Evaluation Tool for Tuberculosis Programs in Resource-limited, Refugee and Post-Conflict Settings

Version 2

CDC
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INTERNATIONAL RESCUE COMMITTEE

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The findings and conclusions in this evaluation tool are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

This January 2013 revised version of the original September 2009 tool, is the result of further consultation with the International Rescue Committee (IRC), Kenya country office and the Bureau of Population Refugee and Migration in 2011−2012. It was originally developed by the International Emergency and Refugee Health Branch of the U.S. CDC and IRC. The original health education component and the revision were funded, in part, by the Rollins School of Public Health of Emory University in Atlanta, GA, USA as portion of master's work.

With drug resistant tuberculosis occurring in all parts of the world, one of the revisions of version 2 is the incorporation of items pertaining to drug resistant tuberculosis in both the laboratory and clinical evaluation components. This revision includes a simpler format and a reduction in length of 40%.

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The Purpose of this Tool

Why this tool?

This tool is designed to support the effective evaluation of tuberculosis (TB) control programs in resource-limited, refugee camp and other post-conflict settings. Although TB control is not considered a part of responding to the acute stage of a humanitarian emergency, TB among refugees and other migratory populations is an important public health problem that has been recognized for some time (*1*,*2*). As more conflicts become protracted and more camps become long-term settlements, the necessity of quality TB control programs increases. In addition, the major of persons with TB live in resource-limited settings of Africa and South-East Asia.

Why is this tool important?

An evaluation framework is an integral part of assuring quality programming. Although some resources exist for evaluation of different elements of healthcare systems and TB control programs and should be used (in particular reference *1*); none were found that examine the whole TB control program nor were basic, practical and user-friendly (*3*). These tools are meant to be inclusive and easy to use.

Who should do the evaluation using this tool?

Given that the setting of these TB control programs is in resource-limited, refugee, and post-conflict settings, the evaluators should be representatives of the implementing partner that is providing healthcare services or the United Nations High Commissioner for Refugees (UNHCR). It is preferred that evaluators be from national or regional headquarters, rather than those directly providing healthcare services, to help limit bias.

Who should also use this tool?

This tool is primarily intended to improve performance of medical and laboratory refugee camp staff or others in post-conflict, resource-limited settings who plan, organize, conduct, and supervise TB activities. Therefore, this tool can be a helpful reference for program staff to improve programming between evaluations in these and other resource-limited settings.

Why was it developed?

On June 21, 2007, during a priority-setting meeting with the United Nations Children's Fund (UNICEF), the International Rescue Committee (IRC) asked the Centers for Disease Control and Prevention (CDC), International Emergency and Refugee Health Branch (IERHB) to develop tools to evaluate IRC's tuberculosis (TB) control programs. This tool was designed over the following months and then piloted in northeastern Kenya at five TB control programs in June-July 2008 and February 2009 and in central Kenya in February 2009. This current revision resulted from site and office visits in Ethiopia and Kenya and further desk work in 2011.

Where can I get more copies of the tool?

The tool is available for downloading at:
http://www.cdc.gov/globalhealth/ierh/ResearchandSurvey/tbtool.htm.
For CDs please e-mail: IERHB@cdc.gov. Please include your name, affiliation, mailing address and a local telephone number.

Explanation of this Tool

What is in this tool?

The evaluation tools are broken down into 4 components

1. Laboratory—especially acid fast microscopy
2. Health education—at time of admission and during treatment
3. Clinical—case management and treatment
4. Data management and logistics—statistical evaluation of laboratory activities and program performance.

- Each component has 3 parts
  - a. Evaluation worksheets are provided for the evaluator to complete
  - b. Scoring guide that includes a comments and recommendations section
  - c. Explanation worksheet of the importance of each item scored
- References and Resources and Appendices with posters and patient charter

Each of the four components of this tool should be printed and the responsible person should review the worksheets before starting.

Further Explanation of the three Parts

Each component has 3 parts- all are important.

a. The evaluation worksheet is a list of numbered items. After each item the evaluator should write the score. The importance of each numbered item is explained in the explanation worksheet. Note if an item is not applicable (N/A) or not evaluated (N/E) for that worksheet this item score should be subtracted from the total for that worksheet. Please notice that worksheets may have multiple pages.

The guidelines from the National TB Program (NTP) in the host country and the refugees' country of origin should be followed and used as references. All evaluations should be done in close collaboration with the NTP and the United Nations High Commissioner for Refugees (UNHCR). Although, all components are critical to a well-functioning program, the TB control program may put greater emphasis on some components compared with others, such as laboratory.

b. The scoring guide has information on how to score and rate each part. Each item on the worksheet has a maximum point value listed after the item number. Partial points can be given for some items; some of these reduced points are specifically indicated. If an item is N/A or N/E for that worksheet this item score should be subtracted from the total for that worksheet. All the item points must be added together to produce an overall score and rating (excellent, good, poor, failed) for the component. These scores should only be used as a guide to indicate the quality of that component; local constraints and resources may dictate different scores, ratings, and intervals of re-assessment. The overall rating suggests how long the program can go without further evaluation and highlights strengths and weaknesses of that component of programming. The scores (suggested or locally adapted) of sub-sections of each component are important to share with the program because these components cover a broad range of topics and different sub-sections may have different levels of competencies.

Within the scoring guide is the **Comments and Recommendations** section, where the evaluator can specify specific deficiencies as noted by partial point values and leave concrete recommendations. **If major deficiencies are observed in any component or sub-section during the evaluation, the evaluator should intervene to improve the program where needed.**

c. The explanation worksheet accompanies the evaluation worksheet and each numbered item is explained. The explanation worksheet also contains numbered references that can be found in the back of the tool. These additional references provide additional guidance and training resources. Please notice that explanation worksheets, as the evaluation worksheets, may have multiple pages.

Evaluation Team, Timing and Duration

The evaluation is best carried out by a team of evaluators who each have expertise in the field he or she is assessing. A laboratorian should evaluate the laboratory evaluation component; a TB clinician or expert with knowledge of the clinical-care side of TB treatment should evaluate the clinical and reporting components. Health education can be done by either a clinician familiar with TB programs or an expert in the area of behavior change communication.

This tool is designed to be used by both overseeing organizations as an evaluation, and by project managers and staff as a tool to improve program quality. When visiting a site, the evaluator from the overseeing organization should notify the clinic or TB program to be evaluated so the staff can prepare for the arrival of the evaluation team. This is especially important for assessing the health education and clinical components of the tool because several patient encounters will need to be observed. Program managers and staff can also use the evaluation as a tool to use to improve the quality of their programs.

When notifying staff of an evaluation, explain that the team will be largely observing them perform their normal activities. Although staff may be asked some questions, they should attempt to function according to their standard daily routines.

Lastly, this tool is not meant to be a comprehensive document. As always, guidelines from the World Health Organization (WHO) and NTP in the host country and the refugees' country of origin should be followed and used as references. To keep the tool simple and user-friendly, the authors designed it to be completed by two evaluators in an 8-hour day. Local IRC healthcare staff completed this evaluation tool in an 8-hour day during the pilot process.

COMPONENT 1: LABORATORY EVALUATION TOOL

Why the acid-fast smear microscopy laboratory component of tool?

Laboratories form the foundation for diagnosing TB and can often be the first points of contact for TB suspects. A well-functioning laboratory plays a crucial role in TB control. By responding quickly and providing quality service, the laboratory will enable early diagnosis, hence decreasing spread, ensuring appropriate treatment, and minimizing possible complications, including death (*4*).

Who should do this evaluation?

The evaluator needs to have a good understanding of acid-fast bacilli (AFB) smear microscopy and general laboratory practice. Methods assessed include specimen collection, smear preparation, acid-fast stain procedure, reading, and reporting. The evaluator must understand appropriate methods and ensure that they are being followed. The use of standard laboratory reference texts is encouraged and should be observed (*4*, *5*). As always, guidelines from the World Health Organization (WHO) and National TB Program (NTP) in the host country and the refugees' country of origin should be used and followed.

Further explanation of tool

There are 3 parts:

1. Evaluation worksheet for evaluator to complete
2. Scoring guide that provide suggested scores, rating, and comments and recommendations section
3. Explanation worksheet that explains importance of each item scored, including references

Point values are assigned from the experience gained during the pilot testing and during the revision and are only suggestions. If you, as the evaluator, believe the scoring should be different, that is appropriate. Your experience along with the tool should direct scoring. Resulting scores (suggested or locally adapted) of sub-sections of this component would be important to share with the program because the component covers a broad range of topics and different sub-sections may have different levels of competencies. In addition, you may want to give partial points. Partial item point values should be explained and recommendations given in the **Comments and Recommendations** section after the score guide. If major deficiencies are observed in any sub-section during the evaluation, the evaluator should intervene to improve the program where needed.

COMPONENT 1: LABORATORY EVALUATION WORKSHEET

Site _____ **Country** _____ **Date** ____/____/____
Dd/mm/yy

Write point score in last column if item passed. Write "0" if item failed. Write *N/A* if "not applicable" or *N/E* if "not evaluated."

Item No.	Point Value	Description (explanations of these items are on the next sheet)	Suggested Score
		Record Keeping: ***Evaluator observes***	**10**
1	4	Laboratory log/register is legible (legible, collection dates, quality of sputum sample [i.e., saliva] and results records) *(Give 1 point each for overall legible and for specific dates, sputum quality, and smear results)*	
2	2	Lab uses one result form per patient 1) labeling form with identification number or name and 2) patient location; this may be filled by clinician *(Give 1 point for each element)*	
3	2	Slides labeled permanently with identification number or patient's name	
4	2	Lab keeps smears for at least 1 month and stores them appropriately *(Give 1 point for each element)*	
		Sputum Collection and Transport: ***Evaluator observes laboratory staff***	**15**
5	3	Adequate supply of clean sputum containers with wide mouth and screw top (enough for 1-2 months of patients)	
6	2	Tell patients how to give adequate sputum specimen (see Appendix A)	
7	2	Obtain at least one morning sputum *(Ask technicians to explain sputum collection and timing; do not ask yes or no questions)*	
8	3	Collect sputum outside, away from others *(Ask to see location to ensure away from others)*	
9	3	Transport sputum immediately after collection or store in cold area for less than 2 days	
10	2	If transported, packaged appropriately (tightly sealed, no leakage)	
		Smearing Method Measures: ***Evaluator observes laboratory staff***	**14**
11	1	Use new, clean slides and has an adequate supply (enough for 2-3 months of patients)	
12	1	Use clean applicator for smearing	
13	2	Air-dry slide *(Ask technicians about drying times, do not ask as yes or no question)*	
14	2	Heat-fix slide (with flame or slide warmer to 65-75°C) *(Ask technicians whether heat fixing is performed. If yes, ask him/her to explain what is done [do not ask as yes or no questions])*	
For items 15-16: *Arbitrarily select 10 different stored slides (preferably from different months). If all slides good, give 4 points; if 7-8 slides good, give 3 points, if 5-6 slides good, give 2 points; otherwise, give 0 points.*			
15	4	Make appropriate smear size (1-2 cm x 2-3 cm)	
16	4	Make appropriate evenness and thickness throughout the slide	
		Stain/Reagent Preparation: ***Evaluator observes laboratory staff***	**16**
17	2	Use stains without precipitate (*Probably need to assess by examining slides)*	
18	3	Use reagent grade stains (commercial or prepared onsite)	
19	2	Store stains away from bright light or heat source	
If stains prepared on site, answer items 20-24, then skip to 26			
20	1	Use colorless or white crystal phenol and stores it in refrigerator or cool area	
21	1	Use clean water (preferably distilled, not tap water)	
22	1	Use balance to weigh 0.1 gram of stain powders	
23	3	Use approved stain formulas	
24	1	Record dates of when stains prepared and determines expiration date	
If commercial stain used, answer items 25			
25	7	Use commercial stains within expiration date	
26	2	Use stains (commercial or prepared on site) within 12 months of opening/preparing (preferably within 6 months) *(look for recorded dates)*	

Item No.	Point Value	Description (explanations of these items are on the next sheet)	Suggested Score
		Staining Procedure: ***Evaluator observes laboratory staff***	**8**
27	4	Use approved staining procedure	
28	1	Use timer for staining procedure	
29	1	Stain individual slides to prevent cross contamination	
30	2	Change solution in bottles used to stain slides every 2 weeks and records change *(Give 1 point for each element)*	
		Microscopy and Reading: ***Evaluator observes laboratory staff***	**20**
31	2	Have 100X magnification (plus 10X eye piece)	
32	2	Use microscope that is in good working order, i.e., has mechanical stage that moves freely in both axes and well maintained	
33	1	Use clean oil for slide and removes oil from slide before storing with absorbent paper (reduces risk of fungus) *(Give ½ point for each element)*	
34	4	Read each slide for 5 minutes or 100-150 fields *(Ask technicians amount of time needed to determine slide is negative; do not ask yes or no questions.* ***If only observed for 2 minutes at 100x oil immersion before reporting as negative, give 2 points)***	
35	1	Have microscope area with appropriate lighting (good ambient light on cloudy days) and sufficient seating space and without distraction or vibration	
36	2	Use positive control smear at least every week and after new reagent (*Give 1 points, if only every two weeks*)	
37	1	Use negative control smear at least every week and after new reagent	
38	3	Perform external proficiency testing at least every 6-12 months and results observed by evaluator 1-2 months after performed (*If no results, give 0 points; done yearly give 2 points*)	
39	2	Use internationally accepted grading system for reporting results	
40	1	Perform second reading on all positive slides	
41	1	Report results to clinician within 24 hours from specimen receipt	
		Safety Measures: ***Evaluator observes laboratory***	**18**
42	3	Uses biological safety cabinet (BSC). If no BSC, performs smear processing in separate area with good ventilation (open window) *(Give 2 points for good ventilation)*	
43	2	Has a hand washing facility with soap (W*ithout soap, give 1 point*) *(Ideally, evaluator will observe hand washing technique with brisk rubbing of one hand over the other)*	
44	3	Disposes of contaminated material appropriately (especially sputum and used smear-making materials) *(Need to see incinerator, area of burning or burial)*	
45	2	Cleans bench tops before and after smear preparation and immediately after <u>all</u> spills with appropriate disinfectant (see explanation for appropriate types)	
46	1	Restricts access to laboratory	
47	1	Stores flammable reagents in flammables storage cabinet	
48	2	Using standard operating procedures (SOP) in the laboratory *(Give 0 if cannot present SOP)*	
49	2	Performs 1) administrative laboratory work in separate room from 2) smear preparation and staining area *(Give 1 point for each element)*	
50	1	Provides continuing education training program for lab personnel and has documentation	
51	1	Provides annual chest X-ray (or tuberculin skin testing) for laboratory personnel	
		Cultures, including drug resistance: ***Evaluator observes laboratory***	**7**
52	2	Has access to cultures, at least for relapsed or continued smear-positive patients	
53	3	Has access to first line drug sensitivity testing (DST), at least for relapsed or continued positive smears	
54	2	Knows that culture facility has external proficiency testing at least every 6-12 months because have asked and results received within 1-2 months	
A		**SCORE ACHIEVED** (add score achieved for items 1-54)	
B		**VALUE OF N/A OR N/E RESPONSES**	
C		**SUGGESTED TOTAL SCORE POSSIBLE** (108 points minus value in line B)	

Component 1: Laboratory Scoring Guide

Site _____ **Country** _____ **Date** ____/____/____
Dd/mm/yy

	SUGGESTED SCORE GUIDE
	TOTAL SCORE from previous page (Line A)
	TOTAL SCORE POSSIBLE from previous page (Line C)
	RATING If Line C=108, use RANGE below; if TOTAL POSSIBLE POINTS <108, use PERCENTAGE

PERCENTAGE Line A divided by Line C (A/C)*100	**RANGE** Use if Line C=108	**RATING**	**SUGGESTED TIME UNTIL NEXT ASSESSMENT**
>=85%	91-108	Excellent	Needs assessment in 12-18 months
70-84%	75-90	Good	Needs assessment in 9-11 months
50-69%	54-74	Poor	Needs assessment in 6-8 months
<=49%	<=53	Failed	Needs assessment in 2-5 months

COMMENTS AND RECOMMENDATIONS

COMPONENT 1: LABORATORY EXPLANATION WORKSHEET

Item No.	Explanation
	Record Keeping
1-4	Good laboratory practices include a register or log that is legible and complete—date, sputum quality and results included and storing smears appropriately (slide box or with tissue paper between slides) for 3 months (1 at minimum). National TB Programs (NTP) usually provide registers and individual request forms; if not, the program is responsible for making both. In addition to reduce risk of confusing slides, label each permanently (pencil may be used, if end frosted). A good sputum sample is 3-5 ml, thick, mucoid quality, with pieces of purulent material, blood, and volume (*3*).
	Sputum Collection and Transport
5	Using dirty sputum containers increases risk of artifact on smear. Use a wide-mouth opening and screw-cap container to minimize risk of contaminating outside.
6-7	3 early mornings sputum samples give highest yield of obtaining a positive smear. For practical reasons, this might not be feasible or NTP guidelines. Because of lab workload in countries **where external quality assurance exists**, 2 sputum samples (1 morning) are now endorsed by WHO (*6*). Instruct patients at lab or clinic or both locations (see Appendix A). Examine sputum for quality and amount. Request repeat specimen for clear saliva and nasal discharge (but even saliva can yield positive result).
8-10	Minimize risk to other persons; collection has greatest exposure risk to laboratory personnel; however, leakage during transport has risk to personnel and reduces quality of sputum
	Smearing Method Measures
11	Reduce risk of artifact leading to interpreting result as positive finding (false-positive result).
12	With clean applicator (stick, pipette, or wire loop [if loop, remove sputum from prior specimen before flame]) collect pieces of thick, purulent material.
13-14	Do not dry smear with sunlight or ultraviolet (UV) light or leave in an unprotected area. To keep smear on slide, heat fix air-dried smear to slide by passing it with smear side up 2-3 times over flame for 2-3 seconds or by placing it on 65°-75°C electric slide warmer for >2 hours.
15-16	Size (1-2 x 2-3 cm), thickness (once dry, read print through thick film at 4-5 cm), and even across whole smear.
	Stain/Reagent Preparation
17	Dirt or precipitate in stain can lead to false-positive result. Need to assess for precipitate by examining slides or filter stain during evaluation.
18	Use only reagent grade stains.
19	Store reagents (except phenol) at room temperature or precipitates may form. Keep reagents in the dark, away from bright light in a cabinet or in brown bottles to ensure they do not break down.
20	Phenol for making fuchsin-phenol stain must be colorless or white crystal. Brown-tinted or liquid phenol is unacceptable. It must be kept in a cool, dark place (preferably a refrigerator) to remain white crystal. Phenol maintained at room temperature might degrade.
21	To reduce risk of artifact (environmental mycobacteria), use freshly prepared distilled/ deionized water.
22	Scales are needed to measure quantities for stain reagents.
23-24	Only approved formulas should be used (*4*). Good laboratory practice requires all stain reagents be dated at time of preparation. From preparation date determine expiration date.
25	Chemical stock containers should be dated when received and when first opened.
26	Use prepared staining reagents within 6-12 months of preparation and commercial stains within 6-12 months of opening (but not after expiration date).
	Staining Procedure
27	Fuchsin-phenol must be applied, heated until steaming, then rinsed with tap water and drained; decolorized with acid-alcohol (25% sulfuric acid or 3% hydrochloric acid), then rinsed and drained; methylene blue applied, then rinsed and drained; and then dried at room temperature. Times may vary, though one suggestion of times is: fuchsin-phenol for 5-10 minutes, then rinsed; acid-alcohol for 2-3 minutes, then rinsed; and methylene blue for 1 minute, then rinsed.
28	Too difficult to ensure appropriate times to ensure appropriate staining without a timer.
29-30	Staining jars should not be used because of cross-contamination. Best practice is to stain slides individually. Staining bottles should be changed every 2 weeks and documented.

Item No.	Explanation
	Microscopy and Reading
31	Use 100X magnification (plus 10X eye piece) to scan smear and count any AFB seen.
32	Systematically observe slide, i.e., side-to-side or up-and-down pattern; stage must operate in both axes. To correctly read slides, microscope needs to be free of dust that might interfere with reading. Use known positive and negative controls to determine quality of staining and microscope. Clean, cover with vinyl or cotton cloth, and store microscope in secure place free from moisture and dust.
33	Use clean, clear, and low in viscosity oil (not wood oil) to ensure optimum optical conditions. Oil must be wiped off objective lens with lens or fine tissue paper at the end of each working day. Remove oil from slides with tissue paper before storing to reduce risk of artifact and fungus.
34	At 100X magnification, use side-to-side or up-and-down sweeps of smear, taking care not to scan the same area twice. Observe 100-150 fields or for 5 minutes before calling a smear negative for AFB.
35	Have appropriate lighting and seating. Comfortable seating and microscope area free from distractions or vibrations aids the technicians' attention span and more accurate observation of slide.
36-37	Stain a positive control smear containing AFB and a negative control smear containing no AFB at least weekly, daily recommended. Each new stain solution must be tested with a positive control and negative control smear before staining of patients' smears.
38	National or International Proficiency Testing Programs provide clinical specimens or slides to be tested to determine lab's ability to give an accurate readings. Observe proficiency testing results and that they are performed regularly (preferably every 6 months with results received within 1-2 months).
39	A reporting scheme of AFB found must be used. One scheme is: • 0 AFB/100 fields: negative • 1-9 AFB/100 fields: actual number of AFB seen on whole slide • 10-99 AFB/100 fields: 1+ • 1-10 AFB/field in 50 fields: 2+ • >10 AFB/field in 20 fields: 3+ With revised WHO case definition (*6*), the presence of at least 1 acid fast bacilli (AFB+) in at least 1 sputum sample is a sputum smear-positive pulmonary TB case.
40	For good quality assurance, previously examined slides should be rechecked in a blinded fashion. In addition, recheck positive slides for confirmation should be done. See External Quality Assessment for AFB Smear Microscopy (http://wwwn.cdc.gov/dls/ila/documents/eqa_afb.pdf).
41	To response to the needs of physicians and patients (and to minimize exposure), test results should be available within 24 hours of specimen receipt.
	Safety Measures
42	Although a Biological Safety Cabinet (BSC) is not required, it is recommended. If develop simple-to-make cabinets with low-level sophistication and materials, need to assess function. Place a piece of tissue paper at opening to confirm air flow to inside cabinet
43	Good laboratory practices (GLP) is to have hand washing station and wash hands frequently with soap and water before and after every procedure.
44	Dispose contaminated material (i.e., used sputum cups, applicators, and slides) in accordance with standard procedures; this includes burning (incineration), burying, or autoclaving.
45	GLP includes cleaning of benches and equipment. Use phenolic agents or bleach solution for disinfectant for all spills and before/after making smears (bleach solution is good for blood pathogens, not TB).To ensure greater ease with cleaning the benches and reduce risk of trapping infectious materials, it should be a continuous surface and have separate area for smear preparation and staining
46	To minimize risk for exposure, access to laboratory should be restricted with doors closed.
47	Flammables (alcohols and organic solvents), strong acids, and strong bases should be stored in a flammables storage cabinet to minimize risk of spills that may cause fires or injuries.
48	Standard operating procedures (SOP) for procedures used must be written, used, and readily available. Find examples at: http://www.epa.gov/quality/qs-docs/g6-final.pdf or http://www.fao.org/docrep/W7295E/w7295e04.htm)
49	Reduce risk of exposure to infectious materials.
50	Ensure that staff are professionals and maintain professional growth.
51	Assess potential of TB disease; aerosolized *Mycobacterium tuberculosis* may be produced when handling leaking specimens, opening sample containers, and preparing smears.
52-54	WHO does not require drug sensitivity testing (DST) but recommends it for HIV-infected, relapse or retreatment patients. Many NTPs have DST and should do proficiency testing. WHO endorses Xpert® (http://www.finddiagnostics.org/media/press/101208.html) for rapid detection of TB and resistance.

COMPONENT 2: HEALTH EDUCATION EVALUATION TOOL

Why the health education component of tool?

Health education and the relationship between patients and provider are important aspects to ensure treatment success. Use this section to observe patient intake on a typical day of either initiating treatment, providing directly observed therapy (DOT), or refilling medication. Ideally include patients in the intensive phase, at the beginning the continuation phase, and at some other point in the continuation phase of treatment.

This tool should be used in combination with the clinical encounter evaluation tool, as items are not repeated between the two.

Who should do this evaluation?

The evaluator should have a working knowledge of tuberculosis (TB) and either speak the language or use an independent translator so as not to disrupt the clinic.

Further explanation of tool

There are 3 parts:

1. Evaluation worksheet for evaluator to complete
2. Scoring guide that provide suggested scores, rating and comments and recommendations section
3. Explanation worksheet that explains importance of each item scored, including references

In completing the evaluation worksheet, the evaluators should watch three to five patients coming for various stages of treatment. The point values are assigned from the experience gained during the pilot testing and during the revision and are only suggestions. If you, as the evaluator, believe that scoring should be different that is appropriate, your experience along with the tool should direct your scoring. Resulting scores (suggested or locally adapted) of sub-sections of this component would be important to share with the program because the component covers a broad range of topics and different sub-sections may have different levels of competencies. In addition, you may want to give partial points. Partial item point values should be explained and recommendations given in the **Comments and Recommendations** section after the score guide. If major deficiencies are observed in any sub-section during the evaluation, the evaluator should intervene to improve the program where needed.

COMPONENT 2: HEALTH EDUCATION EVALUATION WORKSHEET

Site _____ **Country** _____ **Date** ____/____/____
dd/mm/yy

Write point score in last column if item passed. Write "0" if item failed; *N/A* if "not applicable" or *N/E* if "not evaluated."

Item No.	Point Value	Description	Suggested Score
	Individual Patient Education: ***Evaluator observes healthcare workers (HCW) with 3-5 patients; if item not observed, ask HCW open-ended questions about each item possible***		
		Adherence	**10**
1	3	Ask patients (or caregivers, if patients are children) if they missed any days of therapy	
2	2	If they (patients/ caregivers) missed days, ask what was done (e.g., took the next day) and counsel for better adherence *(If no problems, ask HCW how they would counsel patient)*	
3	4	Remind patients about the dangers of defaulting from treatment	
4	1	If starting continuation phase, tell patients differences between intensive and continuation treatment phases *(If not observed, ask HCW how they would explain differences)*	
		Side Effects	**15**
5	4	Ask patients about any new symptoms (possible side effects to treatment)	
6	4	Remind patients to come to the clinic immediately, if they have severe side effects, such as cola colored urine, yellow eyes, and rash	
7	2	Ask female patients about pregnancy *(If male or if not pregnant, give 2 points)*	
8	2	Ask about eyesight and inability to see red and green colors, if on ethambutol *(If ethambutol not given, give 2 points)*	
9	1	Offer ibuprofen (or other anti-inflammatory drug), if having joint pains	
10	2	Give pyridoxine/vitamin B6, if tingling or burning sensation in hands or feet	
		Contacts	**8**
11	2	Tell (or told at start of therapy) patients about risk to others of their TB disease	
12	6	Tell patients to bring neighbors, family members, or other contacts who have been coughing for 2-3 weeks AND their children <5 years of age (regardless of symptoms), to the clinic for evaluation *(Give 3 points each)*	
		Risks	**7**
13	3	Tell patients about risks to their liver of drinking alcohol and taking acetaminophen/paracetamol *(Give 2 points for each)*	
14	1	Tell patients about risks to their lungs of smoking	
15	3	Offer patients HIV testing, if not accepted before *(If already done, give 3 points) (If testing not offered or location where offered not explained to patient, give 0 points)*	
		Follow-up	**5**
16	2	Ask about and address any and all patient fears, misunderstandings, and questions	
17	3	Make next appointment for patients and tell them exactly where they need to return, including for sputum smears *(If all explained except location of lab, give 2 points)*	
	Community Education: ***Evaluator observes workers or TB programs***		
		Health Outreach Program	**5**
18	2	Ask patient whether he or she had heard about TB from community health workers home visits, public media and/or social organizations before treatment *(Give 1 point, for 1 health outreach, but not a multiple outreaches)*	
19	1	Use cured patients as teaching resources	
20	2	Hold group sessions as well as individual sessions	
A		**SCORE ACHIEVED** (add score achieved for items 1-20)	
B		**VALUE OF ALL N/A OR N/E RESPONSES**	
C		**SUGGESTED TOTAL SCORE POSSIBLE** (50 points possible minus line B)	

COMPONENT 2: HEALTH EDUCATION SCORING GUIDE

Site _____ **Country** _____ **Date** ____/____/____
dd/mm/yy

	SUGGESTED SCORE GUIDE
	TOTAL SCORE from previous page (Line A)
	TOTAL SCORE POSSIBLE from previous page (Line C)
	RATING If Line C=50, use RANGE below; if TOTAL POSSIBLE POINTS <50, use PERCENTAGE

PERCENTAGE Line A divided by Line C (A/C)*100	**RANGE** Use if Line C=50	**RATING**	**SUGGESTED TIME UNTIL NEXT ASSESSMENT**
>=85%	43-50	Excellent	Need assessment in 12-18 months
70-84%	35-42	Good	Need assessment in 9-11 months
50-69%	25-34	Poor	Need assessment in 6-8 months
<=49%	<=24	Failed	Need assessment in 2-5 months

COMPONENT 2: HEALTH EDUCATION EXPLANATION WORKSHEET

Item No.	Explanation
	Individual Patient Education – ***observe education with 3-5 patients; if item not observed, ask HCW open-ended questions about each item possible***
	Adherence
1-3	If patients stop drugs before treatment completed (even for a short time), the remaining bacteria can grow stronger than the drugs being taken; the person can develop drug-resistant TB, so different drugs will be needed for cure. If a patient stops completely, he or she could spread TB to others, especially family members. Young children infected with TB can become very ill, even die. Education should include that for each day of therapy missed, additional days of treatment will be given. Health staff can help patients predict potential treatment problems and proactively solve them. Simple daily life events and circumstances can cause patients to not adhere to treatment regimen. Staff should talk about these obstacles and help the patient find solutions, such as: • Link a daily routine to taking medicines o Routine activities could be mealtime, before or after their prayers, or bathing. Activities will be different according to each population. • If a dose is forgotten, take it as soon as possible. If it is almost time for the next dose, skip the missed dose and go back to the daily routine. The most important thing the staff can do is to help the patient find adherence problems is: • Define what the problem is with the patients, • Search for solutions together, and • Anticipate future problems. • For children on treatment, developing a daily medication routine in partnership with a responsible adult caregiver is important for adherence success. Providing positive reinforcement is important to involve the child and build trust. At each monthly visit, revisit adherence problems the patient has faced to make sure that they do not continue to be problems. One way to assess for missed pills is to have patients return each visit with pill bottle or blister pack **(ideally, treatment should be provided under directly observed therapy)**
4	Explain continuation versus intensive therapy, even though the number of pills may be the same with combination pills.
	Side Effects
5-10	Ask about and explain severe side effects and contraindications; most people have no problems with treatment. Most side effects will occur early in treatment and go away on their own after a few weeks. Tell the patient to report <u>any</u> side effects, except orange/red urine when taking rifampicin. The most common side effect is stomach-gut complaints, such as loss of appetite, stomach pain, nausea, and vomiting. If nausea develops after taking drugs, take them with food or milk and eat multiple small meals and before going to sleep. Most of the drugs are broken down by the liver, so swelling or damage of the liver can occur. Severe liver damage (called severe hepatotoxicity) occurs in only 1 in 1,000 people, causing nausea and vomiting <u>and</u> the urine to turn dark (like the color of cola, NOT to be confused with urine turning orange/red from rifampicin). Tell the patient if he or she develops dark-colored (not red/orange) urine to stop taking the drugs and return to clinic immediately. A monthly color vision examination to assess ethambutol toxicity should be part of the screening examination. Other side effects include (see Appendix A) (*9*): • Skin reactions such as itching or skin rash • Reactions of the nerves such as burning (with isoniazid) • Pains in the joints (with pyrazinamide) • Dizziness • Decrease in sight or difficulty telling red and green colors apart (with ethambutol) • Deafness (with streptomycin)
	Continue on next page

Item No.	Explanation
	Contacts
11-12	**Anyone can get TB,** when TB patients cough, sneeze, or even talk or sing near another person the TB bacteria can be breathed in and TB develop. This is especially true for children younger than 5 years old and for people with weak defenses, (i.e., someone with HIV). The biggest chance of getting TB is from spending a lot of time (8 hours or more) with someone who has TB and is not being treated, especially where there is poor air flow or in poorly ventilated areas. TB patients should be separated from others and stay in a well-ventilated area. Each patient should have a covered container for sputum, which is disposed of safely (add bleach to contents). TB patients should wear masks when in contact with others. Any young children and others close to the TB patient who have TB symptoms (night sweats, fever, a cough lasting more than 2-3 weeks, weight loss, fatigue, chest pain while breathing or coughing) need to report to the clinic immediately to be tested for TB. Young children may have no symptoms, except failure to gain weight or weight loss and should be referred for evaluation. **Methods for contact tracing of close contacts can be found in the references** (*10*).
	Risks
13-14	Explain risks and contraindications. Patients may abuse alcohol or local brew during their treatment but reveal it. Therefore, counsel all patients (with exception) on the risks that alcohol and local brew pose to their health. Specifically, the combination can have bad effects on the liver and nerves. Health workers should be open and honest when talking about alcohol use and be careful not to be judgmental. In addition explain: • Paracetamol or acetaminophens, like alcohol, are broken down by the liver. So paracetamol can harm the liver. For headaches, joint or muscle pain, or fevers, tell patients to ibuprofen or aspirin, if anything. **Children should not take aspirin, if they have a fever.** • Cigarette smoking can scar the lungs and prevent the lungs from clearing the sputum or phlegm. TB patients should stop smoking or never start.
15	Recommend and encourage HIV testing. HIV affects the body's defenses or immune system, and makes people more vulnerable to TB; TB can develop more often, rapidly, and more often travel outside the lungs to other parts of the body, like the lining of the brain, causing TB meningitis. **Having TB does not mean the patient has HIV.** Both HIV and TB have treatment and TB can be cured. All HIV-infected adults and adolescents should be screened for TB disease using a clinical algorithm and offered isoniazid if the screen is negative. HIV-infected children, who do not have risk of TB nor any TB disease found, should receive isoniazid. (Adults: isoniazid 5 mg/kg or 300 mg daily; children: isoniazid 10mg/kg daily, or 300mg daily maximum) for 6-9 months. (*1, 11, 12, 13, 14*)
	Follow-up
16-17	Staffs need to be open by addressing fears, welcoming questions, making next appointment.
	Community Education
	Health Outreach
18	Broadly disseminate messages using a variety of mediums to maximize the number of people with TB knowledge and their ability to communicate these messages to others. Saturate the community with knowledge, healthy behaviors regarding prevention, early case detection, and decreasing stigma become social norms. **Religious services** can be one of the best ways to disseminate messages. Religious leaders are often well respected for their views even in nonreligious matters such as health. They also have a captive audience at religious services, which can be used creatively to talk about disease in the community. **Social organizations** such as women's groups, youth groups, etc. often can creatively adapt messages to local situations and often have capable and willing participants. **Economic organizations** such as farmer's cooperatives or local business owners can also be important allies to get messages into the community. In low-resource settings, these organizations are often composed of men, who are responsible for decision-making in their households. Thus, getting their cooperation and understanding can affect entire households. **Other** media not mentioned here also should receive partial points.
19	Use cured patients as teaching resources because of their knowledge of the disease, treatment regimens, drug side-effects, etc. Do not identify any individuals currently with TB. They can also be helpful in decreasing the stigma associated with the disease by demonstrating that TB is curable.
20	Use group sessions as well as individual sessions to reach as many people in as many ways as possible.

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COMPONENT 3: CLINICAL ENCOUNTER EVALUATION TOOL

Why the clinical encounter component of tool?

The relationship between patients and provider and health education are important aspects to ensure treatment success. The tool should be used in combination with the health education tool, as items are not repeated between the two.

Who should do this evaluation?

The evaluator should be a TB clinician or expert with knowledge of the clinical-care side of TB treatment. As always, guidelines from the National TB Program (NTP) in the host country and the refugees' country of origin should be followed and used as a reference. Other references are provided (*11-15*).

Further explanation of tool

There are 3 parts:

1. Evaluation worksheet for evaluator to complete
2. Scoring guide that provide suggested scores, rating, and comments and recommendations section
3. Explanation worksheet that explains importance of each item scored, including references.

Evaluators should watch three to five patients coming for various stages of treatment (intensive and continuation phase). The point values are assigned from the experience gained during the pilot testing and during the revision and are only suggestions. If you, as the evaluator, believe the scoring should be different, that is appropriate; your experience along with the tool should direct your scoring. Resulting scores (suggested or locally adapted) of sub-sections of this component would be important to share with program because the component covers a broad range of topics and different sub-sections may have different levels of competencies. In addition, you may want to give partial points. Partial item point values should be explained and recommendations given in the **Comments and Recommendations** section after the score guide. If major deficiencies are observed in any sub-section during the evaluation, the evaluator should intervene to improve the program where needed.

COMPONENT 3: CLINICAL EVALUATION WORKSHEET

Site _____ **Country** _____ **Date** ____/____/____
dd/mm/yy

Write point score in last column if item passed. Write "0" if item failed; *N/A* if "not applicable" or *N/E* if "not evaluated."

Item No.	Point Value	Description	Score Suggested
		Clinical Patient Evaluation: ***Evaluator observes healthcare workers (HCW); if item not observed, ask HCW open-ended question about item, not yes or no questions***	**24**
1	2	Give (or gave at start of therapy) patients a simple explanation of what TB disease is and how it is contracted	
2	1	Ask (or asked at start of therapy) patient about exposure history (source of disease)	
3	4	Ask and record (or asked and recorded at start of therapy) about any prior TB treatment, specifies medications given	
4	2	Ask about allergies to other (non-tuberculosis) medications and past medical history (PMH) and record it (with the symptoms of allergic reaction, if possible) *(Give 1 point each for allergies and PMH)*	
5	1	Sign (or signed at start of therapy) charter with patient (see Appendix B)	
6	4	Give at start and complete each visit an individual patient card with name and follow-up visits **(see Component 2, item 17)**	
For item 6: *Evaluator obtains information by examining 5 medical records of patients (preferably medical records of discharged patient). If a weight is obtained monthly, give 4 points; If 4 weights are obtained in 6 months of treatment, give 3 points; if 3 weights are obtained, give 2 points; otherwise, give 0 points.* ***OR*** *evaluator can observe 4-5 patient encounters. If all patients weighed and recorded, give 4 points; if 4 patients weighed and recorded, give 3 points; if 3 patients weighed and recorded, give 2 points; otherwise, give 0 point. Weights must be recorded, otherwise 0 points*			
7	4	Obtain, record, and use weight information. Ask HCW how the weight is used *(If obtain and record but do not use weight to assess patient's progress, give 2 points)*	
8	4	Ask patient about possible signs of drug resistance *(After patients seen, ask HCW what are the signs. Do not ask as yes or no questions)*	
9	2	Provide supplemental feeding monthly *(If only during intensive phase, give 1points)*	
		Clinic Infection Control: ***Evaluator observes HCW***	**10**
10	2	Patient sitting in well-ventilated area while waiting for HCW	
11	2	Level of infection control in clinic—sunlight, ventilation *(Give 1 point each)*	
12	2	Necessary materials (gloves, disposal or reusable medical materials, masks, disinfectant) *(If all materials seen, give total points; Give ½ points per element)*	
13	2	Administer streptomycin under aseptic means (if multiuse vial, top is cleaned and sterile syringe used each time. **Never** leave needle in vial)	
14	2	Dispose of needles safely	
		Medications: ***Evaluator observes HCW***	**25**
For items 15-20: *Ask HCW to explain the different medications (do not ask as yes or no questions but ask for his/her explanation of phases). These days drug resistance is an increasing concern so ask about it too*			
15	4	Know intensive and continuation medications for first-time treatment per WHO or national guidelines *(Give 2 points for each phase)*	
16	4	Know intensive and continuation medication for retreatment *(2 points per phase)*	
17	2	Evaluator observes chart with maximum dosage for each medication *(often found on wall of clinic, but may need to ask for it)*	
18	3	Know what multiple-drug resistant (MDR) TB means	
19	3	Knows must treat MDR TB 18-24 months after negative culture *(Ask HCW treatment duration. Do not ask as yes or no questions)*	
20	3	Uses appropriate guidelines for MDR TB treatment	

Item No.	Point Value	Description	Score Suggested
21	6	Program gives DOT (observed swallowing), for how long (√ the box)? ☐ not given ☐ 2 months ☐ total course *(Give 6 points for total course, give 3 points for 2 months; give 5 points for >2 months but less than total course; if DOT not given, but blister packs asked for and examined at each subsequent visit, give 1 point)* ***Patients must be observed***	
		Laboratory Follow-up: *Evaluator observes HCW*	**8**
For items 22-23: *Ask HWC to explain sputum smear intervals (do not ask as yes or no questions but ask for their explanation). In addition for item 19, review the patient records or the medical records of those presenting today*			
22	4	Request sputum smears at intervals according to Ministry of Health or World Health Organization for initial smear-positive case *(If less than 3 times, give 2 points; if less than 2 times, give 0 points)*	
23	2	Repeat sputum smears in 1−2 month(s) for patients with positive smear	
24	2	Evaluator observes HIV testing methods for reliability (cold chain maintained, kits within expiration date—full assessment under HIV program) *(Give 1 point, if kits within expiration date and 1 point, if good chain equipment used [refrigerator in correct range for kits]. NOTE: kits should be those that can be stored at 30℃; however, many areas where refugees reside and resource-limited areas can have average daily temperatures >35℃).*	
		Contact Tracing and Prophylaxis: *Evaluator observes HCW*	**5**
For items 25-26: *Ask the health workers (HCW) to explain prophylaxis and protection of BCG. (Do not ask as yes or no questions but ask for his/her explanation).*			
25	3	Give prophylaxis to children <5 years old and HIV-infected persons with exposure to smear-positive case *(Give 2 points, if give prophylaxis only to HIV-infected persons)*	
26	2	Can describe protection and lack of protection of BCG *(Give1 point for each element)*	
		Policies: *Evaluator observes clinic staff*	**6**
27	2	Have mechanism (referral sheet for transfer in and transfer out) and follow-up activities for transfers (NOTE: some programs have patients hospitalized for 2 weeks until smear negative; need to ensure excellent infection control, if this is a practice) *(If referral sheet but no follow-up activities back from referral facility, give 1 point).*	
28	4	Have access to radiology services for cases (*If only smear negative, give 2 points)*	
		Hospital: *Evaluator observes hospital staff*	**10**
29	2	Have established criteria for hospitalization (some program admit for 2 weeks, see item 27) *(If only verbal criteria that are well explained but not written, give 2 points)*	
30	3	Have infection control in hospital—sunlight, ventilation, mask wearing *(If only sunlight and ventilation, give 2 points)*	
31	1	Provide sputum pots/mugs with covers and disinfectant to hospitalized patients	
32	4	Have adequate waste management: 1) type: incinerator; burial not desirable for hospital capacity; and 2) frequency: build-up of waste not observed *(give 2 point per element: if burial, give 1 of 2 points; if build-up, give 0 of 2 points)*	
A		**SCORE ACHIEVED** (add score achieved for items 1-32)	
B		**SUBTRACT NUMBER OF N/A OR N/E RESPONSES**	
C		**SUGGESTED TOTAL SCORE POSSIBLE** (88 points possible minus value in line B, above)	

COMPONENT 3: CLINICAL SCORING GUIDE

Site _____ **Country** _____ **Date** ____/____/____
dd/mm/yy

	SUGGESTED SCORE GUIDE
	TOTAL SCORE from previous page (Line A)
	TOTAL SCORE POSSIBLE from previous page (Line C)
	RATING If Line C=88, use RANGE below; if TOTAL POSSIBLE POINTS <88, use PERCENTAGE

PERCENTAGE Line A divided by Line C (A/C)*100	**RANGE** Use if Line C=85	**RATING**	**SUGGESTED TIME UNTIL NEXT ASSESSMENT**
>=85%	74-88	Excellent	Need assessment in 12-18 months
70-84%	61-73	Good	Need assessment in 9-11 months
50-69%	44-60	Poor	Need assessment in 6-8 months
<=49%	<=43	Failed	Need assessment in 2-5 months

COMMENTS AND RECOMMENDATIONS

COMPONENT 3: CLINICAL EVALUATION EXPLANATION

Item No.	Explanation
	Clinical Patient Evaluation
1-4	Observe at least one first-time assessment of a patient, among the 3-5 patients, with potential TB (in an environment with minimal risk of exposure, e.g., outside) to determine if all items are being asked (these items may only be asked the first-time). If a new patient encounter is not observed, ask the healthcare workers (HCW) after all patients are seen what he or she asks new patients (you may want to pretend to be the patient to make this less artificial). Asking about history of exposure with TB, including whether **contact had drug-resistant TB**; and medication allergies is not as important as asking about prior TB treatment. Children acquire TB from adults, **it is important to find contact in children. Prior treatment increases a person's risk of having drug-resistant TB.**
5	Having patients sign a charter places greater responsibility of care on the individual and is a good but not required procedure (see Appendix B) (*16*).
6	Having patients have their own card with follow-up appointments adds to compliance; attention needs to be given respect confidentiality of these patients
7	View at least five arbitrarily selected medical records to determine whether weights are obtained and recorded monthly (children should be weighed at each visit). In some settings, weekly (during intensive phase) or monthly (during continuation phase) **weights may be the only objective sign of improvement** on treatment, so must be reviewed.
8	Continued cough and other symptoms, no weight gain, and continued smear-positive sputum might imply drug-resistant TB. Also, close contacts of a patient with drug-resistant TB have a greater risk of acquiring drug resistant TB themselves. HCW needs to ask patients about these symptoms.
9	Most programs/organizations support supplemental feeding of HIV patients; should be done for TB patients, too.
	Clinic Infection Control
10-12	Ensure patients are not sitting in a confined area for periods of time; although gloves and masks are not required, appropriate disposal and disinfection of medical material is required. Use phenolic agents or bleach solution for disinfectant. Gloves and coats or gowns do not prevent TB transmission, but they are good medical practice. Good clinical practice includes using gloves, disposal material and disinfectants (to destroy microorganisms on non-living objects). (NOTE: these materials do not prevent TB transmission, they are good medical practice)
13	Nosocomial (hospital-acquired) infections result from poor technique during injection procedures.
14	Needlestick injuries of HCW increase their risk for bloodborne infections. Never recap needles. Dispose of them in a puncture-proof container. If standard 'sharps container' is not available, a container of thick plastic, metal, or wood can be used.
	Medications
15-16	Use World Health Organization (WHO) or National TB Program (NTP) regimen for pan-sensitive TB.
17	Observe chart with dosage by weight and presence of scale.
18-20	Drug resistant TB is occurring in all parts of the world and must be keep in mind whenever dealing with relapse patients or patients with persistently positive sputum in spite of treatment. Multiple-drug resistance (MDR) is defined as resistant to rifampicin and isoniazid; extensively drug resistance (XDR) is resistant to these and any fluoroquinolone and at least 1 of 3 second-line injectable drugs (amikacin, kanamycin, capreomycin) (http://www.cdc.gov/tb/topic/drtb/default.htm). Treatment of these resistant forms requires consultation with an expert in treatment as second-line drugs are patient's last best hope for cure. Treatment requires 18-24 months after negative culture. Guidelines include NTP, WHO (http://www.who.int/tb/publications/2010/9789241547833/en), International Standards for Tuberculosis Care (http://www.theunion.org/index.php/en/resources/technical-publications/item/194-international-standards-for-tuberculosis-care), Curry International Tuberculosis Center (http://www.currytbcenter.ucsf.edu/drtb/docs/MDRTB_book_2011.pdf). (*17-19*)
21	HCW should be trained in the importance of directly observed therapy (DOT). HCW need to see the person swallowing the pills. This should occur at least during the intensive phase. DOT can be given daily (except Sunday) or, if rifampicin given, three times per week.

Item No.	Explanation
	Laboratory Follow-up
22-23	Sputum smears are obtained according to schedule of WHO or NTP guidelines, including after positive smears.
24	All TB patients are offered HIV counseling and testing, but only if testing is known to be reliable—cold chain guaranteed and documented.
	Contact Tracing
25-26	Family members, especially children and those infected with HIV, have the greatest risk of becoming infected and developing TB, and need to be followed clinically on a regular basis. If exposed to smear-positive family members but without disease, HIV-infected persons and children <5 years should receive prophylaxis (Adults: isoniazid 5 mg/kg or 300 mg daily; Children: isoniazid 10mg/kg daily, or maximum 300mg daily) for 6-9 months. As shown in some studies, BCG does not prevent pulmonary TB, but it does reduce the risk for disseminated or extrapulmonary TB, especially in children <5 years old (*20-22*). Live vaccines should not be given to HIV-infected persons. If tuberculin skin test (TST) is available, children of smear-negative family members should be tested and given prophylaxis if TST is 10 mm or more (*11-12, 23*).
	Policy
27	Set mechanism and timing for follow-up on defaulters, usually by 2 missed appointments. Community health workers can be helpful with finding patients who have defaulted therapy. HCW should generate lists at least monthly (more often for patients in intensive phase). Set mechanism and activities for **reintegration or repatriation, if communication established and healthcare available and reliable in country of origin** (*1*).
28	Although chest radiograph is not a part of WHO case definition of TB, access to this service is important in difficult cases where the sputum smear is negative.
	Hospital
29	Indications for hospitalization • Severe disease (e.g., meningitis, extreme wasting, blood in sputum) requiring nursing care and close observation • Serious treatment complications (e.g., jaundice, severe skin reaction such as Stevens Johnson syndrome) • Serious concomitant disease (e.g., malaria, diabetes, liver or kidney failure) • Logistical difficulty (e.g., patient from remote area) • If accommodations and treatment possible, continued smear-positive patient who is not improving
30-32	Great risk of TB transmission exists in hospitals where patients are already immunocompromised to some degree. TB patients should be separated from other patients in a well-ventilated area. Each patient should have a covered container for sputum, which is disposed of safely (preferably incinerated or autoclaved). TB patients should be transported to other areas of the hospital as little as possible and should wear masks during transport. Administrative control (prompt recognition, separation and treatment of infectious patients) and environmental control (ventilation, UV light) measures are the first two lines of defense against nosocomial transmission of TB. Because TB is transmitted in the air, gloves and coats or gowns do not reduce the risk of TB transmission but hand washing and glove use are good hospital and laboratory practice. Quaternary ammonium compounds are ineffective for destroying *M. tuberculosis*; chlorine in high concentrations at a 1:5 dilution (250 ppm) for 10 minutes (less concentration and time, not biocidal) and 5% phenol in water have killing action (*24*). Use of personal protective equipment and good waste management are important in reducing infections to patients and staff.

COMPONENT 4: DATA MANAGEMENT AND LOGISTICS TOOL

Why the data management component of the tool?

Systematic record keeping plays another crucial role to a well-functioning TB program. Good record keeping is necessary for following and managing individual patients effectively, determining whether the program is performing according to accepted standards, and identifying problems that require corrective actions (*1*). In addition, regular monitoring of a program is paramount; WHO guidance for monitoring and evaluation can be found elsewhere *(25).*

Who should do this evaluation?

The evaluator should be a clinician or TB expert with knowledge of the clinical and programmatic care side of TB treatment. As always, guidelines from the National TB Program (NTP) in the host country and the refugees' country of origin should be followed and used as a reference. In addition, other references are provided (*1, 13, 15, 17, and addition found in References section*).

Further explanation of tool

There are 3 parts:

4. Evaluation worksheet for evaluator to complete
5. Scoring guide that provide suggested scores, rating, and comments and recommendations section
6. Explanation worksheet that explains importance of each item scored, including references.

The point values are assigned from the experience gained during the pilot testing and are only suggestions. If you, as the evaluator, believe the scoring should be different that is appropriate, your experience along with the tool should direct your scoring. Resulting scores (suggested or locally adapted) of sub-sections of this component would be important to share with program because the component covers a broad range of topics and different sub-sections may have different levels of competencies. In addition, you may want to give partial points. Partial item point values should be explained and recommendations given in the **Comments and Recommendations** section after the score guide. If major deficiencies are observed in any sub-section during the evaluation, the evaluator should intervene to improve the program where needed.

COMPONENT 4: DATA MANAGEMENT EVALUATION WORKSHEET

Site _____ Country _____ Date ____/____/____
dd/mm/yy

Write point score in last column if item passed. Write "0" if item failed; *N/A* if "not applicable" or *N/E* if "not evaluated."

Item No.	Point Value	Description (explanations of these items are on the next sheet)	Score Suggested
		Registers: *Evaluator observes*	**22**
1	2	Patient registry exists, is used consistently, and is functional	
		Record Keeping for Diagnosis and Treatment: *Evaluator observes*	
For items 2-6: *Arbitrarily (not consecutive) select 10 TB medical records of the last 5 months for patients in continuation phase (If 9-10 medical records are correct for an item, give 4 points; if 7-8 medical records correct, give 3 points; if 5-6 medical records correct, give 2 points; if less correct, give 0 points)* *If medical records are not used, check appointment cards of 5 patients (If 5 appointment cards are correct for an item, give 4 points; if 4 appointment cards correct, give 3 points; if 3 appointment cards correct, give 2 points; if less correct, give 0 points*) for:			
2	4	Results of initial smear indicated	
3	4	Smears examination at 2 months indicated	
4	4	Additional smears indicated (at 5 months, at end of treatment)	
5	4	Dates and regimen of intensive phase of treatment indicated *(Give 2 points for each [date and regimen] if written for each visit; give 1 point for each, if 1 missing; give 0 points, if 2 or more missing)*	
6	4	Dates and regimen of continuation phase of treatment indicated *(Give 2 points for each, if written for each visit; give 1 point for each, if 1 missing; give 0 points, if 2 or more missing)*	
		Reports: *Staff can provide evaluator*	**12**
7	2	Know how to and generate monthly or quarterly (every 3 months) reports for number of patients	
8	2	Know how to and generate monthly or quarterly reports for patient types—pulmonary/extrapulmonary, smear-positive/smear-negative	
9	4	Know how to and generate monthly or quarterly reports for patient outcomes—rates for cure, treatment completion, default, relapse, transfer, death	
10	2	Clinic gives numbers to the National TB Program on at least quarterly basis	
11	2	Clinic gives numbers to HIS (Health Information System of United Nations Refugee Agency—put N/A if not refugee setting) on a monthly basis	
		Default Tracing: *Evaluator asks healthcare workers (HCW)*	**12**
12	4	HCW begins tracing patients 7 days after overdue appointments (or 14 days) in intensive phase *(If tracing at 21- 30 days from appointment, give 2 points; if tracing at 28-35 days from appointment, give 1 point)*	
13	4	HCW begins tracing patients 1 months after overdue appointments (or 2 months) in continuation phase *(If tracing at 3-4 months from appointment, give 2 points; if tracing at 4-5 months from appointment, give 1 point)*	
14	4	Clinic has default rate ≤10% *(If 11%-15%, give 2 points; if >15%, give 0 points)*	
		Contact Tracing and Treatment: *Clinic*	**4**
15	4	Has proportion of pediatric patients (for example, <15 years old) to total patients ≥11% in high burden countries *(If 5%-10%, give 3 points; if <5%, give 0 points)* OR proportion of pediatric patients receiving isoniazid preventive treatment ≥85% in low burden countries (*if 60%-84%, give 3 points, if <60%, give 0 points*)	
Continue on next page			

Item No.	Point Value	Description (explanations of these items are on the next sheet)	Score Suggested
		Treatment, Medication, Supplies: *Clinic*	**20**
16	4	Has sufficient supply of anti-TB drugs: no stock outs have occurred in last 6 months (*If 1 stock out for less than 1 week, give 2 point; anything more give 0 points)*	
17	4	Maintains drugs in appropriate location (not too hot—this can be assured with thermometer monitoring temperature during the hottest time of day)	
18	4	Drugs are from a reputable source, such as the National TB Program (NTP)	
19	4	Does not have expired drugs	
20	4	Has adequate supplies of needles, syringes, diluents for injection for 2 months beyond next shipment *(If 1 month, give 2 points)*	
A		**SCORE ACHIEVED** (add score achieved for items 1-20)	
B		**SUBTRACT NUMBER OF N/A OR N/E RESPONSES**	
C		**SUGGESTED TOTAL SCORE POSSIBLE** (70 points possible minus value in line B, above)	

COMPONENT 4: DATA MANAGEMENT SCORING GUIDE

Site _____ **Country** _____ **Date** ____/____/____
dd/mm/yy

	SUGGESTED SCORE GUIDE
	TOTAL SCORE from previous page (Line A)
	TOTAL SCORE POSSIBLE from previous page (Line C)
	RATING If Line C=70, use RANGE below; if TOTAL POSSIBLE POINTS <70, use PERCENTAGE

PERCENTAGE Line A divided by Line C (A/C)*100	**RANGE** Use if Line C=70	**RATING**	**SUGGESTED TIME UNTIL NEXT ASSESSMENT**
>=85%	60-70	Excellent	Need assessment in 12-18 months
70-84%	49-59	Good	Need assessment in 9-11 months
50-69%	35-48	Poor	Need assessment in 6-8 months
<=49%	<=34	Failed	Need assessment in 2-5 months

COMMENTS AND RECOMMENDATIONS

COMPONENT 4: DATA MANAGEMENT EXPLANATION WORKSHEET

Item No.	Explanation
	Registers
1	Good record keeping is important for a well-functioning laboratory and clinic. Actual register books or logs should be provided by (National TB Program [NTP] often provide). Observe registries and check for continual entries (no missing weeks or months that are not during holidays). Ensure that only one register each per lab, suspect TB, and TB patients is used at a time.
	Record Keeping for Diagnosis and Treatment
2-6	Accurate record keeping is a key requirement for good program performance. Use NTP or WHO guidelines for frequency of sputum examinations. A common frequency is to have sputum examination results recorded at the start of intensive therapy; after 2-3 months of therapy (at completion of intensive therapy); after 5 months of therapy; if failure is identified; and at completion (6 or 8 months) of therapy. Use WHO (*15*) or NTP first-time and retreatment regimens. Besides the dates of starting the regimen for intensive and continuation phases and subsequent visits, the actual drugs given are listed.
	Reports
7-10	Regular analysis and reporting of cases is a key requirement for good program performance. Ask health worker how it is done and observe either monthly or quarterly (every 3 months: e.g., Jan-Mar, Apr-Jun, Jul-Sept, Oct-Dec) tallies and system. Reporting aggregated data to NTP is important for good program management and This should occur on at least a quarterly basis. Reported analyses include (*1*): • Number (#) of suspect cases (lab registry)=A • # sputum samples examined (lab registry)=B • Number of positive sputum smears (lab registry)=C • # smear-positive patients=D • **Percent positive smears** [(C divided by B)*100] • **Percent of smear-positive patients** [(D divided by A)*100] **Cure rate**= Number of smear-negative patients in last month of treatment divided by those with newly diagnosed smear-positive TB or divided by those alive at end of treatment (survivors) [in same period of time]. (>85% is global cure rate target) **Default rate**= Number of patients whose treatment was interrupted for >2 consecutive months divided by the number with newly diagnosed smear-positive TB in same period of time. **Relapse rate**= Number of patients who were previously treated and cured or completed treatment and now smear-positive divided by the number with newly diagnosed smear-positive TB in same period of time. **Transfer rate**=Number of patients who were transferred to another TB program to continue treatment divided by the number with newly diagnosed smear-positive TB in same period of time. **Death rate**=Number of patients who died from any cause during treatment divided by those with newly diagnosed smear-positive TB or divided by those alive at end of treatment.
11	United Nations Refugee Agency (UNHCR) Health Information System (HIS) should be used as the reporting system for refugee camps. HIS has the ability to generate Ministry of Health reports.
	Default Tracing
12-14	Aggressive education about adherence throughout treatment process and home visits to trace non-adherent patients as soon as they interrupt their treatment (at time of second missed visit) is paramount to successful TB control program. Use outreach workers, such as TB treatment supporters, to achieve this. Default rate is an excellent indicator of how well your program is doing. This rate should be analyzed on a quarterly basis and should remain <10%.
	Contact Tracing
15	High rates of childhood TB (<5 years of age) compared with total cases imply good rates of contact tracing and case ascertainment for a program in high burden countries. Over 40% (33%-50%) of household contacts can be infected (*5*), children have greater risk of progressing to disease. Need to ensure children receive isoniazid.
	Treatment, Medication, Supplies
16-17	For good program performance, guarantee the supply and quality of medications. Days of drugs out of stock can increase risks for developing drug-resistant TB. Because tropical countries with hot climates have a high rate of TB disease, maintaining drugs and not using expired drugs is paramount.
18-19	In addition to stock-outs, drugs that are expired or not tested for efficacy can lead to drug resistance. Drugs must always be procured from a reputable institution, such as the NTP. Quality assurance of the medications needs to be a part of the determination of their efficacy.
20	For good program performance, guarantee the stock of supplies.

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Online Resources

All resources are also available for printing on the companion CD-ROM to this tool.

CENTERS FOR DISEASE CONTROL AND PREVENTION

Educational material and training

- TB Elimination: http://www.findtbresources.org/scripts/index.cfm?FuseAction=OrderMatl
- http://www.cdc.gov/tb/pubs/default.htm

Fact sheets

- Exposure to TB
- TB Can Be Treated
- You Can Prevent TB
- TB and HIV/AIDS
- Testing for TB

Posters: http://www.cdc.gov/tb/pubs/Posters/default.htm

- Mantoux tuberculosis skin test poster
- Stop TB fact sheet

Interview techniques

- Effective TB Interviewing for Contact Investigation: Self-Study Modules (available at: http://www.cdc.gov/tb/pubs/Interviewing/selfstudy/ default.htm)

WORLD HEALTH ORGANIZATION

http://www.who.int/tb/en/

- TB epidemiology and surveillance workshop, all templates: http://www.who.int/tb/surveillanceworkshop/all_templates/default.htm
- TB community supporter materials: http://whqlibdoc.who.int/hq/2003/WHO_CDS_TB_2003.312.pdf
- Community TB care in Africa project: http://www.who.int/tb/people_and_communities/commcare/background/en/index1.html
- A guide for tuberculosis treatment supporters, 2002: http://whqlibdoc.who.int/hq/2002/WHO_CDS_TB_2002.300.pdf
- A guide to monitoring and evaluation for collaborative TB/HIV activities, 2004: http://www.who.int/hiv/pub/tb/tb_hiv_2004/en

OTHER ORGANIZATIONS

- International Union Against TB and Lung Disease: http://www.iuatld.org/index_en.phtml
- Partners in Health Community TB Treatment Supporter Training Guide: http://model.pih.org/accompagnateurs_curriculum
- Francis J. Curry National Center International Resources: http://www.nationaltbcenter.edu/international/index.cfm
- Stop TB Resource Center: http://www.stoptb.org/resource_center/documents.asp

Laboratory Resources

International Laboratory Standards/Guidelines: http://wwwn.cdc.gov/dls/ila/TB_Toolbox.aspx

External Quality Control for AFB Smear Microscopy: http://wwwn.cdc.gov/dls/ila/documents/eqa_afb.pdf

AFB Smear Staining (poster): http://wwwn.cdc.gov/dls/ila/documents/AFBSmearStaining.pdf

Quality Issues of AFB Smear Preparation and Staining Technique (poster): http://wwwn.cdc.gov/dls/ila/documents/qi.pdf

African and Asian Resources

Kenya specific TB communication strategy information—Lights of Hope: A National Communication Strategy for Fighting Tuberculosis in Kenya: http://www.path.org/publications/details.php?i=1399

Treatment supporters and patient booklets for Tanzania and Namibia (developed by the Norwegian organization LHL):
http://www.lhl.no/portal/page?_pageid=513,189797&_dad=portal&_schema=PORTAL&articleId=38836&artSectionId=1875

Low-literacy patient educational materials developed for South Africa: http://www.booksofhope.com/

TB: a clinical manual for South East Asia:
http://www.popline.org/docs/1631/288834.html

Promoting cultural sensitivity: an ethnographic guide for tuberculosis programs providing services to Hmong persons from Laos:
http://www.cdc.gov/tb/EthnographicGuides/Hmong/default.htm

Appendix A: Supplemental Health Education Materials

Health education poster that staff can hang on the walls in labs or clinics to remind themselves and make patients aware of proper methods for collecting sputum. Available in PDF form (for printing purposes) on the tool's companion CD-ROM. The evaluator may want to print some out before traveling to TB control program for distribution to augment existing educational materials.

Sputum Collection

Patient Must Know:

- Importance of giving sputum rather than saliva
- Visual difference between sputum and saliva
- Importance of not being near others when producing sputum

Patient Must:

- Rinse mouth with water (provide cup and water)
- Open container but keep cap and inside clean
- Take three to four (3-4) deep breaths
- Hold breath for 3-5 seconds after each deep breath
- Give deep cough with last breath to bring up sputum from lungs
- Put sputum, not saliva, into container
- Provide enough (3-5 mL) sputum

Health education poster that the staff can put on walls of TB control program to remind themselves and make patients aware of mild side effects of therapy. Available in PDF form for printing on the tool's companion's CD-ROM. The evaluator may want to print some out before traveling to TB control program for distribution to augment existing educational materials.

MILD SIDE EFFECTS

DRUG	SIDE EFFECT	MANAGEMENT
Rifampicin	1.) No appetite, nausea, stomach pain; 2.) Rash 3.) Orange/Red Urine	1.) Small meals, eating before bedtime; 2.) Antihistamines, if worsen see health officer 3.) Reassure patient— an expected effect of drug
Pyrazinamide (PZA)	1.) Joint pain; 2.) No appetite, nausea, stomach pain; 3.) Rash	1.) Ibuprofen or aspirin (if not a child); 2.) Small meals, eating before bedtime; 3.) Antihistamines, if worsen see health officer
Isoniazid (INH)	1.) Burning/tingling in hands/feet; 2.) No appetite, nausea, stomach pain; 3.) Rash	1.) Vitamin B6/Pyridoxine 100mg; 2.) Small meals, eat before bedtime 3.) Antihistamines, if worsen see health officer
Ethambutol	Eye problems	Stop medicaton and see health officer immedicately

# of TB Drugs

Health education poster that the staff can put on walls of TB control program to remind themselves and make patients aware of mild side effects of therapy. Available in PDF form for printing on the tool's companion's CD-ROM. The evaluator may want to print some out before traveling to TB control program for distribution to augment existing educational materials.

TB ADMISSION TALK

PATIENTS MUST KNOW:

- TB can be **CURED** and disease symptoms (chronic cough, fever, night sweats, weight loss, loss of appetite) go away with treatment
- About TB disease and how it is contracted and **SPREAD**
- Directly observed therapy (**DOT**) lasts for at least 2 months
- If a day of treatment is **MISSED, TAKE IT** as soon as you remember but not too close to your next dose (not within 8 hours)
- **MEDICATIONS LENGTH** – intensive and continuation phases
- **RISKS OF DEFAULTING** to yourselves and your families' health
- **SIDE EFFECTS** to medications. If any severe side-effects occur, come to the clinic immediately
- **PREGNANT WOMEN** should not take streptomycin injections
- **COVER MOUTH** and nose when coughing or sneezing
- Bring in children less than **5 YEARS OLD** to be examined, because of **HIGH RISKS** of TB disease
- **BRING IN CONTACTS** – neighbors, family members, or other who are coughing for 2-3 weeks to be tested for TB
- **VACCINATE CHILDREN** less than 5 years of age with BCG to prevent severe forms of TB
- **TAKE NO ALCOHOL** while on treatment because of possible liver damage
- **TAKE NO PARACETAMOL** while on treatment because of possible liver damage
- Get **HIV TESTING,** there is treatment

Appendix B: TB Patient Rights and Duties

By signing this charter, you are promised the following about your tuberculosis (TB) care while in this clinic (the healthcare worker will check each item as it is discussed with you):

CARE

- ☐ You will not be asked to pay for your sputum tests, your medical exams, or your TB treatments. All services are free.
- ☐ You will receive advice by clinic staff about your treatment and your health.

RESPECT

- ☐ You will be treated with respect when you come to this clinic. You will not be treated any differently because of your gender, religion, culture, your health status, ethnicity, or nationality.
- ☐ Your medical information will be shared with healthcare workers only.

INFORMATION

- ☐ You will get information about your health and risks to your children, family, friends, neighbors, and others so you can help protect them.
- ☐ You will be told about your treatment program and common risks to medicines and how to manage them.
- ☐ You will know the names of your medications, how much of each you will take, and how they work.
- ☐ Your TB card is yours to keep as a record of your treatment and will be filled out each time you come to the clinic to show you your progress.

SUPPORT

- ☐ You have the right to complain if you have any problem with your treatment.
- ☐ You have the right to seek support and advice and share experiences. You may do so at the tuberculosis clinic or other areas.

By signing this charter, you agree to the following (the healthcare worker will check each item as it is discussed with you)**:**

TREATMENT

- ☐ You will take your medication exactly as it is explained to you. You will take it every day for the entire time (6-8 months).
- ☐ You will tell us if you have any problems with your medicine, if you start feeling sick, if you miss any days of medicine, or if you stop taking your medicine for any reason.

INFORMATION

- ☐ You will tell us about your health—both in the past and now, including past illnesses, treatments, and side effects so that we can best help you.
- ☐ You will tell us about people you are close to, including your children, family, friends, and neighbors so we can see if they have TB disease.

FAMILY AND COMMUNITY HEALTH

- ☐ You will tell us if any of your family, neighbors, or community show signs of TB disease.
- ☐ You will tell others to come to the clinic if you think they have TB disease.

RESPECT

- ☐ You will respect other TB patients, their privacy, and their dignity.

_____	_____
Patient Name	Staff Name
_____	_____
Patient Signature	Staff Signature

Date: _____