

Protocol for survey to determine direct and indirect costs due to TB and to estimate proportion of TB-affected households experiencing catastrophic total costs due to TB

Field testing version

World Health Organization, Global TB Programme

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Glossary for terms used in this protocol

Catastrophic total costs due to TB.

Definition 1. Total costs (indirect and direct combined) exceeding a given threshold (e.g. 20%) of the household's annual income. The total indirect and direct costs of TB are defined as the sum of: a) Out-of-pocket payments for TB diagnosis and treatment made by TB patient's households, net of any reimbursements; b) Payments related to the use of TB health services, such as payments for transportation, accommodation or food net of any reimbursements to the individual who made the payments (i.e. guardian or patient); c) Income losses incurred by both the TB patient and any accompanying household member, net of any welfare payment.

Definition 2. Dissaving (such as loans taken, property or livestock sale) incurred by patients to face health costs associated with the TB disease.

Source: Working definition adopted by the Task force (March, 2015)

Catastrophic health expenditure. Out-of-pocket payments for health care (for all conditions), exceeding a given fraction of a household's expenditure. The focus is on the burden of direct outlay of cash made by households to improve or restore the health of any of their members (WHO and World Bank, 2015).

Dissaving: Economics literature refers to "dissaving" in reference to borrowing or selling assets to finance, for example, health care expenditure. The term highlights the fact that it involves reducing the financial strength of a household, in the same way that saving increases a household's resilience to financial shocks.

Direct costs: Out-of-pocket payment for TB care and Out-of-pocket payments non-medical (see definition) are direct costs.

Food payment. Out-of-pocket payments for food bought in relation to travelling to the health care visit, and during visit or hospitalization, patient and household member (e.g. if meals at the hospital are not provided). Food costs are part of direct non-medical costs (see definition).

Household income (before and during the TB episode): reported amount of money received by the household in the year before and the year during TB episode, respectively, in exchange for labor or services, from the sale of goods or property, or as a profit from financial investments and welfare payments. Alternatively annual household income estimated based on asset ownership. The indicator of catastrophic total costs (approach 1 – see definition) uses in the denominator, the household income earned before the TB episode, net of welfare payments.

Indirect costs of seeking TB treatment: Productivity and economic costs of a patient or household incurred as a result of TB health care seeking and hospitalization, during the TB episode. During field testing phase, it is recommended that indirect costs are estimated using two alternative methods: a) self-reported household income loss net of welfare payments (net effect of income change pre as compared to during the TB episode) and b) total period of absence (in hours) multiplied by hourly wage rate of the absent worker. For the latter method (b) several options will be explored in the sensitivity analysis, for the choice of hourly wage rate used.

NTP network. Health facilities, public or private, treating and notifying TB in line with the guidelines of the national TB programme.

Out-of-pocket payment for health care (medical). Direct payment made to health-care providers by individuals *at the time of service use*, i.e. excluding prepayment for health services – for example in the form of taxes or specific insurance premiums or contributions – and, where possible, net of any reimbursements to the individual who made the payments. OOP payment (including gratuities and payments in-kind) includes payment to formal medical professionals, informal traditional or alternative practitioners, clinics, health centres, pharmacies and hospitals for medical services and products such as consultations, diagnosis, treatment and medicine (WHO and World Bank, 2015).

Out-of-pocket payment for TB care. Out-pocket payments for TB treatment (e.g. consultation fee, drugs, diagnosis, hospitalization etc)

Out-of-pocket payment, non-medical. Out-pocket payments made by patient or guardian related to the use of TB health services, such as payments for transportation, accommodation, food etc.

Out-of-pocket payment net. Total out-of-pocket payment (medical and non-medical) minus any reimbursement received for payments made is a net payment.

TB episode. The period of time from self-reported onset of TB-related symptoms until end of treatment or death.

Travel costs. Total payments by the patient for travel to the facility. Travel costs are part of direct non-medical payments for TB treatment.

Welfare payments Refers to paid sick leave, disability grant, cash transfer for poor families or other cash transfer.

1. Background and rationale

Tuberculosis (TB) patients often incur large costs related to illness, as well as to seeking and receiving health care. Such costs can create access and adherence barriers which can affect health outcomes and increase risk of transmission of disease. These costs can also contribute to the economic burden of households. In low- and middle-income countries, TB patients face costs that on average amount to half their annual income (Tanimura et al 2014). In all settings, TB affects the poorest segment of society the worst. The poverty-aggravating effects of TB are therefore gravest for those that are already most vulnerable.

While out-of-pocket medical expenditures are important, lost income is often the dominant contributor to economic hardship. Direct non-medical costs, such as costs for travel and food during health seeking are also significant given the often long health seeking period and the six months to two years period of treatment (Tanimura et al 2014).

To overcome access and adherence barriers, as well as to minimize the economic burden for TB patients (and their households) it is therefore essential to address both direct and indirect costs. Interventions are needed to address high medical costs, as well as costs of food and transport, and lost earnings. Therefore, both health financing and delivery models, as well as social protection mechanisms (such as job protection, paid sick leave, social welfare payments, or other transfers in cash or kind) need to be considered (Mauch et al 2012, Lönnroth et al 2014).

One of the three targets for the End TB Strategy is that no TB patient or their household should face “catastrophic total costs” due to TB, and this target should be achieved by 2020. This target is in line with policy efforts to move health systems closer to universal health coverage (UHC) because TB cannot be eliminated without addressing the barriers to uptake and completion of needed treatment, an important aspect of service coverage. The share of the population incurring “catastrophic expenditures” (expenditures beyond a defined threshold of a household’s capacity to pay) is one measure of financial protection that is commonly used as an indicator of progress towards UHC (WHO and World Bank, 2015). The TB-specific indicator of “catastrophic total costs” is different from the population-based indicator of “catastrophic expenditures” because it incorporates, both direct medical payments for treatment, direct non-medical payments (such as transportation, lodging charges) and indirect costs, such as income losses. The TB-specific indicator is also restricted to a particular population: diagnosed TB patients treated in NTP networks. Furthermore, the objective of the TB-specific measure is to identify and reduce barriers to treatment adherence and not, strictly speaking, to measure financial protection for households.

Measuring financial protection for households at the level of an individual disease, would make little sense as it would suggest a policy concern with impoverishment from one disease as compared to other diseases. Hence, due to differences in both the concept and the approach to measurement, the indicator of catastrophic TB cost is not comparable to the population-based indicator of catastrophic expenditures, and should not be used in relation to any other measure apart from “TB catastrophic total costs” over time in the same country.

It should be noted that the TB-specific indicator of “catastrophic total costs” does not capture all TB-related costs for patients and households. It does not explicitly measure income loss due to disability per se, or other factors (e.g. stigma and discrimination) leading to loss of employment or earnings, unless such income loss is closely related to, or impossible to distinguish, from lost earnings due to health seeking, health care visits and hospitalization.

That is, the indicator measures indirect costs related to TB care, but not strictly speaking to the illness itself. This is part of the rationale for measuring the indicators only among people who are diagnosed and treated for TB. Moreover, indirect costs of TB for the patient and the household can extend well beyond the treatment period, also for people who are declared cured from TB. People may be left with short- or long-term (even life-long) sequelae of the disease. Effects of coping mechanisms, such as selling household assets or taking children out of school can impair household economy for years. For the documentation of long-term need of social and economic support for TB-affected households, measures of costs need to have a longer term time-window than the present indicator.

That being said, however, the relevance and importance of this work are clear: reducing these direct and indirect costs related to TB care will contribute to improvements in treatment adherence and in financial protection. Thus, the planned work to assess the magnitude of patient costs and identify the main cost drivers, can be used to monitor financial barriers to adherence and inform related health and social policy changes to improve TB control. This perspective is essential because, given the nature of the TB treatment protocol, reforms to the health financing system alone are unlikely to be sufficient to enable the diagnosed TB-affected population to overcome fully the barriers to successful completion of treatment. Action on the demand-side is essential, such as e.g. extension of certain social protection mechanisms to ensure treatment success for people in the informal sector and the vulnerable population groups that comprise most of the TB affected population. Reforms to service delivery strategies are likely also needed in many settings to reduce direct and indirect costs associated with care-seeking. Another potential benefit of implementing this type of survey is that it can also inform the development of more in-depth operational research to investigate identified problems and to evaluate proposed solutions.

Countries are recommended to assess the composition and magnitude of these direct and indirect costs through periodic health facility-based surveys. This is complementary to other needed assessments of local and national TB epidemiology, health seeking, and health care and social service coverage and bottlenecks for TB patients. Such assessments are a fundamental part of the End TB Strategy, which stresses the need for national adaptation based on the local epidemiological and health systems situation.

This protocol provides guidance on how to conduct a facility-based survey to assess the economic burden (i.e. direct and indirect costs) incurred by TB patients (and their households) and to identify cost drivers in order to guide policies on cost mitigation and delivery model improvements. The protocol also provides guidance on how to measure the proportion of TB patients (and their households) experiencing catastrophic total cost, and can thus be used to determine baseline and periodically measure progress towards the End TB Strategy target.

The document outlines a standardized methodology. Nonetheless, the protocol and the related survey instrument need to be adapted to the country setting. There are several methodological challenges, which are outlined in the protocol. The current version of the generic protocol is intended for field testing and for validation of proposed approaches. It includes a number of design options. After a field testing period, which is anticipated to last during 2015 and 2016, the protocol will be revised and simplified further. In the final version there will be fewer options and less need for country adaptation. Similarly, the generic questionnaire instrument will be shortened and simplified after the field testing.

2. Study objectives

2.1 Primary objectives

1. To document the magnitude and main drivers of patient costs in order to guide policies on cost mitigation for the purpose of reducing financial barriers to access and adherence.
2. To determine baseline and periodically measure the percentage of diagnosed TB patients treated in the NTP network (and their households) in the country, who incur direct and indirect costs beyond a defined threshold of their annual income.
3. To determine the correlation between facing costs above different thresholds of annual household income and the borrowing or selling assets to finance health care expenditure (or dissaving), in order to assess if the measure of dissaving is a sufficient metric of catastrophic total costs (for field testing period to inform selection of proxy for final protocol)
4. To help design a standardized approach for periodic measurements of financial barriers to adherence based on baseline experience and to enable reporting on the 2020 End TB Strategy target that no family affected by TB will incur total (direct and indirect) catastrophic costs as specifically defined in the context of this work.

2.2. Possible secondary objectives

5. To assess costs for specific subgroups, for example disaggregated by type of TB (MDR vs. drug-susceptible TB, etc), age, sex, and income.
6. To determine the association between costs incurred and TB treatment outcomes

2.3 Potential policy implications

For TB programs and other departments within the Ministry of Health, implementation partners, Ministry of Social Welfare (or equivalent) and other relevant stakeholders, analysis should help inform:

1. Design policies and interventions to minimize barriers for accessing and adhering to TB care and mitigate the economic impact of diagnosed TB for patients and their families;
2. Design of research that might be needed, and/or to further examine the determinants of cost barriers in the diagnosed TB patient population, and/or to assess the effectiveness of policies and interventions to mitigate these costs.

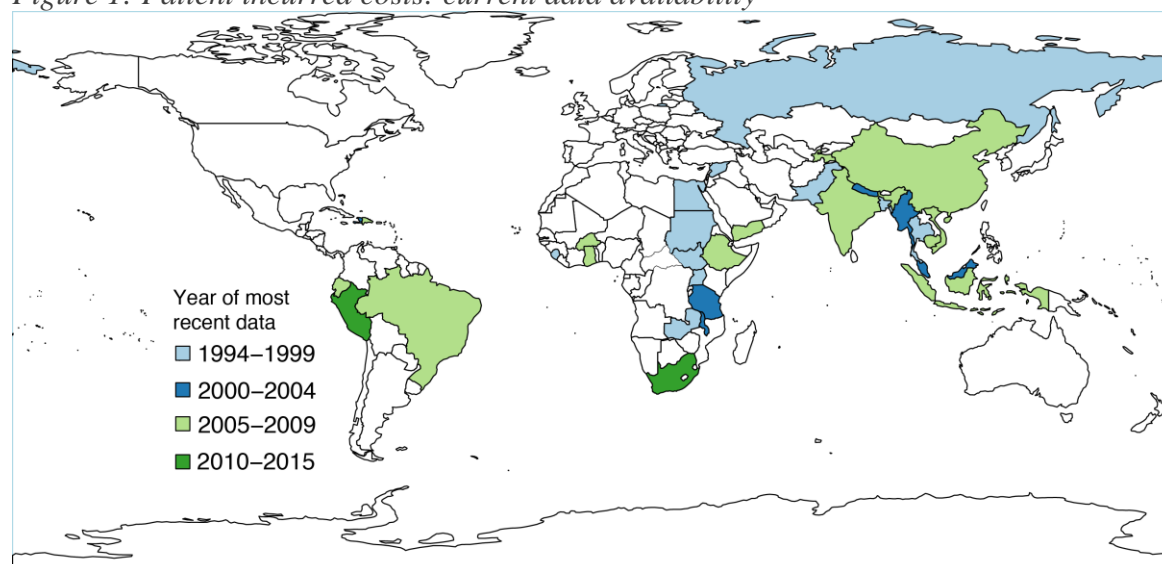
3. Methods

3.1 Development of the methodology

The WHO Global TB Programme (GTB) convened a task force on catastrophic total cost measurement in March 2015. Before the task force meeting GTB had developed a first draft of the protocol and instrument, building on the extensive previous work that has been done to measure costs for TB patients and affected households, notably the patient cost tool (TBCTA 2011) and its adaptation for MDR-TB patients (TBCTA, 2014).

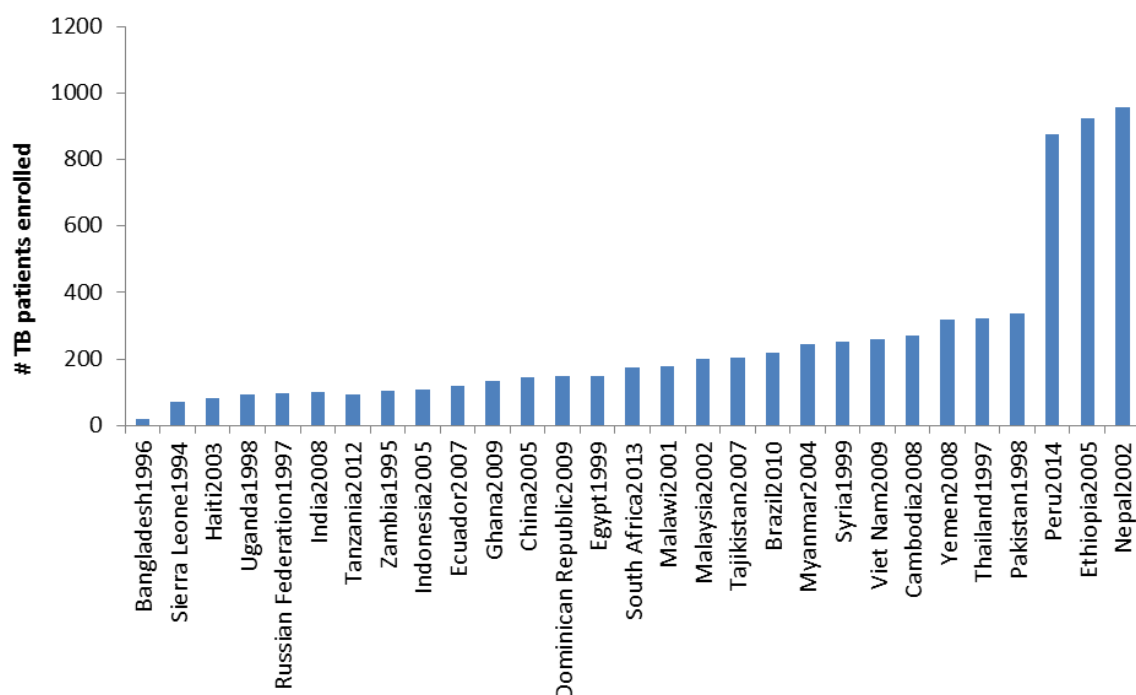
Previous experiences include 46 surveys that included direct and indirect TB patient cost data (Tanimura 2014, Foster, 2015). Most of the studies focused on determining the main cost drivers in order to inform policy on efforts to reduce costs for patients. Twelve studies calculated costs as a percentage of household income. However, only one study reported the percentage experiencing catastrophic total costs, and it did so using a data driven cut-off of >20% of annual household income. The same study assessed the association between adverse TB outcomes and occurrence of catastrophic total costs (Wingfield, 2014). Other studies of cost in relation to income reported only mean and/or median values and ranges for the whole study population or for subgroups. As shown in fig. 1 only two countries have published data on costs as a percentage of household income after 2010: Peru and South Africa. Before 2010, 9 countries (India, Ghana, Viet Nam, Dominican Republic, China, Peru, Bangladesh, Thailand, India and Brazil) analysed costs as a percentage of household income. Figure 2 shows the sample sizes used in selected studies.

Figure 1: Patient incurred costs: current data availability



Source: WHO/GTB compilation based on Tanimura et al, 2014, Foster et al, 2015 and Wingfield T et al, 2014.

Figure 2. Sample size of most recent TB patient cost surveys. (Country name followed by cost year not publication year)



Source: WHO/MTB compilation based on Tanimura et al, 2014, Laurence Y, forthcoming. Note that larger sample size exist in countries from earlier surveys and cost years. E.g. India 2007(# 896), India 2005 (# 1050), South Africa 2010 (# 1999), South Africa 2001 (# 1182), Brazil 2008 (# 218).

There is thus a rich literature on magnitude and types of costs faced by TB patients and their households. However, the task force members -- most of whom were involved in one or several of the previous studies -- acknowledged that much of the data are outdated, diverse methodology has been used and there is a need to further standardize general data collection approaches as well as the measurement of the catastrophic total cost indicator.

The task force reviewed and provided feedback on the initial draft. Thereafter the protocol and instrument have undergone several revisions and inputs have been received from additional experts. It has been presented to a PAHO/World Bank meeting in May 2015. The instrument has been piloted tested on a limited scale in Kenya in April 2015, and country adaptation and full piloting has been done for one country (Myanmar) in August 2015.

3.2 General methodological considerations for measuring percentage experiencing catastrophic total cost

Box 1: Catastrophic total costs incurred by TB patient's households: operational definition(s) adopted by the Task force (March, 2015)

The end-TB indicator refers to the “percentage of TB patients treated within the NTP network (and their households) facing catastrophic total costs”. Two approaches will be analyzed.

Approach 1

Catastrophic total costs due to TB are defined as total costs (indirect and direct combined) exceeding a given threshold (e.g. 20%) of the household's income.

The total indirect and direct costs of TB are defined as the sum of;

- out-pocket payments for TB diagnosis and treatment made by TB patient's households (direct net medical payment for TB treatment denoted $OOPM_i^{TB,h}$ where i identifies the patient and h her household);
- payments related to the use of TB health services, such as payments for transportation, accommodation or food (non-medical out-of-pocket payments for TB treatment denoted $OOPNM_i^{TB,h}$) net of any reimbursements to the individual who made the payments and
- income losses related to TB care incurred by both the TB patient and any household member net of any welfare payment (indirect net cost of seeking TB treatment denoted $IN_i^{TB,h}$)

The proportion of patient's households treated in the NTP network with total costs exceeding a given threshold (e.g. 20% denoted τ^{TB}) of household's annual income y_i^h , is calculated as:

$$I_{NTP}^{TB} = \frac{1}{n_{NTP}^{TB}} \sum_{i=1}^{n_{NTP}^{TB}} 1 \left(\frac{\sum_{j=1}^{n_i} (OOPM_j^{TB,h} + OOPNM_j^{TB,h} + IN_j^{TB,h})}{y_i^h} > \tau^{TB} \right)$$

Where i denotes the household of patient j . If more than one household member is registered for treatment, costs for all patients within a household will be collected (if possible logistically) or estimated. n_{NTP}^{TB} , the total sample size across all NTP networks engaged in this survey. $1()$ is the indicator function which equal to 1 if the condition is satisfied and 0 otherwise.

I_{NTP}^{TB} proportion of TB-affected households that are experiencing catastrophic total costs. The nationally-representative sample estimate uses patients as the unit of analysis. However economic consequences in the context of the household of the patient will be analysed. The analysis will bear in mind, the number of patients sampled that belong to the same household. Some form of adjustment will take into account clustering at the household level whenever needed.

$OOPM_j^{TB,h}$ out-of-pocket payments for TB diagnosis and treatment made by TB patient's household members net of reimbursements (j). These are direct net medical payment for TB treatment.

$OOPNM_j^{TB,h}$ out-of-pocket payments related to the use of TB health services, such as payments for transportation, accommodation or food net of any reimbursements to the individual (patient or guardian) who made the payments

Multiple patients per household will result in direct and indirect costs added.

$IN_j^{TB,h}$ time loss valuation or reported income loss incurred by both the TB patient and any household guardian net of any welfare payment

y_i^h reported amount of money received by the household in the year before the TB episode started, in exchange for labor or services, from the sale of goods or property, or as a profit from financial investments and welfare payments. Alternatively household income will be estimated based on asset ownership.

1() is the indicator function which is equal to 1 when the condition is satisfied and zero otherwise

n_{NTP}^{TB} , the total sample size across all NTP networks engaged in this survey

τ^{TB} threshold (20% tentatively selected)

In the light of the operational definition and formula, I_{NTP}^{TB} can be interpreted as the proportion of TB-affected households patients (treated within the NTP network) with total costs exceeding a given threshold of household's income.

Approach 2

The percentage of TB patients treated within the NTP network (and their households) facing catastrophic total costs is calculated as the share of TB patients treated within the national TB programme network (and their households) experiencing dissaving (i.e taking a loan, or selling property or livestock to face health costs associated with the TB disease).

$$I_{NTP}^{TB,Dis} = \frac{1}{n_{NTP}^{TB}} \sum_{i=1}^{n_{NTP}^{TB}} 1(Dis_i^{TB,h} == 1)$$

Where

$Dis_i^{TB,h}$ identifies TB diagnosed patients 'household treated in NTP networks that are experiencing dissaving due to TB, during the TB episode (up to 2 years);

1() is the indicator function which is equal to 1 when the condition is satisfied and zero otherwise

n_{NTP}^{TB} the population of interest, patients treated in NTP network

The task force proposed two provisional approaches to measure the percentage of TB-affected households facing catastrophic total costs. This field-testing version of the protocol

includes both options with the aim to further validate and elaborate the definition and measurement approach.

The first approach calculates the percentage of TB-affected patients (and their households) that face costs (medical, non-medical expenditures as well as income loss net of transfers and reimbursements) that are above a certain percentage of annual household income. The taskforce suggested to tentatively use 20% as threshold in this analysis, since this level has been associated with poor clinical TB outcomes (Wingfield et al 2014). Other data-driven cut-offs may be tested, depending on association with clinical outcomes, with dissaving strategies or other measures of impoverishment.

The second approach calculates the percentage of households experiencing “dissaving” (such as taking a loan or selling property or livestock). This proxy indicator by definition indicates financial weakening of a household. Occurrence of dissaving has been associated with total household costs of TB (Madan et al 2015). However, further work is needed to assess the correlation between high total cost due to TB illness in relation to income and seemingly irreversible coping strategies. The present study protocol will contribute to the development of this proxy indicator. As evidence of the correlation between dissaving and catastrophic total costs increases, the task force will use the evidence to adapt the operational measure of catastrophic total costs. Collecting and analyzing data for this indicator is probably less methodologically challenging than collecting data for the first approach.

A patient survey at the health facility level has been identified as the most appropriate data collection approach. In national household surveys, when incorporating a health expenditure module, it is not possible in general to attribute health spending to any specific disease. The sample size required for population-based surveys to identify a sufficiently large sample of persons with TB is very large. Moreover, only self-reported TB can be used as criteria for inclusion, which introduces a large risk of bias. Finally, these surveys do not normally incorporate non-medical expenditures or indirect cost related to health episodes. It is therefore not feasible to use such platforms to determine costs for people with TB.

For practical reasons, it is proposed in this protocol that the study population should be restricted to persons who have started TB treatment in a health facility that delivers TB care in line with the national TB programme (NTP) guidelines, and registers and records the treatment in standard TB treatment cards and registers. This means that costs for persons treated “outside the NTP”, e.g. in private and public clinics not linked to the NTP will not be captured. Moreover, costs for persons who do not access healthcare and are never diagnosed and treated for TB will not be considered. In this protocol the term “NTP network” will be used as shorthand for those health facilities treating and notifying TB in line with NTP guidelines, which may also include private and NGO facilities collaborating with NTP. Therefore, the operational definition of the catastrophic total cost indicator is “percentage of diagnosed TB patients treated within the NTP network (and their households) facing catastrophic total costs”.

In the case of countries where significant proportions of patients seek care outside the NTP network, separate surveys may be conducted to capture costs in the private sector outside the NTP network if feasible, to better understand the drivers of such costs. However such data will not be appropriate for comparisons across countries and should not be included in the national estimate of catastrophic total costs due to TB. Moreover, separate surveys may be conducted to capture costs among prevalent TB cases in the community (e.g. through the

inclusion of cost questions in a TB prevalence survey instrument). However, such data should not contribute to the national estimate of proportion facing catastrophic total costs, in order to ensure standardized measurement with comparability over time and across countries.

It should be noted that the operational definition of the catastrophic total cost indicator differs in essence from one of the well-established approach used to measure the lack of financial protection at the country level, namely the indicator of catastrophic health *expenditure*. The incidence of catastrophic health expenditure is defined as the share of the *population* spending more than a given fraction of household's expenditure on OOP payments for health care. The focus is on the burden of direct outlay of cash made by households to improve or restore the health of any of their members (WHO and World Bank, 2015). OOP payment is defined exclusively in relation to direct medical payments made to health providers at time of use net of any reimbursement received and includes payments for all household's members (WHO and World Bank, 2015). It is a measure of the performance of the health financing system, at the overall population level. The indicator of catastrophic *total costs* incurred by households *affected by TB*, refer instead to the total economic burden (direct and indirect costs combined), related to one diagnosed health condition only, treated in a particular type of setting, in relation to total household income. The two indicators are therefore not comparable.

3.3 Overview of the study design

Basic design: Cross sectional survey with retrospective data collection and projections

In the basic cross-sectional design all consecutive TB and MDR-TB patients registered for treatment who are attending a sampled facility for a follow up visit (after a minimum of 2 weeks into the present intensive or continuation treatment phase) should be invited to the survey.

Each patient should be interviewed only once and will report on expenditures retrospectively. When this design is used, some patients will be interviewed in the intensive treatment phase and others in the continuation treatment phase, with expenditure and time loss data collected for that particular phase only. Moreover, within these two categories, patients will be interviewed at different time points during their treatment. Data collection for patients in different treatment phases will allow the collection of data that can be used to impute data and model projections of future and past costs during the entire illness episode (Figure 4).

This approach will simplify sampling and make data collection efficient since most patients attending the facility during the study period will be eligible to be invited to the survey. Since no follow-up interview is required, such a study can be completed within 2-3 months in countries with moderate to high TB incidence.

The survey instrument has five parts (Figure 3):

Part I Patient information to be obtained from TB treatment card before interview (for all patients)

Part II Informed consent, inclusion/exclusion criteria, and checklist for which parts of the questionnaire to fill for different patients treated under different TB treatment categories and phases (for all patients)

Part III Overview of TB treatments before current treatment, up to 2 years before the current treatment started (for re-treatment cases only)

Part IV Costs before the current TB treatment (for new cases interviewed in the intensive phase only)

Part V Cost during current TB/MDR-TB treatment (for all patients)

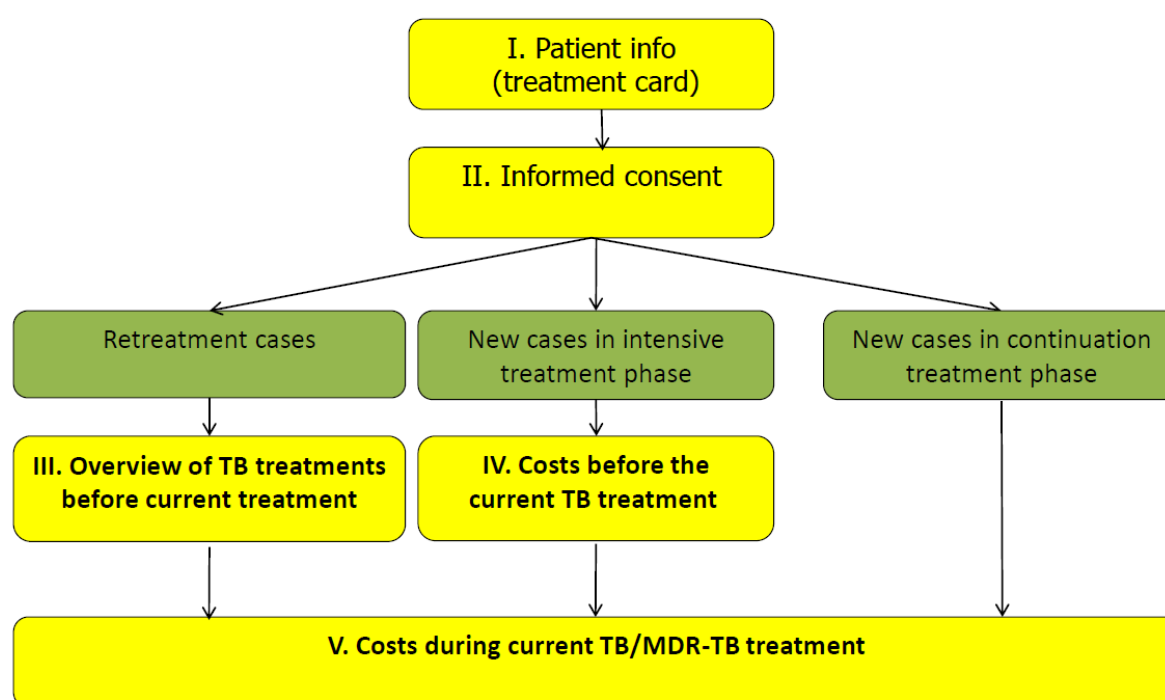


Figure 3. Interview instrument parts.

Information from the TB treatment card (Part I), informed consent (Part II), and information about costs related to the current TB treatment (Part V), should be collected for all patients.

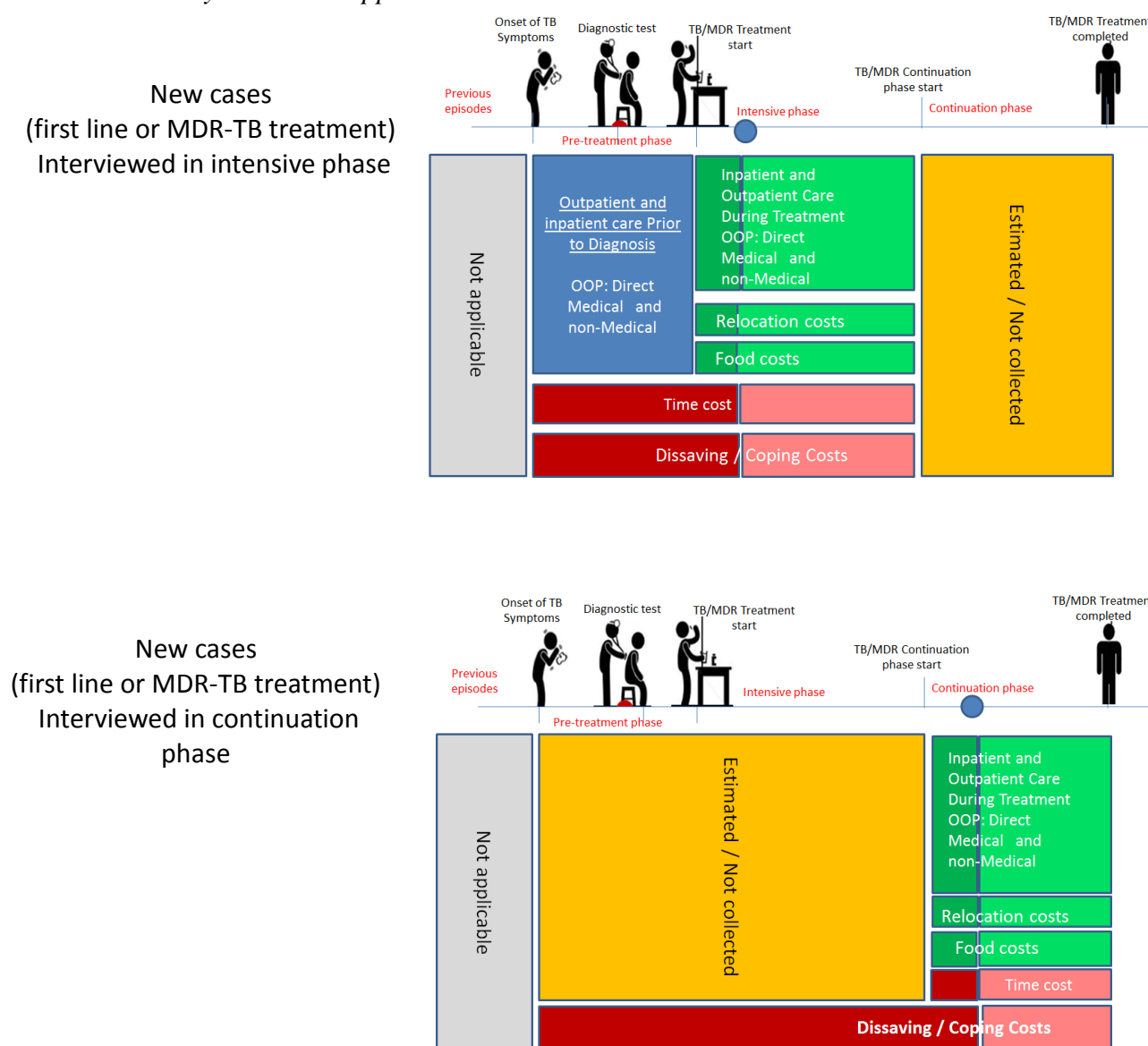
Information about costs related to health seeking and diagnostic procedures before the person was registered as a TB patients within the NTP network (Part IV) should be collected only for new patients (either on 1st line treatment or on MDR treatment) who are interviewed in the intensive phase. For new patients who are interviewed in the continuation phase, information should be collected only about costs related to the continuation phase (with a few exceptions, such as hospitalization cost and coping costs, which should also be collected for the intensive phase for these patients). This is because of the considerable challenge for patients to remember events and costs incurred many months prior to the time of the interview.

For the same reason, no detailed information should be collected about costs related to health seeking and diagnostic procedures before the person was registered as a TB patients within the NTP network for previously treated cases (either on 1st line treatment or on MDR treatment), regardless of which treatment phase the patient is in at the time of the interview.

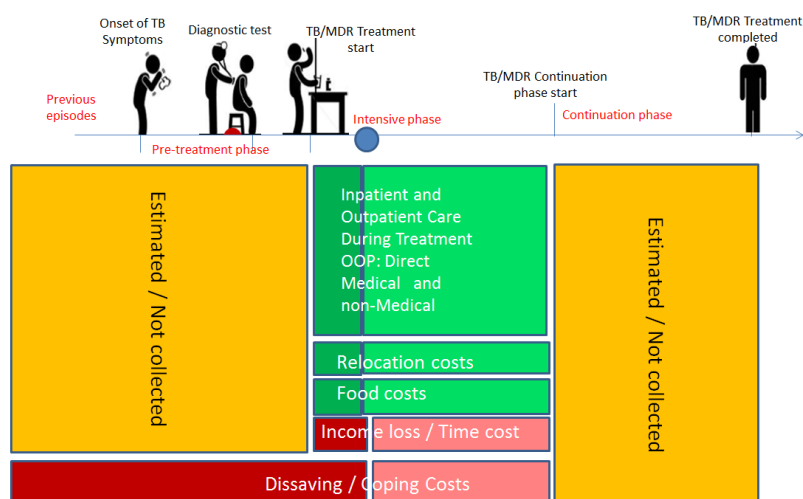
Instead, all previously treated cases will be asked brief summary questions about the number of previous TB treatments, the start year and duration of previous TB treatments, number of hospitalization episodes and their duration during previous TB treatments (part III). This will be collected for previous treatment up to 2 years before the start of the present treatment episode.

Information collected in part IV for new cases interviewed in the intensive phase will be used to impute data and model costs for patients interviewed in the continuation phase and for re-treatment cases. Similarly, information about costs in the continuation phase collected from patient interviewed in this phase will be used to project costs for patients interviewed in the intensive phase (figure 4).

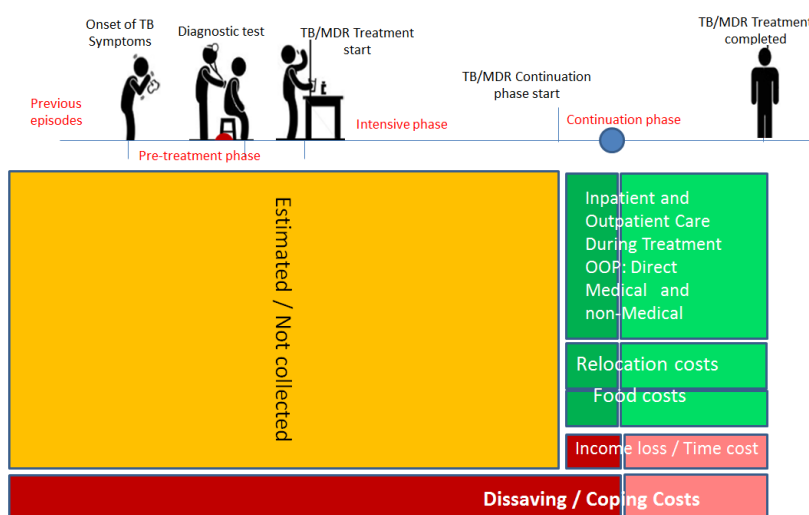
Figure 4. Overview of the analytical approach with respect to data collection timing (Basic design: Cross sectional survey with retrospective data collection and projections). Blue dot signals interview moment. Lighter shades of green and red, mean extrapolation of past costs into the future. Yellow means costs are estimated based on some answers and other patient's data. Grey means not applicable.



Previously treated cases
(first line or MDR-TB treatment)
Interviewed in intensive phase



Previously treated cases
(first line or MDR-TB
treatment)
Interviewed in
continuation phase



Optional design: Longitudinal cohort design with repeat data collection for the same study subjects

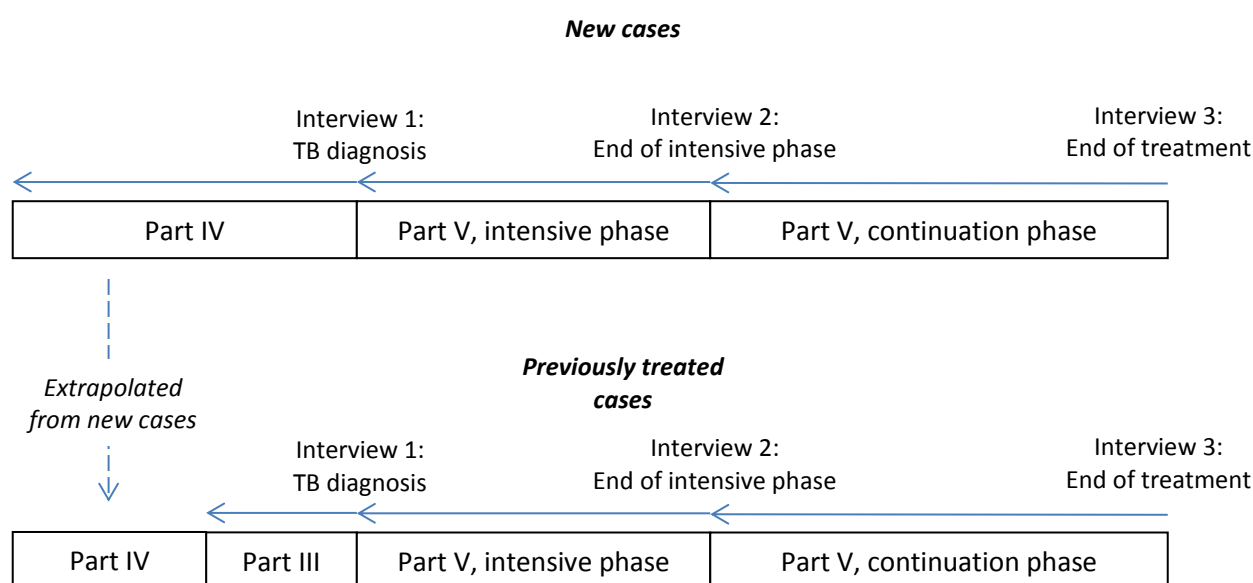
While the basic design has the advantage that it simplifies data collection and the study can be completed quickly, the disadvantage is that both forward and backward projections are required in order to model cost during the entire illness episode. This introduces additional uncertainties. A longitudinal design can overcome this challenge, but requires repeat interviews, a slower enrollment process (the only eligible participants are those who are just starting their treatment), longer time to complete the study (especially for MDR-TB patients), and a more elaborate and expensive plan and infrastructure to enable identification of the survey participants for a repeat interview, including a method for tracking patients who transfer out or are lost to follow-up. The standard TB treatment register and modalities for cohort analysis can be used as a platform for this purpose. An additional advantage of this design is that it can capture information about patients who do not start treatment (after TB

diagnosis) and patients interrupting treatment, which can be correlated to information about previous costs.

The ideal longitudinal design involves (figure 3):

1. A first interview at the time of TB treatment initiation (alternatively after TB diagnosis).
 - a. Interview instrument part III for previously treated cases
 - b. Interview instrument part IV for new cases
2. A second interview at the end of the intensive treatment phase, with interview instrument part V
3. A final interview at the end of treatment, again with interview instrument part V

Figure 5. Overview of design for longitudinal study



The cross section and longitudinal design can be combined. For example, a longitudinal design can be used for a sub-sample of patients, which can be used to validate the analytical approach based on modeled projections.

3.4 Sampling strategy

Study population

The study population includes all patients (including children) who are on TB or MDR treatment (in continuation or intensive phase) within the NTP network (public and private facilities). This means that sampling from the study population will be done in health facilities belonging to the NTP network.

This protocol excludes people who are treated in facilities that are unlinked to NTP (i.e. private facilities that are not formal part of a public-private mix initiative). It also excludes people who have not been put on TB treatment. Findings can therefore only be extrapolated to the subset of TB patient who receive care under NTP network and their household, and conclusions cannot be drawn about all people with TB in the country. While this is a limitation, it is the only feasible way to establish a sampling frame for the study. In addition, the impact of TB costs are analysed on the household level so if more than one household member is registered for treatment, costs for all the patients within a household will be collected (if possible logistically) or estimated. Interpretations of study findings need to be done accordingly.

Sampling strategy options

A national *simple random sample of TB patients* on treatment is theoretically possible to draw in countries that have electronic registers with real time surveillance information that can be used as sampling frame. Few countries have such a register. Moreover, this sampling strategy has not been reported in previous TB patient cost surveys and its feasibility is thus untested. This approach is not further discussed in this document. However, since it is a theoretically attractive approach, countries with the right conditions are encouraged to explore this strategy in consultation with a statistician or survey design specialist.

In most settings it is appropriate to use *cluster sampling*, which means that health facilities are sampled. All TB patients found in the district TB register and attending sampled facilities during the study period are eligible for inclusion in the study, and all included patients attending one sampled facility become a cluster. An advantage of using cluster sampling is that patient recruitment and data collection generally is easier from the logistics and financial point of view than when simple random sampling is used. A disadvantage is that sample size need to be increased, as compared to simple random sampling due to clustering effects (since people within clusters may be more similar to each other than to the rest of the TB patients in the country).

In order to ensure national representativeness, the standard recommended approach is to use *random cluster sampling*. In random cluster sampling, facilities are randomly selected from a sampling frame of health facilities in the NTP network. The efficiency of random cluster sampling can be enhanced by stratification (see below).

If random cluster sampling is not feasible, *purposive cluster sampling* may be considered. In purposive cluster sampling, facilities are purposively (non-randomly) selected from the same sampling frame based on set criteria for creating good representation of different types of facilities, different geographical areas, etc. While purposive sampling may improve

feasibility in some situations, the principal problem is that it violates one of the underlying assumptions for the sample size calculations and standard statistical analysis and inference described below, namely that the selection of clusters is random. Therefore, efforts should always be made to use random sampling. Purposive sampling is appropriate if there is a specific objective to determine costs in a specific facility or geographical area.

A special situation is when the survey is integrated into another facility-based patient survey, cohort, or trial in the country. If that type of survey platforms is based on a random sample of facilities, it is equivalent to a random cluster design. If, on the other hand, the study is done in purposively selected facilities, the same limitation apply as for other types of purposive sampling, as described above.

Steps for cluster sampling

Sampling of clusters

The cluster sampling frame is a list of facilities treating TB within the NTP network, from which study facilities should be selected. Such list of facilities is normally available within NTP on national, provincial and/or district level.

A simple random sample of facilities may be drawn from a national level list. However, it is normally advisable to do the cluster sampling in a step-wise manner, from sampling of geographical units, to sampling of facilities within the geographical units. Primary units can be provinces or equivalent administrative level. Secondary units are usually districts or the NTPs basic management units (BMU). There may be one or several relevant TB facilities within a sampled BMU. The number of BMUs to sample in each geographical area should be proportional to number of TB patients registered in the BMU, e.g. in the previous years. In a random cluster sample design, both primary and secondary units are sampled randomly in a step-wise manner.

The step-wise approach can be combined with a stratified design in order to increase the precision and representativeness of the sample. In addition, the approach of stratification allows the estimation of stratum-specific estimates of catastrophic total costs in TB, but their precision is lower compared to the overall nationwide estimate. For example, stratification can be done for urban and rural facilities is: if 25% of TB notifications are in urban areas and 75% in rural areas, then the survey should allocate about 25% of facilities (clusters) enrolment in urban areas and 75% in rural areas. Other stratification criteria for selection of geographical areas or facilities may include: poor vs. less poor provinces; hospitals vs. primary care facilities; public vs. private/NGO providers in the NTP network; facilities treating MDR-TB, etc.

Sampling of TB patients

Within sampled facilities, consecutive patients on TB treatment visiting the facility are eligible for inclusion. Inclusion of consecutive patients attending the facility can be considered equivalent to random sampling, provided that no additional inclusion criteria are introduced (e.g. attending at certain times of the day only). The TB register of the facility (hospital or ambulatory care) can be used as entry-point for the sampling of patients at facility level.

All consenting patients on treatment for TB or MDR-TB are eligible for the patient survey. (If the patient has not been treated for a minimum of 2 weeks of the current treatment phase the interview should be postponed until this time).

If the number of facilities selected from each area is proportional to number of registered TB patients in each area, the same patient sample size should be used within each sampled facility, regardless of catchment population and patient load. If not, the number of patients to be sampled should instead be proportional to the number of registered TB patients in the facility.

Stratified sampling of patients within facilities can also be considered, by defining quota for inclusion corresponding to patient characteristics in the country, e.g. by: patients on first line or MDR TB treatment; new or previously treated cases; children/adults, etc. However, stratified sampling of patients within facilities is logistically more challenging than stratified sampling of facilities, since the former requires careful monitoring of inclusion and measures to over- or under-sample certain sub-groups of patients.

Once the sample size for a facility has been determined, and any stratified sample size, consecutive patients attending the facility should be invited to the survey until the required sample size is achieved. In practice this can be done by assessing for each patient returning for a follow up visit, DOT, or picking up drugs.

3.5. Sample size calculation for a cluster sample survey

It is advisable to consult a biostatistician for the calculation of sample size. A number of assumptions need to be made for the sample size calculation. It is advisable to do a small pilot phase to confirm assumptions before establishing the final sample size for the study. Please note that while sample estimate is done using patients as the unit of analysis, the economic consequences are analysed in the context of the household of the patient. No additional layer of cluster sampling will be introduced to estimate how many families/households the interviewed and the national notifications (not possible without an electronic case-based registry) represent but the analysis will bear in mind the number of patients sampled that belong to the same household.

Sample size required in a regular cluster sample survey

Step 1. Hypothesize/guess the true proportion of households experiencing catastrophic total costs due to TB illness (π_g). To inform this, here are some suggestions of data sources;

- Data from any previous TB patient cost survey
- Data from TB patient cost surveys in similar countries
- Recent household expenditure surveys may include a health module that disaggregates the main cause of disease although answers might be regrouped as “infectious” and not TB specifically. It should also be noted that this data captures direct medical costs only and excludes non-medical and time loss value.

Step 2. Decide the relative precision around the estimate drawn from the survey (d). It is recommended that the relative precision is between 20% and 40%. This precision refers to the relative width of the 95% confidence interval. For example, if the assumed proportion

experiencing catastrophic total cost is 30%, then a relative precision of 20% means a 95% confidence interval ranging from 24% to 36%.

Step 3. Estimate the magnitude of the "design effect" (DEFF) related to cluster sampling. Since clustered-sampled (CS) surveys have larger statistical uncertainty compared to simple-random sampled (SRS) ones (for given assumptions) sample size needs to be increased for CS surveys (by multiplying sample size for SRS by a factor called the "design effect").

Sample size is then calculated with the following formula:

Equation 3.5a

$$N = N_{SRS} * DEFF \rightarrow N = \left[1.96^2 \frac{(1 - \pi_g)}{d^2 \pi_g} \right] \times \left[1 + (m - 1) \frac{k^2 \pi_g}{(1 - \pi_g)} \right]$$

N	Number of people included in the patient survey
N_{SRS}	Simple Random Sampling size
π_g	“Prior guess” of the true proportion of families experiencing catastrophic total costs due to TB illness (expressed as a proportion)
d	Relative precision (expressed as a proportion). Recommended 0.20 or 0.25
m	Cluster size (=number of targeted individuals), assumed to be constant across clusters
k	Coefficient of between-cluster variation. Recommended to assume is in the range 0.4 – 0.6

Step 4. When the sample represents a large proportion of the study population of interest (all TB patients treated in the entire NTP network in a year) is large (5% or more), the sample size must be corrected using a "finite population correction" to account for the added precision gained by sampling a larger percentage of the population:

$$N_{FPC} = \frac{N}{1 + \frac{N-1}{T}}$$

Where N_{FPC} is the finite population corrected sample size, N is the original sample size, and T the size of the sampling frame of TB cases notified nationally per year. The effect of the finite population correction is that the required sample size diminishes the closer the sample size N is to the population size T . If the original sample size is calculated to 500 cases in a country that has 3,000 TB notifications, the finite population corrected sample size is 428.

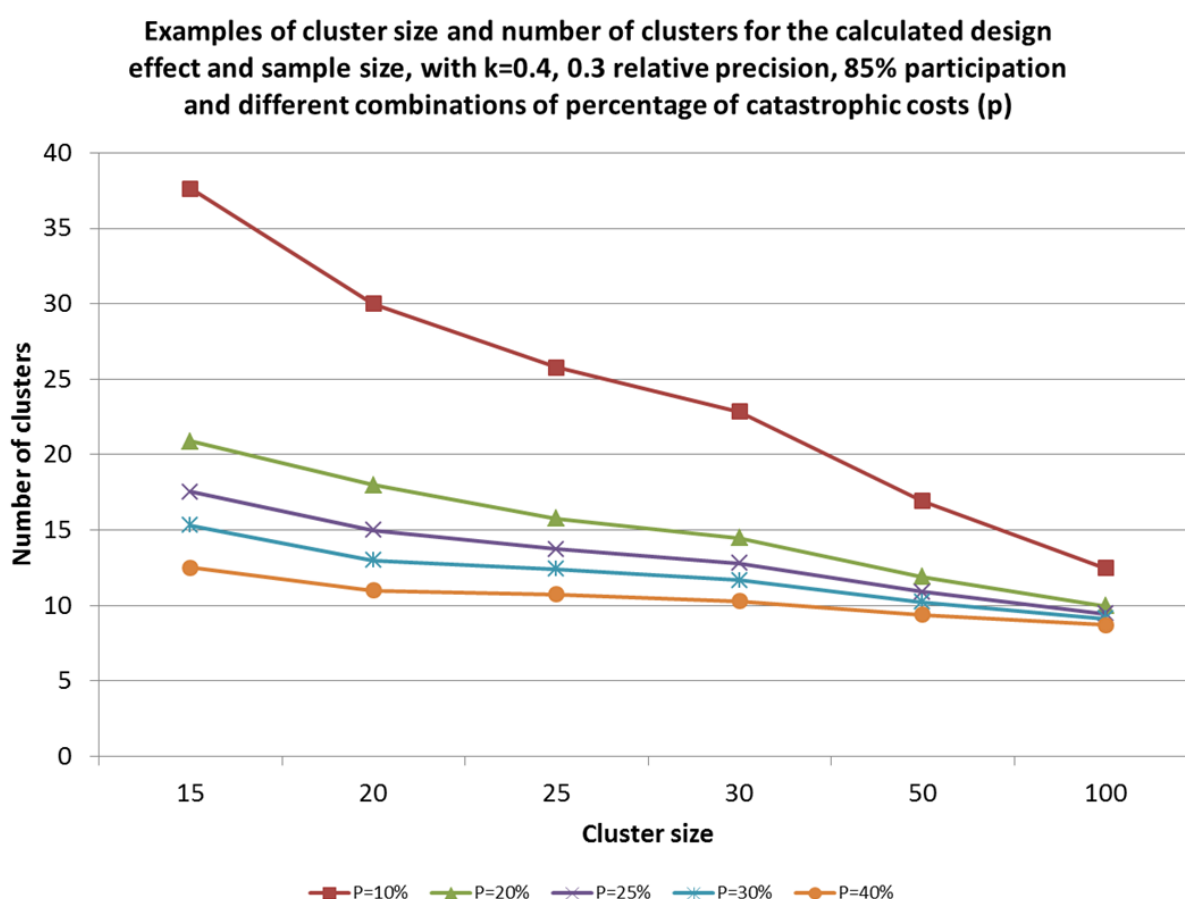
Step 5. Calculated sample size can be increased to allow for non-participation in the survey. Estimate the participation rate (i.e. guess sample size for non-participants): assume for

instance 90% participation. New sample size = (sample size)/0.9. However, in practice a target sample size for included patients, rather than invited patients can be set at the facility level, with instruction to continue sampling until the number has been achieved. In this case, the assumed participation is 100%.

Figure 6 shows an example of sample size calculation (required number of clusters and cluster size) for different levels of assumed percentage of patients experiencing catastrophic total costs, when the desired relative precision is 30%, and cluster sampling is used with an assumed clustering effect of 0.4, and 85% participation rate, without finite population correction.

A web application is available on <http://samplesize.dotcloudapp.com>, to calculate sample size and number of clusters based on your assumptions on the various ingredients.

Figure 6. Required number of clusters and cluster size for different levels of assumed percentage of patients experiencing catastrophic total cost, when the desired relative precision is 30%, cluster sampling is used with an assumed clustering effect of 0.4, and 85% participation rate.



Box 2: Selecting clusters and individuals within each cluster

Example. A sample size of 423 of TB patients (new or prev. treated) has been calculated after taking into account the effect of cluster sampling and a fixed cluster sample size of

15. The following steps must be taken:

a. Establish a list of the health centers with their annual number of patients (see table below).

b. Calculate the cumulative number of patients and record them in an additional column. Cumulative number for second center will be (number in first center) + (number in second center). Cumulative number for third center will be (cumulative number for second center) + (number in third center), and so on. The total number of patients treated in the country is 4000.

c. Determine the sampling interval: $4000/28 = 143$.

d. Select a number between 0 and 143 at random (using a table of random numbers or the last digits of a currency note, for example). In this case, the number selected is 120.

e. The first cluster is selected using 120: it will be in the center n°8 because 120 falls between 0 and 123 (number of patients in center n°8).

f. Selection of the next clusters is done by adding the sampling interval 143 each time to this first number 120. The next number $(120 + 143) = 263$ falls in health facility 12 (cumulative number of patients for second center/cluster); the second cluster is therefore selected in center 12. The third number $(263 + 143) = 406$ also falls in health facility 12; the third cluster is therefore also selected in the center n°12.

Sampling interval (SI)
= total cumulative
population / number
of health centre we
want to identify =
 $4000/28=143$

1st identified centre

2nd identified centre

Also in 2nd centre

There are 30
health facilities in
total with a
combined
cumulative
population of
4 000

Health Centre	Notifications in n-1	Cumulative notifications	Cluster N.
1	20	20	
2	18	38	
3	17	55	
4	15	70	
5	10	80	
6	5	85	
7	16	101	
8	22	123	1
9	15	138	
10	14	152	
11	20	172	
12	300	472	2, 3
13	17	489	
14	15	504	
15	1500	2004	4 to 14
16	5	2009	
17	16	2025	
18	22	2047	
19	150	2197	
20	14	2211	
21	1500	3711	15 to 26
22	15	3726	
23	20	3746	
24	20	3766	27
25	85	3851	
26	5	3856	
27	16	3872	
28	99	3971	
29	15	3986	28
30	14	4000	
Total notifications	4000		

Health facility choice

Random start (RS) = #8
random number between
1 and 143 (=SI)

= RS + SI = 120 + 143 = 263 #12

= RS + (2*SI) = 120 + (2*143) = 406 #12

= RS + (3*SI) = 120 + (3*143) = 549 #15

= RS + (4*SI) = 120 + (4*143) = 692 #15

Etc.

Sample size required to prove that the percentage experiencing catastrophic total cost is 0%, using Lot Quality Assurance Sampling

In a situation in which the percentage of patients experiencing catastrophic costs is assumed to be zero, or close to zero (such as in countries with high financial risk protection through universal health coverage and good social protection coverage), the sample size calculation can be based on an allowable upper limit error for 0% catastrophic total cost. Table 1 shows the required sample size (using similar assumptions as for random cluster sampling above) for different levels of desired precision. For example, if 200 randomly selected patients are interviewed and none have experienced catastrophic total costs, we can judge with 95% certainty that the true proportion in the country is somewhere between 0% and 1.8%.

Table 1. Required sample size (using same assumptions as for cluster- randomized sampling above) for different levels of desired precision

Total number of patients interviewed	Total number of patients with catastrophic cost	Percentage of catastrophic cost (95% CI)
50	0	0 (0 – 7%)
100	0	0 (0 – 4%)
150	0	0 (0 – 2.4%)
200	0	0 (0 – 1.8%)
300	0	0 (0 – 1.2%)

4. Planning and conducting the survey

The protocol is structured around the following steps required to implement the survey:

1. Establish survey team and obtain additional technical assistance
2. Adapt generic survey instrument and protocol to local conditions
3. Ethics review
4. Train interviewers
5. Pre-test (and then reiterate step 2-4 if necessary)
6. Collect data using the survey instrument
7. Manage the data
8. Analyze
9. Disseminate results
10. Budget for the study

4.1. Establish survey team and obtain additional technical assistance

The survey should determine the proportion of TB-affected households that experience catastrophic total costs in the country. A national approach is therefore required to adapt this generic protocol and the generic survey instrument to national situation, and to establish an appropriate approach to obtain a nationally representative sample.

It is appropriate that the NTP takes the lead in establishing a survey team. However, a dialogue with national and international partners engaged in TB programme implementation and research is important. Moreover, it is advisable to consult with or contract academic

institutions with experience in conducting patient surveys, for example those conducting epidemiological, social science or health economics research. A statistician may also be valuable, to assist sample size calculations and data analysis, and, if resources permit, an IT expert can help to adapt to e-survey tools. Alternatively WHO/MTB may also be available to provide some support remotely if the e-survey is used.

Composition of survey team

The following functions should ideally be covered by the survey team (figure 4).

Principal investigator (PI)

- Responsible for designing the study, ethical clearance, maintaining the quality of the study's conduct and writing the final study report
- Acts as liaison for communication outside the survey, in particular with NTP, public health service, local research institution and possibly the funding agency (securing funds for the survey)
- If necessary the PI will appoint and supervise the work of a data analyst and a data manager

Tasks:

- Validate the Protocol for survey to estimate proportion of TB-patients experiencing catastrophic total costs
- Ensure that survey implementation and analysis are conducted according to the protocol and the plan
- Discuss any problems encountered during the survey, propose and decide the solution
- Validate the survey results

Survey coordinator

- Appointed by and reporting to the principal investigator
- Responsible for the day-to-day management of the survey
- Actively involved in the design of the study
- Prepares training manual and study materials
- Trains team leaders and interviewers
- Supervises the work of data collection by team leaders through periodic reports
- Assesses reports from team leaders and data manager

Tasks:

- Coordinates overall implementation of survey to estimate proportion of TB-patients experiencing catastrophic total costs
- Plan the field implementation and training needed
- Organize the writing of SOP (if required)
- Together with the PI, contact and coordinate with local authorities
- Ensure the quality assurance for all processes is implemented according to the protocol
- Supervise the health facility implementation
- Oversees the provision of supplies and required materials
- Supervises the cash flow, fund distribution and their accountability
- Leads the analysis of results
- Organizes the writing of activity reports and final report
- Plans the detailed budget of the survey

- Provide any logistic support for the survey team

Data analyst: Responsible for data analysis throughout the survey and periodic data cleaning. This function is optional. Data analysis may be done by the PI if he/she is a health economist, economist or statistician with experience in these surveys.

Data manager:

- Coordinates data management activities for the survey: receiving, batching, cleaning, merging data from different sources
- Is responsible for the validation of double-entered data files
- Ensures that data are properly stored and backed up
- Checks validated data files regularly for systematic errors (cleaning)
- Develops data entry software and tools, effective and feasible to support the survey
- Prepares database to be ready for analysis and data entry screens
- Contributes in the analysis of results
- Is responsible for completion of regular data management reports
- Liaises with the survey coordinator on a regular basis
- Reports without delay any problems encountered in data management.

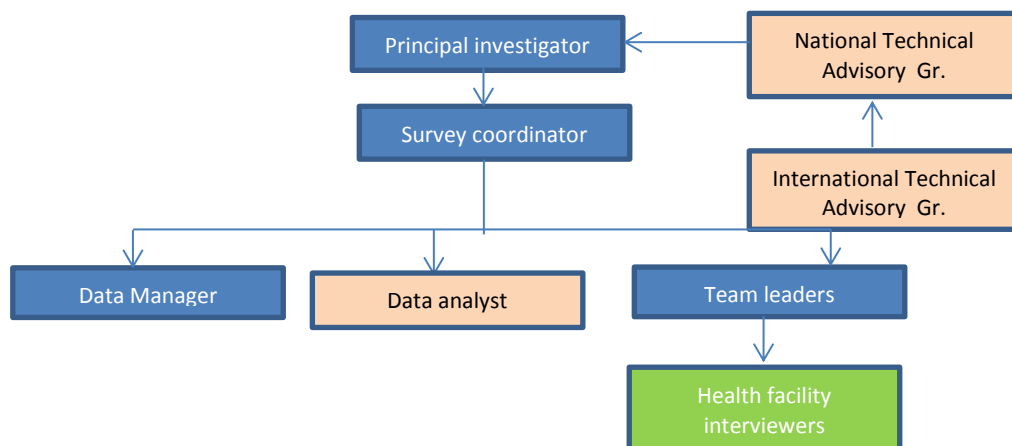
Team leaders

- Responsible for the organization and proper implementation of the survey in their appointed facility or cluster of facilities
- Coordinates the day-to-day survey work
- Ensures that interviews and data validation is implemented according to appropriate standards
- Prepares periodic reports for the survey coordinator that include, the number of subjects enrolled in the survey, and a tabulation of all activities performed; discuss without delays problems encountered and solutions implemented. Reports are drawn up after finalizing data collection in the cluster, and are sent to the survey coordinator
- Responsible for uploading the survey data collected off-line into the on-line software

Facility staff/interviewers

- Responsible for obtaining informed consent for carrying out the interviews and recording patient records information required in the survey
- Responsible for carrying out the interviews and recording patient records information required in the survey
- Potentially, responsible for uploading the survey data collected off-line and into the on-line designated software (delegated by team leader, after quality ensured)
- To assure quality the number of interviewers should be kept to a minimum to reduce the magnitude of interpersonal variation.

Figure 7. Organogram for survey team (orange color means optional function)



Technical advisory group function

The technical advisory group advises the principal investigator and survey coordinator on all technical aspects of the survey and also on issues such as the survey approval and acceptance process. It provides technical input (statistical, epidemiology, health economics) for the activities of the principal investigator and consists of experts in these fields. Collaboration with the group is intense during the design and adaptation of the protocol, but ad-hoc advice during actual data collection should also be available. Members perform these activities on a part-time basis. Their workload will be different in different phases of the survey, ranging from ad hoc meetings during the implementation to more intensive involvement during the design or the analysis phase.

The technical advisory group may include international experts. In the initial stages, for the purpose of field testing the generic survey instrument and ensure consistency across surveys conducted in different countries, there will also be an international technical advisory group which will be coordinated by WHO.

Composition of national technical advisory group:

- Social scientist / epidemiologist / survey expert
- Health economist/analyst
- Statistician

Terms of reference

- Advise on the survey protocol
- Advise on the design, pre-testing and production of survey materials
- Provide technical assistance in training and pilot-testing
- Provide ad-hoc advice during survey implementation
- Provide feedback on interpretation of results

Suggested qualifications for survey staff

Principal investigator (PI):

- At least 5 years of managerial experience in the field of public health
- Strong managerial skills, including being able to delegate tasks
- Extensive knowledge of TB
- Extensive knowledge of facility-based surveys
- Working within or having access to an organization that has an infrastructure supporting facility-based surveys

Survey coordinator (SC): Experience of planning and conducting patient surveys or facility-based surveys, preferably including health seeking and cost items.

Data manager:

- team leader and motivator
- proven extensive experience with surveys
- appropriate skills for building and maintaining relational databases
- able to carry out merging of databases
- able to carry out and validate double data-entry procedures
- analytical skills to provide summary statistics and identify systematic entry errors
- good administrative skills including maintenance of adequate documentation

Data analyst

- Health Economics or statistical analysis experience and qualifications
- Experience in TB

Team leader (TL): not specifically recruited for the survey but their cooperation is requested from the organisation to which they are appointed. This activity can be performed part-time (5-10%)

Health facility interviewers (I)

- Prior experiences of surveys and structured interviewing is an asset
- Fluent in the local language spoken in the cluster
- Good administration and organizational skills
- Adequate social skills to interact with patients, and preferably prior experience in field work in a research setting.
- This activity should be performed by temporary staff hired specifically for the survey.

Recruitment

Due to the confidentiality of patients' answers it is recommended that temporary staff would be hired through routine recruitment procedures in the country. Given the temporary nature of the jobs, it is worthwhile to assess the possibilities of recruiting staff on a secondment basis from universities, research, or nongovernmental organisations in the country.

4.2. Adapt generic survey instrument to local conditions and translate to local language

WHO recommends the use of the attached generic patient questionnaire, endorsed at the WHO Global TB Programme Task Force Meeting (March 2015). This questionnaire builds on existing TB and MDR patient questionnaires and tools to estimate patient costs (TBCTA, 2009).

The generic patient questionnaire provides a standardized method to assess if households affected by TB experience financial hardship. However, the instrument needs to be adapted by the PI and advisory group to local conditions; in particular the country will need to adapt phrasing of questions and answer categories to type of health providers, TB delivery models, relevant socio-demographic categories, household assets to construct the socio-economic index and types of health insurance and social protection schemes in the country. These sections have been highlighted in **red font** in the generic survey instrument:

- **Provider types** (for questions about health seeking prior to TB diagnosis, and place of TB treatment): What are the types of providers patients may have utilized before TB was diagnosed (public, private, informal sector, etc)? What are the options for TB treatment under NTP? Who is in the NTP network (who treats TB according to NTP guidelines)? Does this include private providers? NGOs?
- **TB care delivery models**: models for ambulatory care, DOT, picking up TB drugs, standard clinical follow up visits, etc.
- **Socio-demographic variables**: what are the common classifications of occupation and employment, etc in the country? By default, the survey shows ILO's classification (ISCO-08).
- **Net revenue from labour related activities (net labour income)**: one of the most difficult questions to answer might be related to the monthly wages or income derived from labour activities, yet it is key for the analysis of catastrophic total costs. An option for adaptation of this question to facilitate unbiased answers might be to present income brackets if difficult for patient to specify. Another is to pose the question differently, i.e. an alternative approach, not tested before, would be to ask the TB patient how many days he would need to work to be able to earn the equivalent of the national poverty line. For global comparisons a benchmark the 1.25\$ a day per capita may be used. As this approach has not been validated before, it is at the discretion of the PI to embark on this approach. Presumably if TB patients are extremely poor, the national poverty line let alone the international poverty line might be too high. Similarly if you are interested in household's income, you can ask how many days all working members of the household would need to work to earn the equivalent of the national or international poverty line.
- **Health insurance and social protection/transfer schemes**: in this country what are the available options (cash or in-kind to enhance food security, improve nutrition, provide minimum income security and access to services, and provide income replacement and social support in the event of illness e.g. paid sick leave, disability grant, cash transfer for poor families? What are the eligibility criteria (e.g. poor and vulnerable group)?
- **Household asset to construct a socio-economic index questions**: this section of the questionnaire presents an example of questions chosen from a national survey that were shown to work well separating groups/quintiles (Annex 2), however the PI should adapt this questions as per the latest survey work in the country, such as from a demographic and health survey (DHS).

Users are strongly advised not to delete any questions (additions are at the PI's discretion) nor modify the content. Codification of answers is proposed in the questionnaire and there is no need to modify nor translate these coded variables .

Language

The generic survey instrument and protocol will be available in English, French and Spanish. Surveys will be conducted in the respondent's mother-tongue; each country will therefore translate the generic questionnaire. Ideally, the questionnaire should be back-translated to ensure accuracy of translation. This will be done by someone who has not seen the original version, and is not familiar with the background context of the questionnaire. The back-translated version is then compared with the original one and differences in meaning need to be adjusted. A bilingual peer should compare both versions and evaluate the questions according to content, meaning and clarity of expression.

Currency: This study recommends use of local currency preferably. Exchange rate to the USD – data and source to appear by default in the e-survey tool

4.3 Ethics review

Before initiating this project, the PI should consult with the appropriate local ethics review committee. A detailed protocol (and application form) should be submitted to the ethics committee.

The patients are identified by routine care provided within the NTP network. The data of the survey are owned by the institution that the PI represents. The decision on dissemination and/or publication of the data will be with that institutions, which in most cases would be the NTP.

Information to be provided by investigators to the ethics committee include:

- Application form
- Detailed survey protocol which includes:
 - A justification for undertaking the investigation
 - A clear statement of the objectives
 - A precise description of all proposed procedures and interventions
 - A plan indicating the number of subjects involved
 - The criteria determining recruitment of participants
 - Participant information sheets and forms to obtain informed consent
 - Evidence that the investigator is properly qualified and experienced and that the investigator has access to adequate facilities for the safe and efficient conduct of the survey
 - A description of proposed means of protecting confidentiality during the processing and publication of survey results
 - A reference to any other ethical considerations that may be involved, indicating how international ethical standards will be respected
 - A plan for disseminating results, including for the community being studied
 - A plan to protect researchers from any risk of TB during the conduct of the study.

Information to the patient

Each potential survey participant must be adequately informed of the following in a format (verbal, written) and language acceptable to her/him (Annex 3: Consent form):

- the purpose, methods and procedures of the survey
- why and how the potential participants were selected

- possible discomforts involved
- what social welfare options are available to the TB or MDR patient
- the right to abstain from participation in the survey or to withdraw consent to participate at any time without reprisal
- the sources of funding of the survey, any possible conflicts of interest, institutional affiliation of the researcher
- description of how anonymity and/or confidentiality will be protected
- the extent to which results will be made available to the participant and/or the community

Interviewers will be provided with a list of welfare programs (and contact details) that TB patients might be able to access, so that interviewers share this info with the patient. The mapping of existing social protection schemes will be provided by the PI.

Consent

Patients will be informed in their mother tongue about the purpose of the study. Patients will be told about the confidentiality of the data collected, each interview will take about an hour to complete it and it will be their right to withdraw from the study at any time. To ascertain whether the individual really understands the implications of consent, the survey will allow individuals to ask questions for clarification. After ensuring that the subject has understood the information, the investigator should then obtain the subject's freely given informed consent. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

Compensation

Patients may be compensated in cash or kind (transport voucher) for the time, travel or inconvenience allocated during the interview. It is not acceptable to expect participants to pay out of pocket if they have to travel or take time off work to participate in the survey, but any compensation should be reasonable so that it does not induce someone to take part in the survey simply for financial gain. Whether any compensation will be given, and the amount, needs to be decided by the survey coordinator and clearly stated in the information sheet.

4.4. Train interviewers

Training of interviewers is key to the conduct of this survey. It must be conducted in the adapted and tested survey tool (electronic or paper). The duration of the training will vary from one to several days depending on previous experience of the interviewers in facility-based surveys and their knowledge of TB. No re-interviewing is available in this survey. Team-leaders should check the quality of the training periodically.

The survey coordinator should make arrangements for such training. There should be a maximum of 1 or 2 trainers per country. All interviewers should be systematically trained and assessed before being declared suitable to conduct the interviews.

As all patients in NTP network facilities may be interviewed (no pre-selection required), interviewers will be given a "cheat sheet" from the statistician to know what kinds of patients need to be added towards the end in order to reach the representativeness given the all-comers strategy.

Objective of the training:

For interviewers to:

- be aware of ethical issues in performing such interviews
- to learn interviewing techniques (such as adequate probing)
- to be able to select the appropriate study participants
- to be fully familiar with the questionnaire
- to understand the indicators used in the questionnaire
- to enter data appropriately
- to feed back any uncertainties or concerns with the questionnaire or the data collection procedures to the survey coordinator

For team leaders and survey coordinators to:

- Assess the suitability of interviewers to conduct the survey
- Monitor the quality and completeness of data collection

Method

During the training, data collectors should practice the questionnaire on each other and in simulated facilities to ensure that they also understand the questions and responses.

The training will be conducted by the PI or the survey coordinator, and may also involve WHO staff or other national or international partners involved in the study.

The deliverables of the training are for interviewers to know how to:

1. Introduce themselves and the survey to the participant
2. Convey to the patient the justification for inclusion criteria for the survey
3. Convey to the patient the informed consent process
4. Be able to put participant at ease and ensure comfortable environment in which to ask questions
5. Be familiar with the questionnaire so that questions are asked conversationally rather than being read stiffly.
6. Convey questions in the order in which they are written on the questionnaire, using the same wording (using the local language) as on the questionnaire. It may be that certain questions need further explanation and may need the interviewer to prompt responses from the patient regarding time and types of costs.
Depending on how far the patient has progressed with treatment, it might be difficult for him/her to recall cost items. The interviewer should make it as easy as possible for the patient to recall by using local methods of time structuring;
7. Understand and able to explain indicator definitions.
(types of costs, what is meant by cost of food, cost of travel and cost of accommodation, what is included and what is excluded and how they can help patients recalling items by prompting). This will help to ensure consistency in interviews and prompting by interviewers.
8. Avoid influencing the answers to questions by using friendly but neutral body language and not educating the patient.
9. Ensure that all questions are answered. If a participant refuses to answer a question or cannot give an answer, the appropriate field should be completed.
10. Keep control of the interview (off track conversations, silences)
11. Check patient records (included in case of non-participation in the survey)
12. Be sensitized on the different phases (intensive, continuation) and types of TB treatment (hospitalization, different forms of DOT, etc) and associated costs (sputum conversion

test, follow up test, medicine collection etc.), to avoid double counting costs. It also needs to be clear to the interviewers what counts as TB drugs and what are additional drugs that are prescribed/bought.

13. Be informed about the nature of TB, what their participation means for their own health and how they can protect themselves.

Depending on which kind of patients are interviewed (new, re-treatment or MDR patients), and how far the patient is into treatment, risks to interviewer health differ. For example, patients who are in their first month of treatment might still be infectious. The interviewer needs to be aware of that and knowledgeable about infection control measures; i.e. conducting the interview outside or in a well-ventilated room.

4.5. Piloting

Pilot testing will provide an opportunity to identify any problems with the survey tool and validate assumptions made for sample size calculation, timing of interview, and budget. Trained interviewers should be commissioned to perform pilot-testing. The wording of questions, their sequence, and the structure of the questionnaire can be improved on the basis of the findings of the pilot testing. Questions and instructions may be added. However, questions should not be deleted, and the content of questions should not change, other than changes to adapt to local context (see text *in red font* in the generic instrument).

Steps in pre-testing as suggested by patient's survey tools:

1. Obtain peer evaluation of adapted draft questionnaire
2. Test the revised questionnaire on friends, colleagues etc
3. Prepare instructions and train interviewers for pilot test
4. Commission trained interviewers to pre-test the questionnaire on a sample of respondents (ca. 10-20)
5. Obtain comments from interviewers and subjects; review pre-test responses to check for potential misunderstandings
6. Revise questions that cause difficulty (after consultation with advisory group, in order not to change the key elements of the generic instrument)
7. (Pretest again – recommended if time permits)
8. (Revise again)
9. Prepare revised instructions and train interviewers for implementation of full data collection
10. Monitor performance of the questionnaire during early phase of study

The survey questionnaire, data entry screens (electronic version of survey questionnaire), transfer of data and feedback loops, should be pilot tested to ensure that illogical or missing steps are identified and corrected before starting the patient survey.

4.6. Collect data through the survey tool

Timing of interviews

The questionnaire/survey tool is designed to interview all patients showing up for treatment that are registered for treatment for TB or MDR at an NTP network facility. However, a

minimum of 2 weeks of the present treatment phase should have been completed before the interview in order to enable collection of data concerning the ongoing treatment phase. Patients that have completed less than 2 weeks of intensive, or continuation phase, will not be interviewed.

For the recommended basic cross sectional survey, interviews will be carried out once per patient, after a minimum of two weeks into the treatment phase (different timing is recommended for the longitudinal design option is used, see section 3). This approach will allow capturing costs prior to TB diagnosis for some patients, and costs during different treatment phases for different patient categories. Costs for the entire illness episode will be projected based on collected information from the patient, as well as imputed and modelled based on information collected from other patients (see analysis section):

- **New patients (on first line or MDR-TB treatment) interviewed in the intensive phase** will be responding to questions about current intensive treatment as well as costs incurred from the onset of TB symptoms to the start of TB treatment (i.e. diagnosis). **New patients (on first line or MDR-TB treatment) interviewed in the continuation phase** will be responding to questions about the continuation treatment period only. Patients in the continuation phase will not be asked to recall costs from the period before continuation treatment started except for hospitalization and coping costs. Costs related to their intensive phase and pre-treatment will be estimated on the basis of some questions concerning their own health services use and costs, as well as on information collected from patients interviewed in the intensive phase.
- **Previously treated patients (on first line or MDR-TB treatment) interviewed in the intensive phase** will be responding to questions about costs during the intensive previously treated phase and about coping costs since the onset of TB symptoms
- **Previously treated patients (on first line or MDR-TB treatment) interviewed in the intensive continuation phase** will be responding to questions about the continuation treatment period only and about coping costs since the onset of TB symptoms.
- **For all previously treated cases**, brief questions about previous treatment will be asked. Based on that information, as well as on information obtained in interviews with new patients in the intensive phase, the costs related to diagnosis and previous treatment episodes will be estimated.

Place of interviews within the facility

The interview should take place in a separate space/room where the interview can take place undisturbed, while preserving the privacy of the patient. The principal investigator informed by the survey coordinator, depending on local conditions and waiting queues will decide if patients should be interviewed while they wait for consultation (making sure they do not lose their place in the queue) or after the consultation. The interviewer needs to be aware of infection control measures; i.e. conducting the interview outside or in a well-ventilated room and wear an N-95 respirator etc.

Time required for the interview

The time required to conduct the interview is approximately 45-90 minutes (depending on number of modules to be used). Prior to the interview, the interviewer will be required to complete some questions by checking patient records, which takes 15 minutes approximately. Ideally, interviewers will be informed prior to collecting data about the prevailing rates of doctors consultation fees, costs for investigations, and market price of drugs and medical bills

as a reference. If data was collected electronically Interviewers will also need to log into the Internet periodically to upload the data collected.

Role division

The patient survey will be done by the interviewers based at the NTP network facilities. They will read the generic questionnaire to patients in their mother tongue and may directly enter patient responses into the paper questionnaire or e-survey instrument on their computer or Android device. They will validate the responses and check patient records. Team leaders at the facility level will supervise daily the data collected and validated by the interviewer.

Survey supervisor should check all questionnaires at the end of each day, at least during the start of the survey, to ensure errors are promptly identified and corrected. Thereafter supervisors can check data quality periodically. Data entry can be done either by interviewer (if e-survey), but team leader, by supervisor, or by specially recruited data entry clerks. This should be decided by the survey advisory group.

Translation for migrants

While the survey tool will be available in the local language, in the case of migrants participating in the survey there might be a need to hire a translator from the migrant's language into the local language.

E-survey

An electronic generic survey system has been set up in WHO Data Coordination Platform (DCP) for secure management of electronic forms and data in real-time between health and development partners (www.whodcp.org), and the TB patient cost survey described here, has also been uploaded to this system. This platform is part of the [mHero](http://mHero.org) technology suite for effective Ebola response and monitoring (UNMEER). It has also been used for reproductive health. It was chosen mainly because it is open access, allows collecting data offline and uploading online to send to the data repository and may be used for routine data collection in the future if desired. This application allows versioning which means that as the e-patient survey is streamlined following the pilot phase, the data previously collected will not be lost. The WHO Data coordination platform will be available for follow-up and software maintenance. The required technology for the country to use the e-survey is Explorer 8 (or later versions), Mozilla, Chrome, Firefox. To note that the platform does not mean WHO will hold or own the data: the country will.

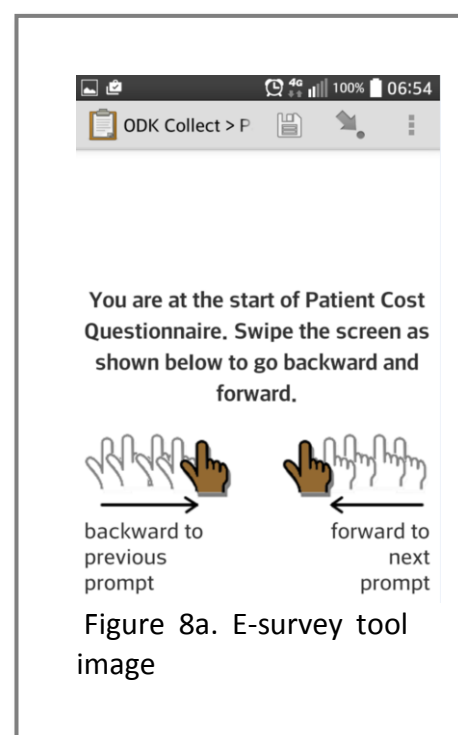
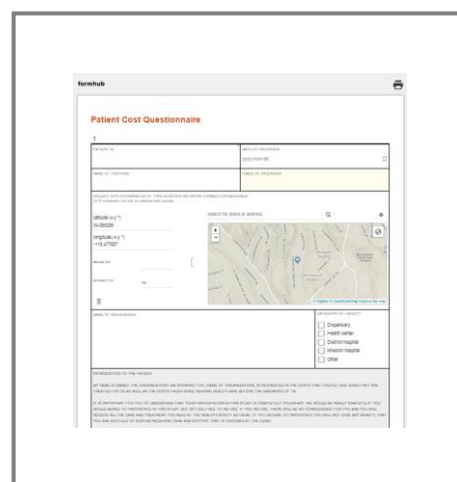


Figure 8a. E-survey tool image

The DCP can be accessed via a computer's web browser or through ODK (Open Data Kit) Collect, a free Android application. On either platform, the survey will require a network connection for the first occasion it is opened. Once the survey has been loaded one time, users will no longer need an active network connection to access it. If there is an active connection, patient responses will automatically be loaded into a web database. In cases of limited network connection, the form can still be completed and the application/web address will record and save responses internally to be sent to the database when network connectivity is established. On mobile devices, this will require an SD card. Fortunately, these can be purchased cheaply. GTB will assist the end user's setup of ODK Collect if needed as well as provide technical support throughout data collection.

The following link contains an electronic version of the current generic patient cost survey:

<https://cwq6e.enketo.org/webform>

Countries can adapt the questionnaire, translate it and upload it onto this platform, in replacement of the generic protocol. This generic e-survey contains skip patterns and can direct respondents to different sections of the survey according to their type of TB and whether they are interviewed during the intensive or continuation phase. This electronic questionnaire automatically generates key cost calculations. Countries may adapt and change as the generic survey is adapted at country level.

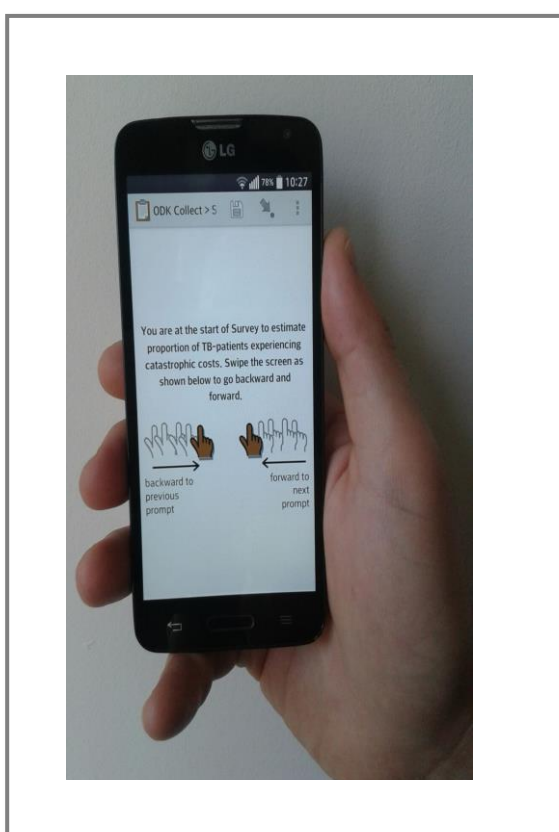
Both local language and English question will appear simultaneously if the e-survey tool is used. If an electronic data entry survey is chosen, an informed consent paper will need to be signed or finger printed by the patient. A photo of the signature or digital print may be added and uploaded to the server and included in the patient survey data.

4.7. Manage and enter the data

Data management consists of the processes and procedures for collecting, monitoring, handling, storing, processing, validating and archiving data from the start of the patient survey to its completion. Data transferred from health facility to the NTP and to the designated technical assistance partner, needs to be managed properly to ensure they are accurate and reliable, precise and complete, while always maintaining confidentiality and data integrity.

The generic questionnaire is available both on paper and on a standard electronic questionnaire and data entry form that can be used on androids and laptops.

Key steps for data management are:



1. Patient record number, patient name, date of birth and gender are mandatory in the survey (paper or electronic). They are essential for the validation of records by the team that carries out the analysis.

2. The choice of software used in this survey (the WHO Data Coordination Platform), has been guided by the expertise of a database developer at WHO. The software package includes a relational database with robust security. Validation and consistency checks can be used in data entry screens for quality control. Data should be entered and checked continuously during data collection.

3. Direct data entry during interviews is done off-line on the e-survey tool, followed by on-line data up load or done on paper and then followed by electronic data entry at central data management unit. If the interview is carried out using a paper-based survey, electronic data entry will be carried out by data entry clerks at a central data management unit or equivalent. Alternatively interviewers may use the WHO Data Coordination Platform (DCP) off-line to directly make data entry during the interview on the computer device (laptop, notebook, personal digital assistant or mobile phone/android) and will be required to periodically connect to the internet to upload the completed patient questionnaires.

4. All essential documents and electronic files pertaining to the patient survey should be securely stored. These are: signed protocol and amendments, information given to survey participants, financial reports of the survey, signed agreements between involved parties, for example between investigator(s) and sponsoring agency or contracted research organisations, including access to data, reports and publications; dated, documented approval or favourable opinion of institutional review board or independent ethics committee. All survey staff handling data (both on paper and electronically) should respect the confidentiality of the information collected.

5. Adapted and translated questionnaires can easily be imported into the electronic survey form. WHO GTB can assist with this step.

6. Supervision of data collection. Supervision of data collection at health facility level should take place as quickly as possible after data collection so that surveyed individuals can still be approached to check any errors or discrepancies.

7. Periodic cleaning and analysis. The Global TB Programme can assist with periodic data cleaning and analysis. Doing so periodically will allow for communications about potential errors in the survey before they are replicated many times over.

In addition to the above, if the optional longitudinal survey design is chosen, each patient will be followed using the unique identifier and patient registration number in the TB register.

The electronic data collection form performs basic calculations and has internal data error checks.

4.8. Analysis of patient costs

4.8.1 Introduction to the section

This section presents the proposed analysis plan which responds to the objectives of the study, while outlining the key methodological challenges. The main focus is on the basic cross-sectional design (i.e. patient interviewed once only). A brief summary of the analytical approach for the longitudinal design is also included.

The first study objective is to document the magnitude and main drivers of patient costs in order to guide policies on cost mitigation. The analysis section describes how to calculate the out-of-pocket medical and non-medical payments as well as an estimation of indirect costs, both before TB treatment starts and during the TB treatment. This disaggregation helps identify broad entry points for interventions to mitigate cost. The protocol does not describe further disaggregated analysis useful for the understanding of which types of costs are most important in a given setting. This involves, for example, disaggregating out-of-pocket payments into payments for medicines, tests, consultation fees etc, and disaggregating out-of-pocket non-medical payments into payments for travel, food, etc. Moreover, associations should be analyzed between costs and patient characteristics (type of TB, socioeconomic position, sex), place and model of care (ambulatory, self-administered, hospital-based etc), type of provider (public, private, NGO, etc), and health seeking before TB diagnosis (health providers utilized, time to diagnosis, etc). Descriptive analyses of the type of social and economic support that patients receive should also be done. Such analyses will help inform policy decisions aimed to reduce costs and access barriers. The detailed analytical approach should correspond to the information needs in a given setting, and this generic protocol therefore does not go into details about the required analytical steps and considerations.

The second survey objective is to determine the percentage of TB patients treated in the NTP network (and their households) in the country who incur catastrophic total costs. Two approaches will be analysed.

Approach 1

Medical and non-medical out-of-pocket payments and indirect costs exceeding a given fraction of household's income, as defined in Box.1 and expressed in the equation 4.8.1a

Approach 2 calculates the percentage of households experiencing “dissaving” (such as taking a loan or selling property or livestock). The indicator for this approach, expressed on equation 4.8.1b calculates the percentage of households experiencing any level of dissaving (such as taking a loan or selling property or livestock) to face health costs associated with the TB disease.

The core of the present analysis section details the approach 1 as it is the main indicator and it is the most data intensive and methodologically challenging approach.

Equation 4.8.1a: Proportion of TB-affected households that are experiencing catastrophic total costs (Approach 1)

$$I_{NTP}^{TB} = \frac{1}{n_{NTP}^{TB}} \sum_{i=1}^{n_{NTP}^{TB}} 1 \left(\frac{\sum_{j=1}^{n_i} (OOPM_j^{TB,h} + OOPNM_j^{TB,h} + IN_j^{TB,h})}{y_i^h} > \tau^{TB} \right)$$

Where

Where i denotes the household of patient j . If more than one household member is registered for treatment, costs for all patients within a household will be collected (if possible logistically) or estimated. n_{NTP}^{TB} , the total sample size across all NTP networks engaged in this survey. $1()$ is the indicator function which equal to 1 if the condition is satisfied and 0 otherwise.

I_{NTP}^{TB} proportion of TB-affected households that are experiencing catastrophic total costs
 $OOPM_j^{TB,h}$ the out-pocket payments for TB diagnosis and treatment made by TB patient's household members net of reimbursements (j). These are direct net medical payment for TB treatment.

$OOPNM_j^{TB,h}$ out-of-pocket payments related to the use of TB health services, such as payments for transportation, accommodation or food net of any reimbursements to the individual (patient or guardian) who made the payments

Multiple patients per household will result in direct and indirect costs added.

$IN_j^{TB,h}$ time loss valuation or reported income loss incurred by both the TB patient and any escort member net of any welfare payment

y_i^h reported amount of money received by the household in the year before the TB episode started, in exchange for labor or services, from the sale of goods or property, or as a profit from financial investments and welfare payments. Alternatively household income will be estimated based on asset ownership.

$1()$ is the indicator function which is equal to 1 when the condition is satisfied and zero otherwise

n_{NTP}^{TB} , the total sample size across all NTP networks engaged in this survey

τ^{TB} threshold (20% tentatively selected)

A standardized analytical approach is required in order to allow cross-country comparisons and global monitoring of this key indicator for the End TB Strategy. This section therefore provides detailed instructions on how to calculate the numerator and the denominator for this indicator. As discussed above, it is important to note that this indicator is not a subset of, or comparable to, WHO's indicators of households experiencing catastrophic health *expenditure*, which is a general indicator of the lack of financial protection in the overall population.

During the field testing phase of this protocol, results for two alternative approaches for the measurement of catastrophic total cost should be calculated. The other alternative approach is defined as the share of respondents experiencing dissaving. This will be estimated as follows:

Equation 4.8.1b: Proportion of TB-affected households that are experiencing catastrophic total cost (Approach 2)

$$I_{NTP}^{TB,Dis} = \frac{1}{n_{NTP}^{TB}} \sum_{i=1}^{n_{NTP}^{TB}} 1(Dis_i^{TB,h} == 1)$$

Where

$Dis_i^{TB,h}$ identifies TB diagnosed patients ‘household treated in NTP networks that are experiencing dissaving due to TB, during the TB episode (up to 2 years) ;

1() is the indicator function which is equal to 1 when the condition is satisfied and zero otherwise

n_{NTP}^{TB} the population of interest, patients treated in NTP network

Validation will support the final choice for the routine implementation of the survey worldwide and will allow streamlining the survey instrument. A description of the two approaches required is presented below.

The unit of analysis is the patient but we consider the economic consequences in the context of the household of the patient in the analysis. The analysis will bear in mind, the number of patients sampled that belong to the same household and will make adjustments. Costs are calculated from the patient perspective and ignore costs to the provider (e.g. staff time) and other societal costs with the exception of caregiver time.

Costs should be first analyzed using local currency units as the patients are directly reporting them. All local currency amounts will be converted into 2015 US\$ as well as PPP\$. To do so we will utilize conversion rates and deflators for the year in question provided by the World Bank.

A data dictionary is provided with the protocol (see the column “variable” in the paper and e-survey instrument). Variable names are pre-assigned to facilitate the use of coding into statistical packages. If GTB provides support for data analysis, it will be conducted in Stata 13 (College Station, TX).

As part of the analytical tools proposed to monitor catastrophic cost within NTP patients at national level, a Stata program set up by the GTB will be disseminated using the indicators from the recommended patient survey. Pre-assigned variable names coding each of the patient’s answers are used in the program.

Participant countries are encouraged to establish a national data repository for patient survey data. It is a long term endeavour that involves planning for various aspects (human resources, management, funding, terms of references, standard operating procedures, confidentiality agreements) and therefore requires resources and commitment.

4.8.2 Key methodological challenges for the analysis of costs needed to implement the first definition of catastrophic TB costs.

The calculation of the percentage of TB-affected patients (and their households) that face costs that are above a certain percentage of annual household income faces three key methodological challenges that need to be addressed.

The first methodological challenge relates to obtaining the **appropriate measure of household income** (required for the denominator of the first measure/approach). Self-reported income can be unreliable, especially in settings where informal economy dominates. In such a situation it is preferable to use an asset score to determine which income quintile the patient/household belongs to, and apply the average income for that socioeconomic quintile. The asset score approach should be based on questions validated in each respective country. Part V of the survey instrument (question; “Constructing a socio-economic status index with household asset questions”) should be adopted or adapted from national Demographic and Household Survey asset questions, National Household Consumption Survey, Lifestyle Monitoring Data or similar. If a suitable validated asset score for establishing income quintiles is not available, this will have to be developed using (principal) component analysis, preferably in collaboration with the national statistics office. Even if a validated asset score exists in a country, it may be preferable to further refine and simplify the score, especially to try to reduce the number of asset questions to be asked in the survey. (Annex 2)

The second methodological challenge is posed when **estimating patient's productivity loss** that is required to account for the indirect costs in the numerator of the first approach (Ref. [Equation 4.8.1a](#)) . Box 2 explains the various approaches used in health economics.

The third methodological challenge relates to the **threshold used to determine if costs incurred by patients are catastrophic or not** for households affected by TB. While WHO and the World Bank have well-established thresholds to determine if health care expenditures are catastrophic or not, there is no established threshold available to determine when the economic burden of TB in patients is defined as "catastrophic". The WHO Global TB Programme's task force proposed tentatively to use a threshold of 20% since this level has been associated with poor clinical outcomes (Wingfield et al, 2014). This threshold will be explored as part of the field testing of the protocol.

Box 3: Estimating indirect costs and valuing patient's time: a methodological challenge

The focus of the current protocol involves valuating the *financial* burden of TB on patients, i.e. direct medical payments as well as non-medical payments such as food and transport, but it also involves valuating the *economic* burden, that is estimating the so-called “indirect costs” which are the productivity or economic costs for an individual or household incurred as a result of spending time seeking treatment and receiving care (Barter et al., 2012, Drummond et al., 2007 and Russell, 2004).

Two methodological issues are faced when valuing patient's time. First, it is difficult to define what patients would have done with this time (paid work, unpaid work, leisure) if they had not spent it staying in or visiting health facilities. In other words, it is the opportunity cost that can be difficult to define (WHO, 2002). The second methodology issue is how the opportunity cost should be valued in monetary terms. There is paucity in terms of the measurement of costs associated with the time lost while being unable to work due to seeking care or being too ill to work (Foster, N. 2015). There are several methods to value time loss and they were developed to analyse the consequences at the macroeconomic level rather than at the household level (microeconomic):

The most common method used is the input-based **Human Capital Approach**. Following this approach, an individual's time (or loss of productive time from treatment and illness) is valued based on their estimated productive output based on their reported income *prior* to being ill (by multiplying the estimated productive time lost due to treatment and illness with the reported income *prior* to being ill). This approach is criticized on equity grounds as the higher the income of a patient, the higher the value of their time and it excludes the value of time loss of those not employed or those working but not paid. Lensberg (2013) suggests using a general average wage rate rather than the patient's wage in order to compensate for the equity imbalance. Alternative approaches include the **equality of wages method** where time loss is valued equally across individuals by using a proxy such as the minimum wage or the average reported income for the cohort (Mauch et al., 2011 and Sinanovic et al., 2003). A central limitation of the input-based approach is that it assumes that every economically active person is a wage earner, when in reality many individuals or households derive income from small businesses that they own and operate. In addition, studies that use an input-based approach to calculate lost household production are most likely overestimated because they assume that the duration of an individual's absence from work fully corresponds to the market value of those lost days. Such an assumption overlooks the so-called 'coping strategies' used by households to mitigate the adverse circumstances of one of their member's being ill (WHO, 2009). On the other hand, coping strategies may contribute to the economic burden, for example if important household assets are sold off, children are taken out of school to contribute to household earnings, or loans with high interests are taken, and the negative impact of such “coping” may be long lasting and potentially irreversible.

When analysing time loss from a macroeconomic perspective, WHO recommends wherever possible the use of an “**output-related approach**” is used to value productivity losses (i.e. patient's time loss) (WHO, 2009). To measure the value of lost market production, it is important to assess the value of the production of the sick person and his/her family compared to the counterfactual of what would have happened in the absence of the illness. This can be achieved via what has been termed the output-related approach (Goldschmidt-Clermont, 1987), which focuses on measurable changes in income or product rather than time inputs. Only a few studies have used this approach to date (Attanayake et al., 2000). A central requirement for estimating the actual (rather than potential) losses in production is the comparison of households with and without the health condition in question, so that it is the net effect that is captured and attributed to the condition in question. In the context of this survey, where we are interested on the impact on the household, this approach would be translated into ascertaining change in income during the TB episode as compared to prior to the TB episode. This approach accounts for the situations when days ill or seeking care do not necessarily translate neatly into days of lost work. To use the WHO recommended approach it is necessary to identify total net losses in income since it is better equipped to isolate only the fraction of market production of a household that is actually (rather than potentially) lost. However, this approach requires that change in income can be determined in the study, which is a challenge especially where an informal labour market dominates.

In the field testing period of the current survey, several approaches should be tested and compared in order to avoid over-estimating indirect costs.

4.8.3 Estimating costs during the TB episode

Time horizon for TB episode

The survey aims to capture costs related to the whole TB episode where “TB episode” is defined as the period of time from self-reported onset of TB-related symptoms until the end of the continuation phase of treatment.

Equation 4.8.3a: TB episode

$$Episode_t^{TB} = Pretreatment_t^{TB} + Intensive\ phase_t^{TB} + Continuation\ phase_t^{TB}$$

Where $t \leq 2$ years for previously treated patients or MDR patients

Where $t \leq 1$ year for new TB patients

As mentioned in the methods section, to avoid recall bias, we establish the maximum time horizon at two years (to cover for the MDR treatment duration).

Total costs of a TB episode

The total cost includes all medical and non-medical out-of-pocket payments (direct cost) and indirect costs incurred both by the patient and any guardian or other household member accompanying the patient to a health facility.

Equation 4.8.3b: Total cost of the whole TB episode

The total cost of the whole TB episode is calculated as:

$$\begin{aligned} Episode\ Cost_t^{TB} &= Pretreatment\ cost_t^{TB} + Intensive\ phase\ cost_t^{TB} \\ &+ Continuation\ phase\ cost_t^{TB} \end{aligned}$$

Patients will be interviewed in different phases of the illness episode, and reporting on retrospective expenditures and time loss. As explained and depicted in Part III of the protocol data is collected for the particular episode phase the patient is in. Cost will be predominantly estimated for other phases and estimation will be done using costs calculated for similar patients interviewed in the other phases of illness, matched by type of TB and facility. For example, a new drug-susceptible patient interviewed during their continuation phase will not report all costs they incurred during the intensive phase. This patient would be assigned the average cost of the intensive phase among other similar drug-susceptible patients who were interviewed at that facility during the intensive phase.

The total cost for the TB episode thus includes (as shown graphically in Fig. 4)

1. Medical and non-medical out-of-pocket payments and indirect costs incurred **from onset of TB symptoms to TB treatment start (i.e. prior to treatment initiation)**
 - If new patient in intensive phase:
 - Reported medical and non-medical out-of-pocket payments for outpatient and inpatient care prior to diagnosis (direct costs)
 - Reported dissaving/coping costs (Part V)
 - Reported time loss (or reported income loss, where possible). Valued time loss prior to treatment start may be calculated if the analysis chooses the Human

Capital approach to value time loss. Various options are possible to select a wage to determine time loss:

- i. wage of the lowest paid unskilled government worker (Cameroon, 2009; WHO/HAI, 2008)
 - ii. patient's reported pre-illness wage (or labour income) in survey (WHO, 2002 and Drummond et al, 2007)
 - iii. average wage rate for all working individuals in the country (Lensberg B et al, 2013)
 - iv. individual income estimated from household income itself determined through asset scoring. (Novel option that could be explored).
- If new patient in continuation phase or previously treated:
 - Estimated medical and non-medical out-of-pocket payments for outpatient and inpatient care prior to diagnosis (direct costs)
 - Reported dissaving/coping costs prior to treatment start (Part V)
 - Reported income loss (where possible) (Part V); or
 - Time loss imputed based on time loss reported from other similar patients prior to treatment start (To avoid recall bias, detailed information about time loss prior to treatment is not collected) and wage determined as described above).
2. Costs incurred **during previous TB episodes** to be examined for previously treated cases only.

To avoid recall bias, detailed information about costs incurred during previous treatments is not collected from previously treated patients. However Part III collects overview data on duration of previous treatment and number and length of any hospitalizations. The direct information from the patient about their previous TB treatment combined with an extrapolation of their current treatment expenditures will be used to estimate a direct cost for the previous treatment.
3. Cost for TB care and treatment incurred **from (TB/MDR) treatment start and during the intensive phase**
 - If patient in intensive phase: out-of-pocket payments and time loss are directly reported
 - If patient in continuation phase: the cost in the intensive treatment phase will be estimated based on information collected during the continuation phase for the same patient. The mode of therapy (e.g. self-administered or directly observed), and the information collected for patients interviewed in the intensive phase of the two phases will play a critical role in this estimation. If the same patient's continuation phase cannot be used to estimate the cost of their intensive phase we will use an average cost from other patients in the same facility. Regressions are done on small samples and key cost drivers identified, laying the basis to extrapolation to larger samples. (See annex 1: illustration of estimations).
4. Cost for treatment incurred **during the continuation phase** (TB or MDR)
 - If patient in continuation phase: out-of-pocket payments and time loss are directly reported and calculated (Part V)
 - If patient in intensive phase: costs are estimated using data from patients interviewed in the continuation phase

Equation 4.8.3c: Total cost of a phase of illness

The costs related to each phase of illness and treatment is calculated, for example as:

$$\text{Pretreatment cost}_t^{TB} = OOPM_i^{TB} + OOPNM_i^{TB} + IN_i^{TB}$$

Where

$OOPM_i^{TB}$ is the net out-pocket payments for TB diagnosis and treatment made by each TB patient (direct net medical payment for TB treatment)

$OOPNM_i^{TB}$ net payments related to the use of TB health services, such as payments for transportation, accommodation or food

IN_i^{TB} time loss valued for both the TB patient or escort member net of any welfare payment

Cost should be summed for all health care visit and hospitalizations in each phase of illness. For DOT, visits to pick up drugs and other visits for medical follow up, cost data are collected for the latest visit only. The total cost for each type of visit should then be estimated on the basis of the cost of the last visits multiplied by the frequency of visits to pick up drugs or do medical follow up.

Calculating patient's time loss or cost of productivity loss

This section describes the practical approach to time costs to use in the analysis of this protocol (Table 2). During the field testing phase both alternative methods, the output-based and the input-based method will be calculated (and results compared) to estimate indirect costs. The recommendations are consistent with the recommendations from recent literature (WHO, 2009, Lensberg B. et al 2013, Drummond et al, 2007) but this is an area in development and it will be revised during the implementation phase if need be.

Acknowledging that this is one of the most challenging areas of the analysis, the survey instrument allows for the various methods to be explored and compared around a sensitivity analysis.

Table 2: Practical approach to time costs to use in this protocol

Patient's time valuation method	Patient's in formal paid work	Other patients	Recommended by
Output-based approach	Net effect of reported income change pre and during TB episode.	Net effect of income change pre and post TB	Wherever feasible by WHO, 2009
Input-based approach: Human capital approach (resolving the equity imbalance)	Number of hours or days reported related to seeking and receiving care will be multiplied by a general average wage rate for all working individuals in the country	<p><u>Option 1.</u> Value at zero their time (conservative)</p> <p><u>Option 2.</u> Value according to average wage of those patients who were in paid work</p> <p><u>Option 3.</u> Value according to the average income pre-illness of those patients in the same income quintile. Positioning of the patient within a quintile is possible thanks to the asset ownership and SES questions within the survey.</p> <p><u>In addition to previous options.</u> A sensitivity analysis that excludes consideration of time lost altogether (equivalent to valuing everyone's time at zero) should be done commenting on the difference that this makes to the conclusions to be drawn from the analysis.</p>	Use of general average wage rate is recommended by Lensberg B et al, 2013
Input-based approach: Human capital approach (not resolving equity imbalance)	Number of hours or days reported related to seeking and receiving care will be multiplied by patient's reported income prior to illness (in survey)	Same as above	WHO, 2002 and Drummond et al, 2007

Table 3. Data availability in the survey to value patient's time according to the method

Patient's time valuation method	Data required	Available in	Recommendation
Output-based approach	a) Income pre TB episode b) Income during TB episode c) Income loss due to TB	a) Reported income in survey b) Reported income in survey c) Calculated based on reported a) and b) If using this approach, data in the survey allows calculating indirect costs for the whole TB episode not through the phases (pre-treatment, intensive, continuation phase)	Where feasible but mostly for macroeconomic analysis purposes, WHO (2009) recommended approach to calculate productivity losses.
Human Capital Approach (resolved equity imbalance)	a) Number of hours lost by the patient b) Average wage rate for all working individuals in the country .	a) Reported time loss in the various phases of the TB episode b) National data If using this approach, data in the survey allows calculating indirect costs by treatment phase (pre-treatment, intensive, continuation phase)	This approach, along with input-based approaches is not the preferred WHO (2009) approach but it allows estimating indirect costs in the various phases of the TB treatment episode. Lensberg (2013) recommends this approach. Lensberg (2013) recommends using average general wage. WHO-GTB suggest using: a) Reported wages b) Estimated individual income based on estimated household income itself determined through asset scoring. Sensitivity analysis should be performed in particular when patients interviewed are not active in the formal labour market.
Human Capital Approach (unresolved equity imbalance)	a) Number of hours lost by the patient b) Average reported wage rate	a) Reported time loss in the various phases of the TB episode b) Reported annual wage in survey If using this approach, data in the survey allows calculating indirect costs by treatment phase (pre-treatment, intensive, continuation phase)	This approach, along with other input-based approaches, is not recommended by WHO (2009) but it allows estimating indirect costs in the various phases of the TB treatment episode. Drummond et al (2007) recommended this approach. Sensitivity analysis should be performed in particular when patients interviewed are not active in the formal labour market.

As shown on Table 3. The cost of patient's productivity loss will be calculated as follow (methods are ordered according to WHO recommendations).

a) Using the output-related approach. This implies valuating time loss based on the net effect of reported income change pre and post TB (WHO, 2009).

This recommended approach relies however on individual income before and during TB treatment being collected with reasonable reliability (such as in settings where formal economy dominates). Using this approach implies **calculating indirect costs for the whole TB episode** not through the phases (pre-treatment, intensive, continuation phase)

Equation 4.8.3d: Total cost of a visit

$$IN_i^{TB} \text{ using output-related approach} = y_{loss}^i = (y_{preTB}^{m,i} - y_{TB}^{m,i}) * m_{TB}^i$$

Where

IN_i^{TB} time loss valued for both the TB patient or any escort member net of any welfare payment

$y_{preTB}^{m,i}$ individual income loss (TB patient and any escort member) net of welfare payment

$y_{TB}^{m,i}$ individual (labour) income (of TB patient and any escort member) reported monthly before TB illness

m_{TB}^i TB illness duration in months

b) Using the Human Capital Approach

- Adjusting for equity considerations:

The number of hours or days reported related to seeking and receiving care will be multiplied by either

b.1) an estimate of the individual income. As the preferred measure of income is household income estimated based on asset scoring, the estimate of individual labour income will be derived from that indicator.

b.2) a general average wage rate for all working individuals in the country (Lensberg, 2013).

b.3) Valuing patients' time that are not employed at a wage of zero or at a mid-point between 0 and the general wage average.

b.4) Valuing patient's time at a wage associated with the income quintile that household asset scoring helped estimate.

A sensitivity analysis may be run to explore the above options.

- Not adjusting, i.e. using reported wage rates.

Equation 4.8.3e: Time loss valuation (Human Capital Approach, not adjusting wages)

$$IN_i^{TB,h} \text{ using Human Capital Approach} = (t_{visit} * w) + (t_{hospitalisation} * w) + (t_{travel} * w) + (t_{pick up drugs} * w)$$

Where

t_{visit} Time spent per visit including waiting time

$t_{hospitalisation}$ Hospitalisation duration

t_{travel} Travel time

$t_{pick up drugs}$ Time employed to pick up drugs

w may be either a) zero, b) wage of the lowest paid unskilled government worker (Cameroon, 2009; WHO/HAI, 2008), c) patient's reported pre-illness wage (or labour income) in survey (WHO, 2002 and Drummond et al, 2007), d) average wage rate for all working individuals in the country Lensberg B et al, 2013

or e) individual income estimated from household income itself determined through asset scoring. (Novel option that could be explored).

Coping costs

Coping events such as taking a loan or selling assets are thought to be significant enough to be remembered by the patient and hence collected for all patients regardless of which phase of the TB episode they are interviewed in (part V). Reported interest rates and foregone income due to selling income-generating assets will be summed for the whole illness episode (but not beyond the time of recorded or estimated treatment completion, e.g. if a patient is interviewed at week 2 of intensive phase, it is assumed that they will keep their loan until the end of treatment).

Guardian/companion costs

Guardian/companion costs are included in this survey. They will be calculated as the direct non-medical expenditures of a guardian (or other person accompanying the patient) plus their time loss cost.

Equation 4.8.3f: Guardian cost

$$C^g = OOPNM_j^{TB} + IN_j^g$$

Where

C^g Guardian cost

$OOPNM_j^{TB} = Travel + Food + Other (incl. accommodation)$

$IN_j^g = guardian's\ time\ loss\ valued$

The latter portion will use the same approach to value time as proposed for the patient's time loss. For all patients, direct non-medical costs for guardian costs (transport, food, and accommodation) are included. If the patient is aged under 15 years, all non-medical direct and indirect costs questions concern the guardian.

4.8.4. Estimating household annual income before the TB illness episode

The survey instrument (part V) allows computing annual household income before the TB episode through:

- a) self-reported disposable individual income (where disposable refers to net of tax)
- b) self-reported disposable household income
- c) estimated household income on the basis of:
 - a. the average net (of tax) wage rate (based on national income data)
 - b. asset scoring

An example of how to estimate annual income based on asset scoring is provided in Annex 2. Some useful references are Ferguson B. D et al, 2003, Harttgen K and Vollmer S., 2013. and Seema Vyas et al, 2006.

4.8.5. Determining percentage of households experiencing economic burden or catastrophic total cost.

Consensus on a tentative measurement of the economic burden incurred by TB patients was reached last March 2015, however it is subject to refinement based on pilot testing. Therefore for the pilot testing phase, the Global TB Programme recommends using the following two approaches.

Approach 1 – calculation of total episode cost as percentage of annual disposable household income before the TB episode – this method has been used successfully in recent studies (Tanimura et al, 2014). It can use either self-reported income or income derived through asset score-based assignment.

Approach 2 – enumerating proportion experiencing dissaving – is a potential proxy indicator of catastrophic cost that requires further validation. Two approaches will be assessed in the field testing.

Approach 1: calculate the total episode cost as percentage of annual household income before the TB episode (see Equations 4.8.1.a and 4.8.5.a)

The first approach is to calculate the total episode cost as percentage of annual household income before the TB episode, as per equation 4.8.1.a.

A dichotomous variable should be created for catastrophic total cost occurrence using the following thresholds:

Equation(s) 4.8.5.a: Selection of threshold determining catastrophic total cost (τ^{TB})

- if $C_i^{TB,h} \geq 0.2 * y_i^h$ then costs are “catastrophic” for the patient’s household. This threshold is based on Wingfield et al, 2014.
- *Other thresholds will be explored* (sensitivity analysis)
- $C_i^{TB,h} \geq 0.1 * y_i^h$
- $C_i^{TB,h} \geq 0.15 * y_i^h$
- $C_i^{TB,h} \geq 0.25 * y_i^h$
- $C_i^{TB,h} \geq 0.3 * y_i^h$

Where

$C_i^{TB,h}$ is defined as $OOP_i^{TB,h} + OOPNM_i^{TB,h} + IN_i^{TB,h}$ that is TB episode cost (one or multiple patients per household) net of transfers and reimbursements
 y_i^h Annual household disposable income *net of taxes*.

Other data-driven cut-offs may be defined in a given setting, depending on association with clinical outcomes; with dissaving strategies or other measures of impoverishment.

Each patient (household) will be given a binary (Yes/No) value for whether or not they incurred catastrophic total cost due to their TB disease, as defined by the chosen percentage cutoff. These binary values will allow for a calculation of the percentage of TB respondents treated in NTP networks who incurred catastrophic total cost for each country. These

percentages may also be reported by income quintile, sex, type of TB, clinic and geographical cluster within countries, if sample size allows.

Approach 2. Percentage of households experiencing “dissaving” (see Equation 4.8.1.b)

This is an alternative approach to the “Approach 1”. This second approach calculates the percentage of households experiencing “dissaving” (such as taking a loan or selling property or livestock).

The indicator for this approach, expressed on equation 4.8.1b calculates the percentage of households experiencing any level of dissaving (such as taking a loan or selling property or livestock) to face health costs associated with the TB disease.

This proxy indicator by definition indicates financial weakening of a household. Occurrence of dissaving has been associated with total costs of TB (Madan et al 2015). However, further work is needed to assess the correlation between high total cost due to TB illness in relation to income and seemingly irreversible coping strategies. The present study protocol will contribute to the development of this proxy indicator. WHO may adapt an operational definition of catastrophic cost based on information on dissaving.

Patients often borrow, use their accumulated savings, and sell financial assets to cope with high costs. The term ‘dissaving’, highlights the fact that it involves reducing the financial strength of a household, in contrast to how savings increases a household’s resilience to financial shocks (Madan J., 2015). Holding assets is an important mechanism for saving in low income households, which often do not have access to any type of financial institution, formal or informal.

Potentially, dissaving can be measured much more simply than cost in relation to expenditure and income. It is likely to be associated with financial hardship, and may be a useful proxy indicator for catastrophic cost.

Using data from Part V “Coping costs”, the frequency at which patients had to resort to dissaving, borrowing, or selling assets to cope with TB-related expenses should be established. The percentage of patients that report any of these activities should be reported as well as the average dollar amount of these activities

In future analysis, the Task Force may explore the option of using a threshold for the amount of dissaving although there are several approaches to consider beyond a simple percentage.

It should be explored if using an indicator based on the amount of dissaving is giving better precision. Another possible approach could be to assess the presence and/or amount of ‘distressed dissaving’ i.e. sale of income generating assets, through question 122; “The assets that you sold, were they previously supporting the family income (or expenditure)? If yes indicate monthly income previously generated by the assets”.

Taking a loan or selling household items, property, or livestock are not the only adverse coping mechanisms to consider when measuring economic impact of TB on a household. For example, children may be forced to leave school in order to work and support the family of a sick individual. This action could mitigate poverty impacts in the short-term but is likely to

have long-term economic consequences for the household. Such events should be reported as additional indicators of financial and social hardship due to TB and data is collected through the survey instrument.

The validation of dissaving as a potential proxy indicator for catastrophic cost is not described in this protocol, and will be covered elsewhere.

Longitudinal design

The analysis of data from a longitudinal design should follow the same principles as outlines above. With this design, no imputations for estimating costs in various phases of the episode will be required since data will be collected concerning the entire illness episode for each patient through repeat interviews, at least at the start of the treatment and at the end of the treatment. The exception is for cost for previous treatments for previously treated cases, for which standard costs for whole treatments and/or hospitalizations still needs to be imputed.

We suggest for those embarking in the optional longitudinal survey design to repeat questions on dissaving (and even add additional dissaving questions) on the subsequent interviews, in order to help WHO and partners validate “dissaving” as a proxy for “experiencing catastrophic total cost”. It is likely that dissaving increases cumulatively, and perhaps the operational solution for periodic surveys would be to only ask about dissaving at the end of treatment (though that would miss defaulters who default due to financial constraints), or at 2 months and at the end (and then no other questions). This topic requires further discussion as results are analyzed.

Non-response analysis

Using data from part II, it will be possible to compare those patients who agreed to participate with those who declined to do so. A table describing the frequencies of age, sex, type of TB, and HIV status by participation status can be produced. This table should also show the results of t-tests to see if any of these factors differ significantly by participation status. Any large discrepancies between the two groups would harm the external validity of any estimates produced.

Assessment of differences between sub-populations

Assessment of differences between sub-populations can be performed, depending on sample size. Cross-tabulations of catastrophic cost experience can be produced by income quintile, age, sex, type of TB status, insurance status, etc. Furthermore, a multivariable logistic regression may be run to determine which factors are most significantly associated with an individual TB patient experiencing catastrophic total cost. These analyses could shed light on where NTPs, funding agencies, or national governments may be able to reduce direct and indirect costs by changing health care payments/reimbursements, health care delivery modalities, or provision of social protection to mitigate costs for TB patients most efficiently.

4.9 Implementation and dissemination plan

Plan for dissemination and publication of the project findings

Data collection using the task force recommended method, will be initiated in at least 5 countries in 2015 and at least 10 countries in 2016 according to methods agreed in at the Task Force meeting (March 2015 meeting)

Timeline for dissemination

By September 2016, at least 3 countries (embarking in the Q3 2015 on the survey) should be ready to disseminate results.

Principal investigators will take the lead in publication and dissemination of results in the scientific media, but also to the community and/ or the participants, and consider dissemination to the policy makers where relevant.

Table 2. Suggested timeline for a country starting in 2015

	2015				2016											
	S	O	N	D	E	F	M	A	M	J	J	A	S			
Adaptation of the generic protocol and questionnaire																
Ethics Committee Submission																
SOP Writing																
Translation of questionnaire into local language																
Electronic survey adaptation																
Kick Off Meeting																
Data Collection																
a) Patient Recruitment																
b) Site Supervision Visits																
Analytical Plans																
Activity Report to funder																
Data Cleaning / Analysis																
Final Report																
Dissemination of Results																

4.11. Budget

Total budget required for this survey probably ranges from US\$ 10.000 to US\$50.000 depending on ambition level and amount of external support needed. Major factors that influence the amounts of funding required for the survey are sample size and staff costs. The number of clusters and sample size affect the number of survey teams.

The typical components of a budget for a patient cost survey are:

- Staff salaries or incentives and insurance
- Technical assistance
- Computer equipment, supplies and maintenance (including android phones and tablets purchased)
- Mobile Air-time for interviewers
- Training (incl. fees and per diems)
- Survey documentation
- Meetings and workshops
- Ethical Review
- Pre-visit to each cluster
- Contingency
- Patient incentives
- Analysis of data and preparation of survey report
- Final review and agreement of results
- Workshop
- Publication in scientific journal

Table 3. Example of budget template to establish budget for the patient cost survey

Survey to estimate proportion of TB-patients experiencing catastrophic costs: the budget						Note
Budget line	Price Unit (local currency) Monthly	Incentive	# Unit	Total in local currency	Total in USD	
Human resources						Includes salary, incentive, insurance. If staff is employed part time, reflect this in the
Principal Investigator						
Survey coordinator						
Data analyst						
Data manager						
Team leader						
Facility interviewers						
Subtotal Human resources						
Technical assistance						
Technical advisory group: social scientist/epidemiologist/survey expert						
Technical advisory group: health economist/analyst						
Technical advisory group: statistician						
Subtotal Technical assistance						
Information and Communication technologies (ICT)						
Computer equipment (and maintenance)						
Computer supplies						
Android phones						Purchase/Rental
Tablets						Purchase/Rental
Communication (telephone/internet/courier)						
Mobile Air-time for interviewers						
Cost of creating a survey database						
Data repository						
Subtotal ICT						
Travel						
Preparation phase: Kick-off meeting (training)						
Preparation phase: pre-survey visit to each cluster						
Preparation phase: training workshop (for health facility interviewers)						Includes fees and per diem
Implementation phase: Local travel (fuel and other travel costs)						
Implementation phase: monitoring visit						
Subtotal Travel						
Patient incentives						
Subtotal Patient incentives						
Other						
Survey documentation						
Protocol translation into local language						
Back translation from local language into English						
Ethics Committee fee						
Dissemination: analysis of data and preparation of survey report						
Dissemination: final review and agreement of results						
Dissemination: publication in scientific journal fee						
Subtotal Other						
Contingency						
Total (without % overhead)						
Total (with % overhead)						
Sources of funding						
				Government		
				Donor 1: <<name>>		
				Donor 2: <<name>>		
				Gap		
				Total		

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Annex 1 Analysis: basic result calculations (mock data)

Table 1. Direct costs for the TB patient during the TB episode, net of reimbursements

Household ID	Patient ID	Case Type	Phase of Interview	Before Diagnosis Cost (Part IV)		During Treatment Cost (Part V)					Additional Extrapolated Cost Until Treatment Completion	Total		
				Medical	Non-Medical	Medical	Non-Medical	Cost for Nutritional/Food Supplements	Relocation Costs			Reimbursement	Direct costs	Direct costs, net of reimbursement
1234	101	DS-TB, new	Intensive	\$ 22	\$ 12	\$ 126	\$ 100	\$ -	\$ 158		\$ 223	\$ 302	\$ 641	\$ 339
1235	102	MDR-TB, retreatment	Continuation	\$ 46	\$ 14	\$ 212	\$ 84	\$ -	\$ -	\$ -	\$ 420	\$ 1,500	\$ 2,000	\$ 500
1236	103	DS-TB, new	Intensive	\$ 23	\$ 40	\$ 180	\$ 212	\$ 34	\$ -	\$ -	\$ 148	\$ 111	\$ 637	\$ 526
1237	104	DS-TB, new	Continuation	\$ 2	\$ 50	\$ 212	\$ 38	\$ 40	\$ -	\$ -	\$ 112	\$ 440	\$ 454	\$ 14
1238	105	DS-TB, new	Continuation	\$ -	\$ 31	\$ 112	\$ 88	\$ 10	\$ -	\$ -	\$ 120	\$ 20	\$ 361	\$ 341
1239	106	MDR-TB, new	Continuation	\$ 88	\$ 19	\$ 680	\$ 79	\$ 20	\$ -	\$ -	\$ 630	\$ 1,000	\$ 1,516	\$ 516
1235	107	MDR-TB, new	Intensive	\$ 44	\$ 17	\$ 444	\$ 112	\$ -	\$ 200	\$ -	\$ 610	\$ 1,500	\$ 2,500	\$ 1,000
1241	108	DS-TB, retreatment	Intensive	\$ 43	\$ 88	\$ 112	\$ 102	\$ -	\$ -	\$ -	\$ 290	\$ 88	\$ 635	\$ 547
1242	109	DS-TB, new	Intensive	\$ 23	\$ 12	\$ 88	\$ 44	\$ -	\$ -	\$ -	\$ 180	\$ 101	\$ 347	\$ 246
1243	110	DS-TB, new	Continuation	\$ 18	\$ 20	\$ 101	\$ 28	\$ -	\$ -	\$ -	\$ 87	\$ -	\$ 254	\$ 254

* Figures in red are estimates based completely on data not-reported by the patient.

Table 2. Indirect costs throughout the TB episode: non-medical costs per guardian, household's time loss and income loss

Household ID	Patient ID	Non-medical guardian costs			Time loss (hours) before Diagnosis (Part IV)		Time loss (hours) during Treatment (Part V)		Reported income loss (US\$) before and during TB episode (Part V)		Welfare payments (US\$)*		Time loss valuation (US\$) throughout the TB episode (input-related approach) Gross		
		Non-medical costs	Nutritional/Food Supplement costs	Relocation Costs	Time loss - per patient (hours)	Time loss per guardian (hours)	Time loss per patient (hours)	Time loss per guardian (hours)	Patient's reported annual income loss (\$)	Household reported annual income loss (\$)	Patient (\$)	Household (\$)	Time loss valuation per patient (\$)	Time loss valuation per guardian (\$)	Time loss valuation per household (\$)
1234	101	\$ 40	\$ 60	\$ -	24	4	400	120	\$ 400	\$ 420	\$ -	\$ -	\$ 509	\$ 149	\$ 658
1235	102	\$ 20	\$ 100	\$ 900	100	0	280	0	\$ 500	\$ 600	\$ 300	\$ 310	\$ 456	\$ -	\$ 456
1236	103	\$ -	\$ -	\$ -	30	0	210	0	\$ 150	\$ 400	\$ -	\$ -	\$ 288	\$ -	\$ 288
1237	104	\$ -	\$ -	\$ -	50	0	420	0	\$ -	\$ 200	\$ -	\$ -	\$ 564	\$ -	\$ 564
1238	105	\$ -	\$ -	\$ -	70	0	190	0	\$ 500	\$ 500	\$ -	\$ -	\$ 312	\$ -	\$ 312
1239	106	\$ 50	\$ 20	\$ 600	120	0	109	0	\$ 700	\$ 750	\$ 300	\$ 350	\$ 275	\$ -	\$ 275
1235	107	\$ 100	\$ 40	\$ 600	100	0	110	0	\$ -	\$ 600	\$ 300	\$ 310	\$ 252	\$ -	\$ 252
1241	108	\$ -	\$ -	\$ -	50	5	220	220	\$ 100	\$ 150	\$ -	\$ -	\$ 324	\$ 270	\$ 594
1242	109	\$ -	\$ -	\$ -	12	0	78	0	\$ 150	\$ 160	\$ -	\$ -	\$ 108	\$ -	\$ 108
1243	110	\$ -	\$ -	\$ -	26	0	500	0	\$ 400	\$ 450	\$ -	\$ -	\$ 631	\$ -	\$ 631

* Annual welfare payments in addition to medical/non-medical expenses reimbursements

Table 3. Direct and indirect costs for the household during the TB episode

Household ID	Patient ID	Case Type	Phase of Interview	Direct costs	Reimbursement of medical expenses and non-medical expenses	Estimated indirect cost (1)*	Estimated indirect cost (2)**	Welfare payments	Direct plus indirect cost (1)* -gross	Reimbursement and welfare payments	Costs net of reimbursement and welfare payments (Total)
1234	101	DS-TB, new	Intensive	\$ 641	\$ 302	\$ 520	\$ 758	\$ -	\$ 1,161	\$ 302	\$ 859
1235	102	MDR-TB, retreatment	Continuation	\$ 2,000	\$ 1,500	\$ 1,620	\$ 1,476	\$ 310	\$ 3,620	\$ 1,810	\$ 1,810
1236	103	DS-TB, new	Intensive	\$ 637	\$ 111	\$ 400	\$ 288	\$ -	\$ 1,037	\$ 111	\$ 926
1237	104	DS-TB, new	Continuation	\$ 454	\$ 440	\$ 200	\$ 564	\$ -	\$ 654	\$ 440	\$ 214
1238	105	DS-TB, new	Continuation	\$ 361	\$ 20	\$ 500	\$ 312	\$ -	\$ 861	\$ 20	\$ 841
1239	106	MDR-TB, new	Continuation	\$ 1,516	\$ 1,000	\$ 1,420	\$ 945	\$ 350	\$ 2,936	\$ 1,350	\$ 1,586
1235	107	MDR-TB, new	Intensive	\$ 2,500	\$ 1,500	\$ 1,340	\$ 992	\$ 310	\$ 3,840	\$ 1,810	\$ 2,030
1241	108	DS-TB, retreatment	Intensive	\$ 635	\$ 88	\$ 150	\$ 594	\$ -	\$ 785	\$ 88	\$ 697
1242	109	DS-TB, new	Intensive	\$ 347	\$ 101	\$ 160	\$ 108	\$ -	\$ 507	\$ 101	\$ 406
1243	110	DS-TB, new	Continuation	\$ 254	\$ -	\$ 450	\$ 631	\$ -	\$ 704	\$ -	\$ 704

* Indirect costs are here estimated as the sum of non-medical guardian cost plus reported household income loss (output-related approach)

** Indirect costs are here estimated as the sum of non-medical guardian cost plus a valuation of household time loss during TB episode using "Human Capital approach"

Table 4: Catastrophic cost determination: indicator 1

Household ID	Patient ID	Household's net direct and indirect costs**	Household Income (HHI)	Catastrophic? (15% of HHI)	Catastrophic? (20% of HHI)	Catastrophic? (25% of HHI)
1234	101	\$859	\$2,200	Yes	Yes	Yes
1235	102	\$1,810	\$1,900	Yes	Yes	Yes
1236	103	\$926	\$4,007	Yes	Yes	No
1237	104	\$214	\$2,050	No	No	No
1238	105	\$841	\$800	Yes	Yes	Yes
1239	106	\$1,586	\$8,200	Yes	No	No
1235	107	\$2,030	\$2,200	Yes	Yes	Yes
1241	108	\$697	\$1,240	Yes	Yes	Yes
1242	109	\$406	\$1,502	Yes	Yes	Yes
1243	110	\$704	\$888	Yes	Yes	Yes

* Figures in red are estimated using PCA on household assets combined with other data sources to estimate income.

**Indirect costs are estimated based on reported or estimated income loss (output-related approach)

Table 5. Catastrophic cost determination: indicator 2

Household ID	Patient ID	Dissaving	Borrow	Sold Property	Household coping cost, total	Catastrophic?
1234	101	\$485	-	-	\$485	Yes
1235	102	-	\$350	-	\$350	Yes
1236	103	-	-	-	-	No
1237	104	-	-	-	-	No
1238	105	-	-	-	-	No
1239	106	-	-	-	-	No
1235	107	\$118	\$68	\$227	\$413	Yes
1241	108	\$50	-	\$50	-	Yes
1242	109	\$100	\$25	-	-	Yes
1243	110	\$244	-	\$125	\$369	Yes

Table 6. Non-respondent analysis

Patient ID	Respondents	Non-Respondents	Significant
Male (%)	58	56	
Age (years)	33	38	**
Pulmonary (%)	82	81	
MDR-TB (%)	11	10	
Total duration (months)	8	7	*
Retreatment (%)	17	6	***
HIV+ (%)	11	10	

Notes: *p<0.05, ** p<0.01, *** p<0.001.

Annex 2: Estimating income based on asset questions: A Practical Example in Ethiopia

We identified a recent household survey in Ethiopia, the 2013-2014 Ethiopian Socioeconomic Survey, Household Questionnaire that is nationally representative and asks questions on household income, ownership of household assets and dwelling characteristics. Through the World Bank's Microdata Catalog, we were able to download this dataset and begin the analysis.

The first step was to see which factors are most predictive of disposable (labour) income (i.e. income net of taxes). This step should be undertaken during survey development so that the Patient Cost survey can include several asset questions that are shown to be predictive of income in the country. In this example, these were having 1) a flush toilet, 2) piped water, 3) a mattress, 4) a radio, 5) a cellphone, 6) a wristwatch, and 7) a blanket.

Once the questions are selected, we use a regression equation to show the relationship between these questions and reported household income. A similar method has been used to link assets to household income and expenditure in Vietnam.¹ The resulting coefficients of this regression will be used to predict household income for respondents in the Patient Cost Survey. Our prediction equation for Ethiopia is:

$$\hat{Y}_j = 111 + 187(\text{Flush Toilet}) + 202(\text{Piped Water}) + 13(\text{Mattress}) + 58(\text{Radio}) + 28(\text{Cell Phone}) + 51(\text{Wrist Watch}) + 11(\text{Blanket})$$

where \hat{Y}_j is total income in household j .

In our Patient Costs survey, if a respondent has all of these characteristics in their household they would be assigned an annual household income of US\$ 663. If they had only a blanket, cell phone, and wristwatch they would be assigned a household income of US\$ 201 per year.

1. Hoa NB, Tiemersma EW, Sy DN, et al. Household expenditure and tuberculosis prevalence in VietNam: prediction by a set of household indicators. *Int J Tuberc Lung Dis.* Jan 2011;15(1):32-37.

Annex 3 Consent form

Introduction to the patient:

My name is (name). The organization I am working for, (name of organization), is interested in the costs that people face when they are treated for TB as well as the costs faced while seeking health care before the diagnosis of TB.

The information that you choose to share will be used for research purposes. It will be shared with other researchers for further analysis and published, but all your personal information will first be deleted in order to ensure full confidentiality.

It is important for you to understand that your participation in this study is completely voluntary. We would be really grateful if you would agree to participate in this study, but do feel free to decline. If you decline, there will be no consequence for you and you will receive all the care and treatment you need at the health facility as usual. If you decline to participate you will not lose any benefit that you are entitled to such as receiving care and support that is provided at the clinic.

If you decide to participate, I would like to stress that you will not receive any reimbursements for the costs that you report on in this interview.

If you choose to participate in this study, you may still withdraw from the study at any stage without giving any explanation for your withdrawal. Your answers will be kept confidential. At some point I will ask you about your personal income and the income of your household. We will NOT provide this information to any tax or welfare authorities, even after the study has been completed.

In charge of this study is the Principal Investigator: (name, address, email). The outcome of this study will be disseminated in an open source journal and you may request a copy from the principal investigator.

This survey will take approximately 60-90 minutes.

Question	Answer categories (circle appropriate number or fill answer on the answer line)		Action for interviewer	Variable name
Do you have any questions?			Answer patient's questions	Add qu
28. Do you want to participate?	Yes No, because:	1. Language not good enough 2. Time constraint 3. Not comfortable 4. Other, specify:	Yes → Thank you! Go to interview No → End the interview here having filled part I from patient card	quest nquest

Patient signature _____ (A duplicate of this signed questionnaire should be offered to the patient)

Note: sections in **red font** should be adapted to local situation

Patient registration number in facility TB register: _____ Questionnaire number (District No - Facility No - Patient No): ____-____-____

Part I. Patient information to be obtained from TB treatment card before interview			
Question	Answer categories (circle appropriate number or fill answer on the answer line)	Action for interviewer The questions in part I are not part of the interview and should be pre-filled before the interview	Variable name (This column does not require translation nor adaptation)
1. Date of Interview	(Day/month/year)/...../.....		Date_interv
2. Name of Province		Provin_interv
3. Name of District		Distr_interv
4. Place of interview (facility name)		Facilt_interv
5. Interviewer Name		Facil_name_interv
6. Category of treating facility	1. Public primary health care facility 2. Public hospital 3. NGO/charitable health center or hospital 4. Private clinic or hospital 5. Other _____	The "treating facility" is the place where the patient's treatment card is kept	Facility
7. Name of the patient			Patient
8. Sex	1. Male 2. Female	Circle appropriate number or fill answer on the answer line	Sex
9. Age of patient:	____years		Age
10. Date of first bacteriological TB test	(Day/month/year)/...../..... not done or unknown		Date_test
11. Bacteriological TB test used	1. Smear microscopy: not done, done-positive, done negative 2. Culture: not done, done-positive, done negative 3. Molecular test (such as Xpert MTB/RIF): not done, done-positive, done negative		Bc_ss Bc_c Bc_xpert
12. Date of diagnosis	(Day/month/year)/...../.....		Date_diagn
13. Place of diagnosis	1. Public primary health care facility 2. Public hospital 3. NGO/charitable health center or hospital 4. Private clinic or hospital 5. Other _____		Place_diagn

Patient registration number in facility TB register: _____

Questionnaire number (District No - Facility No - Patient No): ____-____-____

14. Type of TB	1. Pulmonary, bacteriologically confirmed 2. Pulmonary, bacteriologically unconfirmed 3. Extra-pulmonary		<i>tb-type</i>
15. Drug susceptibility test done (with result)?	1. Yes 2. No/unknown	<i>The answer "yes" means the patient has submitted a sample for either a rapid test such as GeneXpert, LPA or for culture/DST, or both. If no, skip to question 18</i>	<i>dst</i>
16. If yes, with what test	1. Gene Xpert MTB/Rif: yes/no/unknown 2. LPA: yes/no/unknown 2. Culture with DST: yes/no/unknown 4. Other: yes/no/unknown	<i>Circle the result, several answers are possible.</i>	<i>dst_xpert dst_lpa dst_cu dst_oth</i>
17. If yes, drug susceptible results	1. Rif-resistant 2. MDR-TB 3. Non Rif-resistant/MDR, DR-TB 4. Non Rif-resistant/MDR, DS-TB 5. Unknown	<i>Provide the answers for each test. Possible options are shown here.</i>	<i>dst_rr dst_mdr dst_nrr_dr dst_nrr_ds dst_unk</i>
18. On MDR-TB treatment	1. Yes 2. No		<i>mdr</i>
19. Treatment regimen prescribed	1. 2HRZE/4HR 2. Other first line regimen: _____ 3. Second line standardised regimen: _____ 4. Second line individualized regimen: _____		<i>regimen regimen_other regimen_sld regimen_sld_ind</i>
20. Total duration of planned treatment from start	_____ months intensive _____ months continuation		<i>Duration_tt_int Duration_tt_cont</i>
21. Treatment registration group	Not MDR 1. 1 st line, new 2. 1 st line, relapse 3. 1 st line, re-treatment after loss to follow-up 4. 1 st line, re-treatment after failure MDR 5. MDR, new (initial MDR) 6. MDR, relapse	<i>If "Other" (answer 10), exclude from the study</i>	<i>register</i>

Patient registration number in facility TB register: _____ Questionnaire number (District No - Facility No - Patient No): ____-____-____

	7. MDR, re-treatment after loss to follow-up 8. MDR, re-treatment after failure of first treatment with 1st-line drugs 9. MDR, re-treatment after failure of retreatment regimen with 1st-line drugs 10. Other , specify:		
22. Start date of current TB treatment	(Day/month/year)/...../.....		Start_dstb
23. The patient is currently in intensive or continuation treatment phase?	1. Intensive phase, ____ weeks of phase completed 2. Continuation phase, ____ weeks of phase completed	<i>If patient has completed less than 2 weeks of the current treatment phase, exclude, or postpone interview. Interview takes place after a minimum 2 weeks have been completed.</i> <i>Intensive phase for MDR-TB regimens is the initial treatment period which includes an injectable drug (usually 4 to 8 months).</i>	Phase
24. Type of treatment support/supervision; DOT or self-administered treatment?	1. DOT in both the intensive and the continuation phase 2. DOT in intensive phase and self-administered treatment in the continuation phase 3. Self-administered treatment in both the intensive and the continuation phase 4. Other _____ 5. Not known	<ul style="list-style-type: none"> As indicated in the treatment card, or as per the policy in the treating facility if not written on treatment card. The patient will be asked about DOT or self-administered treatment later in the interview. If self-administered treatment in both the intensive and the continuation phase, skip to question 26 	Drug_admin
25. If DOT, who is the current DOT provider/supporter?	1. Health facility 2. Community health worker/volunteer 3. Workplace 4. Family member 5. Other _____	As indicated in the treatment card. The patient will be asked about DOT supported later in the interview.	Drug_admin_type
26. HIV status (as indicated on treatment card)	1. positive 2. negative 3. not tested 4. unknown	As indicated in the treatment card.	Hivstatus
27. If hospitalized at the time of interview, when is the planned date for discharge?	(Day/month/year)/...../..... Not known	<i>If ambulatory treatment has not yet started, questions in Part V referring to ambulatory care costs cannot be answered. For such a person, the cost of ambulatory treatment will be extrapolated</i>	Discharged

Patient registration number in facility TB register: _____

Questionnaire number (District No - Facility No - Patient No): ____-____-____

		<i>from other patients' data.</i>	
28. Currency used in interview:	<i>report type of currency, e.g. USD</i>	<i>Currency</i>

Patient registration number in facility TB register: _____

Questionnaire number (District No - Facility No - Patient No): ____-____-____

Part II. Informed consent

Introduction to the patient:

My name is (name). The organization I am working for, (name of organization), is interested in the costs that people face when they are treated for TB as well as the costs faced while seeking health care before the diagnosis of TB.

The information that you choose to share will be used for research purposes. It will be shared with other researchers for further analysis and published, but all your personal information will first be deleted in order to ensure full confidentiality.

It is important for you to understand that your participation in this study is completely voluntary. We would be really grateful if you would agree to participate in this study, but do feel free to decline. If you decline, there will be no consequence for you and you will receive all the care and treatment you need at the health facility as usual. If you decline to participate you will not lose any benefit that you are entitled to such as receiving care and support that is provided at the clinic.

If you decide to participate, I would like to stress that you will not receive any reimbursements for the expenses that you report on in this interview.

If you choose to participate in this study, you may still withdraw from the study at any stage without giving any explanation for your withdrawal. Your answers will be kept confidential. At some point I will ask you about your personal income (revenue) and the income of your household. We will NOT provide this information to any tax or welfare authorities, even after the study has been completed.

In charge of this study is the Principal Investigator: (name, address, email). The outcome of this study will be disseminated in an open source journal and you may request a copy from the principal investigator.

This survey will take approximately 60-90 minutes.

Question	Answer categories (circle appropriate number or fill answer on the answer line)		Action for interviewer	Variable name
Do you have any questions?			Answer patient's questions	Add_qu
29. Do you want to participate?	Yes No, because:	1. Language not good enough 2. Time constraint 3. Not comfortable 4. Other, specify:	Yes → Thank you! Go to interview No → End the interview here having filled part I from patient card This form should be signed by the child under 18 and guardian.	quest nquest

Patient signature _____ (A duplicate of this signed questionnaire should be offered to the patient)

Patient registration number in facility TB register: _____ Questionnaire number (District No - Facility No - Patient No): ____-____-____

Inclusion or exclusion			
Question	Answer categories (circle appropriate number or fill answer on the answer line)	Action for interviewer	Variable name and data entry boxes
30. Decision about inclusion or exclusion	1. Included 2. Excluded	If included, skip to question 32	Incl
31. If excluded, reason for exclusion	1. No informed consent 2. Treatment registration group is "other" (answer 10 in question 21)	After completing this question, the survey is completed for this patient excluded from the survey.	Incl_y
32. Interviewee identity	1. Patient 2. Guardian 3. Other (please name) _____		Interviewee

Checklist for which parts of the questionnaire to fill for different treatment categories						
Answer to question 20	Answer to question 22	Treatment category and treatment phase at time of interview	Questionnaire part III (tick when filled)	Questionnaire part IV (tick when filled)	Questionnaire part V (tick when filled)	Supervisor check
		Not MDR				
1	1	First line, new case, interviewed in the intensive treatment phase	Do not fill	Filled <input type="checkbox"/>	Filled <input type="checkbox"/>	
1	2	First line, new case, interviewed in the continuation treatment phase	Do not fill	Do not fill	Filled <input type="checkbox"/>	
2-4	1 or 2	First line, relapse or retreatment	Filled <input type="checkbox"/>	Do not fill	Filled <input type="checkbox"/>	
		MDR				
5	1	MDR, new case, , interviewed in the intensive treatment phase	Do not fill	Filled <input type="checkbox"/>	Filled <input type="checkbox"/>	
5	2	MDR, new case, interviewed in the continuation treatment phase	Do not fill	Do not fill	Filled <input type="checkbox"/>	
6-9	1 or 2	MDR, relapse or re-treatment	Filled <input type="checkbox"/>	Do not fill	Filled <input type="checkbox"/>	

Patient registration number in facility TB register: _____

Questionnaire number (District No - Facility No - Patient No): ____-____-____

Part III. Overview of TB treatments before current treatment (for re-treatment cases only) <i>This part is to be filled if patient is on first line re-treatment and MDR re-treatment cases only! If new case (MDR or non-MDR treatment): skip to section IV.</i>			
33. How many times have you been treated for TB before the current treatment, including completed as well as non-completed treatments?	_____ times	For each treatment, fill details below.	Pretrt
First treatment			
34. Which year were you treated for <i>the first time</i> for TB?	_____		Pretrt_1
35. Where were you treated?	1. Public primary health care facility 2. Public hospital 3. NGO/charitable health center or hospital 4. Private clinic or hospital 5. Other	<i>Let's say that someone had TB when they were 22 years old, then were cured, then got TB again when they were 40 years old. Here we are asking about treatments around the age of 40, not the treatment when s/he was 22 years old.</i>	Pretrt_1_facil
36. Was it first line or MDR-TB treatment?	1. First line TB treatment 2. MDR-TB treatment 3. Unknown	Explain to patient that "First line means standard treatment for non-MDR TB in your country"	Pretrt_1_type
37. How many months of treatment did you complete:	__ months		Pretrt_1_nmths
38. Were you hospitalized during this treatment? If yes, for how long in total?	1. Yes, for __ days 2. No		Pretrt_1_hosp
Second treatment			
39. Which year were you treated for <i>the second time</i> for TB?	_____		Pretrt_2
40. Where were you treated?	1. Public primary health care facility 2. Public hospital 3. NGO/charitable health center or hospital 4. Private clinic or hospital 5. Other		Pretrt_2_facil
41. Was it first line or MDR-TB treatment?	1. First line TB treatment 2. MDR-TB treatment 3. Unknown	Explain to patient that "First line means standard treatment for non-MDR TB in your country"	Pretrt_2_type

Patient registration number in facility TB register: _____

Questionnaire number (District No - Facility No - Patient No): ____-____-____

42. How many months of treatment did you complete:	__ months		Pretrt_2_nmths
43. Were you hospitalized during this treatment? If yes, for how long in total?	1. Yes, for __days 2. No		Pretrt_2_hosp
Third treatment			
44. Which year were you treated for <i>the third time</i> for TB?	_____		Pretrt_3
45. Where were you treated?	1. Public primary health care facility 2. Public hospital 3. NGO/charitable health center or hospital 4. Private clinic or hospital 5. Other		Pretrt_3_facil
46. Was it first line or MDR-TB treatment?	1. First line TB treatment 2. MDR-TB treatment 3. Unknown	Explain to patient that "First line means standard treatment for non-MDR TB in your country"	Pretrt_3_type
47. How many months of treatment did you complete:	__ months		Pretrt_3_nmths
48. Were you hospitalized during this treatment? If yes, for how long in total?	1. Yes, for __days 2. No		Pretrt_3_hosp

Part IV - Costs before the current TB treatment (filled for new cases in intensive phase only)

- New cases in intensive phase, non-MDR TB treatment, as well as those on MDR-TB treatment.
- For retreatment case or new case interviewed in the continuation phase: skip to Part V

Out-of-pocket expenditure, reimbursements and time loss before and during TB diagnosis (before start of TB treatment)

Question	Answer categories (check all that apply or fill answer on the answer line)	Instructions and actions for interviewer	Variable names/codes
49. For this episode of TB, when did you first experience symptoms of TB of this TB episode?	Weeks before treatment started: _____	First construct a timeline of events, either starting with the first TB symptom, or start with time of TB diagnosis and work backwards. Use the locally adapted calendar with main seasonal events that the patient can relate to and use as a reference point for timing. To help the patient remember when the illness started, you can ask which TB symptom was first experienced, after having probed for cough, weight loss, chest pain, night sweats. If there is a problem defining the difference between TB symptoms and other health problems, ask which symptom led the patient to seek care, then ask when that symptom first occurred or became worse and started to worry the patient.	sympt
50. Before your TB treatment started at this facility, from which of the following types of facilities did you seek care or advice for symptoms of the current illness (including hospitalizations; several facility types can be mentioned)? How many weeks before starting TB treatment in the current facility did you visit each of these providers?	1 st visit, provider type <input type="checkbox"/> Weeks before treatment started: _____ 2 nd visit, provider type <input type="checkbox"/> Weeks before treatment started: _____ 3 rd visit, provider type <input type="checkbox"/> Weeks before treatment started: _____ 4 th visit, provider type <input type="checkbox"/> Weeks before treatment started: _____ 5 th visit, provider type <input type="checkbox"/> Weeks before treatment started: _____ 6 th visit, provider type <input type="checkbox"/> Weeks before treatment started: _____ 7 th visit, provider type <input type="checkbox"/> Weeks before treatment started: _____ 8 th visit, provider type <input type="checkbox"/> Weeks before treatment started: _____ 9 th visit, provider type <input type="checkbox"/> Weeks before treatment started: _____	Enter in chronological order, using one of these provider categories for each visit, and entering how many weeks before TB treatment start each visit was. Also report on table below. 1. Dispensary 2. Health centre 3. Public hospital 4. Pharmacy / Drugstore 5. Herbalist / traditional practitioners 6. Private clinic 7. Private hospital 7. Community Health Worker 8. Other facility:.....	Firstvisit Secondvisit Etc... Firstvisweeks Secvisweek Etc
51. How much money and time did	• See table below, and ask for each item		

<p>you spend for each of these visits before you were diagnosed with TB, including the visit when you actually received your diagnosis?</p>	<ul style="list-style-type: none"> • Fill one line per visit • For all that don't apply, mark/select NA • If there were payments for an item, but the patient cannot remember the amount, mark NR • Add more rows if more visits were made before diagnosis of TB! <p>Explanation of table headings:</p> <p>Visits: Includes outpatient visits as well as hospitalizations. Should be filled in chronological order, 1st visit=visit 1.</p> <p>Type of provider: fill in provider type according to categories in question 50 where patient sought treatment or advice.</p> <p>Travel time: Hours or days spent to travel to and from facility</p> <p>Time spent for visit: Fill in hours for outpatient visits and days for hospitalizations</p> <p>Day charge: Fees for hospital days. Only for hospitalizations, and <u>only to be filled if not covered by the cost items below (consultation fee, radiography etc.)</u></p> <p>Consultation fee: Other charges, not covered under day charge, including direct payment to health care staff</p> <p>Radiography and other imaging: out-of-pocket payments for imaging investigation (x-rays, CT-scan, ultrasound), TB-specific and other</p> <p>Lab test fees: out-of-pocket payments for all tests, TB specific and others</p> <p>Other procedures: out-of-pocket payments for biopsy, bronchial lavage etc. but not surgery unrelated to TB</p> <p>Medicine fees: Any medicine (TB or other) prescribed before TB was diagnosed under NTP</p> <p>Other, including nutritional supplements: any other treatments, such as nutritional supplements medically indicated</p> <p>Travel: out-of-pocket payments for travel to the facility (does not include income loss), for both patient and any household member.</p> <p>Food: out-of-pocket payments for additional food bought in relation to travelling the health care visit, and during visit or hospitalization, for both patient and any household member</p> <p>Other, including accommodation: includes out-of-pocket payments related to renting a room/bed during health care visits, and any other non-medical payments related to health care visit, for both patient and any household member</p> <p>Health insurance reimbursement: amount reimbursed to patient through medical insurance (private or social security) so far, does not include expected future reimbursement</p> <p>Out-of-pocket payments (gross): Direct payment made to health-care providers by individuals at the time of service use, i.e. excluding prepayment for health services – for example in the form of taxes or specific insurance premiums or contributions. It is calculated as the sum of direct medical (A) and direct non-medical (B) costs. If patient cannot remember the details of costs above, ask for the total out-of-pocket payments of the visit, hospitalization.</p> <p>Out-of-pocket payment (net): medical and non-medical out-of-pocket payments minus reimbursements. These net payments: should be calculated by supervisor after the interview. Not to be calculated during the interview.</p>
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Patient registration number in facility TB register: _____

Questionnaire number (District No - Facility No - Patient No): ____-____-____

Visit	Type of provider (see list)	Travel time Days: Hours:		Time spent for visit Days: Hours:		Medical out-of-pocket payments, (Total per visit) (A)							Non-medical out-of-pocket payments, (Total per visit) (B)				Out-of-pocket payments (A+B) (Gross)	(C)	Out-of-pocket payments per stay (A+B-C) (Net)
		Day charges (for hospitalizations only) A1	Consultation fee A2	Radio-graphy and other imaging A3	Lab tests A4	Other procedure A5	Medicines A6	Other, incl. nutritional supplements A7	Medical payments, total ΣA1-7	Travel B1	Food during health care visit or hospital stay B2	Other, including accommodation B3	Non-medical out-of-pocket payments (Total) ΣB1-3	Total out-of-pocket payments (ΣA1-7) + (ΣB1-3)	Health insurance reimbursement				
1 st		D: H:	D: H:																
2 nd		D: H:	D: H:																
3 rd		D: H:	D: H:																
4 th		D: H:	D: H:																
5 th		D: H:	D: H:																
6 th		D: H:	D: H:																
7 th		D: H:	D: H:																
8 th		D: H:	D: H:																
9 th		D: H:	D: H:																
10 th		D: H:	D: H:																

Total time spent	ΣD: ΣH:	ΣD: ΣH:
<div> <div>Medical out-of-pocket payment, total</div> <div>ΣA</div> </div>		
<div> <div>Non-medical out-of-pocket payment, total</div> <div>ΣB</div> </div>		
<div> <div>Gross out-of-pocket payment, total</div> <div>ΣA+B</div> </div>		
<div> <div>Reimbursements, total</div> <div>ΣC</div> </div>		

Patient registration number in facility TB register: _____

Questionnaire number (District No - Facility No - Patient No): ____-____-____

Net out-of-pocket payment (A)+(B)-(C), total

Part V. Cost during current TB/MDR-TB treatment (to be filled for all patients)
For patients in continuation phase ask for hospitalization and visits in the continuation phase only.

Question	Answer categories (check all that apply or fill answer on the answer line)	Instructions and actions for interviewer	Variable name/code
52. Are you currently hospitalized?	1. Yes 2. No	If yes, the cost data collected applies to the first row of the table question 54	Hosp
53. Have you been previously hospitalized <u>during your current TB treatment phase</u> and because of TB? If yes, how many times?	1. Yes ____ Times 2. No	<p>1. <i>Concerns only hospitalization during the current treatment phase: For patients in continuation phase, ask only for hospitalization in this phase.</i></p> <p>2. <i>Does not include hospitalization before the current TB treatment started:</i></p> <ul style="list-style-type: none"> • <i>For new cases, hospitalizations prior to TB treatment started should be filled in part IV.</i> • <i>For retreatment cases, hospitalization during previous treatments should be filled in part III.</i> <p><i>If answer to both question 53 and 52 are "no", then skip to question 55</i></p>	Hosp_prev
54. About how much money and time did you spend for each of these hospitalizations?	<ul style="list-style-type: none"> • See table below, and ask for each item. Fill one line per visit. • For all that don't apply, mark/select NA • If there were payments for an item, but the patient cannot remember the amount, mark NR <p>Explanation of table headings:</p> <p>Type of hospital: fill in provider type according to categories in question 6</p> <p>Number of days hospitalized: includes outpatient visits as well as hospitalizations. Should be filled in chronological order</p> <p>Day charges: total fees for hospital days for whole hospitalization in total. Only to be filled if not covered by the cost items below)</p> <p>Consultation fee: other charges, not covered under day charge, including direct payment to health care staff</p> <p>Radiography and other imaging: any imaging investigation (x-rays, CT-scan, ultrasound), TB-specific and other</p> <p>Lab test fees: includes all tests, TB specific and others, including cost of transporting samples, if paid by patient</p> <p>Other procedures: includes biopsy, bronchial lavage, etc. but not surgery unrelated to TB</p> <p>Medicine to treat TB: fees for TB medicines only, bought inside or outside hospital</p> <p>Other medicines, including nutritional supplements: any other medicine, including nutritional supplements</p> <p>Out-of-pocket payments (gross): It is the sum of out-of-pocket medical and non-medical. If patient cannot remember the details of payments above, or has a hospital bill for all costs combined, ask for the total out-of-pocket payment for the hospitalization.</p> <p>Out-of-pocket payment (net): sum of medical and non-medical out-of-pocket payments minus reimbursements. These net payments: should be calculated by supervisor after the interview. Not to be calculated during the interview.</p> <p>Travel: out-of-pocket payment for travel to the facility (does not include income loss), for both patient and any household member.</p> <p>Food: out-of-pocket payment for food bought in relation to travelling to and during the hospitalization, patient and household member.</p> <p>Other, including accommodation: payments related to renting a room/bed during health care visits, and any other non-medical expenses for patient and</p>		

Patient registration number in facility TB register: _____

Questionnaire number (District No - Facility No - Patient No): ____-____-____

household member.

Health insurance reimbursement: amount reimbursed to patient so far, does not include expected future reimbursement

				Medical out-of-pocket payments, (Total per stay) (A)								Non-medical out-of-pocket payments, (Total per stay) (B)				Out-of-pocket payments per stay (A+B) (Gross)	(C)	Out-of-pocket payments per stay (A+B-C) (Net)	
Hosp italiz ation	Type of hospital (see list)	Numbe r of days hospita lised	Travel time	Day charge s (total for stay) A1	Consultation fee (total for stay) A2	Radiography and other imaging (total for stay) A3	Lab tests including cost of transporting samples (total for stay) A4	Other procedures, including surgery, biopsy, etc A5	Medicines to treat TB (total for stay) A6	Other medicines, including nutritional supplements (total for stay) A7	Medical payment(Total) ΣA1-7	Travel (total for stay) B1	Food (total for stay) B2	Other (payment for linen, soap, other services & administrat ive) (total for stay) B3	Non- medical out-of- pocket payments (Total) ΣB1-3	Total out- of-pocket payments	Health insurance Reimburse ment		
1 st																			
2 nd																			
3 rd																			
4 th																			
5 th																			
6 th																			
Total hospital days (for income loss)				Σ															
Medical out-of-pocket payments, total											Σ A								
Non-medical out-of-pocket payment, total															Σ B				
Gross out-of-pocket payment																Σ(A+B)			
Reimbursement, total																	Σ C		

Patient registration number in facility TB register: _____

Questionnaire number (District No - Facility No - Patient No): ____-____-____

Net out-of-pocket payment (ΣA)+(ΣB)-(ΣC), total $\Sigma(A+B-C)$ **Costs for DOT and food costs during ambulatory care**

Question	Answer categories (check all that apply or fill answer on the answer line)	Action for interviewer	Variable name
55. On a daily basis, do you currently take your medicines yourself without supervision or support (self-administered) or do you have a treatment supervisor or supporter (DOT)?	1. Self-administered 2. DOT	<ul style="list-style-type: none"> • DOT (Directly observed treatment) visit is for the supervision of daily intake of medicines, i.e, what is done every day. These questions are not referring to less frequent trips to pick up drugs (e.g., weekly), which are explored from question 61 onwards. • This question concerns the treatment phase the patient is currently in • If patient is interviewed in the intensive phase and on DOT skip to question 56 • If patient is interviewed in the intensive phase and on self-administered treatment skip to question 61 • Responses to be validated against treatment card 	Saf Dot
56. If DOT, how many times a week?	(number)	The maximum will be 7 times a week	Dot_n
57. If you are now in the continuation phase, did you take your medicines in the intensive phase yourself without supervision or support (self-administered) or did you have a treatment supervisor or supporter (DOT)?	1. Self-administered 2. DOT 3. Patient is now in the intensive phase	If patient is interviewed in the continuation phase and has been on self-administered treatment both now and in the intensive treatment, skip to question 61 Responses to be validated against treatment card	Saf_int Dot_int

Patient registration number in facility TB register: _____

Questionnaire number (District No - Facility No - Patient No): ____-____-____

58. If DOT, who is the DOT provider/supporter?	1. Health facility 2. Community health worker/volunteer 3. Workplace 4. Family member 5. Other _____	Validated against question 25 in the treatment card	Drug_admin_type_bis
59. If DOT, how long did the last DOT visit take, including travel time and waiting time (total turnaround time)? minutes		Travel_dur_dot
60. What was the cost of transport (return) for the last DOT visit, including parking costs, in total for you and any accompanying household member?			C_travel_dot
61. How much did you spend on food and drinks for the last DOT visit (on the road, while waiting, lunch etc.), in total for you and any accompanying household member?			C_food_dot
Costs of picking up drugs and food costs during ambulatory care			
62. Do you or a household member pick up TB drugs (for self-administered treatment or to bring to your DOT supervisor/supporter)?	1. Yes. 2. No	<i>This does not concern DOT visits, which should be recorded in questions 57-60, but should be filled if patient or other household member picks up drugs for either bringing to DOT provider or for self-administered treatment. If patient is on DOT and patient or household member is not picking up drugs to bring to DOT provider then the answer is no. If no, skip to question 69</i>	4drug
63. If yes, how often do you or a household member pick up TB drugs in the current treatment phase?	Every week Every 2 weeks Every month Other _____		4drug_n
64. Was there a fee paid to the DOT provider?	1. Yes If yes, amount: _____ 2. No		C_4drug

Patient registration number in facility TB register: _____

Questionnaire number (District No - Facility No - Patient No): ____-____-____

65. Where do you or your household member pick up your TB drugs?	1. Dispensary 2. Health centre 3. Public hospital 4. Pharmacy / Drugstore 5. Herbalist / traditional practitioners 6. Private clinic 7. Private hospital 7. Community Health Worker 8. Other facility A:..... 9. Other facility B:.....	If the patient has visited different places, tick the most recent one.	Drug_srce
66. What accommodation cost did you and any accompanying household member have when you last picked up drugs?			C_Lodge_4drug
67. How long did the last visit to pick up drugs take, including travel time and waiting time (total turnaround time)? minutes		visit_dur_4drug
68. What was the cost of transport (return) last time you picked up drugs, including parking costs, in total for you and any accompanying household member?			C_travel_4drug
69. How much did you spend on food and drinks last time you picked up drugs (on the road, while waiting, lunch etc.), in total for you and any accompanying household member?			C_food_4drug

Cost during outpatient visits for medical follow-up (see the doctor or nurse, have tests)

Question	Answer categories (check all that apply or fill answer on the answer line)	Action for interviewer	Variable name
70. How many TB-related medical follow-up visits have you had so far <u>during this treatment phase</u> (to see the doctor or nurse, have follow-up tests, etc.)?	_____ times	This concerns clinical check-up, follow up, and additional visits due to side effects or other TB related issues. It does not include DOT visits or visits to pick up drugs. For patients in the continuation phase, ask only how many visits since	fu

Patient registration number in facility TB register: _____

Questionnaire number (District No - Facility No - Patient No): ____-____-____

		<i>the start of the intensive phase.</i>	
71. How long did the last follow-up medical outpatient visit take, including travel time and waiting time (total turnaround time)? minutes		Travel_dur_fu
72. What was the cost of transport (return) at the last follow-up medical outpatient visit, including parking, in total for you and any accompanying household member?		<i>Cost related to the latest visit. If the interview takes place at the end of such a visit use the costs for the present visit</i>	C_travel_fu
73. What accommodation cost did you have for the last visit, in total, for you and any accompanying household member?		<i>Cost related to the latest visit. If the interview takes place at the end of such a visit use the costs for the present visit</i>	C_lodge_fu
74. What fees did you pay during your last follow-up medical outpatient visit for <u>registration/consultation</u> ?	Registration/consultation fee.....	<i>Cost related to the latest visit. If the interview takes place at the end of such a visit use the costs for the present visit</i>	C_visit_Reg
75. What fees did you pay during your last follow-up medical outpatient visit for <u>radiography and other imaging</u> ?		<i>See table qu. 54 for explanations</i>	C_visit_xray
76. What fees did you pay during your last follow-up medical outpatient visit for <u>tests, TB tests and others</u> ?	Fees for tests.....	<i>Cost related to the latest visit. If the interview takes place at the end of such a visit use the costs for the present visit</i>	C_visit_Test
77. What fees did you pay during your last follow-up medical outpatient visit for <u>other procedures</u> ?		<i>Cost related to the latest visit. If the interview takes place at the end of such a visit use the costs for the present visit</i>	C_visit_nTBtest
78. What fees did you pay at your last follow-up medical outpatient visit for <u>TB medicines</u> , including prescriptions for medicines bought outside the facility?	Drug fees	<i>Cost related to the latest visit. If the interview takes place at the end of such a visit use the costs for the present visit</i>	C_visit_Drug
79. What fees did you pay during your last follow-up medical outpatient visit for <u>other medicines</u> , including nutritional supplements?		<i>Cost related to the latest visit. If the interview takes place at the end of such a visit use the costs for the present visit</i>	C_visit_nTBdrugs
80. What <u>other fees</u> not listed in the previous questions did you pay during your last follow-up medical outpatient visit?	Other fees.....	<i>Cost related to the latest visit. If the interview takes place at the end of</i>	C_visit_Other

Patient registration number in facility TB register: _____

Questionnaire number (District No - Facility No - Patient No): ____-____-____

		<i>such a visit use the costs for the present visit and provide local examples</i>	
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Costs for nutritional/food supplements

81. Do you buy any nutritional supplements <u>outside your regular diet</u> because of the TB illness, for example vitamins, meat, energy drinks, or fruits as recommended by health care staff?	1. Yes 2. No	<i>If no, skip to question 82</i>	<i>Food_diet</i>
82. If yes, how much did you spend on nutritional supplements in the past week approximately?			<i>C_food_diet</i>

<p>Time loss for guardians</p> <ul style="list-style-type: none"> <i>Not to be filled if the patient is under 15 years – for children, all questions concerning costs, time spent, income, and income loss in sections IV and V concern cost for the guardian.</i> <i>Note: out-of-pocket costs of transport, food, accommodation for guardian should be included in questions on Part V (tables).</i>

Question	Answer categories	Action for interviewer	Variable name
83. Did somebody in your household accompany you for your last: a) DOT visit b) Visit to pick up drugs (or picked up drugs for you) c) Medical follow up visits d) Hospitalization	1. Yes 2. No 1. Yes 2. No 1. Yes 2. No 1. Yes 2. No	<i>Several responses possible Time loss to be calculated with previous responses by patient</i>	guard
84. If yes, did that person lose an income during that time?	1. Yes 2. No	<i>If several responses in question 82, ask about the latest visit when a household member accompanied</i>	Yloss_guard

Health insurance scheme

Question	Answer categories (check all that apply or fill answer on the answer line)	Action for interviewer	Variable name
85. Do you have any of the following health insurance types?	1. reimbursement scheme 2. medical allowance	<i>To be adapted to locally available schemes</i>	ins1 ins2

Patient registration number in facility TB register: _____ Questionnaire number (District No - Facility No - Patient No): ____-____-____

	3. donor 4. family/community fund 5. Private health insurance 6. Other (specify)		ins3 ins4 ins5 ins6
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Social position			
Question	Answer categories (circle the most appropriate or fill answer on the answer line)	Action for interviewer If patient is under 15 years old, these questions concern the guardian	Variable name
86. What education level did you complete?	1. Not yet started school 2. Not attended school 3. primary school 4. secondary school 5. University 6. graduate school 7. Other Or, total years of schooling: _____	Convert to the number of _____ years If patient is under 15 years, this question is for the guardian.	Edu Edu_other
87. What education level did the head of the household/primary income earner in the household complete?	1. Not yet started school 2. Not attended school 3. primary school 4. secondary school 5. graduate school 6. University 7. Other Or, total years of schooling: _____	Convert to the number of _____ years If patient is under 15 years, this question is for the guardian.	Edu_main Edu_main_oth
88. What is your main occupation?	1. School student 2. Technician 3. Service 4. Factory worker 5. Farmer 6. Government employee 7. Teacher 8. Retiree 9. Homemaker	If patient is under 15 years, this question is for the guardian. <i>This section will be adapted to the local occupation definitions (ref. Statistical dpt/Household survey categories)</i>	Empl_type Empl_oth

Patient registration number in facility TB register: _____ Questionnaire number (District No - Facility No - Patient No): ____-____-____

	10. Unemployed 11. 11. Other (specify)		
89. What was your primary employment, or normal work, or normal other main activity before you contracted TB?	0. Unemployed 1. Formal paid work 2. Informal paid work 4. Retired 5. Student 6. Housework 7. Other (specify): _____	If patient is under 15 years, this question is for the guardian. This refers to the time before TB symptoms developed. Name all options first	Empl_form_prev Empl_oth_prev Automatic check: Empl_*_oth vs Empl_*
Constructing a socio-economic status index with household asset questions. Questions for this section are used to estimate an income range for the indirect cost calculations as well as a measure of household expenditures and income for the denominator of the catastrophic cost measure. Reported income (questions 91 to 95) is the least preferred measure in countries with large informal economy so adapting correctly the questions here is key to estimating household income or expenditures. <i>The PI should design these questions using validated asset scores from the latest socio-economic or demographic and health survey in the country. The appropriate choice of questions is essential. The scoring per patient will be obtained relative that of other patients. The mapping to the quintiles/centiles that can be assigned to the household is based on the asset scores. Answers from the asset questions will be used to produce a "poverty score" for each respondent through component analysis. This statistical procedure weights these questions by their ability to separate individuals into wealth groups.</i> <i>Below are questions that have proved useful predictors of income distribution in (the latest) Cambodia's Household Survey 2010. Principal component analysis was used to assign households to a household income quintile. They appear merely as an example here. Please turn to the PI (and statistician) for adaptation of this section.</i>			
90. What is your usual main source of <u>drinking</u> water?	1. Piped or Bottled 2. Well 3. Other	Other includes all sources that are not from a piped source, bottle, or well. This includes natural spring, borehole, rainwater, etc.	water_source
91. What kind of toilet facilities do you have?	1. Flush toilet 2. Other		flush_toilet
92. Does your household have?	Electricity 1. Yes 2. No Television 1. Yes 2. No Motorcycle 1. Yes 2. No Wardrobe 1. Yes 2. No CD/DVD player 1. Yes 2. No		electricity television motorcycle wardrobe cd_dvd
Income (reported) before contracting TB <i>In countries with large informal economies, answers to these questions should be examined critically and compared to the estimated income based on asset scores (precedent questions)</i>			
93. Were you the person who earned the highest income in your household before you contracted TB?	1. Yes 2. No	If patient is under 15 years, this question is for the guardian.	Empl_main

Patient registration number in facility TB register: _____

Questionnaire number (District No - Facility No - Patient No): ____-____-____

94. How were you usually paid before you contracted TB?	1. bank transferred salary 2. cash 3. in kind 4. cash and in kind 5. not paid	<i>If patient is under 15 years, this question is for the guardian.</i>	Paid_type
95. How many hours a week were you working before you contracted TB?	_____hours	<i>If patient is under 15 years, this question is for the guardian. This refers to the time before TB symptoms developed.</i>	Empl_dur_prev
96. If you were in paid work, how much do you estimate your average net wage or average net revenue from labour related activities (labour income), per month was <u>before you contracted TB</u> ?	1. (net wage) 2. (net labour income)	<i>If patient is under 15 years, this question is for the guardian.</i> <i>In setting with an important informal sector you may not want to explicitly refer to taxes to make sure people are giving the right answer.</i> <i>May be presented in income brackets if difficult for patient to specify.</i> <i>Another alternative approach (not tested yet) –would be to ask the patient how many days he/she would need to work to be able to earn the equivalent of the national poverty line. (benchmark the 1.25\$ a day per capita). The actual income will be calculated based on hours worked per week.</i>	W_pat_pre Inc_pat_pre
97. How much do you estimate the average revenue from labour (income), after tax, of <u>your household</u> is per month, <u>before you contracted TB</u> ?		<i>Refers to all persons in the household</i> <i>In setting with an important informal sector you may not want to explicitly refer to taxes to make sure people are giving the right answer. May be presented in income brackets if difficult for patient to specify.</i>	Inc_hous_pre Welfare_hous_pre Gov_hous_pre Other_hous_pre
Income changes and social consequences			
Question	Answer categories (circle the most appropriate or fill answer on the answer line)	Action for interviewer <i>If patient is under 15 years old, these questions concern the guardian</i>	Variable name
98. What is your current primary employment, or normal work, or normal other main activity?	1. Managers 2. Professionals 3. Technicians and associate professionals 4. Clerical support workers	<i>If patient is under 15 years, this question is for the guardian.</i> <i>(Default classification is ISCO-08)</i>	Empl Empl_oth

	<ul style="list-style-type: none"> 5. Service and sales workers 6. Skilled agricultural, forestry and fishery workers 7. Craft and related trades workers 8. Plant and machine operators, and assemblers 9. Elementary occupations 10. Armed forces 		
99. If you are now in continuation treatment phase, what was your primary employment, or normal work, or normal other main activity in the intensive treatment phase?	<ul style="list-style-type: none"> 1. Managers 2. Professionals 3. Technicians and associate professionals 4. Clerical support workers 5. Service and sales workers 6. Skilled agricultural, forestry and fishery workers 7. Craft and related trades workers 8. Plant and machine operators, and assemblers 9. Elementary occupations 10. Armed forces 	<p><i>If patient is under 15 years, this question is for the guardian.</i></p> <p><i>This refers to the time from TB treatment started to end of intensive phase.</i> <i>(Default classification is ISCO-08)</i></p>	Empl_intens
100. If you were in paid work, how much do you estimate your average net wage or average net revenue from labour related activities (net labour income), per month is <u>now</u> ?	<ul style="list-style-type: none"> 1. (net wage) 2. (net labour income) 	<p><i>If patient is under 15 years, this question is for the guardian.</i></p> <p><i>In setting with an important informal sector you may not want to explicitly refer to taxes to make sure people are giving the right answer.</i></p> <p><i>May be presented in income brackets if difficult for patient to specify.</i></p> <p><i>Another alternative approach (not tested yet) –would be to ask the patient how many days he/she would need to work to be able to earn the equivalent of the national poverty line. (benchmark the 1.25\$ a day per capita). The actual income will be calculated based on hours worked per week.</i></p>	W_pat_tb Inc_pat_tb

Patient registration number in facility TB register: _____ Questionnaire number (District No - Facility No - Patient No): ____-____-____

101. How much do you estimate the average revenue from labour (net labour income), after tax, of your household is per month <u>now</u> ?	(net labour income)	<i>Refers to all persons in the household</i> <i>May be presented in income brackets if difficult for patient to specify.</i>	Inc_hous_tb
102. How many hours per week are you working now?	____ hours	<i>If patient is under 15 years, this question is for the guardian.</i>	Empl_dur_tb
103. If you are now in the continuation phase, how many hours per week were you working in the intensive phase?	____ hours	<i>If patient is under 15 years, this question is for the guardian.</i> <i>This refers to the time from TB treatment started to end of intensive phase.</i>	Empl_dur_intens
104. Approximately how many working days of income have you lost due to your TB illness overall?	... working days before diagnosis of TB (but due to TB disease) AND ... working days after TB diagnosis	<i>Working days of income: e.g., if a patient was not able to work for 5 half days and lost income for these, the number of days lost is 0.5*5=2.5. Report for total TB episode, incl. all days before and after job loss.</i>	lost_tb_pre lost_tb_now lost_tb_tot
105. Did you or your household receive any social welfare payment after you were diagnosed with TB? If yes, what type and amount (after tax) during the last month?	0. No 1. Option 1 ____ per month 2. Option 2 ____ per month 3. Option 3 ____ per month 4. Option 4 ____ per month	<i>If patient is under 15 years, this question is for the guardian.</i> <i>Categories according to the following categories</i> <i>1. Paid sick leave</i> <i>2. Disability grant</i> <i>3. Cash transfer for poor families</i> <i>4. Other cash transfer</i> <i>In setting with an important informal sector you may not want to explicitly refer to taxes to make sure people are giving the right answer.</i>	Welfare_type_TB
106. Do you currently receive vouchers or goods in kind to cope with TB illness? If yes, <u>what estimated amount per month</u>	1. Yes a. Travel voucher: ____ per month b. Food support: ____ per month c. Other, enablers etc ____ per month 2. No	<i>If patient is under 15 years, this question is for the guardian.</i> <i>More than one category allowed.</i> <i>If no, skip to question 107.</i>	Cop_kind

Patient registration number in facility TB register: _ _ _ _ _

Questionnaire number (District No - Facility No - Patient No): _ _ - _ _ - _ _

107. From whom do you receive the voucher/ goods	1. Government 2. NGO 3. Employer 4. Private donation 5. Other, specify	<i>If patient is under 15 years, this question is for the guardian.</i> <i>More than one answer allowed</i>	Cop_kind_srce
108. How many adult and children regularly sleep in your house? (including patient, if variable, at time of diagnosis)	Adult # Children #	<i>This question can be excluded if it is already included in the "Household asset" set of questions adapted from the Socio-economic or Household survey of the country.</i>	Hous_membr
109. How many rooms are there in the house excluding the bathroom?	#		Hous_room
110. Besides yourself, does anyone else of your household receive treatment for TB? If Yes: How many?	1. Yes: _____ person(s) 2. No	<i>If No, go to end question.</i>	Hous_tb
111. Has the TB illness affected your social or private life in any way?	1. No 2. Food insecurity 3. Divorce or Separated from spouse/partner 4. Loss of Job 5. Interrupted schooling 6. Social exclusion 7. Other	More than one category allowed.	Social Social_oth

Patient registration number in facility TB register: _____

Questionnaire number (District No - Facility No - Patient No): ____-____-____

Coping			
Question	Answer categories (circle the most appropriate or fill answer on the answer line)	Action for interviewer If patient is under 15 years, these questions are for the guardian.	Variable name
112. Did you or your household use any savings (cash or bank deposits) to cover costs due to the TB illness?	1. Yes 2.No	If no, skip to question 113	S
113. If yes, how much did you use: a) before TB treatment started? b) In the intensive treatment phase? c) In the continuation treatment phase? d) In total	____ before TB treatment started ____ In the intensive phase ____ In the continuation phase ____	In case the detail by treatment phase is not available, request the total.	S_pre S_int S_cont S_tot
114. Did you borrow any money to cover costs due to the TB illness?	1. Yes 2.No	If No, go to question 119	loan
115. If yes, how much did you borrow: a) before TB treatment started? b) In the intensive treatment phase? c) In the continuation treatment phase?	____ before TB treatment started ____ In the intensive phase ____ In the continuation phase ____ In total		Rcvd_loan
116. From whom did you borrow?	1. Family 2. Neighbors/friends 3. Private bank 4. Cooperative 5. Employer 6. "Unofficial lender" (Black market) 7. Other, specify	Multiple responses allowed. Circle all that are mentioned	Rcvd_loan_srce
117. Are you expected to pay the loan(s) back?	1. Yes 2.No	If no, confirm it is a donation, and skip to question 119	Rcvd_donation
118. Have you started paying back the loan? If yes, when did you start?	1. Yes, before treatment started 2. Yes, during the Intensive treatment phase 3. Yes, during the continuation 4. Phase 5. No	If no skip to question 119	Loan_back

Patient registration number in facility TB register: _____ Questionnaire number (District No - Facility No - Patient No): ____-____-____

119. What is the monthly repayment on the loan, including interest?	1. Amount _____ per month 2. I have not started repayment or interest payment	<i>For informal payments, please tease out the average monthly repayment if any.</i>	<i>C_loan</i>
120. Have you sold any of your property to finance the cost of the TB illness?	1. Yes 2. No	<i>If no, skip to question 125</i>	<i>cop</i>
121. If yes, what did you sell?	1. Land 2. Livestock 3. Transport/vehicle 4. Household item 5. Farm produce 6. Gold/jewelry 7. Other (specify):	<i>Multiple responses allowed. Circle all that are mentioned</i>	<i>Cop_srce</i>
122. If yes, when did you sell property?	1. Before TB treatment started 2. In the intensive phase 3. In the continuation phase	<i>Multiple responses allowed. Circle all that are mentioned</i>	<i>Cop_t</i>
123. How much money did you receive from the sale of all items of your property? a) before TB treatment started? b) In the intensive treatment phase? c) In the continuation treatment phase?	_____ before TB treatment started _____ In the intensive phase _____ In the continuation phase _____ In total		<i>cop_pre cop_int cop_cont cop_tot</i>
124. The assets that you sold, were they previously supporting the family income (or expenditure)? If yes indicate monthly income previously generated by the assets.	1.. Yes (amount): _____ 2. No	<i>In setting with an important informal sector you may not want to explicitly refer to taxes to make sure people are giving the right answer.</i>	<i>yield</i>
125. What is the estimated market value of all the property you sold?	Value: _____		<i>Cop_value</i>
126. Did anyone in your household drop out of school or interrupt schooling to assist the household as a consequence of your TB illness?	1. Yes, _____ persons 2. No	<i>If no skip to question 127</i>	<i>dropschol</i>
127. What were their age and sex and for how long did they drop out?	1. Age: __ Sex: __ Duration: __ months 2. Age: __ Sex: __ Duration: __ months 3. Age: __ Sex: __ Duration: __ months	<i>Fill one line per person who dropped out or interrupted school.</i>	<i>Dropschol_age Dropschol_t Dropschol_sex</i>
128. On a scale of 1 to 5, in which 1 is no impact and 5 is very serious impact, to what extent has the TB illness affected the household financially?	1 = No impact 2 = Little impact 3 = Moderate impact		<i>Ecoimpct</i>

Patient registration number in facility TB register: _____ Questionnaire number (District No - Facility No - Patient No): ____-____-____

	4 = Serious impact 5 = Very serious impact		
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Other members of the household on treatment?			
Question	Answer categories (<i>circle the most appropriate or fill answer on the answer line</i>)	Action for interviewer <i>If patient is under 15 years, these questions are for the guardian.</i>	Variable name
129. Are there any members of your household currently on treatment?	1. Yes (number) 2.No	<i>If no, skip to end of questionnaire.</i>	<i>Member2</i>
130. Category of treating facility for household member(s)	1. Public primary health care facility 2. Public hospital 3. NGO/charitable health center or hospital 4. Private clinic or hospital 5. Other	If more than one additional household member please note separately the answers for each household member.	<i>Facility_member2</i>

Patient registration number in facility TB register: _____ Questionnaire number (District No - Facility No - Patient No): ____-____-____

Thank you for your cooperation! Is there anything you would like to ask or say?			
Comments by Interviewer:			
Date (dd/mm/yyyy):/...../.....	Signature interviewer: