Save the Children

Instruction and Template for
PROPOSAL Submission
Consultancy Title: National Tuberculosis Patient Cost Survey in Nepal
PR No. PR298456

Date of Proposal Submission: <Insert date>

This instruction & template for proposal development consists of the following sections:

1. **Section A**: Instruction for Proposal Development
2. **Section B**: Proposal Development Form
3. **Section C**: Essential Evaluation Questions

Section A: Instruction for Proposal Development

Please READ and FOLLOW the instructions before completing the proposal form

1. A proposal will not be considered for review if:
   - It is received after the deadline.
   - It is not submitted in designated email ID.
   - There are any missing documents mentioned in the ToR
   - Information submitted by the company is found to be false
   - It is incomplete.

2. A proposal submitted through email should have four (4) separate files:
   1st for essential documents
   2nd for technical proposal
   3rd for financial proposal
   4th for other supporting documents as per ToR

- All attached documents should be clearly labelled so it is clear to understand what each file relates to.
- Emails should not exceed 15mb – if the file sizes are large, please split the submission into two emails.
- Do not copy other SCI email addresses into the email when you submit it as this will invalidate your bid.

4. Only shortlisted bidder/s will be contacted by Save the Children at each stage of the selection process.

5. Shortlisted bidder/s will be invited to deliver a 15minute presentation to the Procurement Committee on their technical proposal.

Section B: Proposal Development Form

I. Organization Information (NA in case of individual consultant)

Name of the organization: .....

Address : .....
District/State : .....
Country : .....
Phone number : .....
E-mail : .....
Website : .....

II. Details of contact person

Name : .....
Position : .....
Phone Number : ..... (Landline) ..... (Mobile)
E-mail : .....

III. Major topics and sub-topics for proposal development

1. Organization Background

1.1 Work experience.

(a) Does your organization have experience in conducting surveys/research/evaluation of health-related programs/interventions in Nepal? If yes, please provide details in below table:

S. No.	Title of surveys / research / evaluation	Study location (district & province)	Client Name	Date Completed	Attach a copy of published research / survey / evaluation report or provide link.
1					
2					
3					
4					
5					

Add rows as required.

(b) Does your organization have experience in conducting health related economic studies / Survey? If yes, please provide details in below table:

S. No.	Title of Studies / Survey	Client Name	Date Completed	Attach a copy of published survey / evaluation report or provide link.
1				
2				
3				
4				
5				

Add rows as required.

1.2 Existing and current human resource and organization organogram.

1.3 Does your organization have full-time dedicated staff with expertise in public health or equivalent, epidemiology, statistician, economist in conducting research/surveys/evaluations of the health program? If yes, please provide details below:

S. No.	Full Name of Staff	Designation	Expertise	Date joined	Attach a copy of appointment letter.
1					
2					
3					
4					
5					

Add rows as required.

2. Signatory and Proposed team information:

SN	Full Name (Avoid abbreviations)	Gender	Date of birth (dd/mm/yyyy AD)	Proposed position for this survey	Academic Qualification	Home Address (district & province)

Add rows as required.

3. Please provide your understanding of ToR, proposed methodology / approach and workplan to conduct this assignment.

.....
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.....

4. Proposed Budget with clear breakdowns (specify the proposed cost is inclusive / exclusive of VAT)

Bidder shall submit financial proposal in separate file with file name – financial proposal.

Section C: Essential Evaluation Questions

ESSENTIAL CRITERIA (Exclusion if not met)

In order to qualify as a bidder you must be able to answer 'Yes' against all of the Essential Criteria. After passing the essential criteria you will be scored against Capability and Commercial criteria.

<table>
<tr><th>S. No.</th><th>Criteria</th><th>Please specify Yes / No</th></tr>
<tr><td>a)</td><td>Do you have a legitimate business/official address OR are you registered for trading or tax purposes with the authorities.
If yes, have you attached a copy of registration documents with this proposal?</td><td></td></tr>
<tr><td>b)</td><td>We, the Bidder, hereby confirm we compliance with the following policies and requirements:
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<tr><td>Terms & Conditions of Bidding</td><td> 
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<tr><td>Terms & Conditions of Purchase</td><td> 
SC-C-01 Short Form Goods and Services A</td></tr>
<tr><td>Supplier Sustainability Policy and the included mandatory policies</td><td>Click Here to Access</td></tr>
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<tr><td>c)</td><td>Do you confirm that the company is not linked directly or indirectly to any terrorism related activity, and does not sell any Dual-Purpose goods / services that may be used in a terror related activity?</td><td></td></tr>
<tr><td>d)</td><td>Do you confirm that you are not a prohibited party under applicable sanctions laws or anti-terrorism laws or provide goods under sanction by the United States of America or the European Union and accepts that SCI will undertake independent checks to validate this?</td><td></td></tr>
<tr><td>e)</td><td>Do you confirm that you are not a prohibited party or on government blacklisting</td><td></td></tr>
<tr><td>f)</td><td>Have you attached a copy of VAT registration certificate?</td><td></td></tr>
<tr><td>g)</td><td>Have you attached a copy of Tax Clearance certificate of Fiscal Year 2078/079?</td><td></td></tr>
<tr><td>h)</td><td>Have you attached CVs of Proposed Consultant/s?</td><td></td></tr>
<tr><td>i)</td><td>Does your organization have experience in conducting surveys/research/evaluation of health-related programs/interventions in Nepal within last five years? If yes, have you provided a copy / link of published research / survey / evaluation report(s) as evidence to qualify above criteria with this proposal?</td><td></td></tr>
</table>

National Tuberculosis Patient Cost Survey in Nepal- 2023

Study Protocol

January 2023

NATIONAL TUBERCULOSIS CONTROL CENTER
MINISTRY OF HEALTH AND POPULATION, NEPAL

List of abbreviations

Abbreviation	Description
BMU	Basic Management Unit
d	Level of precision
DEFF	Design effect
DOTS	Directly Observed Therapy Short-Course
DR	Drug resistant (NB: this does not refer to isoniazid monoresistance)
HIV	Human immunodeficiency virus
MDR-TB	Multi-drug resistant tuberculosis
N	Number
MoHP	Ministry of Health and Population
NHSS	Nepal Health Sector Strategy
NRs	Nepalese Rupees
NSP	National (Tuberculosis) Strategic Plan
NTCC	National Tuberculosis Control Center
PPS	Probability proportional to size (sampling)
RR	Rifampicin resistant
TB	Tuberculosis
USD	United States Dollars
WHO	World Health Organization
XDR-TB	Extensively-drug resistant tuberculosis

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Project summary

Tuberculosis (TB) kills 1.6 million people each year worldwide, more than any other single infectious disease apart from Covid-19.[1] In 2021, approximately 10.6 million became ill with TB, of whom 3 million were unable to access health care services and so were diagnosed and treated through unregistered or private systems, or went undiagnosed and untreated.[1] More than 90% of people with TB are from low and middle income countries (LMICs) with high prevalence of poverty and malnutrition, both of which are social determinants of TB.[2,3] These social determinants are further compounded by limited social protection coverage and high costs of accessing TB diagnosis and care, which can delay diagnosis and treatment, and push TB-affected households into further impoverishment. Indeed, research has shown that many TB-affected households, especially in LMICs, incur high TB-related costs.[4]

The World Health Organization's (WHO) *End TB Strategy* outlines the ambitious goal of TB elimination by 2035. Progress towards this target will be measured using three main indicators: 1) TB incidence, 2) TB mortality, and 3) catastrophic costs related to TB diagnosis and care. WHO have reported estimated TB incidence and mortality since 1997, however the indicator on catastrophic costs is new since 2015. The operational definition of "catastrophic costs as a result of TB" refers to medical and non-medical out-of-pocket payments and indirect costs exceeding a given threshold (e.g. 20%) of the household's annual income. Estimation of TB patient costs is carried out via health facility surveys and WHO recommends that they be carried out in the next few years to establish baseline information on the economic burden of TB and inform the development of effective strategies to defray economic hardship, including improved coverage of social protection that reaches high-risk underserved groups, and mitigation of sociocultural barriers through patient-centred care.[5]

Nepal is a low-income country with a revised incidence rate of 245 per 100,000 population resulting from the findings of the National Tuberculosis Prevalence Survey 2017/18 and mortality, with TB being the seventh leading cause of death from any cause.[6,7] The Government of Nepal has adopted the End TB Strategy, including the target of zero catastrophic costs for TB-affected families, and aims for a "TB Free Nepal" by 2050.[7] Despite free basic TB diagnostic tests and medicines, subnational studies have suggested that approximately one in two people with TB will face catastrophic costs while accessing TB care in Nepal.[8] Barriers to accessing care are more pronounced for people of rural communities and/or poorer socioeconomic status, who often face disproportionately high costs of transportation related to direct observation of therapy (DOT) in health facilities that are distant from their homes. This could contribute to non-adherence to TB treatment and adverse outcomes.[9]

Despite multiple subnational TB patient costs surveys having been carried out in Nepal, there have been no nationally representative TB Patient Cost surveys. This study will assess the social and economic costs associated with TB diagnosis and care in Nepal, including an estimate of the national prevalence of catastrophic costs, and will be used to design and advocate for policies and interventions to: 1) minimise barriers in accessing and adhering to TB treatment and care, and 2) mitigate the social and economic impact of TB for patients and their families in the country.

1. Background and rationale

Tuberculosis (TB) is one of the major public health concerns globally, killing 1.6 million people each year worldwide, more than any other single infectious disease.[1] In 2021, approximately 10.6 million became ill with TB, of whom 3 million were unable to access health care services and so were diagnosed and treated through unregistered or private systems, or went undiagnosed and untreated.[1] More than 90% of people with TB are from low and middle income countries (LMICs) with high prevalence of poverty and malnutrition, both of which are social determinants of TB.[2,3]

TB is the archetypal disease of poverty and typifies health inequity.[10–14] Not only do poorer people have higher likelihood of TB exposure, infection and disease but they are also more likely to have difficulties accessing TB diagnosis and care, and to become poorer due to their illness (the "medical poverty trap").[14–16] Among the reasons behind this are stigma (both TB- and poverty-related), hidden costs of "free" TB diagnosis and care, and lack of access to social protection (e.g. health and sickness insurance),[17,18] all of which hamper the ability of TB-affected households to access and engage with TB services.[4,19] This can lead to catastrophic TB-related costs and compound impoverishment, especially in the poorest TB-affected households of TB endemic low- and middle-income countries (LMICs).[20–23]

A systematic review,[4] which assessed the results of 49 studies on TB patient costs, concluded that these costs ranged from $55 to $8198 USD (unweighted average of $847 USD). Income loss comprised the greatest proportion of all costs at 60% (range 16-94%), with another 20% (range 0-62%) due to direct medical costs and the remaining 20% (range 0-84%) due to direct non-medical costs. Half of the costs were incurred prior to the commencement of TB treatment. The total costs amounted to 58% (range 5-306%) of annual individual income and 39% (range 4-148%) of annual household income. Costs were higher for patients with lower incomes and for people with multi-drug resistant TB.

National and sub-national studies in a range of settings have reinforced the findings of the systematic review. For example, in a study involving TB patients and controls from "shantytowns" in Peru, 39% of patients incurred catastrophic costs (defined as >20% of annual household income spent on TB care).[16] Poorer patients spent less but this amounted to a greater proportion of their overall income (27% versus 48% for the least poor and the poorest households, respectively).[16] The authors estimated that approximately 18% of adverse TB treatment outcomes were attributable to catastrophic costs. In another study from Malawi, the authors found that TB patients incurred $13 USD (or 18 days income) for TB care, and lost 22 days of working time due to their illness.[24] Poor patients incurred greater absolute costs (248% versus 129% of monthly income) and if the patient was a woman, the opportunity costs were also greater.[24] The authors concluded that, despite the fact that TB treatment was free at that time in Malawi, the costs for TB treatment were prohibitively high. Another study which assessed TB treatment associated costs in Ghana, Viet Nam and the Dominican Republic, found that average patient costs were much higher ($538-1268 USD) and equated to approximately one year's worth of an individual's income. In addition, up to 37% of TB patients had to sell property and up to 47% borrowed money to fund their TB care.[25] Other studies in diverse LMICs tell a similar story; one of further impoverishment due to TB.[22,23,26] Therefore, studies in several settings have demonstrated that TB care is costly and may push people who are already poor, further into poverty.

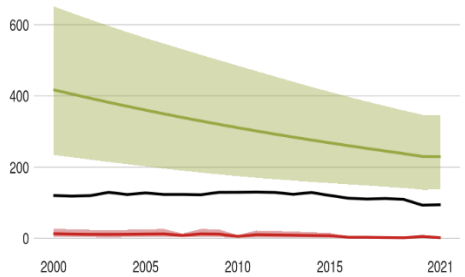
The Sustainable Development Goals (SDGs) recognise that health, poverty, and wellbeing are inextricably linked and must all be addressed in concert.[27] Aligned with the SDGs, the World Health Organization's (WHO) 2015 End TB Strategy[28] includes a target of "zero TB-affected families facing catastrophic costs" by 2030 and advocates provision of social and economic (socioeconomic) support for TB-affected households.[29] Socioeconomic support could be achieved through long-term national social protection schemes (social security protection and guarantees aimed at preventing or alleviating poverty, vulnerability, and social exclusion)[30] and/or other socioeconomic interventions (including but not limited to cash transfers, mutual support groups, or nutritional support) for TB-affected households,

targeted especially towards the poorest and most vulnerable.[31,32] National-level evidence to identify the drivers and magnitude of patient costs and the prevalence of catastrophic costs among TB-affected households is accumulating through TB Patient Cost Surveys, which have now been conducted in at least 28 countries.[1] This data will be vital to measure progress against the global indicator of catastrophic costs and guide implementation of social protection interventions for TB-affected households.

Nepal is a lower-income country with a TB incidence of 229 per 100,000 people (Figure 1).[1] For the past two decades, Nepal has seen improvements in child and maternal mortality, provision and uptake of antenatal care and skilled birth attendants, childhood vaccination coverage, and HIV knowledge and testing.[33] Leprosy is now in the elimination phase and malaria in the pre-elimination phase.[34] Despite these advances, under-nutrition remains an issue with more than one third of children being stunted, more than one quarter underweight, and 10% wasted.[33] Children in the poorest and rural households are disproportionately affected and malnutrition remains a significant risk factor in both children and adults for development of TB disease.[35]

TB is recognised as a major public health problem in Nepal in the National Health Sector Strategy 2016-2021,[36] the WHO Nepal Country Cooperation Strategy 2018-2022,[34] and the NTCC's National Strategic Plan to end TB 2021/22-2025/6.[37] The Government of Nepal has adopted the End TB Strategy, including the target of zero TB-affected families incurring catastrophic costs, and aims to have a "TB Free Nepal" by 2050.[7] Despite huge advances in DOTS coverage and high (>90%) TB treatment success rates in Nepal, 30% of TB cases are missed (e.g. not diagnosed, notified, or treated) in Nepal and TB is associated with significant mortality, being the seventh leading cause of death.[6] WHO and World Bank data suggest that less than half the population is reached by a basic social protection floor and one-quarter live below the poverty line.[38] Moreover, although Nepal has well-established directly-observed therapy (DOT), recently expanded GeneXpert molecular diagnostic capabilities, and increased active case finding activities, delivery of TB care is hampered by profound geographical challenges, including mountainous areas with poor road access, which can negatively impact on TB treatment and prevention outcomes.[38–42] In addition, cohort studies in Nepal have found that TB stigma and discrimination in communities, hospitals, households, and especially self-stigmatisation by TB-affected people, is prevalent.[43–45]

Figure 1: Incidence (green) of new and relapse cases notified (black line), and HIV-positive TB incidence (red), per 100,000 population per year[46]

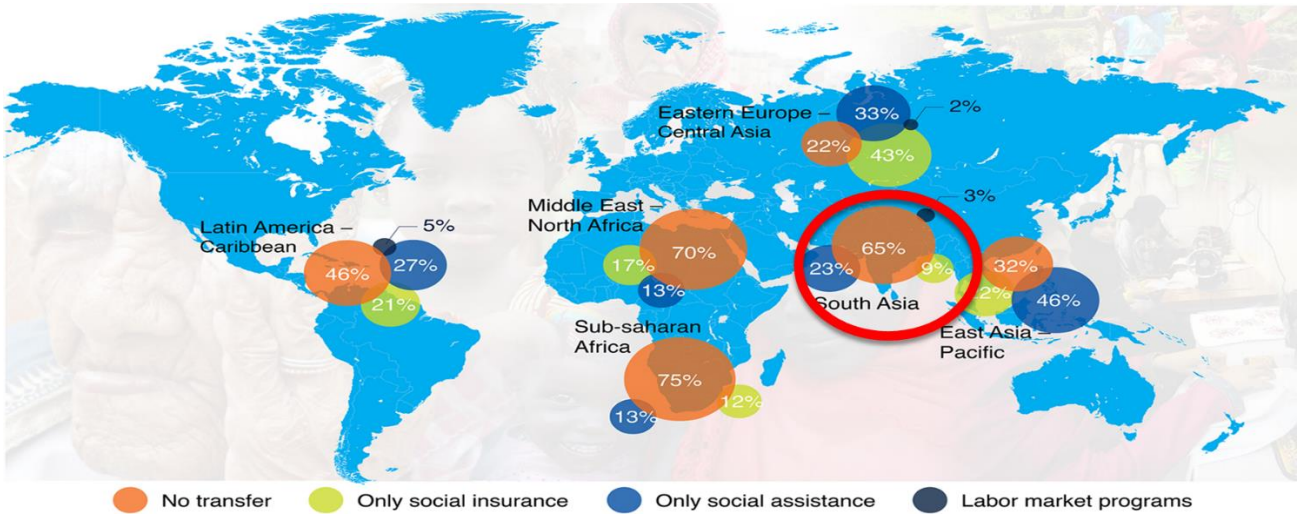


NTP-provided economic support to people with TB predominantly focuses on ensuring access to hostels and covering nutritional and travel costs for people affected by multi-drug resistant (MDR) TB. This economic support amounts to Nepalese Rs. 3,000 (approximately USD 26) per ambulatory-based patient and Rs. 1000 (~USD 9) for hostel-based patients per month throughout treatment. Workshop participants reported that the original impetus for this scheme was a perception that patients with drug-resistant TB in Nepal face the greatest psychosocial and economic challenges in accessing and engaging with care. Economic support is not routinely provided to people with drug-sensitive TB (DS-TB) but, in late 2018, the government of Nepal committed to initiate a social protection programme for people with TB and HIV in Nepal, regardless of drug-resistant status.

In many resource-constrained settings, out-of-pocket payments constitute the majority of total health expenditure.[47] The Indian sub-continent and Nepal are no exception. These payments put an enormous economic strain on patients and their households, leading to a substantial proportion incurring catastrophic health expenditure.[47] Where available, social protection can defray such out-of-pocket expenses and mitigate catastrophic health expenditure, especially for poverty-related diseases such as TB, which are also associated with profound loss of income.[17,18,48] However, despite

social protection coverage continuing to expand, only one quarter of people worldwide have adequate social protection cover and more than half of people have no social protection coverage whatsoever (Figure 2).[49] This dearth of social protection is especially concentrated in low-income countries like Nepal, in which less than 20% of people are covered.[49]

Figure 2: Proportion of population with social protection coverage by world region (Source: ILO).



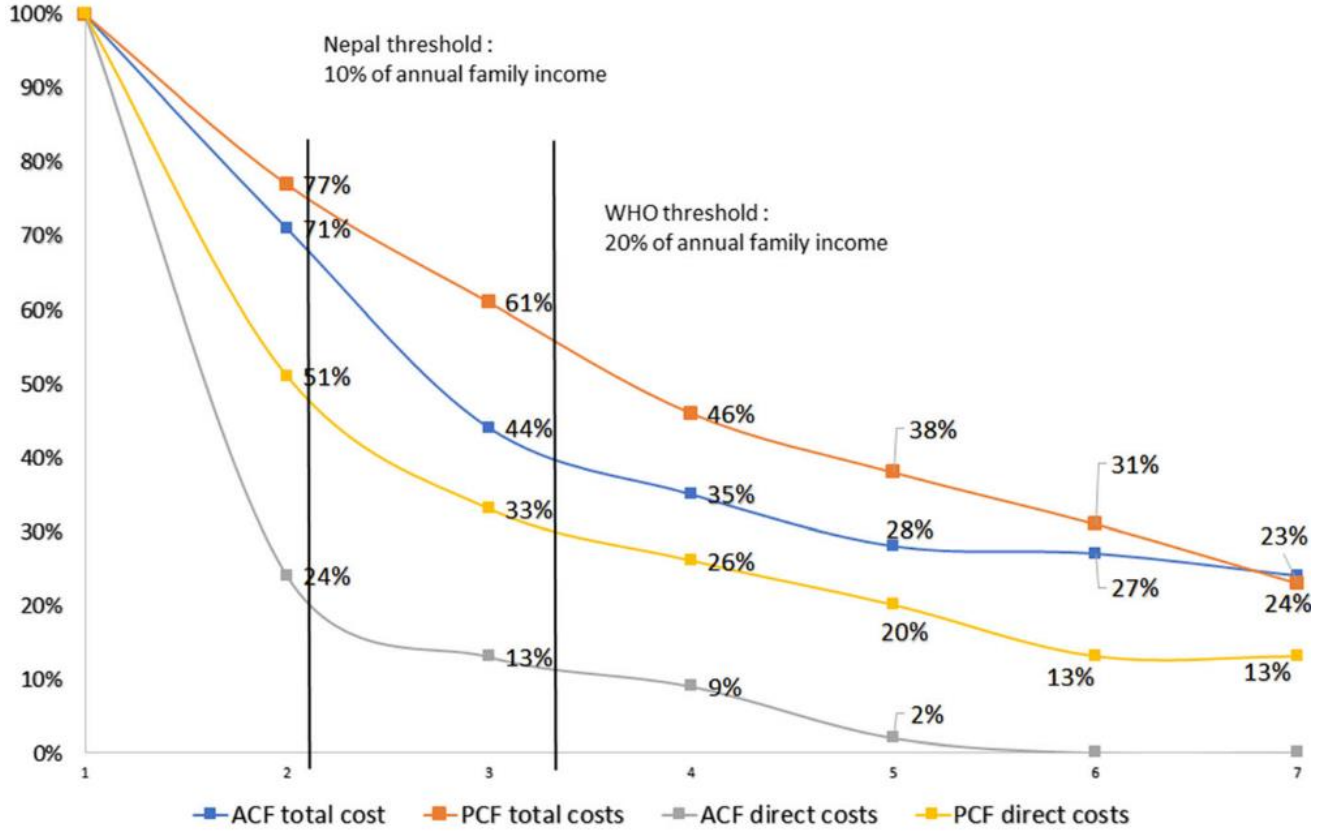
It has long been recognised that social protection has the potential to contribute to TB control and elimination.[15] With regards to TB-specific interventions (e.g. those focused only towards people affected by TB), randomised controlled trials, systematic reviews and meta-analyses have shown that TB treatment outcomes can be improved by cash transfers[50] and psycho-emotional and/or socioeconomic support packages.[51–53] Other studies have shown that regional or national social protection programmes can be "TB-sensitive" (e.g. support TB-affected people although not being primarily directed towards them) and contribute to improving TB treatment outcomes[54–56] and reducing TB incidence, prevalence, and mortality.[17,18] Indeed, social protection and socioeconomic support is not only included as part of a key pillar of the End TB Strategy but also in WHO's clinical TB treatment guidelines.[57]

Nepal has made many advances in improvements to access to healthcare and reducing the financial burden on patients and their households, through implementation of social protection. Nepal's Social Security Act of 2017 legislated for a free package of basic healthcare and was expanded to cover more illnesses in 2018 through National Health Insurance regulation.[58] Social protection, including cash transfers, has been provided for some years to certain groups in Nepal (including old age allowances, child grants, and a pilot scheme of grants for the ultra-poor),[59,60] and following humanitarian crises such as the 2015 earthquake.[61] However, understanding of the magnitude and drivers of TB-related costs and catastrophic costs for TB-affected households is required to design and implement targeted, locally-appropriate social protection measures to mitigate them.

No nationally representative TB Patient Cost survey has yet been completed in Nepal, there have been three major longitudinal cohort studies using adapted WHO TB Patient Costs Survey methods administered at multiple time points during TB treatment. These studies were implemented by Birat Nepal Medical Trust, the first conducted during a TB-REACH Wave 5 Project, the second during the EU Horizon2020-funded IMPACT-TB Active Case Finding Project (www.impacttbproject.org),[62] and the third as part of an ongoing pilot trial of socioeconomic support for TB-affected households (ISRCTN 17025974).[63,64] The surveys measured the economic impact of TB on affected households through measurements of: direct costs (out-of-pocket medical expenses such as medicines and clinics; and non-medical expenses including travel and accommodation related to clinics and additional food expenditure); and indirect costs (including lost time and income, opportunity costs, and coping strategies).[65] The results showed that the economic

burden on TB-affected households was high, especially due to costs relating to travel, lost income, and associated with seeking a mixture of both public- and private- healthcare. The prevalence of catastrophic costs (total TB associated costs of more than 20% of the same TB-affected household's annual income)[20,65,66] of TB-affected households was high with approximately 60% of people with TB found by passive case finding incurring catastrophic costs.[62] The prevalence of catastrophic costs was lower in people with TB found by active case finding (Figure 3).

Figure 3: Prevalence of catastrophic costs in tuberculosis patients diagnosed through active case finding (ACF) and passive case finding (PCF) during the pre-treatment and intensive phases, Nepal, 2018



Other key findings of the studies were high prevalence of food insecurity amongst TB-affected households, and access to and engagement with TB diagnosis and care being associated with worsening poverty.[62] Although active case finding (ACF) was able to mitigate some of these costs, especially those incurred pre-treatment, it was not able to fully eliminate catastrophic costs or reduce poverty or food insecurity. These results indicate that ACF alone will be insufficient to achieve elimination of catastrophic costs in line with the WHO 2015 End TB Strategy and suggest that there may be synergistic benefit from ACF being combined with integrated and comprehensive socioeconomic support and social protection packages.[11,62]

The World Health Organization recommends that countries assess the composition and magnitude of these direct and indirect costs through periodic health facility-based surveys.[18] This is complementary to other needed assessments of local and national TB epidemiology, health seeking, and health care and social service coverage and bottlenecks for TB patients.[18] Such assessments are a fundamental part of the *End TB Strategy*, which stresses the need for national adaptation based on the local epidemiological and health systems situation.[18]

In order to measure this indicator in a routine and comparable way, WHO have developed a generic survey protocol and data collection tool for field testing.[18] The generic protocol provides guidance on how to conduct a facility-based

survey to assess the economic burden (i.e. direct and indirect costs) incurred by TB patients (and their households) and to identify cost drivers in order to guide policies on cost mitigation and also potential interventions to mitigate costs. The protocol also provides guidance on how to measure the proportion of TB patients (and their households) experiencing catastrophic costs, and can thus be used to determine a baseline and periodically measure progress towards the *End TB Strategy* target of zero catastrophic costs. The generic data collection tool is discussed in more detail under *Study instrument (data collection tool)*, in this protocol. This generic collection tool has already been adapted, piloted, and refined by Birat Nepal Medical Trust with nearly 800 people with TB in Nepal and has been shown to be reliable, replicable, locally-appropriate and suitable to the Nepalese context.[62,67,68]

There have been no nationally representative studies conducted on the social and economic impact of TB on patients in Nepal. Therefore, this study will aim to conduct a baseline assessment of the social and economic burden of TB on TB patients and their families in Nepal, using a nationally representative sample.

1.2 Relevance of the problem to national health objectives

This survey is aligned with national strategic health and TB priorities in Nepal. A key pillar of the Nepal Health Sector Strategy (NHSS) 2016 to 2021 is to ensure citizens' fundamental rights to stay healthy with accountable and equitable health service delivery that reaches underserved populations.[36] Conducting a survey of the costs occurred during TB illness in order to inform interventions to address the social and economic determinants and impact of TB are aligned with multiple outcomes of the NHSS, WHO, and Nepal NTC (Table 1).[7,34,36]

Table 1: Relevance of TB Patient Costs Survey to Nepal's strategic national health objectives

Strategy	***Specific outcome or recommendation***

NHSS[36]	**Outcome 1 – Rebuilt and strengthened health systems**
	• OP1b2: Improved medical and public education competencies: vocational training for TB-HIV co-infected people
	Outcome 3 – equitable utilization of health care services
	• OP3.1 Improved access to health services, especially for unreached populations
	  ○ Conduct study to inform health service expansion to achieve UHC
	Outcome 5 - Improved sector management and governance
	• OP5.4 Multi-sectoral coordination mechanisms strengthened: Establish and provide support to operationalise support groups for TB/HIV co-infected clients (self-help groups)
	Outcome 6 – improved sustainability of health sector financing
	• OP6.2 Social health protection mechanisms strengthened
	  ○ Assessment of existing social protection schemes for efficiency gains
	  ○ Develop and implement a plan for harmonization and integration of different social health protection schemes
	  ○ Provide financial and other subsidies for TB patients and their family members
	Outcome 7 – improved healthy lifestyles and environment
	• OP7.1 Healthy behaviours and practices promoted
	  ○ Implement advocacy campaign to garner political commitment for TB
	  ○ Implement EIC and community awareness activities
	  ○ Promote psychosocial support system for all TB patients
	  ○ NTOP7.1: Number and proportion of DR-TB patients provided with skills development training
	  ○ NTOP7.2 Number and proportion of MDR patients provided with care and support including cash incentive
	Outcome 9 – improved availability and use of evidence in decision-making processes at all levels
	• OP9.2 Survey, research and operational studies in priority areas to inform policy

WHO[34]	**Strategic priority 2:** effective delivery of priority public health programs including TB control **Strategic Priority 4:** multi-sectoral engagement and partnerships for improved health outcomes and to combat AMR, which is relevant to treatment and prevention of DR-TB
NTC[7,37]	**Healthcare access:** Increase healthcare access of underserved/unreached/high-risk groups through CB-DOTS and working with community-based organisations, CSOs, FCHV. Such groups include: HIV, malnourished, women, diabetics, marginalised groups, and poor. Addressing discrimination and stigma will be given high priority in CB-DOTS support. **Economic burden:** Implementation of programs to progressively reduce financial burden on patients and their families incurred by TB to zero. Financial support should be provided for transport & food, diagnostic procedures and follow up visits. **Psychosocial burden:** Psychosocial support and vocational training programs to be prepared and introduced in a phase-wise manner in coordination with community based organizations and provisions will be made for their regular monitoring and supervision.

2. Study goal and objectives

The proposed study aims to undertake an economic evaluation of TB patient costs in Nepal.

The primary objectives of the study include:

1. Determine the direct and indirect costs due to TB illness, diagnosis and care;
2. Estimate the proportion of households experiencing catastrophic costs due to TB including those affected by drug-sensitive (DS) and drug-resistant (DR) TB;
3. Assess the association between catastrophic costs and adverse TB treatment outcomes;
4. Provide recommendations on policies and interventions to minimise barriers for accessing and adhering to TB treatment and care, and mitigate the economic impact of TB for patients and their families; and
5. Plan future research to further examine the determinants of cost barriers among TB patients and/ or to assess the effectiveness of policies and interventions to mitigate these costs.

The secondary objectives of the study include:

6. An equity analysis to determine the association of poverty level, rural vs urban living, HIV status, access to social protection, and drug-resistance with catastrophic costs; and
7. An exploratory analysis of the social impact of TB including stigma and mental illness.

2.1 Study hypothesis

Based on preliminary results from the subnational TB patient costs surveys,[62,69] we estimate that approximately 60% of DS-TB-affected households and 80% of DR-TB-affected households in Nepal will incur catastrophic costs. We hypothesise that TB-affected households that are poorer, live rurally, do not have access to social protection, or are affected by DR-TB will be more likely to incur catastrophic costs. In addition, as has been demonstrated in other settings, we predict that patients who belong to households that incur catastrophic costs will be less likely to achieve treatment success.

Finally, based on data from other settings[16] and a mixed-methods study in Nepal,[68] we predict that patients who belong to households that experience catastrophic costs will be poorer and be more likely to experience high levels of stigma, have mental illness, and have an adverse treatment outcome (e.g. not achieve treatment success).

3. Methods

3.1 Study design

Two complementary cross-sectional surveys (with retrospective data collection on patient costs and projections) to assess the direct and indirect costs associated with a diagnosis of TB and ongoing TB care:

1. DS-TB: A health-facility survey of people with DS-TB and their households
2. DR-TB: A hostel, health-facility, or household survey of people with DR-TB and their households

This design is considered optimal because:

- People with DS- and DR-TB are provided with different care and support packages in Nepal;
- People with DR-TB, especially MDR-TB, may be treated in DR-TB hostels for some or all of their treatment duration and may not be reached by a health-facility survey;
- Evidence from other settings[46] suggests differential prevalence of catastrophic costs in DS- and DR-TB households with DR-TB households having higher prevalence; and
- Disaggregation of the socioeconomic impact of DR- and DS-TB has informed design of tailored policies and interventions to address this impact in multiple other settings.[46]

Figure 4 below provides an overview of the cross sectional design and analytical approach with respect to timing of interviews, retrospective data collection, forward projections and imputations to recreate longitudinal information from one interview per patient only.

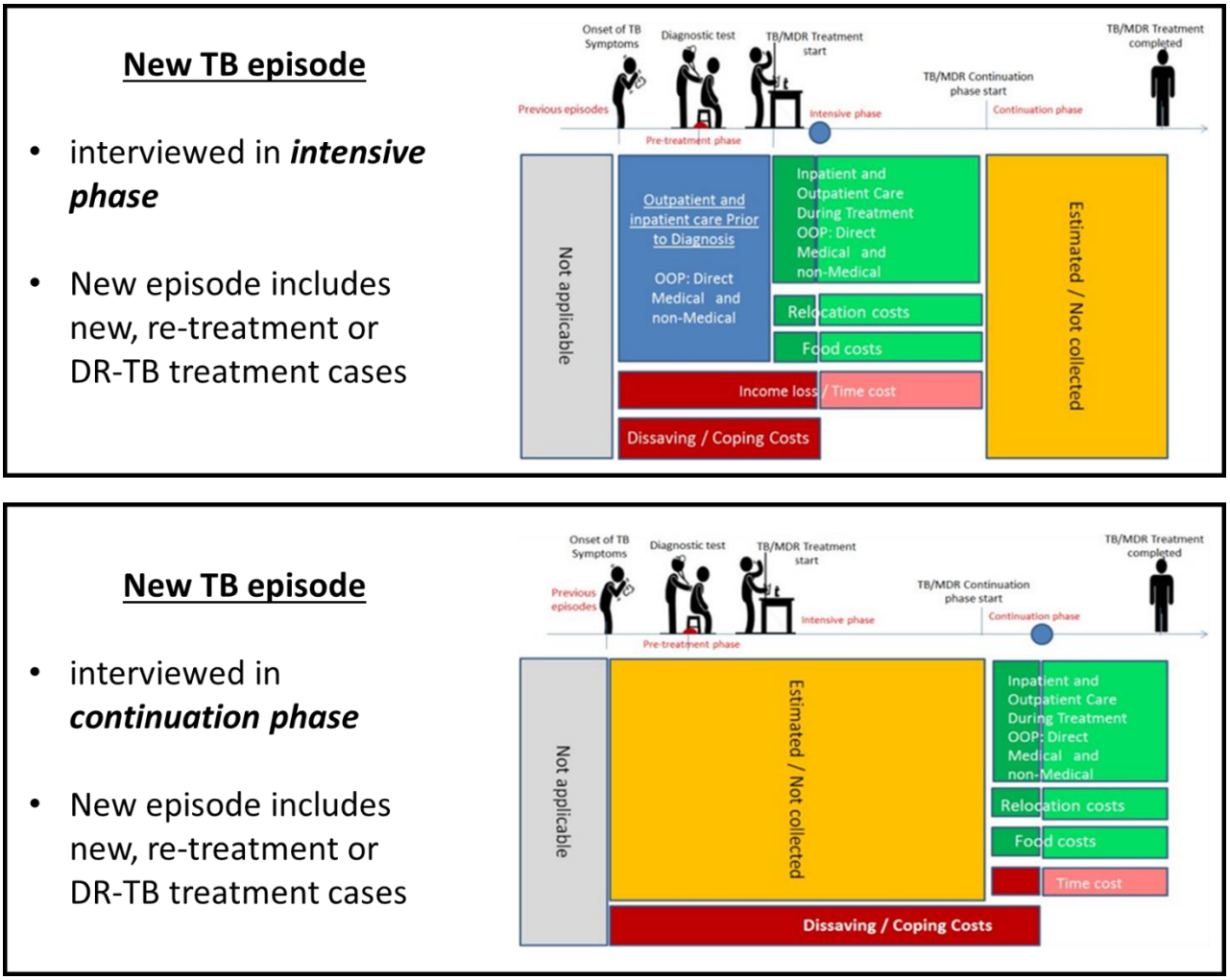


Figure 4. Overview of the cross-sectional survey design and analytical approach with retrospective data

collection and projections for different types of TB patients. *Blue dot indicates interview moment. Darker shades of green and red means retrospective data collected at the interview. Lighter shades of green and red, mean 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 patient's data*

Each enrolled patient will be interviewed only once and will report on 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 (approximately 50% of patients will be recruited in the intensive phase and 50% in the continuation phase), and data is collected on that particular phase only.

For people with DS-TB, the intensive phase refers to the first two months of treatment with quadruple therapy (e.g. rifampicin, isoniazid, pyrazinamide, and ethambutol). The continuation phase refers to the remaining four months of treatment.
For people with DR-TB, the intensive phase refers to the months during which they receive injectable agents (e.g. aminoglycosides). The continuation phase refers to the months of treatment after cessation of injectables. People with DR-TB who are taking an all-oral regimen are considered not to have an intensive phase.[70,71]

For patients interviewed in the intensive treatment phase, retrospective data on time spent seeking and receiving care and related expenditures prior to TB diagnosis will also be collected. Data collection for patients in different treatment phases will allow imputation of past and future costs during the entire illness episode (Figure 4). This approach will simplify sampling and make data collection efficient since most patients attending the facility during the survey period will be eligible to partake in the survey.

3.2 Study setting

Nepal is a landlocked country with a rich history, culture, and tradition. Home to a large diversity of people, it is a nation with the complex socio-cultural and socio-economic landscape. It shares borders with India to its east, west and south, and China to its north. Topographically, it is divided into three ecological zones: mountain, hill, and terai (flat) with an area of 147,181 km^2. Nepal has a population of 29.2 million in 2021 [72]. Among them, 48.96% were male and 51.04 % were female. More than half (54%) of the total population inhabit in the flat areas, followed by 40% in the hill and 6% in the mountain area. The majority of the population (66 %) lives in urban areas. The annual population growth rate is 0.93%. About 35% of the population is under 14 years and youth aged 15 to 24 years constitute about 20% of the total population. Based on the population projection by December 2016, Nepal's population was projected to be between 28.5 to 29 million[73]. Between 2000 and 2017 the GDP per capita in Nepal increased about 4 times. However, in recent years the growth has been stagnant with GDP per capita remaining low by international standards.

Following the implementation of its latest constitution in 2015, Nepal replaced a unitary government with a federal system. This transformed Nepal into a federal democratic republic with three levels of government: a federal level, seven provinces, and 753 local government areas ("palikas"). Palikas range from large municipal authorities that are responsible for up to 200,000 people to rural palikas covering wider area but with smaller populations of around 15,000. The 77 districts from the previous in-country structure are retained for interim management. In each province, the Ministry for Social Development is responsible for developing health policies, budgeting, monitoring and evaluation of the health programs as well as guidance to the local levels. The local levels are responsible to develop, implement, and evaluate the programme at their respective areas.

Life expectancy in Nepal is 66.6 years (65.5 years for men and 67.9 years for women).[74] The estimated maternal mortality ratio was 258 per 100,000 live birth in 2015 (Maternal Mortality in 1990-2015 Nepal, UN), which is relatively high compared to the neighbouring countries like Bangladesh (173) and India (145).[75] Communicable diseases are prevalent but there is transition with non-communicable diseases increasing. Ischaemic heart disease causes the highest mortality in Nepal.[76]

3.3 Study population

The study population includes all people (including children) notified to the NTP who are receiving DS-TB or DR-TB treatment within the NTP network during the survey period. DR-TB treatment includes treatment for rifampicin-resistant TB (RR-TB), multi-drug resistant TB (MDR-TB), pre-extensively drug-resistant TB (pre-XDR-TB), and extensively drug-resistant TB (XDR-TB).

This protocol excludes people who are treated in facilities that are unlinked to the NTP (i.e. private facilities that do not report to the NTP). It also excludes people who have not been put on TB treatment or have been on treatment less than 2 weeks before the interview. Findings can therefore only be extrapolated to the subset of TB patients 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 study.

3.4 Eligibility criteria

Inclusion criteria:

i. All notified TB patients regardless of age or whether they are being newly treated or re-treated at the study health facility and who have been recorded in the health facility TB register
ii. The patient has been initiated on TB treatment and has had at least two weeks of TB treatment (in either the intensive phase or continuation phase)

Exclusion criteria:

i. The health facility is not within the NTP network (i.e. a public health facility or a private facility not registered by NTP to provide TB services)
ii. Patient has been on TB treatment for less than 14 days
iii. Patient is less than 18 years old and is not accompanied by a parent or legal guardian
iv. Patient does not give consent to participate

3.5 Sampling strategy

As a case-based electronic register is not available in Nepal and so this survey will employ a *cluster sampling strategy,* which means that health facilities which provide basic TB services (i.e. Basic Management Units or BMUs) are the unit being sampled. All TB patients who satisfied the inclusion criteria are eligible for the study.

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. To avoid the risk of drawing a sample that misses the largest centres, a weighted probability-proportional to size (PPS) cluster sampling technique will be used. The clusters will be allocated depending on the number of TB notifications for the year 2019.

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

3.5.1 Sample size calculation

The sample computation has been based on the cluster sampling formula below which is available on the WHO Global TB software (http://samplesize.herokuapp.com) or from Dr Tom Wingfield (WHO).

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

Where:

N	Number of people included in the patient survey
N_{SRS}	Simple Random Sampling size
π_g	"Prior guess" of the true proportion of families experiencing catastrophic total costs due to TB illness (expressed as a proportion), taken as 60% for people with DS-TB and 80% for people with DR-TB
d	Relative precision (expressed as a proportion).
m	Cluster size (=number of targeted individuals), assumed to be constant across clusters.
k	Coefficient of between-cluster variation.

DS-TB Survey Sample Size Calculations: Taking the current total of 37,700 DS-TB patients reported to the Nepal TB Control Center in 2021/22 (N), with a design effect (DEFF) of 2.0 (as recommended by WHO for studies using cluster sampling strategy), catastrophic costs prevalence of 50%, 60%, and 70%, and an absolute precision level (d) of 6%, a minimum sample size was generated using the WHO software as shown in Table 2a below:

Table 2a. Required sample size for different levels of desired precision for a DS-TB Patient Cost Survey in Nepal.

Estimation of proportion of people with DS-TB with catastrophic costs	Absolute precision d=6.0 %			
	Cluster size	Cluster size	Cluster size	Sample
	- 30 clusters -	- 40 clusters -	- 50 clusters -	size
50%	18	14	11	530
60%	**17**	**13**	**11**	**509**
70%	15	12	9	446

For the purposes of the DS-TB survey, we have assumed from recent, related studies that 60% of patients incur catastrophic costs.[62,69] Assuming an average cluster size of 11 patients and total number 50 clusters countrywide, **509 DS-TB patients should complete the survey**. Assuming 10% attrition from time of recruitment to survey completion (e.g. 10% of recruited participants who do not complete a survey), it would be recommended to **continue recruitment to 600 people with DS-TB**.

DR-TB Survey Sample Size Estimates: Taking the current total of 662 people with DR-TB notified to the Nepal TB Control Centre in 2021/22 (N), with a design effect (DEFF) of 2.0 (as recommended by WHO for studies using cluster sampling strategy), catastrophic costs prevalence of 70%, 80%, and 90%, and an absolute precision level (d) of 5%, a minimum sample size was generated using the WHO software as shown in Table 2b below:

Table 2b. Required sample size for different levels of desired precision for a DR-TB patient cost survey in Nepal

Anticipated guess of proportion of DR-TB patients with catastrophic costs	Absolute precision d=5.0 %			
	Cluster size	Cluster size	Cluster size	Sample
	- 10 clusters -	- 15 clusters -	- 20 clusters -	size
70%	44	29	22	435
80%	**36**	**24**	**18**	**359**
90%	23	16	12	230

For the purposes of the DR-TB survey and from surveys in other low-income settings,[23,77,78] we have assumed that 80% of patients incur catastrophic costs. Assuming an average cluster size of 18 patients and total number 20 clusters countrywide, **359 DR-TB patients should complete the survey**. Assuming 10% attrition from time of recruitment to survey completion (e.g. 10% of recruited participants who do not complete a survey), it would be recommended to **continue recruitment until 400 people with DR-TB have been recruited**.

In situations where the number of patients at any given BMU is less than the anticipated cluster size, nearby BMUs will be annexed accordingly. If there are more patients on treatment in a given facility than the target cluster size, enrolment of consecutive patients attending follow up visits will be continued until the required number has been obtained. It is estimated that patient enrolment will last approximately 3 months for the DS-TB survey and 6 months for the DR-TB survey.

3.5.2 Selecting clusters

DS-TB clusters: The clusters for the DS-TB survey are selected based on the list of BMUs and their DS-TB notifications in 2021/22 utilizing the PPS method. Pragmatically, health centres were the primary BMU but in cases where entire districts had annual TB case notification rates of less than 100, the district was included as a single BMU. Also, health centres or districts with annual TB notification rates of less than 10 were excluded. Health centres selected randomly by PPS that had 10-30 annual notifications were combined in a cluster with the most geographically proximate health centres where possible, so that each cluster had collective annual TB case notification rates of more than 30. This method was assumed suitable to recruit at least 11 patients per cluster as per sample size calculations. The number of clusters is 50 and the sampling interval is 792 (37700 patients / 50 clusters). The detailed list of DS-TB BMUs and cluster selection is in Appendix Bi. The list of selected DS-TB clusters is provided in Table 3a.

DR-TB clusters: The clusters for DR-TB survey are selected based on the list of BMUs and their DR-TB notifications in 2021/22. Due to limited DR-TB patient numbers and sample size, the PPS method was not used and, instead, all DR-TB centres were included apart from those with no recorded DR-TB patients in 2021/22, which were excluded. The number of clusters is 20 and the sampling interval is 33 (662 DR-TB patients / 20 clusters).
The detailed list of DR-TB BMUs and cluster selection is in Appendix Bii. The list of selected DR-TB clusters is provided in Table 3b.

Table 3a: List of selected BMUs for a DS-TB patient cost survey in Nepal

Province	District	Treatment Center/DOTS centers/BMUs	Total notified TB cases	Cluster Number	Target number of participants to recruit*
1	OKHALDHUNGA	OKHALDHUNGA COMMUNITY HOSPITAL OKHALDHUNGA	46	1	12
1	JHAPA	SANISCHARE PHC_JHAPA	57	2	12
1	JHAPA	PRITHIVINAGAR HP_JHAPA	20	3	6
1	JHAPA	MAHESHPUR HP_JHAPA	11	3	6
1	MORANG	RAJGHAT HP MORANG	20	4	12
1	SUNSARI	DHARAN HP_SUNSARI	26	5	12
1	SUNSARI	SONAPUR HP_SUNSARI	11	6	6
1	SUNSARI	AURABARNI HP_SUNSARI	10	6	6
2	SAPTARI	THELIYA HP_SAPTARI	10	7	6
2	SAPTARI	BELHI CHAPENA HP_SAPTARI	16	7	6
2	SIRAHA	KARJANHA HP_SIRAHA	12	8	6
2	SIRAHA	KALYANPUR KA.BA. HP_SIRAHA	14	8	6
2	DHANUSA	MAHENDRANAGAR PHC_DHANUSA	31	9	6
2	DHANUSA	DIGAMBARPUR HP_DHANUSA	16	9	6
2	DHANUSA	INSTITUTIONAL CLINIC JANAKPUR_DHANUSA	140	10	12
2	MAHOTTARI	PARAUL HP_MAHOTTARI	12	11	6
2	MAHOTTARI	BALBA HP _MAHOTTARI	16	11	6
2	SARLAHI	PARWANIPUR HP_SARLAHI	19	12	6
2	SARLAHI	RANIGANJ HP_SARLAHI	15	12	6
2	SARLAHI	HEMPUR HP_SARLAHI	14	13	6
2	SARLAHI	JAMUNIYA PHC _SARLAHI	12	13	6
2	RAUTAHAT	SIMARA BHAWANIPUR HP_RAUTAHAT	16	14	6
2	RAUTAHAT	SANTAPUR (DOSTIYA) HP _RAUTAHAT	18	14	6
2	RAUTAHAT	INSTITUNIONAL CLINIC GAUR _206	37	15	12
2	BARA	CHHATAWA HP_BARA	12	16	6
2	BARA	BISHRAMPUR HP_BARA	11	16	6
2	BARA	JAMUNIYA BASIC HEALTH SERVICE CENTER SUBARNA_206	10	17	6
2	BARA	PRASURAMPUR HP_BARA	11	17	6
2	PARSA	RAMGHADWA HP_PARSA	13	18	6
2	PARSA	SIRSIYA KHALABTOLA HP_PARSA	11	18	6
3	SINDHUPALCHOK	BARHABISE (RAMCHE) PHC _SINDHUPALCHOK	20	19	6
3	DHADING	SALYANTAR PHC_DHADING	11	19	6
3	KATHMANDU	GOKARNA PRIMARY HOSPITAL_KATHMANDU	58	20	12
3	KATHMANDU	FUTUNG HP_KATHMANDU	24	21	12
3	KATHMANDU	HELPING HANDS COMMUNITY HOSPITAL _KATHMANDU	171	22	12
3	KATHMANDU	UHC_15_KATHMANDU	96	23	12
3	KATHMANDU	JANTRA _KATHMANDU	36	24	12
3	BHAKTAPUR	LOKANTHALI HP_BHAKTAPUR	54	25	12
3	LALITPUR	ALKA HOSPITAL_LALITPUR	48	26	12
3	SINDHULI	SIRTHOULI PHC_SINDHULI	26	27	12

Province	District	Treatment Center/DOTS centers/BMUs	Total notified TB cases	Cluster Number	Target number of participants to recruit*
3	MAKWANPUR	MOHAN BAJRACHARYA URBAN HEALTH CENTRE_MAKAWANPUR	23	28	6
3	MAKWANPUR	PIPLE URBAN HEALTH CENTRE_MAKAWANPUR	15	28	6
3	CHITWAN	NATIONAL ANTI TUBERCLOSIS ASSOCIATION_CHITAWAN	65	29	12
3	CHITWAN	KHAIRAHANI NAGAR HOSPITAL_CHITAWAN	65	30	12
4	KASKI	DPHO DOTS CENTRE	131	31	12
4	NAWALPARASI	GAIDAKOT HP_NAWALPARASI	65	32	12
4	SYANGJA	GARHAUN GHYANGLING PHC_SYANGJA	27	33	6
4	SYANGJA	TULSI BHANJYANG HP_SYANGJA	15	33	6
5	PYUTHAN	LIGHA HP_PYUTHAN	10	34	6
5	PYUTHAN	KWADI URBAN HEALTH CENTER_PYUTHAN	11	34	6
5	ARGHAKHANCHI	ARGHAKHANCHI HOSPITAL SANDHIKHARKA	22	35	6
5	ARGHAKHANCHI	THADA PHC_ARGHAKHANCHI	13	35	6
5	NAWALPARASI	PALHI PHC_NAWALPARASI	20	36	12
5	RUPANDEHI	PARROHA HP_RUPANDEHI	63	37	12
5	RUPANDEHI	BHIM HOSPITAL_ RUPANDEHI	133	38	12
5	KAPILBASTU	GUGAULI HP_KAPILBASTU	14	39	6
5	KAPILBASTU	PATHARDEIYA HP_KAPILBASTU	12	39	6
5	DANG	NARAYANPUR HP DANG	108	40	12
5	DANG	MANPUR HP DANG	39	41	6
5	DANG	BIJAURI HP_DANG	13	41	6
5	BANKE	SHAMSERGUNJ HP_BANKE	28	42	6
5	BANKE	CHISAPANI HP BANKE	18	42	6
5	BANKE	HIRMINIYA HP_BANKE	16	43	6
5	BANKE	KALAPHATA HP_BANKE	12	43	6
5	BARDIYA	JAMUNI_HP	38	44	12
6	RUKUM	DISTRICT HOSPITAL_ RUKUM	28	45	12
6	SURKHET	MUNICIPALITY HOSPITAL_BIRENDRANAGAR_SURKHET	31	46	6
6	SURKHET	NAULAPUR BASIC HEALTH SERVICE CENTER	16	46	6
7	DARCHULA	GOKULESHWOR HOSPITAL_DARCHAULA	12	47	6
7	DADELDHURA	SADANI HP_DADELDHURA	16	47	6
7	KAILALI	MALAKHETI HOSPITAL_KAILALI	117	48	12
7	KAILALI	TIKAPUR HOSPITAL_ KAILALI	123	49	12
7	KANCHANPUR	SUDA HP_KANCHANPUR	32	50	6
7	KANCHANPUR	HALDUKHAL UHC_KANCHANPUR	16	50	6
			TOTAL RECRUITMENTS		600

*Legend: *Aiming for 11 participants with completed surveys per cluster but recruiting 12 participants per cluster with the assumption of 10% attrition following recruitment and prior to completing the surveys.*

Table 3b: List of selected BMUs for a DR-TB patient cost survey in Nepal

Province	Location	DR-TB Treatment Centers / BMUs	Total TB cases notified 2021/22	Cluster	Target number of participants to recruit*
1	Morang	NEPAL ANTI TUBERCULOSIS ASSOCIATION (NATA)_MORANG	83	1,2,3	60
1	Dharan	BPKIHS_ DHARAN_SUNSARI	20		
2	Dhanusha	LALGADH HOSPITAL _DHANUSA	67	4,5	40
2	Parsa	NATIONAL MEDICAL HOSPITAL_PARSA	42	6	20
2	Rautahat	CHANDRANIGAHAPUR HOSPTIAL_ RAUTAHAT	31	7	20
3	Bhaktapur	NATIONAL TUBERCULOSIS CONTROL CENTRE_BHAKTAPUR	32	8	20
3	Kalimati	GENETUP _KATHMANDU	69	9,10	40
4	Pokhara	TUBERCULOSIS TREATMENT CENTER_POKHARA	16	11,12	40
4	Baglung	DHAULAGIRI HOSPITAL_BAGLUNG	7		
4	Nawalparasi	MIDPOINT DISTRICT HOSPITAL_NAWALPARASI EAST	32		
5	Butwal	LUMBINI PROVINCIAL HOSPITAL_ RUPANDEHI	102	13,14,15	60
5	Dang	RAPTI ACADEMY OF HEALTH SCIENCE_DANG	10	16,17	40
5	Banke	TB-NEPAL_ BANKE	52		
6	Surkhet	PROVINCIAL HOSPITAL_SURKHET	15	18	20
6	Zumla	KARNALI ACADEMY OF HEALTH SCIENCE_JUMLA	2		
7	Kanchanpur	MAHAKALI ZONAL HOSPITAL_KANCHANPUR	12		
7	Kailali	SETI ZONAL HOSPITAL_ KAILALI	5		
7	Dhadeldhura	DADELDHURA HOSPITAL_DADELDHURA	5		
7	Acham	BAYALPATA HOSPITAL (NYAYA HEALTH)_ACHHAM	7		
7	Kailali	LAXMINARAYAN REFERRAL HOSPITAL_ KAILALI	53	19,20	40
			Total recruitments		400

*Legend: Okhaldhunga Community Hospital, Okhaldhunga, and Health Office Bhadrapur, Jhapa, recorded 0 DR-TB cases in since 2020 and hence were excluded (see Appendix Bii). *Aiming for 11 participants with completed surveys per cluster but recruiting 12 participants per cluster with the assumption of 10% attrition following recruitment and prior to completing the survey.*

3.5.3 Selecting TB patients within sampled facilities

DS-TB

For each of the selected clusters, the data collection team will visit the relevant facilities and select eligible patients to be invited, in collaboration with the local TB coordinator and managers of the facility. The following steps will be taken:

1. The target number for recruitment is 20 patients per cluster, divided into 10 patients in the intensive and continuation phases, respectively.
2. A list of all TB patients currently on treatment in the cluster will be created and numbered 1 onwards.
3. From the list, randomly select 10 patients in the intensive phase and 10 patients in the continuation phase (using a random number table or the "=RANDBETWEEN(X, Y)" command in Excel where X = 1 and Y = the total number of patients on the list
4. Make an appointment with the selected patients for interview. Interviews can be organised at the health facility, at the patient's home or another location as agreed by the survey team and patient.

DR-TB

In principle, the same procedure as for DS-TB will be followed. As DR-TB treatment is more centralized and predominantly located in DR-TB hostels, the survey team or patients may require to travel longer distance than DS-TB. The interview venue might also need to be arranged flexibly (e.g. district DR-TB hostel or other related health facility, etc).

1. The target number for recruitment is 12 patients per cluster, divided into 6 patients in the intensive and continuation phases, respectively.
2. A list of all TB patients currently on treatment will be created.
3. From the list, randomly select 6 patients in the intensive phase and 6 patients in the continuation phase
4. Make an appointment with the selected patients for interview. Interviews can be organised at the health facility, DR-TB hostel, or another location as agreed by the survey team and patient (Note: although public health precautions must be noted if the patient has pulmonary MDR-TB and is still in the infectious period)

All patients should be a minimum of 2 weeks into the current intensive or continuation treatment phase. If the patient has not been treated for a minimum of 2 weeks in the current treatment phase, the interview should be postponed until this time.

Each potential survey participant must be adequately informed of the following in a format (verbal, written) and language acceptable to her/him (Appendix C: Information sheet):

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

3.6 Data collection

The primary focus of the survey is on patient costs, including the magnitude 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 completion of treatment). A secondary focus of the survey is access to and uptake of social protection and the psychosocial impact including stigma and mental illness.

We will collect information required to estimate household income, which is needed both for the denominator of the measure of catastrophic total costs due to TB, and for the estimation of income loss, which is part of the denominator of the same measure. We will estimate household income in two ways; by collecting information on self-reported individual and household income and also self-reported household expenditure. We will also collect information on living conditions and assets which will allow us to allocate multidimensional wealth quintiles to the survey population.

We will also collect data to enable disaggregated cost analyses, identification of predictors of costs, descriptive analysis of health care utilization and an assessment of how patients and household cope with costs. In summary, we will collect information on:

- Clinical parameters
- Demographic variables and household composition
- Socioeconomic position
- Health care utilization
- Time spent seeking and receiving care
- Direct medical, direct non-medical and indirect costs
- Household and individual income
- Household expenditure
- Household assets
- Household consumption
- Coping mechanisms (taken loans, sold assets, etc.)
- Perceived impacts of costs
- Stigma level (using an adapted van Rie scale previously validated in Nepal)[68,79]
- Quality of life (using the Euro-HIS-QoL-8 previously validated in Nepal)[68,80]
- Mental health (using the PHQ-9 questionnaire)

We will use a standardized questionnaire that has been developed by WHO for TB Patient Cost Surveys. This tool has already been modified, piloted, and used in multiple studies in Nepal and is validated for use in the Nepalese context.[62,67,68] The questionnaire has four parts (Table 4).

Table 4: Content of the Tuberculosis Patient Cost Survey

Survey component	Content
Part I	Informed consent, inclusion/exclusion criteria
Part II	Patient information to be obtained from TB treatment card before interview (for all patients)
Part III	Time loss, costs and coping, 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)

The pathway for the survey questionnaire is outlined in Figure 5 below.

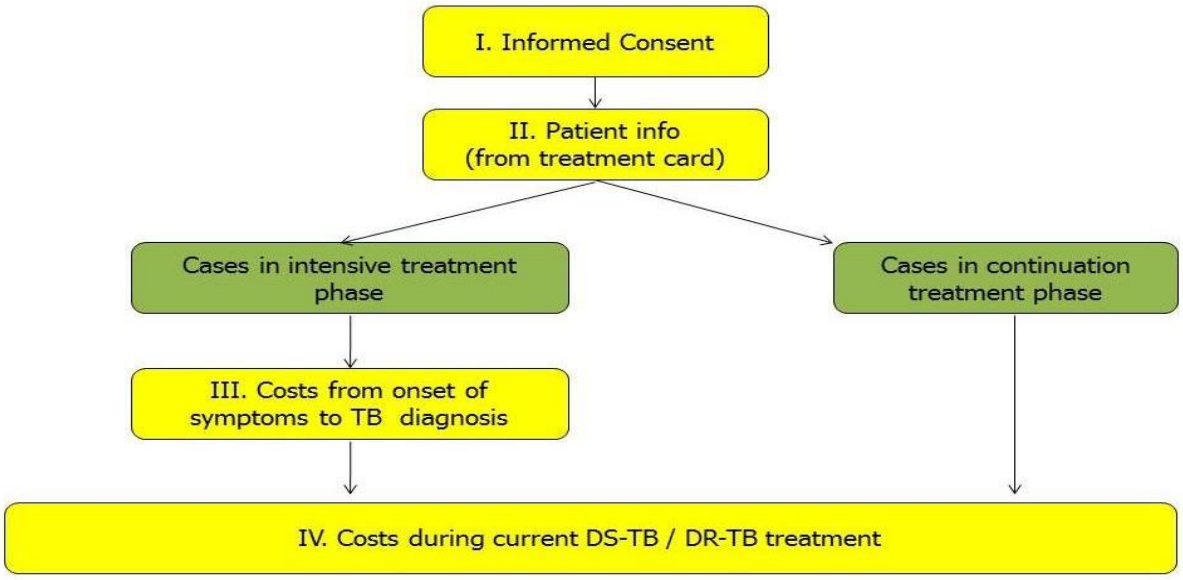


Figure 5: Flow of questionnaire components for the tuberculosis patient cost survey in Nepal

Information from the TB treatment card (Part II), and information about costs related to the current TB treatment (Part IV), will be collected for all patients. Information about costs and time loss related to health seeking and diagnostic procedures before the person was registered as a TB patient within the NTP network (Part III) will be collected only from patients who are interviewed in the intensive phase. This is because of the considerable challenge for patients to remember events and costs incurred many months prior to the time of the interview. For patients who are interviewed in the continuation phase, information will be collected only about costs related to the continuation phase (with a few exceptions, such as hospitalization costs and coping, which should also be collected for the intensive phase for these patients).

Information collected in part III for new cases interviewed in the intensive phase will be used to impute data and model costs for patients interviewed in the continuation phase. Similarly, information about costs in the continuation phase collected from patient interviewed in this phase will be used to project costs for patients interviewed in the intensive phase.

We will use data collection online tools by WHO, with trained interviewers interviewing the patient and completing the questionnaires. All completed questionnaires will be send to the NTP and data entry will take place at the central level.

3.7 Survey training and pilot

Interviewers will be selected from the health care workers of the selected health centers. Training of interviewers is key to the success of this survey. We will conduct a 2-day training for all staff to be involved in the survey. Training will cover survey methodology, protocol details and good clinical practice. No re-interviewing is available in this survey. Interviewer's team leaders will check the quality of the interview periodically. The objectives of the training for interviewers will include:

- 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
- Understand the indicators used in the questionnaire
- To feed back any uncertainties or concerns with the questionnaire or the data collection procedures to the survey coordinator

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

After the training, survey interviewers will be able to

- Introduce themselves and the survey to the participant.
- Convey to the patient the justification for inclusion criteria for the survey.
- Convey to the patient the informed consent process.
- Be able to put participant at ease and ensure a comfortable environment in which to ask questions
- Be familiar with the questionnaire so that questions are asked conversationally rather than formally
- Convey questions in the order in which they are written on the questionnaire, using the same wording (using the local language) as on the questionnaire. It may be that certain questions need further explanation and may need the interviewer to prompt responses from the patient regarding time and types of costs. *Depending on how far the patient has progressed with treatment, it might be difficult for him/her to recall cost items. The interviewer should make it as easy as possible for the patient to recall by using local methods of time structuring*.
- Understand and able to explain indicator definitions. *Types of costs, what is meant by cost of food, cost of travel and cost of accommodation, what is included and what is excluded and how they can help patients recalling items by prompting. This will help to ensure consistency in interviews and prompting by interviewers.*
- Avoid influencing the answers to questions by using friendly but neutral body language and not educating the patient.
- 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.
- Keep control of the interview (off track conversations, long silences).
- Check patient records (included in case of non-participation in the survey).
- Be sensitized on the different phases (i.e. intensive, continuation) and types of TB treatment (hospitalization, different forms of DOT, etc.) and associated costs (sputum conversion test, follow up test, medicine collection etc.), to avoid double counting costs. It also needs to be clear to the interviewers what counts as TB drugs and what are additional drugs that are prescribed/bought.
- Be informed about the nature of TB, what their participation means for their own health and how they can protect themselves.
- Gain knowledge on infection control procedures while collecting.

The training will be conducted by experienced national TB programme, WHO and academic staff, some of whom have been involved in other TB patient cost surveys in the region.

3.8 Interview

Interviews will be conducted by trained health care workers using pre-tested questionnaires. We intend to interview patients in the facility where they attend regular visits for TB care. The interview will take place in a separate space/room to allow privacy and an undisturbed condition. The interviewers will be aware of infection control measures, i.e. conducting the interview outside or in a well-ventilated room and wear an N-95 respirator if needed. As all the patients interviewed will be on effective treatment for more than 2 weeks, therefore the infection risk is minimal. All patients will be treated with dignity and respect and not as just TB patients. Interviewers will be specially instructed in how to conduct a good interview without judging and with respect of patients.

Before the interview, patients will be informed in Nepalese (the lingua franca in Nepal) about the purpose of the study and will be given the study information sheet (Appendix C). Patients will be told about the confidentiality of the data collected, time of the interview, and about their right to withdraw from the study at any time. To ascertain whether the patient really understands the implications of consent, the interviewer will allow patients to ask questions for clarification and provide time to read the study information sheet. After ensuring that the patient has understood the information, the interviewer will ask patient to sign Informed Consent or Assent form (Appendix D). If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

Depending on queue length, patients may be interviewed while they wait for consultation or while waiting to take medicine (making sure they do not lose their place in the queue) or after the clinics visit. The time required to conduct the interview is approximately 60 minutes (depending on the number of modules in the questionnaire to be used). Prior to the interview, and after written informed consent has been obtained, the interviewer will be required to complete some questions by checking patient records, which takes 15 minutes approximately.

During the interview, the interviewers will read the questions to patients in Nepali or other local language (e.g. Maithili), and will record and validate the responses. The questionnaire is designed to interview all patients showing up for treatment that are registered for treatment for TB or MDR-TB treatment at an NTP network facility. However, a minimum of 2 weeks of the present treatment phase should have been completed before the interview in order to enable collection of data concerning the ongoing treatment phase. Patients that have completed less than 2 weeks of intensive, or continuation phase, will not be interviewed. Children aged under 18 who are not accompanied by guardian will not be eligible to participate. If children aged under 18 are accompanied by a guardian or parent, it is this person who will answer the questions.

3.9 Data management

Data collection of the survey will be completely paper-less. Data will be entered into an electronic database (a WHO database will be used) directly by enumerators via tablets, which will then be verified and forwarded by the survey manager focal person from the outsourced agency during first step-verification and will be finally validated by the survey's central team at NTCC. All completed questionnaires will be checked by team leaders and uploaded electronically on real-time basis through trained enumerators. At the central level, the data will be kept securely under the survey Data Management Unit, under the supervision of the survey coordinator. The database will be password protected and only the study team will have access to the data. Therefore, no one other than the research team will have access to the information in the questionnaires. We will aim to protect patient confidentiality by limiting access to the data to the research team only, and by presenting summarized data in publications and reports.

The data will be kept for a period of five years after publication. After this time, it will be archived. The data may be used for future research to compare patient costs across countries, which is a priority for WHO to further refine the patient costs indicator. In the event data release is required for publication, an appropriate request should be forward to the owner of data (i.e., the NTCC and MoHP) for decision-making.

Staff from the NTCC will have overall management responsibility for the implementation, monitoring and reporting of the study, including data management. The specific roles and responsibilities of the Principal Investigators are listed in Appendix E.

3.10 Data analysis

We will describe the study population using descriptive statistics. We will then calculate mean out-of-pocket direct medical and direct non-medical costs and indirect costs before TB treatment starts and after TB treatment. We will calculate direct and indirect costs combined as a proportion of annual household income. We will determine where and when the costs are being incurred, stratified by whether they are direct medical costs, direct non-medical costs, or indirect costs, and will determine the proportions of costs incurred before TB diagnosis or after TB diagnosis. We will determine the proportion of TB patients who incur catastrophic costs, the proportion who experience dissaving and the proportion who have social consequences (such as divorce, withdrawing a child from school, etc.) due to their TB diagnosis. We will stratify our analyses by age, sex, BMU, wealth quintile and possibly other factors.

We will use monthly household expenditure as the method of choice for determining income. To measure expenditure patients will be asked a series of questions about how much (if any) they have spent on certain goods and services, including food items, non-food items, durable goods (i.e., goods that last for a long amount of time, such as bicycles), and housing. However, as part of sensitivity analyses, we will also determine income based on self-reported income.

Catastrophic costs will be determined using the following approach: the sum of a) *out-pocket payments* for TB diagnosis and treatment by TB patients in a given household and b) payments related to the use of TB health services, such as payments for transportation, accommodation or food and c) income losses incurred by both the TB patient and any escort member *net of any welfare payment* that exceeds a given threshold (e.g. 20%) of the household's income.

The total indirect and direct costs of TB will be defined as the sum of:

a) Out-pocket payments for TB diagnosis and treatment made by TB patient's households (direct net medical payment for TB treatment denoted $OOPM_i^{TB,h}$ where I identify the patient and h the patient's household);

b) Payments related to the use of TB health services, such as payments for transportation, accommodation or food (non-medical out-of-pocket payments for TB treatment denoted $OOPNM_i^{TB,h}$) net of any reimbursements to the individual who made the payments, and

c) Income losses related to TB care incurred by both the TB patient and any household member net of any welfare payment (indirect net cost of seeking TB treatment denoted $IN_i^{TB,h}$)

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

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

where i denotes the household of patient j.[18] n_{NTP}^{TB} , is the total sample size across all national TB programme networks engaged in this survey.[18] 1() is the indicator function which is equal to 1 if the condition is satisfied

and zero otherwise.[18]

Our additional sensitivity analysis will be to assess different thresholds of "catastrophic" i.e. we will use the agreed threshold of 20% but will also determine what proportion of TB patients spend a larger proportion of their household income on TB.

In 2023/24, we will collect TB treatment outcomes from the TB registers for all TB patients who consented to be in the study. The TB treatment outcomes will have been recorded using standard definitions consistent with the national TB guidelines and international recommendations. These outcomes will be linked to the TB patient cost survey data. We will calculate the proportion of patients with catastrophic costs who have a "favorable" TB treatment outcome (defined as the sum of the treatment outcomes of "cured" and "Treatment success" with the total number of TB patients who have an outcome recorded as the denominator) and will compare this to the patients who did not experience catastrophic costs, using a chi-square test.

3.11 Data ownership

All data generated from this survey is the property of the NTCC and MoHP on behalf of the government of Nepal. Therefore, the MoHP will be the sole owner of all rights to the data generated. In the event data release is required for publication, an appropriate request should be forwarded to the owner of data.

4. Survey operations

4.1 Composition of the survey team

A patient cost survey team will include an Advisory Committee chaired by the Additional Secretary from MoHP, a Working Committee chaired by the Principal Investigator (Director, NTCC) and an outsource agency comprising of Survey Focal Person and data enumerators for field level implementation and the selected cluster sites, as outlined below in Figure 6.

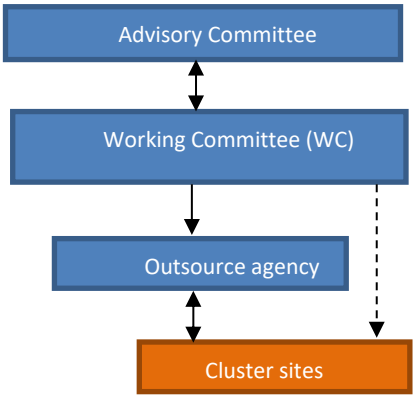


Figure 6: Composition of the Nepal tuberculosis patient cost survey team

5. Expected outcomes

The outputs resulting from this study will include a detailed assessment of the economic costs incurred by TB patients in Nepal which will aid in the design of policies and interventions to minimize barriers for accessing and adhering to TB treatment, with the overall goal of improving access to TB care. It is also anticipated that the research will contribute to the validation and refinement of WHO designed survey methodologies and tools. Finally, the research will allow the identification and prioritization of future research required to develop and/or scale-up policies and interventions to mitigate against these costs, and later to assess the effectiveness of these policies and interventions.

6. Ethical considerations

This survey will involve the administration of a questionnaire to participants (i.e. TB patients) about their TB diagnosis, treatment and health seeking behaviors, and the costs associated with these. Therefore, it is anticipated that there are very few risks associated with this kind of study as it involves the administration of a questionnaire only, using trained interviewers. The potential risk that the study investigators can foresee is for patients who have been adversely financially or socially affected by TB and who recall these events, and for whom this causes distress. While recalling these events there is a risk that patients may become worried or distressed and it may be necessary for the interviewer to temporarily stop the interview and reassure the patient. The interviewer will have the option of referring that person to a nurse or doctor if further psychological support is needed. There is a very small risk that someone may be identified based on the responses provided to the interviewer. To mitigate against this risk, all information will be kept in password protected database which will be accessed by the study team only, and any presentations or publications will

only contain summarized and de-identified data. There are no foreseen risks to the interviewers beyond the scope of any other health care worker. TB patients will only be interviewed after two weeks of TB treatment, therefore there is negligible risk of TB infection from patient to interviewer.

We will seek ethics approval from the Nepal Health Research Council and the WHO Southeast Asia Regional Office Ethics Review Committee.

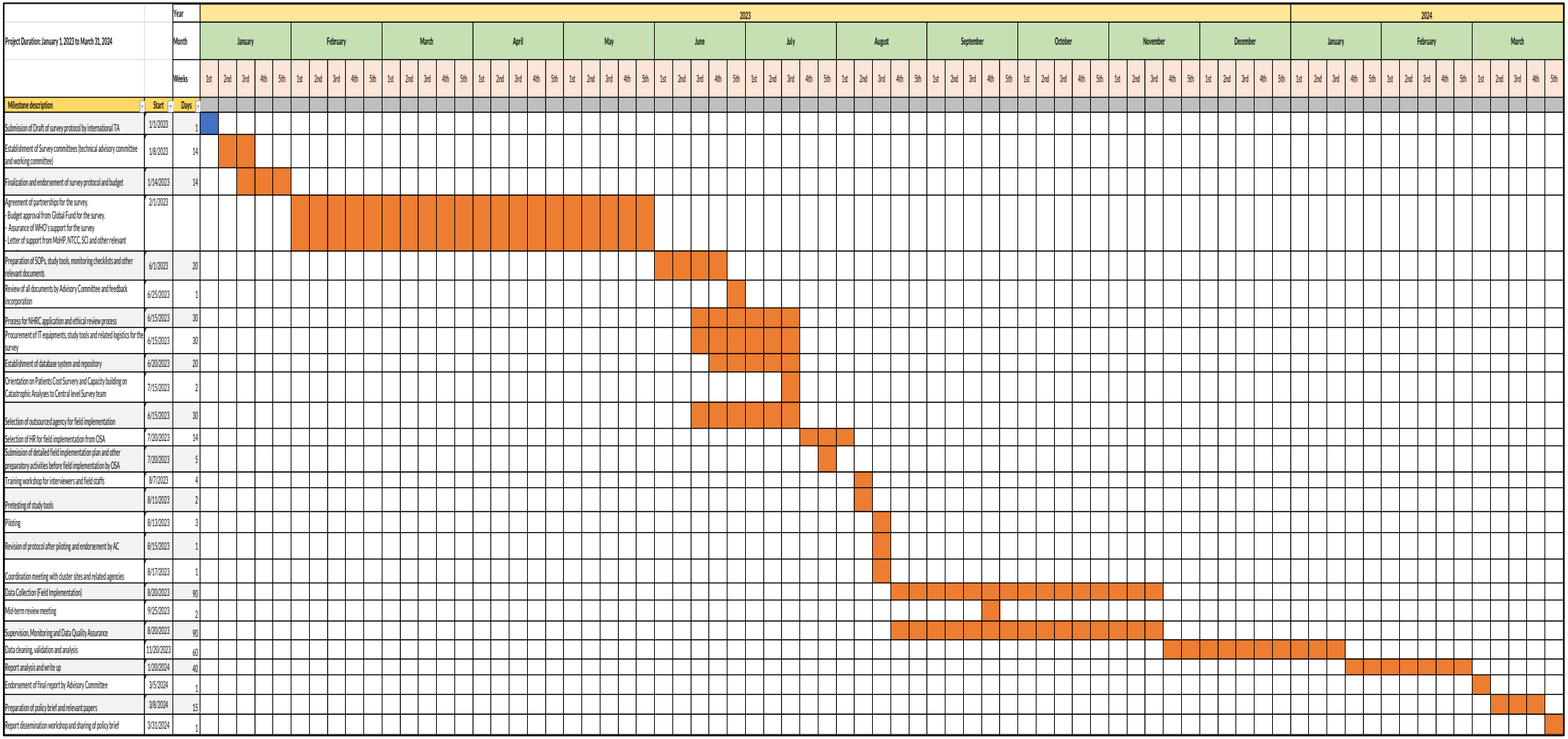
When approaching TB patients to ask them to enroll in the study, we will provide them with a written information sheet which will outline the purpose of the study and provide contact details for the study investigators (Appendix C). Written informed consent or assent will be sought from all participants (Appendix D). For TB patients who are children aged under 18 years of age written informed consent will be sought from a parent or guardian. For patients aged 15-17 years we will seek written informed consent and assent from the patient. For TB patients who are aged 18 years and above, we will seek written informed consent.
Agreement or refusal to participate in the study will not impact on the provision of subsequent health care services that TB patients receive from staff at the BMUs and the information sheet contains a statement to this effect.

7. Dissemination of results

The potential users of the results of this study will be Nepal Government Ministries, WHO, policy makers, and researchers. The Nepal MoHP and other departments such as planning, treasury will find the results of this study directly applicable to their work as the main agencies who deal with health and social welfare. Previous studies on this topic have demonstrated that lost income accounts for a large proportion of TB patient costs.[9]

Therefore, the results of this research will be disseminated to the Nepal MoHP, all relevant stakeholders and the relevant WHO offices in the first instance (i.e., the Nepal Country Office and the Southeast Asia Region Office). The results of this research will be developed into a policy brief which will be presented to the Nepal MoHP and all relevant stakeholders after the study has finished. Following on from this, the research will be written up in the form of a report and a publication for the peer reviewed scientific literature. The results will also be presented in relevant fora (i.e., Ministry meetings/ conferences etc.) as appropriate and may form a case study for future iterations of the WHO TB Patient Cost Survey handbook.

8. Timeline


Project Duration: January 1, 2023 to March 31, 2024
Year
Month
Weeks
2023
2024
January
February
March
April
May
June
July
August
September
October
November
December
1st
2nd
3rd
4th
5th
Milestone description
Start
Days
Submission of Draft of survey protocol by international TA 1/1/2023 1
Establishment of Survey committees (technical advisory committee and working committee) 1/8/2023 14
Finalization and endorsement of survey protocol and budget 1/14/2023 14
Agreement of partnerships for the survey.
- Budget approval from Global Fund for the survey.
- Assurance of WHO's support for the survey
- Letter of support from MoHP, NTCC, SCI and other relevant 2/1/2023
Preparation of SOPs, study tools, monitoring checklists and other relevant documents 6/1/2023 20
Review of all documents by Advisory Committee and feedback incorporation 6/25/2023 1
Process for NHRC application and ethical review process 6/15/2023 30
Procurement of IT equipments, study tools and related logistics for the survey 6/15/2023 30
Establishment of database system and repository 6/20/2023 20
Orientation on Patients Cost Survey and Capacity building on Catastrophic Analyses to Central level Survey team 7/15/2023 2
Selection of outsourced agency for field implementation 6/15/2023 30
Selection of HR for field implementation from OSA 7/20/2023 14
Submission of detailed field implementation plan and other preparatory activities before field implementation by OSA 7/20/2023 5
Training workshop for interviewers and field staffs 8/7/2023 4
Pretesting of study tools 8/11/2023 2
Piloting 8/13/2023 3
Revision of protocol after piloting and endorsement by AC 8/15/2023 1
Coordination meeting with cluster sites and related agencies 8/17/2023 1
Data Collection (Field Implementation) 8/20/2023 90
Mid-term review meeting 9/25/2023 2
Supervision, Monitoring and Data Quality Assurance 8/20/2023 90
Data cleaning, validation and analysis 11/20/2023 60
Report analysis and write up 1/20/2024 40
Endorsement of final report by Advisory Committee 3/5/2024 1
Preparation of policy brief and relevant papers 3/8/2024 15
Report dissemination workshop and sharing of policy brief 3/31/2024 1

9. Survey Committees

I. Advisory Committee, its' members and ToR

Members:

1	Chairperson	Additional Secretary, MoHP
2	Vice Chair	Director General, DoHS
3	Member	Representative, Nationals Statistics Office
4	Member	Representative, National Planning Commission
5	Member	Chief, Planning and Monitoring Division, MoHP
6	Member	Member Secretary, NHRC
7	Member	Chief, Coordination Division, MoHP
8	Member	Director, SAARC TB and HIV/AIDS Center
9	Member	Representative, WHO
10	Member	Representative, Save the Children/Global Fund
11	Member Secretary	Director, NTCC (Principal Investigator)

Responsible for:

The AC is responsible for providing guidance for the survey.

Major Roles & Responsibilities:

- Provides guidance for successful implementation of the survey.
- Recommend amending the protocol as per need.
- Monitor the quality of the survey and can change the procedures at any time if required.
- Coordinate with other line ministries, international organizations, and other stakeholders for the smooth implementation of the survey.
- Provide recommendation for the report dissemination of the survey.
- Nominate any specialist as an invitee member as per the requirement for the survey.

II. Working Committee, its' members and ToR

Members:

1	Chairperson	Director, NTCC (Principal Investigator)
2	Member	Senior Chest Physician, NTCC
3	Member	Undersecretary, Administrative section, NTCC
4	Member	Senior Medical Laboratory Technologist, NTCC
5	Member	Statistics Officer, NTCC
6	Member	Finance Officer, NTCC
7	Member	Senior Program Manager, Save the Children/GF/NTCC
8	Member	Senior Planning and M&E specialist, Save the Children/GF/NTCC
9	Member	TB Survey and Surveillance Liaison Coordinator, Save the Children/GF/NTCC
10	Member	IT and Database Officer, Save the Children/GF/NTCC
11	Member	Finance Officer, Save the Children/GF/NTCC
12	Member	Representative, Outsourced agency
13	Member	Representative, WHO/NTCC
14	Member	Representative, Monitoring and Evaluation Section, MoHP
15	Member Secretary	Chief, PMESR, NTCC (Co-Investigator/Survey Coordinator)

Responsible for:

Under the guidance of AC, the WC is responsible for overall implementation of the survey.

Major Roles & Responsibilities:

- Develop TB PCS survey protocol with budget and detail work plans.
- Based on the protocol, the WC is responsible for development of all key document and guidelines (eg. SOPs, training materials, survey checklists etc.) needed for the survey.
- Monitor and provide directions for the implementation of the survey activities, thereby, ensure the quality as per the requirement assuring quality survey tools, HR and budget.
- Provide direction and supervise the performance of the outsource agency.
- Provide inputs on the design, pre-testing and in the development of study materials.
- Provide technical assistance in the training and piloting.
- Coordinate and communicate with national/ international consultants and experts involved in the survey.
- Provide other necessary instructions and approvals as per requirement throughout the survey period.
- Report to the Advisory Committee on a regular basis and for any urgent issues.
- Nominate any specialist as an invitee member as per the requirement for the survey.

10. Sponsor Monitoring

As one of the study sponsors, WHO may conduct monitoring or auditing of study activities to ensure the scientific integrity of the study and to ensure the rights and protection of study participants. Monitoring and auditing activities may be conducted by:

- WHO Staff ("internal")
- Authorized representatives of WHO (e.g., a contracted party considered to be "external")
- Both internal and external parties

Monitoring or auditing may be performed by means of on-site visits to the Investigator's facilities or through other communications such as telephone calls or written correspondence. The visits will be scheduled at

mutually agreeable times, and the frequency of visits will be at the discretion of WHO. During the visit, any study-related materials may be reviewed and the Investigator along with study staff should be available for discussion of findings. The study may also be subject to inspection by regulatory authorities (national or foreign) as well as the Institutional Ethics Committees/Institutional Review Boards to review compliance and regulatory requirements.

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Appendix A: Definitions of terms used in the Nepal tuberculosis patient cost survey

Term	Definition
Catastrophic costs	The operational definition of "catastrophic costs as a result of TB" refers to medical and non-medical out-of-pocket payments and indirect costs exceeding a given threshold (e.g. 20%) of the household's income. Both medical and non-medical costs are net of any reimbursements to the individual who made the payments.[4]
Direct medical costs	Direct medical costs refer to the sum of out-pocket payments for TB diagnosis and treatment made by TB patients in a given household.[4]
Direct non-medical costs	Direct non-medical out-of-pocket costs are payments related to the use of TB health services, such as payments for transportation, accommodation or food.[4]
Indirect costs	Indirect costs refer to patient or guardian lost time, lost wages (net of welfare payments) and lost income due to TB healthcare seeking and hospitalization during the TB episode.[4]
Out-of-pocket (health or medical) payments	Out-of-pocket payments are defined as direct payments made by individuals to health care providers at the time-of-service use. This excludes any prepayment for health services, for example in the form of taxes or specific insurance premiums or contributions and, where possible, net of any reimbursements to the individual who made the payment.[25]

Appendix Bi: Clusters selection for the Nepal DS-TB patient cost survey by probability proportional to size method

Province	District	Treatment Center/DOTS center/BMU	Total notified TB cases 2021/2022	Cluster 50 / 11 PPS number	Cluster Number	Target number of participants to recruit
1	OKHALDHUNGA	OKHALDHUNGA COMMUNITY HOSPITAL OKHALDHUNGA	46	156	1	12
1	JHAPA	SANISCHARE PHC_JHAPA	57	910	2	12
1	JHAPA	PRITHIVINAGAR HP_JHAPA	20	Neighbour	3	6
1	JHAPA	MAHESHPUR HP_JHAPA	11	1664	3	6
1	MORANG	RAJGHAT HP MORANG	20	2418	4	12
1	SUNSARI	DHARAN HP_SUNSARI	26	3172	5	12
1	SUNSARI	SONAPUR HP_SUNSARI	11	Neighbour	6	6
1	SUNSARI	AURABARNI HP_SUNSARI	10	3926	6	6
2	SAPTARI	THELIYA HP_SAPTARI	10	Neighbour	7	6
2	SAPTARI	BELHI CHAPENA HP_SAPTARI	16	4680	7	6
2	SIRAHA	KARJANHA HP_SIRAHA	12	Neighbour	8	6
2	SIRAHA	KALYANPUR KA.BA. HP_SIRAHA	14	5434	8	6
2	DHANUSA	MAHENDRANAGAR PHC_DHANUSA	31	Neighbour	9	6
2	DHANUSA	DIGAMBARPUR HP_DHANUSA	16	6188	9	6
2	DHANUSA	INSTITUTIONAL CLINIC JANAKPUR_DHANUSA	140	6942	10	12
2	MAHOTTARI	PARAUL HP_MAHOTTARI	12	Neighbour	11	6
2	MAHOTTARI	BALBA HP _MAHOTTARI	16	7696	11	6
2	SARLAHI	PARWANIPUR HP_SARLAHI	19	Neighbour	12	6
2	SARLAHI	RANIGANJ HP_SARLAHI	15	8450	12	6
2	SARLAHI	HEMPUR HP_SARLAHI	14	Neighbour	13	6
2	SARLAHI	JAMUNIYA PHC _SARLAHI	12	9204	13	6
2	RAUTAHAT	SIMARA BHAWANIPUR HP_RAUTAHAT	16	Neighbour	14	6
2	RAUTAHAT	SANTAPUR (DOSTIYA) HP _RAUTAHAT	18	9958	14	6
2	RAUTAHAT	INSTITUNIONAL CLINIC GAUR _206	37	10712	15	12
2	BARA	CHHATAWA HP_BARA	12	Neighbour	16	6
2	BARA	BISHRAMPUR HP_BARA	11	11466	16	6
2	BARA	JAMUNIYA BASIC HEALTH SERVICE CENTER SUBARNA_206	10	Neighbour	17	6
2	BARA	PRASURAMPUR HP_BARA	11	12220	17	6
2	PARSA	RAMGHADWA HP_PARSA	13	Neighbour	18	6
2	PARSA	SIRSIYA KHALABTOLA HP_PARSA	11	12974	18	6

Province	District	Treatment Center/DOTS center/BMU	Total notified TB cases 2021/2022	Cluster 50 / 11 PPS number	Cluster Number	Target number of participants to recruit
3	SINDHUPALCHOK	BARHABISE (RAMCHE) PHC _SINDHUPALCHOK	20	Neighbour	19	6
3	DHADING	SALYANTAR PHC_DHADING	11	13728	19	6
3	KATHMANDU	GOKARNA PRIMARY HOSPITAL_KATHMANDU	58	14482	20	12
3	KATHMANDU	FUTUNG HP_KATHMANDU	24	15236	21	12
3	KATHMANDU	HELPING HANDS COMMUNITY HOSPITAL _KATHMANDU	171	15990	22	12
3	KATHMANDU	UHC_15_KATHMANDU	96	16744	23	12
3	KATHMANDU	JANTRA _KATHMANDU	36	17498	24	12
3	BHAKTAPUR	LOKANTHALI HP_BHAKTAPUR	54	18252	25	12
3	LALITPUR	ALKA HOSPITAL_LALITPUR	48	19006	26	12
3	SINDHULI	SIRTHOULI PHC_SINDHULI	26	19760	27	12
3	MAKWANPUR	MOHAN BAJRACHARYA URBAN HEALTH CENTRE_MAKAWANPUR	23	Neighbour	28	6
3	MAKWANPUR	PIPLE URBAN HEALTH CENTRE_MAKAWANPUR	15	20514	28	6
3	CHITWAN	NATIONAL ANTI TUBERCLOSIS ASSOCIATION_CHITAWAN	65	21268	29	12
3	CHITWAN	KHAIRAHANI NAGAR HOSPITAL_CHITAWAN	65	22022	30	12
4	KASKI	DPHO DOTS CENTRE	131	22776	31	12
4	NAWALPARASI	GAIDAKOT HP_NAWALPARASI	65	23530	32	12
4	SYANGJA	GARHAUN GHYANGLING PHC_SYANGJA	27	Neighbour	33	6
4	SYANGJA	TULSI BHANJYANG HP_SYANGJA	15	24284	33	6
5	PYUTHAN	LIGHA HP_PYUTHAN	10	Neighbour	34	6
5	PYUTHAN	KWADI URBAN HEALTH CENTER_PYUTHAN	11	25038	34	6
5	ARGHAKHANCHI	ARGHAKHANCHI HOSPITAL SANDHIKHARKA	22	Neighbour	35	6
5	ARGHAKHANCHI	THADA PHC_ARGHAKHANCHI	13	25792	35	6
5	NAWALPARASI	PALHI PHC_NAWALPARASI	20	26546	36	12
5	RUPANDEHI	PARROHA HP_RUPANDEHI	63	27300	37	12
5	RUPANDEHI	BHIM HOSPITAL_ RUPANDEHI	133	28054	38	12
5	KAPILBASTU	GUGAULI HP_KAPILBASTU	14	Neighbour	39	6
5	KAPILBASTU	PATHARDEIYA HP_KAPILBASTU	12	28808	39	6
5	DANG	NARAYANPUR HP DANG	108	29562	40	12
5	DANG	MANPUR HP DANG	39	Neighbour	41	6
5	DANG	BIJAURI HP_DANG	13	30316	41	6
5	BANKE	SHAMSERGUNJ HP_BANKE	28	Neighbour	42	6
5	BANKE	CHISAPANI HP BANKE	18	31070	42	6
5	BANKE	HIRMINIYA HP_BANKE	16	Neighbour	43	6

Province	**District**	**Treatment Center/DOTS center/BMU**	**Total notified TB cases 2021/2022**	**Cluster 50 / 11 PPS number**	**Cluster Number**	**Target number of participants to recruit**
5	BANKE	KALAPHATA HP_BANKE	12	31824	43	6
5	BARDIYA	JAMUNI_HP	38	32578	44	12
6	RUKUM	DISTRICT HOSPITAL_ RUKUM	28	33332	45	12
6	SURKHET	MUNICIPALITY HOSPITAL_BIRENDRANAGAR_SURKHET	31	Neighbour	46	6
6	SURKHET	NAULAPUR BASIC HEALTH SERVIOCE CENTER	16	34086	46	6
7	DARCHULA	GOKULESHWOR HOSPITAL_DARCHAULA	12	Neighbour	47	6
7	DADELDHURA	SADANI HP_DADELDHURA	16	34840	47	6
7	KAILALI	MALAKHETI HOSPITAL_KAILALI	117	35594	48	12
7	KAILALI	TIKAPUR HOSPITAL_ KAILALI	123	36348	49	12
7	KANCHANPUR	SUDA HP_KANCHANPUR	32	Neighbour	50	6
7	KANCHANPUR	Haldukhal UHC_ Kanchanpur	16	37102	50	6
				Target recruitments		**600**

Appendix Bii: Clusters selection for the Nepal DR-TB patient cost survey

Province	Location	DR-TB Treatment Centers / BMUs	Total TB cases notified 2021/22	Cluster	Target number of participants to recruit
1	Morang	NEPAL ANTI TUBERCULOSIS ASSOCIATION (NATA)_MORANG	83	1,2,3	60
1	Dharan	BPKIHS_ DHARAN_SUNSARI	20		
1	Okhaldhunga	OKHALDHUNGA COMMUNITY HOSPITAL_OKHALDHUNGA	0	Excluded	0
1	Jhapa	HEALTH OFFICE BHADRAPUR_JHAPA	0	Excluded	0
2	Dhanusha	LALGADH HOSPITAL _DHANUSA	67	4,5	40
2	Parsa	NATIONAL MEDICAL HOSPITAL_PARSA	42	6	20
2	Rautahat	CHANDRANIGAHAPUR HOSPTIAL_ RAUTAHAT	31	7	20
3	Bhaktapur	NATIONAL TUBERCULOSIS CONTROL CENTRE_BHAKTAPUR	32	8	20
3	Kalimati	GENETUP _KATHMANDU	69	9,10	40
4	Pokhara	TUBERCULOSIS TREATMENT CENTER_POKHARA	16	11,12	40
4	Baglung	DHAULAGIRI HOSPITAL_BAGLUNG	7		
4	Nawalparasi	MIDPOINT DISTRICT HOSPITAL_NAWALPARASI EAST	32		
5	Butwal	LUMBINI PROVINCIAL HOSPITAL_ RUPANDEHI	102	13,14,15	60
5	Dang	RAPTI ACADEMY OF HEALTH SCIENCE_DANG	10	16,17	40
5	Banke	TB-NEPAL_ BANKE	52		
6	Surkhet	PROVINCIAL HOSPITAL_SURKHET	15	18	20
6	Zumla	KARNALI ACADEMY OF HEALTH SCIENCE_JUMLA	2		
7	Kanchanpur	MAHAKALI ZONAL HOSPITAL_KANCHANPUR	12		
7	Kailali	SETI ZONAL HOSPITAL_ KAILALI	5		
7	Dhadeldhura	DADELDHURA HOSPITAL_DADELDHURA	5		
7	Acham	BAYALPATA HOSPITAL (NYAYA HEALTH)_ACHHAM	7		
7	Kailali	LAXMINARAYAN REFERRAL HOSPITAL_ KAILALI	53	19,20	40
			Target recruitments		**400**

Appendix C: Information sheet for the Nepal DR- and DS-TB patient cost surveys

1. Researcher:

Hello, my name is [Insert name here]. I am currently working as an enumerator with [Insert name of outsourced agency] under the guidance of National Tuberculosis Control Center to conduct the survey to look at how much people pay for TB services.

2. Project Title: Economic evaluation of the patient costs and socioeconomic impact of tuberculosis illness, diagnosis and care in Nepal

3. General Outline of the Project:

- This study will look at the costs and socioeconomic impact associated with a TB illness, diagnosis and TB care in Nepal. We will interview TB patients to ask them questions about the costs of seeking a TB diagnosis and TB care and issues related to stigma, mental health, and quality of life associated with TB. We will then look at these costs to see what costs are associated with TB care. We will use this information to advocate for better social services for patients with TB.
- We will aim to enrol approximately 1000 patients from TB centres throughout Nepal, including adults with TB and parents of children with TB, some of whom have "drug-sensitive" TB and others of whom have "drug-resistant" TB
- We will use this information to produce an assessment of the costs and social impact for TB patients. We will then write a report for the Ministry of Health and Population and a paper for a scientific journal. We will share a summary of this work with the BMU managers and therefore you will be able to access this information in your next visit after the completion of this study in 2019. These reports will not include any names or confidential information.

4. Participant Involvement:

- Taking part in any research project is voluntary. If you do not wish for yourself/your child to take part, then he/she is not obliged to. If you decide that you/ your child will take part and later change your mind, you are free to withdraw you/ your child from the study until the study is published. If you do this, your information will not be used in the study and will be destroyed. Your decision regarding participation in this research will not affect your relationship with the providers of the national TB program, or your relationship with any doctors, nurses or other medical staff. You can decline to answer a question during the interview if you wish.
- If you wish to take part in this study, you will be asked to undertake an interview which will take about one hour. We will also collect some information about you from the TB Register or TB Treatment Card and will add it to the interview form. The information that we collect from the TB Register or TB Treatment Card will be information that you have provided us previously such as your age, sex, type of TB, where you were diagnosed with TB, etc. When we conduct the interview we will ask you a series of questions about your health, your experience with health care services and your income and expenses and during the period before you were diagnosed with TB and during TB treatment. For example we will ask questions about previous TB treatment, TB symptoms, which health care services you visited when you were sick with TB, how much money you spent on health care services when you were sick, whether you were hospitalized with TB, whether you have health insurance, what your occupation is and what kind of house you live in. We will also ask you about your perception of stigma and questions about your mental health and quality of life.
- The interview will take place at the health center and will take approximately one hour. You will be interviewed once. Therefore, the total time requested of you in this research is approximately 60 minutes.
- You will not be paid for the interview.
- There are very few risks to you if you choose to participate in this study as the research involves an interview only and the collection of some information from the TB Register. However, there is a very small risk that recalling some of the details about your TB diagnosis or the costs or stigma related to this might cause

some emotional distress. If this is the case, we request that you talk to your local doctor or nurse about this. There is also a very small risk that you could be identified by someone else, based on what you have told us. However, we will keep all of your information in a password protected online database which will only be accessed by the study team and when we publish this information, all data will be kept confidential so that individual people cannot be identified.

- It is unlikely that you will personally benefit from participating in this research but there will be broader benefits to the communities in which you live in years to come. The benefit of this research to communities is that we will have a good understanding of the costs involved in TB diagnosis and care in Nepal. This will provide important information for the Government of Nepal to help them develop better policies for people accessing health care so that costs are not a major barrier to health care access. Also, TB costs is an important indicator for the End TB Strategy that the World Health Organization have developed, and measurement of TB patient costs will help the World Health Organization to assess how costs of TB care can be further reduced.
- If you choose not to participate in this study, your TB care will not be affected. Your decision regarding participation in this research will not affect your relationship with the providers of the national TB program, or your relationship with any doctors, nurses, or other medical staff.

5. Inclusion criteria

- We are including all TB patients in this study if they have had at least two weeks of TB treatment.

6. Exclusion criteria

- We will exclude anyone who is not able to provide written informed consent, i.e., unconscious patients, or those with a severe mental illness.

7. Confidentiality:

- We will be asking you information about your health, the health care services you have accessed, your income and expenses and other information. The only people who will have access to the information that you provide is the research team. Your confidentiality will be protected as far as allowed by law. We will aim to keep all details that you provide confidential by limiting access to the data to the research team only and by not using names when we publish the results of our research in journals or reports.

8. Data Storage:

- The questionnaires we collect will be stored on in a password protected online database. No one other than the research team will have access to the information in the questionnaires. The data will be kept for a period of five years after publication. After this time, it will be archived. The data may be used for future research to compare patient costs across countries.

9. Queries and Concerns:

- If you need more information about this study or if you have any problems regarding this study, please speak to one of the research staff at the local health center. Any questions or problems can also be addressed by National Tuberculosis Control Center in Bhaktapur who is responsible for the overall survey. The contact details of the concerned investigators as below. If you are unable to contact these people directly you can ask the TB staff at the respective cluster sites to do this on your behalf.

Principal Investigator:
Dr. Rita Bhandari Joshi
Director, National Tuberculosis Control Center, MoHP.
Phone: 01-6630033, 01-6630073
Email: ntpdirector@nepalntp.gov.np

Survey Coordinator (Co-investigator):
Dr. Sharad Kumar Sharma
Chief of PMER section, National Tuberculosis Center, MoHP

Phone: 01-6630033, 01-6630073
Email: ghimires2002@gmail.com

If any of the questions that you are asked because you distress, you should discuss this with your doctor or nurse.

10. Ethics Committee Clearance:

- The ethical aspects of this research have been approved by the Nepal Health Research Council. If you have any concerns or complaints about how this research has been conducted, please contact:

Ethical Review Board
National Health Research Council
Ramshah Path, Kathmandu, Nepal
Contact no.: 977-1-4254220 / 977-1-4254220,
Fax : 977-1-4262469 / 977-1-4268284
Email: nhrc@nhrc.gov.np

Appendix D: Consent and assent forms

WRITTEN CONSENT for participants aged 18 years and above

National Tuberculosis Patient Cost Survey in Nepal, 2023

I have read and understood the Information Sheet, you have given me about the survey and I have had any questions and concerns about the project (listed here)

_____

_____)

addressed to my satisfaction.

I agree to participate in an interview: YES ☐ NO ☐

I agree that the interviewer can record some information from my TB Treatment Card onto the questionnaire:

YES ☐ NO ☐

Signature of participant:…… Date:…….

Signature of witness:…… Date:…….

WRITTEN ASSENT for participants for participants aged 15 to 17 years

National Tuberculosis Patient Cost Survey in Nepal, 2023

We are inviting you to be in a study. This form will give you the information you need to know to help you to decide if you want to take part in this study. The purpose of the study is to determine how much patients and their families spend on getting a diagnosis and care for TB. By doing this study, we hope to understand the costs of TB care to find out if the costs are too much for families.

You can participate in the study because you have been diagnosed with TB. In order for you to participate in the study, your parent or guardian has to provide permission. You are free to decide if you want to be a part of this study or not to be a part of this study. Even if your parents give you permission, you are free to decide not to participate. Or if you decide to participate now and you want to pull out later, that is fine too. It is your decision. We will keep your information confidential. This means that we will not share your information with anyone, and we won't use your name either; a research number will be used instead of your name.

At any time if you have any questions about this study, you can ask the person who is reading this form to you or you can contact the people in charge of this study.

This study has been explained to me. I am checking the boxes below to show that I agree to take part in this study. I have had a chance to ask questions. I know that I can stop participating at any time. I also understand that if I have questions about the project. I can call the researchers. I understand that my parent or guardian has a copy of the same information. ***Please check the boxes below to indicate your decision about participating in this study <u>and</u> parents or guardians must also sign the written parental or guardian consent below.***

I agree to participate in an interview: YES ☐ NO ☐

I agree that the interviewer can record some information from my TB Treatment Card onto the questionnaire: YES ☐ NO ☐

Date:……
Witness (name and signature):……

WRITTEN PARENTAL or GUARDIAN CONSENT for participants aged 0 to 18 years

National Tuberculosis Patient Cost Survey in Nepal, 2023

I have read and understood the Information Sheet you have given me about the survey and I have had any questions and concerns about the project (listed here

_____

_____)

addressed to my satisfaction.

I agree to allow my child to participate in an interview: YES ☐ NO ☐

I agree that the interviewer can record some information from my child's TB Treatment Card onto the questionnaire: YES ☐ NO ☐

Child's name:……..

Parent's or guardian's name:……

Parent's or guardian's signature:…… Date:……..

Witness (name and signature):…… Date:……..

Appendix E: Responsibilities of the Principal Investigator

The Principal Investigator for this study is Dr Rita Bhandari Joshi, Director, NTCC. The Principal Investigator has the following responsibilities:

- To co-ordinate the management and implementation of the study in collaboration;
- To oversee the submission of materials to the relevant human research ethics committees;
- To keep the associate investigators informed of the progress of the study;
- To oversee the implementation of the study on the ground, including routine monitoring of data collection procedures;
- To ensure that privacy of the participants is protected and that confidentiality of data is maintained;
- To ensure that participants are adequately informed of the benefits and risks of the study and that written informed consent is being sought from participants as per the study protocol, and that the consent documents are being stored in a safe place;
- To ensure that participants are being recruited as per the agreed method and to monitor the progress of patient recruitment particularly at the start of the study where many existing TB patients will be recruited;
- To respond to any adverse events reported by participants or enumerators;
- To ensure that data collectors are well trained and that they are supervised in the field;
- To ensure that the results of the study are written up in formats that are accessible to policy makers and other major stakeholders;
- To ensure that the results of the study are provided to the Basic Management Units so that TB patients (past, future and the TB patients who participated in the study) can access the results if they wish to do so; and
- To oversee the management of the study budget and comply with all national requirements for the management of research funds.

Save the Children

Date: 20th June 2023

Request for Proposal (RFP) Reference No: PR298456

Dear Sir/Madam,

Save the Children requests submission of proposal to provide goods/services in accordance with the conditions detailed in the attached documents. Save the Children intends to enter into a contract for the following services: consultancy assignment entitled "National Tuberculosis Patient Cost Survey in Nepal".

We include the following information for your review:

Policy	Policy / Document
Terms & Conditions of Bidding	1. Terms & Conditions of Biddi
Terms & Conditions of Purchase	SC-C-01 Short Form Goods and Services A
Supplier Sustainability Policy and the included mandatory policies	Click Here to Access

Your proposal must be received in the following format:

- Full completion of the "Consultancy Proposal Form" document in order that your proposal may be regarded as compliant. Those proposals not completed may be treated as void.
- Proposal to be submitted via email to **nepal.proposals@savethechildren.org**

The email subject should indicate "Proposal for PR298456 "National Tuberculosis Patient Cost Survey in Nepal".

Your proposal must be received at **nepal.proposals@savethechildren.org** not later than **9th July 2023** ("the Closing Date"). Failure to meet the Closing Date may result in the proposal / proposal being void. Returned proposals must remain open for consideration for a period of not less than 60 days from the Closing Date. Save the Children is under no obligation to award the contract or to award it to the lowest bidder.

Should you require further information or clarification on the proposal requirements, please contact Mr. Asesh Baidya (Contact Person) in writing at the following address: eoiconsultant.nepal@savethechildren.org

We look forward to receiving a proposal from you and thank you for your interest in our account.

Yours faithfully,

Asesh Baidya

Procurement Coordinator - Consultancy

PART 1: PROPOSAL INFORMATION

Introduction

Save the Children is the world's leading independent organisation for children. We work in 120 countries. We save children's lives; we fight for their rights; we help them fulfil their potential. We work together, with our partners, to inspire breakthroughs in the way the world treats children and to achieve immediate and lasting change in their lives.

Provisional timetable

Activity	Date
Publication / Circulation of Request for proposal	20th June 2023
Last day for bidders to send clarification questions to Save the Children	5th July 2023
Last day for SCI to answer clarification questions to bidders	7th July 2023
Return of Proposals (Closing Date)	**9th July 2023**
Award Contract and "Go-Live" with Supplier	20th July 2023

Indicative information

Background

Tuberculosis (TB) kills 1.6 million people each year worldwide, more than any other single infectious disease apart from Covid-19. In 2021, approximately 10.6 million became ill with TB, of whom 3 million were unable to access health care services and so were diagnosed and treated through unregistered or private systems or went undiagnosed and untreated. More than 90% of people with TB are from low- and middle-income countries (LMICs) with high prevalence of poverty and malnutrition, both of which are social determinants of TB. These social determinants are further compounded by limited social protection coverage and high costs of accessing TB diagnosis and care, which can delay diagnosis and treatment, and push TB-affected households into further impoverishment. Indeed, research has shown that many TB-affected households, especially in LMICs, incur high TB-related costs.

The World Health Organization's (WHO) End TB Strategy outlines the ambitious goal of TB elimination by 2035. Progress towards this target will be measured using three main indicators:

1) TB incidence, 2) TB mortality, and 3) catastrophic costs related to TB diagnosis and care. WHO have reported estimated TB incidence and mortality since 1997, however the indicator on catastrophic costs is new since 2015. The operational definition of "catastrophic costs as a result of TB" refers to medical and non-medical out-of-pocket payments and indirect costs exceeding a given threshold (e.g., 20%) of the household's annual income. Estimation of TB patient costs is carried out via health facility surveys and WHO recommends that they be carried out in the next few years to establish baseline information on the economic burden of TB and inform the development of effective strategies to defray economic hardship, including improved coverage of social protection that reaches high-risk underserved groups, and mitigation of sociocultural barriers through patient-centred care.

Nepal is a low-income country with significant TB incidence (case notification rate 229 per 100,000 population in 2021) and mortality, with TB being the seventh leading cause of death from any cause. The Government of Nepal has adopted the End TB Strategy, including the target of zero catastrophic costs for TB-affected families, and aims for a "TB Free Nepal" by 2050. Despite free basic TB diagnostic tests and medicines, subnational studies have suggested that approximately one in two people with TB will face catastrophic costs while accessing TB care in Nepal. Barriers to accessing care are more pronounced for people of rural communities and/or poorer socioeconomic status, who often face disproportionately high costs of transportation related to direct observation of therapy (DOT) in health facilities that are distant from their homes. This could contribute to non-adherence to TB treatment and adverse outcomes.

Despite multiple subnational TB patient costs surveys having been carried out in Nepal, there have been no nationally representative TB Patient Cost surveys (PCS). This study will assess the social and economic costs associated with TB diagnosis and care in Nepal, including an estimate of the national prevalence of catastrophic costs, and will be used to design and advocate for policies and interventions to: 1) minimize barriers in accessing and adhering to TB treatment and care, and 2) mitigate the social and economic impact of TB for patients and their families in the country.

Award criteria

Award of the contract will be based on the following criteria:

ESSENTIAL CRITERIA (Exclusion if not met)

Bidders must meet the following criteria:

- That the bidder has legitimate business /official premises, or that they are registered for trading and tax as appropriate.
- That they are not any prohibited parties or on government blacklisting
- Bidder's confirmation of compliance with the attached Conditions of proposal, Terms and Conditions of Purchase, Supplier Sustainability Policy and the included mandatory policies.
- Organization is registered with relevant Government Authority.
- VAT Registration and Tax Clearance of FY2078/079.

- Experience and Qualification as mentioned in ToR.

Evaluation Criteria

The following criteria are considered very important in the evaluation of this proposal.

Capability Criteria (Technical Proposal): 50

Criteria	Weight	Sub-Criteria	% Weight
Capability	50	**Understanding of the TOR (2)** **Proposed Methodology (15)** **Workplan (3)**	20
		Qualification and Experience of team leader: (5) Academic Qualification (3) PhD :3, Master's: 2, Below Master's: 1 Work Experience in health-related research/ survey / evaluation (2) – 2 or more evaluation / research / survey= 2 1 evaluation / research / survey= 1 None= 0 **Qualification and Experience of Survey Coordinator: (3)** Master's or above in health-related field: 2 Below Master's in health-related field: 1 At least 1 year of work experience in health-related survey / research / evaluation: 1 **Qualification and Experience of Survey Supervisor: (2)** Bachelor's or above in health-related field: 1	20

Criteria	Weight	Sub-Criteria	% Weight
		At least 1 year of work experience in health-related survey / research / evaluation: 1 **Organizational Experience: (5)** Experience in conducting health related surveys/research/evaluations by covering multiple provinces of Nepal by the organization. Yes = 2.5, No = 0 Experience in conducting health related economic studies/surveys. Yes = 2.5, No = 0 (Bidder(s) shall submit a copy / link of published research / survey / evaluation report(s) as evidence to qualify above criteria) Consulting firm consists of full-time dedicated staff with at least 2 different expertise (public health or equivalent, epidemiology, statistician, economist) in conducting research/surveys/evaluations of the health program (**5**) However, the organization can propose additional team members to accomplish objective of survey. Yes = 5, No=0 Evidence: A list of full-time staff should be provided in a table and separately provide their appointment letters.	
		Interview (for shortlisted bidder/s only)	**10**

Sustainability Criteria: 10%

Criteria	Sub-Criteria	% Weight
Sustainability	Team composition is inclusive of provincial and gender (at least 33% of proposed team)	**10**

Remark	Bidders shall secure minimum of 28 marks out of 40 in capability criteria to be eligible for financial evaluation / review & Interview.

Commercial Criteria (Financial Proposal): 40%

Financial proposal will be scored in inverse proportionate basis.

How to apply for the services

Proposal Submission Guideline/Required Documents

Proposal Submission Deadline- **9th July 2023**

- Required Documents-
  - Filled out Consultancy Proposal Form (enclosed with this ToR)
  - CV of the proposed consultant with full date of birth in dd/mm/yyyy format.
  - Copies of- Firm registration certificate, VAT registration certificate, tax clearance certificate of FY 2078/079.

- A proposal should have four (4) separate files:
  1st for essential documents
  2nd for technical proposal
  3rd for financial proposal
  4th for other supporting documents as per ToR
  Each of the above should be properly labelled respectively as "essential documents", "technical proposal", "financial proposal" and "other supporting documents as per ToR"

Proposals should be submitted via email to nepal.proposals@savethechildren.org

Proposals submitted in another email addresses will not be considered in the process. (Please note that, consultant **must not** cc / bcc / forward proposals to any other email addresses).

National Tuberculosis Patient Cost Survey in Nepal

PR298456

Terms of Reference (ToR)

Background on Save the Children

Save the Children is the leading global independent organisation for children. Save the Children believes every child deserves a future. Around the world, we work every day to give children a healthy start in life, the opportunity to learn and protection from harm. When crisis strikes, and children are most vulnerable, we are always among the first to respond and the last to leave. We ensure children's unique needs are met and their voices are heard. We deliver lasting results for millions of children, including those hardest to reach.

We do whatever it takes for children – every day and in times of crisis – transforming their lives and the future we share.

Our vision: A world in which every child attains the right to survival, protection, development and participation.

Our mission: To inspire breakthroughs in the way the world treats children, and to achieve immediate and lasting change in their lives.

Our values: Accountability, ambition, collaboration, creativity and integrity.

We are committed to ensuring our resources are used as efficiently as possible, in order to focus them on achieving maximum impact for children.

Background information/context

Tuberculosis (TB) kills 1.6 million people each year worldwide, more than any other single infectious disease apart from Covid-19. In 2021, approximately 10.6 million became ill with TB, of whom 3 million were unable to access health care services and so were diagnosed and treated through unregistered or private systems or went undiagnosed and untreated. More than 90% of people with TB are from low- and middle-income countries (LMICs) with high prevalence of poverty and malnutrition, both of which are social determinants of TB. These social determinants are further compounded by limited social protection coverage and high costs of accessing TB diagnosis and care, which can delay diagnosis and treatment, and push TB-affected households into further impoverishment. Indeed, research has shown that many TB-affected households, especially in LMICs, incur high TB-related costs.

The World Health Organization's (WHO) End TB Strategy outlines the ambitious goal of TB elimination by 2035. Progress towards this target will be measured using three main indicators: 1) TB incidence, 2) TB mortality, and 3) catastrophic costs related to TB diagnosis and care. WHO have reported estimated TB incidence and mortality since 1997, however the indicator

on catastrophic costs is new since 2015. The operational definition of "catastrophic costs as a result of TB" refers to medical and non-medical out-of-pocket payments and indirect costs exceeding a given threshold (e.g., 20%) of the household's annual income. Estimation of TB patient costs is carried out via health facility surveys and WHO recommends that they be carried out in the next few years to establish baseline information on the economic burden of TB and inform the development of effective strategies to defray economic hardship, including improved coverage of social protection that reaches high-risk underserved groups, and mitigation of sociocultural barriers through patient-centred care.

Nepal is a low-income country with significant TB incidence (case notification rate 229 per 100,000 population in 2021) and mortality, with TB being the seventh leading cause of death from any cause. The Government of Nepal has adopted the End TB Strategy, including the target of zero catastrophic costs for TB-affected families, and aims for a "TB Free Nepal" by 2050. Despite free basic TB diagnostic tests and medicines, subnational studies have suggested that approximately one in two people with TB will face catastrophic costs while accessing TB care in Nepal. Barriers to accessing care are more pronounced for people of rural communities and/or poorer socioeconomic status, who often face disproportionately high costs of transportation related to direct observation of therapy (DOT) in health facilities that are distant from their homes. This could contribute to non-adherence to TB treatment and adverse outcomes.

Despite multiple subnational TB patient costs surveys having been carried out in Nepal, there have been no nationally representative TB Patient Cost surveys (PCS). This study will assess the social and economic costs associated with TB diagnosis and care in Nepal, including an estimate of the national prevalence of catastrophic costs, and will be used to design and advocate for policies and interventions to: 1) minimize barriers in accessing and adhering to TB treatment and care, and 2) mitigate the social and economic impact of TB for patients and their families in the country.

Objectives

1. Determine the direct and indirect costs due to TB illness, diagnosis, and care;
2. Estimate the proportion of households experiencing catastrophic costs due to TB including those affected by drug-sensitive (DS) and drug-resistant (DR) TB;
3. Assess the association between catastrophic costs and adverse TB treatment outcomes;
4. Provide recommendations on policies and interventions to minimise barriers for accessing and adhering to TB treatment and care, and mitigate the economic impact of TB for patients and their families;
5. Plan future research to further examine the determinants of cost barriers among TB patients and/ or to assess the effectiveness of policies and interventions to mitigate these costs;
6. An equity analysis to determine the association of poverty level, rural vs urban living, HIV status, access to social protection, and drug-resistance with catastrophic costs; and
7. An exploratory analysis of the social impact of TB including stigma and mental illness.

Scope of Work

The Agency will work closely with NTCC.

i- Consultation meetings with NTCC and other relevant stakeholders for uniform understanding of the scope of the work and planning the activities. Develop cluster specific workplan as per the protocol.
ii- Review of existing database and protocols, Standard Operating Procedures (SOPs), Quality Assurance (QA) checklists and other relevant documents. to have full understanding and necessary preparation for PCS.
iii- Recruitment of Human Resource for the survey as per the protocol.
iv- Establish good coordination and supportive environment at cluster sites and respective provincial and local governments.
v- Training to Field level staff- Enumerators/Field supervisors for survey.
vi- Logistic supply and management in all the selected cluster sites.
vii- Monitoring/supervision and internal quality assurance in process and procedures of field implementation and data collection.
viii- Collection, Review, and quality assurance of survey data in collaboration with NTCC/ Save the Children International (SCI).
ix- Support to develop final survey reports in collaboration with NTCC/SCI and WHO.

Location and official travel involved

The logistic arrangements, including transportation cost will be managed by the consulting firm as per own HR or Financial policy.

Services the Supplier will provide
Services the agency will provide as just as "Scope of work and deliverables" mentioned in the ToR.

The following attributes are required for the selection of the consultancy firm and its team:

This agency will be carried-out by an experienced and qualified team members. The consulting firm will be selected through a competitive and transparent process.

Relevant experience criteria will include:

Experience and skill set required.

Essential:

- The consulting firm has experience in conducting at least one surveys/research/evaluation of health-related programs/interventions in Nepal within last five years period.

Preferred:

- The consulting firm has experience in conducting at least one health related surveys/research/evaluations by covering multiple provinces of Nepal.
- The consulting firm has experience in conducting health related economic studies/surveys.
- Consulting firm consists of full-time dedicated staff with different expertise (public health or equivalent, epidemiology, statistician, economist) in conducting quality and quantity-based research/surveys/evaluations of the health program.

Deliverables of the Project

SCI expects the following deliverables to be provided:

Deliverable number	Deliverable title	Description	Format and style
1	Recruitment of HR from Consulting firm for the survey.	1. Survey Coordinator- one position 2. Survey Supervisors- two positions. 3. Enumerators (at least bachelor's in public health or equivalent) - 20 positions - Resume, Contact details and Job description of recruited staffs along with their duty station, names of supervisors/ subordinates must be submitted.	Word file
2	Field implementation plan development	Submission of detailed field implementation plan incorporating risk mitigation plan	Word file
3	Training to Field Staffs	Submission of report on Training to data enumerators and field supervisors	Word file
4	Pre-testing and Piloting	Submission of pre-testing and piloting reports with completed questionnaires in electronic form	Word file
5	Logistic Supply Management to all cluster sites of the survey	Submission of Tablet distribution list and conditions of the tablets at monthly basis.	Word file
6	Coordination meeting at provincial, local and health facility levels	Submission of report on Conduction of coordination or induction meetings to all relevant stakeholders from provincial health	Word file

Deliverable number	Deliverable title	Description	Format and style
		directorates, and health section of respective Palikas of cluster sites	
7	Data collection	1. Progress reports on Data collection from all the cluster sites based on allocated sample sizes. 2. Progress reports on Verification and quality assurance of collected data online before forwarding to database team at NTCC. 3. Submission of completed and quality record of questionnaire in electronic form after one-step verification from RO's central team	Word file, Excel, .csv
8	Monitoring/supervision	1. Monthly report on monitoring of the quality of data collected from the enumerators along with monthly detailed monitoring plan. 2. Filled supervision checklist	Word file
9	Review, and Quality assurance of survey data	1. Report of regular feedback of quality information in questionnaire and ensure any issues identified are addressed and resent by the sites. 2. Data validation and amendments report by visiting the cluster sites using given data validation checklist.	Word file
10	Final Data Validation and Sharing on Field operation completion	1. Final data validation visits for observed data discrepancies in related cluster sites and submission of its report with checklist 2. Submission of final report on field operation 3. Submission of report on conduction of final sharing meeting with Technical Advisory and Working Committees	Word file

Timeline

Estimated Commencement Date: July 20, 2023

Estimated End Date: November 20, 2023

Deliverable number	Deliverable title	Submit to	Completion date
1	Field implementation plan development	Survey Focal Person (NTCC/SCI)	July 25, 2023
2	Recruitment of HR from Consulting firm for the survey	Survey Focal Person (NTCC/SCI)	August 5, 2023
3	Logistic Supply Management to all cluster sites of the survey	Survey Focal Person (NTCC/SCI)	August 7, 2023
4	Training to Field Staffs	Survey Focal Person (NTCC/SCI)	August 10, 2023
5	Pre-testing and Piloting	Survey Focal Person (NTCC/SCI)	August 15, 2023
6	Coordination meeting at provincial, local and health facility levels	Survey Focal Person (NTCC/SCI)	August 17, 2023
7	Data collection (3 months period)	Survey Focal Person (NTCC/SCI)	August 20, 2023-November 20, 2023 Milestone completion reports at: September 15 2023, October 15 2023 and November 20 2023
8	Monitoring/Supervision	Survey Focal Person (NTCC/SCI)	Monthly with Milestone completion

Deliverable number	Deliverable title	Submit to	Completion date
			reports at: September 15 2023, October 15 2023 and November 20 2023
9	Review, and Quality assurance of survey data	Survey Focal Person (NTCC/SCI)	Monthly with Milestone completion reports at: September 15 2023, October 15 2023 and November 20 2023
10	Final Data Validation and Sharing on Field operation completion	Survey Focal Person (NTCC/SCI)	October 31, 2023 November 30, 2023

Status updates/reporting

The agency shall provide the below status updates for the duration of the services to NTCC and SCI:

- Monthly progress update
- Final report and sharing meeting on completion.

Acceptance

All Deliverables are to be reviewed and accepted by SCI and Patient Cost Survey's Working Committee at NTCC.

General assumptions and dependencies

Working Committee of PCS will support in coordination and in other technical aspects of the survey as per need of Consulting firm.

Intellectual Property Rights

The Consulting firm acknowledges and agree that the SCI and NTCC will hold all intellectual property rights but not limited to copyright and trademark rights. The Consulting firm agrees not to claim any such ownership in intellectual property at any time prior to or after the completion and delivery.

Confidentiality

The consulting firm discloses to any third party the business of NTCC and SCI, details regarding the survey (the "Confidential Information"), (i) make copies of any Confidential Information or any content based on the concepts contained within the Confidential Information for personal use or for distribution unless requested to do so by SCI and NTCC, or (ii) use Confidential Information other than solely for the benefit of the SCI and NTCC.

Payment information

I. Payment will be made on a milestone basis (in installment basis), upon satisfactory completion of the milestone.
II. Upon the recommendation of hiring manager after successful completion of set milestones, SCI will release the payment as fixed in milestones set for the survey completion.

The Fees are inclusive of all costs, overheads, and expenses, including travel, subsistence, and accommodation.

Following are the minimum budget activities that consulting firm need to include in their financial proposal, however consulting firms can also propose other activities costs that are required for the completion of survey.

S.N.	Budget Activities
1	Human resources
2	Training to Data Enumerators
3	Pretesting
4	Survey Piloting
5	Survey implementation
5.1	Health Facility/Palika/Province coordination meeting
5.2	Patients' Incentives (travel cost)
5.3	On-site monitoring and data validation visits

How to apply for the services

Proposal Submission Guideline/Required Documents

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