

TUBERCULOSIS PATIENT COST SURVEYS: A HANDBOOK



World Health
Organization

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Preface

Tuberculosis (TB) is mainly a disease of poor and marginalized people and communities. An already precarious socioeconomic situation can worsen considerably when an individual or household is struck by TB; potentially entrenching them in a vicious poverty-disease circle. Costs related to diagnosis and treatment are often compounded by costs for transport to a place of care, for temporary accommodation and food, as well as the income foregone when seeking and receiving treatment, and/or lost employment due to disability or discrimination. These costs can have catastrophic consequences. A systematic review of available studies on TB patient and household costs has suggested that, on average, losses can be equivalent to more than one year's income. Patients with multidrug-resistant TB (MDR-TB) and their households tend to face particularly devastating costs. As a result, many affected people are unable to pursue the full journey from TB diagnosis through successful treatment, with consequences for their own health and well-being and at the risk of perpetuating disease transmission.

To spur action, the WHO End TB Strategy includes, among its highly ambitious top three impact targets, the elimination by 2020 of catastrophic costs for TB patients and their households. The Strategy lays out approaches to improve people- and patient-centred care, and to pursue bold policies to move rapidly towards universal health coverage (UHC). It also outlines additional approaches within and beyond the health sector to advance social protection and action on the social determinants of TB, and to enable related research and innovation.

To measure progress towards the high-level End TB Strategy target, WHO recommends baseline and periodic measurement using an indicator termed "catastrophic total costs due to TB".¹ Measurement is based on the conduct of surveys examining the costs to patients associated with TB, and can enable the estimation of the proportion of patients experiencing catastrophic costs. In shorthand, these are referred to as "TB patient cost surveys".

¹ The TB-specific indicator of "catastrophic total costs due to TB" is different from, and not comparable to, the WHO-recommended population-based indicator of "large health care expenditures", which focuses on out-of-pocket health care expenditures (but not non-medical direct or indirect costs) for all health needs in a household and is one measure of financial risk protection. This indicator is used to measure overall progress towards UHC.(1) The two indicators are complementary.

TB patient cost surveys have two primary objectives:

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 national TB programme (NTP) network who incur catastrophic total costs due to TB.

This handbook provides a standardized methodology for conducting health facility-based cross-sectional surveys to assess the direct and indirect costs incurred by TB patients and their households, building on experience gathered using a previous costing tool and an iterated WHO pilot protocol and tool.

The primary target audience for the Handbook includes NTPs and partners involved in supporting TB programme planning, implementation, evaluation and associated operational research.

This Handbook replaces the field-testing version of a generic protocol that was developed by WHO with experts in a WHO-led TB Patient Cost Task Force in 2015, building on a previous tool. Revision of the protocol was based on experience gained through national TB patient cost surveys conducted in Myanmar (2015), Viet Nam (2016), Timor Leste (2017), Ghana (2016), Mongolia (2017), the Philippines (2017), Uganda (2017), China (2017) and Kenya (2017), as well as additional advice provided by the Task Force. Experience from initial surveys shows that data collection can be completed in less than six months.

The Handbook provides further background on the rationale and development of the TB patient cost survey approach. It then describes the situation assessment that is needed before a survey is designed and implemented. This is followed by an outline of the survey methodology, including study design, sampling approach, data collection and management, and data analysis. Finally, the Handbook provides advice on conducting dialogue on the survey results and policy implications and in disseminating findings, thereby enabling action and related research for effective modifications in care delivery models, in patient support, and wider cross-sectoral interventions.

WHO envisages that at a minimum, the Handbook will be used for surveys in all high TB burden countries ahead of 2020 – the first milestone year for the End TB Strategy targets – and alongside other key surveillance, monitoring and evaluation, and operational research tools to improve TB care and prevention, and end the epidemic.

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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 (T-PaCT henceforth, “the Global Task Force”)
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

Glossary

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 (4).

¹ Definition from System of National Accounts S 93. SNA 4.132 [4.20]
<http://stats.oecd.org/glossary/detail.asp?ID=1255>

1.

Background and objectives

1.1 Background

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.

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 (6–8).

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 (WHO 2016). 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 (1). 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.

Good data are essential for the development of appropriate policies and interventions. They are also needed to monitor progress toward the End TB Strategy target to eliminate catastrophic total costs due to TB. Countries thus need to document the magnitude, nature and drivers of TB-related costs for patients and households. To this end, there have been several efforts to develop generic TB patient costing tools. KNCV, WHO and the Japan Anti-Tuberculosis Association (JATA) developed such a tool in 2011, which was shown to be useful in driving policy change in some countries. In order to further standardize the tool and enable measurement of the proportion of TB-affected households that experience catastrophic costs nationwide, the WHO Global TB Programme (GTB) conducted a systematic review of patient cost surveys in 2014 and convened a Global Task Force on TB Patient Cost Surveys in 2015. The Global Task Force developed a field testing version of a generic protocol and survey instrument which was subsequently used and evaluated in 10 countries ahead of a second Global Task Force meeting in 2017, where the methodology was reviewed and revised (Fig. 1.1). Operational experiences of survey planning, implementation, analysis, results dissemination and policy-translation were also reviewed. The result is this Handbook.

The relevance and importance of this work are clear: reducing direct and indirect costs related to TB care will contribute to improvements in access and treatment adherence (WHO TB treatment guidelines 2017) as well as protection against economic hardship. Survey findings can be used to monitor financial access barriers and inform related health and social policy changes to improve TB prevention and care.

1.2 Survey objectives

TB patient cost surveys have two primary objectives:

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.

Results may be disaggregated by specific subgroups, e.g. MDR vs. drug-susceptible TB, age, sex, income level, etc. For optional additional study objectives, see Chapter 11.

Fig. 1.1 First countries implementing WHO, 2015 methodology to implement national patient cost survey, December 2015–April 2017

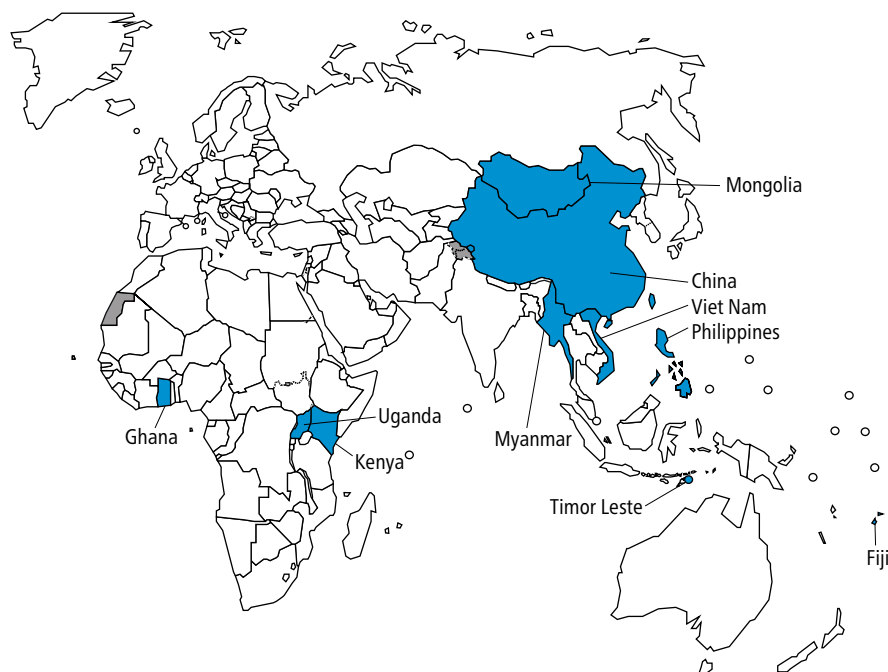


Table 1.1 End TB Strategy targets

Vision, goal, targets, milestones

			TARGETS			
			MILESTONES		SDG ^a	END TB
			2020	2025	2030	2035
Vision A world free of TB ZERO TB deaths ZERO TB disease, and ZERO TB suffering	Reduction in number of TB deaths <i>Compared with 2015 (%)</i>		35%	75%	90%	95%
	Reduction in TB incidence rate <i>Compared with 2015 (%)</i>		20%	50%	80%	90%
Goal End the global TB epidemic	TB-affected families facing catastrophic costs due to TB (%)		0%	0%	0%	0%

^a The United Nations Sustainable Development Goals (SDGs) include ending the TB epidemic by 2030 under Goal 3.
Source: end_tb_brochure <http://www.who.int/tb/strategy/end-tb/en/>

2.

Situation assessment

A situation assessment is required before implementation of a survey. The situation assessment will inform the design of the survey (including the sampling and questionnaire design), the implementation of the survey (including management and oversight, see Chapters 4 and 5) and will also provide background information required for policy dialogue after patient cost survey data have been generated, see Chapter 10.

Prior to starting a national TB patient cost survey, it is therefore important to gather sufficient information about TB epidemiology, health financing, health insurance programmes, health care fee structures, health care delivery models, and social protection schemes that are legislated and/or provided in country. Previous patient-level cost surveys (national or subnational), other research to identify financial barriers to care, and previous evaluations of interventions to address costs borne by patients should also be reviewed before a national survey is planned. This may also include general information and research on conditions other than TB, which can help give a broader picture of socioeconomic health care barriers and the consequences of disease in a given setting.

2.1 TB epidemiology

Data on TB notifications by region and district are required to plan the sampling strategy. The NTP should generate a list of health care facilities that provide TB treatment services within the NTP network (including any private providers notifying TB patients) and the number of patients with TB registered at each facility in the previous year. If there is a plan to stratify the sampling and/or final results, for example by gender, age, or type of TB (DS-TB versus DR-TB; new vs previously treated; pulmonary vs extra-pulmonary), then health facility-level epidemiological data on these variables are required.

2.2 Health system and health care utilization

A basic understanding of how people with TB (as well as people in general) access health services is important in order to adapt the questions in the survey instrument (see Annex 2) concerning health care utilization from the onset of TB symptoms to TB diagnosis. A list of the common types of health care providers should be made.

Mapping of available health financing schemes and health care fees for TB-specific tests and treatments, as well as other relevant clinical services, will help in two ways. First, such knowledge can help the interview process concerning questions about health

insurance coverage and direct medical costs, and it can also be used to validate answers during the interviews. Second, it will help inform the policy dialogue after survey results dissemination, especially on possible fee reductions or improved health insurance coverage for relevant clinical services.

2.3 Social protection mapping

The social protection mechanisms that are available in country should be identified in advance of a survey, as should a list of programmes for which TB patients are or could be eligible, including social security, targeted transfers for vulnerable populations, and voucher or subsidy plans. This will help inform questions in the instrument concerning social protection received during the TB episode.

A good understanding of social protection and access for TB-affected households will contribute significantly to the overarching policy dialogue, as it provides the opportunity to determine TB patient needs. It may also identify new avenues to access, and/or adjust and/or link to existing schemes that are not currently fully utilized. Examples of social protection mechanisms that could be mapped are included in Box 2.1.

2.4 Review of demographic and health survey, and household income and expenditure surveys

The survey instrument (see Chapter 4) includes a section with questions to help estimate annual household income as a measure of the household's ability to pay for basic needs. Designing this part of the questionnaire requires household asset questions and/or household consumption or expenditure questions from other national household surveys, such as the demographic and health survey, living standards surveys, or household income, consumption or expenditure surveys. These survey instruments are usually available from the national statistics office, or an equivalent institution. Collecting these external questionnaires is an important part of survey preparations.

2.5 Stakeholder identification

A stakeholder analysis is important for both practical and advocacy purposes. As such, relevant stakeholders should be involved in the survey planning, and the results of the survey should be made available to stakeholders able to act on the results. Stakeholder buy-in can also be beneficial at the approval stage for obtaining permission to enroll patients at the facility.

The survey team will normally include staff from the Ministry of Health and the National TB Programme (NTP), along with other key partners (see Chapter 8). The survey team should ensure that senior staff in the Ministry of Health are informed about the survey. A multisectoral stakeholder meeting during the planning phase can inform design and create shared ownership (Box 2.2). The same group of stakeholders will be brought together at the end of the survey when the results are shared in a multisectoral workshop.

Stakeholders may vary by country, but should always include government agencies that

Box 2.1 Social protection mapping

The following types of social protection schemes may be identified and described:

1. TB-specific social protection schemes that currently exist, such as:
 - a. cash transfers for TB patients (conditional or unconditional)
 - b. food support for TB patients (in-kind, vouchers, cash allowance)
 - c. travel support for TB patients (in-kind, vouchers, cash allowance)
 - d. housing support for TB patients
 - e. vocational training, micro-credit or enterprise support for TB patients
 - f. psychosocial support and management of drug use/addiction and other mental health problems for TB patients.
2. General social protection schemes for which TB patients may be eligible (list not exhaustive), such as:
 - a. social assistance
 - i. cash or in-kind transfers (conditional or unconditional)
 - ii. social security/pensions
 - iii. school feeding
 - iv. nutrition support
 - v. subsidies (education, health, etc.)
 - b. social insurance
 - i. health insurance
 - ii. unemployment insurance
 - iii. pensions (old age, disability, etc.)
 - c. labour market interventions
 - i. vocational skills training programs
 - ii. employment services
 - iii. social services that facilitate mobility.
3. Rights-based country legislation:
 - a. right to employment
 - b. right to social protection, and or services
 - c. right to life
 - d. rights for those living with disabilities.

Source: World Bank. World Bank's 2012–2022 Social Protection and Labor Strategy for Resilience, Equity and Opportunity.

Box 2.2 Stakeholder meeting prior to the implementation of the tuberculosis patient cost survey in Fiji, 2017

In February 2017, staff from the WHO Division of Pacific Technical Support and the Fiji Ministry of Health and Medical Services convened a stakeholder meeting to brief representatives from other government ministries, United Nations agencies (such as the United Nations Development Programme, which is currently the Principal Recipient for the Fiji Islands TB grant from the Global Fund), the Reserve Bank, Fiji National University, the Global Fund Country Co-ordinating Mechanism, non-governmental organizations and others, about the proposed TB patient cost survey, prior to its implementation. The objectives of this meeting were twofold: first to provide information to interested parties on impending survey implementation, and second to ensure early engagement with policy-makers and others who can effect policy change, so that survey results may be more easily considered and adopted by policy-makers.

At the meeting, staff from WHO presented the End TB Strategy, the rationale for and definition of the catastrophic costs indicator, and the plans to ensure global monitoring of this indicator. A Ministry of Health and Medical Services representative presented on the epidemiology of TB in Fiji and on plans to implement a TB patient cost survey, including the rationale for doing so. This was followed by a discussion and the Global Fund Country Co-ordinating Mechanism endorsement of the study. Discussions included anticipated survey findings and possible mechanisms to protect vulnerable patients from catastrophic costs. The Ministry of Health and Medical Services plans to convene the same group of stakeholders when the survey is finished, in order to disseminate the results and discuss policy implications.

are responsible for social protection, such as the ministries of social affairs and/or labour. Other relevant government employees may be included, such as senior figures in health and social insurance, development and/or poverty reduction, gender, food and agriculture, and penitentiary systems. Other key stakeholders may include private sector partners including health care providers, university or research institutions, professional societies, bilateral and multilateral partners, and nongovernmental and civil society organizations including patient representatives.

As part of the situation assessment, it is useful to review recent health or economic surveys in the country and determine which ministries, academic institutions or technical partner organizations conducted them. An organization with experience in designing or implementing such a survey (particularly in health or economics) may have a great deal of valuable methodological and operational knowledge for the design and implementation of the TB patient cost survey. Moreover, they may be able to help source an experienced individual to implement the survey.

3.

Survey design overview and limitations

3.1 Survey design

There are many ways to monitor costs incurred by patients, but this handbook focuses on a cross-sectional, facility-based design, which was identified as the most feasible and practical by the Global Task Force. In this design, all patients registered for TB treatment in NTP and who are attending a sampled facility for a visit during the study period should be invited to participate in the survey.

Each patient should be interviewed only once and report on TB care-related expenditures and time spent seeking and receiving care. Some patients will be interviewed in the intensive treatment phase and others in the continuation treatment phase, with data collected on that particular phase only. For patients interviewed in the intensive treatment phase only, retrospective data on the frequency and duration spent seeking and receiving care (so called “utilization data”), and related expenditures prior to TB diagnosis, will also be collected. Data collection for patients in either the intensive or continuation phase will allow estimation of past and future costs during the entire illness episode (Fig. 3.1).

This approach will simplify sampling and make data collection efficient since most patients attending the facility during the survey period will be eligible to partake in the survey. Since no follow-up interview is required, such data collection can be completed within two-to-three months in countries with moderate-to-high TB incidence. It should however be noted that using a cross-sectional design and then estimating a longitudinal result requires a number of simplifying assumptions and introduces a number of challenges for the analysis and interpretation of results.

Fig. 3.1 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. The analytical approach is discussed in Chapter 6.

3.2 Survey limitations

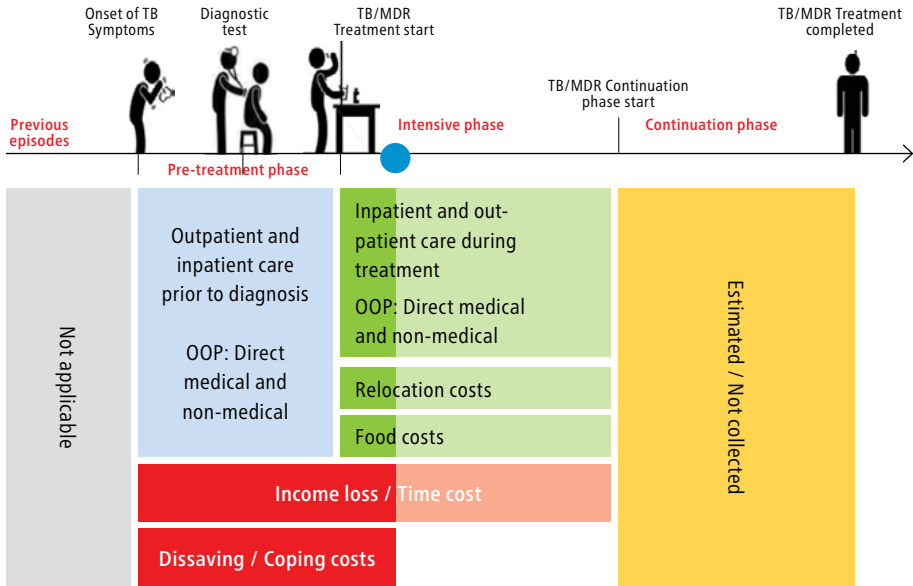
Due to the cross-sectional nature of this work, the survey suffers from limitations that should be considered when reporting or discussing policy implications.

- **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

Fig. 3.1 Overview of the cross-sectional survey design and analytical approach

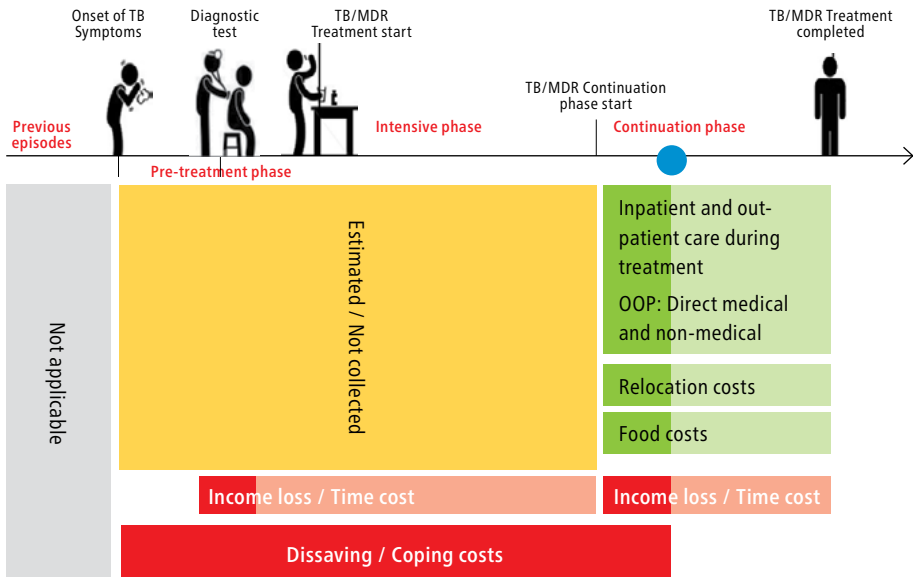
The blue dot indicates the interview moment. Darker shades of blue, green and red represent retrospective data collected at the interview. Lighter shades of green and red represent extrapolation of costs into the future. Yellow means costs are estimated based on both information from the interviewed 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)

● interview time: treatment to date – **continuation phase**



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.

4.

Survey population and sampling

4.1 Survey population

The survey population includes all patients (including children accompanied by a guardian) who are on DS-TB or MDR-TB treatment (in the continuation or intensive phase) within the NTP network. Sampling will be done among health facilities, public or private, that treat and notify TB in line with the guidelines of the national TB programme.

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 in that household should, in principle, be estimated by interviewing all household members on treatment. However, previous surveys have shown that inclusion of estimated costs for additional household members with TB only marginally changes estimates for the proportion of TB-affected households facing catastrophic costs. Therefore, the inclusion of additional questions on whether or not additional household members are being treated for TB and their costs can be optionally added at the end of the instrument. In case several members of the same household are interviewed, household income or consumption questions should only be asked to the main breadwinner or purchaser.

Survey findings can therefore only be generalized to the subset of people with TB who receive care under the NTP network (and their households), 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 survey.

4.2 Inclusion and exclusion criteria

Inclusion and exclusion criteria are defined according to the population of interest described in the survey objectives. Eligible patients are all consecutive patients registered for TB treatment (regardless of age, and whether they are affected by drug-susceptible or resistant TB), who are attending a sampled facility and who are a minimum of 14 days into the present intensive or continuation treatment phase. Newly diagnosed patients, not having started treatment, are not eligible for the survey.

Ineligible patients are patients treated in facilities that are unconnected to the NTP, confirmed TB cases who have not yet started TB treatment or have been in the current treatment phase for less than two weeks, and children under 15-years-old without their guardian.

4.3 Sampling

There are three possible approaches for obtaining a representative sample of the population of interest, of which random cluster sampling is the most appropriate in most settings.

100% sampling method

This sampling method is most suitable for small countries with small numbers of health centres treating TB. All eligible patients presenting to each health centre in the country within a defined time period are enrolled until the survey sample size is reached. Large and small centres are equally represented without the need for a complicated sampling method. This approach is being tested in Solomon Islands (Box 4.1).

Box 4.1 Solomon Islands sampling strategy

Solomon Islands – an island nation in the South Pacific Ocean – reports approximately 420 TB patients per year in a population of just under 600,000 people. The required sample size for the Solomon Islands TB patient cost survey was estimated at 211 TB patients, based on the number of health centres offering TB treatment, the number of patients diagnosed and treated in the country per year, and assuming a level of 30% catastrophic costs, with 4% absolute precision.

Solomon Islands is divided into nine administrative divisions. Each division has a designated TB centre that provides diagnostic, treatment and follow-up services for TB patients and their families. The sampling for the TB patient cost survey in Solomon Islands will involve sampling from all 10 centres instead of a sample of health facilities. From each centre, TB patients will be enrolled sequentially as they came to the clinic for TB care (provided that they have had at least two weeks of TB treatment in their current phase).

Simple random sampling (SRS)

A national simple random sample of patients on TB or MDR-TB treatment is theoretically possible to draw in countries that have electronic registers with real-time surveillance information that can be used as a sampling frame. Use of this sampling strategy has not been reported in previous TB patient cost surveys and its feasibility is thus untested. This strategy is likely to be more expensive as it may be difficult to reach sampled respondents (unless telephone interviews are conducted, which have not been tested and for which it is probably difficult to ensure validity). However, since it is a theoretically attractive sampling approach, countries with the right conditions are encouraged to explore this strategy.

Cluster sampling

Cluster sampling methods are best used in situations in which it is logistically difficult to cover the entire area of the country and where the number of health centres where TB patients are registered is high. In this method, clusters are usually health facilities but

can also be administrative regions or geographical areas. To avoid the risk of drawing a sample that misses the largest centres, a weighted probability-proportional-to-size (PPS) cluster sampling technique should be used. For this, information about the number of notifications per cluster will be required (see Chapter 2). In countries where a complete list of facilities and their respective number of notifications is not available, administrative units or geographical areas may be used as clusters instead.

An advantage of using cluster sampling is that patient recruitment and data collection is generally easier from the logistical and financial point of view than when simple random sampling is used. A disadvantage is that sample size needs to be increased, as compared to simple random sampling, due to clustering effects (since people within clusters may have more similarities than to TB-affected patients elsewhere in the country).

The optimal number of clusters depends on the variability of the prevalence of experiencing catastrophic costs between and within clusters, and the survey cost of including a new cluster compared with the cost of increasing the size of an existing cluster. Based on previous surveys, at least 25 clusters are recommended with a cluster size of between 10 and 40 patients.

Regardless of which of the above sampling approaches is used, a stratified sampling technique can improve representation of important subgroups such as, for example, people with MDR-TB. If disaggregated estimates for different subgroups are required, sample size calculations are needed for each relevant subgroup, which will increase the overall sample size.

Sample size calculations and sampling procedures are further described in Annex 3.

4.4 Patient enrollment

There are two main ways to enroll patients. The first (and most commonly used) is to continue enrollment of consecutive patients attending follow up visits until the required number has been obtained. The second is to draw a random sample of patients on treatment in the facility based on the district TB register. See Box 4.2 for an example of such sampling in the Philippines.

Although stratified sampling of patients in the intensified and continuation phase is not necessary, it can create a good balance between the two groups and ensure a sufficient number of patients reporting pre-treatment cost data, which is only collected from patients in the intensive phase.

Planned interviews can also be useful to avoid missed opportunities to interview patients who are close to treatment completion when the survey starts and also to avoid idle time for the interviewer. See Box 4.3 for an example of such enrollment in the Viet Nam survey.

Box 4.2 Patient enrollment using random sampling of patients on treatment within survey clusters

The Philippines national TB patient cost survey team compiled lists from sampled health facilities of all patients on treatment who met the survey's inclusion criteria. Once these lists were provided, they randomly selected the target number of patients from each and scheduled them to come to the clinic for an interview/visit. Patients unable to attend the clinic were interviewed by survey administrators at their home. This method has the advantage of reducing bias as it broadens the survey beyond those attending the facility during the survey period. However, it may be more costly than opportunistically enrolling patients as they arrive at the facility. In the Philippines, this approach was implemented in the context of 188 clusters, with each cluster including 10 patients.

Box 4.3 Patient enrollment in Viet Nam

A list of eligible patients from a facility was compiled by registration date. Each sampled facility aimed to survey 36 patients, with 18 currently in the intensive phase of treatment and 18 in the continuation phase. If the number of eligible patients on treatment at the time of data collection was less than 36, all were eligible for enrollment. However, if the list of eligible patients was equal or more than 36, health care staff would randomly select 18 patients from the intensive phase group and 18 in the continuation phase, and first enrol those who had the earliest registration in each group. This method allowed the interviewer to approach patients who were a minimum of 14 days into the treatment phase.

Interview dates were planned so that the first DS-TB patient enrolled would be 5.5 months into treatment at the time of the interview. Interview dates were set, at patients' convenience, via house visits or during a follow-up visit to the facility. One-to-two days before the appointment, health care staff called to give a reminder about the time and place for the interview. Health care staff could ask patients to bring all bills related to payments for diagnosis and treatment to the interview.

Source: Standard Operating Procedure for Viet Nam national TB patient cost survey

5.

Data collection and management

5.1 Data to be collected

Overview of the data collection instrument

A link to the generic data-collection instrument is included in Annex 1. Annex 2 outlines the main adaptations of the generic survey instrument that are required in each country. The survey instrument has four parts, as outlined in Table 5.1. The survey pathway for the particular survey instrument components are outlined in Fig. 5.1.

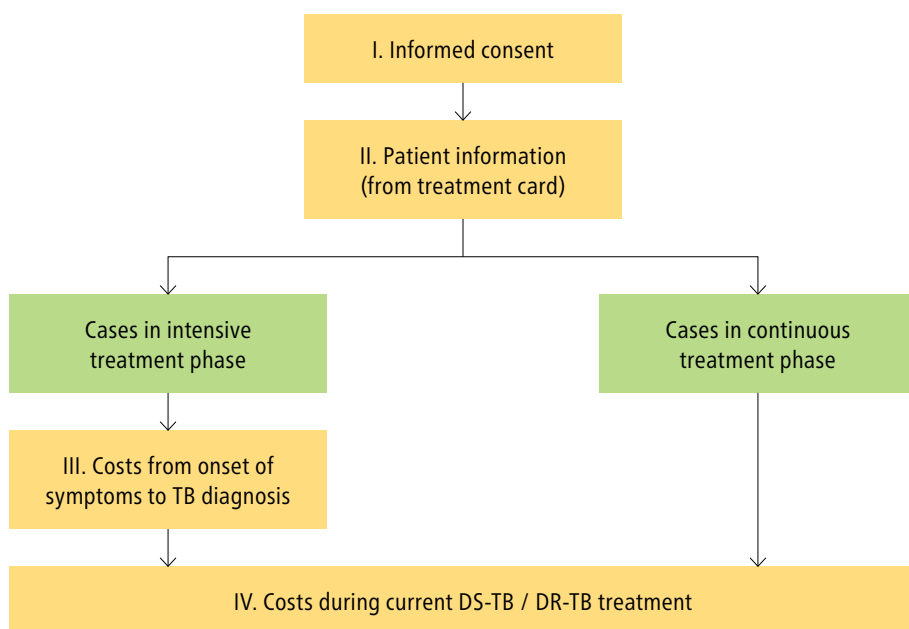
Table 5.1 Content of the four components of the survey instrument

SURVEY 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

Fig. 5.1 Flow of survey instrument components

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.

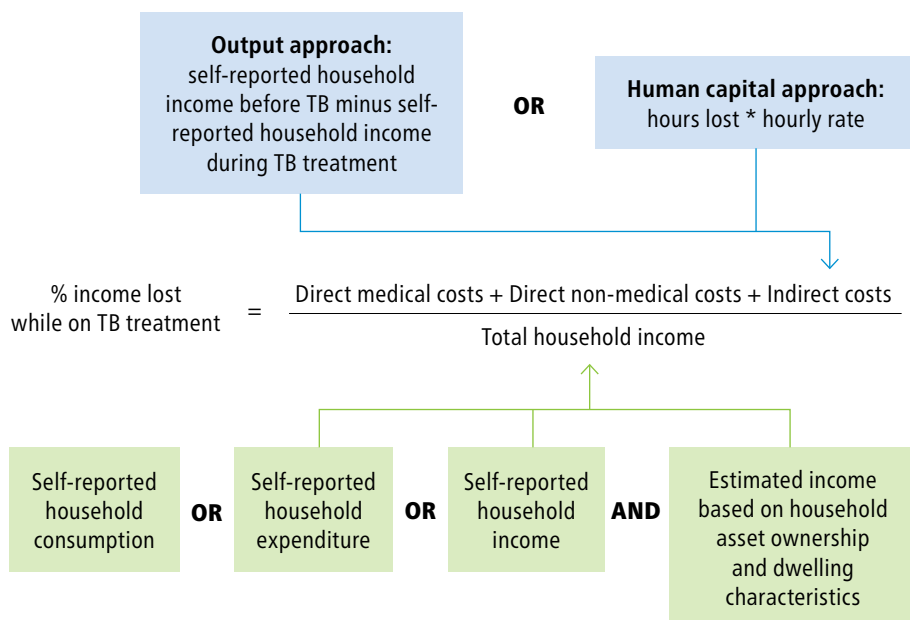
Overview of data collected by the generic data-collection instrument

The data collection instrument is designed to provide information on:

- clinical parameters
- demographic variables, employment, and household composition
- socioeconomic position
- health care utilization (in all type of institutions for pre-treatment and in “NTP network facilities” during treatment)
- time spent and income lost while seeking and receiving care
- direct medical costs, direct non-medical costs, and indirect costs
- household and individual income
- caregiver time
- coping mechanisms (loans taken, assets sold, etc.)
- social consequences and perceived impacts of costs.

One of the objectives of the survey is to estimate the End TB Strategy indicator, i.e. the percentage of TB-affected patients experiencing total costs above 20% of household income. This means calculating the percentage of a patient's income lost from the onset of TB symptoms. The latter calculation requires data on both costs and income:

Fig. 5.2 Overview of data collected by the generic data-collection instrument



However, the primary focus of the survey is to measure costs borne by TB-affected patients, including the level and composition of different types of direct medical, direct non-medical and indirect costs (income loss) for the entire TB episode (before and during TB treatment, but not after completed treatment).

The survey also collects information required to estimate household income based on living standards. Household income data is needed both for the denominator of the End TB Strategy indicator, and for the calculation of income loss during treatment (indirect costs in the numerator, Fig. 5.2).

The various categories of income and cost data to be collected are outlined in more detail below. Analytical approaches are described in detail in Chapter 6.

Household income data

Household income measures can be based on self-reported household consumption data, self-reported household expenditure data, self-reported annual household income, or reported household asset ownership. The survey instrument will include questions corresponding to one or several of the four approaches. It is up to the survey team to

select the most robust measure of living standard in the country, bearing in mind the advantages and disadvantages of each of the measures (2). In low- and middle-income countries, the choice made by the study team will often be between asset-based income and consumption-based income, with most economists preferring consumption because it is rooted in economic theory. Asset ownership can be “safely” collected at the facility level, conversely collecting consumption data from a non-breadwinner or purchaser at the facility level is not ideal and could be biased. Triangulation with multiple measures of income data collected could be ideal and a pilot survey could evaluate several options. In future, as more cross-country TB patient cost survey data is analysed, a comparison of various measures of living standards collected at the facility level may bring further insights into what is feasible to collect and how robust such measures are.

If asset-based income, consumption-based or expenditure-based income is used in the survey, the list of questions is specific to the country conducting the TB patient cost survey and thus the generic instrument includes the section heading but no default questions. Ideally, these questions should come from validated items from the latest demographic and health survey (DHS), the household income and expenditure survey, living standards measurement study (LSMS) or similar sources of information. For asset questions, it is important to use a sufficiently thorough (at least 10) list of assets and/or dwelling characteristics to allow enough variation among respondents. The national statistics bureau and/or relevant government departments can provide information on the latest national surveys and the list of questions used to determine ownership of assets and/or dwelling characteristics.

Direct cost data in this survey

Direct payments made by patients while seeking or accessing TB services are considered “direct costs” and they include medical and non-medical payments, net of reimbursements.¹

Direct medical costs incurred pre-diagnosis, during hospitalization, a medical visit, a directly observed treatment (DOT) visit, or a visit to pick up TB drugs, will be collected. For hospitalizations and visits, the survey further breaks these costs down by activity: bed day charges, consultation fees, radiography, medicines, laboratory tests, and other procedures if the respondent is able to disaggregate them.

Direct non-medical costs include the cost of transportation to and from a medical visit and the cost of food that the patient (and their accompanying household members) had to purchase while travelling to a health facility. This includes food required during hospitalization or food and nutritional supplements recommended and additional to the regular food basket. Sometimes patients will have to travel for more than one day to seek care and, in this instance, the cost of overnight accommodation would also be included as a direct non-medical cost. Sometime, patients and their caregivers will relocate to the

¹ Non-medical costs are classified as “indirect costs” by some authors, but not here as they are considered as direct expenses borne by TB-affected patients. It is important to report travel, accommodation, food and nutritional supplements individually and not just as “non-medical” direct costs.

city for TB treatment and in this case the moving and accommodation cost would also be considered a direct non-medical cost.

Indirect cost data in this survey

Indirect costs are measured through the income that patients report losing during treatment (Fig. 5.2), or through a measure of the opportunity cost for seeking or being in care, that is a valuation of time “lost” for the patient and their household members throughout the TB episode. The survey collects data that allows the estimation of indirect costs through two alternative methods: the output approach and the human capital approach.

The output approach uses self-reported household income at three points in time (prior to the onset of TB symptoms, at the time of diagnosis and during the “current” treatment phase) to estimate income change before and during the TB episode. This is the simplest and conceptually most appropriate method but only works well in settings with a predominantly formal economy where study subjects can report valid household income in monetary values. If the reported household income data is not trusted then the output approach is not recommended to value indirect costs. Instead time loss valuation should be used.

The human capital approach uses reported time use while seeking and receiving care during the TB episode (in hours) multiplied by an individual hourly income. Children are by default given an hourly wage of zero, and instead estimated hourly income data for the caregiver(s) are used. Hourly income is estimated on the basis of individually reported income data collected from all survey participants, or on the basis of estimated household income and data on the composition of the household. These are the two suggested methods.

- Self-reported hourly income is calculated based on reported individual income in conjunction with reported hours worked. This is preferred where study subjects can report valid individual income.
- Individual income is estimated based on self-reported or estimated household income (see household income data above). Once household income has been estimated, individual income can then be estimated by ascribing a proportion of the household’s annual income to the individual based on the number of reported adult household members. Hourly income is calculated based on self-reported number of work hours, or if that information is missing, then on an assumed 40-hour working week (or the national work week average).

See Chapter 6 for more details on the analytical approaches.

5.2 Data-collection and data-entry procedures

Place of interview

The least resource-demanding approach is to interview patients in the facility where they receive TB care. This discussion should preferably take place in a separate space/room to allow an undisturbed interview that ensures infection control, as well as privacy and confidentiality. In all interactions, the interviewers shall maintain confidentiality in order to avoid any consequence or change in care provision due to answers provided. Depending on queue length, patients may be interviewed while waiting for a consultation (ensuring they do not lose their place in the queue) or after the consultation. An alternative is to conduct pre-arranged interviews in the household, which is usually more time-consuming and costly for the survey team, but which may increase feasibility for patients and potentially reduce selection bias (see Chapter 4).

Informed consent

Before the interview, the interviewer should briefly explain the purpose of the study to the patient. The patient should be given time to read and understand the informed consent form (see Chapter 7). This may mean having versions of the form in all local languages. If the patient agrees to join the study, then health care staff should ask the patient to sign the form, or the interviewer should note that verbal consent was provided. Informed consent forms should be kept and filed by the interviewer.

Interview

Interviewers will read the questions to patients in their mother tongue and may directly enter patient responses on the paper questionnaire, or on a standard electronic survey questionnaire, or e-survey (see Data entry section). They will check patient records and seek to ensure valid responses. While the survey instrument should be available in local languages, a translator may be needed if migrants participate in the survey.

Time required for the interview

The time required to conduct the interview following the generic survey instrument is approximately 45–60 minutes. Prior to the interview, the interviewer will be required to complete some questions by checking patient records, which takes approximately 15 minutes.

Data entry

The generic questionnaire is available both on paper and as an e-survey with a data entry form that can be used on tablet devices and laptops. Direct data entry during interviews is done either:

- offline using the e-survey tool, followed by online data upload (several questionnaires will be uploaded at a time; internet connectivity is only required for the latter process); or

- on paper, if the interview is carried out using a paper-based survey, with subsequent electronic data entry by data entry clerks at a central unit.

Box 5.2 Example of instructions provided by survey coordinator to interviewers on how to fill in the questionnaire electronically (Uganda) and on paper (Viet Nam)

Uganda instructions to interviewers

Interviews will be conducted by trained facility interviewers. The facility interviewer shall arrive at a selected health facility at 08:00 and shall wait for TB patients to arrive for treatment. The interviewer shall look for an appropriate venue where interviews will be conducted within the facility. When the TB patient has completed accessing treatment, the health worker shall refer the patient with a TB card to the facility interviewers. Patients will be provided with written informed consent forms in the language they understand best. In all patient interaction, the interviewers shall keep confidentiality and respect of cultural and religious beliefs of respondents. If the patient consents, the facility interviewers will review the patient TB card and determine whether the participant is eligible for the survey and if eligible the facility interviewers shall then fill in Part I and II getting information from the patient TB card and TB register and there after interview the patient. Interviews will last approximately 45 minutes to one hour. Below are the steps to access the e-questionnaire on the tablets.

1. Enter log in details or draw pattern to log in to the tablet.
2. Click on ONA icon on a tablet and click fill blank form.
3. Click on National TB related catastrophic costs in Uganda, the form will load for 3 seconds and swipe forward or use arrows to move back and forward as you enter data.
4. Before filling data from the TB card and TB Register, assess the eligibility of the patient to participate in the study (Patient should have been on treatment for 14 days and above).
5. Checks will be made to determine if the patient is eligible for the study or not.
6. The patient will be excluded in the study if:
 - a. patient is a child below 18 and is un-accompanied
 - b. patient has been in treatment group other
 - c. patient fails to consent to participate in the study.
7. For patients included into the study ask all questions till the end.
8. Save the data and open a new questionnaire for the next patient.
9. Questions will be read to patients in their mother tongue.
10. Only the consent document will be translated into the main local languages.

Viet Nam instructions to interviewers

1. Before the interview, health care staff will briefly introduce the purpose of the study for the patient again.

Continued

Box 5.2 Continued

2. Let patient read and understand "Informed consent form". If the patient agrees to join the study, then health care staff ask the patient to sign an "Informed consent form". (Health care staff can read and explain "Informed consent form" if the patient cannot read or has a problem in reading).
3. Conduct an interview with the patient based on the questionnaire. Health care staff should make sure patient correctly understands all questions.
4. Health care staff fill all information from patient interview into questionnaire.
5. Health care staff pay incentive for patients participating in the study. They will keep receipts.

Health care staff collect "Informed consent form" with patient's signature, filled questionnaire and financial related information.

5.3 E-survey

An electronic generic survey system has been set up and can be used on laptops or devices running iOS or Android. This electronic survey is based on XLS forms, a secure management of electronic forms and data in real-time. This platform was established using ONA (ona.io), as it had been used successfully by reproductive health and Ebola research colleagues at WHO. It was chosen mainly because it is open access, allows data collection offline and later online uploads to send to the data repository, and may be used for routine data collection in the future if desired. This application also allows version control, which means that as the e-patient survey is streamlined following the pilot phase, the data previously collected will not be lost. The technology required for a country to use the e-survey is an updated web browser such as Google Chrome, Internet Explorer, or Mozilla Firefox. There are other similar platforms that are or will be available in the market which may have similar features.

The electronic survey hosted in ONA can be accessed via a web browser or through ODK (Open Data Kit) Collect, a free Android application. The survey will require a network connection the first time it is opened. Once the survey has been loaded, users will no longer need an active network connection for access. If there is an active connection, patient responses will automatically be loaded to a web database once submitted. In cases of limited network connection, the form can still be completed and the survey will save responses so that material can be sent to the database once network connectivity is re-established. The database is secure, with designated individuals accessing it through a username and password.

The generic e-survey contains skip patterns and can direct respondents to different sections of the survey according to TB type and whether interviewees are spoken to during the intensive or continuation phase. This electronic questionnaire can be programmed to automatically generate essential cost calculations.

Questions can be displayed in many languages, selected from a dropdown list. If a country requires further customization, including additional translations not already included, it can request the XLS form of the “generic instrument” from tbddata@who.int, then translate, adapt and upload as a replacement for the generic version.

If an electronic data entry survey is chosen, the ethics review board may require the informed consent form to be completed as a hard-copy, with a patient signature or finger print. Alternatively, an electronic signature can be used with the electronic survey tool.

5.4 Quality control

The survey coordinator should establish the plan for field supervision. The team leader should check all questionnaires at the end of each day, at least at the start of the survey, to ensure errors are promptly identified and corrected. Thereafter the data manager can check data quality periodically. If data are collected on paper, subsequent electronic data entry can be done either by the interviewer, supervisor, or by specially recruited data entry clerks. This should be decided by the survey advisory group.

Box 5.3 describes supervision experience in two countries.

Box 5.3 Field supervision country examples

In **Uganda’s National Patient cost survey (2017)**, supervision from the central unit of each study site was conducted at the beginning of data collection. The survey coordinator selected a supervisory team. At each location, the site’s survey supervisor checked all questionnaires at the end of each day to identify and correct any errors. The purpose of supervision was to support the field team in quality data collection and participant enrollment. Team leaders at the facility level would review the data collected and validated by the facility interviewers daily.

In **Viet Nam’s National Patient cost survey (2016)**, two monitoring trips were conducted by national research officers, a specialist from WHO Viet Nam and provincial coordinators, during the one month data collection period. The aim of the first monitoring visit was focused on practically guiding district staff in the conduct of interviews, and to provide suggestions to improve interviews and data collection. The second monitoring visit was focused on assessing the quality of data collected. Each completed questionnaire was reviewed carefully; information from records was cross-checked with health records and register books. If questionnaires needed to be validated, district staff members were asked to arrange follow-up interviews to correct the information.

5.5 Data cleaning

Data analysts should check data for extreme values using simple tabulations (e.g. time loss answers, income reported, number of clinic visits pre-diagnosis, which should accord with previous patient pathway analysis etc.) and communicate with the survey team about any potential problems. Issues, such as implausible data points or questions consistently missing, may prompt an examination of the original survey record (if paper-based) or re-

interviewing the patient, if possible. In the second instance, a decision to overwrite data with an assumed value would be required. Some extreme values are justified and should not be overwritten. The data analyst will decide whether a result is correctly reported data or an error. This may involve contacting the original interviewer and/or having a discussion with the PI. The data analyst will also have to convert certain text responses into numerical or categorical data.

5.6 Pilot study on data collection and entry

A time-limited pilot survey should be organized in some of the sampled sites 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. Pilots can often be done in conjunction with, or shortly after, the survey training (see Chapter 8).

6.

Analysis

6.1 Descriptive statistics

After the data has undergone cleaning, basic descriptive statistics and cross-tabulations should be produced to display the patient population, health care utilization, model of TB care (place of treatment, number of visits etc.), demographics (e.g. age, gender) and TB treatment information (e.g. MDR status, phase of treatment, diagnostic delay). An example table of descriptive statistics is provided within Annex 4, alongside shell tables for presenting survey results.

Code for the analysis of survey data is available in both Stata and R available upon request from tbdata@who.int.

6.2 Estimating household income

Annual household income can be estimated in several ways within a TB patient cost survey (Fig. 5.2). It is advisable that the survey team conducting national TB patient cost surveys decide which method is most appropriate before designing the survey. This decision will be based on previous successful national experience of measuring household “income”. Based on the choice, the local research team will re-use the relevant questions from the most recent survey (consumption, expenditure or living standard). A reduced set of questions may be sufficient (and allow shortening of the TB patient cost survey questionnaire), but in order to select the appropriate set some preparatory work is required (Box 6.1). As mentioned earlier, there are advantages and disadvantages to the various measures of living standards and they are not equivalent (2). Countries should choose the more robust and less biased measure. If countries need assistance in deciding on which method should be used or implementation of that method, they can consult WHO or other technical agencies supporting the survey. A summary of four methods of estimating household income is provided below. If implementers select one method (e.g. Monthly self-reported household income) in addition to the prediction of household annual income based on asset ownership/dwelling characteristics, questions regarding the other two methods (e.g. 1) “Monthly household consumption” and “Monthly household expenditure”) could be deleted from the instrument, or left in, to compare results using various methods and perform sensitivity analyses. The latter will be useful for cross-country analysis and future refinement of survey methodology.

1. Monthly household consumption

One measure of estimating income is household consumption: the resources that households actually consume. Measurement of consumption is widely used by economists in household and economic surveys and is thought by some to be a more accurate measure of income than self-reported income itself. While this method can be used in any country setting, it is most useful in countries where the informal work sector dominates, causing self-reported income to be less accurate (as described above).

To measure consumption within TB patient cost surveys, respondents are asked a series of questions about how much (if anything) they have spent on certain goods and services, including food items, non-food items, durable goods (i.e. goods that last for a long time, such as bicycles), and housing. As mentioned earlier, the selection of questions regarding consumption is done on the basis of previous household consumption or living standard surveys. In practice, the questions on household consumption have been a subset of those asked in the previous survey which had a greater focus on household socioeconomic status. For example, rather than asking for household consumption on all possible types of vehicles, the survey could group these all into one question about vehicle expenditure, as the disaggregation is not of particular interest here. However, interviewers should describe these broader categories to patients and should, if necessary, probe to ensure major areas of spending are not excluded. The generic survey instrument does not include any default questions on household consumption as this section of the survey is tailored to country-specific consumer patterns.

If survey respondents are asked about their monthly household consumption for certain categories, these amounts will need to be multiplied by 12 and added up during analysis to arrive at the annual household consumption.

2. Monthly household expenditure

Expenditure excludes consumption that is not based on market transactions. Home production would be excluded from this measure (but included under consumption). On the other hand, expenditure would include purchases made but not consumed within the reporting time frame (2).

3. Monthly self-reported household income

Self-reported household income has been the primary method of measuring income in recent TB patient cost surveys, primarily due to its simplicity. This method may be most reliable in countries where the formal work sector predominates (e.g. Government, the private sector, or other highly regulated employers) and monthly self-reported income can be based on information from payslips.

In countries with a large informal work sector, monthly self-reported household income is subject to limitations. For example, income may fluctuate greatly from month to month if patients are reliant on intermittent, casual or seasonal work. In addition, self-reported income is open to recall and reporting bias (especially when respondents do not receive a

regular payslip), potentially leading to respondents over- or under-estimating or reporting their actual household income.

4. *Prediction of household annual income based on asset ownership/dwelling characteristics*

Another method is to estimate household annual income based on a list of asset questions (e.g. ownership of vehicles, mobile phones, etc.) and/or dwelling characteristics (e.g. the number of rooms in a house, what the walls of the house are made of, etc.). This method may be useful in countries with a large informal work sector and where a validated set of questions on asset ownership or dwelling characteristics exists.

During analysis of the data gathered by this approach, comparative poverty levels and scores will be calculated for respondents and their households. This is done by creating a regression equation between the asset variables and reported household income in the external dataset (i.e. living standard survey or similar). See Box 6.1 for full details on how asset questions can be transformed into an estimate of annual household income.

Box 6.1 Selecting country-specific asset variables

In order to select asset variables that are best linked with income/expenditure, it is advisable to identify a recent survey in the country which measures both asset ownership and household income/expenditure. Such surveys can often be downloaded through the World Bank's microdata library (<http://microdata.worldbank.org/index.php/home>). These surveys often have long lists of validated asset questions. If no recent survey is available in the country, a survey from a neighbouring country with a similar economic profile can be considered.

Once the data has been acquired from this past survey, a multivariable linear regression should be used to predict household income or expenditure using all of the asset variables in the survey. The next step is to select the asset items that have the strongest link to total household income/expenditure by looking at those with the smallest p-values or largest test statistics from the resulting regression. This list of selected assets, originally used in an external survey, will be included in the TB patient cost survey instrument. We recommend choosing at least 10 items in order to differentiate income levels effectively among households.

6.3 Estimating costs

The cross-sectional survey design requires the calculation of costs. The following method is suggested.

- To estimate costs in the remainder of the patient's current treatment phase: extrapolate the patient's costs in that treatment phase to date. E.g., if only one third of the treatment phase has been completed, costs to date in that treatment phase are multiplied by three. This is done by using the questions of planned phase duration and phase days completed.

- To estimate costs from the other phase of treatment: use the median reported costs and number of hours from other patients who were sampled in that treatment phase. In this calculation, costs from DS-TB and MDR-TB patients are considered separately. A more nuanced approach (to perform in sensitivity analysis) could be to extrapolate based on similar (location, age, socio-economic status) patients only. This approach would avoid any potential masking of inequalities in total costs derived from the use of median costs and time to extrapolate to other patients.

Both of these calculations are done within the statistical code that is available on request.

Direct *Guardian costs* should also be added during the calculation of costs if the guardians are part of the same household as the patient. The direct costs of guardians are reported by the respondent. Since April 2017, the Global Task Force agreed that indirect costs of guardians should not be part of the End TB Strategy indicator measurement.

6.4 Determining 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.

6.5 Coping strategies

An analysis of coping strategies will give insight into how patients are dealing with the cost of TB treatment. Each coping strategy can be examined as a binary measure, i.e., whether or not the household employed that strategy, or as an absolute amount of coping. Although undertaking these activities does not equate to experiencing catastrophic costs, they are an important consideration when designing and advocating measures to reduce costs. It is advisable to look into the correlation between costs and/or experiencing catastrophic costs, and the undertaking of coping strategies.

6.6 Social consequences

The generic survey instrument asks questions on the social consequences of TB disease and treatment such as social exclusion, divorce, children dropping out of school, etc. These indicators may be more easily understood by policy-makers than the definition of catastrophic costs and thus a full analysis should include descriptive statistics on the frequency of experiencing these consequences.

6.7 Adjusting for intra-cluster correlation to obtain a national estimate

The proportion of patients (and their households) in the survey that face catastrophic costs may need to be adjusted to be nationally representative. This may be due to under- or over-enrollment in particular clusters and/or the need to adjust for intra-cluster correlation.

Clustering adjustments

In cluster sample surveys, observations from the same cluster lack statistical independence, because individuals within clusters are likely to share more similarities than individuals in other clusters. To account for intra-cluster correlation, robust standard errors should be computed. This can be done through an individual-level analysis of the survey data using logistic regression. The resulting estimate would provide larger standard errors, and thus wider confidence intervals, than standard logistic regression which helps correct for the lack of statistical independence of individuals within clusters.

Weights

For settings in which cluster sampling was selected as the sampling strategy, but where some clusters had insufficient patients interviewed during data collection, existing data from these units should be compared with completed units.

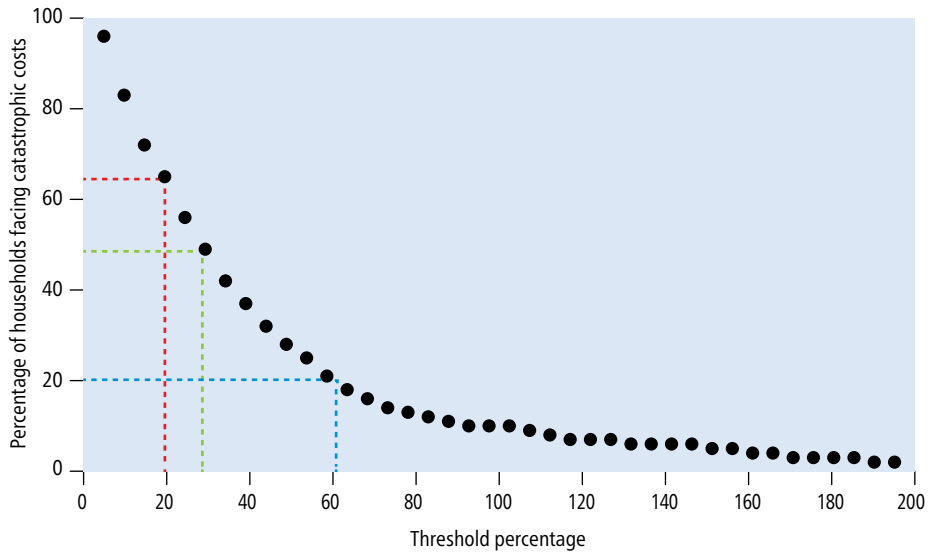
If the number of patients enrolled in each cluster varies widely (which should not happen if the study protocol is adhered to), then the actual sampling method can no longer be considered to be PPS. If there is concern that the cluster itself might be associated with a disproportionate risk of experiencing catastrophic costs, it will be important to make a correction in the analysis for this potential bias.

This can be addressed by assigning a weight to each cluster that is proportional to the number of interviewed individuals in each cluster. For instance, if the planned cluster size was 27 patients and there is a large variation in the actual cluster size due to difficulties in enrolling patients, the weight assigned to each new patient within a given cluster will be equal to 27 divided by the actual number of new patients interviewed. The analysis should be carried out with and without weights, and differences in output values should be examined carefully.

6.8 Sensitivity analyses

It is recommended that the main findings be reported alongside sensitivity analyses. One key example of this is to use both the output approach and the human capital approach of valuing indirect cost. Another is to use different approaches for income assessment. It may also be valuable to present the proportion of TB-affected patients (and their households) facing catastrophic costs if direct costs alone are counted, or if medical expenses alone are counted. These approaches ignore lost income or a valuation of lost time, which may prove difficult to measure accurately. Another sensitivity analysis that has been valuable in previously conducted surveys is to alter the percentage of income threshold used to define catastrophic cost (Fig. 6.1).

Fig. 6.1 Example of impact of changing threshold to define catastrophic costs and the count of TB affected households experiencing catastrophic total costs



7.

Ethical considerations

7.1 Ethics approval

Before initiating this project, a detailed protocol should be submitted to an ethics committee for approval. Information to be provided by investigators to the ethics committee includes the ethical approval application form, CV(s) of principal investigator(s), and a detailed survey protocol including:

- 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
- ethics concerns and how they will be addressed.

Annex 11 provides an example of questions posed by the ethics review committee and answers provided by the study team.

7.2 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 be 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.

7.3 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.

Part II of the data collection instrument includes a generic consent form (see Annex 1), which should be adapted to local circumstances as part of the overall adaptation of the survey protocol. Information should include:

- the purpose and procedures of the survey
- why and how the potential participants were selected
- any possible discomfort
- the right to abstain from participation in the survey or to withdraw consent at any time without reprisal
- institutional affiliation of the researcher and their contact details
- 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
- what compensation, if any, will be given, e.g. for transport costs or time lost due to participation
- what social support and social assistance are available to the TB or MDR patient, in particular if it has been identified in pre-survey social protection mapping (see section 2.3).

In addition to adapting the informed consent language from the generic protocol, an additional form for consent for paediatric TB patients may be included.

7.4 Compensation for survey participants

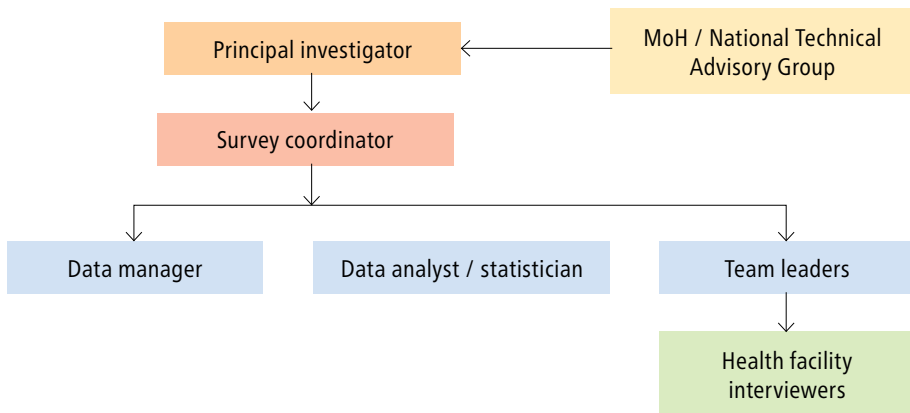
Patients may be compensated in cash or in kind for the time, travel or inconvenience associated with the interview. It is not acceptable to expect participants to cover the costs of travel or lost work time to participate in the survey, but any compensation should be reasonable so that it does not induce someone to take part in the survey simply for financial gain. A decision on compensation and the amount, needs to be decided by the survey coordinator and clearly stated in the information sheet. Section 9 (survey budget) describes ranges of compensation in survey implementing countries.

8.

Organization of the survey team and training

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. This section provides an overview of the composition, roles and responsibilities of the survey team. The exact composition and reporting lines for teams will vary but clear roles and responsibilities, consistent with qualifications and experience, are critical. Fig. 8.1 provides a generic organogram for the survey team, which needs to be adapted to the national context. Details on suggested composition and qualifications of the survey team members are listed in Annex 5.

Fig. 8.1 Organogram for the TB patient cost survey team



8.1 Oversight and management

The ultimate responsibility for the management of the survey rests with the Ministry of Health (MoH). A national technical advisory group may be established, also including representatives from other stakeholders beyond TB and health, and possibly international partners, to provide technical support. Remote technical assistance can be made available from the Global Task Force on TB patient cost surveys.

Even if the Ministry of Health leads, actual survey implementation may be better conducted by a local academic institution with experience in conducting health facility based surveys, for example those conducting epidemiological, social science or health economics research. If conduct of the survey is contracted out to an academic organization or research institute, this organization needs to report regularly, either directly to the health ministry or to an MoH-led technical advisory group. A contract should define deliverables (including timings), human resources, quality assurance and quality control measures, data ownership and financial arrangements.

8.2 The survey team composition

The survey team should include at a minimum: a principal investigator, a survey coordinator, a data manager and interviewers. Team leaders are desirable if the survey coordinator's presence in each cluster is infrequent. Interviewers should not be regular health staff in the facilities where the interviews take place, in order to reduce risk of bias and conflict of interest.

A statistician will be valuable to assist with sample size calculations and data analysis, and, if resources permit, an IT expert can help to adapt the protocol to e-survey tools.

8.3 Recruitment of the team

It is unlikely that all staff needed for the survey will be readily available at the implementing institution, particularly the survey coordinator and the interviewers. Staff should be recruited using routine recruitment procedures in the country, and this process should begin as soon as practicable once ethics approval and survey funding are secured. Given the temporary nature of the jobs, it is worthwhile to consider the secondment of staff from universities, research, or nongovernmental organizations in the country. Attrition can partly be avoided by starting the survey soon after the training of interviewers and by providing a supportive working environment or other incentives, such as a professional reference for future employment or a survey participation certificate.

8.4 Development of standard operating procedures (SOP) and survey supervision plan

Experience from first implementing countries has shown SOPs are needed in the following areas (see Annex 12 for examples):

1. SOP for procedures for facility-based staff to ensure quality data collection:
 - a. Survey purpose and scope
 - b. Responsible person
 - c. Procedure (Study timeline; screening and preparation of the eligible patient list for the study; patient selection; conduct of interviews)

2. SOP for procedures for Provincial level coordinators to ensure data quality supervision:
 - a. Survey purpose and scope
 - b. Responsible person
 - c. Procedure (provision of questionnaire and other related documents to district unit, support district unit in selecting patients, interviewing, supervising and checking questionnaires completed by interviewers)
3. SOP for data entry describing person in charge and procedures including random checks on data entered in two formats: paper and web (ONA).

Indicators and benchmarks should be clearly defined in the survey protocol, and team leaders and supervisors should be well trained to take action whenever benchmarks are not being met. Regular supervision should be undertaken. See Annex 13 for an example of an external survey monitoring plan and Annex 14 for an example of a survey review checklist.

8.5 Training

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.

Training duration will vary from one-to-several days depending on previous experience of the interviewers in facility-based surveys and their knowledge of TB and online data collection tools.

Possible objectives of the training for interviewers are listed in Annex 6 and an example of two-day training for data collectors is shown in Box 8.1. A generalized sample training programme is available in Annex 7.

8.6 Development of timeline

A timeline for the survey planning, implementation and analysis needs to be developed. See Annex 8 for a template and an example.

Box 8.1 Two-day training for data collectors (Viet Nam, July 2016)**Objective of the training**

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.

Team leaders and survey coordinators should:

- assess the suitability of interviewers to conduct the survey.

Interviewer training deliverables

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.

Continued

Box 8.1 Continued

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.

9.

Budgeting

9.1 Budget estimation before detailed survey planning

A rough budget estimate is required at the initial planning stage, in order to assess the availability of funding, and whether further resource mobilization is needed. To guide the rough budget estimate for the initial planning stage, a hypothetical number of participants per survey (ranging from 750 to 1800 in high TB-burden countries) multiplied by an average budget per participant of US\$ 80 for Asia and US\$ 120 for Africa may be used.¹

Detailed budgeting needs to be done in parallel with the development of the survey protocol since budget limitations can have important implications for sample size, number of clusters and retention of survey staff etc. See Annex 9 for an example of a template to establish a detailed survey budget. This is by no means exhaustive but shows the most important items for which a budget is likely to be needed. The final budget should also be reflected in the TB National Strategic Plan budget.

Several major factors influence the size of the total survey budget.

- **Sample size, number of clusters and geographic distances.** The sample size and the number of clusters affect how many interviewers (and survey teams) are required, how many mobile data collection devices are needed (if used), and the length of the data collection period.
- **Staff costs.** It is usually necessary to hire staff specifically for the survey, although some surveys have fully or partly relied on regular programme staff. Human resources accounted for 31%–37% of budgets in countries implementing this survey for the first time (Fig. 9.1).
- **Number of interviewers.** The expected volume of patients per day at a cluster also affects the number of interviewers required. Myanmar used 10 interviewers for 25 clusters, Uganda used 15 interviewers for 67 clusters, Viet Nam used 22 data collectors for 20 clusters and Kenya used 30 interviewers for 30 clusters. In the Philippines, 298 health care workers were employed and did home-based interviewing when patients were not at the health facility.

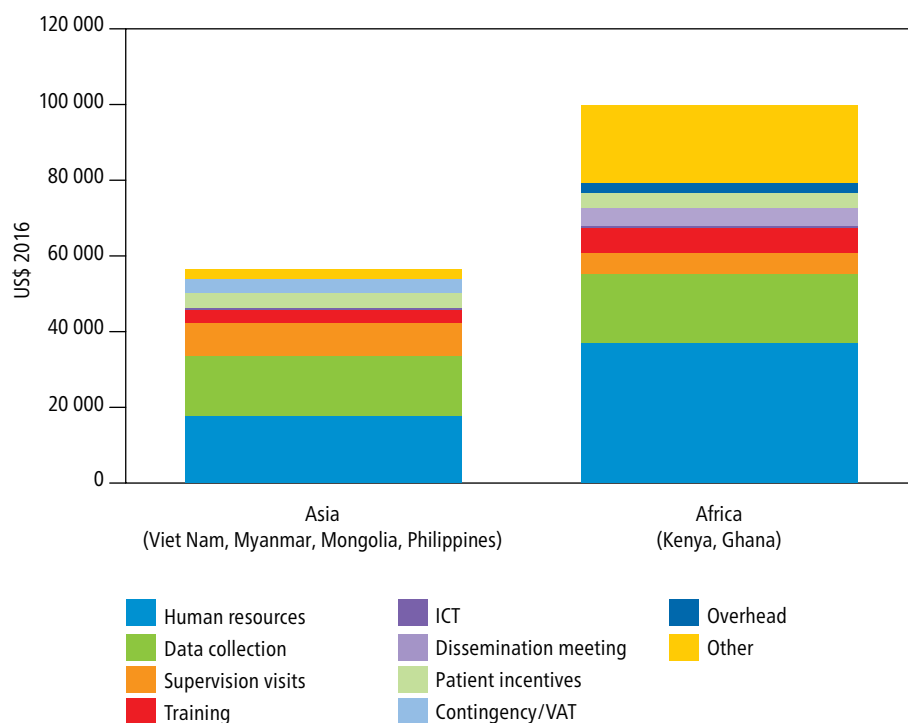
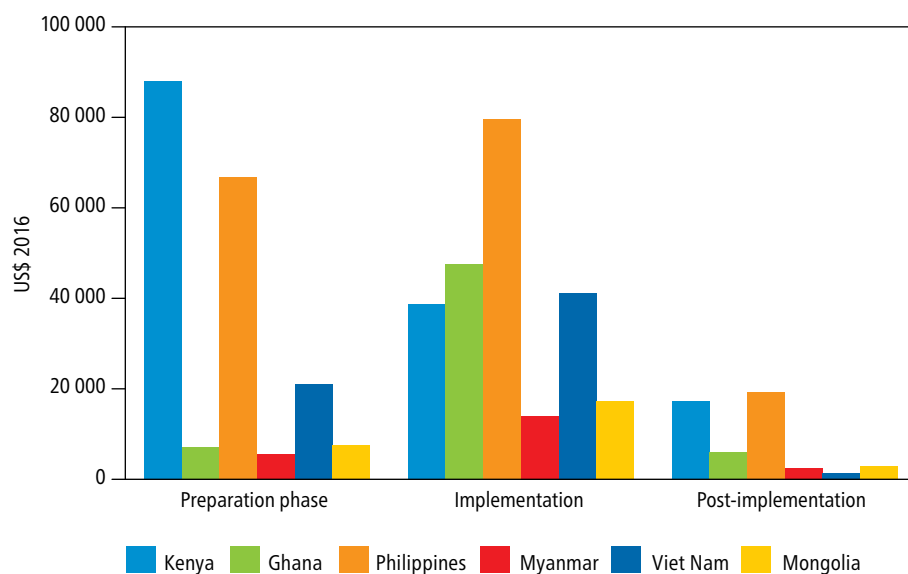
¹ The values provided here are estimated based on an average of the budgets used in first eight implementing countries (Kenya, Ghana, Myanmar, Viet Nam, Mongolia, Timor Leste, Solomon Islands, Philippines).

- **Technical assistance.** Funding for technical assistance should be part of the budget if the survey is counting on external technical support. For international support, a minimum of a one-week mission and one-to-three weeks of remote support should be planned for. These are the areas where support was requested by first country implementers of WHO 2015 methodology: protocol adaptation, sample size estimation, training of survey team and interviewers, and post-implementation (analysis and results dissemination).

9.2 Typical components of a budget

The main components that need to be budgeted in a TB patient cost survey are illustrated in Figs 9.1 and 9.2. The major items are below.

- **Human resources.** These include the salary share or compensation for the principal investigator, survey coordinator, data analyst, data manager, team leader and interviewers.
- **Technical assistance.** This includes travel and fees for technical assistance provision.
- **Survey adaptation.** This includes costs-related protocol development, adaptation of the instrument, including translation and back translation, and situation analysis.
- **Ethics.** This includes applications and ethics review committee fee.
- **Information Communication and Technology (ICT) and supplies.** These may include computers, mobile data collection device rental, technical support fee for web-based data collection form, stationary and survey database set up.
- **Patient incentives.** To compensate for visit travel cost (an incentive ranging from US\$ 1.60–\$3 per patient was provided to patients interviewed in recent surveys).
- **Data collection.** These costs include travel related costs for interviewers and team leaders.
- **Supervision visits.** These include travel and per diem for supervision visits.
- **Data cleaning and analysis.** Staff or consultant time cost for data analysis if additional to the cost of hiring a data manager and analyst (included in HR) or using technical assistance for this activity (included under technical assistance).
- **Training and meetings.** This includes the cost of training before data collection starts, such as interviewer training, plus regular survey meetings and a results dissemination meeting with partners within and outside the health sector.
- **Report writing and publication fee.** Staff or consultant time cost for survey report writing, review or manuscript drafting, and publication fee to submit findings to scientific journals.

Fig. 9.1 Average regional patient cost survey budget ranges by major line item**Fig. 9.2** Patient cost survey budget by phase, selected countries in 2016–2017

9.3 Budget structure

It is useful to structure the budget in four main parts.

- **Human resources and technical assistance:** throughout the survey;
- **Preparatory phase:** training, survey protocol adaptation, pre-survey visits and survey pilot;
- **Implementation phase:** patient incentives, data collection and supervision visits;
- **Post-field operations phase:** data analysis and cleaning, report writing, final review, publication fee and dissemination meeting.

9.4 Total budget required

The total budget required for a patient cost survey has ranged from US\$ 27 000 to US\$ 166 000 (Table 9.1), mostly excluding funding for international technical assistance provision. The budget (excluding technical assistance) per survey participant ranged from around US\$ 22–129.

Table 9.1 Examples of recent budgets for patient cost surveys that followed WHO methodology

REGION	COUNTRY	BUDGET (US\$)	YEAR OF SURVEY	SAMPLE SIZE	BUDGET PER SURVEY PARTICIPANT (US\$)	FUNDING SOURCE
Africa	Ghana	55 455	2016	725	76	LSHTM/USAID
	Kenya	144 034	2017	1117	129	Global Fund
Asia	Myanmar	22 000	2015	1000	22	WHO Myanmar
	Viet Nam	63 726	2016	735	87	Challenge TB/KNCV
	Mongolia	27 664	2017	400	69	WHO Mongolia and WHO WPRO
	Timor Leste and Solomon Islands	38 842	2016	656	59	Australian National University and WHO WPRO
	Philippines	165 611	2016	1800	92	Global Fund
Americas	Cochabamba, Bolivia	16 300	2016	500	33	Université Libre de Bruxelles

9.5 Sources of funding

With the End TB Strategy, TB patient cost surveys are now part of the process to identify necessary policy changes and also contribute to monitoring progress towards strategy targets, including elimination of catastrophic costs. This means that surveys to measure costs borne by TB-affected households should be part of a country's national strategic plan for TB care and prevention, and should be considered for domestic financing, inclusion in concept notes to the Global Fund or other international financing arrangements.

International donors that have so far provided funding include Global Fund, US CDC, USAID (including Challenge TB funding), World Bank, national research grant bodies, and WHO. Table 9.1 includes the confirmed or planned funding source for the first countries carrying out a nationally representative patient cost survey using the WHO 2015 methodology.

10.

Survey findings dissemination, and policy and practice implications

10.1 Introduction

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.

10.2 Technical consultation to review survey results

Before embarking on a broad multi-stakeholder consultation to discuss the outcomes of the survey, the NTP and the principal investigator may wish to hold a small technical consultation with key stakeholders. This will provide an opportunity to review the survey

Table 10.1 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	<ul style="list-style-type: none"> Streamline the TB patient pathway <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Reduce/subsidise/eliminate out-of-pocket (OOP) payment <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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) Improve the quality of TB care <ul style="list-style-type: none"> Update and promote the national standard of TB care with an emphasis on people-centred care Eliminate irrational treatment, hospitalization and testing 	<ul style="list-style-type: none"> Reduce/subsidise/eliminate OOP <ul style="list-style-type: none"> 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

COST CATEGORY	POSSIBLE CHANGE IN SERVICE DELIVERY	TB PATIENT SOCIAL SUPPORT AND SOCIAL PROTECTION SCHEMES
Direct non-medical	<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • Provide assistance via TB programme <ul style="list-style-type: none"> – 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)	<ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> – 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) 	<ul style="list-style-type: none"> • Facilitate enrollment of eligible patients/households in existing social protection schemes <ul style="list-style-type: none"> – 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

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.

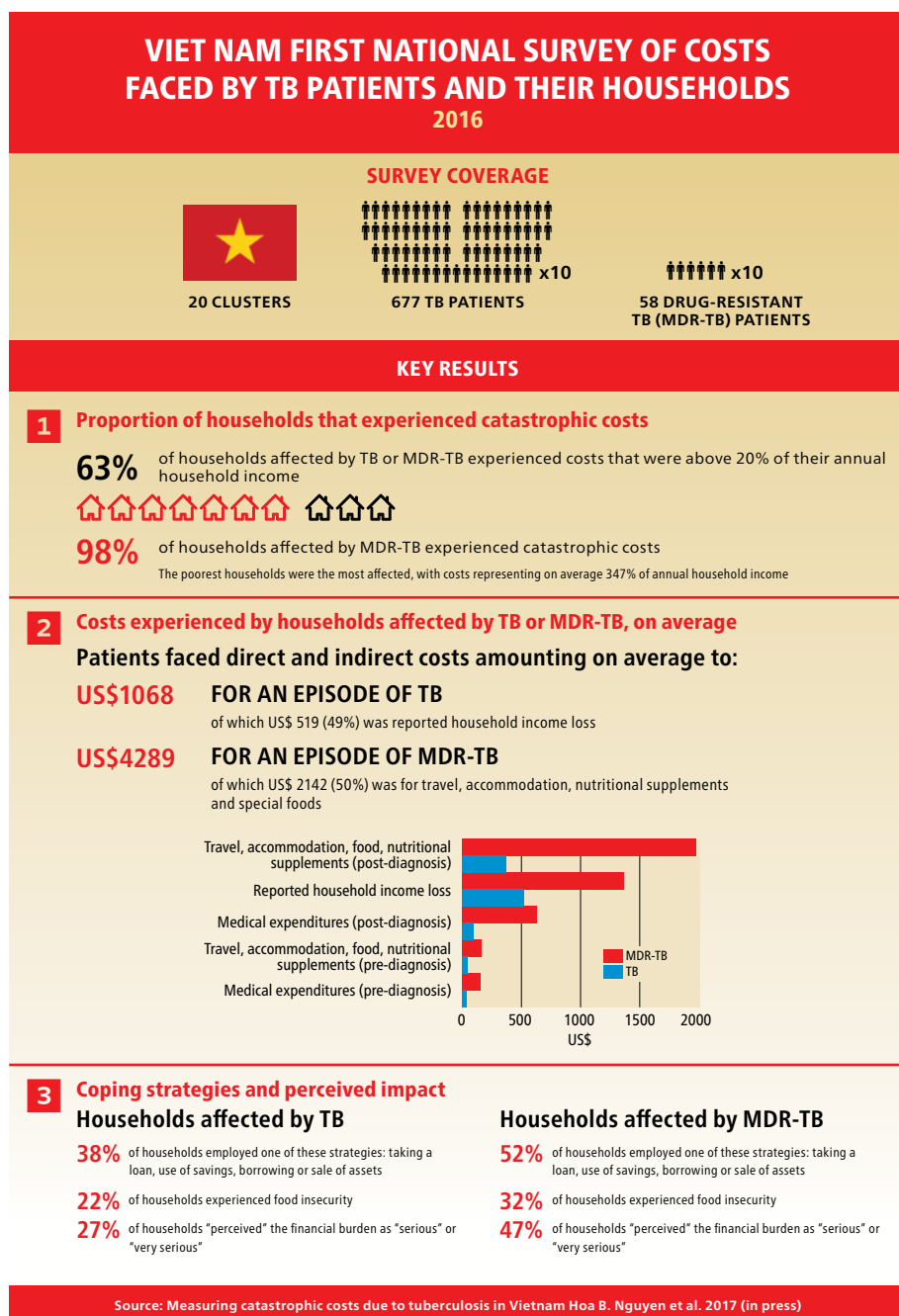
10.3 Survey report and other communication materials

Based on the technical consultation, a draft survey report should be developed (a model template is provided in Annex 10). 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 (Chapter 2) 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.

10.4 Stakeholder consultation

A multi-stakeholder consultation can be the most effective venue to disseminate the result, by engaging key stakeholders, securing political commitment and advocating for strong social support to TB patients and their families. Based on the draft report developed after a technical consultation, key findings are discussed with all stakeholders. Priority interventions should be clearly identified in the domains of health service delivery and financing, as well as enhancing social protection. The roles and responsibilities of key partners should be clearly spelt out within the overall framework of a national action plan to eliminate catastrophic patient costs due to TB. The following boxes describe the national stakeholders' meeting in Viet Nam and the action agreed as a result of the consultation.

Fig. 10.1 Viet Nam first national survey of TB costs

Box 10.1 Results dissemination meeting and policy dialogue in Viet Nam: stakeholder consultation

The first national TB patient cost survey in Viet Nam, conducted in 2016, found that 63% of TB-affected households experienced catastrophic costs, and 98% of households of MDR-TB patients. After the survey was completed, the National TB Programme (NTP) organized a stakeholders' meeting to share survey results, identify key areas for policy action, and develop a framework for the monitoring and evaluation of new policies, interventions and approaches to reduce patient costs. Partners invited included representatives from the social protection department of the Ministry of Social Welfare (MOLISA), the Ministry of Health departments of planning and finance, medical services administration, international cooperation, and health strategy, the Farmers Union, the Women's Union, WHO, the national TB research network (VICTORY), former TB patients, and local and international research institutions.

After presentations on the survey findings, TB service financing and delivery, the current national strategic plan and the social protection landscape in Viet Nam, there were group and plenary discussions on policy implications and next steps. It was concluded that about 30% of TB patients do not have access to health insurance. The existing insurance covers hospital care but does not cover all relevant tests and treatments. As a consequence, many patients incur out-of-pocket expenses for some medical services directly or indirectly linked to TB care. Moreover, most TB patients do not have access to social assistance, sickness insurance or other social protection. Coordination between the health and social sectors is limited, although a recently implemented pilot project coordinated by MOLISA is developing mechanisms to provide support for MDR-TB patients. Early lessons from the pilot are that social protection policies for TB patients remain inadequate, that social workers have limited knowledge about TB and health workers have limited knowledge about existing social protection schemes, such as health insurance cards for the poor.

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 patient-centred 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.

Box 10.2 Results dissemination meeting and policy dialogue in Viet Nam (Hanoi, March 2017): Action plan

The following next steps were agreed.

1. To develop and cost a comprehensive package of ambulatory TB services and advocate for coverage under national health insurance.
2. To include TB-specific patient social support in the Global Fund funding application.
3. To prepare a social fund for TB patients that can be used for needs-based purchasing of health insurance cards for the poor, as well as for providing travel vouchers, food packages, or cash, according to need. The fund will mobilize financial contributions by business, benefactors, etc.
4. To develop a roadmap for collaboration between the NTP, Ministry of Health and Ministry of Labour and Social Affairs (MOLISA) to:
 - scale up and apply the existing MOLISA mechanism to purchase health insurance cards for the poor to TB patients;
 - make existing general social protection schemes more sensitive to the needs of TB patients;
 - assess additional financial and human resource needs;
 - train health service staff on social protection and social service staff on relevant aspects of TB, including who should be referred for TB testing;
 - monitor and evaluate initiatives. The ongoing MOLISA pilot on social protection for MDR-TB patients will be further assessed to inform this process.
5. To engage with the labour sector in order to review current regulations for worker's protection (e.g. to avoid dismissal from work due to TB and access to sickness insurance), with a view to strengthen and better employ legal frameworks.
6. To use existing research platforms to test new approaches to reduce patient costs.
7. To adapt the Social Protection Action Research and Knowledge Sharing (SPARKS) network monitoring and evaluation (M&E) framework, and incorporate operational research under VICTORY.
8. To work towards a national policy guide on interventions to reduce/compensate TB patient costs.

11.

Add-on research

Further descriptive studies may be required to complement national TB patient cost surveys and to better document costs and cost drivers for different sub-groups, and identify the most relevant and feasible interventions to reduce or mitigate costs. Furthermore, the global evidence base on the effectiveness and cost-effectiveness of interventions to reduce or mitigate TB patient costs needs to be expanded, particularly with regards to social protection interventions.

Monitoring and evaluation, as well as operational research is needed to fine-tune interventions on national and sub-national levels. Examples of research priorities related to TB patient costs, social protection and research methods are being developed through the SPARKS network (9). The SPARKS global network is intended to facilitate action-oriented research on the public health impact of social protection, with the main focus on low- and middle-income countries.

Further methodological research is needed to refine the survey methodology, optimize the measurements of costs and income, and better define a valid threshold for catastrophic costs. As part of the latter objective, short- and long-term social and health consequences of different levels of economic shock need to be further documented through both quantitative and qualitative studies.

A few research options are listed below.

11.1 Linking cost survey data to treatment outcomes

Using unique patient identifiers such as the TB register number, TB treatment outcomes can be obtained for survey participants. This would enable analyses of the association between costs (as well as other potential determinants) and TB treatment outcomes. Analyses could include simple descriptive analyses of patient outcome by whether or not different cost levels were incurred, or more complex multivariable logistic regression analyses examining whether costs were an independent risk factor for adverse TB treatment outcome rather than other confounding factors, such as poverty or employment status.

Such analyses would be useful to help validate or change the tentative catastrophic costs thresholds endorsed by WHO (total TB-related costs greater than 20% of annual household income). The choice of this threshold was mainly influenced by data from 900 TB-affected households in Peru which showed that above this threshold, patients with TB were twice as

likely to experience adverse TB treatment outcomes, including treatment failure, loss-to-follow-up, recurrence of disease, or even death (10). Moreover, if costs above this threshold were removed, this would eliminate adverse TB treatment outcomes for more TB patients in the cohort than any other threshold tested in sensitivity analysis, e.g. 10%, 30% (10). More studies are needed to assess if this threshold is relevant also in other settings, and for different sub-groups, such as by type of TB or income level. However, it should be noted that these studies do not address which threshold is most associated with social distress for the household, which is a distinct topic.

11.2 Qualitative research

Qualitative research approaches can be used to gain a deeper understanding of the nature of the costs people face (for example to explore why certain costs are high and others low) as well as to explore cost implications and various positive- and negative-coping mechanisms. Qualitative data could be gathered during patient interviews or separately at individual in-depth interviews, focus groups, workshops, or household visits. Moreover, such methods are useful to solicit ideas about feasible and acceptable interventions to reduce or mitigate costs. For this purpose, qualitative interviews can be performed both with patients and household members, as well as with health and social service care staff and policy-makers.

People-friendly service delivery models are crucial to ensure good access and to reduce care costs. Qualitative approaches as well as quantitative surveys can be used to study quality of care from the patient's perspective (11). Aspects of stigma and discrimination can also be captured, for example to further explore the risk of income loss due to social exclusion, or employment loss due to TB.

Interviewing TB-affected households in order to understand their attitudes and perceptions to health, healthcare, costs, and specifically TB, can improve healthcare access and enhance positive health outcomes. In order to have an impact, the intervention must not only be feasible and effective, but must be acceptable to the local population and suitable to their health needs. A negative example would be a bank transfer scheme that was neither feasible nor acceptable in a primarily agrarian, rural community, in which livestock and land was the main currency. Box 11.1 presents an example of the use of qualitative research to inform an intervention design.

11.3 Pragmatic operational research to evaluate new interventions and policy changes

The identification of high costs for TB-affected households should lead to interventions and policy changes that help reduce these costs. New initiatives to reduce costs and improve access need to be monitored and evaluated. The study designs for such research may include: before-and-after studies in which a particular outcome (e.g. treatment success rate and occurrence of catastrophic costs) are evaluated prior to and following introduction

Box 11.1 Case Study, Peru

During a randomized controlled trial of a socioeconomic intervention to improve TB preventive therapy initiation and TB treatment success in 32 shanty towns in Callao (Peru), the Innovation For Health And Development (IFHAD) research team collected longitudinal data on TB-affected households' perception of the TB care and socioeconomic support they were receiving (12). These results proved crucial because they showed the importance that the households placed not just on economic support (in this case cash transfers) but also the social support provided as information and education during household visits and community meetings. Moreover, the IFHAD team helped to form a TB civil-society group (LUPORFAT – Lucha Por Familias Afectadas por TBC), which was consulted prior to and throughout the study to ensure the maximal impact of a locally appropriate and acceptable intervention. This has been essential in refining the intervention for the *Community Randomized Evaluation of a Socioeconomic Intervention to Prevent TB* (CRESIPT) study, which started recruiting patients in late 2016.

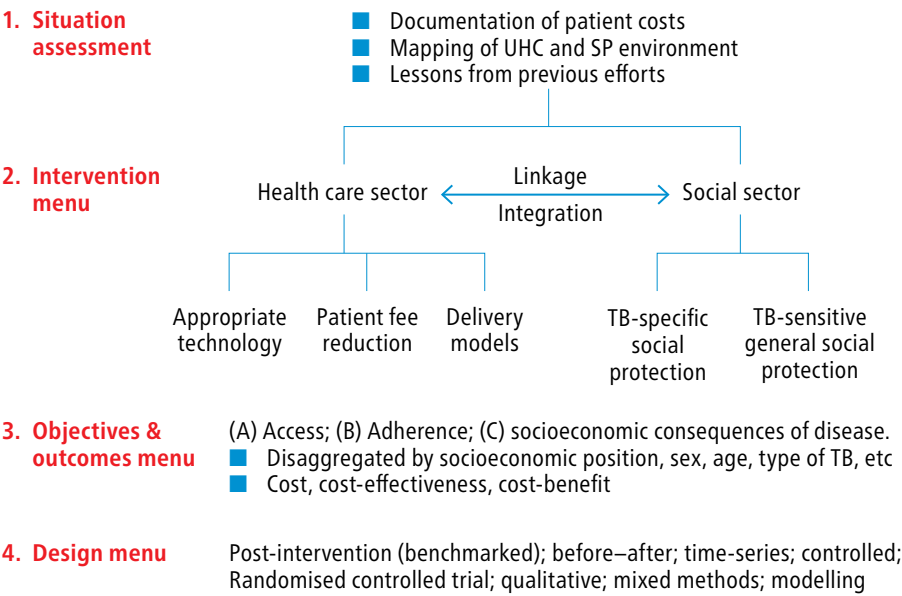
of an intervention; and experiments (natural, quasi-experimental or randomized) in which a particular outcome is evaluated in clusters (e.g. households, health care centres, districts) receiving an intervention, versus clusters not receiving an intervention.

Fig. 11.1 depicts a simple framework developed by SPARKS for the identification of intervention options based on a situation assessment, and summarizes menus for objectives/outcomes of interest and research design. Broadly, interventions can focus on the health sector (fee structure, technology used, delivery models) or the social protection sector (sickness insurance, other cash transfers, etc.), or both. Intersectoral collaboration, improved referral chains, and better-defined role division should be considered and could be an intervention in its own right. For more information see the SPARKS work plan (9).

11.4 Cost-effectiveness analyses and wider economic implications

Health economics analyses can adopt a health system perspective by including only health system costs or a societal perspective by also including patient costs, both as a part of the cost inputs and as an outcome in its own right. The TB Patient cost survey can be used for the latter approach, which can result in a more comprehensive economic picture. Further to considering costs to patients and households, predictions of the costs of TB illness to the wider economy (i.e. through estimations of the impact on national gross domestic product and multi-factor productivity) could be made. The data can be used for economic modelling studies too. Moreover, the generic instrument can be adapted for inclusion in other studies that aim to generate patient-level data for economic evaluations such as trials and quasi-experiments that have other primary outcomes than patient costs.

Fig. 11.1 Framework for pragmatic operational research on interventions to reduce TB patient costs



11.5 Adaptation of the survey instrument for longitudinal designs or trials

The generic instrument can be adapted for longitudinal studies (studies with repeat interviews rather than a cross-sectional design). These include, for example, descriptive cohort studies to assess the long-term health and social sequelae of TB; and intervention studies with other primary outcomes than patient costs, such as interventions to improve early TB detection.

One example of using the generic instrument in a longitudinal study is TB Sequel, which is shown in Box 11.2.

Box 11.2 TB Sequel study in four African countries

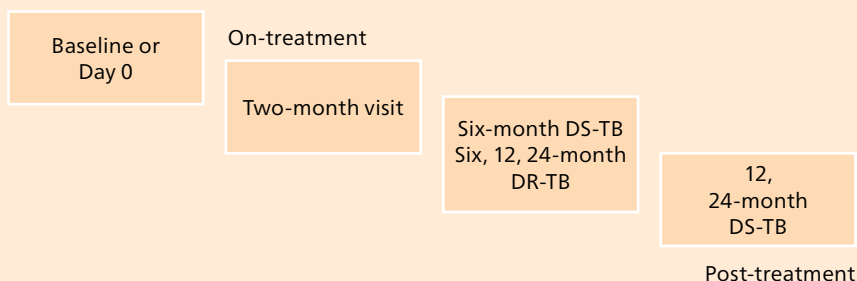
TB Sequel is a multi-country, multi-centre prospective cohort study designed to understand the pathogenesis and risk factors of long-term sequelae of pulmonary TB. The study, funded by the German Ministry of Health, is a five-year study conducted in four African countries (South Africa, Tanzania, Mozambique and the Gambia). A total of 1600 pulmonary TB patients (about 400 patients per study site) will be enrolled at the time of TB diagnosis and prospectively followed for at least two years after TB treatment initiation, with optional extended follow-up beyond two years. The primary objective of this study is to describe the evolution of pulmonary symptoms and functional lung impairment during and after TB treatment, including the proportion of patients affected and the type and severity of impairments, as they evolve over time.

A socioeconomic sub-study under TB Sequel has four aims:

- (i) describe the health-related quality of life of adults receiving treatment for pulmonary TB;
- (ii) determine the economic costs to patients and households of pulmonary TB and treatment;
- (iii) identify socioeconomic and clinical factors associated with poor quality of life and severe economic consequences of TB for patients; and
- (iv) assess the costs incurred by the health system for treating pulmonary TB.

The generic instrument has been adapted by the study team for use at enrollment and at two, six, 12 and 24 months after enrollment, time points that are intended to capture costs for diagnosis, during treatment, at the end of treatment, and long-term follow up once treatment has been completed. The original instruments were the *Tool to Estimate TB Patient's Costs*, developed by KNCV Tuberculosis Foundation, WHO and the Japan Anti-Tuberculosis Association; and *The WHO generic instrument – Protocol for survey to determine direct and indirect costs due to TB and estimate proportion of TB-affected households experiencing catastrophic costs* from November 2015. These were revised for longitudinal data collection into a four-stage survey instrument, as shown below.

Pre-treatment



Continued

Box 11.2 Continued

The Day 0 instrument is designed to collect baseline socioeconomic information as well as pre-diagnostic and diagnostic costs and also coping costs from when the patient first experienced symptoms or sought advice or treatment, until the start of treatment. The on-treatment instrument, at two and six months for patients with drug sensitive TB and two, six, 12 and 24 months for those with drug resistant TB, collects direct out-of-pocket costs related to treatment and/or hospitalization during treatment, socioeconomic information such as income loss and social support as well as coping costs. The post-treatment instrument does not collect any treatment costs but collects direct out-of-pocket costs for any hospitalization and both socioeconomic information and coping costs during long-term follow-up once treatment has been completed.

The adapted instrument is similar to the generic tools in that it includes questions about direct out-of-pocket costs (net of reimbursements) of medical care (consultation costs, diagnostic tests, medicine costs, hospitalization fees, etc.), direct costs for transport and food while seeking treatment, income loss (human capital approach, as well as reported foregone income) and socioeconomic coping mechanisms (taking loans, selling property, taking children out of school). Questions about prior searches for health treatment, including the number and types of health care facilities, are included. Data on the socioeconomic position of the patient and the household at baseline and income, and income changes at patient- and household-level are also included. Moreover, the instrument collects information about health insurance coverage and reimbursements, and any social welfare or paid sick leave received.

Using the adapted tool for longitudinal studies provides the opportunity to repeat measures and make comparisons over time, and even describe changes that extend beyond treatment completion. While longitudinal studies are more expensive to conduct than cross-sectional studies, they are particularly valuable when seeking to describe the economic burden of TB during different phases of TB treatment (e.g. intensive vs. continuous phase), or determining whether the economic consequences or coping mechanisms are reversible when patients recover from TB (e.g. resume work, improved labour productivity, ability to repay loans etc.).

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Annexes

Annex 1.

Generic survey instrument

The Global TB Programme has created a generic TB patient cost survey instrument in ONA. Survey implementers can use the data dictionary underlying <https://enketo.ona.io/x/#Y5T9> as a starting point to generate their country survey. A screenshot of the electronic survey is shown below. A paper-based version of the instrument is available as a Word document on <http://www.who.int/tb/areas-of-work/monitoring-evaluation/en/>

Fig. A1.1 Screenshot of TB patient cost survey generic instrument: an electronic version using ONA platform

Part I. Patient information to be obtained from TB treatment card before interview

PATIENT REGISTRATION NUMBER IN FACILITY TB REGISTER		QUESTIONNAIRE NUMBER (DISTRICT / DISPENSARY NO./ PATIENT NO.)	
DATE OF INTERVIEW yyyy-mm-dd		NAME OF PROVINCE none selected	
NAME OF DISTRICT		PLACE OF INTERVIEW (FACILITY NAME)	
INTERVIEWER NAME		CATEGORY OF TREATING FACILITY <input type="radio"/> Family health center <input type="radio"/> Public clinic <input type="radio"/> NGO <input type="radio"/> Private clinic <input type="radio"/> Other	
NAME OF THE PATIENT		SEX <input type="radio"/> Male <input type="radio"/> Female	AGE OF THE PATIENT
DATE OF BACTERIOLOGICAL TB TEST RESULT yyyy-mm-dd	DATE OF DIAGNOSIS yyyy-mm-dd	PLACE OF DIAGNOSIS <input type="radio"/> Family health center <input type="radio"/> Public clinic <input type="radio"/> NGO <input type="radio"/> Private clinic <input type="radio"/> Other	TYPE OF TB <input type="radio"/> Pulmonary, bacteriologically confirmed <input type="radio"/> Pulmonary, bacteriologically unconfirmed <input type="radio"/> Extra-pulmonary
ON MDI-TB TREATMENT? <input type="radio"/> Yes <input type="radio"/> No	TOTAL DURATION OF PLANNED INTENSIVE TREATMENT FROM START (MONTHS)	TOTAL DURATION OF PLANNED CONTINUATION TREATMENT FROM START (MONTHS)	START DATE OF CURRENT TB TREATMENT yyyy-mm-dd
THE PATIENT IS CURRENTLY IN INTENSIVE OR CONTINUATION TREATMENT PHASE? <input type="radio"/> Intensive phase <input type="radio"/> Continuation phase	HOW MANY DAYS OF THIS PHASE HAS THE PATIENT COMPLETED?	HIV STATUS (AS INDICATED ON TREATMENT CARD) <input type="radio"/> HIV positive <input type="radio"/> HIV negative <input type="radio"/> Not done <input type="radio"/> Unknown	

Next

Annex 2.

Adapting generic instrument to local context

SURVEY TOOL COMPONENT	MAIN AREAS REQUIRING ADAPTATION FROM GENERIC INSTRUMENT
Part I : information from treatment card	<p>Mark pivotal questions that determine the skip pattern of the questionnaire, e.g. on MDR-TB treatment? In Intensive/continuation phase?</p> <p>This instrument part may be split into two:</p> <ol style="list-style-type: none">data available from treatment cardsdata available from other sources. The latter need documenting (and standard operating procedures drafted for interviewers to easily access the information). <p>Document choices for:</p> <ul style="list-style-type: none">name of region and place of interview based on sampled facilitiesinterviewer name (including the name of selected interviewers). <p>Replace choices for:</p> <ul style="list-style-type: none">places of diagnosishealth facilitytreatment provider types for DOT. <p>Detailed treatment regimen choices prescribed for DS-TB, MDR-TB and XDR-TB needs documenting</p> <p>Document currency (usually local currency or US\$)</p>
Part II : informed consent	<p>Complete with principal investigator's name and address</p> <p>Adapt text about incentives for patients</p> <p>Appropriately document time loss unit (minutes or hours) for drug pick up, DOT visits etc. (Subsequently converted to hours during analysis).</p>
Part III	Type of provider to reflect local typology/categories
Part III : Pre-diagnosis costs	<p>Type of provider to reflect local typology/categories, including non-public health care facilities</p> <p>Health care provider terminology to reflect local terminology</p>

SURVEY TOOL COMPONENT	MAIN AREAS REQUIRING ADAPTATION FROM GENERIC INSTRUMENT
Part IV: Current phase costs	<p>Type of provider to reflect local typology/categories, including non-public health care facilities</p> <p>Adaption of socio-demographic questions (education, employment, occupation) using local standard categories from other national surveys</p> <p>Socioeconomic status index: this section has no default questions as it should be composed of a list of assets that households may or may not own. It is entirely country-specific and should be built based on the most recent national living standard survey questionnaire (or similar)</p> <p>Health insurance and social protection/transfer schemes: choices presented should be based on mapping of health insurance and transfer schemes available</p> <p>Adapt all question about measuring living standards, i.e. household "income" (required for the End TB indicator denominator). This implies first making a choice of the measure and then designing the questionnaire on expenditure, consumption and/or assets, in addition to the default "household income reported". Similarly, for the section on assets owned by the household, consumption or expenditure questions are country-specific and the questionnaire design should be done reusing existing household consumption, or expenditure questionnaires used in other living standard surveys in the country.</p> <p>Individual monthly income is asked in order to obtain an hourly wage and value time loss (human capital approach method only): make sure the wording clearly expresses that it is a monthly payment received in return for work (employed or self-employed)</p>

Annex 3.

Sample size calculation and sampling procedure for a cluster sample survey

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

Step 1. Estimate the true proportion of households experiencing catastrophic total costs due to TB illness (πg). There are several possible sources of data.

- Data from any previous TB patient cost survey.
- Data from TB patient cost surveys in countries with similar income levels, TB services and model of care.
- Recent household expenditure surveys that include a health module that disaggregates the main cause of disease, although answers might be regrouped as “infectious” and not TB specifically. TB is also self-reported in these surveys, rather than being a registered and notified case. It should also be noted that these data capture direct medical costs only and exclude travel, accommodation, food and nutritional supplements as well as losses of income while on treatment.

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”).

Step 4. When the sample represents a large proportion (5% or more) of the survey population of interest (all TB patients treated in the entire NTP network in a year), 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:

$$N = DEFF + \frac{1.96^2 n (1 - \pi g) \pi g}{d^2 (n - 1) + 1.96^2 (1 - \pi g) \pi g}$$

Where NFPC 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 3000 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 instructions to continue sampling until the number has been achieved. In this case, the assumed participation is 100%.

A web application using the methodology here described, is available at

<http://samplesize.herokuapp.com>

to calculate sample size and number of clusters based on your assumptions.

Cluster Selection: step by step

To determine the number of patients per cluster, the required total sample size is divided by the number of clusters. In all selected health centres, consecutive patients are enrolled in the survey until the required number of new cases is reached.

For each new survey, clusters must be reselected using the most recent TB notification data available. Clusters from a previous survey cannot be assumed to be representative of the current situation.

Example. A sample size of 360 new TB patients has been calculated after taking into account the effect of cluster sampling: 30 clusters of $360/30 = 12$ new patients to be selected per cluster. Then follow the steps below.

- a. Determine the sampling unit. This is the level at which clusters are selected. The most common sampling unit in patient cost surveys is the health facility/centre treating TB within the NTP network. However, larger units, such as a township or region, may be used as the sampling unit for logistical reasons or if data are not available at the facility level.
- b. Establish a list, known as the cluster sampling frame, of sampling units and their annual number of TB patients, from which survey clusters should be selected. Such a list is normally available within the NTP on a national, provincial and/or district level. An example of the cluster sampling frame, using health centres as the sampling unit, is shown below.
- c. Calculate the cumulative number of patients and record them in an additional column. The cumulative number for the second centre will be (number in first centre) + (number in second centre). The cumulative number for the third centre will be (cumulative

number for second centre) + (number in third centre), and so on. The total number of patients diagnosed in the example country is 6322.

- d. Determine the sampling interval: $6322/30 = 211$.
- e. Select a number between 0 and 211 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**.
- f. The first cluster is selected using **120**: it will be in the first centre because 120 falls between 0 and 246 (number of patients in the first centre).
- g. Selection of the subsequent clusters is done by adding the sampling interval of 211 to this first number of 120. The next number $(120 + 211) = 331$ falls between 246 and 1823 (cumulative number of patients for second centre); the second cluster is therefore selected in the second centre. The third number $(331 + 211) = 542$ also falls between 246 and 1823; the third cluster is therefore also selected in the second centre.

This 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 like this: if 25% of TB notifications are in urban areas and 75% in rural areas, then the survey should allocate about 25% of facilities (clusters) enrollment in urban areas and 75% in rural areas. Other stratification options may include geographical regions or patient MDR-status which would require repeating the process above, from total sample size to cluster selection, separately for each stratum.

Box A3.1 Sampling strategy in Viet Nam's patient cost survey

In Viet Nam, provinces were first stratified by three zones with the corresponding proportions of total notifications. So, the clusters (20 in total) in each zone were proportionate to the notifications in each zone, i.e. seven clusters in the North, two in Central, 11 in South. To increase the feasibility due to budget and time constraints, they chose one-to-three provinces per zone using either PPS or SRS method: two provinces in the North (by PPS); one province in the Central (SRS) and three provinces in the South (by PPS). The number of districts in each sampled province was decided according to the proportion of notification among selected provinces in each zone. The districts in each province were selected randomly. Within sampled district TB units (DTUs), consecutive patients on TB or MDR treatment visiting the facility were eligible for inclusion. The TB register of the DTU can be used as entry-point for the sampling of patients at DTUs.

Table A3.1 Example sampling frame and cluster selection

NAME OF HEALTH FACILITY	NO. OF PATIENTS REGISTERED FOR TREATMENT PER YEAR	CUMULATIVE NO. OF NEW PATIENTS	CLUSTER NO.
A	246	246	1
B	1577	1823	2, 3, 4, 5, 6, 7, 8, 9
C	468	2291	10, 11
D	340	2631	12
E	220	2851	13
F	246	3097	14, 15
G	190	3287	16
H	1124	4411	17, 18, 19, 20, 21
I	61	4472	
J	154	4626	22
K	139	4765	23
L	60	4825	
M	14	4839	
N	38	4877	
O	19	4896	
P	41	4937	
Q	120	5057	24
R	455	5512	25, 26
S	51	5563	
T	26	5589	
U	199	5788	27
V	21	5809	
W	32	5841	28
X	69	5910	
Y	6	5916	
Z	145	6061	29
AA	129	6190	
BB	87	6277	30
CC	10	6287	
DD	35	6322	

Note: Reproduced from ten Dam HG. Surveillance of tuberculosis by means of tuberculin surveys. Geneva, World Health Organization, 1985. Document WHO/TB/85.145.

Annex 4.

Reporting survey results

This Annex describes suggested tables in a survey report, including:

- A4.1 Breakdown of all individuals identified by the survey into eligible and ineligible;
- A4.2 Descriptive statistics and selected socio-demographic characteristics of survey sample, by MDR status and overall;
- A4.3 Model of care for survey sample;
- A4.4 Hours lost seeking or accessing care and reported individual income, by patient;
- A4.5 Estimated total costs borne by patients' households affected by TB, MDR-TB or all, median breakdown [US\$ year (N=)];
- A4.6 Reported dissaving mechanisms and social consequences;
- A4.7 Households classified as facing catastrophic costs under various thresholds;
- A4.8 Risk factors of experiencing catastrophic costs.

Table A4.1 Breakdown of all individuals identified by the survey into eligible and ineligible

	Eligible	Ineligible	Total
	N (%)	N (%)	N (%)
Sex			
Male			
Female			
Children under 15 years			
Phase			
Intensive			
Continuation			
Treatment registration group			
1st Line			
2nd Line			
Other			

Table A4.2 Descriptive statistics and selected socio-demographic characteristics of survey sample, by MDR status and overall

	MDR-TB	DS-TB	Total
	N (%)	N (%)	N (%)
Descriptive statistics			
Sex			
Male			
Female			
Age group			
0–14			
15–24			
25–34			
35–44			
45–54			
55–64			
65+			
Phase			
Intensive			
Continuation			
Recorded HIV Status			
Positive			
Negative			
Unknown			
Re-treatment status			
New			
Retreatment/Relapse			
Household income pre-TB			
Reported (month), mean			
Estimated based on assets owned (annual), mean			
Estimated based on consumption (annual), mean			
Proportion living under poverty line			
Socio-demographic characteristics of survey sample			
Patient's education status, %			
Not yet started school			
Primary school			
Secondary school			
High school			
University or higher			
Patient was main income earner prior to disease, %			
Occupation pre-disease (by main categories)			

Table A4.3 Model of care for survey sample

	MDR-TB	DS-TB	All
	N (%)	N (%)	N (%)
Hospitalization			
Hospitalized at time of interview			
Hospitalized during current phase			
Days hospitalized during current phase, mean			
Ambulatory care			
Number of visits per episode: total, mean			
Number of visits: DOT, mean			
Number of visits: follow-up, mean			
Number of visits: drug pick-up, mean			
Number of visits pre-diagnosis, mean			
Number of visits pre-diagnosis (non-public facility), mean			
Treatment duration			
Treatment duration: intensive phase, months, mean			
Treatment duration: continuation phase, months, mean			
Treatment delay			
Days of treatment delay, mean			

Table A4.4 Hours lost seeking or accessing care and reported individual income, by patient

	MDR-TB				DS-TB				All			
	N	Mean	Median	(IQR)	N	Mean	Median	(IQR)	N	Mean	Median	(IQR)
Hours lost by patient, overall												
Hours lost by patient, pre-diagnosis												
Hours lost by patient, intensive phase												
Hours lost by patient, continuation phase												
Individual income reported by patient												
Pre-diagnosis												
At time of diagnosis												
At time of interview												

Table A4.5 Estimated total costs borne by patients’ households affected by TB, MDR-TB or all, median breakdown [US\$ year (N=)]
The analyst will present results including the preferred indirect cost measure in the main analysis. The alternative should be shown in sensitivity analysis.

		DS-TB			MDR-TB			All		
		Mean	Median	[IQR]	Mean	Median	[IQR]	Mean	Median	[IQR]
Pre-diagnosis	(A) Medical									
	(B) Travel									
	(C) Accommodation									
	(D) Food									
	(E) Nutritional supplements									
	(F) Hours lost by patient x hourly wage									
Post-diagnosis	(G) Medical									
	(H) Travel									
	(I) Accommodation									
	(J) Food									
	(K) Nutritional supplements									
	(L) Household income loss or hours lost by patient x hourly wage									
Medical costs	(A+G)									
Non-medical costs	(B+C+D+E+H+I+J+K)									
Indirect costs	Output approach (F + L) Human capital approach									
Total										

Table A4.6 Reported dissaving mechanisms and social consequences

	Income Quintiles					
	POOREST	LESS POOR	AVERAGE	LESS WEALTHY	WEALTHIEST	OVERALL
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Dissaving Strategies						
Loan						
Sale of assets						
Food insecurity						
Divorce or separated from spouse/partner						
Loss of Job						
Child interrupted schooling						
Social exclusion						
Any days of work lost						
Self-reported impact: <i>The impact on your household financially since you experienced TB symptoms has been that your household became:</i>						
Much poorer						
Poorer						
Unchanged						
Richer						
Household received social protection after TB diagnosis						

Table A4.7 Households classified as facing catastrophic costs under various thresholds

CATASTROPHIC COST THRESHOLD	HOUSEHOLDS CLASSIFIED AS FACING CATASTROPHIC COSTS
Percentage of annual household income spent/lost on direct costs and indirect costs	N (%)
20%	
30%	
40%	
50%	
60%	
Percentage of annual household income spent on direct costs only	N (%)
20%	
30%	
40%	
50%	
60%	

Table A4.8 Risk factors of experiencing catastrophic costs

	CATASTROPHIC COST INCURRED (%)	ODDS RATIO (95% CI)
Age group		
0–14		Reference
15–24		
25–34		
35–44		
45–54		
55–64		
65+		
Sex		
Male		
Female		Reference
MDR-TB		
DS-TB		Reference
Long delay (> 4 weeks before diagnosis)		
HIV+		
HIV-		Reference
Income Quintile		
Poorest		
Less Poor		
Average		
Less Wealthy		
Wealthiest		Reference

Annex 5.

Survey team duties and qualifications

Principal investigator (PI)

Each national TB patient cost survey should have a designated principal investigator (PI). More than one PI can also be nominated and responsibilities assigned. The PI assumes overall responsibility for all survey activities and is a nominated person on the protocol and in any ethics committee applications. This job (unlike the survey coordinator's) is not full time during the survey implementation but 25%–50%. Bearing this in mind, the Ministry of Health will either be the investigator or will contract an external organization which has experience in overseeing and managing research or health facility-based surveys and can amongst other responsibilities, maintain and ensure the quality of the study's conduct and is able to write the final study report.

Roles and responsibilities:

- oversees the development of the research protocol and ethical clearance;
- liaises with partners and stakeholders outside the survey team, in particular with staff from the national TB programme, the public health service, local research institutions, other government departments and possibly the funding agency;
- secures and reports on funding for the survey, ensuring that funds are managed according to national procedures;
- develops and adapts the protocol in adherence to the WHO standard methodology described in this handbook;
- if necessary, appoints the survey co-ordinator, data manager or data analyst;
- assembles the survey team that has all the expertise needed to design, implement, and analyse the survey;
- liaises with the survey coordinator on a frequent basis and oversees their work;
- maintains and ensures the quality of the study's conduct and writes the final study report, ensuring that it is disseminated to the key stakeholders identified during the stakeholder analysis; and
- convenes jointly with NTP the dissemination of results with stakeholders (health and non-health).

Key tasks:

- ensure that survey implementation and analysis are conducted according to the protocol and the plan;
- discuss problems encountered during the survey, and then propose and decide on solutions in collaboration with the survey team and the technical advisory group (if needed);
- endorse the survey results;
- translate survey results into policy recommendations;
- engage with NTP for results dissemination; and
- support NTP in drafting policy briefs to translate survey results into policy recommendations and intervention design.

Qualifications:

- preferably at least five years of managerial experience in the field of public health;
- strong managerial skills, including an ability to delegate;
- ideally familiar with TB management, including the context in which the survey is being conducted;
- knowledge of facility-based surveys or public health research; and
- works within or has access to an organization that has an infrastructure that can support facility-based surveys or public health research in the field.

Survey coordinator

The day-to-day management of the survey is the responsibility of the survey coordinator who may be a ministry of health staff member, associated with the national institute for health (or related entity), a university faculty member or someone from an external organization such as an independent research institute. The survey coordinator should report to the PI. The main work of the survey coordinator is managing the implementation of the survey. If possible, this person should be actively involved in the design of the study and protocol development.

The survey coordinator supervises the work of team leaders and interviewers who collect the data. This requires close collaboration between the survey coordinator and the interviewers (and potentially also the team leaders from health facilities) in the field either via direct supervision, or regular reports from the staff, or using an online communication tool that facilitates quality control. The work of the survey coordinator can be intense, and the position may need to be half time or more.

Roles and responsibilities:

- oversees the day-to-day management of the survey;
- assists in the design of the survey, including adaptation of the generic protocol to the local context;
- prepares training manual and survey materials;

- prepares standard operating procedures;
- trains team leaders and interviewers before survey pilot programme and data collection;
- provides retraining if mid-term review identifies a need;
- supervises data collection by team leaders and interviewers through site visits or through periodic reports;
- assesses reports from team leaders and/or the data manager; and
- monitors operational implementation of the survey.

Key tasks:

- coordinates overall implementation of survey in the field;
- plans field implementation and required training, including preparation of training materials;
- oversees the writing of manual or standard operating procedures (if required);
- together with the PI, contacts and coordinates with local authorities;
- ensures quality assurance processes are implemented according to the protocol;
- supervises implementation in health facilities;
- plans and coordinates survey monitoring visits comprising all partners involved in survey implementation;
- oversees the provision of supplies and required materials;
- supervises the cash flow and distribution of funds and is accountable for the same (if delegated to do so by the PI);
- oversees or leads analysis of the results;
- organizes the writing of activity reports and the final report;
- plans detailed survey budget and periodically reports to funders on fund utilization (as per contract);
- provides any required logistic support for the survey team;
- arranges pilot programme and its evaluation;
- liaises with the principal investigator on a regular basis, and provides the principal investigator with updates;
- liaises with local officials in the health care facilities (during pre-survey visits and actual field work); and
- reports without delay any major problems in preparation, execution or data management of the survey.

Qualifications:

- preferably at least three years of research experience in the field of public health;
- strong managerial and coordination skills;
- knowledge of public health research and epidemiology;
- expertise in field work; and
- experience in planning and conducting patient surveys or facility-based surveys, preferably including health seeking and health costs.

Data manager

The data manager is responsible for managing data collected by interviewers. This person should have some expertise in data management for surveys or public health research, and prior experience in managing datasets would be highly beneficial. The majority of countries will collect data using an online tool (e.g., ONA). If this is the case, the data manager should be familiar with the online data collection system and should be able to troubleshoot and rectify any data collection problems. Depending on the composition of the survey team, the data manager will usually report to the PI.

Roles and responsibilities:

- coordinates data management activities for the survey: receiving, batching, cleaning, and merging data from different sources (e.g. outcome registry vs patient cost survey data);
- responsible for the validation of double-entered data files (if using paper-based survey);
- ensures that data are properly stored and backed up;
- checks validated data files regularly for systematic errors and alerts survey coordinator of the need to verify data quality with interviewers;
- develops data entry software, and effective and feasible tools to support the survey;
- readies database for analysis and data entry screens;
- contributes to results analysis (led by data analyst);
- completes regular data management reports;
- regularly liaises with the survey coordinator; and
- immediately reports problems in data management.

Qualifications:

- proven experience in leading and motivating teams;
- proven and extensive experience with managing data for health facility based surveys or public health research, including quality control for datasets;
- experience in analysing data to provide summary statistics;
- experience in troubleshooting data collection problems including the identification of systematic entry and ad hoc errors; and
- good administrative skills including maintenance of adequate documentation for surveys or public health research.

Data analyst

The data analyst is responsible for data cleaning and analysis throughout the survey and also periodic data cleaning in coordination with the data manager. The data analyst can be an existing employee of the ministry of health (or an external organization) and does not need to work full time on the survey. Local universities or research institutes can often be good places to identify a data analyst. Data analysis may be undertaken by the PI or the data manager if he/she is a health economist, economist or statistician with experience

in such surveys. Therefore, a dedicated person for this function is optional. However, if this person is not included in the survey team, the roles and responsibilities need to be absorbed by another member of the team, for instance by the PI.

Roles and responsibilities:

- undertakes regular data analysis throughout the survey to monitor data quality;
- undertakes data analysis at the completion of the survey and shares it with the survey team.

Qualifications:

- experience and or qualifications in health economics, statistics or similar;
- experience in cleaning and analysing data; and
- knowledge of online data collection tools (if applicable).

Team leaders

Team leaders supervise the field work performed by the survey team, to ensure that all activities are carried out in full, according to the protocol and in an ethical manner. Team leaders will usually be employees of the health facilities in which the survey is being carried out and may not therefore be specifically recruited for the survey. They will need to devote 5–10% of their time to the survey during the fieldwork phase and their cooperation is requested from the organization to which they are appointed. Team leaders should oversee the work of the interviewers at their facility and ensure that interviews are carried out in an ethical and considerate manner. They also ensure that recruitment is implemented according to the protocol, including the sampling scheme. If the survey co-ordinator is not able to visit health facilities regularly for supervisory visits, the team leader may do some supervision and prepare supervisory reports in their absence.

Roles and responsibilities:

- organizes and properly implements the survey in their appointed facility or cluster of facilities;
- oversees day-to-day implementation of the survey at the health facility level;
- ensures that all patients who are eligible for the survey have been approached and that patient selection is done according to protocol (i.e. minimum 14 days on treatment, see eligibility criteria) and that this is documented;
- regularly reviews data collected;
- checks that interviewers complete the relevant sections of the questionnaire (Part II) depending on Part I documentation;
- confirms that the informed consent process is carried out according to the study protocol;
- ensures that interviews are being carried out in an ethical manner, and with due regard for privacy and confidentiality;
- retrain or corrects interviewers if this is deemed necessary;

- ensures that survey data are uploaded through the online software, especially when they are collected offline;
- maintains and safeguards survey hardware including tablets or laptops;
- provides periodic reports and sends these reports to the survey coordinator. These reports can include the number of persons enrolled in the survey at the facility, compared to cluster target size, the number who have been approached to participate and a tabulation of all activities performed;
- liaises regularly with the survey coordinator to provide updates on survey implementation at the health facility level;
- reports problems with survey implementation to the survey coordinator;
- motivates interviewers to carry out their duties; and
- provides final data report to the survey coordinator once the survey has finished.

Qualifications:

- preferably at least two years' experience in public health and facility management;
- managerial skills;
- expertise in field work;
- team player and motivator; and
- attention to detail and accuracy when conducting administrative procedures.

Facility staff/interviewers

Interviewers will be based at the health facilities for the duration of the survey. Health care workers will preferably not be interviewing nor present during interviews. Additional information about interviewers' terms of reference is available in Annex 5. They will conduct interviews with patients. They will need to be employed for the survey (see Recruitment) and may or may not need to work full time, depending on the volume of patients. Interviewers may need to sign confidentiality agreements. They should have good social and communication skills and should be thoroughly trained in interview techniques and the structure and questions in the data collection tool. Interviewers should also be able to manage technology if the online data collection tool is used. To ensure data quality, the number of interviewers should be kept to a minimum to decrease the likelihood of variation in interview styles and techniques (which may result in interviewer bias).

Roles and responsibilities:

- obtain informed consent (and possibly assent, in the case of children) and store informed consent forms according to survey procedures;
- carry out interviews with TB patients with due respect for privacy and confidentiality;
- record patient information from the TB treatment card; and
- potentially, upload the survey data collected offline into the online designated software (delegated by team leader, after quality assurance has been carried out).

Qualifications:

- prior experience in surveys and interviewing patients;
- fluent in the language spoken in the cluster or health facility;
- good administration and organizational skills;
- well-developed social and communication skills, particularly with regards to patients; and
- prior experience in undertaking field work for public health research or facility-based surveys.

Technical advisory group

The technical advisory group advises the PI 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, epidemiological and health economics) into all activities for which the PI is responsible and consists of experts in these fields. Collaboration with the technical advisory group is intense during the design and adaptation of the protocol, but ad-hoc during actual data collection. Members of the technical advisory group perform these activities on a part-time basis. Their workload will vary according to the phases of the survey, ranging from ad hoc meetings during the implementation to more intensive involvement during the design or analysis phase.

The technical advisory group may include international experts. In the initial stages, for the purpose of the generic survey instrument (in this handbook) and to ensure consistency across surveys conducted in different countries, there will also be an international technical advisory group which will be coordinated by WHO. The suggested composition of the national technical advisory group and terms of reference are provided below.

Composition of national technical advisory group:

- social scientist/epidemiologist/survey expert
- knowledge of TB Programme
- health economist/analyst
- statistician or data analyst.

Terms of reference for the national tuberculosis advisory group:

- advise on the survey protocol;
- advise on the design, pre-testing and production of survey materials (e-survey instrument design, SOP revision etc.);
- provide technical assistance during training and pilot-testing;
- provide ad-hoc advice to survey coordinator during survey implementation based on preliminary data analysis, monitoring missions;
- support local analyst in analysis of results: and
- provide feedback on interpretation of results, results dissemination strategy, and policy implications and follow-up.

Annex 6.

Training objectives

For interviewers to:

- be aware of ethical issues in performing patient interviews
- be aware of issues regarding confidentiality and privacy
- be aware of cultural issues that might affect interviews or survey implementation
- learn, understand and apply sound interviewing techniques (such as probing)
- be able to select the appropriate study participants
- be fully familiar with the questionnaire
- understand the indicators used in the questionnaire
- enter and record data appropriately and accurately
- offer feedback on uncertainties or concerns with the questionnaire or data collection procedures to the team leader or survey coordinator.

For team leaders and survey coordinators the objectives of the training are to:

- assess the suitability of interviewers to conduct the survey
- monitor the quality and completeness of data collection
- monitor study procedures.

Training should produce interviewers able to do the following.

- Introduce themselves and the survey to the participant.
- Convey the purpose of the survey and the rationale for involvement.
- Obtain informed consent and store consent forms appropriately.
- Put participant at ease and ensure a comfortable environment in which to ask questions.
- Display familiarity with the questionnaire to create a conversational rather than a formal tone when asking questions.
- Convey questions in the order in which they are written on the questionnaire, using the same wording (in the local language) as on the questionnaire. Certain questions may require further explanation and may require 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 costs by using local methods of time structuring. The use of calendars with local holidays, local paydays or other local events may be helpful.

- Understand and be able to explain the definitions of selected questions. For example, the 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 recall these items.
- Avoid influencing the answers to questions by using friendly but neutral body language.
- Ensure that all questions are answered. Note that there are some questions in Part I that require an answer and that without it, it will not be possible to select the right questions for interviewees. Later in the interview, if a participant refuses to answer a question or cannot give an answer, the appropriate field should be completed.
- Keep control of the interview (i.e. minimize off track conversations, long silences, etc.).
- Check patient records (including in the case of non-participation of eligible patients in the survey).
- Be sensitized and informed about TB including: different phases of TB treatment (i.e. the intensive versus continuation phases), types of TB care (i.e. hospitalization, different forms of Directly Observed Therapy, etc.) and associated costs for various items associated with TB care (i.e. sputum testing, follow up tests, chest x-rays, collection of medicines etc.) to avoid double counting of costs. For example, it needs to be clear to the interviewers what constitutes a TB drug and what are the additional drugs that might be prescribed or bought.
- 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 (i.e. bacteriologically confirmed, clinically diagnosed, pulmonary or extra pulmonary, new, re-treatment or patients with multi-drug resistant TB), and how far the patient is into treatment, the risks to the interviewer's health may 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 should understand infection control measures; i.e. conducting the interview outside or in a well-ventilated room.
- Use of the electronic survey instrument, including trouble-shooting problems, saving questionnaires and uploading questionnaires.

Annex 7.

Sample training programme

Here is a sample training programme for a tuberculosis patient cost survey training programme prior to survey implementation. It is designed to train data collectors and the in-country managers of survey implementation.

Table A7.1 Agenda for training programme

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-investigators	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-investigators	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-investigators	As above
DAY TWO			
09.00–9.30	The informed consent process	Ministry representative or Principal 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-investigators	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-investigators	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-investigators	As above To give all interviewers a practical understanding of using tablets for data collection.
15.00–15.30	Afternoon tea		
15.30–16.00	Next steps and wrap up	Principal Investigator/ Co-investigators 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-investigators	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 8.

Sample timeline and country example (Philippines)

Fig. A8.1 Sample timeline template

ACTIVITY	MONTH											
	1	2	3	4	5	6	7	8	9	10	11	12
Adaptation of the generic protocol and questionnaire												
Ethics committee submission												
SOP Writing												
Translation of questionnaire into local languages												
Electronic survey adaptation												
Training for survey team												
Data collection												
Analysis plan												
Data cleaning / analysis												
Initial dissemination of results												

Annex 9.

Budget template

Table A9.1 Budget template

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				
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, training in preparation phase				
Preparation phase: survey launch 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				

BUDGET LINE	PRICE UNIT L.C.U.	# UNIT (OR % TIME)	TOTAL L.C.U.	TOTAL IN US\$
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				

BUDGET LINE	PRICE UNIT L.C.U.	# UNIT (OR % TIME)	TOTAL L.C.U.	TOTAL IN US\$
Dissemination				
Analysis of data				
Report writing				
Final review and agreement of results				
Scientific journal publication fee				
Dissemination meeting or event				
Contingency				
Total (without % overhead)				
Total (with % overhead)				
Sources of funding				
Government				
Donor 1: <<name>>				
Donor 2: <<name>>				
Gap				
Total				

Annex 10.

Survey report template

Chapter 1. Background and objectives

1. Background
2. The organization of TB services (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 breakdown

- 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

Annex 11.

Example of ethics review questions and answers provided

Table A11.1 Ethics review questions and answers

REVIEW REQUIREMENT	COMMENTS FROM INVESTIGATORS
<p>The proposed research design is scientifically sound and will not unnecessarily expose human research participants to risk</p> <p>a. Is the hypothesis or research question clear? Is it clearly stated?</p> <p>b. Is the study design appropriate to prove the hypothesis or answer the research question?</p> <p>c. Will the research contribute to generalizable knowledge and is it worth exposing human research participants to risk?</p>	<p>The survey design is adopted from the WHO TB Patient Cost Survey handbook.</p> <p>a. The survey question is clearly stated in the proposal in the form of the survey objectives in line with WHO's generic protocol.</p> <p>b. A cross-sectional study will be conducted by retrospectively collecting costs, time loss and coping measures of TB-affected families. This study design is in line with WHO guidance and is appropriate to achieve the survey objectives.</p> <p>c. The survey will acquire baseline information on the proportion of households incurring catastrophic costs due to TB, and inform policy discussions to improve TB care and strengthen support to patients with TB. Hence the results have significant implications for future TB control policy. The sampling framework helps to produce generalizable knowledge to achieve the purpose.</p>

REVIEW REQUIREMENT	COMMENTS FROM INVESTIGATORS
<p>Risks to the participants are reasonable in relation to anticipated benefits, if any, to the participants and the importance of knowledge that may reasonably be expected to result.</p> <p>a. What does the Committee consider the level of risk to be?</p> <p>b. What does the investigator consider the level of risk/discomfort/inconvenience to be?</p> <p>c. Is there a prospect of direct benefit to human research participants?</p>	<p>a. The survey consists of a structured interview with questionnaire. It involves no more than minimal risk to participants.</p> <p>b. Survey participants will be asked to share some personal and sensitive information such as household income, which may make them uncomfortable. We will ensure the participants are informed about the principle of voluntary participation and the right to withdraw from the survey at any time.</p> <p>c. No direct benefit apart from honoraria.</p>
<p>Participant selection is equitable</p> <p>a. Who is to be enrolled? Men? Women? Ethnic minorities? Children (rationale for inclusion/exclusion addressed)? Seriously ill patients? Healthy volunteers?</p> <p>b. Are these research participants appropriate for the protocol?</p>	<p>a. Patients who are in treatment at facilities linked with the national TB programme. All TB patients, regardless of age, gender, types of TB and drug-resistance patterns, will be eligible for enrollment provided they have been on treatment for 14 days in that specific treatment phase. Therefore, our process will be fair and able to achieve equitable representation of TB patients.</p> <p>b. The participants are appropriate for the protocol.</p>
<p>Additional safeguards required for subjects likely to be vulnerable to coercion or undue influence.</p> <p>a. Is appropriate protection in place for vulnerable participants or subjects in special situations (e.g. doctor-patient relationship making them more vulnerable)?</p>	<p>a. We will provide appropriate protection for vulnerable participants, for example, by emphasizing the principle of voluntary participation and the right to withdraw from the survey. Interviews are not conducted by health care staff. We will also consider that patients for whom it is inconvenient to attend onsite, such as the elderly and pregnant women, will be provided with assistance such as transportation.</p>

REVIEW REQUIREMENT	COMMENTS FROM INVESTIGATORS
<p>Informed consent is obtained from research participants or their legally authorized representative(s).</p> <ul style="list-style-type: none"> a. Does the informed consent document include all the required elements? b. Is the consent document understandable to participants? c. Who will obtain the consent and in what setting? 	<ul style="list-style-type: none"> a. The informed consent document includes all the required elements including the objective of the study, use of information and study results, confidentiality and so on. b. The consent document is understandable to participants, and investigators will explain the contents clearly to help them comprehend. c. Onsite investigators will obtain consent before the survey starts. They will be trained before survey implementation.
<p>Risks to the participants are minimized?</p> <ul style="list-style-type: none"> a. Does the research design minimize risks to participants? b. Would use of a data and safety monitoring board or other research oversight process enhance participant safety? 	<ul style="list-style-type: none"> a. The questionnaire (in line with WHO generic questionnaire) is designed to allocate different sections to patients in different treatment phases and types, which minimize the number of questions to be answered by participants and ensures that unnecessary information will not be collected. b. Participant safety will be ensured by the survey group and relevant local health authority in accordance with the survey protocol. Participant safety will be emphasized during training for data collectors and field supervisors.
<p>Subject privacy and confidentiality are maximized.</p> <ul style="list-style-type: none"> a. Will personally identifiable research data be protected to the extent possible from access or use? b. Are any special privacy and confidentiality issues properly addressed, e.g. use of genetic information? 	<ul style="list-style-type: none"> a. Personally identifiable data is protected to the extent possible from access or use. When handling the collected data, participants will be assigned codes to protect their identities. No personal information will be presented to or shared with anyone outside the survey group. b. Informed consent documents properly outline all necessary measures to protect personal privacy and respect confidentiality.

Additional annexes

Additional annexes can be found online at

http://www.who.int/tb/publications/patient_cost_surveys/

These include:

- Sample of standard operating procedures
- Sample survey external monitoring visit checklist
- Survey review checklist
- Checklist to assess bottlenecks faced in survey preparation

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