National TB Patient cost survey to monitor progress towards the target to eliminate catastrophic costs and help design social protection and UHC

Regional consultation meeting to support country implementation and facilitate monitoring and evaluation of top 10 indicators of the End TB Strategy, detection and treatment of latent TB and collaborative TB/HIV activities

20-22 September 2016, Nairobi, Kenya

Ines Garcia Baena, GTB/WHO
Monitor progress towards the target to eliminate catastrophic costs

17h00-17h20

1. Summary of pre-workshop findings

2. Overview of the rationale and basic concept for this End TB indicator and target

3. Outline of the generic protocol to measure patient costs and the proportion of households experiencing catastrophic costs

4. Challenges and available support (TA)
1. Summary of pre-workshop survey findings
### End TB Strategy top 10 indicators

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>TREATMENT COVERAGE</td>
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<td>2.</td>
<td>TREATMENT SUCCESS RATE</td>
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<td>3.</td>
<td>HOUSEHOLDS WITH CATASTROPHIC COSTS DUE TO TB</td>
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<td>4.</td>
<td>TB PATIENTS TESTED WITH A WRD AT DIAGNOSIS</td>
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<td>5.</td>
<td>LTBI TREATMENT COVERAGE</td>
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<td>6.</td>
<td>CONTACT INVESTIGATION COVERAGE</td>
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<td>7.</td>
<td>DST COVERAGE FOR TB PATIENTS</td>
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<td>8.</td>
<td>TREATMENT COVERAGE, NEW TB DRUGS</td>
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<td>9.</td>
<td>DOCUMENTATION OF HIV STATUS AMONG TB PATIENTS</td>
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<td>10.</td>
<td>CASE FATALITY RATIO</td>
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<tr>
<td>Country</td>
<td>M&amp;E plan year</td>
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<td>--------------</td>
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</tr>
<tr>
<td>Benin</td>
<td>No</td>
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<tr>
<td>Ethiopia</td>
<td>2017</td>
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<tr>
<td>Kenya</td>
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<td>Malawi</td>
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<td>Mozambique</td>
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<td>Nigeria</td>
<td>2016 &amp; 2017</td>
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<tr>
<td>South Africa</td>
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<td>Swaziland</td>
<td>TBD</td>
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<td>UR Tanzania</td>
<td>2017</td>
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<td>Uganda</td>
<td>2016</td>
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<td>Zimbabwe</td>
<td>2018</td>
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Assessing access barriers to tuberculosis care with the Tool to Estimate Patients' Costs: pilot results from two districts in Kenya

Verena Mauch 1, Naomi Woods 2, Beatrice Kirubi 1, Hillary Kiguruto 1, Joseph Sittenfeld 1 and Eveline Klinkenberg 2

1 Contributed equally


Can Malawi’s poor access to services? Patients with a tuberculosis...
1. Overview and rationale
### Milestones in WHO's End TB strategy

<table>
<thead>
<tr>
<th>Year</th>
<th>Targets</th>
<th>Goal</th>
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<tbody>
<tr>
<td>2020</td>
<td><em>35% reduction in TB deaths</em>&lt;br&gt;*20% reduction TB incidence rate (&lt;85/100 000)&lt;br&gt;*No affected families with catastrophic costs due to TB</td>
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<tr>
<td>2025</td>
<td><em>75% reduction in TB deaths</em>&lt;br&gt;*50% reduction TB incidence rate (&lt;55/100 000)&lt;br&gt;*No affected families with catastrophic costs due to TB</td>
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<td>2030</td>
<td><em>90% reduction in TB deaths</em>&lt;br&gt;*80% reduction TB incidence rate (&lt;20/100 000)&lt;br&gt;*No affected families with catastrophic costs due to TB</td>
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<tr>
<td>2035</td>
<td><strong>GOAL</strong>&lt;br&gt;*95% reduction in TB deaths&lt;br&gt;*90% reduction TB incidence rate (&lt;10/100 000)&lt;br&gt;*No affected families with catastrophic costs due to TB</td>
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</tbody>
</table>
% 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

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Reduce or compensate direct and indirect costs

% 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

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GLOBAL TB PROGRAMME

World Health Organization
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%
- Other costs: 26%

"Out-of-pocket health expenditure"

- Before treatment: 50% of total costs
- During treatment: 50% of total costs

GLOBAL TB PROGRAMME

World Health Organization
Facility-based survey: sampling frame
TB (and MDR) patients in the "NTP network"

TB in community

In the health system

Notified TB (in "NTP network")

i.e. treating/notifyin g/registering according to NTP guidelines

Need to interpret data in light of:
• Detection gap
• Notification gap
End TB indicator in WHO survey post-2015

- **Operational definition of percentage of TB-affected households that experience catastrophic costs due to TB:** 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 of patients with catastrophic costs.
  - **Denominator:** All patients

- **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 from onset of symptoms to end of TB treatment
  - **Denominator:** Annual household income
"Catastrophic health expenditure" (WB/WHO) vs. "Catastrophic total costs due to TB" (WHO, 2015)

"Catastrophic health expenditure"

Indicator of: financial protection (all diseases)

Monitored to track progress towards UHC (by WHO and World Bank)

Survey type: national household surveys (DHS)

(Health conditions are “self-reported” unless point of care test available e.g. HIV)

Definition

Direct medical costs (all health conditions) ≥ X% (non - food household expenditure)  
Where X% : 40%


"Catastrophic total costs due to TB"

Indicator of: financial and social protection amongst TB-affected households

Monitored to understand cost barriers for access and adherence to TB services (by NTPs and WHO/GTB)

Survey type: facility-based survey (cross-sectional)

Definition

Direct TB medical and non medical costs + indirect costs – reimbursements ≥ X% Annual household income  
Where X% : 20% (tentative, sensitivity analysis)

Source: Wingfield et al, 2014

Reference: “Core messages regarding WHO support to countries in measuring direct and indirect costs incurred by TB patients and their households as part of the WHA-approved End TB Strategy”
Facility-based survey: new post-2015?

Is a new activity for NTPs however

- WHO survey method and instrument is built on
  - "The patient cost tool" (KNCV, WHO and JATA, 2010) further adapted to people with MDR-TB (KNCV 2014)
  - Previous research

- Task force (2015) proposed generic survey protocol and instrument to the new End TB indicator, and standardize approaches further. First survey implementers in 2015/2016 have adapted these.
26 countries have complete (yet outdated, small sample size) patient cost data. 9 countries (green) calculate costs as % household income.

Source: Compiled after Tanimura et al 2014 and Yoko, L 2015
PATIENT COSTS SURVEYS POST-2015

*adapting WHO, 2015 generic protocol*

Source: Global TB Programme tracking of survey implementation, July 2016
3. Outline of generic protocol and instrument for measuring patient costs and the proportion experiencing catastrophic costs (WHO, 2015)

http://www.who.int/entity/tb/advisory_bodies/impact_measurement_taskforce/meetings/tf6_background_5a_patient_cost_surveys_protocol.pdf?ua=1
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
End TB indicator - Percentage of TB-affected households that experience catastrophic costs due to TB

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*

**Costs are defined as catastrophic if:**

1. \[
\text{Direct Cost} + \left( \frac{HH \text{ Income}_{PRE} - HH \text{ Income}_{POST}}{HH \text{ Income}_{PRE}} \right) > 20\%
\]

2. \[
\text{Direct Costs} + (\text{Hours} \times \text{Hourly wage}) > 20\%
\]

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

\[ IN_{iTB,h} = HH \text{ Income}_{PRE} - HH \text{ Income}_{POST} \]

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

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

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

\textit{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.
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  Intensive phase  Continuation phase

Not applicable

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
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
Web Survey Tool: DCP (ONA)

https://ona.io/home/

Nationwide TB-related catastrophic costs survey in Myanmar

Coping Costs

- Did you or your household use any savings (cash or bank deposits) to cover costs due to the TB illness?
  - Yes
  - No

- 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 parking)?

- Did anyone in your household drop out of school or interrupt schooling to assist the household as a consequence of your TB illness?

Nationwide TB-related catastrophic costs survey in Viet Nam - 08 September 2016

Phần Ib. Thông tin bệnh nhân được thu thập trước khi phòng và trị Sổ đăng ký phòng xét nghiệm, Sổ đăng ký điều trị và Sổ khám bệnh, Thể điều trị lao kháng đa thuốc

23. Ngày thực hiện xét nghiệm chẩn đoán vi sinh lân đầu tiên
   yyyy-mm-dd

24. Ngày bệnh nhân được chẩn đoán lao
   yyyy-mm-dd

25. Điểm chích Dok
   - Trâm y tế xã
   - Tổ chức lao/Bệnh viện da khoa huyện/bệnh viện chuyên khoa lao
   - Other

26. Tính trạng HIV (được ghi trong phiếu điều trị)
   - HIV Dưỡng tính
   - HIV Âm tính
   - Không thực hiện, không biết
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

IMPORTANT: If you have an additional objective to study economic burden in certain groups (e.g. in MDR, in intensive vs continuation, urban vs rural...) then stratification required when sampling and budgeting for this survey. If sample strategy includes no stratification then no separate analysis for TB and MDR will be nationally representative.
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>Absolute precision d=4.0 %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cluster size - 25 clusters</td>
<td>Cluster size - 30 clusters</td>
</tr>
<tr>
<td>20.0%</td>
<td>123</td>
<td>103</td>
</tr>
<tr>
<td>30.0%</td>
<td>161</td>
<td>135</td>
</tr>
<tr>
<td>40.0%</td>
<td>184</td>
<td>154</td>
</tr>
</tbody>
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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

- Number of clusters: 20 minimum
- Cluster size: 10 patients minimum
- Cluster = health facility or geographical area containing all facilities in NTP network (public or private but treating/notifying/registering according to NTP guidelines)
- Sampling of facilities then TB patients (among cases notified one year before, PPS -> use the list of and the number of notified cases in each facility
Patient selection within a cluster

All patients on TB (and TB/HIV co-infected) and MDR treatment (all ages) in intensive and continuation phase in NTP network clinics are eligible for inclusion if at least 14 days on treatment.

**IMPORTANT:** Supervision on the ground and clear SOPs are key. If data collection is within short period, need to avoid over-selection of patients who require more frequent visits.
First survey with WHO methodology: Myanmar

- 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
4. Challenges and available support
Key challenges so far

1. Fundraising and contractual agreements with research partners
2. Timely ethics review committee application (local and WHO)
3. Reaching successful balance between independent assessment and NTP leadership:
   a. NTP endorsement of study is required
   b. Early involvement of WHO/CO required for cost mitigation policy uptake post-dissemination
4. Local adaptation of survey instrument (including selection of asset ownership questions)
5. Selecting patients: recruitment of patients in practice (in randomly selected facilities) -> need for clear SOP and supervision
6. Analysis of survey data: WHO code (Stata) based on generic protocol available however be aware that

- several options/approaches presented during field test
- seasonal variation in costs (direct or indirect) could be a potential bias
- dealing with multiple TB patients in one household
- indirect cost measurement: insufficient consensus from health economics theory
- assumptions open for debate: a) constant resource utilization throughout treatment phase should be ideally evidence-based; b) treatment completion
c) Tentative threshold defining costs as “catastrophic” is 20% (sensitivity analysis)

7. WHO DCP/ONA back up service involves (small) fee
Key challenges so far (cont.)

8. Study design involves extrapolation
   • 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)

9. Instrument is 60 mins long – field testing version
   • 40-60 mins long - shorter desirable - Task force consultation mid 2017

10. Sampling:
   a) data to inform parameters for sample size calculation might not be available, hence pilot desirable
   b) Stratification is not required to monitor End TB indicator but needed if analysis of costs within specific groups/strata. Plan sampling according to study objective!
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
Available support at WHO

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skype: garciabaenaiwho.int
Getting started: documentation available

1. Communication note regarding the focus of this work
4. Template to establish the patient cost survey budget and timeline.
6. Link to survey software that may be used in Patient cost surveys: ONA/WHO DCP https://ona.io/home/. 
Verbal feedback from participants:
Dr. Joseph Kuye, Nigeria (Kick off survey meeting last week)
Dr Ebony Quinto, Uganda (Preparatory work by Makerere University)