**Title page**

**Full title:** Uptake of governmental social protection, and financial hardship during drug-resistant tuberculosis treatment in Rio de Janeiro, Brazil

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**“Take home” message:** Governmental social protection contributes to preventing household financial hardship from DR TB in Brazil

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**End TB Strategy: universal health coverage and social protection for preventing financial hardship.**

Despite most countries offering tuberculosis (TB) diagnosis and treatment free of charge, TB-related costs remain an important barrier for accessing TB care [1]. TB-related costs include: direct medical expenses (e.g., consultations), direct non-medical expenses (e.g., transport and food accessing health services), and lost income from time off work related to disability, discrimination, and/or infection control laws [2]. With the treatment duration of drug-resistant (DR) TB lasting up to 24 months, affected households are especially vulnerable to TB-related costs [1]. In Cambodia, Ecuador, Ethiopia, Indonesia, Kazakhstan, and Peru, average DR TB-related costs range between 75%-223% of annual household income [3–7].

The World Health Organization’s (WHO’s) End TB Strategy mandates that by 2025 nobody should experience financial hardship because of TB [8]. Countries are encouraged to monitor progress towards this milestone by collecting regular estimates of the prevalence of financial hardship due to TB [9]. Financial hardship might be measured as total costs exceeding 20% of pre-illness annual household income; relying on a financial coping strategy (i.e., taking a loan/selling assets); or, total costs that are impoverishing [9, 10].

To prevent financial hardship from TB, countries should facilitate people’s access to universal health coverage (UHC) and social protection [9]. Worldwide, Brazil, is increasingly seen as a model country for inclusive social development. Here, the national Unified Health System provides all health services free of charge, and three governmental social protection policies Auxilio-Doenca, Bolsa Familia and Beneficio da Prestacao Continuada (BPC) help people manage financial consequences of illness [11–13]. Currently, it is unknown if these measures protect the most vulnerable TB-affected households, those experiencing DR TB, from financial hardship.

**Evaluating uptake of social protection and financial hardship amongst DR TB-affected households in Rio de Janeiro.**

In May 2016, there were 1,601 people with DR TB in Brazil (0.77 cases per 100,000 population), with 29% residing in Rio de Janeiro state [14]. To evaluate if uptake of social protection during treatment is associated with reduced risk of experiencing financial hardship, we conducted a cross-sectional survey between June-October 2016. We surveyed people with DR TB who had been receiving treatment for at least one month, and were attending the outpatient clinic of the Professor Helio Fraga reference centre (CRPHF) in Rio de Janeiro state. Ethical approval was obtained from the Escola Nacional de Saúde Pública Sérgio Arouca ethics committee (1.4238.240, CAEE: 53187516.0000.5240). All participants gave written informed consent before participating.

Datawere collected by two social workers, using a local adaptation of the field-testing version of the WHO’s TB patient cost survey instrument detailed and available online [15]. Questions on pre-diagnostic healthcare-seeking behaviours, and costs incurred during previous courses of TB treatment were excluded because of concerns about reporting accuracy for events experienced far in the past. The revised questionnaire was pretested for clarity on three patients. Monetary values were collected in Brazilian reais (R$), and converted to 2016 United States dollar (US$) (R$3.5=US$1.0) [16].

We measured direct expenses as monthly expenses accessing directly observed therapy (DOT) and the CRPHF extrapolated over participants’ prescribed treatment (mean: 17.6 months), added to any expenses for TB-related transport accessing a hospital, supplementary food and/or private healthcare. Lost income was the difference in monthly household income pre-illness versus during-treatment extrapolated over participants’ prescribed treatment [17]. Social protection was the monthly value of payments received because of DR TB extrapolated over participants’ prescribed treatment. All values were self-reported. Total costs were calculated as direct expenses plus lost income after subtracting social protection.

The exposure variable, was uptake of governmental social protection from Auxilio-Doenca, Bolsa Familia and/or BPC because of DR TB. The outcome, financial hardship,included separately incurring total costs ≥20% of pre-illness annual household income; using a financial coping strategy; incurring total costs that pushed pre-illness monthly household income per capita below Brazil’s 2016 poverty line (US$48.6 a month) [18]; and, experiencing all three situations simultaneously. We investigated the association between uptake of social protection and these four measures of financial hardship by multivariable logistic regression adjusting for socioeconomic and clinical variables associated with the outcome at p<0.1, and the two a priori confounding variables sex and age. The likelihood ratio test was used to assess the association of exposure variables with dependent variables.

**Summary of social protection uptake and financial hardship amongst DR TB-affected households in Rio de Janeiro.**

In the survey period, 131 people were invited to participate in the survey, six had not completed one month’s treatment, five did not give consent to participate, and one was excluded from the analysis because of implausible income data, leaving 119 participants (68% male; mean age: 42; ethnicity: 48% brown, 29% black, 23% white, 1% indigenous). Before DR TB, most participants had a pre-illness monthly household income per capita less than one minimum salary (63%), and were the principle household income provider (53%). Some received social protection before DR TB (16%). Most had acquired versus primary DR TB (55%), and multidrug-resistant TB (3% suspected, 29% mono-/poly-resistant, 60% multidrug-resistant, 9% extensively drug-resistant).

Overall, 38% of participants reported uptake of social protection because of DR TB. Amongst them, 80% received Auxilio-Doenca, 7% received Auxilio-Doenca and Bolsa Familia, 9% received Bolsa Familia, and 4% received BPC. Participants taking-up social protection were more likely to be male (p=0.005), younger (p=0.06), and in paid employment before DR TB (p=0.08).

Mean direct expenses were US$809 (SD: US$601), representing 14% (SD: 17%) of annual household income. Mean lost income was US$6,207 (SD: US$6,671), representing 81% (SD: 54%) of annual household income. Mean social protection payments were US$1,970 (SD: US$2,897). Mean total costs, after subtracting social protection, were US$5,046 (SD: US$6,290), representing 64% (SD: 58%) of annual household income. Participants taking-up social protection were more likely to incur lower total costs (p=0.005).

Overall, 68% of participants incurred total costs ≥20% of household income, 54% used a coping strategy, 24% were impoverished, and 18% experienced all three hardships, Figure 1. In multivariable logistic regression, uptake of social protection was independently associated with lower risk of incurring total costs ≥20% of household income (p=0.04); impoverishment (p=0.002); and, experiencing all three hardships (p<0.001); but not with using a coping strategy (p=0.58), Table 1.

**Summary of lessons learnt, and next steps forward.**

In Rio de Janeiro, total costs incurred during treatment result in financial hardship for many DR TB-affected households. The main contributor to total costs is lost income. Uptake of governmental social protection because of DR TB is common, and is associated with reduced likelihood of experiencing financial hardship, especially multiple kinds simultaneously.

To our knowledge, this is the first attempt to evaluate the association between uptake of governmental social protection and financial hardship amongst DR TB-affected households [3–7]. Our results are consistent with trial evidence from Lima, Peru, demonstrating the effectiveness of a non-governmental social protection intervention to defray TB-related catastrophic costs, and extends it to real-world governmental measures [3]. A survey from South Africa explores uptake of governmental social protection amongst people with TB, but does not evaluate its association with financial hardship [5].

Limitations include the survey’s small sample size, which barred stratification of our analysis by potential effect modifiers (e.g., uptake of distinct social protection measures). Nevertheless, there was adequate power to detect an association between our exposure and outcome. The survey’s cross-sectional design might have underestimated the prevalence of using a coping strategy and uptake of social protection, as the risk of these activities likely accumulates over treatment. Our use of four indicators of financial hardship ensures our conclusions are robust to any potential misclassification.

Our results highlight that even where UHC and social protection measures are available, efforts are still needed to protect all DR TB-affected households from financial hardship. In Rio de Janeiro state, some municipalities provide vouchers to defray patients’ transport expenses for CRPHF visits. Sharing of these experiences between municipal authorities should be encouraged. Peoples’ access to social protection should also be facilitated, for example, by explicit inclusion of the disabling profile of DR TB in the eligibility criteria of BPC, the government’s disability grant. Strengthening of labour unions would also support transitions to a more formal labour market, which would enable greater access to Auxilio-Doenca [19]. Helping previously employed people to restart work when they are fit would also avoid long absences from work.

Whilst UHC and social protection is available across Brazil, marked socioeconomic differences limits the generalisability of our results to other regions. For a more complete understanding of the association between uptake of social protection and financial hardship there is need for a nationally representative sample of DR TB-affected households. This should be followed up over time to better capture the complex dynamics of financial hardship.

Outside of Brazil, access to UHC and social protection remains low in many countries [20]. Nevertheless, progress is being made on both these fronts worldwide [21, 22]. A country-level modelling study highlights seven other low- and middle-income countries where governmental social protection is available to TB-affected households [23]. Individual-level research is now needed to investigate if TB-affected households are accessing these measures, and like we have done in Rio de Janeiro, evaluate if their uptake is associated with reduced risk of financial hardship.

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FIGURE 1: Summary of financial hardship across study participants, n=119. The area of each ellipse is proportional to the number of participants in that set. The area-proportional Venn diagram was drawn using eulerAPE [24]. \*Refers to pre-illness annual household income, †Defined using Brazil’s 2016 poverty line of monthly household income per capita US$48.6 a month [18], ‡Two participants had pre-illness annual household income US$0, and were in poverty pre-illness, §One participant had missing data on use of coping strategies, ¶One participant was in poverty pre-illness, #One participant had pre-illness annual household income US$0, and was in poverty pre-illness.

TABLE 1 Multivariable logistic regression assessing the association between uptake of social protection and financial hardship.

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|   | **Multivariable logistic regression** |
|   | **OR (95% CIs)** | **p-value** |
| **Financial hardship** |  |  |
| Total costs ≥20% of household income\*† | 0.37 (0.14-0.94)α | 0.04 |
| Used coping strategy‡ | 1.31 (0.50-3.47)β | 0.58 |
| Impoverished§¶ | 0.16 (0.04-0.54)γ | 0.002 |
| All three financial hardships# | 0.01 (0.00-0.07)δ | <0.001 |

Socioeconomic and clinical characteristics associated (p<0.1) with outcomes in univariable logistic regression were included in multivariable logistic regression models. \*Refers to pre-illness annual household income. †Three participants with pre-illness annual household income US$0 were excluded, n=116, ‡One participant with missing data on use of coping strategies was excluded, n=118, §Five participants in poverty pre-illness were excluded, n=114, ¶Defined using Brazil’s 2016 poverty line of monthly household income per capita US$48.6 a month [18], #Six participants with either pre-illness annual household income US$0, missing data on use of coping strategies, or in poverty pre-illness were excluded, n=113. α Mutually adjusted for sex, age, education, acquired DR TB, and time to DOT clinic; β Mutually adjusted for sex, age, pre-illness household head, pre-illness household income per capita, acquired DR TB, and time to DOT clinic; γ Mutually adjusted for sex, age, education, and pre-illness household income per capita; δ Mutually adjusted for sex, age, pre-illness household head, pre-illness household income per capita, acquired DR TB, and time to DOT clinic. OR, odds ratio; CI, confidence interval.

**References**

1. Tanimura T, Jaramillo E, Weil D, Raviglione M, Lönnroth K. Financial burden for tuberculosis patients in low- and middle-income countries: a systematic review. *Eur. Respir. J.* 2014; 43: 1763–1775.

2. Morris MD, Quezada L, Bhat P, Moser K, Smith J, Perez H, Laniado-Laborin R, Estrada-Guzman J, Rodwell TC. Social, Economic, and Psychological Impacts of MDR-TB Treatment in Tijuana, Mexico: A Patient’s Perspective. *Int. J. Tuberc. Lung Dis.* 2013; 17: 954–960.

3. Wingfield T, Boccia D, Tovar M, Gavino A, Zevallos K, Montoya R, Lönnroth K, Evans CA. Defining Catastrophic Costs and Comparing Their Importance for Adverse Tuberculosis Outcome with Multi-Drug Resistance: A Prospective Cohort Study, Peru. *PLoS Med* [Internet] 2014 [cited 2017 Dec 1]; Available from: http://dx.doi.org/10.1371/journal.pmed.1001675.

4. Rouzier VA, Oxlade O, Verduga R, Gresely L, Menzies D. Patient and family costs associated with tuberculosis, including multidrug-resistant tuberculosis, in Ecuador. *Int. J. Tuberc. Lung Dis.* 2010; 14: 1316–1322.

5. Ramma L, Cox H, Wilkinson L, Foster N, Cunnama L, Vassall A, Sinanovic E. Patients’ costs associated with seeking and accessing treatment for drug-resistant tuberculosis in South Africa. *Int. J. Tuberc. Lung Dis.* 2015; 19: 1513–1519.

6. van den Hof S, Collins D, Hafidz F, Beyene D, Tursynbayeva A, Tiemersma E. The socioeconomic impact of multidrug resistant tuberculosis on patients: results from Ethiopia, Indonesia and Kazakhstan. *BMC Infect. Dis.* [Internet] 2016 [cited 2017 Dec 1]; Available from: https://doi.org/10.1186/s12879-016-1802-x.

7. Pichenda K, Nakamura K, Morita A, Kizuki M, Seino K, Takano T. Non-hospital DOT and early diagnosis of tuberculosis reduce costs while achieving treatment success. *Int. J. Tuberc. Lung Dis.* 2012; 16: 828–834.

8. World Health Organization. End TB Strategy [Internet]. 2015 [cited 2017 Dec 1].Available from: http://www.who.int/entity/tb/post2015\_TBstrategy.pdf.

9. Lönnroth K, Glaziou P, Weil D, Floyd K, Uplekar M, Raviglione M. Beyond UHC: Monitoring Health and Social Protection Coverage in the Context of Tuberculosis Care and Prevention. *PLoS Med.* [Internet] 2014 [cited 2017 Dec 1]; Available from: https://doi.org/10.1371/journal.pmed.1001693.

10. Madan J, Lönnroth K, Laokri S, Squire SB. What can dissaving tell us about catastrophic costs? Linear and logistic regression analysis of the relationship between patient costs and financial coping strategies adopted by tuberculosis patients in Bangladesh, Tanzania and Bangalore, India. *BMC Health Serv. Res.* [Internet] 2015 [cited 2017 Dec 1]; Available from: https://doi.org/10.1186/s12913-015-1138-z.

11. Instituto Nacional Do Seguro Social. Auxílio-doença [Internet]. [cited 2016 Jul 6].Available from: https://www.inss.gov.br/beneficios/auxilio-doenca/.

12. Medeiros M, Britto T, Veras Soares F. Targeted Cash Transfer Programmes in Brazil: BPC and the Bolsa Familia [Internet]. Brasilia: International Poverty Centre; 2008 [cited 2017 Dec 1].Available from: http://www.ipc-undp.org/pub/IPCWorkingPaper46.pdf.

13. Gazola Hellmann A. How Does Bolsa Familia Work? Best Practices in the Implementation of Conditional Cash Transfer Programs in Latin America and the Caribbean [Internet]. Washington: Inter-American Development Bank; 2015 [cited 2017 Dec 1].Available from: https://publications.iadb.org/bitstream/handle/11319/7210/How\_does\_Bolsa\_Familia\_Work.pdf?sequence=5&isAllowed=y.

14. Ministério da Saúde. Sistema de Informação de Tratamentos Especiais de Tuberculose (SITETB) [Internet]. [cited 2017 Dec 1].Available from: http://sitetb.saude.gov.br/sitetb/login.seam;jsessionid=CF67B43BE3A0B2E589E3412DF4953A2E?cid=4790.

15. World Health Organization. Tuberculosis patient cost surveys: a handbook [Internet]. 2017 [cited 2018 Jan 3].Available from: http://www.who.int/tb/publications/patient\_cost\_surveys/en/.

16. The World Bank. Official exchange rate (LCU per US$, period average) [Internet]. [cited 2017 Dec 1].Available from: http://data.worldbank.org/indicator/PA.NUS.FCRF?locations=BR&page=5.

17. World Health Organization. WHO guide to identifying the economic consequences of disease and injury [Internet]. 2009 [cited 2017 Dec 1].Available from: http://www.who.int/iris/handle/10665/137037.

18. Ministry of Social Development. What is poverty? [Internet]. Braz. Learn. Initiat. World Poverty WWP [cited 2018 Jan 10].Available from: https://wwp.org.br/en/what-is-poverty/.

19. International Labour Organization. Transitioning from the informal to the formal economy [Internet]. 2014 [cited 2017 Dec 1].Available from: http://www.ilo.org/ilc/ILCSessions/103/reports/reports-to-the-conference/WCMS\_241897/lang--en/index.htm.

20. Rebecca Wolfe. Covering the informal sector. Report from a workshop on expanding access to health services and financial protection for people outside the formal employment sector [Internet]. London School of Hygiene and Tropical Medicine: Resilient and Responsive Health Systems (RESYST); 2014 p. 25Available from: https://www.gov.uk/dfid-research-outputs/covering-the-informal-sector-report-from-a-workshop-on-expanding-access-to-health-services-and-financial-protection-for-people-outside-the-formal-employment-sector.

21. Wagstaff A, Flores G, Hsu J, Smitz M-F, Chepynoga K, Buisman LR, Wilgenburg K van, Eozenou P. Progress on catastrophic health spending in 133 countries: a retrospective observational study. *Lancet Glob. Health* 2018; 6: e169–e179.

22. Honorati M, Gentilini U, Yemtsov RG. The State of Social Safety Nets 2015 [Internet]. 2015 [cited 2017 Nov 30].Available from: http://documents.worldbank.org/curated/en/415491467994645020/pdf/97882-PUB-REVISED-Box393232B-PUBLIC-DOCDATE-6-29-2015-DOI-10-1596978-1-4648-0543-1-EPI-1464805431.pdf.

23. Rudgard WE, Evans CA, Sweeney S, Wingfield T, Lönnroth K, Barreira D, Boccia D. Comparison of two cash transfer strategies to prevent catastrophic costs for poor tuberculosis-affected households in low- and middle-income countries: An economic modelling study. *PLOS Med.* 2017; 14: e1002418.

24. Micallef L, Rodgers P. eulerAPE: Drawing Area-Proportional 3-Venn Diagrams Using Ellipses. *PLOS ONE* 2014; 9: e101717.