic centre	5 (3 urban; 6 rural)	5	5
Patient direct costs of fortnightly drug collection from local health facility	8 (11 urban; 4 rural)	8	8
Direct costs of additional DOT visits	n.a.	18 (26 urban; 10 rural)	2
Opportunity costs of visits to diagnostic centre	5 (4 urban; 6 rural)	5	5
Opportunity costs of fortnightly drug collection	6	6	6
Opportunity costs of additional DOT visits	n.a.	14	5
Total patient costs	23	55	31

Table 3. Constraints to treatment – patients' responses

Barriers to treatment	Intensive phase (%)	Continuation phase (%)
Health-related problems	36	19
Time for round trip	31	21
Cost of travel/visit	29	17
Excessive waiting time at treatment centre	16	7
Unavailability of person to accompany	14	6
Social events – birth, death, marriages, etc.	11	9
Job/occupational reasons	9	10
Unfriendly attitude of staff	4	1
Lack of support by 'significant people'	1	0
Other	2	1

Table 4 shows the total escort costs, by treatment arm, gender and place of residence. These costs are not included in the total cost and cost-effectiveness results as their influence on compliance is not established and they may be less applicable in other contexts.

Health service costs

An average visit to the diagnostic centre cost the health service Rs.24 for clinical assessment. Adding in the costs of other inputs, such as pharmacy costs, record-keeping, etc. the costs of treating one patient were estimated at Rs.1364 in the intensive phase (for three visits) and Rs.1149 in the continuing phase (for two visits). This comes to a total of Rs.2513 per patient.

The cost of a visit to the treatment centre for drug collection came to Rs.93 per patient (including the cost of drugs). The total for rural patients was therefore Rs.1581 for 17 visits. The urban patients collected their drugs from the diagnostic centre, at a cost of Rs.40 per visit, or Rs.680 in total for 17 visits.

The additional costs to the health service of DOT depend on the treatment arm. Rural patients in the health centre sub-group made 40 additional visits for DOT to the treatment centre, at a cost of Rs.93 per visit (Rs.3720 in total). Urban patients visited the diagnostic centre 40 additional times, at a cost of Rs.24 per visit (Rs.960 in total). CHW-supervised patients had an extra 53 visits from CHW/LHW, at a cost of Rs.6 per visit (Rs.106 in total).

Programme strengthening costs averaged Rs.425 per person for all treatment arms.

Table 5 presents the total health service costs, by treatment arms. As with the total patient costs, the differences between the final figures are entirely due to the DOT element of the package.

Table 4. Costs of escorts (by treatment arm and by gender)

	Urban, male (US$)	Urban, female (US$)	Rural, male (US$)	Rural, female (US$)
Unsupervised treatment	10	18	8	16
Health facility	26	46	12	33
Community health worker	9	19	7	19
Family member	10	18	8	16

Table 5. Average health service costs for DOT per patient (by treatment arm)

	Unsupervised/family member DOT (US$)	Health facility DOT (US$)	Community health worker DOT (US$)
Programme strengthening cost	8.5	8.5	8.5
Costs of clinical contacts at diagnostic centre for diagnosis and follow up	50	50	50
Costs of clinical contacts at local health facility for fortnightly drug collection	23 (14 urban; 32 rural)	23	23
Health service costs of additional DOT visits	n.a.	47 (19 urban; 74 rural)	6
Total health service costs	81.5	128.5	87.5

In Table 6, patient and health service costs are added to give the overall cost of each treatment arm. Total costs are presented for rural and urban areas, within each treatment arm. The cost of the health facility and CHW DOT arms are presented in relation to the benchmark of self-administered or family DOT approaches, in order to illustrate the magnitude of increase in total costs for these arms.

The results (in Table 7) suggest that self-administered treatment has been the most cost-effective approach in this case ($164 per case cured), though CHW supervision is only slightly more costly ($172 per case cured) and achieves a higher cure rate. Least cost-effective is health centre DOT ($310 per case cured).

A sensitivity analysis was done on the final cost per case cured, to see how it was affected by changes in the cure rates. The upper and lower limits of confidence intervals for differences between the different DOT arms and the control group cure rates were taken from the original clinical trial. The results are shown in Table 8.

Discussion

In terms of cost-effectiveness, from this analysis health centre DOT comes out as least cost-effective, which is an interesting result as this has been the recommended model of practice within the current WHO DOTS package. According to these results, self-administered treatment is the most cost-effective. However, the preferred option might be treatment supervised by CHWs, which is slightly more costly but has a higher cure rate. The incremental cost of shifting from self-administered to CHW supervision is $239 per extra case cured.

The sensitivity analysis supports these conclusions. At every level of likely cure rates, the health centre option comes out as the least cost-effective, and the self-administered group as most cost-effective. The only exception is when the CHW group cure rates are at the top of their range; this option then becomes the most cost-effective approach.

Cure rates for the CHW group have to be treated with some caution though, as this group was not fully randomized in the clinical trial (patients were randomized to the health worker arm as a whole, but within that were divided into health centre and CHW sub-groups according to how far they lived from the health centres). It is therefore possible that there is some bias in the allocation of patients between these two sub-groups.

For the health worker group as a whole, there is no statistically significant improvement in cure rates compared with the other two arms. As the cure rates are broadly the same

Table 6. Total cost to health service and patients of different treatment arms

	Unsupervised/family member DOT	Health facility DOT	Community health worker DOT
Total cost	$102 ($93 urban; $110 rural)	$180 ($153 urban; $208 rural)	$115 ($107 urban; $124 rural)
Total cost as % of benchmark (unsupervised arm)	100%	176% (164% urban; 189% rural)	114% (115% urban; 113% rural)

Table 7. Cost-effectiveness of the different treatment strategies

	Health centre DOT	Community health worker DOT	Family member DOT	Unsupervised
Cure rate	58%	67%	55%	62%
Cost per patient treated	$180	$115	$102	$102
Cost per case cured	$310	$172	$185	$164

Table 8. Sensitivity analysis of cure rates and their effect on cost per case cured

Treatment arms (or sub-groups)	Lowest estimate of cure rate (95% CI)	Highest estimate of cure rate (95% CI)
Family member group	38% cure rate $276 per case cured	59% cure rate $178 per case cured
Health centre group	50% cure rate $360 per case cured	70% cure rate $257 per case cured
Community health worker group	59% cure rate $195 per case cured	79% cure rate $146 per case cured

across the different treatment arms, it is possible to speculate that some of the positive motivational effects of DOT were cancelled out by the increased costs which patients faced, leaving the results roughly the same as if no DOT had taken place.

What the cost data highlights is the degree of additional financial burden that direct observation imposes, especially in the case of the health centre patients. This approach increases the health services costs by 126% for urban patients and 182% for rural. At the same time, patient costs rise by even more: 267% for urban patients and 207% for rural patients. During the intensive phase of treatment, DOT at health facilities accounts for 62% of patient costs in urban areas and 52% in rural areas. For the CHW group, DOT accounts for roughly 25% of rural and urban patient costs.

The high costs to the patient of direct observation by health workers (especially in the health centres) are likely to have an influence on compliance levels. Within the trial, 18% of patients randomized to the health worker DOT (either health centre or CHW) were unable to persevere and were given self-administered treatment (Walley et al. 2001). For family member DOT, the figure is 2%, reflecting perhaps the lower patient costs incurred by this arm.

One issue is whether the patients who responded (68%) are representative of the total sample in the trial. The breakdown by trial site, by gender and by location suggests that they should be fairly representative. The proportion responding by trial site has a narrow range of 66–69%. Fifty-two per cent of respondents were female and 48% male (compared with 49% female and 51% male in the full trial sample). In terms of location, 58% were rural and 42% urban (not very different from the trial sample of 56% rural and 44% urban).

Consistent with other results, the escorts' costs show the health facility approach to be most costly. For all treatment arms, women are likely to incur about twice the cost of men in terms of escorts' time and expenses. Another interesting feature is that the costs of access, for escorts, to urban health facilities appears to be higher than for rural patients, which is contrary to what we might have expected.

The reason why CHW patients' escorts incur lower costs in some categories than family member escorts is that family member patients have to visit their local health facility fortnightly to collect drugs, whereas this function is performed by the CHW on behalf of their patients.

This study provides a very comprehensive view of the costs to the health service and to patients of the different DOT strategies. The decision to include patient costs can be justified by the nature of the programme itself, which imposes considerable inconvenience on patients (daily visits to receive drugs), and on their family members where escorts are required. The decision to list escort costs separately is debatable; arguably if the study takes a societal perspective these should have been included. Had we done so, it would have reinforced existing conclusions, as the highest costs are incurred by the health centre group. Similarly, a less conservative valuation of the opportunity costs of patient time would have increased the strength of the current conclusions.

Another debatable item is the inclusion of programme strengthening costs. It might be argued that these are a one-off investment that would not form part of the on-going costs of running the programme. However, we have included them for three reasons: first, because they are a necessary part of implementing DOTS in most regions; secondly, because they may contribute to higher effectiveness and utilization rates, and may therefore lower unit costs in the medium to long term; and thirdly, because they contributed to the cure rates achieved here, and so it would be false to report cost-effectiveness results without including them.

How typical are the costs included here – how likely are they to be valid for other settings? One issue is whether patients are charged for drugs and treatment. In some situations these are free; at other times (especially in the private for-profit sector) patients have to pay. This picture is reflected in this study, with two centres charging (at a subsidized rate) and the third providing treatment free of charge.

The costs reported here do of course reflect utilization levels. How typical are they of other regions? In Pakistan, generally, utilization is high for diagnostic centres, but lower for peripheral treatment centres. As many of the programme costs are stable over large ranges of output, an increase in utilization would result in lower costs per case treated or cured.

One of the main questions of interest is how to increase utilization and compliance rates for TB programmes worldwide. This study suggests that there may be a link with the costs to patients, although this conclusion needs to be examined further in in-depth interviews with patients and relatives. One of the striking differences in the trial was between drop-out rates for men and women: 15% of women dropped out in the intensive phase, compared with 25% for men (a statistically significant difference). One possible explanation for this is that men face higher opportunity costs of treatment and direct observation because they are more likely to be economically active (the focus group discussion suggested that housewives were likely to be able to rearrange and share activities to fit in with treatment). This may have contributed to a dramatic difference in overall cure rates: 71% for women, compared with 50% for men. (In Walley et al. 2001, sex was the only factor tested which was found to have a statistically significant impact on treatment outcome. The relationship with income was not investigated.) Another factor may be that the social consequences of the disease (e.g. on marriageability) are more significant for women than for men (Khan et al. 2000).

Analysis of default rates by treatment arm provides a more complex picture. Default rates are highest for the self-administered arm (33%) and lowest for the health worker arm (27%). However, within the health worker arm, CHW

patients had a lower rate (25%) compared with health centre patients (30%). There may be a number of factors at play here, including positive motivation of health workers and the disincentive effects of distance and time.

In the survey of constraints to treatment, from a patient perspective, time, costs and poor health come out as the top three factors. In addition, there are probably social costs to being identified as having TB. Two-thirds (63%) stated that they keep their disease secret from most of their relatives, while a similar proportion (64%) felt that their relationship with 'significant people' was affected by the disease. Inasmuch as direct observation makes their condition more public, it is likely to generate additional non-monetary social costs, such as stigma effects. When asked why they agreed to direct observation in this trial, the largest response was 'to get short, free and quality treatment' (68%). It seems likely that from a patient's perspective, it is the non-DOT components of DOTS that are attractive.

Conclusion

This study highlights the costs – both direct (fees, transport costs, etc.) and indirect (the cost of time lost from work as a result of treatment) – for patients as well as for health services of the DOT. If this model results in improved outcomes, then the costs may be justified. However, the clinical trial found no significant improvement in cure rates attributable to the element of direct observation within the DOTS model. In this context, there is little justification for imposing a high burden of inconvenience and economic costs on patients – costs that may constitute a major barrier to utilization and compliance with treatment.

Some of the correlations found between drop-out rates and different patient groups (by sex, economic occupation and treatment arm) merit further investigation in a social study to establish more clearly the factors that influence health-seeking behaviour.

On the basis of the analysis here, a provisional recommendation might be made to broaden the range of strategies employed to enhance patient compliance, beyond the element of direct observation (e.g. blister packs of drugs and patient education). Using CHWs for DOT also looks promising. This conclusion is consistent with the results of other related studies carried out to date (for example, Floyd et al. 1997 and Wilkinson and Davies 1997), and also with trends in WHO. WHO/StopTB is now using the DOTS label to refer to the broad TB strategy, and putting less emphasis on the direct observation component.

Cure rates for health centre observation were lower than self-administered patients, and this category generated the highest costs, both to patients and the health service ($310 per case cured). The standard type of observation recommended by the WHO DOTS model therefore came out as having the highest cost per case cured, while the CHW arm achieved the best cure rates and at a cost only slightly above the self-administered group ($172 per case cured, compared with $164). While the cost figures will vary from place to place, the underlying conclusion is likely to remain the same: that DOT (especially at health facilities) imposes considerable patient and health service costs, which can only be justified by proven benefits.

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Biographies

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