

Costs incurred by patients with pulmonary tuberculosis in rural India

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SUMMARY

SETTING: Vellore District, Tamil Nadu, India.

OBJECTIVE: To measure patient costs associated with diagnosis and the complete treatment of tuberculosis (TB).

DESIGN: Prospective structured interview of 100 new smear-positive adult patients being treated for TB in Tamil Nadu, India, selected evenly from 10 representative health facilities in the state. Direct (out-of-pocket) and indirect (lost-time) costs were quantified by period of illness using a standardised questionnaire, and univariate regression investigated predictors of total cost.

RESULTS: Seventy-four per cent of patients were male, with a mean age of 40.2 years. All were given a first-line

regimen, and none had been previously treated. The mean direct cost was US\$34.91 (SD \$46.94), the mean indirect cost was \$526.87 (SD \$375.71), and the total mean cost per patient was \$562.66 (SD \$287.48). Twenty-five patients were admitted to hospital, at a mean cost of \$279.43 (SD \$142.88) per admission. Variation in costs was associated with admission.

CONCLUSION: TB patients in India incur large costs associated with TB illness. The greatest single cost was time lost during admission. Total patient costs represent 193% of the estimated monthly income of a manual labourer.

KEY WORDS: tuberculosis; cost; India

TUBERCULOSIS (TB) imposes a significant impediment to social development in India, the country with the greatest epidemiological burden of TB in the world.¹ It is estimated that 325 000 Indians died of TB in 2006,¹ and although this number is staggering, it does not completely reflect the social burden of the disease. The annual economic loss to the country is estimated to be US\$3 billion, with over 70% of cases occurring in the most economically productive age group (15–54 years).² In India, TB is associated with negative social stigma, causing 100 000 women to be abandoned by their families and 300 000 children to leave school every year.² Fortunately, India continues to have a low human immunodeficiency virus (HIV) co-infection prevalence of 1–13.8%.³

The Revised National TB Control Programme (RNTCP) in India has been very successful at implementing the DOTS strategy, based on sputum smear diagnosis and a reliable supply of good quality drugs, both provided at no cost to the patient. However, the cost of smear microscopy and drugs is only a fraction of the actual costs associated with TB disease in India. The patient pays directly for costs associated with diagnostic and treatment visits, hospital admissions and additional treatments recommended by health pro-

viders, and indirectly, through income lost during the period of diagnosis and treatment.

We examined direct and indirect costs borne by newly treated pulmonary TB patients during the pre-diagnostic phase and 6 months of treatment in Tamil Nadu, India.

METHODS

The present study was undertaken as part of an international collaboration to assess costs of care associated with TB in low- and middle-income countries (Malawi, Brazil, India, China, Ecuador, Zambia, Haiti and Dominican Republic) for the purpose of evaluating the cost-effectiveness of new interventions for TB control. Nine local research officers were appointed and trained in a standard method of obtaining informed consent and performing the interview. A standardised, interviewer-administered questionnaire was translated into Tamil and used to collect data. One hundred eligible patients were interviewed between July and November 2007, at 10 peripheral and regional government TB centres in the State of Tamil Nadu, selected to represent both urban and rural settings and large and small clinics.

Inclusion criteria were being adult (age >18 years) out-patients with smear-positive pulmonary TB who had received between 1 and 3 months of TB treatment. The study was approved by the Ethics Review Board of the Christian Medical College Vellore in June 2007 and by the Research Ethics Board of the McGill University Health Center in January 2006.

Recruitment

From the register at the regional government TB unit, 256 patients were identified. Of these, 156 did not meet the eligibility criteria, were not available at the time of home visit or refused to participate. The remaining 100 patients were interviewed at their homes, except for 10 who were met during pill collection visits. The patients included represented over 80 different villages in the Vellore District.

TB treatment

Under the RNTCP, new smear-positive patients are treated with a standardised, intermittent regimen consisting of 2 months of isoniazid (INH), rifampicin (RMP), pyrazinamide (PZA) and ethambutol (EMB), followed by 4 months of INH and RMP, all given thrice weekly under direct observation by an appointed treatment supervisor. This supervisor is located in close proximity to the patient, near the patient's home or work place.

Analysis

Costs were analysed according to time periods as previously reported (see Table 1 for definitions) and reported using mean and standard deviation (SD).⁴ A standardised questionnaire was applied in all countries after field testing in Zambia.⁴ Pre-diagnosis was defined as the period between first symptoms and final TB diagnosis (including collection and interpretation of sputum smears), and post-diagnosis was defined as the period between diagnosis and interview. All costs were reported in 2008 \$US (US\$1 = 44 Indian rupees [INR]).

Direct costs included out-of-pocket payments made by the patient for consultation, travel, registration, paperwork, blood tests, X-rays, food, medication outside of the standard treatment regimen and admission to hospital; indirect costs included the cost of patient and accompanying family time taken for consultation and medicine collection visits. Patients were interviewed at between 1 and 3 months of treatment, and cost data collected were extrapolated to report costs associated with 6 months of treatment.

One hour of patient time was valued based on local wages paid to unskilled labourers (INR80 [US\$1.82] per hour) (K R John, personal communication). Assuming that a labourer would work for 40 h/week, mean personal monthly income was calculated as INR12 800 (US\$291). Although the majority of patients were employed, most had no insurance, so that

Table 1 Definitions used in the study (adapted from Aspler et al.⁴)

Cost categories	Definition
Time of costs	
Pre-diagnostic ('diagnosis seeking')	Costs incurred during time between self-reported first health encounter and laboratory or radiologically confirmed TB diagnosis
Post-diagnostic ('treatment seeking')	Costs incurred during 6 months of treatment. Includes any clinic visit following the diagnosis (including referrals before treatment) and subsequent medical follow-up visits
Categories of costs	
Direct	Out-of-pocket cash expenditures for TB services as well as those incurred to access the service. Per patient costs were categorised as travel costs, registration and paperwork fees, consultation fees, blood test fees, medication fees, X-ray fees, food costs and other costs
Indirect	Patients lost income due to time needed to receive care. Includes travel time for return trips to clinics/hospital, waiting time and time for consultation with a physician, nurse or treatment supporter
Care-seeking factors	
Patient delay	Period between onset of patient symptoms and first encounter with the health service
Health encounters	Any visit to any health service (government health centre, pharmacy or private clinic)

TB = tuberculosis.

lost work directly caused lost income. Total cost was calculated as the sum of direct and indirect costs.

A one-sample Kolmogorov-Smirnov test⁵ revealed that total cost/patient was normally distributed (two-tailed $P = 0.04$). A univariate linear regression was performed to examine the possible association between total cost per patient and selected demographic, clinical and economic factors, including sex, age, number of people living in the house, education, employment status, income prior to TB, hospitalisation, delay in seeking care and delay in making the diagnosis.

Completed questionnaires were double-entered into a central database (Access XP, Microsoft, Redmond, WA, USA) and statistical analysis was performed using SPSS 15.0 (LEAD technologies, Chicago, IL, USA).

RESULTS

Ninety-five (95%) of the patients were enrolled in a DOTS programme under the RNTCP and prescribed the standardised Category 1 regimen. The other five patients were treated according to a private practitioner's recommendations. None had received previous TB treatment. Table 2 summarises the clinical and demographic parameters of the cohort. Seventy-four (74%) were male, and mean age was 40.2 years.

The mean time between first symptoms and con-

Table 2 Patient demographics

Variable	Female (n = 26) n (%)	Male (n = 74) n (%)	Total (N = 100) n (%)
Age group, years (n = 100)			
18–24	6 (23.0)	10 (13.5)	16 (16.0)
25–34	6 (23.0)	14 (18.9)	20 (20.0)
35–44	6 (23.0)	17 (22.9)	23 (23.0)
≥45	8 (30.7)	33 (44.5)	41 (41.0)
Household size (n = 100)			
1–4	10 (38.4)	31 (41.8)	40 (40.0)
5–6	12 (46.1)	32 (43.2)	44 (44.0)
7–10	4 (15.3)	11 (14.8)	15 (15.0)
>10	0	1 (1.4)	1 (1.0)
Education (n = 100)			
None	8 (30.7)	10 (13.5)	18 (18.0)
Primary school	7 (26.9)	23 (31.0)	30 (30.0)
Some high school	6 (23.0)	11 (14.8)	17 (17.0)
Finished high school	5 (19.2)	26 (35.1)	31 (31.0)
University	0	4 (5.4)	4 (4.0)
Current employment status (n = 100)			
Employed	21 (80.7)	72 (97.2)	93 (93.0)
Unemployed	5 (19.2)	2 (2.7)	7 (7.0)
Patient's monthly income before TB, US\$ (n = 100)			
<91	10 (38.4)	7 (9.4)	17 (17.0)
91–454	9 (34.6)	8 (10.8)	17 (17.0)
455–908	5 (19.2)	26 (35.1)	31 (31.0)
≥909	2 (7.6)	33 (44.5)	35 (35.0)
Patient's current monthly income, US\$ (n = 100)			
<91	17 (65.3)	18 (24.3)	35 (35.0)
91–454	4 (15.3)	13 (17.5)	17 (17.0)
455–908	3 (11.5)	17 (22.9)	20 (20.0)
≥909	2 (7.6)	26 (35.1)	28 (28.0)
Household's monthly income before TB, US\$ (n = 99)			
<91	1 (3.8)	1 (1.35)	2 (2.0)
91–455	1 (3.8)	4 (5.4)	5 (5.0)
455–909	4 (15.3)	10 (13.5)	14 (14.0)
>909	20 (76.9)	58 (78.3)	78 (78.0)
Household's current monthly income, US\$ (n = 99)			
<91	2 (7.6)	2 (2.7)	4 (4.0)
91–454	1 (3.8)	7 (9.4)	8 (8.0)
455–908	4 (15.3)	14 (18.9)	18 (18.0)
≥909	19 (73.0)	50 (67.5)	69 (69.0)

TB = tuberculosis.

sultation (patient delay) was 1.1 months (SD 0.7, range 1–4), and the mean time between first consultation and diagnosis (provider delay) was 0.83 months (SD 0.8, range 1–3). The mean number of pre-diagnostic visits to a health provider was 4.66 (SD 2.2, range 1–12).

Twenty-five (25%) patients were admitted to hospital before or during diagnosis. One patient was admitted twice. The mean duration of admission was 8.0 days (SD 3.4). Twenty-four of the 26 admissions (92%) were accompanied by at least one family member for the entire period of admission.

Table 3 summarises direct costs, reported by period of illness. Eighty-eight patients incurred direct costs during the pre-diagnostic period, averaging \$35.71 (SD \$47.99). The mean direct cost of admission was

Table 3 Summary of direct costs (in 2008 US\$)

	Patients reporting cost		Total patients (N = 100)
	n	US\$ mean (SD)	US\$ mean (SD)
Pre-diagnostic period			
Costs associated with accessing consultation			
Parking	4	1.13 (1.92)	0.05 (0.40)
Travel	82	4.49 (5.59)	3.68 (5.35)
Registration	29	1.33 (0.95)	0.39 (0.79)
Food	68	5.77 (11.8)	3.93 (10.1)
Costs associated with medical consultation			
Paper work	6	10.04 (16.77)	0.50 (4.03)
Consultation	51	2.70 (1.49)	1.38 (1.72)
Blood tests	53	2.90 (1.52)	1.54 (1.82)
Medication	59	10.93 (8.89)	6.45 (8.69)
X-rays	34	4.17 (1.65)	1.42 (2.20)
Costs associated with admission to hospital	26	44.23 (65.70)	11.50 (38.35)
Other costs not accounted for above	17	3.52 (3.48)	0.60 (1.93)
Total direct costs pre-diagnostic period	88	35.71 (47.99)	31.42 (46.47)
Post-diagnostic period			
Costs associated with accessing consultation			
Travel	81	2.76 (2.10)	2.37 (2.18)
Registration	1	3.40 (—)	0.34 (0.34)
Food	64	1.86 (1.82)	1.19 (1.70)
Costs associated with medical consultation			
X-ray	1	2.72 (—)	0.03 (0.27)
Total direct costs post-diagnostic period	82	4.25 (3.17)	3.49 (3.30)
Total direct costs	98	35.67 (47.15)	34.91 (46.94)

SD = standard deviation.

\$44.23 (SD \$65.70) for each of 25 patients admitted. When direct patient costs during the pre-diagnostic period were averaged over all 100 patients, each patient incurred a cost of \$31.42 (SD \$46.47). During the post-diagnostic (6-month treatment) period, 82 patients incurred direct costs, at a mean of \$4.25 (SD \$3.17). When averaged over all 100 patients, each patient incurred a direct post-diagnostic cost of \$3.49 (SD \$3.30). The largest single direct cost in any period was due to admission. The second highest direct cost was medication during pre-diagnosis, at \$10.93 (SD \$8.89) per patient prescribed medication. Medications prescribed during the pre-diagnostic period included antibiotics and treatment for TB symptoms.

Table 4 summarises indirect (time-related) costs associated with each parameter assessed. During the pre-diagnostic period, 94 patients reported loss of time associated with travel, consultation and admission. Assuming the loss of 8 h of labour for every day of admission, admitted patients lost 17.0 h (SD 31.8) of income. Because accompanying family members also lost productive time, admitted patients lost an additional 16.7 h (SD 32.1) from family income. When averaged over all 100 patients, each patient lost 39.1 h

Table 4 Summary of indirect costs in hours

	Patients' reporting time		Total patients (N = 100)	
	n	Hours mean (SD)	Hours mean (SD)	Cost of time (US\$1.82/h) mean (SD)
Pre-diagnostic period				
Travel time	91	2.83 (5.1)	2.57 (4.9)	4.68 (8.88)
Consultation time	91	3.23 (2.2)	2.94 (2.3)	5.34 (4.20)
Time lost during admission	26	65.52 (26.8)	17.04 (31.8)	31.01 (57.95)
Time lost for accompanying family member during admission	24	68.33 (25.8)	16.73 (32.1)	30.45 (58.42)
Subtotal cost			39.11 (63.4)	71.48 (115.39)
Post-diagnostic period				
Travel time medicine collection	98	144.85 (59.5)	141.96 (62.4)	258.36 (113.50)
Consultation time medicine collection	99	109.51 (104.6)	108.42 (104.7)	197.32 (190.48)
Subtotal cost	99	252.90 (141.5)	250.38 (143.0)	455.36 (260.32)
Total indirect cost			289.49 (206.4)	526.87 (375.71)

SD = standard deviation.

(SD 63.4) (including family member time lost during admission), an indirect cost of \$71.48 (SD \$115.39).

During the post-diagnostic period, 99 patients reported loss of time due to travel and consultation during pill collection. Patients travelled a mean of 23.9 min (SD 10.2, range 0–60) each way to collect pills, and collection took a mean of 18.3 min (SD 17.4, range 1–120). When averaged over all 100 patients, each patient lost 250.4 h (SD 143.0), an indirect cost of \$455.36 (SD \$260.32). Total indirect cost, averaged over all 100 patients, was 289.5 h (SD 206.4), for a total indirect cost of \$526.87 (SD \$375.71).

Table 5 combines direct and indirect costs to estimate total costs per patient. The mean total cost to a patient with a new TB diagnosis in India is \$562.66 (SD \$287.48). This represents 193% of the calculated monthly income of a manual labourer in India, and a significant financial impact (as defined by >10% of monthly income⁶).

Table 6 explores reasons for variation in total cost using univariate linear regression. Total cost was significantly higher among patients admitted to hospital

($P < 0.001$). Other analysed variables were not significant predictors of variation in cost.

DISCUSSION

Diagnosis and treatment of TB imposes a heavy direct and indirect cost burden on patients in South India, despite the provision of free smears and drugs by the RNTCP. We have considered costs outside of what the RNTCP provides to report a holistic consideration of financial burden of illness from the patient's perspective.

Indirect costs (time lost) accounted for a far greater burden to patients than direct (out-of-pocket) costs. Our most notable finding is the high cost of lost income associated with DOTS treatment in India. We have only considered time associated with treatment visits, but in reality a manual labourer may lose an entire day of income if required to attend for pill collection; our figure may therefore be an underestimate of the actual indirect cost. This cost has been minimised by decentralising DOTS-based treatment as soon as possible to a location as close as feasible to the patient. This approach is practised in China⁷ and Russia,⁸ and is a part of the national TB control strategy in India,² but it clearly cannot eliminate indirect costs completely.

Payment of direct and indirect costs associated with admission to hospital was required from 25 of our patients. Admission was the largest direct and indirect cost incurred by patients, and was significantly associated with increased total cost. Combining direct costs, loss of patient income and loss of family member income, all associated with admission, gave a total cost of \$279.43 (SD \$142.88) per admission. This would represent 96% of the monthly income of a labourer. Some settings in India practise routine hospital admission of smear-positive TB cases,⁹ and our

Table 5 Overall costs associated with TB diagnosis and treatment (in 2008 US\$)

	Patients reporting cost		Total patients (N = 100)
	n	US\$ mean (SD)	US\$ mean (SD)
Pre diagnostic period			
Total direct costs	88	35.71 (47.99)	31.42 (46.47)
Total indirect costs	94		71.48 (115.39)
Post-diagnostic period			
Total direct costs	82	4.25 (3.17)	3.49 (3.30)
Total indirect costs	99	460.27 (257.51)	455.36 (260.32)
Total cost of TB diagnosis and treatment			562.66 (287.48)

SD = standard deviation; TB = tuberculosis.

Table 6 Patient characteristics and total patient costs: univariate linear regression analysis

Independent variables	<i>n</i>	Total cost 2008 US\$ mean (SD)	Standardised coefficient beta	<i>P</i> value
Demographic				
Sex				
Male	74	573.70 (319.21)	0.066	0.517
Female	26	531.00 (168.30)		
Age, years				
≤41	51	568.15 (281.47)	-0.020	0.847
>41	49	556.95 (296.41)		
Socio-economic factors				
Household size, number				
≤4	40	542.19 (309.39)	0.058	0.564
>4	60	576.31 (273.72)		
Education				
Primary	48	577.61 (310.75)	-0.050	0.620
Secondary	52	548.87 (266.51)		
Current employment status				
Employed	85	570.05 (297.46)	-0.094	0.354
Unemployed	12	559.74 (227.71)		
Monthly income before TB				
<INR40 000	65	579.27 (270.83)	-0.079	0.434
≥INR40 000	35	531.82 (317.91)		
Clinical				
Each additional month of patient delay in care seeking				
		—	0.008	0.937
Each additional month of system delay in diagnosis				
		—	0.120	0.236
Hospitalisation				
No	75	484.58 (228.34)	-0.473	<0.001
Yes	25	796.91 (322.39)		

SD = standard deviation; TB = tuberculosis; INR = Indian rupees (US\$1 = INR44).

data would suggest that subjects are also being admitted for TB diagnosis, although this is unnecessary in India, where sputum smear facilities are widely available to out-patients. Although the RNTCP is based on out-patient diagnosis of TB, a proportion of patients in our study were hospitalised, incurring substantial additional costs.

Time to diagnosis was quite prompt in our study, suggesting that, by self-report, patients did not wait for prolonged periods following onset of symptoms to seek medical care, and providers did not take excessive time to reach a diagnosis. Our patients were all diagnosed through the RNTCP, and not through private practitioners.

Reported hours of income loss are likely to be significantly underestimated, as manual labourers in India are hired on a daily basis. If they are required to attend a brief clinic visit, they will lose an entire day's wages. This loss was not measured in our analysis.

Our results would suggest that costs associated with TB do not vary significantly with demographic differences, and that for patients accessing the government system, costs are relatively uniform.

Although several authors have addressed the costs associated with TB in India,⁹⁻¹³ none have done so from the patient's perspective. Among 156 individual TB patients in a DOTS clinic in Delhi, mean expenditure prior to registration was INR3385 (US\$85), with a mean of 47.1 days of wages lost due to TB.¹⁴ Expen-

diture was highest among the lower socio-economic groups.

Three hundred and four urban and rural TB patients interviewed in focus groups reported total out-of-pocket expenditures of INR5986 (US\$171), with 83 work days lost and mean debts totalling INR2079 (US\$60).¹⁵ Our study suggests that direct costs are slightly lower, probably because our patients are living in rural areas as compared to the urban areas, but total costs are similar.

True mean costs to TB patients in India are likely higher than estimates found in our study, as we only examined patients diagnosed through the RNTCP. The majority of TB patients in India seek help from private physicians, a group with significant deficiencies in understanding the diagnosis and management of TB.^{16,17} Private TB hospitals represent greater annual expenditure than the total budget of the RNTCP.⁹ Private practice is associated with delays in diagnosis and over-reliance on chest X-ray diagnosis instead of sputum smear microscopy, which may explain the higher patient costs.¹⁸⁻²¹

There were some limitations to our study. We did not assess the influence of costs on patient adherence, as patients were interviewed between 1 and 3 months of treatment and results were extrapolated for 6 months of treatment. The timing of the interview was selected to minimise recall bias as much as possible.

In conclusion, despite the provision of free smears

and drugs, Indian TB patients incur considerable direct and indirect costs, especially those patients requiring admission during the pre-diagnostic period. National Tuberculosis Programmes will need to consider the implications of these unmeasured patient costs in developing their national control policies.

Acknowledgements

Many thanks to S Suzana, who performed the calculations for the analysis.

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RÉSUMÉ

CONTEXTE : District de Vellore, Tamil Nadu, Inde.

OBJECTIF : Mesurer les coûts à charge des patients associés au diagnostic et à l'achèvement du traitement de la tuberculose (TB).

SCHEMA : Interview structurée prospective de 100 nouveaux cas à bacilloscopie positive chez des adultes traités pour TB à Tamil Nadu et répartis de façon égale dans 10 services de santé représentatifs de l'Etat. On a quantifié les coûts directs (en liquide) et indirects (perte de temps) par période de maladie grâce à un questionnaire standardisé et on a investigué les facteurs prédictifs du coût total par régression univariée.

RÉSULTATS : Il y a eu 74% de patients de sexe masculin avec un âge moyen de 40,2 ans. Tous ont bénéficié d'un

régime de première ligne et aucun d'entre eux n'avait été traité antérieurement. Le coût direct moyen a été de 34,91 US\$ (DS 46,94\$), le coût indirect moyen de 526,87\$ (DS 375,71\$) et le coût total moyen par patient de 562,66\$ (DS 287,48\$). Chez 25 patients admis à l'hôpital, le coût moyen a été de 279,43\$ (DS 142,88\$) par admission. Les variations de coût sont en relation avec l'hospitalisation.

CONCLUSION : En Inde, les patients TB encourent d'importants coûts en rapport avec leur maladie TB. Le coût unique le plus élevé est le temps perdu au cours de l'hospitalisation. Le coût total pour le patient représente 193% du revenu moyen mensuel estimé d'un travailleur manuel.

RESUMEN

MARCO DE REFERENCIA : El distrito de Vellore, en Tamil Nadu, India.

OBJETIVO : Medir los costos para el paciente asociados con el diagnóstico y el tratamiento completo de la tuberculosis (TB).

MÉTODOS : Se llevó a cabo una entrevista prospectiva estructurada a 100 pacientes con diagnóstico nuevo de TB con baciloscopia positiva, tratados en Tamil Nadu y seleccionados en forma homogénea en 10 establecimientos representativos de atención de salud en el estado. Se

cuantificaron los gastos directos (pagos efectuados) e indirectos (tiempo perdido) durante el período de la enfermedad, mediante un cuestionario normalizado, y se investigaron los factores pronósticos del costo total, mediante un análisis de regresión monofactorial.

RESULTADOS : Setenta y cuatro por ciento de los pacientes fueron hombres, con un promedio de edad de 40,2 años. Todos los pacientes recibieron una pauta terapéutica de primera línea y ninguno refirió antecedente de tratamiento antituberculoso. El costo directo promedio fue 34,91 dólares (desviación estándar [DE] 46,94). El promedio de los gastos indirectos fue 526,87 \$US

(DE 375,71). El costo total promedio por paciente fue 562,66 \$ (DE 287,48). Se hospitalizaron 25 pacientes con un costo promedio de 279,43 \$ (DE 142,88) por hospitalización. La variación en los costos se asoció con la estancia hospitalaria.

CONCLUSIÓN : En la India, los pacientes con TB deben sufragar altos costos relacionados con la enfermedad. El mayor costo aislado correspondió al tiempo perdido durante la hospitalización. El total de costos para el paciente representó 193% del ingreso mensual calculado de un obrero.
