Patient and family costs associated with tuberculosis, including multidrug-resistant tuberculosis, in Ecuador

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_____ S U M M A R Y

BACKGROUND: There is little published information on the costs of multidrug-resistant tuberculosis (MDR-TB) for patients and their families in low- or middle-income countries.

METHODS: Between February and July 2007, patients with microbiologically confirmed active TB who had received 2 months of treatment completed an interviewer-administered questionnaire on direct out-of-pocket expenditures and indirect costs from lost wages. Clinical data were abstracted from their medical records.

RESULTS: Among 104 non-MDR-TB patients, total TB-related patient costs averaged US$960 per patient, compared to an average total cost of US$6880 for 14 participating MDR-TB patients. This represents respectively 31% and 223% of the average Ecuadorian annual in-

come. The high costs associated with MDR-TB were mainly due to the long duration of illness, which averaged 22 months up to the time of the interview. This resulted in very long periods of unemployment. Most patients experienced a significant drop in income, particularly the MDR-TB patients, all of whom were earning less than US$100/month at the time of the interview.

CONCLUSION: Direct and indirect costs borne by patients with active TB and their families are very high in Ecuador, and are highest for patients with MDR-TB. These costs are important barriers to treatment completion.

KEY WORDS: multidrug-resistant tuberculosis; MDR-TB; economic impact; patients' costs

TUBERCULOSIS (TB) is a major cause of illness and death worldwide. In Ecuador, before the implementation of DOTS, the estimated incidence was 240 per 100 000 population,[1] mortality was 45/100 000,[1] case detection was 53% and prevalence of initial multidrug-resistant TB (MDR-TB) was 5.5%—among the highest in the Latin American region.[2] DOTS implementation began in 2001 and achieved national coverage in 2006.[3] This resulted in improved treatment outcomes.[3] By 2007, incidence had decreased to 128/100 000 and mortality to 26/100 000.[4] A pilot project to diagnose and treat MDR-TB was approved by the Green Light Committee and initiated in the Province of Guayas in 2006.

There are significant health system costs associated with TB in both low-income[5–7] and high-income[8,9] countries. TB can also have a significant economic impact on patients and their families.[7,10–12] Although there is some published information on patient costs for drug-susceptible TB[10–13] and on health system costs for drug-resistant TB,[14–18] there is very little information about the economic burden for patients and the families of drug-resistant TB, especially MDR-TB.

The objective of this study was to estimate the direct out-of-pocket expenditures and indirect costs due to lost wages associated with confirmed MDR-TB, compared to the same costs for non-MDR-TB, from the perspectives of patients and their families in Ecuador.

METHODS

Study setting and population

Ecuador is classified as a lower middle-income country by the World Bank, with an average annual per capita income of US$3080 in 2007. The present study was conducted at the Ministry of Health facilities in the province of Guayas in Ecuador between February and July 2007. Guayas accounts for more than half of all cases of active TB and more than 70% of all MDR-TB cases in Ecuador.[3] DOTS is primarily clinic-based, meaning that patients must go to clinics to receive directly observed therapy (DOT). Patients must pay user fees for all services, including consultations, tests and treatments at the Ministry of Health facilities. Once they are diagnosed with active TB, these

fees are waived, although they must continue to pay for tests other than acid-fast bacilli smears, and for treatment other than TB medications. If hospitalized, patients also pay for diagnostic tests and treatment, as well as per diem fees, although the per diem fees are waived if they are diagnosed with active TB.

Within Guayas we selected 22 clinics, representing 55% of all Ministry of Health clinics in the province. These were both rural and urban, to ensure a more representative patient sample, but did not include the more remote clinics because of limited funds for transportation. At these clinics, all patients who had started initial or retreatment therapy for active TB between 6 to 12 weeks earlier, or were on treatment of any duration for confirmed MDR-TB, were approached to participate.

Data collection

Consenting patients completed an interviewer-administered questionnaire in Spanish on direct and indirect expenses from the time of onset of TB symptoms until the interview. Clinical data and information on previous treatment were abstracted from their medical records. Patients were considered to have confirmed MDR-TB if drug susceptibility testing (DST) showed resistance to at least isoniazid (INH, H) and rifampin (RMP, R). In Ecuador, DST is performed only for patients who have failed or relapsed after standardized retreatment. Patients treated with the standardized initial or retreatment regimens therefore do not undergo DST; these are defined as non-MDR patients.

The questionnaire was initially adapted from a World Bank questionnaire addressing the economic impact of adult fatal illness, and modified for TB and used in TB cost studies in Canada, the United States, Haiti, and Dominican Republic,[7,19] and subsequently in seven other countries.[13,20,21]* The interviewer (VAR) received standardized training on questionnaire administration.

The questionnaire asked about out-of-pocket expenditures for any health services or for accessing these services, such as travel costs, registration and paperwork fees, consultation fees, costs for blood tests, medications, X-ray examinations, food, or any other expenses. The questionnaire also asked about patients' lost income due to disability, unemployment due to illness, time spent waiting for or receiving care, and time for travel to clinics or hospitals. During hospitalization, patients were assumed to have lost 8 potential work hours per day. Indirect costs also included the time spent by family members accompanying patients on out-patient visits, or in hospital.

The questionnaire was organized into three main sections: in the first section, patients were asked about costs incurred from the time of the first health encounter with any provider, including nurse, physician, or pharmacist, up to the time of the start of treatment (pre-treatment period). This included physician fees, laboratory or radiologic tests, and medications for which the patients had to pay. The second section covered costs incurred from the start of treatment up to the time of the interview (treatment period). This included visits for medical follow-up evaluations, as well as those required for taking DOT. The third section enquired about the impact on income, loans, additional help paid for, and other impacts throughout the course of illness.

All patients with confirmed MDR-TB had previously been treated for TB. For these patients, the interval between the onset of TB-related symptoms and questionnaire completion ranged from 12 to 27 months, limiting the accuracy of recall of costs related to these earlier episodes of TB. These patients therefore did not complete the pre-treatment section of the questionnaire.

Ethics

The study was approved by an ethics committee of the McGill University Health Centre Research Institute, and by the director of the TB control program of the Province of Guayas, Ecuador.

Data analysis

Data were entered into Microsoft Access XP (Microsoft, Redmond, WA, USA). Statistical analyses were performed using SAS version 9.1.3 (SAS Institute, Cary, NC, USA).

Costs were calculated for the two main phases of the illness, pre-treatment and treatment, as defined above. Sub-totals and totals for each type of cost were calculated as the product of the patient-reported cost parameter (e.g., consultation fee) and frequency (e.g., number of clinic visits). For each patient, the total number of hours spent traveling, waiting, receiving health services, hospitalized, disabled, or unemployed due to TB illness were summed to provide an estimated total hours of work lost. Indirect costs were estimated by multiplying this total by the estimated average hourly wage in Ecuador, using methods previously described and justified elsewhere.[7,13,19–21] In brief, the hourly wage was calculated from the average per capita gross national income in Ecuador[22] divided by 2496 h worked per year (48 h per week for 52 weeks). All costs are reported in 2007 $US (the official currency of Ecuador since 2001). Pre-treatment costs of MDR-TB patients were calculated by multiplying the number of previous treatment episodes times the average total costs for the diagnosis and treatment of non-MDR-TB patients.

RESULTS

In total, 14 patients with MDR-TB and 104 patients without MDR-TB were interviewed between February

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*The questionnaire is available in English, French and Spanish from the corresponding author.

Table 1 Demographic, socio-economic and clinical characteristics of patients studied

	Non-MDR-TB patients (n = 104) n (%)	Confirmed MDR-TB patients (n = 14) n (%)
Sex		
Male	64 (62)	4 (29)
Female	40 (39)	10 (71)
Age, years		
18–24	19 (18)	2 (14)
25–34	33 (32)	2 (14)
35–44	18 (17)	6 (43)
⩾45	29 (28)	4 (29)
Form of TB		
Pulmonary smear-positive	103 (99)	14 (100)
Pulmonary smear-negative	1 (1)	0
Extra-pulmonary	0	0
Classification of treatment history		
New case	84 (81)	0
Retreatment, default	3 (3)	0
Retreatment, failure	2 (2)	13 (97)
Retreatment, relapse	15 (15)	1 (7)
Comorbid illnesses		
None	44 (42)	4 (29)
Any	60 (58)	10 (71)
HIV/AIDS	15 (25)	1 (10)
Diabetes	21 (35)	3 (30)
Household size, persons		
Alone	8 (8)	4 (29)
2–3	21 (20)	2 (14)
4–6	44 (42)	5 (36)
7–9	21 (20)	1 (7)
⩾10	10 (10)	2 (14)
Education		
None	4 (4)	0
Primary school	39 (38)	2 (14)
Some high school	48 (46)	9 (65)
College/university	12 (11)	2 (14)
Response not provided	1 (1)	1 (7)
Current employment status		
Employed	40 (38)	0
Unemployed	64 (62)	14 (100)
Directly related to TB	42 (41)	11 (79)

MDR-TB = multidrug-resistant TB; TB = tuberculosis; HIV = human immuno-deficiency virus; AIDS = acquired immune-deficiency syndrome.

Table 2 Changes in personal income from before TB diagnosis up to the time of the interview

Monthly income pre-diagnosis, US$	Current monthly income, US$			
	<100	100–500	500–1000	>1000
Non-MDR-TB patients				
<100	48*	1*	0*	1
100–500	35†	12*	0*	0
500–1000	3†	1†	0*	0
>1000	0†	0†	2†	0
MDR-TB patients				
<100	7*	0*	0*	0
100–500	6†	0*	0*	0
500–1000	1†	0*	0*	0
>1000		0†	0†	0

*No change or increase.
†Decrease in income.
TB = tuberculosis; MDR-TB = multidrug-resistant TB.

treatment regimen (2HRZE/4H₃R₃), followed by the WHO standardized retreatment regimen (2HRZES/1HRZE/5H₃R₃).* Nine patients had received the standardized initial treatment regimen followed by the standardized retreatment regimen. Two patients had received the standardized initial treatment regimen only. These 14 patients had received a total of 29 full treatment regimens before being diagnosed with MDR-TB. Interestingly, of the 29 previous treatment episodes, only one had ended in patient default.

Among non-MDR-TB patients, the average interval from onset of patient symptoms and first encounter with any health service, including government health center, pharmacy or private clinic (patient delay) was 3.7 months, while the average interval from the first visit to the diagnosis of TB (health system delay) was an additional 2 months. For MDR-TB patients, the average total duration of TB illness from onset of first symptoms until the start of therapy was 22 months. This included a delay of 4.5 months between presentation for care of the current TB illness episode and initiation of MDR-TB therapy. Most of this health system delay was due to delays in receiving laboratory results confirming MDR-TB.

Of the non-MDR-TB patients surveyed, 47 (45%) were earning US$100–500 per month, and six (5%) were earning >US$500/month before the TB diagnosis. Six (43%) of the MDR-TB patients were earning US$100–500/month, and one (7%) >US$500/month before the first TB diagnosis. Many patients experienced an important drop in income during their TB illness; 84% of non-MDR-TB patients and 100% of MDR-TB were earning <US$100/month at the time of the interview (Table 2). This was mainly due to unemployment from direct disability or the

and July 2007. These represented all patients with MDR-TB (at any stage of treatment), and all other TB patients who had been on treatment for 1–3 months at the time the interviewer visited the selected clinics. All 14 MDR-TB patients had smear-positive *Mycobacterium tuberculosis*, as did all but one of the non-MDR-TB patients. As seen in Table 1, 71% of the MDR-TB patients were female, with a mean age of 38 years (range 18–51). Of the non-MDR-TB patients, 38% were female, with a mean age of 34 years (range 14–68). A significant proportion of patients had comorbid illnesses, with HIV/AIDS (human immunodeficiency virus/acquired immune-deficiency syndrome) and diabetes being the most common conditions.

Three MDR-TB patients had received an unknown initial treatment regimen from a private provider, following which they received the World Health Organization (WHO) recommended standardized initial

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*Z = pyrazinamide; E = ethambutol; S = streptomycin. Numbers before the letters indicate the duration in months of the phase of treatment; numbers in subscript indicate the number of times the drug is taken each week.

Table 3 Direct and indirect costs during the period before the start of treatment*

Type of cost	Total US$	Mean per patient US$
Out-patient visits, *n*	403	3.9
Direct costs		
Consultation fees	1 216	11.69
Blood tests	1 741	16.74
Chest radiograph	423	4.07
Non-TB medication	5 247	50.45
Transport	371	3.57
Food	71	0.68
Other	62	0.60
Sub-total direct costs	9 129	87.78
Indirect costs		
Time lost from work, days	249	2.4
Sub-total indirect costs (lost income)	2 450	23.55
Number of days hospitalized, *n*	1 382	13.3
Direct costs		
Paperwork fees	11	0.11
Blood tests	689	6.62
Medication	12 120	116.54
X-rays	48	0.46
Food	60	0.58
Other	36	0.34
Sub-total direct costs	12 964	124.65
Indirect costs		
Time lost from work, days	1 507	14.5
Sub-total indirect costs (lost income)	20 322	195.40

* MDR-TB patients did not complete this section of the questionnaire; non-MDR-TB patients only (see Methods).
TB = tuberculosis; MDR-TB = multidrug-resistant TB.

Table 4 Direct and indirect costs during the treatment period*

	Mean per patient	
	Non-MDR-TB patients (*n* = 104) US$	MDR-TB patients (*n* = 14) US$
Direct costs		
Clinic-based DOT (visits)*	85	390
Travel	42.35	202.80
Food	2.50	13.65
Other	0.34	1.56
Sub-total costs	45.19	218.01
Treatment in hospital, days	2.7	90
Non-TB medication	15.10	195.22
Blood tests/X-rays	2.92	3.11
Other (includes food)	3.27	20.37
Sub-total costs	21.29	218.70
Follow-up (visits)	6	15
Travel	3.12	7.80
Non-TB medication†	24.70	49.35
Other (includes food, tests, X-rays)	11.38	28.45
Sub-total costs	39.20	85.60
Additional costs	30.90	71.40
Sub-total direct costs	136.58	593.71
Indirect costs		
Clinic based DOT, hours lost*	63.8	195
Indirect costs	78.50	239.90
Treatment in hospital, days	4.1	124
Indirect costs	40.20	1217.70
Follow up visit, hours lost	10.8	16.5
Indirect costs	13.30	20.30
Additional time, hours lost	0	(7.9)
Indirect costs	0	9.70
Sub-total indirect costs	132	1487.60
Total treatment-related costs	268.58	2081.31

* Total number of DOT visits and follow-up visits for the entire treatment period were extrapolated based upon the Ecuadorian National TB Program guidelines. All DOT visits were clinic- or hospital-based.
† All non-TB medication purchased during out-of-hospital treatment shown here (not under DOT).
MDR-TB = multidrug-resistant TB; DOT = directly observed therapy; TB = tuberculosis.

recommendation of their physician, or due to being fired because of the TB diagnosis.

Information about costs incurred by patients prior to their first diagnosis of TB could only be collected for non-MDR patients (Table 3), because this period was too long ago for MDR patients to recall many details. The majority of patients' pre-diagnosis costs were related to hospitalization before active TB was recognized. As seen in Table 4, the largest sources of direct costs for MDR patients were for non-TB medications (vitamins, antacids, anti-nausea), and travel for clinic-based DOT, which accounted for respectively 41% and 33% of direct costs during the treatment period. In total, non-MDR patients incurred average costs of $960 compared to $6880 for MDR-TB patients, i.e., more than seven times higher (Table 5). These totals were equivalent to respectively 31% and 223% of the average annual per capita income in Ecuador. The greatest economic losses came from lost income related to time not working, accounting for 85% of the total costs for the confirmed MDR patients, compared to 60% of total costs for the non-MDR patients.

DISCUSSION

In Ecuador, the total TB-related costs for patients with non-MDR-TB accounted for 31% of the average

Table 5 Summary of total costs

	Non MDR-TB (not known) US$	Confirmed MDR-TB US$
Prior to start of current therapy*		
Previous courses of TB therapy	0.2	2.1
Direct costs	212	374
Indirect costs	223	394
During current treatment		
Direct costs	137	594
Indirect costs	132	1488
Throughout the illness period		
Direct costs	35	150
Indirect costs	221	3879
Total		
Direct costs	384	1119
Indirect costs	576	5761
Total costs	960	6880
% of average per capita income†	31	223

* Costs before starting current therapy for MDR-TB patients were extrapolated from responses for this period provided by non-MDR-TB patients (see Methods).
† Based on average per capita income in Ecuador of US$3080 in 2007.
MDR-TB = multidrug-resistant TB; TB = tuberculosis.

Ecuadorian annual income. Total costs were seven times higher for MDR-TB patients, mostly because they lost much more time from work due to prolonged illness and treatment. These high costs represent a potential barrier to completion of treatment for MDR-TB patients, and could impoverish these patients long after treatment is completed.

This study had a number of strengths, including the use of a detailed and standardized interviewer-administered questionnaire which has been used in several other studies.[7,13,20,21] Over 100 non-MDR-TB patients participated, enhancing the precision of cost estimates for this group. All 118 questionnaires were administered by one interviewer, ensuring comparability of results between MDR-TB and non-MDR-TB patients. Interviews with non-MDR-TB patients were conducted within 1–3 months of diagnosis, enhancing accuracy of recall of the events leading up to the diagnosis, as well as events after initiation of therapy. However, because of the much longer and more complicated treatment history of MDR-TB, we limited detailed questioning to the current treatment period. In particular, this meant we could not obtain detailed cost information for the period before the initial TB diagnosis.

Nevertheless, the study had several limitations. The number of MDR-TB patients was small. Although this was adequate to detect striking differences in direct and indirect costs, a larger scale study would be valuable to confirm these findings, examine more carefully why these high costs occur, and begin to examine how patients and families cope with these catastrophic costs. Income was not directly ascertained because we had previously found this approach too intrusive. Instead we asked about income ranges; this was well accepted by respondents and informative, as it demonstrated important reductions in income following TB illness. To estimate income lost, we used average per capita income in Ecuador.[22] This value—of US$246 per month—fell near the midpoint of the range of US$100–500 monthly which was the pre-TB income reported by about half of all respondents. As there are other methods of giving value to work time lost,[23] we also reported total time lost from work, facilitating comparison with other studies that have assigned a value to work time lost in different ways. A final weakness is that some of the non-MDR-TB patients may have had unrecognized MDR-TB. This is most likely among failures of initial therapy.[24–26] However, only two of the non-MDR-TB patients were failures and therefore this misclassification should have been modest.

To our knowledge, this is the first study to report directly gathered patient and household total costs in patients with MDR-TB, compared to other TB patients. One previous study estimated direct costs of MDR-TB only,[27] and a second estimated indirect costs from hospitalization or death due to MDR-TB.[28] Several studies have described the important economic impact of non-MDR-TB. In Thailand, the poorest segment of the population was most affected by a substantial reduction in income: almost one third had to take out bank loans or sell assets to pay for TB-related expenses.[12] In China, the poorest were also disproportionately affected by TB, and were forced to sell productive assets, or were forced into migrant labor.[11] In Tanzania, 68–98% of total costs were due to patients' loss of income related to reduced capacity to work; this far exceeded health system costs.[10]

The most important finding of this study was the important economic burden imposed by TB on all patients and families, and the much greater burden created by MDR-TB. The greater burden of MDR-TB was due to several factors: first, the total duration of illness was much longer, averaging a total of 40 months from symptom onset to end of MDR therapy, compared to an estimated average of 12 months for non-MDR cases. Second, the cost per month was US$172 for MDR-TB, compared to US$82 for the other patients, which meant an ever increasing debt as the months passed. MDR-TB patients had greater barriers to employment, as they were hospitalized for the initial intensive phase of therapy for up to 6 months, and thereafter had to attend every day (and sometimes twice daily) for clinic-based DOT. As a result, none of the MDR-TB patients were working full time at the time of the interview. By contrast, many of the non-MDR-TB patients were still able to work, having never been hospitalized and on thrice weekly supervised therapy.

In a review, Russell noted that expenditure of more than 40% of monthly income is considered catastrophic, and that most studies report TB-related expenditures that are close to that threshold.[29] We found that all MDR-TB patients bore costs far in excess of this threshold, at a level equivalent to the estimated household costs due to AIDS in several regions of sub-Saharan Africa.[29] This economic burden will create substantial pressure on MDR-TB patients to find work, which would make treatment adherence more difficult. It is important to recognize that we only interviewed 'survivors', i.e., patients on MDR-TB treatment, and not the families of patients who had died. These costs therefore represent an underestimate of the burden on families as we did not include estimates of the economic impact of premature death from MDR-TB, which according to one study incurs a much greater economic burden.[28] (We speculate whether this 'survivor effect' may explain why women accounted for 71% of the MDR-TB patients but only 39% of the non-MDR-TB group, as women may have been more likely to survive with MDR-TB.)

One of the most important findings in this study is that the interval between the first diagnosis of active TB and the institution of effective MDR-TB therapy averaged 22 months. During this time, patients

received more than two full courses of therapy, and did not work. This finding suggests that an important way to reduce the economic burden of MDR-TB on patients would be to reduce the time between the onset of TB illness and the institution of effective MDR-TB treatment through earlier DST. The second intervention would be to reduce hospitalization and a third would be to shift from clinic-based to community-based DOT, so that patients could return to work sooner. Another possible intervention would be to provide some financial or nutritional support.

Although confirmation of these findings would be important, this study suggests that TB-related costs for patients and their families in Ecuador are high, and catastrophically high for patients with MDR-TB. Measures that could reduce this economic burden include earlier DST, reduction of hospitalization, and provision of community-based DOT for MDR-TB patients.

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_____ RÉSUMÉ

INTRODUCTION : Les informations sont limitées concernant les coûts de la tuberculose à germes multirésistants (TB-MDR) pour les patients et leurs familles dans les pays à revenus faibles ou moyens.

MÉTHODES : Entre février et juillet 2007, les patients atteints de tuberculose (TB) active confirmée par l'examen microbiologique, qui avaient bénéficié de 2 mois de traitement, ont complété un questionnaire administré par l'interviewer concernant leurs dépenses directes « de leur poche » et les coûts indirects provenant de pertes de salaires. Les données cliniques ont été prélevées dans leurs dossiers médicaux.

RÉSULTATS : Chez 107 patients TB non MDR, les coûts-patient totaux liés à la TB ont été en moyenne de 960 $US par patient par comparaison avec un coût total moyen de 6880 $US pour 14 patients TB-MDR qui ont

participé à l'enquête. Ceci représente respectivement 31% et 223% des revenus annuels moyens en Equateur. Les coûts élevés associés à la TB-MDR ont été dus principalement à la longue durée de la maladie qui a été en moyenne de 22 mois jusqu'au moment de l'interview. Ceci a entraîné des périodes prolongées de chômage. La plupart des patients ont subi une importante chute de revenus, particulièrement les patients TB-MDR, qui dans l'ensemble gagnaient moins de 100 $US par mois au moment de l'interview.

CONCLUSION : Les coûts directs et indirects supportés par les patients atteints de TB active et par leurs familles sont très élevés en Equateur et sont les plus élevés chez les patients atteints de TB-MDR. Ces coûts représentent d'importantes barrières à l'achèvement du traitement.

_____ RESUMEN

MARCA DE REFERENCIA: La información publicada con respecto a los costos que implica la tuberculosis multidrogorresistente (TB-MDR) para los pacientes y sus familias es escasa en los países de bajos o medianos ingresos.

MÉTODOS: Entre febrero y julio del 2007, los pacientes con TB activa confirmada microbiológicamente que habían recibido 2 meses de tratamiento, respondieron en una entrevista a un cuestionario sobre los gastos cotidianos directos y los gastos indirectos por salarios perdidos originados por la enfermedad. Los datos clínicos se obtuvieron a partir de los expedientes clínicos.

RESULTADOS: Los costos totales debidos a la enfermedad para cada uno de los 104 pacientes con TB diferente de la TB-MDR fueron en promedio US$960, en comparación con un promedio de US$6880 para los 14 pacientes con TB-MDR. Estas sumas representan

respectivamente el 31% y el 223% del ingreso anual promedio en el Ecuador. Los altos costos derivados de la TB-MDR se deben en su mayor parte a la extensa duración de la enfermedad, en promedio de 22 meses hasta el momento de la entrevista. La enfermedad ocasiona períodos muy largos de desempleo. La mayoría de los pacientes sufrieron una disminución sensible del ingreso, sobre todo los pacientes con TB-MDR, quienes ganaban todos menos de US$100 por mes en el momento de la entrevista.

CONCLUSIÓN: En el Ecuador, los pacientes con TB y sus familias corren con considerables costos directos e indirectos y estos son más altos cuando se trata de TB-MDR. Los costos representan un obstáculo muy importante a la compleción del tratamiento.