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Patient costs for the diagnosis of tuberculosis in Brazil: comparison of Xpert® MTB/RIF and smear microscopy

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SUMMARY

SETTING: Manaus and Rio de Janeiro, two Brazilian state capitals with the country's fifth and sixth highest tuberculosis (TB) incidence rates (around 90/100 000 population in 2012).

OBJECTIVE: To compare the costs of the Xpert® MTB/RIF assay with those of standard care (two smears) in diagnosing TB from the patient's perspective.

METHOD: We interviewed 218 patients diagnosed with TB in the previous 4 months by Xpert or smear microscopy. Information on non-medical direct costs for transportation and food, indirect costs such as time spent for diagnostic visits and socio-demographic data were gathered.

RESULTS: The median patient income was US$390.24. Median total costs incurred by patients were 54% higher with the smear process than with Xpert (US$25.24 vs. US$16.44, $P < 0.000$) due to higher indirect and direct costs. Male patients incurred higher indirect costs (U$10.27 vs. US$7.51, $P = 0.038$), and patients in Manaus incurred higher total costs.

CONCLUSIONS: Although the diagnosis and treatment of TB in Brazil are free of charge, non-medical direct and indirect costs for patients may represent important barriers to accessing appropriate care. Compared to standard care, Xpert reduced the financial burden for patients. These findings support the decision to scale-up Xpert technology in the country.

KEY WORDS: costs; diagnosis; real-time polymerase chain reaction; sputum smear; tuberculosis

IN 2010, THE WORLD HEALTH ORGANIZATION endorsed the Xpert® MTB/RIF assay (Xpert, Cepheid, Sunnyvale, CA, USA) for countries with a high prevalence of multidrug-resistant tuberculosis and human immunodeficiency virus (HIV) infection[1] after demonstration and validation studies had shown the high accuracy of the test for detecting both *Mycobacterium tuberculosis* DNA and rifampicin resistance (RMP).[2,3] More recently, a meta-analysis confirmed the high accuracy of the test, and cost-effectiveness studies have shown the benefit of implementing this technology.[4,5] South Africa was the first country to widely adopt Xpert technology, and some countries have plans to scale up Xpert in the near future.[6] However, to the best of our knowledge, no economic analyses has been conducted from the patient's perspective to evaluate the eventual benefit of this technology on the financial burden of tuberculosis (TB) patients.

Brazil is one of the 22 high TB burden countries, with around 70 000 new cases reported in 2012.[7] Among these, 9.7% are co-infected with HIV and around 15% are not confirmed by smear microscopy (50% in Manaus and Rio de Janeiro), the standard test for diagnosing TB in the country.[8] Drug resistance is relatively low: 6% to isoniazid and 1.4% to RMP (unpublished data, II National Survey on Drug Resistance, 2010 National Tuberculosis Programme [NTP]). Among retreatment cases, more than 70% have no access to culture and drug susceptibility testing.[8]

In this scenario, the Brazilian NTP decided to conduct an implementation stepped-wedge study of the Xpert assay to replace diagnostic microscopy in the two municipalities (Manaus and Rio de Janeiro) with the fifth and sixth highest incidence rates in the country – 89.3 and 94.4 per 100 000 population, respectively.[8] The study evaluates important operational outcomes such as the confirmation of TB among notified cases and delay to treatment initiation. In addition, a cost-effectiveness analysis from the health system perspective was conducted (unpublished data).

In the present study, we sought to evaluate the non-medical direct and indirect costs of Xpert from the

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patient's perspective in both cities where the roll-out implementation study took place.

METHODS

Setting

The study was conducted in six primary care clinics in Rio de Janeiro and 14 in Manaus between October 2012 and June 2013. The clinics were located in different areas of the cities; those with the highest number of TB diagnoses and those where the Xpert was implemented in the stepped-wedge trial were selected. In Manaus, patients were asked to submit their samples to the reference laboratory, while in Rio de Janeiro patients provided samples to the local clinic and the health system was responsible for the logistics of transporting samples to the reference laboratory. The recommendation to provide two sputum samples was maintained during the trial, although only the first sample was tested if it was adequate for processing (no blood or pus, and sufficient volume, with a minimum of 1 ml required for the technique). In Brazil, TB diagnosis and treatment are provided free of charge.

Study population and data collection

Adult patients aged >18 years with a diagnosis of pulmonary TB of no more than 4 months were eligible, regardless of test results and of the diagnostic process used — either smear microscopy (standard care, two samples recommended by the NTP)[9] or Xpert (one sample recommended during the roll-out study). This time point was chosen to allow more reliable recall of the costs incurred in the pre-diagnostic period.

Patients who provided signed informed consent were interviewed. We applied a standardised questionnaire, validated in a small sample of 10 patients in both municipalities, before starting the data collection. No changes in the tool were necessary. The questionnaire focused only on the costs for the tests, as costs with other items of the diagnostic process have been studied previously in Brazil.[10] Interviews were conducted in a private space, without the presence of any medical staff, to guarantee privacy. The following information was gathered: socio-demographic factors such as sex, age, employment and monthly income; out-of-pocket expenditures incurred during the diagnostic visits, such as food and transportation; and time spent during the diagnostic process, such as travel, waiting time in the clinics and duration of consultation. Costs per visit were calculated and multiplied by the number of informed visits. Costs associated with treatment and with other items of the diagnostic process were not included.

Data analysis

Indirect costs were calculated according to the current job activity. Monthly income was divided by 198 (44 weekly hours, 4.5 weeks/month) to calculate the hourly cost, per national legislation.[11] For those without paid activity (regardless of their availability or lack of income from retirement, allowances or government cash transfer), the lost hours spent during the diagnostic process were valued based on the national minimum wage:[12] 678 Brazilian *reais* (R$), equivalent to 331 US dollars (US$) in 2012. All costs were collected in R$ and converted to $US using the mean 2012 value (US$1 = R$2.05).

Data were double-entered in SPSS 17.0 (Statistical Product and Service Solutions, Chicago, IL, USA). Patient characteristics were compared using the odds ratio (OR). Median costs (excluding, for direct costs, patients who had no costs) were compared using the Mann-Whitney test. A 0.05 significance level was considered.

Ethics

The study was approved by the National Ethical Committee (CONEP 782/2011) and by the Institutional Review Boards of the Rio de Janeiro Health Secretariat (445A/2011) and the *Fundação de Medicina Tropical Dr. Heitor Vieira Dourado* (dated 31 July 2012). All patients provided written informed consent.

RESULTS

A total of 218 patients were invited to participate, and all accepted to be interviewed. The median age was 36 years (interquartile range [IQR] 27–51); 139 (64%) were male; the median income was US$390.24 (IQR 317.00–634.00); 135 (62%) had <8 years of schooling. Of the 132 (61%) patients diagnosed in Manaus, 120 (55%) were diagnosed using Xpert. Patient characteristics by type of diagnosis are given in Table 1. Apart from age (patients who underwent smear testing were younger), there was no significant difference between the two groups.

The median total patient costs with diagnosis by smear microscopy were US$25.24, representing a 54% increase over Xpert (US$16.44, $P < 0.000$). Both direct and indirect costs were higher with smear microscopy, although the proportion of the increase was higher with indirect costs (90% vs. 40%). Transportation was the main cost driver of direct costs (55%) (Table 2). Men incurred higher costs (US$22.05 vs. US$16.64, $P = 0.235$, Table 3) due to indirect costs (US$10.27 vs. US$7.51, $P = 0.038$, Table 3). This was a consequence of their higher incomes (US$439.02 vs. US$317.07, $P = 0.001$), as

Table 1 Characteristics of 218 patients with pulmonary tuberculosis by diagnostic process, Manaus and Rio de Janeiro, 2012–2013

	n	Xpert *n* (%)	Smear *n* (%)	OR (95%CI)
City				
Manaus	132	70 (53)	62 (47)	0.81 (0.47–1.41)
Rio de Janeiro	86	50 (58)	36 (42)	1.0 (reference)
Sex				
Female	79	48 (61)	31 (39)	1.44 (0.82–2.53)
Male	139	72 (52)	67 (48)	1.0 (reference)
Age, years				
<42	124	59 (48)	65 (52)	0.49 (0.28–0.85)
≥42	94	61 (65)	33 (35)	1.0 (reference)
Years of schooling				0.98 (0.56–1.69)*
Illiterate	14	8 (54)	6 (46)	
<1	17	9 (53)	8 (47)	
1–3	38	21 (55)	17 (45)	
4–7	66	36 (55)	30 (45)	
8–12	77	41 (53)	36 (47)	
>12	6	5 (84)	1 (17)	
Income, US$†				
≤331‡	50	39 (65)	21 (35)	1.82 (0.95–3.50)
>331‡	107	54 (51)	53 (49)	1.0 (reference)
Employed				
No	100	51 (51)	49 (49)	0.73 (0.79–2.31)
Yes	118	69 (59)	49 (41)	1.0 (reference)
In activity				
No ($n = 175$)	175	98 (56)	77 (44)	1.21 (0.42–1.60)
Yes ($n = 43$)	43	22 (51)	21 (48)	1.0 (reference)
Occupation				
Retired	23	13 (57)	10 (43)	
Student	12	4 (33)	8 (67)	
Salaried	87	44 (51)	43 (49)	
Informal	56	36 (64)	20 (36)	
Not working	27	16 (59)	11 (41)	
Data missing	13	7 (54)	6 (46)	

*OR calculated with cut-off of 7 years.
†Those without income excluded (US$1 = R$2.05).
‡Minimum wage at the time of data collection.
OR = odds ratio; CI = confidence interval.

time spent on visits was similar (5 vs. 4 h, $P = 0.543$). In addition, total costs in Manaus were higher than in Rio de Janeiro (Table 3).

In both municipalities, indirect costs were similar to direct costs for smears, but were 30% lower than direct costs for Xpert (Table 2). The median difference between the costs of both tests for patients represented 4% of their median income and 5% of the minimum wage.

DISCUSSION

This study has shown that Xpert can significantly reduce the financial burden of patients in diagnosing TB, even in a country where TB care is free of charge and there is a universal public health care system. Xpert reduced both out-of-pocket expenditures and opportunity costs from lost hours. This was independent of the number of samples provided, as routine procedures did not change: patients were requested to provide two samples in both arms of the study. If Brazil scales up Xpert as a substitute for microscopy, only one sample will usually be necessary, and this will therefore likely further reduce costs for patients.

Patient out-of-pocket expenses with TB diagnosis and treatment can be a barrier to appropriate care,[13–16] and the disease has been shown to reduce income,[10,17,18] perpetuating the vicious cycle of poverty, disease and disability. The financial burden of TB care in resource-poor countries can represent up to a year's income when treatment and household costs are also taken into account. Costs in most studies are mainly driven by indirect costs, particularly when hospitalisation is required.[17,19–22]

In our study, the proportion of costs over income was much lower than in other studies. This was partly because we only considered costs with the bacteriological test, as we were interested in specifically comparing the two same-day tests to inform the NTP about the feasibility of adopting the new technology. A previous study in Brazil has already shown that total costs in the pre-diagnostic phase involve other items such as absenteeism and the need for antibiotics and other drugs, among others;[10] these costs were out of the scope of the present study. In addition, salaries in Brazil are higher than in other high-burden countries. Finally, we did not include hospitalised

Table 2 Non-medical direct and indirect costs of 218 pulmonary tuberculosis patients by diagnostic process, Manaus and Rio de Janeiro, 2012–2013

Costs	Xpert ($n = 120$) median (range)	Smear microscopy ($n = 98$) median (range)	Difference of medians	*P* value
Non-medical direct costs, US$*				
Transport	5.56 (1.34–243.90) ($n = 84$, 70%)	8.63 (4.88–97.56) ($n = 68$, 69%)	−3.07	0.002
Food	4.88 (1.95–31.22) ($n = 51$, 43%)	7.32 (1.95–30.73) ($n = 48$, 40%)	−2.44	0.218
Direct costs (total)	9.27 (1.34–256.10) ($n = 97$, 81%)	13.02 (1.95–107.32) ($n = 76$, 78%)	−3.75	0.003
Indirect costs				
Number of visits	2 (1–15)	3 (1–10)	−1	<0.000
Hours lost per visit	1.7 (0.02–13.4)	2.3 (0.7–24.9)	−0,6	<0.000
Total hours lost	3.0 (0.3–31.7)	6.7 (1.3–49.8)	−3,7	<0.000
Indirect cost per visit	3.00 (0.25–146.34)	3.92 (1.29–244.39)	−0.92	<0.000
Indirect cost (total)	6.51 (1.00–365.85)	12.40 (2.00–353.17)	−5.89	<0.000
Total costs (direct + indirect)	16.44 (1.50–621.95)	25.24 (2.00–757.32)	−8.8	<0.000

*Those without transport and/or food costs excluded (US$1 = R$2.05).

Table 3 Factors associated with costs incurred by 218 pulmonary tuberculosis patients according to the diagnostic process, Manaus and Rio de Janeiro, 2012/2013

Variables	Total costs, US$ median (range)	*P* value	Direct costs* (US$) median (range)	*P* value	Indirect costs (US$) median (range)	*P* value
Sex						
Male ($n = 139$)	22.05 (1.50–757.32)	0.235	9.76 (1.34–121.95) ($n = 110, 79\%$)	0.201	10.27 (1.00–353.17)	0.038
Female ($n = 79$)	16.64 (1.50–621.95)		10.73 (1.95–256.10) ($n = 63, 80\%$)		7.51 (1.00–365.85)	
Age group, years						
<42 ($n = 124$)	21.26 (1.50–421.46)	0.656	10.24 (1.34–68.29) ($n = 99, 80\%$)	0.729	9.85 (1.00–353.17)	0.389
≥42 ($n = 94$)	17.93 (1.50–757.32)		10.20 (1.95–256.10) ($n = 74, 79\%$)		9.14 (1.25–365.85)	
Years of schooling						
≤7 ($n = 135$)	18.38 (1.50–621.95)	0.811	10.00 (1.95–256.10) ($n = 104, 77\%$)	0.672	10.14 (1.25–365.85)	0.385
>7 ($n = 83$)	20.95 (1.50–757.32)		10.73 (1.34–107.32) ($n = 69, 83\%$)		8.51 (1.00–353.17)	
Diagnostic test						
Xpert ($n = 120$)	16.44 (1.50–621.95)	<0.000	9.27 (1.34–256.10) ($n = 97, 81\%$)	0.003	6.51 (1.00–365.85)	<0.000
Smear microscopy ($n = 98$)	25.24 (2.00–757.32)		13.02 (1.95–107.32) ($n = 76, 78\%$)		12.40 (2.00–353.17)	
City						
Rio de Janeiro ($n = 86$)	15.96 (1.50–125.12)	0.004	8.66 (1.34–53.66) ($n = 64, 74\%$)	0.002	7.45 (1.50–117.07)	0.078
Manaus ($n = 132$)	23.89 (1.50–757.32)		12.68 (1.95–256.10) ($n = 109, 83\%$)		10.52 (1.00–365.85)	

*Those without transport and/or food costs excluded; US$1 = R$2.05.

patients in our sample; indirect costs were thus much lower than in other studies.[10,22,23] This may also explain why, unlike in other studies, indirect costs were not much higher than direct costs. However, we did observe that indirect costs were the main factor responsible for the difference between the two groups: they were 90% higher for patients who submitted samples for microscopy.

Transportation was the driving component of direct costs, mainly in Manaus, as the health units are spread over the city, and patients' trips to the reference laboratories after their consultations to provide the sputum specimens. The organisation in Rio de Janeiro, where there is a system for the transportation of specimens from health units to laboratories, transfers patient costs to the health system.

Transportation tickets, decentralisation of health care units and cash transfer have all been suggested as possible incentives for TB patients.[14] Brazil has adopted the Family Health Strategy,[24] and TB control actions have been decentralised to district clinics. However, our results show that TB patients still incur relatively high costs. Although the Brazilian Federal Government is currently evaluating a cash transfer incentive for TB patients, this is unlikely to affect individuals who submit samples for TB diagnosis, as the majority are unlikely to have TB.

Our study has a few limitations. Recollection bias might have occurred, as we interviewed patients up to 4 months after the diagnostic process; however, this would affect both groups equally. In addition, economic, social and cultural differences between countries hamper the ability to generalise our findings. The socio-demographic characteristics of our sample are nevertheless representative of patients usually treated for TB globally, who are mostly male, of productive age, with low levels of schooling and income, and data are likely to be valid nationwide. Finally, it was out of the scope of this study to collect comprehensive data on health costs during the diagnostic phase, such as non-specific antibiotics, medical visits, vitamins and other tests. Nonetheless, given the potential of the new Xpert technology in detecting TB during earlier stages of the disease, and thus reduce transmission and morbidity due to its higher sensitivity, it is likely that its use would only further reduce health costs.

In conclusion, the adoption of Xpert in Brazil can help overcome barriers to accessing TB diagnosis, as it is cost saving for patients. However, these diagnostic technologies are only available to those who reach the health care system. As the technology spreads globally, it will be important to document local costs from the perspectives of both the health care system and of the patients, and to understand barriers to accessing the health care system.

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RESUME

CONTEXTE : Manaos et Rio de Janeiro, deux capitales d'états du Brésil avec le cinquième et sixième taux d'incidence le plus élevé (autour de 90/100 000 habitants en 2012).

OBJECTIFS : Comparer les coûts du Xpert® MTB/RIF avec la procédure standard (deux frottis) pour le diagnostic de la tuberculose (TB) du point de vue du patient.

MÉTHODES : Nous avons interrogé 218 patients ayant eu un diagnostic de TB dans les 4 mois précédents soit par Xpert soit par examen microscopique de frottis. Nous avons également recueilli des données relatives aux coûts directs non médicaux — de transport et de nourriture — aux coûts indirects comme le temps passé en consultations ainsi que des données socio-démographiques.

RÉSULTATS : Le revenu médian des patients était de US$390,24. Les coûts médians subis par les patients étaient plus élevés de 54% avec les frottis comparés au Xpert (US$25,24 contre 16,44 ; $P < 0,000$) en raison de coûts à la fois directs et indirects plus élevés. Les hommes subissaient des coûts indirects plus élevés (10,27$ contre 7,51 ; $P = 0,038$). Les patients de Manaos supportaient également les coûts plus importants.

CONCLUSION : Bien que le traitement de la TB au Brésil soit gratuit, les coûts directs non médicaux et indirects imputés aux patients constituent des obstacles importants à l'accès aux soins appropriés. Comparé au protocole standard, le test Xpert a réduit le fardeau financier des patients. Ces résultats soutiennent la décision d'étendre cette stratégie dans le pays.

RESUMEN

MARCO DE REFERENCIA: Las ciudades de Manaos y Río de Janeiro, dos capitales de estado en el Brasil, que ocupan el quinto y el sexto puesto de las tasas de incidencia de tuberculosis (TB) más altas (cerca de 90 100 000 habitantes en el 2012).

OBJETIVOS: Comparar los costos del uso de la prueba Xpert® MTB/RIF con el protocolo corriente (dos baciloscopias) en el diagnóstico de la TB, desde el punto de vista de los pacientes.

MÉTODO: Se entrevistaron 218 pacientes en quienes se había establecido el diagnóstico de TB en los últimos 4 meses, ya sea mediante la prueba Xpert o con el examen microscópico del esputo. Se recogió información sobre los costos directos diferentes de los costos médicos, como el transporte, la alimentación y los costos indirectos como el tiempo ocupado en las consultas diagnósticas, además de los datos sociodemográficos.

RESULTADOS: La mediana del ingreso de los pacientes fue US$390,24. La mediana del total de los costos sufragados por los pacientes fue 54% más alto con el procedimiento de las baciloscopias que con la prueba Xpert (US$25,24 contra US$16,44; $P < 0,000$), debido a los mayores costos directos e indirectos. Los costos indirectos fueron más altos para los hombres (US$10,27 contra US$7,51; $P = 0,038$). Los gastos fueron más altos para los pacientes de Manaos.

CONCLUSIÓN: Si bien en el Brasil el diagnóstico y el tratamiento de la TB se prestan sin costo alguno, los costos directos e indirectos diferentes de los costos médicos pueden representar un obstáculo al acceso a una atención adecuada. En comparación con el método corriente, el uso de la prueba Xpert disminuyó la carga económica de los pacientes. Estos resultados respaldan la decisión de ampliar la escala de aplicación de esta técnica en el país.