Measuring patient costs to monitor progress towards the target to eliminate catastrophic costs and help design social protection and UHC

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Objectives of the session

1. To provide a brief overview of the rational and basic concept for the End TB indicator and target on catastrophic costs.

2. To present an outline of the generic protocol and instrument for measuring patient costs and the proportion experiencing catastrophic costs.

3. To share early experiences on survey implementation.

4. To outline a plan for "Tuberculosis patient cost surveys: a handbook".

5. To discuss the possibility to create a technical review/advisory group/roster to support survey planning and implementation.
1. Overview and rationale
Milestones in WHO's End TB strategy

**2020**
- 35% reduction in TB deaths
- 20% reduction TB incidence rate (<85/100,000)
- No affected families with catastrophic costs due to TB

**2025**
- 75% reduction in TB deaths
- 50% reduction TB incidence rate (<55/100,000)
- No affected families with catastrophic costs due to TB

**2030**
- 90% reduction in TB deaths
- 80% reduction TB incidence rate (<20/100,000)
- No affected families with catastrophic costs due to TB

**2035**
- 95% reduction in TB deaths
- 90% reduction TB incidence rate (<10/100,000)
- No affected families with catastrophic costs due to TB

**GOAL**
- 95% reduction in TB deaths
- 90% reduction TB incidence rate (<10/100,000)
- No affected families with catastrophic costs due to TB
% with catastrophic cost – an indicator of what?

**UHC / Health care delivery**
- Effective interventions
- Free-of-charge care
- Appropriate technology
- Patient-friendly delivery

**Social protection**
- Sickness insurance
- Disability grants
- Travel vouchers
- Food package
- Other cash transfer
- Job security
- Housing support
- Other welfare grants

**Reduce or compensate direct and indirect costs**
- Protect against economic burden of TB

**% with catastrophic total cost of TB**
- Other outcomes
  - Reduced TB risk - prevention
  - Improved access & case detection
  - Improved TB treatment outcomes

**Epidemiological impact**
- Reduced TB prevalence, incidence and death rate
Mean cost as percentage of annual individual income


Higher cost among:
• People with MDR-TB
• People from low socioeconomic groups
Composition of TB related costs, on average

- Medical expenditure: 17%
- Other expenditure: 8%
- Lost income: 33%

During treatment:
- 50% of total costs

Before treatment:
- 50% of total costs

"Out-of-pocket health expenditure"
Sampling frame: TB patients in the "NTP network"

Need to interpret data in light of:
- Detection gap
- Notification gap
Indicator: % households with catastrophic costs

• **Operational definition of % with catastrophic costs:** Proportion of TB patients (and their households) treated within the NTP network who incur total costs equivalent to >20% of annual household income

  ➢ **Numerator:** Number with catastrophic costs.
  ➢ **Denominator:** All patient

• **Definition of catastrophic costs:** Total costs (indirect and direct combined) incurred during illness and treatment exceeding a given threshold (e.g. 20%) of the household’s annual income.

  ➢ **Numerator:** Total direct and indirect cost incurred form onset of symptoms to end of TB treatment
  ➢ **Denominator:** Annual household income
"Catastrophic health expenditure" vs. "Catastrophic total costs due to TB"

"Catastrophic health expenditure"
• Measure of financial protection to monitor progress towards UHC.
• Out-of-pocket payments for health care (for all conditions) exceeding a given fraction of a household’s total consumption (or non-food)
• Financial burden from health care payments for all household members.
• General household surveys are used to generate the data

"Catastrophic total costs due to TB"
• Helps understand cost barriers for access and adherence to TB services
• Measure impact of UHC and social protection specifically on TB
• The total of direct medical, direct nonmedical and indirect costs of TB exceeding a fraction of annual household income
• Only one disease
• Facility-based surveys
Building on "The patient cost tool"

- Generic survey instrument with tools for country adaptation (KNCV, WHO and JATA, 2010)
- Built on rich previous research
- Adapted to people with MDR-TB (KNCV 2014)
- Task force (met in 2014 and 2015) to adapt generic survey protocol and instrument to the new End TB indicator, and standardize approaches further
2. Outline of generic protocol and instrument for measuring patient costs and the proportion experiencing catastrophic costs
Study objectives

**Primary**
1. Document costs and identify main cost drivers to inform policy

2. Monitor progress towards zero percent households with catastrophic costs

**Secondary**
3. Determine the correlation between facing costs above different thresholds of annual household income and dissaving, in order to assess if the measure of dissaving is a sufficient metric of catastrophic costs
4. Determine the association between cost and treatment outcome (using routine cohort data)
Basic design

• Facility-based patient survey: national sample of patients on treatment - all consecutive patients on TB treatment in sampled facilities
• National sample: 500-1000 patients (min. 20 clusters)
• Costs typically: $25,000 - $80,000
• Survey frequency: once every 5 years
• Cross sectional study with retrospective data collection and projections
• Estimated survey implementation time:
  – data collection: 2-3 months
  – all survey: 5-6 months
• Questionnaire (130 questions - 40-60 mins long): 28 questions directly from treatment card, rest to complete depending on treatment type or phase
• Projections based on data collected from other patients
• Field testing version requests adaptation but does not delete any questions
Indicators: % households with catastrophic total costs

Catastrophic cost incidence - indicator 1
% households who incur in costs equivalent to 20% or more of household’s annual income relative to those on treatment

\[
\frac{\text{Direct Cost} + (\text{HH Income}_{\text{PRE}} - \text{HH Income}_{\text{POST}})}{\text{HH Income}_{\text{PRE}}} > 20\%
\]

\[
\frac{\text{Direct Costs} + (\text{Hours} \times \text{Hourly wage})}{\text{HH Income}_{\text{PRE}}} > 20\%
\]

Catastrophic cost incidence - indicator 2
% Households experiencing dissaving relative to those on treatment
Collecting costs and time loss

- Direct medical costs
  - X-rays, medicine, doctor’s fees, etc.
- Direct non-medical costs incurred by patients and caregivers
  - Travel, accommodation, food expenses
- Time/Lost income by patient and caregiver net of welfare payment
- Household assets

**Data collection**
Cost/time and income loss during current treatment episode (2 weeks min)
Time horizon: 2 years*

**Analysis**
Scales up cost and time
- within phase: based on their reported usage
- in other phases: based on utilisation of other patients, i.e. median* “direct cost” and time

Estimates income if not reported
Estimating indirect costs

Output-based approach (option 1 - preferred) – valuation based on income change

\[ IN_{i}^{TB,h} = HH\ Income_{PRE} - HH\ Income_{POST} \]

Human capital approach (option 2) – valuation of time loss

\[ IN_{i}^{TB,h} = (t_{visit} \times w) + (t_{hospitalisation} \times w) + (t_{travel} \times w) + (t_{pick\ up\ drugs} \times w) \]

Where

- \( t_{visit} \): Time spent per visit including waiting time
- \( t_{hospitalisation} \): Hospitalisation
- \( t_{travel} \): Travel time
- \( t_{pick\ up\ drugs} \): Time employed to pick up drugs

**hourly wage** (\( w \)) may be either

a) Zero

b) Wage of the lowest paid unskilled government worker

c) Patient’s reported pre-illness wage (or labour income) in survey

d) Average wage rate for all working individuals in survey

e) Individual income estimated from household income itself determined through asset scoring.
In addition, estimate

- Risk factors for catastrophic cost
  - MDR
  - Urban/rural
  - Income (absolute or groups)
  - Long delay to diagnosis

- Link to treatment outcomes
  - Relatively minimal additional effort
In addition: research on methodology

• Dissaving a convenient proxy for catastrophic costs? What patterns and types of dissaving have the strongest relationship with financial hardship and clinical outcomes?

• Consider total dissaving amount compared to income

• Extrapolation approaches

• Indirect cost measure – output-based approach best?
New cases (first line or MDR-TB treatment) interviewed in intensive phase

Onset of TB Symptoms
Diagnostic test
TB/MDR Treatment start
TB/MDR Continuation phase start
TB/MDR Treatment completed

Previous episodes
Pre-treatment phase
Intensive phase
Continuation phase

Outpatient and inpatient care Prior to Diagnosis
OOP: Direct Medical and non-Medical

Inpatient and Outpatient Care During Treatment
OOP: Direct Medical and non-Medical

Relocation costs
Food costs

Income loss / Time cost
Dissaving / Coping Costs

Estimated / Not collected
New cases (first line or MDR-TB treatment) interviewed in continuation phase

- Onset of TB Symptoms
- Diagnostic test
- TB/MDR Treatment start
- TB/MDR Continuation phase start

Estimated / Not collected

- Inpatient and Outpatient Care During Treatment
  - OOP: Direct Medical and non-Medical
- Relocation costs
- Food costs
- Time cost

Dissaving / Coping Costs
Patients will answer different parts of the questionnaire (130 questions)

I. Patient info (treatment card) 28

II. Informed consent 4

Retreatment cases

New cases in intensive treatment phase

New cases in continuation treatment phase

III. Overview of TB treatments before current treatment 16

IV. Costs before the current TB treatment 3

V. Costs during current TB/MDR-TB treatment 79
Sampling methodology and sample size calculation

Health facilities belonging to the NTP network: all patients (all ages) who are on TB or MDR treatment, in continuation or intensive phase

Nationally representative survey involves random cluster sampling of health facilities

Alternatives:
• Simple random sample of TB patients (if electronic registers)
• Lot Quality Assurance Sampling
## Survey Size Estimation

**How to Estimate the Sample Size for Surveys**

**Welcome!**

This web application is a visualization and quantification tool for determining the required sample size in clustered surveys.

### Required cluster size & sample size

<table>
<thead>
<tr>
<th>Anticipated guess</th>
<th>Absolute precision d=2.0%</th>
<th></th>
<th>Absolute precision d=4.0%</th>
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<tbody>
<tr>
<td></td>
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<td>Cluster size</td>
<td>Cluster size</td>
<td>Sample size</td>
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<td>40 clusters</td>
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</table>

- **Modify parameters...**

[http://samplesize.herokuapp.com](http://samplesize.herokuapp.com)
Select parameters for visualization

TB population size

What is the total number of TB notifications (all types) registered during one year in the country or region under study? \( n = 20000 \)

Anticipated guess

Which is a plausible range for the expected percentage of TB-affected households experiencing catastrophic costs (an informed guess)?

\( \min \pi_g = 30 \% \)
\( \max \pi_g = 50 \% \)

Number of clusters

Please give a range for the number of clusters you are going to use in your survey.

\( \min m = 25 \)
\( \max m = 40 \)

Absolute precision

The absolute precision is the desired precision of the estimate.

Example: if the proportion of TB-affected households experiencing catastrophic costs is expected to be 30\%, an absolute precision of 4\% means that the estimate may err within 4\% of the true proportion, corresponding to a 95\% confidence interval from 26\% to 34\%.

\( d = 4 \% \)

Design effect

The design effect encodes the effect of the correlation between individuals within a cluster. In general, the design effect due to clustering in patient cost surveys ranges from 1.5 to 3. Unless the design effect can be estimated from previous surveys, a design effect of 2 should be assumed.

\( \text{DEFF} = 2 \)
Cluster Selection

• For statistical power, we advise to have (at least) 20 clusters in the survey.

• A cluster can be a health facility or a geographical area containing all facilities in that area.
  – All facilities from the NTP network should be included in the sampling frame

• Eg. Myanmar sample: 1000 patients assuming 25 clusters then 40 patients per cluster

• Using the list of and the number of notified cases in each, we select “clusters” proportional to the number of notifications from previous year although ideally we should have list of the number of TB-affected households per facility.
• 25 clusters with 40 patients per cluster (N=1000)
• Nationally representative
• PPS sampling for cluster selection
• Budget: ~US$ 30,000
  – NTP staff at no additional cost
  – Excluding TA
• 10-11 interviewers (provided by NTP) each responsible for two to three townships.

• Two to three weeks per township to survey 40 TB patients in each.

• Data Collection: December 2015 – February 2016
Nationwide TB-related catastrophic costs survey in Myanmar

Coping Costs

<table>
<thead>
<tr>
<th>COPING</th>
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<tbody>
<tr>
<td>DID YOU OR YOUR HOUSEHOLD USE ANY SAVINGS (CASH OR BANK DEPOSITS) TO COVER COSTS DUE TO THE TB ILLNESS?</td>
</tr>
<tr>
<td>○ Yes</td>
</tr>
<tr>
<td>○ No</td>
</tr>
</tbody>
</table>

| DID YOU BORROW ANY MONEY TO COVER COSTS DUE TO THE TB ILLNESS? (INCLUDING MORTGAGING ANY ASSETS) |
| ○ Yes |
| ○ No |

| HAVE YOU SOLD ANY OF YOUR PROPERTY TO FINANCE THE COST OF THE TB ILLNESS (INCLUDING Pawning)? |
| ○ Yes |
| ○ No |

| DID ANYONE IN YOUR HOUSEHOLD AS A CONSEQUENCE OF THE TB ILLNESS? |
| ○ Yes |
| ○ No |

ON A SCALE OF 1 TO 5, IN WHICH 1 IS NO IMPACT AND 5 IS VERY SERIOUS IMPACT, TO WHAT EXTENT HAS THE TB ILLNESS AFFECTED THE FAMILY FINANCIAL SITUATION?

1. No impact
2. Little impact
3. Moderate impact
4. Serious impact
5. Very serious impact
Web Survey Tool

• Originally used by WHO for Ebola response
• Requires:
  – Laptop or tablet or smartphone
  – Modern web browser (Chrome, Firefox, or IE 7+)
  – Network connection (only sometimes)
  – Local languages installed in web browser
• Benefits:
  – No secondary data entry
  – Automatically skips to correct next question
  – Data sent to central repository at WHO
3. Early experiences on survey implementation
26 countries have complete (outdated, small sample size) patient cost data
9 countries (shown here) calculate costs as % household income

Source: Compiled after Tanimura et al 2014 and Yoko, L 2015
Continuous tracking of implementation and results
PATIENT COST SURVEYS POST-2015

Priority: 30 high TB burden countries

Source: Global TB Programme tracking of survey implementation, April 2016
Continuous tracking of implementation and results
PATIENT COST SURVEYS POST-2015

16/30 HBC confirmed (2), planned (14)
8 non-HBC confirmed (4), planned (4)

Source: Global TB Programme tracking of survey implementation, April 2016
Key challenges so far – survey implementation

– Fundraising
– Reaching successful balance between independent assessment and NTP leadership:
  • NTP endorsement of study is required
  • Early involvement of WHO/CO required for cost mitigation policy uptake post-dissemination
– Timely ethics review committee application
– Local adaptation of survey instrument (including selection of asset ownership questions)
– Analysis of survey data – several options/approaches presented during field test – GTB’s do file dissemination or analysis training might be needed
– WHODCP tool might not be free in future
Key challenges so far - methodology

– **Study design**
  - cross-sectional study cheaper and anonymized patient record possible but challenging cost/time extrapolation (analysis)
  - Dissaving actual not extrapolated (tentative GTB proposal - Task force to discuss)

– **Instrument** – field testing version
  - 40-60 mins long - shorter desirable - Task force consultation early 2017

– **Sampling**: data not available to identify an “anticipated guess”

– **Analysis**:
  - Dealing with multiple TB patients in one household
  - Indirect cost measurement: insufficient consensus from health economics theory
  - Assumptions
    - constant resource utilization throughout treatment phase should be ideally evidence-based
    - treatment completion
4. Plan for “Tuberculosis patient cost surveys: a handbook”
Tuberculosis Patient Cost Surveys: Handbook

• Rationale
• Pre-start requirements - checklist
• Standardize methodology from planning to dissemination of results
  – Design and methods
    • Protocol adaptation by country
    • Sampling
    • Interview, data collection tools and informed consent
    • Budgeting and financing
    • Ethical considerations
  – Management, organization, logistics and field work
  – Analysis and reporting
  – Dissemination of results and cost mitigation policy dialogue
• Protocol review checklist
• Include examples and lessons learned from previous surveys
5. Create a technical review/advisory group/roster to support survey planning and implementation?
Technical Advisory Group

• The goal is to have a diverse group (both geographically and in skill sets) to help countries plan and implement standardized surveys

• Potential co-authors for the handbook

• Contribute to meeting planned late 2016 to review preliminary results and revise protocol
Specific TA needs

SURVEY PREPARATION
- Fundraising
- Sampling
- Protocol revision
- Ethics review committee application
- Local adaptation of survey instrument (including selection of asset ownership questions based on external questionnaire and results of latest Living Standard survey)
- Set up mobile data collection tool in English and local language

SURVEY IMPLEMENTATION
- Pilot testing survey instrument in health facility
- International monitoring visits

RESULTS GENERATION AND DISSEMINATION PHASE
- Analysis: catastrophic cost incidence and further research
- Report/Publication drafting
Next steps

1. Field testing of generic protocol and instrument in 2016

2. Revision/finalisation of protocol (late 2016 – early 2017)

3. First data to be included in the 2017 global TB report

4. Produce "Tuberculosis patient cost surveys: a handbook" (2017?)

5. Surveys in at least all 30 high burden countries before 2020

- Continuous tracking of implementation and results
- Establish technical review/advisory group, building on the existing TF
Questions

• Overall comments (for the data review and protocol revision meeting)?

• What should be the role of the impact measurement TF in pursuing cost surveys?

• Volunteers for TA group/roster?

• Volunteers to peer review of "handbook" draft?
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