**Guidance on the TB CARE I (MDR) TB patient cost tool**

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| **Step** | **Description** | **Responsible** | **Remarks** |
|  | Decide on study population – might include MDR-TB and TB patients, from one or more centers, dependent on the study question. | Principal investigator (PI) and core team | We advise to include only adult patients.  Decide on where the patients will be interviewed (at the health center and/or at home).  For patients who are currently on treatment, an appointment will be arranged if possible in combination with a DOT or follow-up visit to the health care facility. For patients who started treatment but who interrupted treatment, an appointment may be made at the home of the patient. One may choose not to include patients who died or transferred while on treatment because of logistic difficulties. |
|  | Obtain ethical approval for the study, and institutional approval from the targeted health centers. | PI and core team |  |
|  | Collect information about the number of patients in each of the 2 TB and 3 MDR TB patient groups (see Question *j* on first page of generic questionnaire). | PI and core team | First select health facilities to be included. Then make a list of eligible patients per patient group from (MDR suspect and MDR)TB patient registers. Number of patients per group should ideally be 50. If the numbers per eligible group are much larger, make a (preferably) random selection and/or stop inclusion after having reached the target number. |
|  | Review answer options for at least the Questions f, Q3, Q4, as these should describe your study population appropriately (thus, this should result in a few categories that are sufficiently large in numbers and sufficiently different in general characteristics). Revise into approximately the same number of categories as suggested in the generic questionnaire. | PI and core team | Also revise answer options for question j if only TB (reduce to 2 options) or MDR TB (reduce to 3 options) patients will be included.  Also consider to review and revise if necessary the answer options for Q5, Q12c, Q15a, Q16a, Q24b, and Q26. To maximize comparability over study populations, we suggest NOT to revise answer options if not considered strictly necessary. |
|  | Translate the revised questionnaire into the local language of the study population | PI and translator 1 | The language used is an important component to guarantee that the questions are properly understood and adequately answered, especially when interviewing vulnerable populations such as ethnic minorities, the very poor, migrants, and refugees. Unless the population to be interviewed is native English speaking, the questionnaire needs to be translated.  The translation is best done by someone who understands the objective of the questionnaire, the intent of the questions and who speaks both languages fluently PI to check translations for accuracy and correctness. |

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| **Step** | **Description** | **Responsible** | **Remarks** |
|  | Translate the revised questionnaire back into English | PI and a DIFFERENT translator 2 who has not seen the original version of the questionnaire | PI to check translations for accuracy and correctness,  or have a bilingual peer compare both versions and evaluate the questions according to content, meaning and clarity of expression |
|  | Adjust incorrect/imprecise translations | PI and translator 1 |  |
|  | Check all cross-references for correctness, ask members of core project team to review the questionnaire | PI |  |
|  | Train interviewers. Have interviewers check the questionnaire for consistency and comprehensiveness | PI | See below for training guidance. |
|  | Adapt questionnaire if needed | PI |  |
|  | Pilot the questionnaire on a small number of patients, ideally 1-2 patients per patient group (see Question j on first page) | PI and interviewers | This step is needed to check if the questionnaire is also logical and comprehensive to the target population. Questions to be answered:   * Are all words understood? * Are the questions interpreted similarly by all respondents? * Do the closed-ended questions have answers that are applicable to each respondent? * Do some questions evoke answers that can’t be interpreted? |
|  | Adapt questionnaire if needed | PI | Repeat steps 11 and 12 if needed. |
|  | Develop a data-entry file (e.g. in EpiData) | PI and core team | Most questions only have one answer possibility. For Q10, Q11, Q12c, Q24b and Q27, more than one answer is possible. In the data-entry sheet, enable this by providing an entry for each answer option. |
|  | Print sufficient copies of the questionnaire | PI and core team | Print some extra pages for Q14. These might be needed for patients who needed more than 9 visits to get a (MDR) TB diagnosis. It is preferred that interviewers use one of these extra pages than writing extra lines on the questionnaire themselves. |
|  | Daily monitor number of patient interviews | PI | Keep list of (non-)participation and monitor reasons for non-participation. Ensure stop inclusion for interviews if target number is reached. |
|  | Daily monitor and supervise completeness and quality of filled interviews | PI | If filled interview is incomplete or inconsistent, this needs to be completed with interviewer (and patient, if needed). Filled interviews are kept in a safe place. |

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| **Step** | **Description** | **Responsible** | **Remarks** |
|  | Monitor and supervise data-entry | PI | Cross-check with paper forms (e.g. randomly select 10-20% of the forms and compare with computer data) |
|  | Conduct data cleaning and validation | PI | Look for unlikely and missing entries and cross-check with paper forms; adapt if possible. |
|  | Supervise data-analysis and reporting | PI | Separate guidance will be developed for data analysis |
|  | Arrange policy workshop for dissemination of results and discussion of mitigation options | PI | Invite all relevant stakeholders: representing different Ministries Universities, hospitals, NGO’s, CSO’s, and patients |
|  | Follow-up on results of the workshop | PI |  |
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**The 5 groups in different phases of diagnosis and treatment are**:

1. TB patients who are within last month of intensive phase of TB treatment (recall period: last three months including pre-diagnosis period; but including all major coping costs outside the 3-month period)
2. TB patients at least 3 months in continuation phase of TB treatment (recall period: last three months i.e. covers a part of the continuation phase; but including all major coping costs outside the 3-month period);
3. just diagnosed as MDR-TB patient (recall period: last three months but including all major coping costs outside the 3-month period)
4. at least 3 months in intensive phase of MDR-TB treatment (recall period: last three months i.e. covers a part of the intensive phase; but including all major coping costs outside the 3-month period);
5. at least 3 months in continuation phase of MDR-TB treatment (recall period: last three months i.e. covers a part of the continuation phase; but including all major coping costs outside the 3-month period).

**Definitions**

*Patient groups*

TB patient: a person diagnosed with tuberculosis.

MDR-TB patient: a person diagnosed with tuberculosis resistant against rifampicin and isoniazid by phenotypic or genotypic drug susceptibility testing or with Rifampicin resistance according to Xpert MTB/RIF testing and no drug susceptibility test result ruling out MDR-TB (according to prevailing (inter)national guidelines).

*Costs*

Direct costs are out-of-pocket costs linked to seeking diagnosis and treatment including medical expenses, fees, transport, accommodation and food expenditures.

Indirect (opportunity) costs include the cost of foregone income due to the inability to work because of the illness and loss of time due to visits to health facilities, time spent on the road to and at health facilities, lost productivity and loss of job.

Coping costs are defined as household costs to meet daily requirements despite extra expenditures or loss of income. These include the sale of assets, taking up debt, saving on food or other items, taking a child out of school to care for the patient or taking up another job, taking a child out of school to care for the patient or taking up another job.

*Data collection periods*

Pre-treatment period (TB): period from onset of symptoms until start of treatment

Pre-treatment period (MDR-TB): period from being earmarked as a MDR-TB suspect until start of MDR-TB treatment

Intensive phase of treatment: First phase of treatment, in accordance with WHO definitions and local guidelines. Usually, 2-3 months for TB and 6-8 months for MDR-TB

Continuation phase of treatment: Second phase of treatment, in accordance with WHO definitions and local guidelines. Usually, 4-6 months for TB and 12-18 months for MDR-TB

**Important points for the interviewers’ training** (adapted from the original TB CAP patient cost tool instructions)

1. 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; Interviewers should be given examples how to prompt responses regarding time and types of costs.
2. Interviewers need to be instructed about indicator definitions, such as 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.
3. Interviewers need to be sensitized on the different phases (intensive, continuation) and types of TB treatment (hospitalization, different forms of DOT) 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.
4. Difficult concepts such as coping costs need to be explained in detail with clear instructions on the intent behind the questions to ensure that interviewers are able to explain these concepts to patients.
5. It may be complicated for some patients to address questions that refer to their situation “prior to their diagnosis” vs. “post diagnosis” as they may not be clear when or where their diagnosis was made. In addition there may be other big changes in their life that coincide with their illness. It is important to teach interviewers how to tease apart issues (if any) so that changes in income etc. are truly caused by their TB, and not because of some other unrelated event.
6. Interviewers should be informed about the nature of TB, what their participation means for their own health and how they can protect themselves. Depending on which kind of patients are interviewed (new, re-treatment or MDR patients), and how far the patient is into treatment, risks to interviewer health differ. For example, patients who are in their first month of treatment might still be infectious. The interviewer needs to be aware of that and knowledgeable about infection control measures; i.e. providing respirators and/or conducting interviews in well-ventilated areas.
7. Have interviewers sign a confidentiality agreement, if needed.