AN EVALUATION OF COSTS borne BY tb-affected HOUSEHOLDS IN (Country name)

study protocol

Principal investigator : xx

V. 13 novembre 2018

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## Abbreviations

DOT directly observed treatment

DTU district TB unit

GF The Global Fund

JATA Japan Anti-Tuberculosis Association

MDR/RR-TB Multi-drug resistant/Rifampicin-resistant tuberculosis

MoH ministry of health

NTP national TB programme

PI principal investigator

PPM public-private mix

PPS probability proportional to size

SDG Sustainable Development Goals

SOP standard operating procedure

SRS simple random sampling

Global Task Force Global task force on TB patient cost surveys

TB tuberculosis

UHC universal health coverage

US CDC United States Centers for Disease Control and Prevention

USAID United States Agency for International Development

WHO World Health Organization

XDR-TB extensively drug-resistant TB

## Definitions

This section has been extracted from *Tuberculosis patient cost surveys a handbook.*

**Catastrophic household health expenditures / Large household health expenditure**. Out-of-pocket payments for health care (for all illnesses, diseases, injuries for all members of the household), exceeding a given fraction (e.g. 25%) of a household’s total household expenditure or income. Beyond the threshold (e.g. 25%), spending on health is considered disproportionate. The focus is on financial hardship due to direct out-of-pocket payments when using health services from any type of provider that may adversely affect living standards and capacity to pay for basic needs (1). The proportion of the population with large household expenditure on health as a share of total household expenditure or income (e.g. greater than 20%) is a measure of financial protection, a key dimension of universal health coverage monitored through Sustainable Development Goal (SDG) indicator 3.8.2, “Lack of financial protection” (3).

**Catastrophic total costs due to TB.** Total costs borne by patients in tuberculosis treatment, exceeding a given threshold (e.g. 20%) of the household’s annual pre-TB income. The focus is on financial and economic hardship due to direct and indirect costs when accessing health care for TB, which may adversely affect living standards and the capacity to pay for basic needs. The percentage of TB patients (and their households) treated in the NTP network, that incur catastrophic total costs due to TB is one of the three top indicators of the End TB strategy.

**Coping**. Borrowing funds or selling assets to finance, for example, health care expenditure.

**Direct costs of seeking TB treatment.** Out-of-pocket payment for TB services plus out-of-pocket payments for non-medical expenses related to obtaining TB services (e.g. transportation, accommodation, etc.) are direct costs, net of any reimbursements.

**Direct costs, non-medical.** Out-of-pocket payments made by TB-affected patient or guardian related to transportation, accommodation, food, nutritional supplements etc., net of any reimbursements.

**Direct costs, medical.** Out-of-pocket payments made by TB-affected patient or guardian for medical services (consultations, tests, medicines, other medical procedures), net of any reimbursements.

**Household**. A small group of persons who share the same living accommodation, who pool some, or all, of their income and wealth and who consume certain types of goods and services collectively, mainly housing and food.

**Health insurance.** A type of insurance providing coverage of medical expenses that result from illness and/or injury. There are various organizational mechanisms to provide health insurance depending on the country.

**Household income.** The amount of money received by household during the reference period in exchange for labour or services, from the sale of goods or property, or as a profit from financial investments.1

**Household expenditure.** Money payments or the incurrence of a liability to obtain goods and services. Expenditure excludes consumption that does not involve market transaction (e.g. home-grown products) and it includes consumption of “durable goods”.

**Household consumption.** Sum of the monetary values of all items (final goods and services) consumed by the household (including home-grown products) during the reference period.

**Indirect costs of care seeking and TB treatment.** Productivity and economic costs of a patient or household incurred as a result of TB health care visits and hospitalization during the TB episode. Indirect costs are estimated using two alternative methods: a) self-reported household income loss net of welfare payments (that is the net effect of income change before, as compared to during, the TB episode) and b) total period of absence in hours multiplied by the hourly wage rate of the absent worker.

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

**Social assistance.** Refers to in-kind or cash transfers, including disability grants, cash transfers for poor or vulnerable populations, or other types of benefits such as food packages or transport vouchers that are non-contributory.

**Social insurance.** A contributory scheme, usually compulsory, that pools funds from individuals and provides benefits to those contributing, in accordance with specified rules, against risk. The benefit is guaranteed through contributions without any type of need- or means-testing.

**Social protection.** An integrated set of policies and programmes (including social assistance, labour market programmes and social insurance) providing minimum income security in the event of illness or other external and unforeseen event, which aims for poverty reduction, and sustainable and inclusive economic growth.

**TB episode.** The period of time from “self-reported onset of TB-related symptoms”, until end of treatment or death. The basic extrapolation technique proposed in this survey assumes 100% treatment completion.

**TB patient cost survey.** Survey of costs faced by TB-affected patients and their households.

**Universal health coverage.** Access for all to necessary health services (including promotion, prevention, treatment, rehabilitation and palliation) without financial hardship.

## Executive summary

Patients with TB often incur large costs related to illness and disability, as well as seeking and receiving health care. Such costs can create access and adherence barriers which can affect health outcomes and increase the risk of disease transmission. These costs also contribute to the economic burden on households. In low- and middle-income countries, patients with TB face costs that, on average, amount to half their annual income (5). TB affects the poorest segment of society disproportionately and the poverty-aggravating effects of TB are therefore gravest for those who are already vulnerable.

The TB strategy, in line with the Sustainable Development Goals, sets three ambitious goals to end the global TB epidemic by 2030: reducing the incidence of TB and mortality by 80% and 90% respectively and the elimination of catastrophic costs for tuberculosis patients and their households. The inclusion of the catastrophic cost indicator is new, reflecting the importance of alleviating the significant financial and economic burden of TB care as a key element of the global strategy.

In your country, [cite previous studies and studies on TB burden]

This study aims to document the magnitude and main determinants of the different types of costs experienced by TB patients (and the households they belong to) in order to guide policies aimed at reducing financial barriers and limiting as much as possible detrimental socioeconomic impact of the disease and to establish a baseline measure and periodic measurements of the percentage of TB patients (and their households) treated within the NTP network and that suffer catastrophic total costs associated with TB.

This is a cross-sectional study. Each patient will need to be interviewed once only and will be required to report on their TB care expenditures and the time they spend seeking and receiving care.

Survey results have the potential to significantly inform policy discussion in two main ways. First, costs can be mitigated by changing approaches to health financing and service delivery, including revisions to health financing policy, insurance plans, fee structures, and models of care. towards a more patient-centered approach. Second, any costs that remain after optimizing approaches to funding and delivering health care can be mitigated through improved social protection measures, in collaboration with social sector stakeholders.

## Background and general considerations

Patients with TB often incur large costs related to illness and disability, as well as seeking and receiving health care. Such costs can create access and adherence barriers which can affect health outcomes and increase the risk of disease transmission. These costs also contribute to the economic burden on households. In low- and middle-income countries, patients with TB face costs that, on average, amount to half their annual income. TB affects the poorest segment of society disproportionately and the poverty-aggravating effects of TB are therefore gravest for those who are already vulnerable.

While direct payments for health care (sometimes called out-of-pocket medical expenditures) are important, lost income is often the dominant contributor to economic hardship for people with TB. Direct non-medical costs, such as for travel, food and nutritional supplements during care, are also significant given an often-protracted health-seeking period, and treatment lasting six-months-to-two-years. To overcome access and adherence barriers, and to minimize the economic burden for TB-affected patients (and their households), it is therefore essential to address direct medical, direct non-medical, and indirect costs. Interventions are needed to address high medical costs, as well as the cost of food, nutritional supplements and transport, as well as lost earnings. Health financing and patient-centred delivery models, as well as social protection mechanisms (such as job protection, paid sick leave, social assistance, or other transfers in cash or kind), need to be considered.

One of the three targets of the End TB Strategy is that no TB patient or their household should face “catastrophic total costs” due to TB, with this target achieved by 2020. This is in line with policy efforts to move health systems closer to universal health coverage (UHC), since the TB epidemic cannot be ended unless general health care access barriers are addressed. However, it should be noted that the TB-specific indicator of “catastrophic total costs due to TB” is different from the “catastrophic health care expenditures” indicator (i.e., health care expenditures for all conditions beyond a defined threshold of a household’s budget or capacity to pay). The latter is one measure of financial protection that is commonly used as an indicator of overall progress towards UHC. The TB-specific indicator differs because it incorporates not only direct medical payments for treatment, which are the sole component in the UHC indicator, but also direct-non-medical payments (such as transportation and lodging charges) and indirect costs, such as income loss. The TB-specific indicator is restricted to a particular population – diagnosed TB patients treated in NTP networks – whereas the “catastrophic health care expenditures” measurement includes health care spending for all household members and for all health conditions. Hence, due to differences in both the concept and the approach to measurement, the indicator of catastrophic total costs due to TB is not comparable to the population-based indicator of catastrophic expenditures.

To measure the End TB Strategy indicator, countries are encouraged to conduct nationally representative surveys, following the methodology described in the *Tuberculosis Patient cost survey a Handbook* that determines the proportion of TB patients with costs that are 20% or more of their annual income on TB care.

### situation analysis in XX

(Justify why this survey is to be in XX)

• Epidemiology of tuberculosis

• Health system and use of care

• Mapping social protection

• Review of Demographic and Health Surveys and Household Income and Expenditure Surveys

• Stakeholder identification

This survey will inform efforts to mitigate the direct and indirect costs of care through the adaptation of models of care and social protection interventions.

The results of a survey of the costs borne by TB-affected patients can significantly support and inform policy discussions in two distinct areas: it is possible to reduce costs by shifting the delivery of health services to a model based on sick, and any residual costs after optimizing health financing and delivery policies can be mitigated by improved social protection measures. The opportunities revealed by a survey of the costs of tuberculosis for patients need to be fully exploited to facilitate policy discussion in both areas and to stimulate engagement of partners from many sectors.

## Objectives

### Primary Objective

The design, aim and methodology of the survey have been adapted from the WHO protocol.

1. To document the magnitude and main drivers of different types of costs incurred by TB patients (and their households) in order to guide policies to reduce financial access barriers and minimize the adverse socioeconomic impact of TB.

2. To determine the baseline and periodically measure the percentage of TB patients (and their households) treated in the NTP network and incurring catastrophic total costs due to TB.

### Secondary objectives

XX – Add if necessary

## Methodology

#### cross-sectional study with retrospective data collection and projection

This study will use a cross-sectional stuy method at the national level with retrospective collection of data and projection, in line with the methodology recommended by the Global Tuberculosis Programme.

Each patient will be interviewed once and we will retrospectively report on costs, time loss, accommodations and ownership of assets during the current phase.

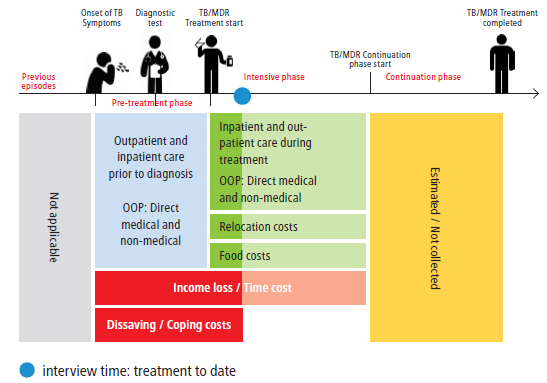
Some patients will be interviewed during the intensive treatment phase and others during the continuation phase of treatment, knowing that the data collection relates to this particular phase only. Patients interviewed during the iIntensive phase only will also report retrospective data on the frequency and duration of care seeking and accessing care (referred to as "utilisation data") and associated expenditures prior to TB diagnosis. Data collected from patients in intensive phase or continuation of treatment will be used to estimate past and future costs for the entire episode of tuberculosis (Figure xx)

This process will simplify sampling and make data collection more efficient, as most patients attending the establishment during the survey period will meet the criteria to participate in the survey. As no follow-up interview is required, this data collection can be done in two or three months in countries with medium to high TB ​​incidence. It should be noted, however, that using cross-sectional sampling and obtaining a longitudinal estimate will impose a number of simplifying assumptions and introduce difficulties in analyzing and interpreting the results.

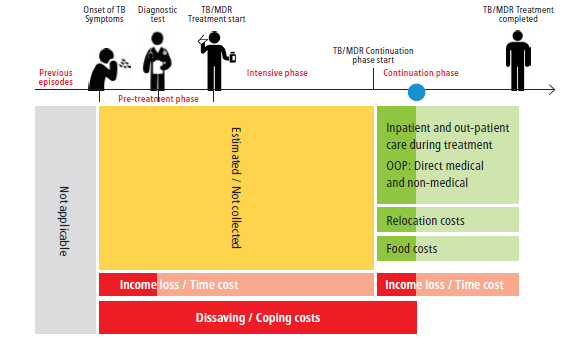
Figure 1 provides an overview of the cross-sectional design and analytical approach on the timing of interviews, retrospective data collection, forward projections and imputations to recreate longitudinal information from one interview per patient only.

Figure 1. Overview of the cross-sectional survey design and analytical approach

The blue dot indicates the interview moment. Darker shades of blue, green and red represent retrospective data collected at the interview. Lighter shades of green and red represent extrapolation of costs into the future. Yellow means costs are estimated based on both information from the interviewed person and imputations based on data from other patients’ data. OOP refers to Out-of-pocket payments.

New cases (first line or MDR-TB treatment): interviewed in intensive phase 

New cases (first line or MDR-TB treatment): interviewed during their continuation phase



*(Source : Figure 3.1 of « Tuberculosis Patient cost surveys : a handbook)*

The instrument has five parts that are illustrated in Figure xx and the content described in xx.

Figure 2. Flow of survey instrument components

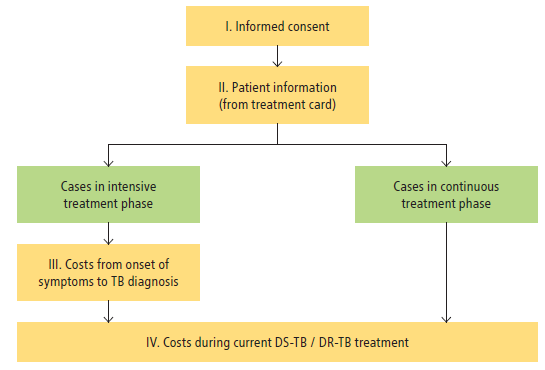


TablE 1. Contenu des quatre composantes de l’instrument d’enquête

|  |  |
| --- | --- |
| STUDY TOOL COMPONENT | CONTENT |
| **Part I** | Patient information to be obtained from TB treatment card before interview (for all eligible patients) |
| **Part II** | Informed consent, inclusion/exclusion criteria, and checklist for which parts of the questionnaire to fill for patients treated under different TB treatment categories and phases (for all patients) |
| **Part III** | Time loss and costs before the current TB treatment  (for new cases interviewed in the intensive phase only) |
| **Part IV** | Time loss, cost and coping during current TB/MDR-TB treatment phase (for all patients) |

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

Information about costs and income loss related to health seeking and diagnostic procedures from the onset of TB symptoms up to the moment the person was registered as a TB patient within the NTP network (Part III) are collected only from new patients either on first or second line treatment, who are interviewed in the intensive phase. This recognizes that it is a considerable challenge for patients to remember events and costs incurred many months prior to the interview. In addition, patients in the intensive phase will also report on costs during the “current” intensive phase (Part IV).

Conversely, for patients who are interviewed in the continuation phase, information collected is limited to costs and time loss experienced during that phase with the exception of one question related to reporting household income at the time of diagnosis.

Information collected in Part III for new cases interviewed in the intensive phase will be used to impute data and estimate costs for patients interviewed in the continuation phase and for re-treatment cases. Similarly, information about costs in the continuation phase collected from patients interviewed in this phase will be used to project continuation phase costs for patients interviewed in the intensive phase.

A more detailed description of the analytical approach follows below.

#### sAMPLING STRATEGY

##### sURVEY POPULATION

The survey population includes all patients (including children accompanied by a guardian) who are receiving drug-sensitive (DS-TB) or multidrug-resistant (MDR-TB) treatment in the clusters sampled. All consenting patients who are on treatment for more than 14 days during the investigation period (eg from xx to xx 2019) will be eligible.

##### inclustion and exclusion criteria

**Inclusion criteria:** The inclusion and exclusion criteria are defined according to the population of interest described in the survey objectives. All patients consecutively enrolled for tuberculosis treatment in a health care facility in the sample (regardless of age and type of tuberculosis, drug-sensitive or drug-resistant) are eligible to participate in the survey, provided they have been at least 14 days the current phase of intensive treatment or continuation of treatment.

**Exclusion criteria:** Newly diagnosed patients who have not started treatment can not participate in the survey.

Patients treated in institutions not connected to the NTP may not be included in the survey, as confirmed tuberculosis cases have not yet started TB treatment or are in the current phase of treatment for less than two weeks. children under 18 unaccompanied by their caretaker.

##### sampling method : random cluster sampling

The districts / municipalities / health center (clusters) were sampled from a national list of XX districts / municipalities / care centers and their selection was proportional to the number of new TB case notifications by districts / municipalities / center of care in 2017.

[To be completed according to strategy in XX]

The recruitment of patients will be done randomly. All patients presenting consecutive follow-up visits until the required number has been reached.

##### sample size calculation and sampling process

A number of assumptions need to be made for the sample size calculation, using existing evidence.

Notifications of new TB cases in 2017 were 151,832

**Step 1.** Estimate the true percentage of households experiencing catastrophic total costs associated with TB disease (g). We chose XX, knowing that the proportion of households with catastrophic (medical) expenditures (SDG 3.8.2) was XX% in 20XX (Source Global Health Observatory)

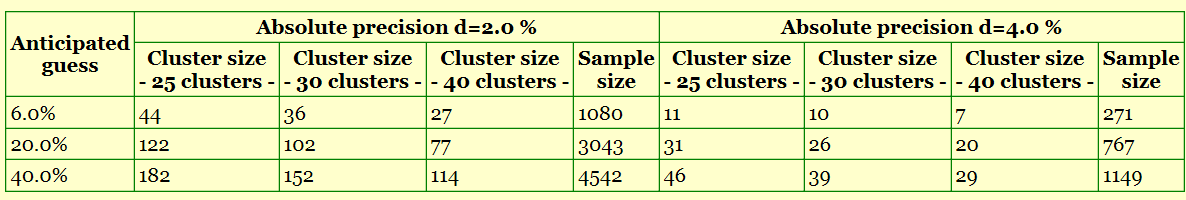
**Step 2.** Decide on the relative precision of the estimate from the survey. We chose 5%

**Step 3**. Estimate the magnitude of the sampling plan effect resulting from the implementation of cluster sampling. We chose 2

**Step 4.** Since the sample represents a significant proportion (5% or more) of the surveyed population of interest (all TB patients treated throughout the NTP network over the course of a year), the The sample size was corrected using a "finite population correction" to account for the gain in accuracy obtained by surveying a larger proportion of the population. We chose XX.

We used the application made available by the Global Tuberculosis Program http://samplesize.herokuapp.com to calculate the sample size and the number of clusters based on these assumptions.

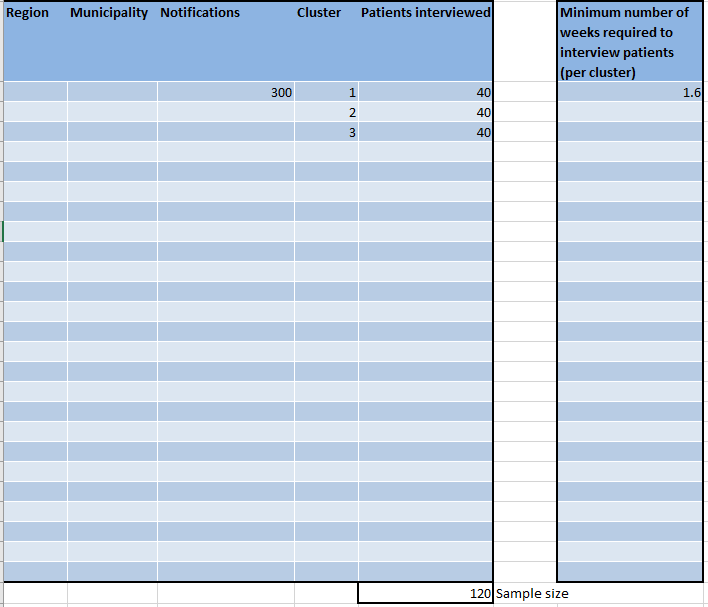
Table 2. Résultat du calcul de l’échantillon de l’enquête (XX)



##### cluster selection step by step

A total of 40 clusters were selected according to a selection xxx. The size of each resulting cluster was 29 patients in each districts / municipalities / health center. The resulting sample size is 1149 patients.

Table 3. final selection of clusters in XX



### Survey planning and implEmentation

#### Data collection

The data collection is done through a structured interview. The time required to conduct an interview using the generic survey instrument is approximately 45 to 60 minutes. Before beginning this interview, the interviewer will have to answer certain questions by consulting the patient's file, which will take him about 15 minutes.

The discussion should preferably take place in a separate space / room for undisturbed maintenance and protection against infection as well as privacy and confidentiality. In all interactions, investigators should respect confidentiality to avoid any consequences or possible modifications to the delivery of care because of the responses provided. Depending on the expected waiting times, patients will be able to be interviewed while waiting to be consulted (making sure they do not lose their place in the queue) or after consultation.

« Name of country» chose to use the use of the electronic questionnaire. The generic questionnaire made available by the Global Tuberculosis Programme has been adapted to the context of xx (Annex 1)

Direct data entry during interviews will be done offline using the e-survey tool, the data will then be uploaded online (multiple questionnaires will be loaded at the same time and an internet connection will only be needed for the last part of this process).

You can access the electronic survey hosted by ONA using an Internet browser or through ODK (Open Data Kit) Collect, a free Android application. You need to have a connection to the network the first time you open the survey. Once loaded, users will no longer need an active connection to the network to access it. If the connection is active, patient responses will automatically be loaded into the database on the web after submission. In cases where the network connection time is limited, it is still possible to fill out the form and the e-survey saves the responses so that they can be sent to the database once the network connection is restored. The database is secure and access is allowed to designated individuals through a username and password.

The generic e-survey contains "go to" instructions and can direct the query to different sections depending on the type of TB respondents and the therapeutic phase (intensive or continuation of treatment) during which they are interviewed. . The electronic questionnaire can be programmed to automatically generate essential cost calculations.

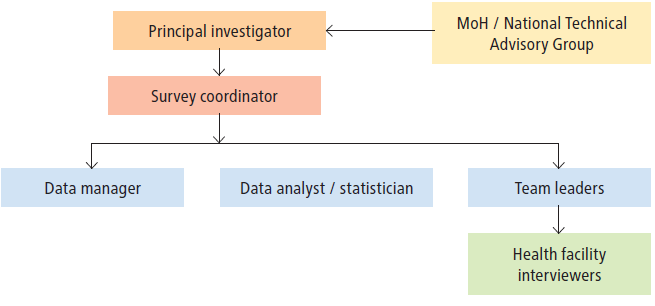
Questions can be displayed in many languages, selected from a drop-down menu.

#### Study team

Organizing and implementing a TB patient cost survey is a significant undertaking and one that requires support from a team. The organization managing and implementing the survey should define the roles and responsibilities of the survey team members during the planning phase.

Figure 3 presents the organigramme of the study team in XX. Details on suggested composition and qualifications of the survey team members are listed in Annex 5.

Figure 3. Organigramme for survey team fot the conduct of TB patient cost survey in XX



Source : adapted from Figure 8.1 of TB patient cost survey : a handbook

Table 4. study team and their role in the study

|  |  |  |  |
| --- | --- | --- | --- |
| **Investigator’s name** | **Role within the study** | **Group/**  **Institution name** | **Country** |
| xx | PI (describe role) |  |  |
| xx | Co-PI (describe role) |  |  |
|  | Co-PI (describe role) | PNT |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

##### 4.2.1 Management and supervision

The ultimate responsibility for managing the survey rests with the Ministry of Health, which has established a National Technical Advisory Group that also includes representatives from other stakeholders beyond the TB and health fields (XXXXX in XX), and international partners (xx, xx and XX, XX (statistician)), who will provide technical support.

The effective implementation of the survey will be conducted by XXXX, which is a local higher education institution with experience in conducting health facility surveys, for example, an institution conducting epidemiological research, social sciences or health economics. WHO (name of country) has established a contract with this agency, which will report regularly, either directly to the Ministry of Health or to a technical advisory group of that Ministry.

The lead investigator hired XX investigators from XXX (name of institution).

Terms of reference for the investigator are shown in Annex 6.

##### 4.2.2 Set up of standard operating procedures and supervision plan for the survey

Following the experience gained by the first countries implementing the survey, we will develop SOPs in the following areas:

1. SOP for staff operating in health care facilities to ensure the quality of data collection

2. SOP for provincial level coordinators to oversee data quality;

Indicators and benchmarks should be clearly defined in the survey protocol and team leaders and supervisors should be properly trained to take action when target values ​​are not met. Regular supervision will be exercised.

#### Informed Consent

Patients need to be informed in their mother tongue about the purpose of the survey, the confidentiality of the data collected, the duration of interview and their right to withdraw from the survey at any time. After questions to ensure clarity and that the subject has understood the information given, the investigator should obtain the subject’s informed consent. If consent cannot be obtained in writing, non-written consent must be documented.

Before the interview, the investigator should briefly explain the purpose of the study to the patient. He will need to give him time to read and understand the informed consent form (Annex 2). This may require having versions of this form in all local languages. If the patient agrees to participate in the study, the caregiver should ask him to sign the form or the investigator should note that verbal consent has been given. Informed consent forms should be retained and completed by the investigator.

Annex 2 includes the informed consent.

#### compensation for the survey participants

Patients participating in the study will receive XXX compensation for travel or inconvenience caused by the interview.

#### protection of confidentiality

Protection of patient confidentiality is essential. The survey participants are identified from TB registers based on clinical records containing personal identifiers and clinical and other information that can be sensitive and need to protected. The data collection instrument does not have to include a name and other data from which an individual can be identified. Instead the TB register number can be used to allow linkage back to the register and medical records in case that is needed for quality control, validation of data or a collection of treatment outcome data for surveyed patients. An alternative is to create a unique record number for each survey participant, with a key (to be kept in a secure place) allowing it to be linked to the TB register number and personal data.

#### approbation ethique

To implement this study, the protocol will need to be submitted to the following ethical review board committees : XXX , WHO AFRO pour approbation.

#### Study team training

A 2-day training will be conducted prior to the start of data collection (pilot) (Annex 3)

##### 4.7.1 Introduction

Training of staff is important to ensure that the survey is implemented in a standardized way, ensuring valid data and comparability of results. The survey coordinator should organize, participate in and lead parts of the training, and the principal investigator (PI) and other partners may also be involved. There should be a maximum of one-to-three trainers per country.

Everyone involved in the implementation of a TB patient cost study should be systematically trained including specific questionnaire and interviewing training. It is vitally important that all interviewers understand every question and that they then ask it in a standardized way. All interviewers should be assessed for suitability to conduct the interviews. During training, interviewers should practice the questionnaire with each other and in simulated facilities to ensure that they also understand the questions and responses.

The training will take place at XX, in (month) 2019 over 2/3 days (based on past experience of interviewers in care facility surveys and their knowledge of TB and data collection tools online). It will be provided by the principal investigator with the participation of all research assistants (data collectors).

##### 4.7.2 training Objectifs

Interviewers should:

— be aware of ethical issues in performing such interviews

— learn interviewing techniques (such as adequate probing)

— be able to select the appropriate study participants

— be fully familiar with the questionnaire and perfectly master the skip pattern

— understand the indicators used in the questionnaire

— offer feedback to the research officers on any uncertainties or concerns with the

questionnaire or the data collection procedures.

#### 4.7.3 training methodology

During the training, data collectors will practice the questionnaire on each other and in simulated facilities to ensure that they also understand the questions and answers. Investigators will also practice entering data using electronic devices (tablets).

#### 4.7.4 TRAINING DElivErables

Team leaders and survey coordinators should assess the suitability of interviewers to conduct the survey.

Prestations enseignées aux intervieweurs :

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. Put participants at ease and ensure a comfortable environment in which to ask questions.

5. Be familiar with the questionnaire so that questions are asked conversationally rather than formally.

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 item costs. The interviewer should make it as easy as possible for the patient to recall by using local methods of time structuring, for instance using the local calendar and festivities, crop timing or similar to help the interviewee recall the timing of health visits.

7. Understand and be 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 to recall 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).

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. Interviewers should also be clear what counts as TB drugs and what are additional drugs that are prescribed/bought.

#### pilotage de l’enquete

A time-limited pilot survey will be conducted in some of the sampled sites/outside the sample to test the entire process of patient enrollment, interviewing, and data entry. The pilot survey can identify and solve unexpected problems before the survey is launched in all sites, and inform revision of the survey instrument. If no significant problems are encountered during the pilot period, the data collected can be included as part of the survey and contribute to the necessary sample size. Including this data in the full survey should only be done if there is a relatively short time period between the pilot and the start of the official survey.

We will conduct the pilot (ADD DATES) in conjunction with, or shortly after, the survey training

#### Interview place and time required for the interview

The least resource-intensive process involves questionning the patients in the institution where their tuberculosis is managed. The discussion should preferably take place in a separate space / room for undisturbed maintenance and protection against infection as well as privacy and confidentiality. In all interactions, investigators should respect confidentiality to avoid any consequences or possible modifications to the delivery of care because of the responses provided. Depending on the expected waiting times, patients will be able to be interviewed while waiting to be consulted (making sure they do not lose their place in the queue) or after consultation. Another option is to arrange pre-planned interviews in the patient's home, which usually takes longer and costs more for the survey team, but improves patient feasibility and potentially reduces selection biases.

The time required to conduct an interview using the generic survey instrument is approximately 45 to 60 minutes. Before beginning this interview, the interviewer will have to answer certain questions by consulting the patient's file, which will take him about 15 minutes.

#### data collection and management

Each survey participant will be assigned a unique identification number called the Personal Identification Number (PIN), which will be used at all stages of data collection and management. Each patient will be followed using the unique identifier and the patient registration number in the TB register.

Tableau 5. The PIN will be composed of the four following variables

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Cluster number | Health Institution number | Personal identification number | TB register number |
| PIN | ## | ### | ### | ###### |

The data manager is responsible for managing the data collected by the interviewers. This person will need some expertise in the management of survey data or public health research and previous experience in managing data sets would be highly appreciated. The majority of countries that collect data use an online tool (eg, ONA) to manage data directly on this software. In the case of these countries, the data manager should be familiar with the online data collection system and be able to cope with common difficulties and rectify any problem of data collection. Depending on the composition of the survey team, the data manager will generally report to the PI.

Team Leaders oversee the fieldwork done by the survey team to ensure that all activities are performed in full, protocol-based and ethical manner. These will usually be employees of the health facilities in which the survey is being conducted and therefore may not be recruited specifically for the facility. They will have to devote 5% to 10% of their time to the investigation during the fieldwork phases and their cooperation is solicited from the organization in which they are appointed. Team leaders should supervise the work of the interviewers in the facility where they are assigned and ensure that interviews are conducted in an ethical and tactful manner. They will also ensure that recruitment is done in accordance with the protocol, especially for the sampling scheme. If the survey coordinator is not able to visit health facilities regularly for supervision visits, the team leader will be able to provide some of the supervision and prepare supervision reports in his / her absence.

#### Analytical approach

After data cleaning, basic descriptive statistics and cross-tabulations will present the patient population, the use of health care, the tuberculosis management model (place of treatment, number of visits, etc.), demographic data (age, gender, etc.) as well as information on TB treatment (for example, status for drug resistance, treatment phase, diagnostic delay). The reporting standards of the World Tuberculosis Program (2017) will be used as a starting point.

(This section is adapted from TB patient cost survey a handbook)

• **Data collected.** The questionnaire will include information about patients, questions about resource use, time spent seeking and receiving care, direct medical care, direct non-medical and indirect costs, household income (3 measurements, see below) and individuals and coping strategies of these households to cope with costs. To minimize recall bias, patients were only asked about their current treatment phase.

• **Extrapolation.** In accordance with the WHO methodology 7, only one interview was administered per patient at a single point in the episode of the disease (after a minimum of 14 days in the treatment phase). Median direct costs for DS-TB and MDR-TB participants by phase were calculated and used to extrapolate direct costs for the undeclared phase. In the sensitivity analysis, the use of mean values ​​instead of the median is explored.

**a) The estimation of the costs borne by the household during an episode of TB or MDR-TB.**

This cross-sectional study plan requires the calculation of costs. To do this, it is proposed to follow the method advocated by WHO, 2017.

For patients interviewed during their intensive phase of TB or MDR-TB treatment, pre-diagnosis and time-loss costs were also collected. The extrapolation of time and costs in the phase, beyond and until the completion of treatment is done using the median values ​​reported by the other patients in the survey. This allows the diagnosis and treatment costs incurred by patients with TB or MDR-TB to be estimated from the onset of TB symptoms until treatment completion or death.

For tutors (for those who care for the sick), direct but not indirect costs will be added (in line with the WHO methodology, 2017).

**b) Estimation of household incomes**

In addition to the cost data collected at the health center level, we will collect and estimate three alternative measures of living standards for TB-affected households:

• Measure 1: annual household consumption expenditure for TB-affected households (approach in principle the most robust but requiring a battery of questions previously tested)

• Measure 2: "permanent" income estimated from assets owned

• Measure 3: income declared before, during diagnosis and during the interview (less robust measure in the context of an economy such as that in XX)

The reason for collecting several income measures is to allow the results to be compared using the different income measures and to choose the most solid (if possible the measure 1), as advised by the existing literature on this subject. In a context like XX, it is inadvisable to calculate the catastrophic cost indicator using measure 3 (reported income). the method that will prove more robust for this survey in XX, will be used as the main approach and the others in sensitivity analysis. We anticipate that the approach that estimates incomes from annual household consumption will be chosen, taking into account the extent of the informal and agrarian economy in XX.

**c) The estimation of indirect costs** related to loss of income or opportunity cost, has two alternative methods of calculation: the valuation of the time lost by the patient in particular or the actual loss of income received. If "reported income" is a non-robust income measure, indirect costs will be calculated by multiplying "lost" hours by an hourly rate (ie using the "human capital approach »)

1. **Determination of catastrophic costs**

Each household will be given a binary value for whether or not they incurred catastrophic total costs due to TB, as defined by the 20% of annual income threshold. In addition, other cut-offs can be used for sensitivity analyses and for varying thresholds by income quintile. These binary values will allow a calculation of the percentage of TB respondents treated in NTP networks who incurred catastrophic total costs. These percentages may also be reported by income quintile, sex, type of TB, clinic and geographical cluster within countries, if the sample size allows.

**e) Coping strategies for dealing with the disease**

The study also aims to assess the strategy that households affected by TB use to cope with the disease. The correlation between the high total cost of tuberculosis in relation to income and seemingly irreversible coping strategies will be examined.

**f) Social consequences**

The generic survey instrument raises questions about the social consequences of tuberculosis and tuberculosis treatment such as social exclusion, divorce, child drop-out, and so on. These indicators can be more easily understood by policymakers than the concept of catastrophic costs, and a full analysis should therefore include statistics that predict the frequency of occurrence of these consequences.

**a) Number of poor households**

We will count the number of households affected by TB whose reported daily income is below the globally defined poverty line that defines "extreme poverty" at US $ 1.90 (at purchasing power parity in 2011) before and after the illness. For this one will use the measure of income (1,2 or 3) which will prove the most robust in XX. We will convert to the current local currency and update the value to the 2019 level using the consumer price index.

**b) Adjustment for intra-cluster correlations to obtain a national estimate**

If necessary, the percentage of patients (and households they belong to) included in the survey and faced with catastrophic costs will be adjusted to be nationally representative. This need may result from under- or over-recruitment in particular clusters and / or the existence of correlations within certain clusters.

**e) Adjustments within the clusters**

To account for the intragrade correlation, we will compute robust standard errors. This calculation can be done during the analysis at the individual level of the survey data using a logistic regression. The resulting estimate should provide larger standard errors and thus wider confidence intervals than standard logistic regression, which will help to correct the lack of statistical independence of individuals within clusters.

f**) Sensitivity analysis**

We will present the results using the main approach (for example using the annual consumption of the household in the denominator of the indicator and the approach of the valuation of the human capital in the numerator) and in parallel one will carry out sensitivity analyzes where one will use the final income-based approach after the illness.

All data cleansing and analysis will be done in Stata 14.0 (StataCorp) or R. The standardized analytical approach of the WHO and the associated generic analysis program 2017 will be adapted to the design of the XX survey.

As far as possible, we will follow the results-reporting recommendations that the Global TB Program recommends (to allow cross-country comparisons).

**g) Study limitations**

Due to the cross-sectional nature of this work, the survey suffers from limitations that should be considered when reporting or discussing policy implications.

**Households affected by catastrophic total costs:** While the survey seeks to capture all households affected by catastrophic total costs due to TB, in practice the sampling frame is notified patients, hence we are including only persons diagnosed with TB in the NTP network, and through them their households.

**Cost estimation:** As patients are only interviewed once, many of their costs have to be estimated. Furthermore, only patients in the intensive phase receive questions on the costs incurred prior to diagnosis.

**Recall bias:** A major challenge for the estimation of total patient costs incurred is recall bias – patients not accurately remembering the amount of time or money they spent in seeking care for their TB diagnosis and treatment. This predominantly affects cost estimates for the pre-treatment period. The suggested approach to only interview persons in the intensive phase about diagnostics costs is intended to minimize this type of bias. Nevertheless, unexpectedly low costs or a low number of reported health care visits prior to TB diagnosis may mean that patients have been unable to report all previous health care utilization, thus underestimating total costs. Overestimation of costs is also possible.

**Costs after treatment completion (including burial costs) are not included:** Both direct and indirect costs of TB for the patient and the household can extend well beyond the treatment period, even for people who are declared cured from TB. People may be left with short- or long-term sequelae of the disease. The need for further medical treatment, sustained disability, as well as the long-term effects of negative coping mechanisms, such as selling household assets or taking children out of school, can impair household economics for years. For the documentation of long-term needs of social and economic support for TB-affected households, measures of costs need to have a longer-term time-window than the present study design allows.

## Survey budget

Table 6. Tb patient cost survey in XX : the budget

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Budget line** | **Price Unit L.C.U.** | **# Unit  (or % time)** | **Total l.c.u.** | **Total in US$** |
| **Preparation cost** |  |  |  |  |
| **Human resources in preparation phase** |  |  |  |  |
| Principal Investigator | **1.00** | **1** | **1.00** | **$ 1.00** |
| Survey coordinator |  |  |  |  |
| Data analyst |  |  |  |  |
| Data manager |  |  |  |  |
| Team leader |  |  |  |  |
| Facility interviewers |  |  |  |  |
| **Technical assistance in preparation phase** |  |  |  |  |
| Technical advisory group: social scientist/epidemiologist/survey expert |  |  |  |  |
| Technical advisory group: health economist/analyst |  |  |  |  |
| Technical advisory group: statistician |  |  |  |  |
| **Meetings, trainings in preparation phase** |  |  |  |  |
| Preparation phase: Kick-off meeting and training for data collectors |  |  |  |  |
| Preparation phase: pre-survey visit to each cluster |  |  |  |  |
| Preparation phase: training workshop (for health facility interviewers) |  |  |  |  |
| **Survey adaptation** |  |  |  |  |
| Situation analysis: mapping of existing social protection schemes available to TB users |  |  |  |  |
| Protocol translation into local language |  |  |  |  |
| Back translation from local language into English |  |  |  |  |
| Ethics Review Committee fee |  |  |  |  |
| **Equipment, data repository and ICT** |  |  |  |  |
| Computer equipment (and maintenance) |  |  |  |  |
| Computer supplies |  |  |  |  |
| Android phones |  |  |  |  |
| Tablets |  |  |  |  |
| Communication (telephone/internet/courier) |  |  |  |  |
| Survey database set up |  |  |  |  |
| Web-based data collection form fee for technical support |  |  |  |  |
| Data repository |  |  |  |  |
| **Survey pilot** |  |  |  |  |
| Travel |  |  |  |  |
| Per diem |  |  |  |  |
| Mobile Air-time for interviewers |  |  |  |  |
| **Survey implementation** |  |  |  |  |
| Data collection: travel, interviewers allowance |  |  |  |  |
| Mobile Air-time for interviewers |  |  |  |  |
| Monitoring visits: travel, per diem |  |  |  |  |
| Patient incentives |  |  |  |  |
| **Human resources in implementation phase** |  |  |  |  |
| Principal Investigator |  |  |  |  |
| Survey coordinator |  |  |  |  |
| Data analyst |  |  |  |  |
| Data manager |  |  |  |  |
| Team leader |  |  |  |  |
| Facility interviewers |  |  |  |  |
| **Technical assistance in implementation phase** |  |  |  |  |
| Technical advisory group: social scientist/epidemiologist/survey expert |  |  |  |  |
| Technical advisory group: health economist/analyst |  |  |  |  |
| Technical advisory group: statistician |  |  |  |  |
| **Data analysis and cleaning** |  |  |  |  |
| Allowance for data entry person |  |  |  |  |
| Allowance for data cleaning person |  |  |  |  |
| **Dissemination** |  |  |  |  |
| Analysis of data |  |  |  |  |
| Report writing |  |  |  |  |
| Final review and agreement of results |  |  |  |  |
| Publication in scientific journal fee |  |  |  |  |
| Dissemination meeting or event |  |  |  |  |
| **Contingency** |  |  |  |  |
| Total (without % overhead) |  |  |  |  |
| Total (with % overhead) |  |  |  |  |
|  |  |  |  |  |
| **Sources of funding** | | | |  |
| **Government** | | | |  |
| **Donor 1: <<name>>** | | | |  |
| **Donor 2: <<name>>** | | | |  |
| **Gap** | | | |  |
| **Total** | | | |  |

## Results dissemination

##### 6.1 Avenues to explore

The outcomes of a TB patient cost survey have the potential to significantly inform policy discussion in two distinct areas. First, costs can be mitigated by changing health service delivery towards patient-centred care, including alterations to health financing schemes, fee structures, and service delivery policies and practices such as decentralization, ambulatory care or community-based care, complementing efforts to move towards UHC. Second, any costs that remain after optimization of health financing and delivery policies, can be mitigated by improved social protection measures in collaboration with stakeholders across the social sector. The opportunities arising from a TB patient cost survey should be fully utilized to facilitate policy discussion in both areas and stimulate the engagement of multisectoral partners.

The survey will also breakdown the financial burden by cost category, namely direct medical, direct non-medical and indirect costs, before and after TB diagnosis. This quantifies the relative importance of each category and informs discussion when exploring the most effective mitigation strategy in a locality. Table 10.1 provides a range of typical intervention options for each cost category, which can be used as a starting point for discussion.

While some interventions are primarily the responsibility of the NTP or MoH, many others require collaboration with other stakeholders. Conducting a patient cost survey provides an opportunity to engage key stakeholders and build collaborative relationships with them. It is most effective if key stakeholders are identified and engaged at the beginning of the process (see Chapter 2 for social protection mapping and stakeholder identification) and they can be consulted on the survey design, for results interpretation and action planning.

In order to effectively translate the survey findings into concrete national action, the following steps are proposed.

##### 6.2 Consultation technique pour examiner les resultats de l’enquete

Before embarking on a broad multi-stakeholder consultation to discuss the outcomes of the survey, the NTP and the PI will organise a technical consultation with key stakeholders. This will provide an opportunity to review the survey findings in detail, clarify operational issues, discuss potential bias and survey limitations, and jointly interpret the result.

The End TB Strategy indicator should be interpreted in context, and it should be borne in mind that the indicator measures the extent to which TB incrementally impacts household financial vulnerability. Even if a household does not experience catastrophic costs due to TB, it may incur significant medical expenditure due to other health conditions. In this regard, it is important to discuss the findings in the context of country’s overall progress towards UHC.

In this technical consultation, discussions can begin to identify the key interventions to reduce a patient’s financial burden. Along with the identified key interventions, clear action should be identified for each of the key stakeholders to formulate a draft national action plan to eliminate TB-related catastrophic costs for patients.

Table 7. Examples of main cost categories and possible interventions that might be considered to eliminate costs or mitigate impact of costs.

|  |  |  |
| --- | --- | --- |
| COST CATEGORY | POSSIBLE CHANGE IN SERVICE DELIVERY | TB PATIENT SOCIAL SUPPORT AND SOCIAL PROTECTION SCHEMES |
| **Direct**  **medical:**  **before TB**  **diagnosis** | * Streamline the TB patient pathway   - Understand and adapt to treatment-seeking behaviours  - Update and promote the national standard of TB diagnosis and eliminate irrational testing  -Extend access to rapid molecular diagnostics  -Effectively use chest radiography   * Improve links with private sector providers using consistent policies (e.g. quality of care, free of charge) * Intensify targeted case finding, including systematic screening for priority risk groups | * Reduce/subsidise/eliminate out-of-pocket (OOP) payment * Increase insurance coverage (general) * Reimburse OOP made by TB patients * Regulate and eliminate informal fees * Engage relevant actors in or outside TB to identify opportunities that can enable better access |
| **Direct**  **medical:**  **after TB**  **diagnosis** | |  | | --- | | * Expand free-of-charge or highly subsidised TB service package including all TB medicines, ancillary drugs, procedure to monitor adverse events and preventive treatment   • Promote integrated management of comorbidities and risk factors (HIV coinfection, diabetes, other lung diseases, tobacco smoking, harmful use of alcohol)   * 1. • Improve the quality of TB care   2. - Update and promote the national standard of TB care with an emphasis on people-centred care   3. - Eliminate irrational treatment, hospitalization and testing | | |  | | --- | | * + Reduce/subsidize/eliminate OOP   - Increase insurance coverage for TB-related services  - Increase insurance coverage for relevant comorbidities and risk factors  - Regulate and eliminate informal fees   * + Improve provider payment mechanism to avoid over-provision of services   + Explore social protection available for specific vulnerable groups and people with medical conditions | |
| **Direct non-medical** | |  | | --- | | * Advocate local health-seeking and for care models bringing services close to patients, including community- and workplace-based care.   - Improve the quality of nutritional advice and regulate irrational nutritional recommendations by health care providers (e.g. supplements) | | * Provide assistance via TB programme * Cash transfer * Specific allowances (e.g. food, transportation, etc.) by cash, voucher, or in-kind   Expand the use of general social assistance schemes  Engage NGOs, civil society organizations (CSOs) and patient groups to ensure patient support suitable for the locality |
| **Indirect costs**  **(income loss)** | Range of interventions to enable earlier diagnosis and patient-centred care delivery that minimize time spent seeking and receiving care (decentralization, shorter waiting times, fewer health care visits, avoid unnecessary hospitalization, etc.)  Improve access to social services   * Improve health workers’ knowledge on social protection schemes * Seamless link between health and social offices (one-stop site) * Engage civil society and community organizations and volunteers in non-health sectors (social work, charity, legal services and volunteers) | • Facilitate enrollment of eligible patients/households in existing social protection schemes  -Social assistance for poor and vulnerable families  -Sickness/disability grant  -Cash or in-kind transfer programme  • Advocate review and/or improvement of social insurance as income replacement during illness.  • Legislate and/or enforce provisions related to social, economic and labour rights to protect individuals during TB illness and care |

*Source : Table 6.1 in TB patient cost survey manual*

##### 6.3 survey report and other communication material

Based on the technical consultation, a draft survey report should be developed. The report can follow a standard format for national health surveys, for example, starting with background, objectives, methods and results followed by discussion. As TB patient cost surveys contain a broad range of implications for the social sector, it is important to provide basic information on the national TB programme and its service delivery structure, as well as national health financing schemes, as part of background information. Information obtained through the situation assessment should also be included in the report, especially a summary of previous health and economic surveys and social protection mapping. To ensure the link with follow-up action, policy implications should be thoroughly discussed and described in the report with a set of policy recommendations. A summary of the stakeholder consultation (see the next section) and resulting action plans should be added before finalizing the report.

Apart from the comprehensive survey report, it is useful to develop communication materials targeting different audiences. They include a technical summary, a brief for policy-makers, and media communication materials such as press release, a fact sheet, infographics, etc.

Examples of materials used in other countries (e.g. Kenya, Uganda, Vietnam) are available (<http://www.kelinkenya.org/wp-content/uploads/2018/07/TB-Patient-Cost-Survey-Report-Final-2018-.pdf> for Kenya or in WHO, 2017)

##### 6.4 Stakeholder consultation

A multi-stakeholder consultation will be convened to disseminate the result, by engaging key stakeholders, securing political commitment and advocating for strong social support to TB patients and their families.

Key survey results will be discussed with all stakeholders on the basis of the draft report developed after the technical consultation. We will identify priority interventions in the areas of medical service delivery and health financing, as well as strengthening social protection. Roles and responsibilities of key partners will be defined in the overall framework of the National Action Plan to eliminate catastrophic costs associated with Tuberculosis.

The purpose of the TB patient cost surveys is not merely to measure the indicator for the global target. As a result of experience gained in several pathfinding countries, it is established that the TB patient cost survey is a great tool to identify critical bottlenecks in TB care that increase human suffering and prevent further progress in TB control.

Therefore, the ultimate purpose of the survey is fulfilled only when all the key participants act to mitigate the financial hardship incurred by patients and families, and ensure patientcentred TB care.

In this regard, a stakeholder consultation is the end point of the whole process of the patient cost survey and, at the same time, the starting point of concerted efforts by national partners to take bold action towards zero catastrophic costs due to TB.

## Survey calendar

TablE 8. Timeline for survey implementation : november 2018-september 2018



## References

Please complete using your prefered reference manager – I have put bibliography suggestions in “comment”

## Annex 1 : Study instrument (XX)

See USB for participants\Instrument

## Annexe 2 : Informed consent

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 will not receive reimbursements from the study organisers for the expenses that you report on in this interview. However, your eligibility for existing reimbursement schemes will be unaffected.

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.

## Annex 3 : 2 day training for interviewers

Table 9. 2 day training will take place in xx (XX 2019)

|  |  |  |  |
| --- | --- | --- | --- |
| Date and Time | Session | Presenter | Objectives of the session |
| Day one | | | |
| 09.00-09.20 | Welcome and introductions | Ministry representative |  |
| 09.20-10.00 | Introduction to the research, including overview of definitions and the research protocol | Principal investigator | To give everyone involved in the research a common understanding of its rationale and to understand the research protocol and procedures |
| 10.00-10.30 | Morning tea and group photo | — |  |
| 10.30-11.15 | Ethics in research | Ministry representative | To give all interviewers an understanding of the ethical issues involved in conducting field-based research, including the informed consent process |
| 11.15-11.45 | Cultural issues in research | Ministry representative |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Date and Time | Session | Presenter | Objectives of the session |
| 11.45-12.30 | Introduction to the questionnaire | Principal investigator/co-investigator | To give all participants sight of the questionnaire in preparation for the afternoon session, when questions will be discussed one-by-one |
| 12.30-13.30 | Lunch | — |  |
| 13.30-15.00 | Review of questions in the questionnaire | Principal investigator/co-investigator | To give all participants a thorough and detailed understanding of the questions |
| 15.00-15.30 | Afternoon tea | — |  |
| 15.30-17.00 | Review of questions in the questionnaire | Principal investigator/co-investigator | As above |
| DEUXIÈME JOURNÉE | | | |
| 09.00-9.30 | Review of questions in the questionnaire | Principal investigator/co-investigator | To give all interviewers an understanding of the informed consent process and a chance to practise obtaining informed consent |
| 9.30-10.30 | Role play, practising interviewing and using the questionnaires (and tablets) | Principal investigator/co-investigator | To give all interviewers a chance to practise using the questionnaire and to practise interview techniques. This provides an opportunity for interviewers to clarify anything that is unclear about the questionnaire or the interview process |
| 10.30-11.00 | Morning tea |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| DATE AND TIME | SESSION | PRESENTER | OBJECTIVES OF THE SESSION |
| 11.00-12.30 | Role play, practising  interviewing and using  the questionnaires  (and tablets) | Principal investigator/co-investigator | As above |
| 12.30-13.30 | Lunch |  |  |
| 13.30-15.00 | Role play, practising  interviewing and using  the questionnaires  (and tablets)  Using tablets for data  collection – practical  considerations | Principal investigator/co-investigator | Comme précédemment  Donner à tous les intervieweurs une connaissance pratique de l’utilisation des tablettes pour la collecte des données |
| 15.00-15.30 | Afternoon tea |  |  |
| 15.30-16.00 | Next steps and wrap  up | Principal investigator/co-investigator Ministry representatives | To offer all interviewers  and everyone involved  in the study an  understanding of what  will happen next with  regards to the study |
| 16.00-18.00 | Survey management  (for Investigator team  only) | Principal investigator/co-investigator | To make clear the roles  and responsibilities of  all investigators  To make clear the  need for additional  documentation (i.e.  Standard Operating  Procedures and the  like)  To give investigators an  understanding of the  use and management  of ONA |
|  |  |  |  |
|  |  |  |  |

## Annex 4 : Survey report (draft structure)

**Chapter 1. Background and objectives**

1. Background

2. The organization of TB services in country X (Service delivery network in the public and private sectors, the standard TB service package, fee schedule, and other relevant information; can be inserted as a box)

3. Summary of previous relevant surveys (e.g. health and economics surveys)

4. Survey objectives

**Chapter 2. Survey organization, structure and budget and funding sources**

**Chapter 3. Methods**

1. Survey design overview and survey population (inclusion and exclusion criteria)

2. Definitions (patient costs, income, catastrophic costs, coping measures)

3. Sampling design and sample size

a. Sampling

b. Patient enrollment

4. Data collection process (including piloting) and tools

5. Data management

6. Data analysis (following WHO, 2017)

7. Ethical considerations

**Chapter 4. Results**

1. Description of the sample

a. Description and assessment of the completeness of survey data

b. Descriptive statistics and selected socio-demographic characteristics of survey sample, by stratum, by drug-resistant status, and overall

c. Model of care for survey sample

d. Distribution of monthly household income pre-TB diagnosis and at time of survey

2. Main results

a. Hours lost seeking or accessing care and reported individual income

b. Estimated total costs borne by patient households affected by TB or MDR-TB, median breakdown92

c. Reported dissaving mechanisms and social consequences

d. Proportion of households facing catastrophic costs

e. Risk factors for households experiencing catastrophic costs

f. Direct medical expenditure as a percentage of annual household income, by income quintile

3. Impact of changing threshold to define catastrophic costs (20%, 30%, 40% etc.)

**Chapter 5. Discussion**

1. Main survey results

2. Comparison with previous surveys

3. Survey quality and limitations

4. Lessons learned for the next round of survey

**Chapter 6. Policy implications and recommendations**

1. Policy implications of the findings

2. Social protection mapping (can be inserted as a box)

3. Stakeholder consultations, policy recommendations and action plans

3. Follow-up research

**Acknowledgements**

**References**

**Annexes**

## Annexe 5 : Patient cost study team members and experiences related to this project

Table 10. Team member in XX and related experiences to this study

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of the investigator** | **Experience relative to this study** | **Group/Institution name** | **Country** |
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## Annex 6 : Terms of reference for the principal investigator (advertised by who co xx)