Title

Measuring economic burden for patients and households affected by tuberculosis: differences between the End TB Strategy and the Universal Health Coverage framework

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Abstract
Tuberculosis (TB) is a disease of poverty. Ensuring access to health care without risk of financial hardship due to out-of-pocket health care expenditures (Universal Health Coverage; UHC) is essential for providing accessible care for underprivileged populations, but it is not enough.

The End TB Strategy promotes both patient-centred TB services and social protection measures, which aim to mitigate economic hardship on TB patients and their households due to direct medical and non-medical expenditures, as well as lost income. The Strategy includes a target that no families should face catastrophic total costs due to TB. The indicator linked to this target aims to capture the total economic burden linked to TB care, and thus differs from the "catastrophic expenditure on health" indicator, a key component of the UHC monitoring framework, aligned to the Sustainable Development Goals.

Countries, especially high TB-burden countries, are expected to conduct nationally-representative TB patient cost surveys to establish baseline measurements for the catastrophic costs indicator. Findings from these surveys should also help identify entry points to develop policies to ensure better financial and social protection for TB patients. In this paper, we define the key measurable concepts for TB patient cost surveys, notably the types of costs that are captured and related affordability measures. We discuss the methods for measuring these notions in the UHC framework and contrast them with how they are measured in TB patient cost surveys.

1. Introduction and background

Tuberculosis (TB) remains a major threat to global public health (1). Poor people in resource-constrained settings are most at risk of the disease and its devastating economic consequences (2). In low- and middle-income countries (LMICs), health care financing is heavily reliant on out-of-pocket payments. Despite basic TB care being officially free of charge, often partly through vertical funding mechanisms, TB patients often struggle to afford TB care and incur costs considered to be "catastrophic" (3-5).

Universal Health Coverage (UHC), which means that everyone can access the quality health services they need without financial hardship (6), has long been on the global TB control agenda. Free diagnosis and treatment have been the cornerstone of global TB control strategies since 1994. The DOTS Strategy emphasises the use of low-cost, cost-effective tools and interventions to enable affordable access to quality TB care, which has resulted in 53 million lives saved. Yet, this has been shown to be insufficient in mitigating economic consequences since non-medical costs and income losses, which account for a large part of the economic burden for households, are not accounted for within the UHC monitoring framework (7-9).

Aligned to the Sustainable Development Goals (SDGs), the World Health Organization´s (WHO) End TB Strategy has an increased focus on poverty alleviation strategies and social protection initiatives that cover costs beyond medical expenses, including income security. It also includes a target of no TB-affected families suffering from catastrophic total costs due to the disease (9, 10). To monitor progress towards this target, the WHO Global TB Programme convened a task force of experts in 2015 to develop a field-testing protocol and survey instrument for nationally-representative, health-facility-based surveys of costs faced by TB patients ad their households (in shorthand, "TB patient cost surveys"), building upon the Tool to Estimate Patients' Costs (11). After field-testing, WHO developed a Handbook for TB patient cost surveys (10). Countries, especially countries with a high burden of TB, are expected to adapt and implement these surveys to document the magnitude and main drivers of costs incurred by TB patients (and their households) and the percentage of TB patients who incur catastrophic costs as a result of the costs of care, and to monitor these metrics over time. Findings from these surveys should also help identify entry points to develop policies to ensure better financial and social protection for TB patients (7).

As of July 2018, eleven countries had conducted a TB patient cost survey using the WHO methodology and instrument (12), four surveys are ongoing or near completion, and thirteen countries are planning

36   and mobilising funding to conduct such surveys (Figure 1).

37

38   In this paper, we describe the key notions that are measured using these TB patient cost surveys,

39   notably the types of costs that are captured, and measures of the affordability of these costs in

40   relation to household income, expressed as occurrence of catastrophic costs and impoverishment. We

41   discuss the standard methods for measuring these concepts and how they have been adapted in the

42   TB patient cost survey Handbook, and conclude by highlighting areas for consideration for those

43   implementing TB patient cost surveys going forward.

44

45   **2. Defining economic burden for patients and households**

46   At the heart of the UHC paradigm, is the concept that families should not face undue financial hardship

47   by accessing health care. This is referred to as financial protection, and it builds on the notion of

48   affordability of care (13, 14).

49

50   WHO and the World Bank track financial protection through two indicators: high (or catastrophic)

51   health spending and impoverishment (6). Catastrophic health spending quantifies the proportion of

52   the population whose resources would be catastrophically reduced by spending on health care (15).

53   When health care expenditures exceed a given percentage of available income (or expenditure

54   capacity), they are considered "catastrophic". The impoverishment approach estimates the

55   proportion of the population that would be pushed below a defined poverty line due to seeking and

56   receiving care (16). Generally, catastrophic spending and impoverishment rates are calculated using

57   household level data captured through population-based surveys.

58

59   **3. Measuring catastrophic health spending**
60
61   When measuring catastrophic health spending, there are two key variables underlying this approach:

62   a) total household out-of-pocket payments for health care (numerator, see sections 3.1 and 3.3); b) a

63   measure of household resources (denominator, see section 3.2). A ratio of health care costs to a

64   measure of ability to pay can then be generated (section 3.3), which is compared to a threshold

65   (section 3.4).

66

67   *3.1. Measuring and valuing household costs*

68

69   While the UHC indicator uses household surveys to capture health care expenditures (medical costs)

70   for all conditions, the TB indicator aims to capture instead the total economic burden related to one

71   diagnosed health condition only (TB). The UHC indicator focuses on direct out-of-pocket medical costs

72   only.

73

74   TB patient cost surveys measure three types of cost: **direct medical costs**, **direct non-medical costs**

75   and **income loss (indirect costs** or **opportunity costs)**. Direct medical costs represent the money

76   actually spent out of pocket by the patient on medical services such as prescribed medications,

77   consultation fees, hospitalisation and laboratory tests. These costs are the same as the direct medical

78   costs measured in the UHC framework.

79

80   Patients (and their carer) often incur other direct costs associated with the utilisation of health care,

81   such as transport costs to and from the health facility, costs for accommodation and food, which are

82   referred to as **direct non-medical costs.** Direct costs are valued by asking patients to recall their actual

83   expenditure.

84

85   When seeking care and when sick, individuals also incur costs associated with lost productivity due to

86   illness/disability and time spent seeking care, or looking after a patient instead of working (i.e. carers).

87   These opportunity costs are referred to as **indirect costs** in the End TB monitoring framework. Two

88   approaches are typically employed to value indirect costs to households: the human capital approach

89   and the output-based approach (17).

90

91   The human capital approach involves valuing an individual's time by multiplying the number of hours

92   spent seeking and receiving care/caring for by their reported or estimated hourly wage rate(18). If

93   based on reported income, this method can have equity concerns, as it then implicitly values the time

94   of more productive (higher income) individuals more highly and doesn't take into account the value

95   of time lost by individuals who are performing unpaid work or are unemployed or retired (19). This

96   can be corrected by using a standard estimated income for these individuals (e.g. the mean for the

97   lower quintiles based on national statistics or the minimum civil servant wage).

98

99   The output-based approach considers reported changes in income/production (20). This approach is

100   recommended by WHO for settings predominately characterised by formal economies, where

101   individuals can reliably report income in monetary terms.

102

103   WHO's generic instrument for TB patient cost surveys collects data that allows the valuation of both

104   indirect costs using the human capital approach and the output-based approach (Table 2)(12). The

105 End TB Strategy indicator is generally computed based on the output-based approach, with the human
106 capital approach used in sensitivity analysis. The reason for capturing these data in TB patient cost
107 surveys is to encourage the valuation of TB-related indirect costs, as such evidence is currently limited
108 (12, 21-23). Researchers to date have generally employed the human capital approach to value
109 productivity losses associated with TB, with varying precision in the estimations of time and income.
110 However, over one-third of studies included in one recent systematic review that presented indirect
111 costs did not clearly explain the methods that were used to calculate them (24).

112

113 The economic burden of illness can be measured on the individual level, but it usually makes sense to
114 look at the economic impact on the whole household especially since other household members also
115 contribute to direct expenditures and may take time off work to care for the ill person or take their
116 children out of school to contribute to the household income (25). The affordability of TB costs is also
117 analysed at the household level due to the impact that TB potentially has on households, as we discuss
118 below.

119
120 *3.2 Measuring ability to pay*
121 Ability to pay is usually measured in terms of income, consumption or expenditure. Income refers to
122 earnings from employment and sale of assets and receipt of transfers. Consumption refers to spending
123 on resources (goods and services) consumed by the household. Expenditure excludes consumption
124 that is not based on market transactions (e.g. home production), and refers to goods or services
125 purchased but not immediately consumed by the household. (26).

126
127 While reported income is the gold standard measure of ability to pay, in low-income settings, where
128 employment is mainly outside the formal sector and income is hard to measure reliably, consumption
129 expenditure is often believed to be a more valid measure of economic resources than income.
130 However, both remain difficult and costly to collect (27-30).

131

132 In the UHC framework, consumption expenditure is often used rather than income to measure
133 catastrophic expenditure and impoverishment (6). It can be argued that deducting food spending from
134 consumption (non-food expenditure) can better capture a household's ability to pay for health
135 expenditures (6). Alternatively, no deduction for necessities is made.

136

137 TB patient cost surveys capture either income or consumption expenditure or both. The TB indicator
138 is computed using the measure of income that is more robust in the specific country setting. For

139 countries collecting more than one measure, the more robust will be used for main analysis and the
140 alternative measures in sensitivity analysis.

141

142 *3.3 Generating a ratio of health care costs to a measure of ability to pay*
143 When computing catastrophic spending within the UHC monitoring framework, the numerator is
144 restricted to direct medical costs (31), and does not measure direct non-medical and indirect costs, as
145 UHC is mainly about moving towards progressive and equitable health care financing, and national
146 financing schemes (tax or insurance-based) covering direct medical costs.

147

148 The End TB monitoring framework, on the other hand, is designed to also collect data that can guide
149 policies on patient-centred service delivery models that can reduce both direct and indirect costs, as
150 well as social protection schemes for income security and social support. A key element of innovation
151 of the End TB Strategy "zero catastrophic costs" indicator is thus that the numerator comprises both
152 direct medical, non-medical and indirect costs. In TB care, indirect costs have been found to account
153 for a sizeable proportion of total costs (on average 60% of total costs (range: 16-94%) in low- and
154 middle-income countries (32)), and therefore they are important elements to capture all care-related
155 expenditures and the economic impact on TB patients from the onset of symptoms to the end of TB
156 treatment. The denominator is further defined as annual household income or annual household
157 consumption expenditure, as outlined in section 3.2 (33). The resulting ratio is then compared to the
158 thresholds defined below to determine whether spending is catastrophic.

159

160 *3.4 Defining thresholds for catastrophic payments*
161 The catastrophic payment threshold is set as a proportion of income (i.e. households should not spend
162 more than a pre-specified fraction of their income on health care). When a household's healthcare
163 payments exceed a pre-defined threshold, they are defined as catastrophic (15). The choice of the
164 threshold is so far arbitrary. Various thresholds have been used in the literature: 10% (34), 15% (35)
165 of household annual income, or 40% of household non-food expenditure (31, 36). WHO and World
166 Bank now track catastrophic spending on the basis of out-of-pocket expenditures exceeding 10% or
167 25% of household total income or consumption(6).

168

169 For global monitoring of the End TB Strategy "zero catastrophic costs" indicator, in 2017, WHO has
170 chosen to use a threshold of 20% of annual household income (12), which was set through expert
171 opinion voting in the task force. This is the threshold that is currently used by National TB Programmes
172 (NTP) implementing TB patient cost surveys and which is annually reported to WHO (1, 37). Countries
173 that are conducting national TB patient cost surveys are encouraged to undertake sensitivity analyses

174 whereby the 20% threshold is altered so that the proportion of patients facing catastrophic costs can

175 be assessed at different thresholds, and potentially inform a review of the threshold in the future

176 (Table 2).

177

178 The threshold can be used to help define two measures of catastrophic health spending, both in the

179 UHC and End TB Strategy framework. The ***catastrophic payment headcount*** measures the incidence

180 of catastrophic health care costs (i.e. the number (or fraction) of individuals who have been exposed

181 to catastrophic expenses). The ***catastrophic payment gap*** (or excess) measure is used to assess the

182 intensity or severity of catastrophic spending by looking at the extent to which health care costs

183 exceed the pre-defined threshold (15) (Table 2).

184

185 The proportion of patients incurring catastrophic costs due to TB is derived from the number of TB

186 patients with catastrophic costs divided by the number of all TB patients treated at facilities linked to

187 a national TB programme. This means that the sampling frame is notified patients on treatment rather

188 than all people with TB in the community, or households in a country. This is for practical reasons since

189 the only available sampling frame is notified TB patients, and household surveys would require a large

190 sample size in order to include a sufficient number of prevalent TB cases.

191

192 **4. Measuring impoverishment**

193 An additional measure of the affordability of care used for UHC monitoring is ***impoverishment***, or

194 whether health care costs push households into poverty (or deeper into poverty). In this case, the

195 threshold is absolute and set in terms of a poverty line. If health care payments cause household

196 income/consumption expenditure to fall below the poverty line, they are considered "impoverishing".

197 The widely used international dollar-a-day poverty line proposed by the World Bank to allow

198 international comparability, was replaced by USD 1.25-a-day in 2009, at 2005 purchasing power parity

199 (38). Countries also have their own national poverty lines which may be relevant for comparing

200 impoverishment over time within a country.

201

202 The ***incidence of impoverishment*** measures the increase in poverty due to health care spending. The

203 ***poverty gap*** is the short-fall from the poverty line. While these are not included in the End TB Strategy

204 monitoring, countries can include them in the analyses of TB patient cost surveys. Table 1 provides a

205 summary of the key measures presented in this section and Section 3.4.

206
207
208 **5. Towards zero families facing catastrophic costs due to TB**: **areas for consideration**

209

210   The End TB Strategy target is a first important step in broadening the concept and measurement of

211   affordability to account not only for medical costs but also for the broader economic impact of TB,

212   including non-medical and indirect costs.

213

214   However, as illustrated above, the application of the concepts and standard methods of financial

215   protection warrants further development in the End TB Strategy. The WHO recently published a

216   handbook based on the experiences and data from the first round of surveys between 2016 and 2017,

217   which provides comprehensive guidance for conducting facility-based cross-sectional surveys to

218   assess TB patient costs (12). This would benefit from periodic methodological updates based on multi-

219   country analyses of survey findings and strengthened collaboration with health economists, NTPs and

220   policy makers. These updates include: methods for calculating confidence intervals for key survey

221   indicators, adjusted for the sampling design; a regression-based approach for imputing missing costs;

222   recommendations on the design of a household expenditure questionnaire (to derive a household

223   income measure based on expenditure); adaptation of the survey instrument to high-income settings.

224

225   There are a number of areas for consideration for those implementing TB patient cost surveys going

226   forward, including: descriptive analyses of costs that unpack direct medical and non-medical costs,

227   and indirect costs, as they can provide valuable information to identify entry points for appropriate

228   polices and interventions to minimise these costs; using both the human capital and the output-based

229   approach to value indirect costs for comparison and correlation; measuring and comparing income

230   and consumption expenditure to compute financial protection measures. Additional approaches and

231   metrics to the standard End TB Strategy framework methodology include: measuring impoverishment,

232   computing the catastrophic payment gap, and sensitivity analyses with different percentages of

233   income thresholds (Table 2).

234

235   Finally, it is important to bear in mind that the cross-sectional study design for a TB patient cost survey

236   recommended by WHO inevitably focuses on the economic consequences of TB by using a measure

237   at one point in time, and therefore it fails to capture the long-term economic consequences of the

238   disease for the household, including the impact on reduced labour supply and productivity, and

239   household resilience. Coping mechanisms were originally explored as part of the development of the

240   TB indicator as deemed to be potentially less labour intensive to collect and easier to integrate in

241   routine surveillance. However, as coping mechanisms are different in different cultures and societies,

242   it'd be difficult to consider them as a proxy for catastrophic payments.

243

244   Several research studies are now ongoing that have adapted the WHO generic protocol to a
245   longitudinal design, including for long-term follow up after TB treatment. These studies will be helpful
246   for the validation and interpretation of cross-sectional TB patient cost survey data. Separate studies
247   of non-notified TB patients, e.g. in private care, are required to measure costs in situation where user
248   charges for clinical care are often higher than in facilities linked to NTPs. Yet other studies sampling
249   people with TB who are not under treatment at the time of the study are needed as the current
250   methodology only includes TB patients who are successfully staying in care. Such studies can be
251   conducted in the context of tracing patients who are lost to follow up (e.g. initial loss to follow up or
252   loss to follow-up during treatment) by reconnecting them with treatment and explore reasons for loss
253   to follow up. Assessing costs incurred by such patients may shed light on costs related to the disease
254   and disability that are not linked to care seeking, and costs of living with TB without getting proper
255   care.
256

257 **Conclusions**
258
259   In this paper, we have described economic burden and affordability concepts and measurements that
260   underlie the End TB Strategy indicator of "zero catastrophic costs" due to TB, and have highlighted the
261   novel elements of this indicator in relation to approaches used in the UHC monitoring framework.
262   Further findings from national surveys, multi-country analyses and research using alternative
263   approaches will be important in providing further evidence to refine metrics and methodology for
264   country-level implementation and global monitoring.
265

266   The conventional concepts and measurement of "financial protection" of the UHC monitoring
267   framework have been taken a step forward in the End TB Strategy to ensure metrics are able to
268   capture the total economic burden of TB on patients and families. This approach has the potential to
269   inform the design of financing and implementation of both health care and social protection policies
270   that aim to prevent both direct and indirect costs of care, and ultimately ensure that TB care is truly
271   affordable for TB patients.
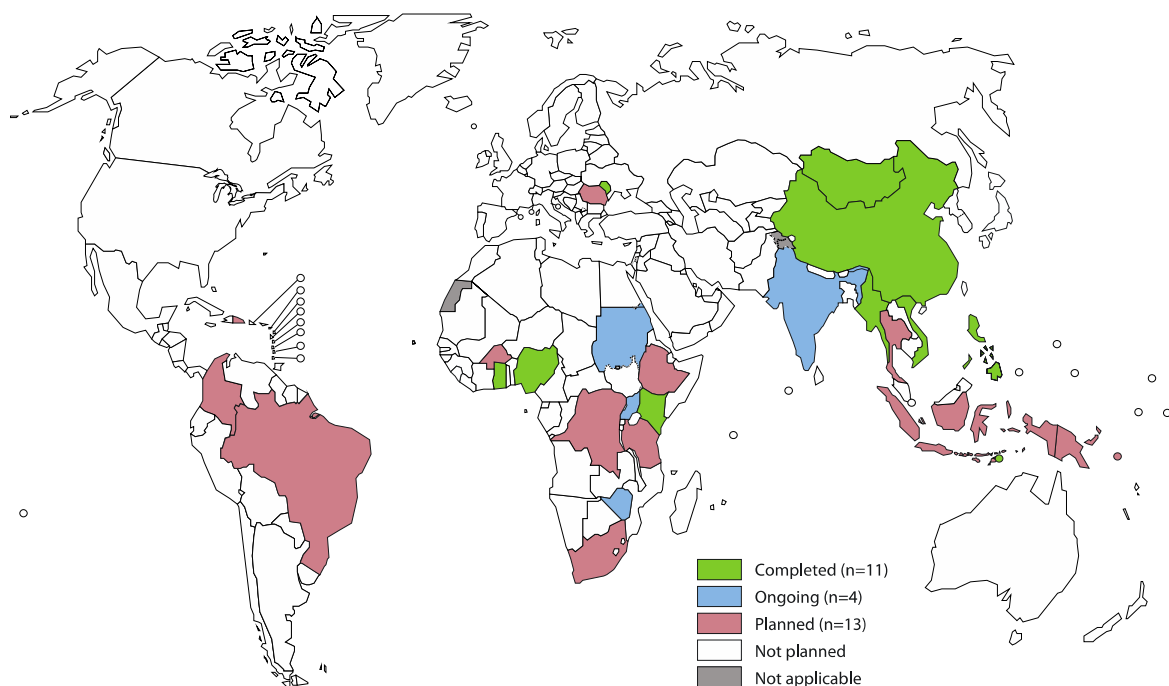272

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Figure 1: Global implementation of tuberculosis patient cost surveys following the World Health Organization methodology, as of July 2018.

Source: WHO Global TB Programme, July 2018

Table 1: Summary of key measures of catastrophic health spending and impoverishment for general UHC monitoring.

1. Concept of catastrophic health expenditure: key indicators	
Indicator	What it is measuring
Catastrophic payment headcount *(or incidence of catastrophic health expenditure)*	Proportion of households in a population who face catastrophic health expenditure
Catastrophic payment gap *(or excess or mean positive catastrophic overshoot)*	Percentage points by which household spending on health exceeds the threshold for catastrophic health expenditure
2. Concept of impoverishment due to health spending: key indicators	
Indicator	What it is measuring
Incidence of impoverishment	Proportion of households in a population who fall into poverty due to health care spending
Poverty gap *(or increase in the depth of poverty)*	Percentage points by which a household falls further into poverty due to health care spending

Source: Adapted from Saksena et al 2014 (39).

Table 2: Summary of recommended and additional approaches, metrics and valuation methods for TB patient cost surveys based on the World Health Organization methodology (12).

Approach/valuation method/metric			Recommended	Additional
Costs	Direct	Cost disaggregation (medical/non-medical)	•	
	Indirect	Human capital approach	•	
		Output-related approach	•	
Measure of living standard	Income	Reported individual and household income pre and post-TB diagnosis	•	
		Asset-based income	•	
	Consumption expenditure		•	
Measures of financial protection	Catastrophe	Catastrophic Payment Headcount	•	
		Catastrophic payment gap		•
	Impoverishment	Incidence of impoverishment		•
		Depth of poverty		•
Threshold	Catastrophe	20% threshold	•	
		Sensitivity analysis with different percentages of income threshold	•	
	Impoverishment	International poverty lines (e.g. USD 1.25-a-day in 2005 PPPs)		•
		National/locally defined relevant poverty lines		•