

DOT for patients with limited access to health care facilities in a hill district of Eastern Nepal

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SUMMARY

SETTING: The hill district in Nepal, where access to health care facilities is difficult.

OBJECTIVE: To compare results before and after a decentralised directly observed treatment (DOT) intervention.

DESIGN: Prospective study of patients registered in Dhankuta district, Nepal, 1996–1999. Patients received their intensive phase treatment under health worker supervision via one of three DOT options: 1) ambulatory from the peripheral government health facilities; 2) ambulatory from an international non-governmental organisation (INGO) TB clinic in district centre; or 3) resident in INGO TB hostel in district centre. Historical data from 1995–1996, with unsupervised short-course chemotherapy, were used for comparison.

RESULTS: Of 307 new cases, respectively 126 (41%), 86 (28%) and 95 (31%) took their intensive phase treatment via options 1, 2 and 3. Smear conversion (at 2 months) and cure rates in new smear-positive pulmonary tuberculosis cases were respectively 81.6% (vs. 58.8% historical, $P = 0.001$) and 84.9% (vs. 76.7% historical,

$P = 0.03$). Overall costs to the INGO provider fell by 7%, mainly as a result of staffing reductions in the INGO services made possible by rationalisation with government services during the intervention.

CONCLUSION: By offering varied DOT delivery routes, including an in-patient option, satisfactory results are possible with DOT even in areas where access to health care facilities is difficult. Provision of in-patient care via an INGO TB hostel allowed a significant proportion of new cases (31%) to receive their intensive phase treatment who otherwise may have had difficulty accessing treatment, due either to the distance to the nearest health facility or to disease severity. Substitution of government hospital beds or local hotel beds for the INGO hostel beds may allow the model to be reproduced elsewhere in similar geographical conditions in Nepal, but further studies should be performed in a non-INGO supported district beforehand.

KEY WORDS: tuberculosis; DOT; hostel care; access to health care; hill district; Nepal

TUBERCULOSIS (TB) is one of the most significant health problems facing Nepal, with an estimated 60% of the adult population infected with TB. Each year, 44 000 people develop active disease; 20 000 of these are sputum-positive pulmonary tuberculosis (PTB) cases, and despite the implementation of a much-improved National Tuberculosis Programme (NTP), 8000–11 000 people still die from TB each year.¹

A mix of government, national non-governmental organisations and international non-governmental organisations (INGO) provides TB services under the NTP in Nepal. The Britain-Nepal Medical Trust (BNMT) is one such INGO which for over 25 years has been assisting His Majesty's Government of Nepal (HMG/N) in TB control activities by providing TB and leprosy services via district TB/Leprosy clinics in eight hill and mountain districts of eastern Nepal. Historically, these clinics have been run and staffed by BNMT employees, with outreach activities to periph-

eral HMG/N health posts. Since 1992, HMG/N health post staff have become increasingly involved in delivery of TB and leprosy services; there has thus been a gradual hand-over of responsibilities by BNMT to the HMG/N staff, plus at the same time an integration of the previously vertically delivered TB services into the general health services.

International agencies such as the World Health Organization (WHO) and the International Union Against Tuberculosis and Lung Disease (IUATLD) promote directly observed treatment, short course (DOTS) as an effective strategy for improving treatment outcomes for tuberculosis.^{2,3} The strategy comprises five pillars, namely political commitment, passive case finding via sputum smear microscopy, standardised treatment with short course chemotherapy (SCC) under direct observation, regular and adequate drug supply, and a monitoring system for programme supervision and evaluation. Although it

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comprises just part of one of these pillars, great emphasis has been placed on the importance of direct observation of treatment (DOT), at least during the intensive phase.

Starting in 1996 with four pilot sites, the DOTS strategy has been both adopted and successfully implemented by the NTP in Nepal. By late 1999, over half of the population had access to DOTS services.¹ The 1998–2003 NTP Plan projected that by the end of 2000 the whole country would be covered by the DOTS programme. However, the population covered by the DOTS programme in late 1999 was either in the Tarai (Lowlands) districts of Nepal or the capital, Kathmandu. The remaining population, over 40% of Nepal's 21 million, lives in hill or mountain districts, where means of transport are limited and access to health care facilities is extremely difficult.⁴ Nationally, although approximately 45% of households can physically access a health facility within a travel time of 30 minutes,⁵ this mainly applies to the Tarai districts and the large urban areas. In many of the hill and mountain districts, where travel times to the nearest health facility are measured in hours or even days, the provision of daily DOT to all TB patients by health workers via the existing general health care facilities is extremely difficult.

There was no clear model on how to implement the full DOTS strategy in these hill and mountain districts. A previous study by BNMT in four hill and mountain districts of eastern Nepal, using unsupervised SCC supplied monthly, despite good cure rates, showed failure and relapse rates that suggested that more intensive supervision of treatment, including DOT, should be organised where possible.⁶ The guidelines of the NTP at the time of our study were that the treatment supervisor must be a health care worker and that during the intensive phase of treatment DOT was to be given daily.⁷

The aim of the study was to test the implementation of a complete DOTS programme in a hill district of Nepal using a range of DOT delivery options, assessing its success by changes in treatment outcome results and costs.

SETTING

This pilot study was implemented in Dhankuta District, a hill district in eastern Nepal. The population of 179 131 is overwhelmingly rural, living in small villages or scattered households over an area of 891 km². The terrain consists of high hills and valleys, with two large towns, Dhankuta (population 20 820) and Hile (4341). One tarmac road bisects the district; all other transport is by foot on narrow trails that wind over the hills and valleys.

A range of health facilities is present within the district. The government Basic Health Service facilities, common to all districts in Nepal, consist of: a 15-bed

District Hospital in Dhankuta town (District Centre), with X-ray and laboratory facilities and staffed by a medical officer, health assistant, laboratory assistant and auxiliary staff; two primary health centres (PHC), theoretically staffed by a doctor, laboratory assistant, health assistant and auxiliary staff; and 11 health posts (HP), theoretically staffed by a health assistant and auxiliary staff. However, due to staff shortages and high transfer rates, staff complements rarely reach 100% at any level of the HMG/N health facilities.^{8,9} BNMT's TB/Leprosy clinic and hostel in Dhankuta was staffed prior to the initiative by two clinic workers, two default tracers and one auxiliary staff.

The health posts and primary health centres are scattered throughout the district, at distances of approximately 10–45 km from the District Centre (equivalent to from 5 to more than 24 hours walking time). All residents of the district are within 3–4 hours walking distance of a health facility.

TB services pre-intervention

Case-finding activities were performed at all health facilities by both HMG/N and BNMT staff, with the diagnostic procedures, microscopy and X-ray, being performed at the District Centre. Suspects presenting to peripheral HMG/N health facilities (HP and PHC) had three sputum samples taken. HMG/N health workers would fix the sputum samples on a microscope slide and send the fixed slide to the District Centre. A courier system, utilising the movements of BNMT's default tracers and peripheral HMG/N staff, was in place to transport fixed slides (approximately one third of the annual total of slides examined) from the peripheral health facilities to the District Centre for microscopy examination.

Case-holding activities at the District Centre were performed exclusively by the BNMT staff at the TB/Leprosy clinic. At the periphery, the BNMT clinic staff would visit the peripheral Government health units once a month on a fixed date to hold a monthly TB/Leprosy clinic day, where TB (and leprosy) patients would receive their monthly drug supplies from the BNMT workers. HMG/N staff did not dispense drugs to the patients.

From 1995, the treatment regimens used were per NTP guidelines, i.e., Category I 2HRZE/6HE, Category II 2SHRZE/1HRZE/5HRE and Category III 2HRZ/6HE.* Except for Category II patients, who were admitted to the hostel during their intensive phase, treatment was unsupervised, with monthly drug supplies being given to patients throughout treatment. The drugs at this time were supplied by BNMT.

* H = isoniazid; R = rifampicin; Z = pyrazinamide; E = ethambutol. Numbers before the letters indicate the duration in months of the phase of treatment.

BNMT staff did all recording and reporting, following formats drawn up by BNMT. The BNMT default tracers, who visited the peripheral health facilities a few days after the monthly 'clinic day', traced any late or defaulting patients identified on the clinic day. They also carried drugs, slides, etc., from the District Centre to these health units according to orders placed by BNMT's clinic workers.

Historically, the TB/Leprosy hostel had been used to house TB re-treatment cases for their intensive phase treatment, and severely ill TB or leprosy patients until they were well enough to take ambulatory treatment. Patients stayed in the hostel free of charge and also received a small, weekly financial grant in order to purchase food while resident in the hostel. The weekly payments rose from 170 Nepali Rupees (NRs) in 1995 to 250 NRs in 2000 (the estimated average daily wage was 150 NRs in 2000). While resident in the hostel, patients received their TB treatment daily from the BNMT staff. The daily treatment, however, was not given under strict DOT conditions. There was an agreement that the hostel patients were to be considered as hospital in-patients (the hostel was situated 50 m from the HMG/N District hospital) and all medical needs, bar the basic TB (and leprosy) treatment, were the responsibility of the HMG/N District Hospital Medical Officer. BNMT's auxiliary staff member was in charge of cleaning and general maintenance of the hostel.

METHOD

Starting in July 1996, a study was undertaken in Dhankuta District to test the feasibility of implementing daily DOT as recommended by the NTP in a hill district of Nepal. The study utilised both a prospective component and historical data for comparison. The prospective study population was all TB patients diagnosed and registered in Dhankuta from July 1996 to November 1999 (40 months); historical data came from 1995 and 1996.

The study involved 1) the introduction of daily DOT during the intensive phase, using the existing treatment regimens, and 2) increasing involvement of the peripheral HMG/N staff in the smear courier system and transport of drugs, forms and patient cards from the District Centre to the respective peripheral health facilities.

Introduction of daily DOT during the intensive phase

Daily DOT was introduced during the intensive phase, using the existing treatment regimens for all new patients (i.e., Categories I and III). New patients were offered three options for taking their daily DOT during the 2 months of their intensive phase treatment: 1) ambulatory from a HMG/N health post or primary health centre (13 in total); 2) ambulatory from the BNMT clinic in the District Centre (Dhankuta

town); or 3) resident in the BNMT hostel in the District Centre (Dhankuta town).

During the continuation phase, medicines were supplied monthly to all cases on ambulatory treatment via option 1 or 2. Treatment regimens were not changed under the intervention and all TB medication was provided free, as is usual for patients enrolled under the NTP in Nepal.

In order to achieve this, a) admission criteria to the hostel were extended to include Category I and III TB patients who were not severely ill, but who were unable to reach an existing peripheral health care facility for their daily DOT in the intensive phase. As before the intervention, Category II cases were admitted to the hostel for intensive phase treatment, as were severe cases until they were well enough to continue with ambulatory treatment, but now the daily treatment was given under strict DOT conditions. New patients under DOT option 3 (resident in the hostel) received the weekly financial grant to buy food as for Category II and severe patients. No financial incentive was given to patients receiving their treatment under options 1 or 2.

b) The responsibility for case-holding activities at the peripheral health facilities was handed over from the BNMT staff to the Government health workers at these facilities. Thus patients could be given their drugs daily rather than the previous once a month on 'TB/Leprosy clinic day'. HMG/N health workers also took over the record keeping of TB patients receiving treatment from the respective health units.

Increasing involvement of the peripheral HMG/N staff

The peripheral HMG/N staff became increasingly involved in the smear courier system and transport of drugs, forms and patient cards from the District Centre to the respective peripheral health facilities.

In addition, the NTP took over from BNMT the responsibility of providing anti-tuberculosis drugs, as well as laboratory materials, forms, patient cards and registers. BNMT still assisted by transporting these items from the regional store in the Tarai to the District Centre. A Government District TB/Leprosy Assistant (DTLA) was now in post, whose responsibilities included supervision of all TB activities in the district and production of the quarterly NTP reports and drug orders, using data from NTP patient cards and registers kept at the district's health units. There were no changes in the diagnostic sites.

Thus the intervention's aims were to move from a situation where only some of the five pillars of the DOTS strategy were in place to a full DOTS programme (e.g., daily health worker-supervised DOT; use of a standardised recording and reporting system) and to increased ownership of the TB control activities by HMG/N.

Patient enrolment and data collection

Prior to the recruitment of patients to the prospective part of the study, meetings were held between the BNMT TB Programme Managers and the senior Government health officers of Dhankuta to plan for the implementation of the full DOTS programme. Thirty HMG/N health staff from health units in the district received a 6-day training course on the TB/DOTS Programme, given by BNMT. In addition, twenty peons (support staff) from the same health units were given a one day training course on sputum smear preparation and transportation.

All patients were registered and monitored by the treatment unit staff and the DTLA according to the NTP guidelines.¹⁰ Treatment outcomes, as defined by NTP guidelines, were ascribed to the individual patients by the DTLA. Data were transferred for analysis from the routine NTP data collection system into an Epi-Info Version 6.01 computer database kept at the BNMT headquarters in Biratnagar.¹¹ Extra data, e.g., site of intensive phase treatment, were collected separately by the BNMT district clinic staff. Supervisory staff from BNMT validated the smear conversion results and treatment outcomes from the routine NTP data records.

Historical outcome results for patients treated before the study were obtained from the computer database and annual reports at the BNMT headquarters, the data having been collected following standard WHO guidelines.^{6,12,13} Although a few of these patients were still on treatment at the start of the study, virtually all had completed their intensive phase treatment and the method of drug delivery was unaltered, both for the remaining period of the intensive phase and the continuation phase, bar the change that meant the monthly drug supply could now be collected on any day rather than on a specified monthly clinic day. The year 1995 and the first half of 1996 were specifically chosen for the historical comparison as they had the most readily available and disaggregated data, and because prior to these dates different drug regimens had been used.

Only the financial costs to BNMT were included in the analysis, as there should have been no increase in HMG/N costs arising from the intervention. The financial information came from BNMT's internal accounting system. The costs included were the direct costs of providing TB services in Dhankuta, i.e., costs of staff working there, of training HMG/N staff, and of running the clinic and hostel (telephone and utility bills, stationery, postal charges & miscellaneous purchases, staff travel costs and per diem payments while out of the district centre, weekly allowances given to the hostel residents). The costs of the hostel were accounted for under a separate budget heading. Drugs costs were not included as the regimens were unchanged under the intervention and hence the cost per patient was unchanged.

Training costs included basic TB training for all the HMG/N staff involved in Dhankuta district, as well as the annual DOTS workshop where all staff involved in TB activities in the district (HMG/N and BNMT) came together, discussed their successes and problems, and together worked out potential solutions to the problems identified.

Patients in the hostel were provided with a bed, use of a kitchen, and a weekly financial grant for food. The 15-bed hostel was built prior to the intervention and the cost of building the hostel and a boundary wall were not included in the calculations. Building maintenance costs in the intervention period (under £270 in total) were included in the heading 'Other' for analysis purposes.

Statistical analysis was performed using $2 \times 2 \chi^2$ tables, with Mantel-Haenszel and Fisher's exact 2-tailed testing. Statistical significance was set as a P value of <0.05 .

RESULTS

The average annual caseload marginally increased under the intervention (all cases 98 vs. 91, new smear-positive PTB cases 46 vs. 44). Of the 307 new cases registered and analysed during the prospective study period, 86 (28%) took their intensive phase treatment from the BNMT district clinic, 126 (41%) from an HMG/N health post or primary health centre and 95 from the BNMT hostel (31%) (Figure). The remaining 18 cases were 'transfer ins' and were not included in the analyses.

Smear-positive PTB cases made up 52.6% (172/327) of cases, of which 88.4% (152/172) were new cases (compared with 62.4% and 77.9%, respectively, amongst the historical group). The smear conversion rate (81.6%) at the end of 2 months of treatment for new smear-positive PTB (NP+) cases under the intervention was significantly higher ($P = 0.001$) than for the historical cases (58.8%) (Table 1). NP+

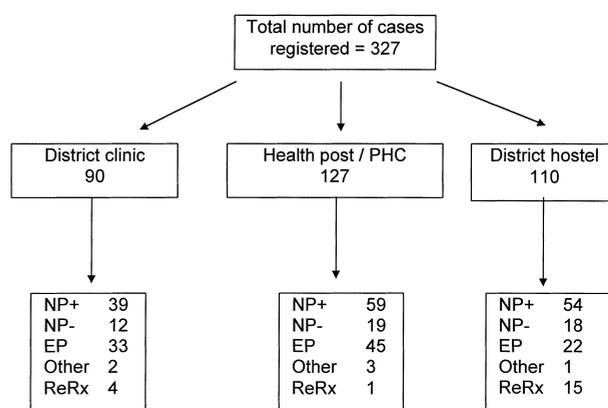


Figure Flowchart of intensive phase treatment site. NP+ = new smear-positive PTB; NP- = new smear-negative PTB; EP = new extra-pulmonary TB; ReRx = retreatment.

Table 1 Comparative results for pre-DOT (1995–1996) versus DOT intervention periods

| | Pre-DOT (%) | DOT (%) | DOT/pre-DOT × 100% | OR | <i>P</i> (Mantel-Haenszel) |
|--|-------------|---------|--------------------|---------------------|----------------------------|
| % NP+ of total case load | 48.6 | 46.8 | 96 | 0.93 (0.64–1.36) | 0.69 |
| Smear conversion rate of NP+ cases at 2 months | 58.8 | 81.6 | 139 | 3.1 (1.47–6.56) | 0.001* |
| NP+ cure rate | 76.7 | 84.9 | 111 | 1.70 (0.83–3.49) | 0.12 |
| NP+ successful treatment outcome rate | 76.7 | 87.5 | 114 | 2.12 (1.00–4.49) | 0.03* |
| All cases overall successful treatment outcome rate† | 80.4 | 83.8 | 104 | 1.26 (0.76–2.04) | 0.34 |

* Statistical significance reached.

† Successful treatment outcome for NP+ and re-treatment cases = cure + treatment completed; for new smear negative pulmonary TB & extra-pulmonary cases = treatment completed only.

NP+ = new smear-positive PTB.

patients treated in the hostel during the intervention had a significantly lower conversion rate (74.1%) than those treated at the district clinic (92.3%) ($P = 0.03$).

New smear-positive PTB cases and re-treatment cases who were recorded as having a successful treatment outcome were cure + treatment completed, whilst for new smear-negative PTB and extra-pulmonary cases treatment completed was regarded as successful.

Under the intervention, cure and successful treatment outcome rates for NP+ cases increased, with cure achieving the NTP's 85% target (Table 1), and

successful outcome being significantly higher than for the historical group ($P = 0.03$). Outcomes for re-treatment and new extra-pulmonary cases were also satisfactory, standing at 85% (17/20) cure and 86.5% treatment completion, respectively (Table 2). However, only 66% of new smear-negative PTB cases completed treatment, with 23.4% dying—a feature seen more and more throughout Nepal over the last few years.

There was a small increase in the 'all cases' successful treatment outcome rate during the intervention (83.8% vs. 80.4%), but this was not statistically sig-

Table 2 Treatment outcome (according to WHO definitions)² by health facility where the intensive phase of treatment was taken

| | Successful treatment outcome | Failure | Died | Default | Transfer out | RR | <i>P</i> value |
|-------------------------------|------------------------------|---------|------------|---------|--------------|---------------------|----------------|
| NP+ | | | | | | | |
| District hostel ($n = 54$) | 43 (79.7%) | 1 | 6 | 2 | 2 | 1.00 | — |
| HP/PHC ($n = 59$) | 53 (89.8%) | 2 | 2 | 1 | 1 | 1.13 (0.96–1.32) | 0.13 (MH) |
| District clinic ($n = 39$) | 37 (94.9%) | — | — | — | 2 | 1.19 (1.02–1.39) | 0.04* (MH) |
| Total ($n = 152$) | 133 (87.5%) | 3 (2%) | 8 (5.2%) | 3 (2%) | 5 (3.3%) | — | — |
| NP– | | | | | | | |
| District hostel ($n = 18$) | 9 (50%) | — | 7 | 1 | 1 | 1.00 | — |
| HP/PHC ($n = 17$)† | 13 (76.5%) | — | 2 | 2 | — | 1.53 (0.90–2.60) | 0.11 (MH) |
| District clinic ($n = 12$) | 9 (75%) | — | 2 | — | 1 | 1.50 (0.85–2.64) | 0.26 (FE) |
| Total ($n = 47$) † | 31 (66%) | — | 11 (23.4%) | 3 | 2 | — | — |
| EP | | | | | | | |
| District hostel ($n = 21$)‡ | 14 (66.7%) | — | 5 | 1 | 1 | 1.00 | — |
| HP/PHC ($n = 44$)‡ | 41 (93.2%) | — | 2 | 1 | — | 1.40 (1.02–1.91) | 0.01* (FE) |
| District clinic ($n = 31$)‡ | 28 (90.3%) | — | — | 1 | 2 | 1.35 (0.98–1.87) | 0.07 (FE) |
| Total ($n = 96$)‡ | 83 (86.5%) | — | 7 (7.3%) | 3 | 3 | — | — |
| Overall total ($n = 295$)§ | 247 (83.7%) | 3 | 26 | 9 | 10 | — | — |

* Statistical significance reached.

† 2 cases had their diagnosis changed.

‡ 4 cases had their diagnosis changed: 1 at the District Hostel, 1 at the HP/PHC and 2 at the District Clinic.

§ The grand total (295) does not include the 20 re-treatment cases, 6 'other' cases and the 6 cases in total who had their diagnosis changed.

RR = relative risk; NP+ = new smear positive PTB; HP = health post; PHC = primary health care; MH = Mantel-Haenszel *P* value; NP– = new smear negative PTB; FE = Fisher's exact 2-tailed *P* value; EP = new extra-pulmonary TB.

Table 3 Average annual costs (in £ sterling) to the INGO provider for pre-DOT (1995–1996) and DOT intervention (July 1996–November 1999) periods

| Cost headings | Annual average | | |
|--|----------------|---------|-------|
| | Pre-DOT (A) | DOT (B) | % B/A |
| Fixed costs | | | |
| 1. INGO staff salaries | 6835 | 5567 | 81 |
| Variable costs | | | |
| 1. HMG/N staff training/annual DOTS workshop | 146 | 578 | 396 |
| 2. Hostel expenses | 140 | 576 | 411* |
| 3. Other† | 770 | 629 | 82 |
| Total | 7891 | 7350 | 93 |
| Cost per case completing treatment | 109.60 | 92.80 | 85 |

* Whilst the number of hostel residents doubled, expenses rose four-fold. The major part of this differential increase in expenses was accounted for by a significantly higher increase in the weekly allowance given to each hostel residents than the current inflation rate.

† Includes district TB/Leprosy clinic expenses (postage and telephone charges, utility bills, freight charges, stationery, etc), INGO staff travel expenses and per diem whilst out of district centre, and miscellaneous purchases.

nificant (Table 1). New cases who took their intensive phase treatment in the district hostel fared worse in relation to treatment outcomes compared with those who took it from either the district clinic or a HP/PHC (Table 2).

Despite the expected rise in staff training costs and hostel expenses, overall costs to BNMT fell by 7% after the intervention (Table 3).

Prior to the intervention, 18 cases/year were admitted to the hostel, compared to 33 afterwards, an extra 15 cases/year admitted as a result of the intervention. These extra cases translate into a need for 2.5 bed years* for TB DOT admissions, in addition to the bed needs of severe cases and re-treatment cases. The total bed needs for comparable areas are estimated at five.† To provide these beds, by means of provision of new hostel beds, would cost £267.80 per year.‡

DISCUSSION

This paper reports on the first district-wide DOTS site in the hill districts of Nepal, where access to health care is difficult because of the terrain. Despite doubts about the feasibility of implementing a complete DOTS programme, especially with the insistence on health worker-supervised daily DOT, in areas where access to health care facilities is difficult,¹⁴ the study results suggest that DOTS can indeed be implemented

in such areas. Although caution should be used when comparing with historical non-study data, successful treatment outcome rates for new smear-positive PTB cases under the DOT intervention were significantly higher than for the historical group, with cure rates achieving the NTP target of 85%. A crucial factor was the availability of a range of DOT options for patients, as in the study district almost one third of new cases required hostel accommodation in order to receive their daily health worker-supervised intensive phase DOT, due to the distance from the nearest health facility or to poor health. The hostel option (i.e., in-patient care) enabled these patients to receive their intensive phase treatment as recommended by the NTP guidelines.⁷

In similar geographical conditions, where patient numbers are likely to be small, it should be possible to implement DOT either as in the study, by providing hostel facilities with minimal staff costs (drug dispensing and cleaning time) or, where bed occupancy allows, by using hospital in-patient facilities. With annual bed occupancy rates averaging 64% across HMG/N District Hospitals in five hill districts in which BNMT works, TB cases could be managed in these hospitals.⁵ Where neither of these options are available, hotel or private hostel accommodation could be considered, at least in the short term. Although a more expensive option, estimated at £1244 annually in Dhankuta,** it would still result in a lower overall annual cost to the provider than before the intervention.

The estimated required numbers of beds could be reduced if a well organised and functioning district-wide DOTS programme was in place, as some, if not

* 15 cases × 2 months intensive phase treatment ÷ 12 = 2.5 bed years.

† 2.5 bed years (DOT cases) + 1.5 bed years (6 re-treatment cases × 3 months intensive phase treatment ÷ 12 months) + 1 bed years (12 'severe' cases × 1 month hostel stay ÷ 12 months) = 5 bed years.

‡ Based on the cost (£10 000) to BNMT of constructing a 15-bed hostel in Sankhuwa Sabha District in 1997/98, gives an annual cost per bed (financial PMT equation where initial capital cost = $x + [x/(1+r)] + [x/(1+r)^2] + \dots + [x/(1+r)^{19}]$ and x = cost/payment per year, r = depreciation rate taken as 5% over 20 years) of £53.56.

§ Based on 1998/99 & 1999/2000 data from Dhankuta, Khotang, Panchthar, Taplejung and Terathum districts, with annual district occupancy rates ranging from 34–94% for the five 15-bed District Hospitals.

** 75 NRs per night × 365 days × 5 beds ÷ 110 to convert to Pounds Sterling.

all, re-treatment cases could also be treated on a daily ambulatory basis at the health facilities of the district instead of admitting all such cases to the hostel.

Having staff and a local community motivated to care for support and cure TB patients is crucial to the success of any TB control programme. A major consequence of the study was a perceived increase in motivation amongst the HMG/N staff. Government staff prior to the intervention performed some TB control activities, but with the day-to-day contact in the provision of daily DOT, TB patients became real to these staff. During the first annual DOTS workshop, HMG/N staff remarked to one researcher (MA) that as the patients' health improved, they felt their own worth and self-esteem grow. Some even took patients into their own homes in order for them to complete their intensive phase of treatment. Responsibility for the NTP by HMG/N staff was also felt by the researchers (DFW, MA, SS) to have increased since implementation of DOTS. Health post staff began increasingly to take over the tracing of late patients, resulting in the withdrawal from the district of one BNMT default tracer, with consequent financial savings to BNMT. Ownership was further enhanced through the annual DOTS workshop.

To the BNMT staff involved in the DOTS activities in Dhankuta and to the researchers, there also appeared to be an increase in community awareness of TB and involvement in the control activities. One village development committee (the lowest local government body in the district) even built their own two-bed hostel for patients taking their daily intensive phase DOT at the local health post. A number of cured patients became the NTP's best advocates, finding suspects and referring them to the health services.¹⁵ This may well have been due to the extra direct health-related and media activities that resulted from the implementation of DOTS in the district. It would be useful in future interventions to include qualitative research methods to gather baseline and post-intervention data to formally assess the important facet of motivation amongst the health workers, patients and community members.

The average annual cost to BNMT decreased following the intervention. These savings were almost entirely due to the reduction in its staff numbers. It is impossible to determine how far this reduction was due to the concurrent and on-going rationalisation of the district-wide resources provided by BNMT and how much to the introduction of DOT, e.g., the default tracer withdrawn as HMG/N health staff took over this work. HMG/N costs were not affected, as programme tasks were integrated into existing jobs. The costs following the intervention are unlikely to change significantly. Although the training costs may fall they will remain fairly high in the future, as further training will be required for new or transferred-in HMG/N staff and for the annual DOTS workshop.

During the study period, there was no strict criterion for entry into the hostel. It was usually left up to patients to decide whether they could make it to the nearest health facility or not, with minimal guidance by the health workers. This led to certain anomalies on occasions, with mild cases being admitted to the hostel when they had functioning health posts within relatively short travel time. This led to a dilemma for BNMT, and following the study evaluation, it was decided to introduce a 'distance to a health facility of over 2 hours walk one-way' as a criterion for entry into the hostel. This cut-off is a widely used indicator of assessing accessibility to health care,^{*} and was felt by all involved in TB activities to be a practical cut-off in the study setting where it was usual for people to walk for hours, if not days, to reach markets. Although this may be interpreted as a restriction of patients' choice in regard to DOT 'options', it was deemed by the BNMT and HMG/N staff to be necessary in order to guarantee the availability of hostel beds for cases with severe access problems.

In the study the hostel appears to have the worst outcomes, with lower cure rates and higher death rates than the clinic or health post. This is not surprising, as a significant proportion of hostel cases were admitted into the hostel because they were severe cases. These patients were more likely to be in a poorer clinical condition and therefore to have poorer treatment outcomes.

A second notable finding was the high death rate amongst new smear-negative PTB cases. This is not unique to Dhankuta district but can be observed right across Nepal. An audit into the deaths of TB cases is currently being conducted by BNMT in eight hill districts; this may shed further light on the problem.

The study concentrated on the treatment side of care. Although treatment was decentralisation, the diagnostic services were not, with case-finding rates remaining almost identical pre- and post-intervention. Smear microscopy services prior to and during the intervention were limited to the District Centre, and perpetuated an access problem. This was mitigated somewhat by the provision of a courier system for fixed sputum smear slides from the more remote health facilities to the District Centre, with the result that all suspects and cases for follow-up examination were not required to travel to the District Centre. It had been hoped to decentralise the diagnostic services to the two Primary Health Centres in the district under the intervention, but this proved impossible due to lack of personnel and microscopes. It is still hoped to introduce microscopy services in these centres when the personnel and equipment are available, thereby decentralising diagnosis and increasing accessibility to TB diagnostic services.

* More fully, '≤10 km or 2 hours walk' = 'accessible'.¹⁶

A major weakness in the cost calculations of this study was that no account was taken of the household and work costs to the patient and family. However the increased case-finding and minimal default rates, thought to be due to the pull of good available services and the range of DOT options offered, suggests to the authors that either costs to patients did not increase with the introduction of DOT, or that if there was an extra cost, patients thought it worthwhile paying it.

Studies from elsewhere have shown successful results by using either weekly health worker DOT or community/family members as DOT supervisors.¹⁷⁻¹⁹ The latter two options were not acceptable to the NTP of Nepal at the time of the study inception. Since 1999, however, the NTP in collaboration with the Nuffield Institute for Health has initiated a trial using community health workers or family members to deliver daily DOT in hill and mountain districts of Nepal much like our study district. As stated by Kamolratanakul et al., "If basic conditions are met, a DOT strategy can be tailored to country-specific conditions by exploring multiple observation options, without decreasing its effectiveness."¹⁸ In the hill and mountain districts of Nepal, where access to health facilities is difficult, a strategy utilising a range of DOT options, one of which is in-patient care in a hostel or hospital facility, would appear to be the solution for implementing DOTS in such areas. However, further studies, replicating the model used in this study in a non-INGO/NGO supported district in Nepal, need to be undertaken before wider implementation of this model is recommended. Such studies should take account of the indirect costs to patients and their families.

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References

- 1 National Tuberculosis Programme, His Majesty's Government of Nepal. TB Control in Nepal 2055-2060 (1998-2003), Long Term Plan. Kathmandu: NTP, 1999.
- 2 World Health Organization (WHO). Treatment of tuberculosis. Guidelines for National Programmes. 2nd ed. Geneva: WHO, 1997.
- 3 International Union Against Tuberculosis and Lung Disease. Management of tuberculosis. A Guide For Low Income Countries. 5th ed. Paris: IUATLD, 2000.
- 4 Gurung H. Nepal: Social demography and expressions. Kathmandu: New Era, 1998.
- 5 Nepal South Asia Centre. Nepal: Human Development Report, 1998. Kathmandu: Nepal South Asia Centre, 1998.
- 6 Jochem K, Fryatt R J, Harper I, et al. Tuberculosis control in remote districts of Nepal comparing patient-responsible short-course chemotherapy with long-course treatment. *Int J Tuberc Lung Dis* 1997; 1: 502-508.
- 7 Ministry of Health, His Majesty's Government of Nepal (HMG/N). National Tuberculosis Programme of Nepal. General Manual. 1st ed. Kathmandu: HMG/N, 1995.
- 8 Gautam B. Descriptive study of health service utilisation in drug scheme and non-drug scheme districts in eastern Nepal. Nuffield Institute of Health. Leeds: University of Leeds, 1994.
- 9 Weakliam D, Hamlet N. Assessing quality of care in the integrated tuberculosis control programme in Surkhet District. *J Nepal Med Assn* 1996; 34: 16-28.
- 10 National Tuberculosis Programme, His Majesty's Government of Nepal. General Manual. 2nd ed. Kathmandu: NTP, 1997.
- 11 Dean A G, Dean J A, Coulombier D. Epi Info, version 6: a word processing, database and statistics program for epidemiology on microcomputers. Atlanta: Centers for Disease Control and Prevention, 1994.
- 12 The Britain-Nepal Medical Trust. Tuberculosis and Leprosy Control Programme, Annual Report 1995. Biratnagar: BNMT, 1996.
- 13 The Britain-Nepal Medical Trust. Tuberculosis and Leprosy Control Programme, Annual Report 1996. Biratnagar: BNMT, 1997.
- 14 Pool H. A flawed strategy for controlling tuberculosis? *Tubercle Lung Dis* 1996; 77: 483.
- 15 The Britain-Nepal Medical Trust. 1997 Annual Report. St Leonard's on Sea: Berfort Reproductions, 1998.
- 16 World Health Organization. Development of indicators for monitoring progress towards Health For All by the Year 2000. Geneva: WHO, 1981.
- 17 Becx-Bleumink M, Djamaluddin S, Loprang F, de Soldenhoff R, Wibowo H, Aryono M. High cure rates in smear-positive tuberculosis patients using ambulatory treatment with once-weekly supervision during the intensive phase in Sulawesi, Republic of Indonesia. *Int J Tuberc Lung Dis* 1999; 3: 1066-1072.
- 18 Kamolratanakul P, Sawert H, Lertmaharit S et al. Randomized controlled trial of directly observed treatment (DOT) for patients with pulmonary tuberculosis in Thailand. *Trans Royal Soc Trop Med Hyg* 1999; 93: 552-557.
- 19 Akkslip S, Rasmithat, Maher D, Sawert H. Direct observation of tuberculosis treatment by supervised family members in Yasothorn Province, Thailand. *Int J Tuberc Lung Dis* 1999; 3: 1061-1065.

RÉSUMÉ

CADRE : District de collines du Népal où l'accès aux services de soins de santé est difficile.

OBJECTIFS : Comparer les résultats avant et après une intervention de traitement directement observé (DOT) décentralisée.

SCHÉMA : Etude prospective de patients enregistrés dans le district de Dhankuta, Nepal, 1996-1999. Au cours de

la phase intensive de leur traitement, les patients ont bénéficié d'une supervision des travailleurs de santé par une des trois options de DOT suivantes : 1) ambulatoire au sein des services de santé périphériques du gouvernement ; 2) ambulatoire à partir d'une polyclinique TB d'une ONG internationale (INGO) dans le centre du district ; 3) comme hospitalisé dans un foyer TB INGO

dans le centre du district. On a utilisé pour comparaison les données historiques de 1995–1996 où la chimiothérapie de courte durée était non supervisée.

RÉSULTATS : Sur les 307 nouveaux cas, respectivement 126 (41%), 86 (28%) et 95 (31%) ont pris le traitement de la phase intensive respectivement selon les options 1, 2 et 3. La négativation des frottis (à 2 mois) et les taux de guérison dans les cas neufs de PTB à bacilloscopie positive ont été de 81,6% (vs. 58,8% historique, $P = 0,001$) et 84,9% (vs. 76,7% historique, $P = 0,03$). Les coûts globaux pour le pourvoyeur de soins INGO sont tombés de 7%, principalement par suite d'une réduction des cadres dans les services INGO rendue possible grâce à une rationalisation avec les services du gouvernement au cours de l'intervention.

CONCLUSION : Grâce à l'offre de différentes voies d'administration du DOT, incluant une option d'hospi-

talisation, des résultats satisfaisants sont possibles grâce au DOT même dans les zones où l'accès aux services de soins de santé est difficile. L'offre de soins du type hospitalisation grâce à un foyer TB INGO a permis à une proportion significative de nouveaux cas (31%) de bénéficier de leur traitement de phase aiguë, qui sans elle auraient eu de grandes difficultés d'y accéder, soit à cause de la distance les séparant du service de soins le plus proche, soit à cause de la gravité de la maladie. Le remplacement de lits hospitaliers gouvernementaux ou de lits d'hôtels locaux par des lits d'un foyer INGO pourrait permettre au modèle d'être reproduit ailleurs dans des conditions géographiques similaires au Népal, mais des études complémentaires devraient être menées auparavant dans un district ne bénéficiant pas de l'aide d'une INGO.

RESUMEN

MARCO DE REFERENCIA : Distrito montañoso en Nepal, donde el acceso para la atención sanitaria es difícil.

OBJETIVO : Comparar los resultados antes y después de una intervención DOT descentralizada.

MÉTODO : Estudio prospectivo de pacientes registrados en el distrito de Dhankuta, 1996–1999. Los pacientes recibieron sus tratamientos en la fase intensiva con supervisión de trabajadores sociales en tres opciones de DOT : 1) ambulatoria con ayuda sanitaria del gobierno ; 2) ambulatoria en dispensarios de tuberculosis de una ONG internacional (INGO TB), en centros distritales de salud ; ó 3) hospitalizados en hospederías de INGO TB en centros distritales. Se utilizaron como comparación los datos históricos de 1995–1996, con quimioterapia de corta duración sin supervisión.

RESULTADOS : Sobre 307 nuevos casos, 126 (41%), 86 (28%) y 95 (31%) recibieron la fase intensiva del tratamiento según las opciones 1, 2 y 3, respectivamente. La conversión del esputo (a los 2 meses) y las tasas de curación en los casos nuevos de PTB con esputo positivo fueron 81,6% (vs. 58,8% histórico, $P < 0,001$) y 84,9%

(vs. 76,7% histórico, $P < 0,03$). Los costos totales del proveedor INGO bajaron el 7%, sobre todo por reducción del personal en los servicios INGO, que fue posible por la racionalización con los servicios del gobierno durante la intervención.

CONCLUSIÓN : Al ofrecer varios tipos de DOT, incluyendo una opción con hospitalización, se obtienen resultados satisfactorios con DOT aún en áreas de difícil acceso. La posibilidad de un tratamiento en hospitalización, a través de un centro INGO TB, permitió a una proporción significativa de casos nuevos (31%) recibir la fase intensiva de su tratamiento, que de otra manera hubiera sido muy difícil, por la distancia a los centros médicos o por la gravedad de la enfermedad. La sustitución de las camas de hospital del gobierno o de camas de hoteles locales por las de los centros INGO permite que este sistema se repita en otras regiones con condiciones geográficas similares de Nepal, aunque se requieren otros estudios para que se apliquen en distritos sin apoyo de una INGO.