



TB CARE II

Ethics of TB Prevention, Care and Control: An Assessment Tool for National Tuberculosis Programmes

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DISCLAIMER

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Background

In 2010, the World Health Organisation (WHO) released *Guidance on Ethics of Tuberculosis Prevention, Care and Control*. This guidance is meant to address all dilemmas related to the rights of TB patients, the community, TB programmes, and health care workers in the management of TB patients.

The purpose of this tool is for programmes to assess themselves on topics covered in the WHO guidelines. The tool will assist programmes in identifying potential strengths and gaps in the ethical treatment of TB patients.

As part of the pilot testing process, responders noted the benefits of using this tool. They indicated that the tool is an important refresher for the key components of TB care which can improve patient care, protect the community and families, and change the environment for health care workers. However, this is based on full use of the tool, recognizing its findings and a commitment to making changes to existing practices.

Description

This tool contains guided questions about TB control activities on various levels in a TB programme. There are no correct or incorrect responses. This instrument can be used to identify ethical issues and help to make decisions on how to address them with current resources.

Process

There are several ways to complete this tool. The questions cover various topics and one person in a program or at the patient-care level may not know how to answer all of the questions. Should one choose to have individuals answer the questions, it may be helpful to designate certain questions for persons with specific roles (e.g., treatment questions for physicians and/or nurses). As roles differ in every region and country, these have not been pre-designated in this document. Each programme should make this decision based on their organization and structure.

An additional approach would be to have a team of people complete the tool together. In order to complete this tool using this approach, a group of personnel should be assembled who understand the following circumstances in a particular country or setting:

- Drug procurement
- Access to care
- Resource availability
- Support for vulnerable populations
- Diagnostic procedures
- Contact tracing
- Research
- Legal interventions

- Provider practices
- Adherence enhancing interventions

Personnel may not be all National TB Programme (NTP) staff but representatives from district level programmes.

The form to be completed is provided *here* (This document may be in PDF but a separate link to a Word document is needed) in Microsoft Word® and can be customized. This revision may include:

- Changing terms that are not understandable in the context in which this tool is being used
- Deleting questions which are not pertinent to the person(s) completing the tool; one may create different documents for each type of individual participating the assessment process
- Adding explanations to questions where required. Explanations, however, should be defining and not leading the respondent to a certain answer

The tool completion is expected to take several hours for a group to complete and about 30-60 minutes for an individual to complete. It will require participants to discuss current practices in the country with relation to the care of persons with TB. Additional documentation may be required to cover the above listed topics including the legal regulations for health care. If the tool is completed as a group, an unbiased facilitator and note taker should be available to guide t and document the process.

The tool is meant as a way for programmes or facilities to assess and discuss the ethical practices within their organization, with the goal of improvement. It is not intended as mechanism for disciplining or penalizing staff. When the tool is used in a group, all staff members should be encouraged to be comfortable sharing their observations and opinions openly.

Detailed instructions are available for several questions that require further explanations. After using the assessment tool, refer to the supplement at the end of the tool on how to interpret and use the information.

Planning, Monitoring and Evaluation

After the assessment of ethical practices, it is important to summarize the results. This can be done in the document itself noting frequencies of response and a list of open-ended responses. One may also separate responses based on who stated them (i.e., by profession, district, level of care, etc.). This latter method can provide some context for certain responses.

This response summary should be considered to address changes in practice and policy. An ethics strategic plan may be considered with realistic timelines, specific and measureable objectives and designated tasks to achieve ethical patient care. The plan can be revisited when feasible to assess if accomplished objective are being sustained.

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Use this instrument to answer questions about TB control activities in your programme. There are no correct or incorrect responses. This instrument can be used to identify ethics issues in your programme and help to make decision on how to address them with current resources.

Name (optional): _____

Job title: _____

Job location (city and facility name): _____

QUESTION	RESPONSE
<u>ACCESS TO CARE</u>	
1. Are anti-TB drugs provided free of charge to all TB patients under all circumstances?	<input type="checkbox"/> Yes (go to 2) <input type="checkbox"/> No (go to 1a) <input type="checkbox"/> I do not know the answer to this (go to 2)
1a. Under what circumstances do patients have to pay for anti-TB drugs (check all that apply)?	<input type="checkbox"/> Treatment for drug-resistant disease <input type="checkbox"/> Private sector care <input type="checkbox"/> Patient goes direct to pharmacy <input type="checkbox"/> Treatment for latent TB infection <input type="checkbox"/> Treatment for exposure to infectious TB <input type="checkbox"/> Other (specify) _____ _____
Comments on any of the responses:	

<p>2. Are <u>all</u> aspects of TB care provided free of charge under <u>all</u> circumstances?</p>	<p><input type="checkbox"/> Yes (go to 3)</p> <p><input type="checkbox"/> No - Not all services, all the time (go to 2a)</p> <p><input type="checkbox"/> I do not know the answer to this (go to 3)</p>
<p>2a. Under what circumstances and reasons do patient need to pay for TB care (select all that apply)?</p>	<p><input type="checkbox"/> X-ray – Circumstance: _____</p> <p><input type="checkbox"/> Sputum collection – Circumstance: _____</p> <p><input type="checkbox"/> Sputum smear microscopy – Circumstance:_____</p> <p><input type="checkbox"/> Drug susceptibility testing– Circumstance: _____</p> <p><input type="checkbox"/> Receipt of personal respiratory protection (mask)– Circumstance: _____</p> <p><input type="checkbox"/> Directly observed therapy (DOT)– Circumstance: _____</p> <p><input type="checkbox"/> Care for related conditions (e.g., HIV) – Circumstance: _____</p> <p><input type="checkbox"/> Other – Circumstance: _____</p>
<p>Comments on any of the responses:</p>	
<p>3. Do patients with drug-resistant TB have the same access to treatment as patients without drug-resistance?</p>	<p><input type="checkbox"/> Yes (go to 4)</p> <p><input type="checkbox"/> No - Not all services, all the time (go to 3a)</p>

	<input type="checkbox"/> I do not know the answer to this (go to 4)
3a. Do patients with drug-resistant TB have access to the following care? (select all that apply)	<input type="checkbox"/> Free drugs <input type="checkbox"/> Personal respiratory protection (masks) <input type="checkbox"/> Care for other related conditions (e.g., HIV) <input type="checkbox"/> Directly observed therapy <input type="checkbox"/> Other _____
Comments on any of the responses:	
4. Does the national TB programme (NTP) receive any support (e.g., money, TB drugs) from international source(s)?	<input type="checkbox"/> Yes _____ (specify source(s)) <input type="checkbox"/> No (provide reason) _____ <input type="checkbox"/> I do not know the answer to this
Comments on any of the responses:	
5. Does the NTP have a process to be sure the quality of TB drugs is good?	<input type="checkbox"/> Yes _____ (specify, e.g., received through GDF) (go to 6) <input type="checkbox"/> No (go to 5a) <input type="checkbox"/> I do not know the answer to this (go to 6)
5a. If quality of drugs is not assured, how do providers decide regimens to use and with what frequency?	
5a1. Providers use the drugs provided as recommended, regardless of quality	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely
5a2. Providers do <u>not</u> treat a patient if there are no quality assured drugs	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely
Comments on any of the responses:	

6. Do patients travel a great distance to a facility for TB services including:	
a. Medical examination	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
b. Directly Observed Therapy (DOT) <i>Directly observed therapy is the process by which a trained health care worker watches and documents the ingestion of anti-TB medications in a patient.</i>	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
c. Sputum collection	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
d. X-ray	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
e. Care for related conditions (e.g., HIV)	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely

	<input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
Other (specify) _____ _____	
State which services above are in the same facility in most cases and under what circumstances: _____ _____	
Comments on any of the responses:	
7. Is access to TB services different for different types of patients (see list below)?	
a. Local minorities	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
b. Homeless persons	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
c. Migrants/refugees	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
d. Prison inmates	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all

	<input type="checkbox"/> I do not know the answer to this
e. Rural populations	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
f. Substance abusers	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
g. Women/children	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
h. Poor	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
i. Other (specify) _____ _____	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all
Comments on any of the responses:	

8. Are there community-based clinics?	<input type="checkbox"/> Yes (See comment area below) <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
9. Are there private (sole practice) providers?	<input type="checkbox"/> Yes (See comment area below) <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
Comments on any of the responses regarding community care (questions 8 and 9) (e.g., adherence to patient's rights and respect, scheduling appointments, waiting areas, waiting time, access to care, etc.):	
<p><u>PATIENT CENTRED CARE</u></p>	
10. Do patient support groups exist? <i>A patient support group is formal meeting or a way for patients to meet with other patients or a counselor about issues related to their care, such as depression.</i>	<input type="checkbox"/> Many <input type="checkbox"/> Some <input type="checkbox"/> Few <input type="checkbox"/> None <input type="checkbox"/> I do not know the answer to this
Comments:	
11. Are there <u>specific</u> support services for vulnerable populations? You may provide comments as to the extent to which services are available to each group:	
a. Local minorities	<input type="checkbox"/> Many <input type="checkbox"/> Some <input type="checkbox"/> Few <input type="checkbox"/> None <input type="checkbox"/> I do not know the answer to this
Comments:	
b. Homeless persons	<input type="checkbox"/> Many

	<input type="checkbox"/> Some <input type="checkbox"/> Few <input type="checkbox"/> None <input type="checkbox"/> I do not know the answer to this
Comments:	
c. Migrants/refugees	<input type="checkbox"/> Many <input type="checkbox"/> Some <input type="checkbox"/> Few <input type="checkbox"/> None <input type="checkbox"/> I do not know the answer to this
Comments:	
d. Indigenous persons/tribe members	<input type="checkbox"/> Many <input type="checkbox"/> Some <input type="checkbox"/> Few <input type="checkbox"/> None <input type="checkbox"/> I do not know the answer to this
Comments:	
e. Prison inmates	<input type="checkbox"/> Many <input type="checkbox"/> Some <input type="checkbox"/> Few <input type="checkbox"/> None <input type="checkbox"/> I do not know the answer to this
Comments:	
f. Rural populations	<input type="checkbox"/> Many

	<input type="checkbox"/> Some <input type="checkbox"/> Few <input type="checkbox"/> None <input type="checkbox"/> I do not know the answer to this
Comments:	
g. Substance abusers	<input type="checkbox"/> Many <input type="checkbox"/> Some <input type="checkbox"/> Few <input type="checkbox"/> None <input type="checkbox"/> I do not know the answer to this
Comments:	
h. Women/children	<input type="checkbox"/> Many <input type="checkbox"/> Some <input type="checkbox"/> Few <input type="checkbox"/> None <input type="checkbox"/> I do not know the answer to this
Comments:	
i. Mine workers	<input type="checkbox"/> Many <input type="checkbox"/> Some <input type="checkbox"/> Few <input type="checkbox"/> None <input type="checkbox"/> I do not know the answer to this
Comments:	
12. Are there trained, community health care workers who provide	<input type="checkbox"/> Many

<p>services for TB patients? <i>Community health care workers are not medical or nursing professionals but persons with no formal health care education.</i></p>	<input type="checkbox"/> Some <input type="checkbox"/> Few <input type="checkbox"/> None <input type="checkbox"/> I do not know the answer to this
<p>Comments:</p>	
<p><u>INFORMATION, COUNSELING, AND CONSENT</u></p>	
<p>13. Are patients provided education/informed consent on the TB testing and treatment process? <i>Education includes the risks and benefits of a procedure or process. It may be done in writing or by just speaking with the patient.</i></p>	
<p>a. TB Testing:</p>	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
<p>b. TB Treatment:</p>	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
<p>c. Personal infection control:</p>	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
<p>d. Contact tracing:</p>	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely

	<input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
e. Drug susceptibility testing:	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
f. HIV testing	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
Comments on any of the responses:	
14. Is contact tracing conducted by health care workers? <i>Contact tracing is a means of finding persons exposed to an infectious case of TB in order to bring them for medical examination to treat new cases and prevent new cases via treatment for latent TB infection and preventive therapy.</i>	<input type="checkbox"/> Most of the time (go to 14a) <input type="checkbox"/> Sometimes (go to 14a) <input type="checkbox"/> Rarely (go to 14b) <input type="checkbox"/> Never (go to 14b) <input type="checkbox"/> I do not know the answer to this
14a. If contact tracing is performed, is the patient's identity always kept confidential?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Identity is revealed if there is no other option to identify contacts <input type="checkbox"/> I do not know the answer to this
14b. If contact tracing is not performed by health care workers, are patients asked or encouraged to notify their contacts of their TB disease?	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely

	<input type="checkbox"/> Never <input type="checkbox"/> I do not know the answer to this
Comments on any of the responses:	
<u>ADHERENCE</u>	
15. Is directly observed therapy (DOT) provided? <i>Directly observed therapy is the process by which a trained health care worker watches and documents the ingestion of anti-TB medications in a patient.</i>	<input type="checkbox"/> Universally used. If so, for what duration during treatment or when is it no longer used? _____ <input type="checkbox"/> It is <u>only</u> used in certain circumstances (check all that apply): <input type="checkbox"/> Drug resistant cases <input type="checkbox"/> HIV-infected cases <input type="checkbox"/> Urban settings <input type="checkbox"/> Rural settings <input type="checkbox"/> Children <input type="checkbox"/> Patients with high likelihood of non-adherence (specify types) _____ <input type="checkbox"/> It is not used <input type="checkbox"/> I do not know the answer to this
16. Are enablers present for patient care? <i>An enabler is a resource which makes a patient's ability to adhere to treatment easier. An example is a bus ticket or free transportation to the clinic.</i>	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Never (go to 17) <input type="checkbox"/> I do not know the answer to this (go to 17)
16a. Are enablers only used for certain types of patients?	<input type="checkbox"/> Yes (specify what type(s)): _____ <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
17. Are incentives offered to patients for adhering to treatment	<input type="checkbox"/> Most of the time

<p>or other medical care? <i>An incentive is a reward for completing agreed upon medical management issues like completion of a treatment course or getting an x-ray.</i></p>	<input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Never (go to 18) <input type="checkbox"/> I do not know the answer to this (go to 18)
<p>17a. Are incentives only used for certain types of patients?</p>	<input type="checkbox"/> Yes (specify what type(s)): <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
<p>18. Are the following in place to enhance adherence? <i>Adherence is defined as completing a task or treatment as advised by health care provider (e.g., taking a full course of treatment).</i></p>	
<p>a. Written agreement at the initiation of treatment</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
<p>b. Visit or contact by letter or telephone/mobile phone if patient is not adherent</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
<p>c. Visit or contact by a health care worker if patient is not adherent</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
<p>d. Change in treatment provision method (e.g., change in time of DOT, provision of other necessary medical services, etc.)</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
<p>19. Will the programme treat patients who are not likely to be adherent? <i>If worker's time or medications will likely be used for a patient who may not take medications as prescribed, is this patient not started on treatment?</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
<p>20. Is there a facility or plan for patients who cannot be cured but</p>	<input type="checkbox"/> Yes

<p>remain infectious?</p>	<p><input type="checkbox"/>No</p> <p><input type="checkbox"/>I do not know the answer to this</p>
<p>Comments on any of the responses for the questions on adherence:</p>	
<p><u>DRUG SUSCEPTIBILITY TESTING AND TREATMENT OF RESISTANT DISEASE</u></p>	
<p>21. Is drug susceptibility testing provided or offered to <u>all</u> patients regardless of the availability of 2nd or 3rd line drugs?</p>	<p><input type="checkbox"/>Most of the time</p> <p><input type="checkbox"/>Sometimes</p> <p><input type="checkbox"/>Rarely</p> <p><input type="checkbox"/>No, the provider does not know</p> <p><input type="checkbox"/>I do not know the answer to this</p>
<p>22. Are providers able to make treatment decisions when drug susceptibility testing is <u>not</u> available? <i>Do physicians know how to treat a patient when they are not clear what drugs will work to cure the patient?</i></p>	<p><input type="checkbox"/>Most of the time</p> <p><input type="checkbox"/>Sometimes</p> <p><input type="checkbox"/>Rarely</p> <p><input type="checkbox"/>No, the provider does not know</p> <p><input type="checkbox"/>I do not know the answer to this</p>
<p>Comments on any of the responses:</p>	
<p><u>HEALTH CARE WORKERS' RIGHTS AND OBLIGATIONS</u></p>	
<p>23. Are the following adequate for health care workers:</p>	
<p>a. Infection control (personal): <i>Personal infection control refers to the availability of respirators and masks, etc.</i></p>	<p><input type="checkbox"/>Most of the time</p> <p><input type="checkbox"/>Sometimes</p> <p><input type="checkbox"/>Rarely</p> <p><input type="checkbox"/>Not at all</p> <p><input type="checkbox"/>I do not know the answer to this</p>

<p>b. Infection control (facility): <i>Personal infection control refers to the airborne infection isolation rooms, ultraviolet germicidal irradiation (UVGI), etc.</i></p>	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
<p>c. Medical supplies:</p>	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
<p>d. Training:</p>	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
<p>e. Equipment:</p>	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
<p>f. Infrastructure:</p>	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
<p>g. Drug supply:</p>	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes

	<input type="checkbox"/> Rarely <input type="checkbox"/> Not at all <input type="checkbox"/> I do not know the answer to this
Comments on any of the responses:	
24. Are the following provided to health care workers:	
a. Health information (written or verbal) on the risks and benefits of caring for TB patients:	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Never <input type="checkbox"/> I do not know the answer to this
b. Training on caring for TB patients:	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Never <input type="checkbox"/> I do not know the answer to this
c. Access to TB screening and diagnosis:	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Never <input type="checkbox"/> I do not know the answer to this
d. Access to treatment for TB, if needed:	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Never <input type="checkbox"/> I do not know the answer to this
e. Clear description of roles and	<input type="checkbox"/> Most of the time

responsibilities:	<input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Never <input type="checkbox"/> I do not know the answer to this
f. Appropriate compensation: <i>Compensation refers to salary, holidays, time away from work if sick.</i>	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Never <input type="checkbox"/> I do not know the answer to this
g. Ability to approach a supervisor to address unsafe or inadequate working conditions:	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Never <input type="checkbox"/> I do not know the answer to this
Comments on any of the responses:	
<u>ISOLATION AND LEGAL INTERVENTIONS</u>	
25. Are infectious patients asked to be separated (isolated) from household members?	<input type="checkbox"/> Most of the time <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Never <input type="checkbox"/> I do not know the answer to this
26. Are there laws, regulations, and/or policies establishing procedures and conditions of involuntary (against the patient's will) isolation?	<input type="checkbox"/> Yes (go to 26a) <input type="checkbox"/> No (go to 26b) <input type="checkbox"/> I do not know the answer to this
26a. At the beginning of treatment, is a patient told that he or she can be isolated or	<input type="checkbox"/> Yes

detained is not adherent?	<input type="checkbox"/> No – The patient is not told even though this is the policy <input type="checkbox"/> No - The patient is not told because our program does not have an isolation or detention policy <input type="checkbox"/> I do not know the answer to this
26b. What is done if a patient:	
i. Is contagious, refused treatment, and all reasonable measures to ensure adherence have been attempted: _____	
ii. Is contagious, has agreed to treatment but is unable to institute infection control (e.g., wear a mask, stay away from other people) in the home: _____	
iii. Is probably not contagious but refuses to be assessed for infectiousness? _____	
27. If you answered yes to question 21: if involuntary isolation or detention is implemented, is there language in the related law, regulation, or policy for:	
a. Strict necessity (<i>isolation or detention should only be used if absolutely needed</i>):	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
b. Least restriction and intrusion (<i>if a patient is isolated or detained it should be done with the least possible inconvenience and done humanly</i>):	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
c. Not arbitrary, unreasonable, or discriminatory (<i>if a patient is isolated or detained there should be an appropriate reason, consistent with a policy based on the non-adherence</i>):	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
Comments on any of the responses:	
<u>RESEARCH</u>	

28. Is there ongoing TB research in country related to:	
a. Medications:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
b. Vaccines	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
c. Treatment regimens	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
d. Social and structural determinants of disease:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this No
e. Infection control:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
f. Adherence strategies:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
g. Drug delivery mechanisms:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
h. Social/behavioral interventions:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
i. Epidemiology:	<input type="checkbox"/> Yes

	<input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
j. Other (specify) _____	
29. If research of any kind is present (if you answered yes to at least one item in questions 28, please respond below):	
a. Are local investigators present (for internationally sponsored research only)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable <input type="checkbox"/> I do not know the answer to this
b. Are participants kept informed of the research findings and how the findings are being used?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
c. Is the research beneficial to the populations in which it is carried out?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
d. Will research results be locally adaptable?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
e. Is an ethics committee/institutional review board involved in the assessment of human subjects research?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
f. Has consent been obtained from persons who participate in research?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
g. Is there an agreement among all researchers	<input type="checkbox"/> Yes

about access to medical care and treatment of persons being studied?	<input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
h. Is there a policy on specimen collection and/or storage?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> I do not know the answer to this
Comments on any of the responses:	

Resolution to the Responses for the Tool

After responding to the questions, please review the information below from the WHO document, [Guidance on ethics of tuberculosis prevention, care and control](http://whqlibdoc.who.int/publications/2010/9789241500531_eng.pdf) (http://whqlibdoc.who.int/publications/2010/9789241500531_eng.pdf).

The information provided is a brief summary on each question, which addresses the consensus by the authoring committee on the appropriate ethical stance that should be taken. The information below in conjunction with gaps identified in the tool, can indicate where further policy changes, internal and external resource allocation, and research may be needed to meet the identified needs on ethics. The complete *Guidance on ethics of tuberculosis prevention, care and control* document will be useful to more fully explore and understand gaps identified through use of the Ethics Assessment Tool.

For more specific information on interventions and examples of the described ethical practices, consult the references at the end of the Guidance document.

Access to Care

Questions 1 and 1a

Anti-TB drugs should be available free of charge to all TB patients. When TB drugs are not free, patients who are unable to afford them may not get treatment and may remain sick and infectious. This both affects the uncured patient and fails to stop transmission in the community.

Questions 2 and 2a

All aspects of TB care should be free of charge. This includes diagnostic care and drug susceptibility testing. Treatment of active TB disease as well as preventive therapy should also be free. TB patients should also have free access to related care such as HIV services since some other infections and medical conditions may affect the course of TB and its treatment.

Questions 3 and 3a

Patients with drug resistant disease should be given the same treatment and care as patients with susceptible disease. This includes access to drugs, infection control, directly observed treatment, and supportive community programmes. Training should be present to ensure that health care workers are providing appropriate medication regimens to patients not only with drug resistant disease, but with susceptible disease to avoid secondary resistance.

Question 4

The international community has an obligation to provide support to resource-poor countries when universal access to care, as outlined above, cannot be provided. Sources of drugs and other services should be sought.

Question 5 and 5a

The National Tuberculosis Programme should ensure that anti-TB drugs are not substandard and can be supplied with regularity; failing to do so can harm individual patients and contribute to the development and spread of drug resistant strains. If drug supply and quality are a concern, it is the NTP's role to inform local providers of not only the problems, but steps to take in treating patients under these conditions.

Question 6, 8, 9, 12

If treatment and care are not easily accessible to TB patients, strategies should be developed to make them accessible. Care can be provided in local communities, on an outpatient basis, using trained local health care and community workers. Care can include a medical examination, directly observed therapy, sputum collection, x-rays, and oversight for other related conditions.

Patient Centered Care

Question 7 and 11

All patients should have access to TB care services regardless of their vulnerabilities. Tailored interventions can be devised to this effect that focus on making access easier. These include the use of local health care providers and setting-based (e.g., prison) services.

Question 10

Patients should be encouraged to come together to in a supportive environment to discuss their medical and psychological concerns. These groups can also work within the community together to resolve challenges related to TB care.

Question 12

Community workers play an important role in treatment and symptom assessment of patients. They should be adequately trained and compensated for their time and work.

Information, Counseling, and Consent

Question 13

TB patients should be provided all information about any procedures or treatments related to their TB diagnosis. This both educates patients and serves to assist them in making decisions about their medical care and adherence. While choices about treatment may be limited, as TB is a communicable disease, assistance should be provided in understanding the importance of medical care. Information should be provided with culture and language specificity in mind.

Question 14, 14a, and 14b

Whether contact tracing is required by local officials, patients should be encouraged to report their TB diagnosis to their close contacts to prevent additional spread of disease. When a health care workers or the local TB programme is involved in contact notification, all efforts should be made to keep the patient's identification confidential. If the patient is not cooperative in this process, his or her name *may* need to be disclosed in order to discover potential contacts. However, this should be considered as a last resort option, and used only after all reasonable efforts to gain the patients cooperation have failed.

Adherence

Question 15

Directly observed therapy (DOT) is a way of supporting patients through their regimen. By assisting in successful completion of treatment, DOT can help to prevent the spread of TB. It should be done when possible, at the convenience of the patient by ensuring a mutually agreed upon time schedule, choice of health care worker, and location for administration. All of this is done with confidentiality and privacy in mind as well as availability of resources.

Question 16

Enablers are a way to allow patients to receive care particularly when access is difficult or other medical conditions may be interfering in care. Examples of enablers include transportation vouchers/tickets or nutritional supplements. Enablers should be provided when needed and can be obtained through outside funding and collaborations.

Question 17

Incentives should be provided, when appropriate, in exchange for treatment adherence or completion (e.g., doll for a child). They should be culturally appropriate and should not be provided if doing so would be considered insulting.

Question 18

If a patient is non-adherent to treatment, all efforts should be made to provide an opportunity for the patient to receive services. Patients should be informed at treatment initiation about the

importance of adherence as well as the consequences of non-adherence. If non-adherence occurs, health care workers should find out what may be causing the problem and try and remedy it together with the patient. If attempts at the latter are not successful, then gradual methods of warnings such as letters and visits to the patient's home should occur.

Question 19

It is difficult to predict adherence in a patient. Therefore, providers are obligated to discuss the importance of adherence at the start of treatment and then provide adherence enhancing interventions (e.g., education, enablers, incentives) throughout treatment if adherence is a concern. Care of any patient should not be denied on the basis of adherence; in the situation where the patient refuses treatment, legal interventions may be taken as a last resort measure.

Question 20

TB programmes and providers must provide care to keep the incurable patient comfortable. If the patient is infectious, infection control mechanisms (including isolation in a mutually agreed upon environment) should be in place so that the patient does not infect others, including health care workers.

Drug Susceptibility Testing and Treatment of Drug Resistant Patients

Question 21

If a programme is unable to treat a drug resistant patient, susceptibility testing should still be initiated, although patients should be provided information on risks and benefits of testing and specifically asked if they are willing to consent even though treatment is not available to them. The results of such testing can assist providers in deciding which regimens to use and not use, guide the patient in making decisions about personal infection control practices, and allow the patient to understand why his or her care may not be successful. Use of diagnostic testing without the ability to treat patients should only be a temporary measure and programmes should develop a timeline and strategy for offering treatment for drug-resistant TB.

Question 22

If a provider is unable to successfully treat a patient based on drug susceptibility results and/or drug availability, he or she should make decisions how to make the patient comfortable and non-infectious to others. If drug susceptibility testing is not available, treatment decisions can be made based on local epidemiology and patient-specific factors. This decision making process should occur in a multidisciplinary fashion, not just looking at medical concerns.

Health Care Worker Rights and Obligations

Questions 23 and 24

Health care workers are obligated to take care of all TB patients. However, in doing so, health care workers take great risks in becoming infected themselves and having the caregiving process become an overwhelming responsibility. TB programmes are obligated to provide to health care workers: adequate personal and facility-based infection control, medical supplies, training, equipment, infrastructure, and drug supply. Workers should be informed of all risks they are taking, be given a clear job description, and be afforded the same care as TB patients related to access to care should they also become infected.

If health care workers do not have appropriate environments to provide care in, they should have a process by which they can appeal to local government or the management of their facility of work for better conditions.

Isolation and Legal Interventions

Question 25

If a patient is considered infectious, isolation should be done with minimal inconvenience to the patient as well as assuring his or her quality of life. This includes separating a patient from his family with careful consideration; if the family members have already been exposed and evaluated as part of a contact tracing process, then it may not be necessary to isolate the patient from them.

Question 25, 26, and 27

Treatment for TB should be accompanied by shared information and education and mutual decision-making between the patient and health care provider. If patients are not adherent after all reasonable attempts have been made, detention may be used as a last resort measure. In this case, the welfare of the community is more important. However, involuntary isolation or detention should be done humanely and be based on established procedures which are applied to all persons, not just to those vulnerable populations for whom there may be no one to advocate on their behalf.

Research

Question 28

Research on the various aspects of TB care should be conducted within a country and at a local level on all aspects of TB care including: drugs, vaccines, treatment regimens, social determinants of disease, infection control, adherence, drug delivery, socio-behavioral interventions, epidemiology and others. It is acceptable to solicit the assistance of non-governmental organisations including universities and international organizations to assist, as long as there is a local investigator present.

Question 29

Research should be carried out to serve the benefit of local patients and communities; not just the researcher. Inherent risks should be calculated and considered prior to the initiation of research. The population in which research is being carried out should be informed of any risk that may occur. They should also be informed about any results of the research results on an ongoing basis. An ethics committee should be consulted prior to research beginning. The committee should not just be comprised of researchers, but experts on ethics as well as members of affected communities. Agreement can then be made about appropriate practices balanced with the best scientific methodology for carrying out research.

Data should be de-identified if it is linked on some way to the patient. This includes medical record information, routine surveillance data and specimens. A policy should exist on the storage of specimens and for what purpose they can be used.