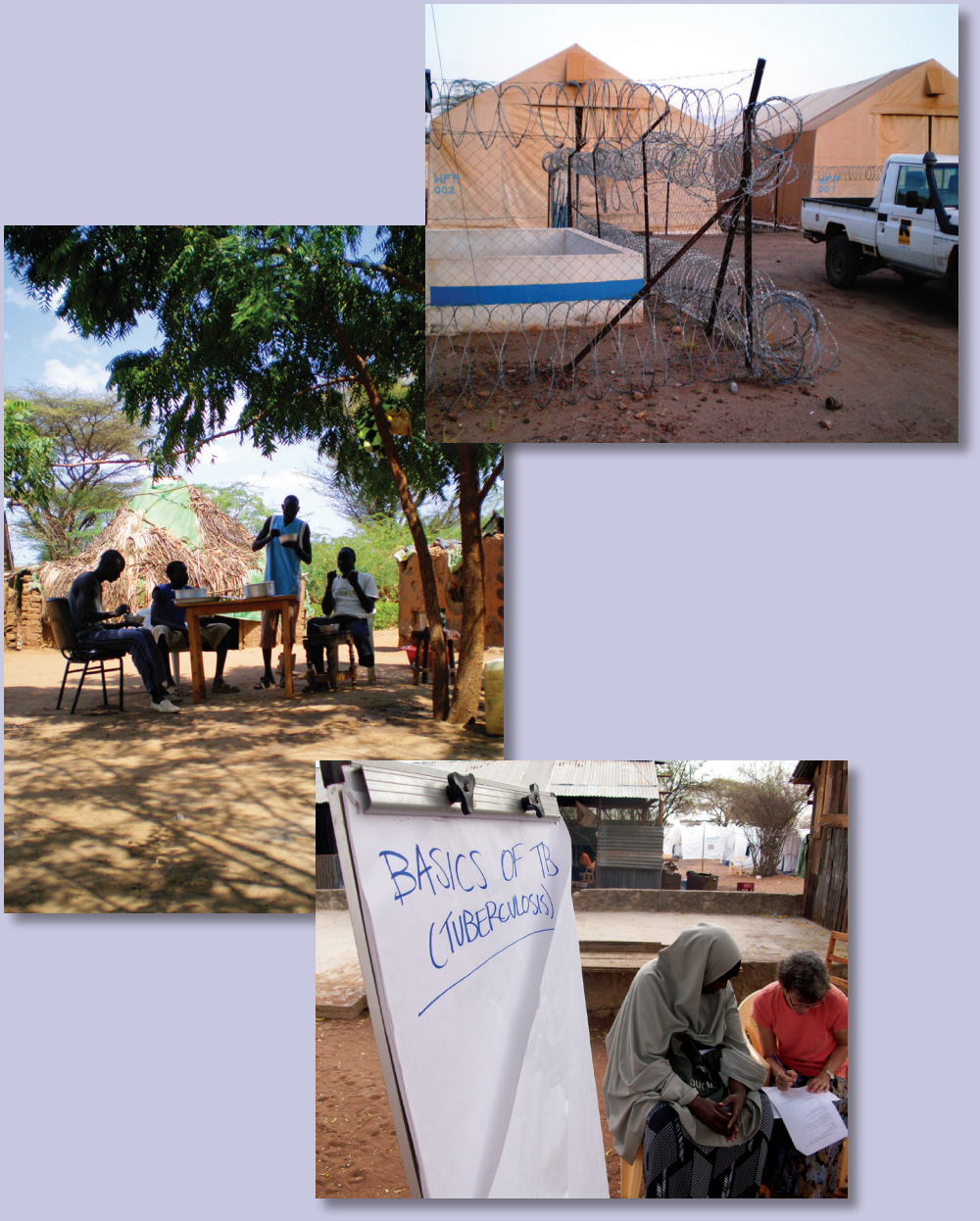
Monitoring and Evaluation Tool for Tuberculosis Programs in Refugee and Post-Conflict Settings



DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

INTERNATIONAL RESCUE COMMITTEE

Monitoring and Evaluation Tool for Tuberculosis Programs in Refugee and Post-Conflict Settings

U.S. Centers for Disease Control and Prevention (CDC)/
International Emergency and Refugee Health Branch

and the

International Rescue Committee

September 2009

This monitoring and evaluation tool has been endorsed by the

- ***American Refugee Committee***
- ***Bureau of Population Refugees and Migration/U.S. State Department***
- ***Emory Rollins School of Public Health***
- ***International Medical Corps***
- ***International Organization for Migration***
- ***Partners in Health***
- ***UN High Commissioner for Refugees***

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Monitoring and Evaluation Tool

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

This monitoring and evaluation tool was developed by the International Emergency and Refugee Health Branch of the U.S. CDC (Janet T. Ousley, MPH, and Susan Temporado Cookson, MD, MPH) and the International Rescue Committee (Wendy Venter, MD, MPH). The health education component was developed and funded by the Rollins School of Public Health of Emory University in Atlanta, GA, USA as part of thesis work.

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The Purpose of This Tool

Why this tool?

This tool is designed to support the effective monitoring and evaluation (M&E) of tuberculosis (TB) control programs in refugee camps and other settings located in resource-poor areas. 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.

Why is this tool important?

An M&E framework is an integral part of 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)*. This tool is 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 post-conflict, resource-limited, and refugee 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 or 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 types of 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 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 at three TB control programs in February 2009.

Where can I get more copies of the tool?

The tool is available for downloading at http://www.cdc.gov/nceh/ierh.

For a copy of the tool on CD ROM, 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 four components:
  - Laboratory—acid fast microscopy
  - Health education—at time of admission and during treatment
  - Clinical—case management and treatment
  - Data management and logistics—statistical evaluation of laboratory activities and program performance.
- Each component has three parts:
  - Evaluation worksheets for the evaluator to complete
  - Scoring guide that includes a comments and recommendations section
  - Explanation worksheet of the importance of each item scored.
- References and Resources:
- Appendices:
  - Posters with key messages for sputum collection and health education
  - Patient charter to use at time of admission
  - Program implementation tool

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 three parts—all are important.

a. **The evaluation worksheet** is a list of numbered items. After each item the evaluator should write the score. Extra copies of worksheets can be printed from the companion CD-ROM or the online tool. 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 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.

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 those reduced points are specifically indicated. 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. All the item points must be added together to produce an overall score and rating (excellent, good, poor or failed) for the component. These scores should only be used as a guide; 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 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** as mentioned above accompanies the evaluation worksheet and each numbered item is explained. The explanation worksheet also contains numbered references that can be found in the reference section. These additional references provide additional guidance and some 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 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 M&E tool in an 8-hour day during the pilot process.

Component 1: Laboratory Evaluation–Acid-Fast Bacilli Microbiology (AFB) Tool

Why the laboratory component of tool?

Laboratories form the foundation for diagnosing TB. 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 good laboratory practice (GLP). Methods assessed include specimen collection, smear preparation, acid-fast stain procedure, reading, and reporting. The evaluator must understand appropriate methods and ensure 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 the 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 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 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.

Part 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*	
1	4	Laboratory log/register is legible (dates of collection, quality of sputum sample [i.e., saliva], and results) *(Give 1 point each for legible dates, sputum quality, and smear results)*	
2	3	Slides labeled permanently with identification number or patient's name (if frosted, may use pencil)	
3	2	Lab uses one result form per patient and labels form with identification number or name *(Give 1 point each for each element)*	
4	2	Lab keeps smears for at least 3 months (one quarter) and stores them appropriately *(Give 1 point for each element)*	
For item 5: *Arbitrarily select 3 different pages of register (preferably from different months), average each page for percentage of samples that were saliva, then take average of the 3 pages. If <=10% saliva, give 5 points; if 11%-20%, give 4 points; if 21%-30%, give 3 points; if otherwise, give 0 points. If specimen quality not indicated in register/log, ask separately, 3 different staff (if possible), what percent of accepted specimens are saliva and average the three percentages.* Indicate the source of information of this worksheet (√ the box): ❑ register ❑ staff			
5	5	Lab encourages sputum, not saliva	
		Sputum Collection: *Laboratory staff*	
6	4	Adequate supply of clean sputum containers with wide mouth and screw top (enough for 3 months of patients)	
7	4	Tell patients how to give adequate sputum specimen (see Appendix A)	
8	4	Obtain at least one morning sputum *(Ask technician to explain sputum collection and timing; do not ask yes or no questions)*	
9	4	Collect sputum outside away from others *(Ask to see location to ensure away from others)*	
		Smearing Method Measures: *Laboratory staff*	
10	2	Uses new, clean slides and have an adequate supply (enough for 3 months of patients)	
11	2	Uses clean applicator (stick, pipette, or wire loop [if loop, remove sputum from prior specimen before flame]) for smearing	
12	2	Air-dry slide *(Ask the laboratory technician about drying times, do not ask as yes or no question)*	
13	2	Heat-fix slide (with flame or slide warmer to 65-75°C) *(Ask the technician whether heat fixing is performed. If yes, ask him or her to explain what is done [do not ask as yes or no questions but ask for his/her explanation of process])*	
For items 14-16: *Arbitrarily select 10 different stored slides (preferably from different months and at least 5 different months). If 9-10 slides meet criteria below, give full points; if 7-8 slides meet criteria, give 4 points, if 5-6 slides meet criteria, give 3 points; if otherwise, give 0 points.*			
14	5	Uses appropriate smear size (1-2 cm x 2-3 cm)	
15	5	Uses appropriate evenness (even throughout)	
16	5	Uses appropriate thickness (once dry, able to read print through thick film at 4-5 cm)	

Part 1: Laboratory Evaluation Worksheet

Item No.	Point Value	Description (explanations of these items are on the next sheet)	Suggested Score
		Stain/Reagent Preparation: *Laboratory staff*	
For item 17: *Arbitrarily select 5 positive slides (preferably from different months and at least 3 different months). If all good, give 4 points; if 4 good, give 2 points; if 3 or less, give 0 points. NOTE: some slides for items 14-16, might be appropriate for item 17*			
17	4	Stain the slides so AFB are not faded, even after 3 months (AFB stain red)	
18	2	Uses stains without precipitate (*probably need to assess by examining slides or filter stain).* Filtering stain before use can reduce precipitate.	
19	4	Uses reagent grade stains (commercial or prepared on site)	
20	1	Stores stains at room temperature and away from bright light or heat source (*Give ½ point for each element*)	
If stains prepared on site, answer items 21-25, then skip to 27			
21	1	Uses colorless or white crystal phenol and store it in refrigerator or cool area (*Give ½ point for each element*)	
22	2	Uses clean water (preferably distilled, not tap water)	
23	1	Uses balance to weigh 0.1 gram of stain powders	
24	4	Uses approved stain formulas	
25	1	Records dates of when stains prepared and determines expiration date	
If commercial stain used, answer items 26			
26	9	Uses commercial stains within expiration date	
27	2	Uses stains (commercial or prepared on site) within 12 months of opening/ preparing (preferably within 6 months) *(look for record of date when the stain was prepared or opened [usually on bottle])*	
		Staining Procedure: *Laboratory Staff*	
28	5	Uses approved staining procedure	
29	3	Uses approved times	
30	2	Uses timer for staining procedure	
31	1	Stains individual slides to prevent cross contamination	
32	1	Changes solution in bottles used to stain slides every 2 weeks and records change *(Give ½ point for each element)*	
		Microscopy and Reading: *Laboratory Staff*	
33	2	Has 100X magnification (plus 10X eye piece)	
34	1	Uses clean oil for slide and remove oil from slide before storing with absorbent paper (reduces risk of fungus) (*Give ½ point for each element*)	
35	4	Reads each slide for 5 minutes or 100-150 fields *(Ask technician 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)*	
36	2	Uses microscope in good working order, i.e., has mechanical stage that moves freely in both axes and well maintained	
37	1	Has microscope area with appropriate lighting (good ambient light on cloudy days) and sufficient seating space and without distraction or vibration (*Give ½ point for each element*)	
38	3	Uses positive control smear at least every week and after new reagent (*Give 2 points, if only every two weeks*)	
39	1	Uses negative control smear at least every week and after new reagent	
40	4	Performs external proficiency testing and results observed by evaluator (*If no results observed, give 0 points*)	
41	1	Processes >15 specimens each week (about 65 each month)	
42	2	Uses internationally accepted grading system for reporting results	
43	1	Performs second reading on all positive slides	
44	1	Reports results within 24 hours from specimen receipt	

Part 1: Laboratory Evaluation Worksheet

Site _____ Country _____ Date _____
dd/mm/yy

Item No.	Point Value	Description (explanations of these items are on the next sheet)	Suggested Score
		Safety Measures: *Laboratory*	
If specimen not centrifuged, answer 45 (Give 1 point) and skip to 47			
45	1	Does not centrifuge specimen	
If specimen centrifuged, answer item 46			
46	1	Dilutes specimen to be centrifuged with equal volume of 5% Na hypochlorite	
47	2	Uses biological safety cabinet (BSC). If no BSC, performs smear processing in separate area with good ventilation (open window) *(Give 1 point for good ventilation)*	
48	2	Has well ventilated airflow through laboratory from less-contaminated to more-contaminated areas	
49	1.5	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)*	
50	4	Disposes of contaminated material appropriately (especially sputum and used smear-making materials) (*Need to see incinerator, area of burning or burial*)	
51	2	Cleans bench tops before and after smear preparation and immediately after any spills	
52	1	Restricts access to laboratory	
53	1	Stores flammable reagents in flammables storage cabinet	
54	1	Has standard operating procedures readily available in laboratory	
55	1	Uses standard operating procedures	
56	1	Performs administrative laboratory work in separate room from processing	
57	0.5	Provides continuing education training program for laboratory personnel	
58	0.25	Provides proof of training (degree, certification, license or credit)	
59	0.25	Provides annual chest X-ray (or tuberculin skin testing) for laboratory personnel	
		Cultures: *Laboratory*	
60	4.5	Has access to cultures and drug sensitivity testing (DST), at least for relapsed or continued smear-positive patients	
A		**Score Achieved** (add score achieved for items 1-22)	
B		**Value of All N/A OR N/E Responses**	
C		**Suggested Total Score Possible** (65 points possible minus value in line B, above)	

Part 2: 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=135, use RANGE below; if TOTAL POSSIBLE POINTS <135, use PERCENTAGE

Percentage Line A divided by Line C (A/C)*100	**Range** Use if Line C=135	**Rating**	**Suggested Time Until Next Assessment**
>=85%	115-135	Excellent	Needs assessment in 12-18 months
70-84%	95-114	Good	Needs assessment in 9-11 months
50-69%	68-94	Poor	Needs assessment in 6-8 months
<=49%	<=67	Failed	Needs assessment in 2-5 months

Comments and Recommendations *(give item no.)*

Part 3: Laboratory Explanation Worksheet

Item No.	Explanation
	Record Keeping
1-4	Good laboratory practices to reduce risk of confusing slides of different patients are labeling and keeping slides and records for at least 3 months. National TB (NTP) Programs usually provide request forms; if not, the program is responsible for making its own. Slides must be stored appropriately, preferably in slide boxes. If slides boxes are not available, store with tissue paper between each slide.
5	Examine sputum for thick, mucoid quality, pieces of purulent material, blood, and volume (3-5 mL for a good specimen) *(3)*. Clear saliva and nasal discharge are not suitable—request repeat specimen, if possible (but even saliva can yield positive result).
	Sputum Collection
6	The use of dirty sputum containers increases risk of artifact on smear. A wide-mouth opening and screw-cap container will minimize risk of contaminating outside and top, if leakage occurs.
7-8	Three early mornings sputum samples give highest yield of obtaining a positive smear. For practical reasons, this might not be feasible or followed by NTP guidelines. Because of laboratory workload in countries where external quality assurance exists, two sputum samples (one morning) are now endorsed by WHO *(6)*. Instructions to patients may be given by lab or clinical staff; either way, specific instructions need to be given (see Appendix A)
9	Minimize risk to other persons; this procedure has greatest exposure risk to laboratory personnel.
	Smearing Method Measures
10	Reduce risk of artifact leading to interpreting result as positive finding (false-positive result).
11	With applicator, collect pieces of thick, purulent material.
12-13	Do not dry smear with sunlight or ultraviolet (UV) light. To keep smear on slide, heat fix air-dried smear to slide by passing slide with smear side up 2-3 times over flame for 2-3 seconds or by placing slide on 65°-75°C electric slide warmer for >2 hours. Do not leave the slide in an unprotected area where it could be damaged.
14-15	Smear size (1-2 cm x 2-3 cm), thickness (once dry, able to read print through thick film at 4-5 cm), and even across whole smear.
	Stain/Reagent Preparation
17	Color retention of white cells and AFB are indications of quality of stain/reagent.
18	Increase quality of stain and reduce risk of artifact—dirt or precipitate can lead to false-positive result. Probably need to assess by examining slides or filter stain.
19	Use only reagent grade stains.
20	Reagents must be stored at room temperature or precipitates may form, leading to false-positive result. Reagents must be kept in the dark and away from bright light to ensure they do not break down. Place them in a cabinet or in brown bottles away from bright light.
If stains prepared on site, answer items 21-25, then skip to 27	
21	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.
22	To reduce risk of artifact (environmental mycobacteria), use freshly prepared distilled/deionized water for staining reagents.
23	Need calibration weight to appropriately know and measure quantities for stain reagents.
24-25	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.
If commercial stain used, answer item 26	
26	Chemical stock containers should be dated when received and when first opened.
27	Use prepared staining reagents within 6-12 months of preparation and commercial stains within 6-12 months of opening (but not after expiration date).

Part 3: Laboratory Explanation Worksheet

Item No.	Explanation
	Staining Procedure
28	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 with tap water and drained; and methylene blue applied, then rinsed, drained, and dried at room temperature.
29	Times may vary, one suggestion: • Fuchsin-phenol for 5-10 minutes, then rinsed; • Acid-alcohol for 2-3 minutes, then rinsed; and • Methylene blue for 1 minute, then rinsed.
30	Too difficult to ensure appropriate times without a timer. Inappropriate times will lead to false answers.
31-32	Staining jars should not be used because of cross-contamination. Best practice is to stain slides individually. The staining bottles should be changed every 2 weeks and documented. Good laboratory practice (GLP) should include maintenance and cleaning of equipment.
	Microscopy and Reading
33	Use 100X magnification (plus 10X eye piece) to scan smear and count any AFB seen.
34	Oil must be clean, clear, and low in viscosity (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.
35	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.
36	To systematically observe slide (side-to-side or up-and-down pattern), stage must operate in both axes. To correctly read slides, microscope needs to be clean of dust that might interfere with identification of bacilli or give erroneous positive results. Use of known positive and negative controls can assist in determining quality of microscope. After cleaning, cover microscope with vinyl or cotton cloth and store in secure place free from moisture and dust. Keep microscope and slides away from dust and dirt to increase life of microscope and reduce artifact.
37	Microscope area should have appropriate lighting and seating. Comfortable seating aids the technician's attention span. Microscope area free from distractions or vibrations allows for greater attention span of technician and more accurate observation of slide.
38-39	Use a positive control smear containing AFB and a negative control smear containing no AFB stained at least once a week, daily recommended. However, each new stain solution must be tested with a positive control and negative control smear before staining of patients' smears.
40	National or International Proficiency Testing Programs provide clinical specimens or slides to be tested by other laboratories to determine the tested laboratory's ability to give an accurate report. If a laboratory has established such a link, it indicates the potential for a high degree of proficiency for the laboratory personnel. Results of proficiency testing must be seen.
41	Laboratories preparing and observing >15 AFB smears per week or 65 AFB smears per month are better able to maintain proficiency in this process (*7,8*). However, each technician should not examine >25 smears per day.

Part 3: Laboratory Explanation Worksheet

Item No.	Explanation
42	A reporting scheme of AFB found must be used. One scheme: • 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 one acid fast bacilli (AFB+) in at least one sputum sample is a sputum smear-positive pulmonary TB case.
43	For good quality assurance, a sample of 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).
44	For good responsiveness to the needs of physicians and patients (and to minimize exposure), test results should be available within 24 hours of specimen receipt.
	Safety Measures
45	Centrifuging can create infectious aerosols. Do not centrifuge unless appropriate safety precautions are in place.
46	If centrifugation takes place, centrifuge must have an internal cover plus cover for chamber. Dilute specimen with equal volume of 5% Na hypochlorite, place in container with leak-proof cover, and label with patient name or number. Centrifuge at >3000Xg (RCF). Sediment from specimens processed for isolation by culture may be used. Centrifugation slows turnaround time for clinician receiving results and not always worthwhile.
47	Although a Biological Safety Cabinet (BSC) is not required, it is recommended. Simple-to-make cabinets requiring low-level sophistication and materials can be made but proof of their functionality needs assessing.
48	To minimize risk for exposure, ensure good ventilation—wind or fan is blowing over the shoulder and not in direction of others in the area.
49	Good laboratory practices (GLP) is to have hand washing station and to wash hands frequently with soap and water before and after every procedure.
50	Dispose of contaminated material (especially used sputum cups, applicators, and slides) in accordance with standard biosafety procedures; this includes burning (incineration), burying, or autoclaving.
51	GLP includes cleaning of benches and equipment. Use phenolic agents or bleach solution for disinfectant for spills and before and after making smears (bleach solution is good for blood but less effective than phenolic agents against TB). To ensure greater ease with cleaning the benches and reduce risk of trapping infectious materials, it should be a continuous surface.
52	To minimize risk for exposure, access to laboratory should be restricted and the door closed at all times.
53	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.

Part 3: Laboratory Explanation Worksheet

Item No.	Explanation
54-55	For a well-functioning laboratory, standard operating procedures (SOP) for procedures used must be written, used, and readily available. Examples can be found on the Internet (Available at: http://www.epa.gov/quality/qs-docs/g6-final.pdf or http://www.fao.org/docrep/W7295E/w7295e04.htm)
56	For a well-functioning laboratory, reduce risk of exposure to infectious materials.
57-58	For a well-functioning laboratory, ensure that professionals staff the lab and that they maintain professional growth.
59	For well functioning laboratory, assess potential of TB disease (although exposure via other aspects of person's life cannot be ruled out in many parts of the world). Aerosols containing *Mycobacterium tuberculosis* may be produced when handling leaking specimens, opening sample containers, and preparing smears. Ensure that sputum collection occurs away from others.
	Culture
60	Although WHO case definition does not require culture and drug sensitivity testing (DST), in this world of increasing drug resistance this ability should be sought out for patients who are being retreated. Many NTPs have the ability to provide DST, especially for cases with suspicion of drug 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 TB and either speak the language or use an independent translator to not 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 the 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 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 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.

Part 1: Health Education 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 *(Evaluator observes healthcare workers (HCW).*	Suggested Score
		Individual Patient Education	
		Adherence	
1	5	Asks patients if they missed any days of therapy	
2	3	If they missed treatment, asks what they did (whether took the next day) and counsel them about strategies for better treatment adherence *(If no adherence problems, give 3 points)*	
3	5	Reminds patients about the dangers of defaulting from treatment	
4	1	If starting continuation phase, tell patients the difference between the intensive and now continuation phases of treatment *(If not applicable, put N/A under score)*	
5	3	Congratulate patients on how far they have come in their treatment, tell them how much longer they have, and how important it is not to default now even though they feel well	
		Side Effects	
6	5	Asks patients about any new symptoms (possible side effects to the medications)	
7	4	Reminds patients to come to the clinic immediately if they have severe side effects, such as cola colored urine	
8	2	Asks female patients about pregnancy, if on streptomycin *(If male or if not pregnant, give 2 points)*	
9	2	Asks about eyesight and inability to see red and green colors, if on ethambutol *(If ethambutol not given, give 2 points)*	
10	2	Offers patients ibuprofen (or other anti-inflammatory drug), if experiencing joint pains	
11	2	Gives patient pyridoxine/vitamin B6, if experiencing tingling or burning sensation in hands or feet	
		Contacts	
12	5	Tells patients to bring their children <5 years of age for testing	
13	5	Tells patients to bring neighbors, family members, or other contacts who have been coughing for 2-3 weeks to the clinic for testing	
		Risks	
14	4	Tells patients about risks to their liver of drinking alcohol and taking acetaminophen/paracetamol while on TB medications *(Give 2 points for each)*	
15	1	Tells patients about risks to their lungs of smoking	
16	3	Offers patients HIV testing, if not accepted before *(If already accepted, give 3 points) (If testing not offered in TB clinic or location where offered not explained to patient, give 0 points)*	

Part 1: Health Education Evaluation Worksheet

Item No.	Point Value	Description *(Evaluator observes healthcare workers (HCW).*	Suggested Score
		Follow-up:	
17	2	Addresses all patient fears, misunderstandings, and questions	
18	5	Makes 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 4 points)*	
19	1	Invites any further patient questions and answer them accordingly	
		Community Education: *(Workers or TB control programs)*	
		Health Outreach Program:	
20	2	Disseminates messages broadly using a variety of media, including religious, social, and economic organizations *(This can only be assessed by making observations within the community and talking to community leaders. Give 1 point for some health outreach, but not a variety of outreach)*	
21	2	Uses cured patients as teaching resources	
22	1	Holds group sessions as well as individual sessions	
A		**Score Achieved** (add score achieved for items 1-22)	
B		**Value of All N/A OR N/E Responses**	
C		**Suggested Total Score Possible** (65 points possible minus value in line B, above)	

Part 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=65, use RANGE below; if TOTAL POSSIBLE POINTS <65, use PERCENTAGE

Percentage Line A divided by Line C (A/C)*100	**Range** Use if Line C=65	**Rating**	**Suggested Time Until Next Assessment**
>=85%	55-65	Excellent	Needs assessment in 12-18 months
70-84%	46-54	Good	Needs assessment in 9-11 months
50-69%	33-45	Poor	Needs assessment in 6-8 months
<=49%	<=32	Failed	Needs assessment in 2-5 months

Comments and Recommendations *(give item no.)*

Part 3: Health Education Explanation Worksheet

Item No.	Explanation
	Individual Patient Education
	Adherence
1-3	If patients stop drugs before treatment course is complete (even for a short time) the bacteria that are not killed can grow stronger than the drugs being taken. The patient's TB bacteria can be stronger than the first-line treatment; the person can develop drug-resistant TB, so more drugs will be needed for cure. If a patient stops completely, he or she will become sick again; could spread TB to others, especially family members and young children; or could even die. Education should also include that for each day of therapy missed, additional days of treatment may be given, especially for HIV-infected patients. There are several ways that health staff can help patients predict potential problems and proactively solve them for successful, uninterrupted treatment. Simple daily life events and circumstances can be responsible for a patient not respecting his or her treatment regimen. The staff talk about these obstacles and help the patient find solutions. • Link a daily routine to taking medicines to reduce the possibility of forgetting to take the medicine. • Possible routine activities could be a meal, before or after morning prayers, or bathing. Potential activities will be different according to each population. • If a dose is forgotten, it should be taken 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 see the causes of adherence problems, 1. Define what the problem is with the patients, 2. Search for solutions together, and 3. Anticipate future problems. It is important at each monthly visit that health staff revisit the 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 patient return each visit with pill bottle or blister pack (ideally, treatment should be provided under directly observed therapy).
4-5	Continuation versus intensive therapy should be explained even though the number of pills may be the same with combination pills.

Part 3: Health Education Explanation Worksheet

Item No.	Explanation
	Side Effects
6-11	Staff explain and ask about severe side effects. Most people have no problems with treatment. Most side effects will occur only in the beginning of 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, to the clinic. The most common side effects are stomach-gut complaints, such as loss of appetite, stomach pain, nausea, or vomiting. If the patient is nauseated after taking drugs, he or she should take medication with food or milk. Eating multiple small meals and eating before going to sleep may help with these symptoms. Because most of the drugs are broken down by the liver, swelling or damage of the liver can occur. However, severe liver damage (called severe hepatotoxicity) occurs in only 1 in 1,000 people. Liver swelling or damage cause nausea and vomiting and the urine to turn dark (like the color of cola). This must not be confused with urine turning orange/red, which happens when taking rifampicin. Tell the patient if he or she feels nauseated <u>and</u> has 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 routine 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)
	Contacts
12-13	Methods for contact tracing of close contacts can be found in the references *(10)*. Anyone can get TB. If one person has TB and coughs, sneezes, or even talks or sings near another, that person can breathe in the TB bacteria and get TB. This is especially true for any children younger than 5 years old and for people with weak defenses, such as people with HIV infection. The biggest chance of getting TB is from spending a lot of time with people who have TB and who are not being treated, especially where there is poor air flow or in poorly ventilated areas. A lot of time usually means 8 hours or more. Any young children and others close to the TB patient who has symptoms of TB (night sweats, fever, a cough lasting more than 2-3 weeks, weight loss, fatigue, chest pain while breathing or coughing) should report to the clinic immediately to be tested for TB. Young children may have no symptoms, except failure to gain weight or weight loss.

Part 3: Health Education Explanation Worksheet

Item No.	Explanation
	Risks
14-15	Health staff needs to explain risks and contraindications. Some patients receiving TB treatment also may be abusing alcohol or local brew at the time of their diagnosis and treatment. It is important that these patients are counseled on the risks that alcohol and local brew pose to those taking TB therapy. Specifically, the combination can have bad effects on the liver and nerves. There is the potential that TB treatment could harm the liver. Liver damage is more likely and more serious in people who are heavy alcohol users. Health workers should be open and honest with patients when talking about alcohol use and should be careful not to be judgmental. In addition explain, • Paracetamol or acetaminophen, like alcohol, is broken down by the liver. So paracetamol can harm the liver. For headaches, joint or muscle pain, or fevers, inform patients that they can take drugs, such as ibuprofen or aspirin. 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.
16	Staff needs to recommend 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. If close exposure to smear-positive patients occurs but the HIV-infected person is without disease, this person should receive prophylaxis (isoniazid 5 mg/kg or 300 mg daily) for 6 months *(1, 11, 12).*
	Follow-up
17-19	Staff needs to be open by addressing fears, welcoming questions, making next appointment.
	Community Education
	Health Outreach
20	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. By saturating 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.
21	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.
22	Use group sessions as well as individual sessions to reach as many people in as many ways as possible.

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 *(11-13)*.

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 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 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.

Part 1: Clinical 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	Score Suggested
		Case Ascertainment: *Evaluator asks community health worker*	
1	3	Patients found by active surveillance—community healthcare workers or TB treatment supporters visit households looking for cases	
		Clinical Patient Evaluation: *Evaluator observes healthcare workers (HCW)*	
2	3	Gives (or gave at start of therapy) patients a simple explanation of what TB disease is and how it is contracted *(if not observed, ask HCW what they would say. Do not ask as yes or no questions)*	
3	4	Asks (or asked at start of therapy) patients about disease symptoms and tell them the symptoms will go away as they start treatment *(Give 2 points each for asking about symptoms and explaining will go away)*	
4	0.25	Asks (or asked at start of therapy) about contact history	
5	4	Asks and record (or asked and recorded at start of therapy) any prior TB treatment, specifies medications	
6	0.5	Asks about allergies to other (non-tuberculosis) medications and records it (with the symptoms of allergic reaction if possible)	
7	4	Obtains and record weight each month *(Evaluator can obtain this information by examining 5 medical records of patients [preferably medical records of discharged patients]. If a weight is obtained monthly, give 4 points. If 4 weights are obtained in 6 months of treatment, give 3 point; if 3 weights are obtained, give 2 points; otherwise, give 0 points.* *OR evaluator can observe 4-5 patient encounters. If all patients with a weight obtained, give 4 points; If only 1 patient without a weight obtained, give 3 points; if 2 patients without a weight obtained, give 2 points; otherwise, give 0 points, weights obtained must be reordered 0 points)*	
8	0.25	Signs (or signed at start of therapy) charter with patient (see Appendix B)	
9	4	Asks patient about possible signs of drug resistance *(After patients seen, ask HCW what are the signs. Do not ask as yes or no questions)*.	
10	3	Provides supplemental feeding monthly *(If only during intensive phase, give 2 points)*	
		Clinic Infection Control: *Evaluator Observes*	
11	2	Patient flow and comfort	
12	3	Level of infection control in clinic—sunlight, ventilation, mask wearing *(If only sunlight and ventilation, give 2.5 points; if only wearing mask but poor ventilation, give 0 points)*	
13	2	Necessary materials (gloves, disposal or reusable medical materials, disinfection) (NOTE: these materials do not prevent TB transmission, they are good medical practice) *(If all materials are seen, give total points; if 2 materials are seen, give 1 point; if less than 2 materials are seen, give 0 points)*	

Part 1: Clinical Evaluation Worksheet

Item No.	Point Value	Description	Score Suggested
14	3	HCW administer streptomycin under antiseptic means (if multiuse vial, top is cleaned and sterile syringe used each time)	
15	3	HCW dispose of needles safely	
		Medications	
For items 16-18: *Ask the health workers (HCW) to explain the different phases of medication (do not ask as yes or no questions but ask for his/her explanation of phases)*			
16	4	HCW know intensive and continuation medications for first-time treatment per WHO or national guidelines *(Give 2 points for each phase)*	
17	4	HCW know intensive and continuation medication for retreatment *(Give 2 points for each phase)*	
18	3	HCW know to stop treatment for persistent smear-positive patients	
19	1	Evaluator observes chart with maximum dosage for each medication *(often found on wall of clinic, but may need to ask for it)*	
20	5	Program gives DOT (observed swallowing), for how long (√ the box)? ❑ not given ❑ 2 months ❑ total course *(Give 5 points for total course, give 3 point for 2 months; if DOT <u>not</u> given, but bottles or blister packs asked for and examined at each subsequent visit, give 1 points)*	
21	4	For DOT, by whom (√ the box)? ❑ medical/clinical officer/auxiliary worker ❑ community health worker ❑ family member *(Give 3 point for non-family member)*	
22	1	Evaluator observes chart with side effects *(often found on wall of clinic, but may need to ask for it)*	
		Laboratory Follow-up	
For items 23-24: *Ask the health workers (HCW) to explain sputum smear intervals (do not ask as yes or no questions but ask for their explanation). In addition for item 23, review the individual patient records or the medical records of those presenting for the day*			
23	4	HCW requests 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)*	
24	3	HCW repeats sputum smears in 1 month for patients with positive smear	
25	2	Evaluator observes HIV testing methods for reliability (cold chain, 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°C; however, many areas where refugees reside and resource-limited areas can have average daily temperatures >35°C).*	

Part 1: Clinical 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	Score Suggested
		Contact Tracing and Prophylaxis: *Evaluator observes HCW*	
For items 26-27: *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).*			
26	3	Gives prophylaxis to children less than 5 years old and to HIV-infected persons with exposure to smear-positive case *(Give 2 points, if give prophylaxis only to HIV-infected persons)*	
27	3	Can describe protection and lack of protection of BCG *(1 point)* Give BCG to unvaccinated children less than 5 years old *(2 points)*	
		Policies: *Clinic staff*	
28	4	Has documented plans and activities for non-adherence (default treatment)	
29	2	Has mechanism (referral sheet for transfer in and transfer our) and follow-up activities for transfers *(If referral sheet but no follow-up activities back from referral facility, give 1 points)*	
30	4.5	Has access to radiology services for cases where smears are negative, but question of TB still remains	
		Hospital: *Staff*	
31	3	Has established criteria for hospitalization *(If only verbal criteria that are well explained, but not written, give 2 points)*	
32	3	Has infection control in hospital—sunlight, ventilation, mask wearing *(If only sunlight and ventilation, give 2.5 points)*	
33	0.5	Provides sputum pots/mugs with covers and disinfectant to hospitalized patients	
34	3	Has adequate waste management (incinerator; burial not desirable for hospital capacity; may be the same the laboratory uses) *(If burial, give 1 point)*	
A		**Score Achieved** (add score achieved for items 1-34)	
B		**Subtract Number of N/A OR N/E Responses**	
C		**Suggested Total Score Possible** (96 points possible minus value in line B, above)	

Part 2: 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=96, use RANGE below; if TOTAL POSSIBLE POINTS <96, use PERCENTAGE

Percentage Line A divided by Line C (A/C)*100	**Range** Use if Line C=96	**Rating**	**Suggested Time Until Next Assessment**
>=85%	82-96	Excellent	Needs assessment in 12-18 months
70-84%	67-81	Good	Needs assessment in 9-11 months
50-69%	48-66	Poor	Needs assessment in 6-8 months
<=49%	<=47	Failed	Needs assessment in 2-5 months

Comments and Recommendations *(give item no.)*

Part 3: Clinical Evaluation Explanation

Item No.	Explanation
	Case Ascertainment
1	Passive detection is waiting for patients to present to clinic with symptoms; given the chronic nature of much TB, this underestimates prevalence of the disease. Active detection is having healthcare workers, volunteer or paid, community health workers or TB treatment supporters (available at: http://whqlibdoc.who.int/hq/2003/WHO_CDS_TB_2003.312.pdf) actively go into the community to look for cases.
	Clinical Patient Evaluation
2-6	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 providers after all patients are seen what they asks new patients (you may want to pretend to be the patient to make this less artificial). Asking about history of contact with TB, unless a child; allergies to other medications is not as important as asking about prior TB treatment. **Prior treatment increases a person's risk of having drug-resistant TB.**
7	View at least five arbitrarily selected medical records to determine whether weights are obtained and recorded monthly. In some settings, weekly (during intensive phase) or monthly (during continuation phase) weights may be the only objective sign of improvement on treatment.
8	Having patients sign a charter places greater responsibility of care on the individual and is a good but not required procedure (see Appendix B) *(14).*
9	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. The healthcare workers need to ask patients about these symptoms.
10	Most programs/organizations support supplemental feeding of HIV patients; such should be done for TB patients as well.
	Clinic Infection Control
11-13	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. Gloves and coats or gowns do not prevent TB transmission, but they are good medical practice.
14	Nosocomial (hospital-acquired) infections can occur as a result of poor technique during injection procedures.
15	Needlestick injuries of healthcare workers 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
16-18	Use World Health Organization (WHO) or National TB Program (NTP) regimen.
19	Observe chart with dosage by weight and presence of scale.
20-21	The workers doing DOT should be trained in the importance of DOT. The workers 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.
22	The most common side effect is stomach-gut complaints such as loss of appetite, stomach pain, nausea, and vomiting. Effects on the liver cause nausea, vomiting, and a change of urine to dark color (like the color of cola). These effects can occur with first-line drugs. Paresthesia can occur with isoniazid and arthralgia with pyrazinamide. A chart with this information must be observed.

Part 3: Clinical Evaluation Explanation

Item No.	Explanation
	Laboratory Follow-up
23-24	Sputum smears are obtained according to schedule of WHO or NTP guidelines and before starting the continuation phase.
25	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
26-27	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 less than 5 years should receive prophylaxis (isoniazid 5 mg/kg or 300 mg daily) for at least 6 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 (*15-17*). 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 is10 mm or more (*11, 12, 18*).
	Policies
28-29	Set mechanism and timing for follow-up on defaulters, usually by 2 missed appointments. Community health workers or TB treatments supporters can be helpful with findings 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)*.
30	Although chest radiograph is not a part of WHO case definition of TB, access to this service is helpful in difficult cases where the sputum smear is negative.
	Hospital
31	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).
32-34	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 handwashing 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 biocidal activity *(19)*. 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*).

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, 20)*.

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 the 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 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.

Part 1: Data Management 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)	Score Suggested
		Registers: *Evaluator*	
1	42	Observes patient registry exists 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*	
7	3	Monthly or quarterly (every 3 months) reports for number of patients	
8	3	Monthly or quarterly reports for patient types—pulmonary/ extrapulmonary, smear-positive/smear-negative	
9	4	Monthly or quarterly reports for patient outcomes—rates for cure, treatment completion, default, relapse, transfer, death	
10	3	Clinic gives numbers to the National TB Program on at least quarterly basis	
11	3	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	
12	4	Healthcare workers (HCW) uses 14 days after overdue appointments for tracing default patient in intensive phase *(If tracing at 21- 30 days, give 2 points; if tracing at 28-35 days, give 1 point)*	
13	4	HCW uses 2 months after overdue appointments for tracing default patient in continuation phase *(If tracing at 3-4 months, give 2 points; if tracing at 4-5 months, give 1 point)*	
14	4	Clinic has default rate ≤10% *(If 11%-15%, give 2 points; if >15%, give 0 points)*	

Part 1: Data Management Evaluation Worksheet

Item No.	Point Value	Description (explanations of these items are on the next sheet)	Score Suggested
		Contact Tracing and Treatment: *Clinic*	
15	4	Has proportion of pediatric patients (<15 years old) to total patients ≥11% *(If 5%-10%, give 3 points; if <5%, give 0 points)*	
		Treatment, Medication, Supplies: *Clinic*	
16	4	Has sufficient supply of anti-TB drugs to allow for 2 months beyond next shipment *(If 1 month, give 3 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	
19	4	Does not have expired drugs	
20	3	Has adequate supplies of needles, syringes, diluent 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** (73 points possible minus value in line B, above)	

Part 2: 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=73, use RANGE below; if TOTAL POSSIBLE POINTS <73, use PERCENTAGE

Percentage Line A divided by Line C (A/C)*100	**Range** Use if Line C=75	**Rating**	**Suggested Time Until Next Assessment**
>=85%	62-73	Excellent	Needs assessment in 12-18 months
70-84%	51-61	Good	Needs assessment in 9-11 months
50-69%	37-50	Poor	Needs assessment in 6-8 months
<=49%	<=36	Failed	Needs assessment in 2-5 months

Comments and Recommendations *(give item no.)*

Part 3: 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). 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; and at completion (6 or 8 months) of therapy. Use WHO (*13*) or NTP first-time and retreatment regimens.
	Reports
7-10	Regular analysis and reporting of cases is a key requirement for good program performance. Observe either monthly or quarterly (every 3 months: January-March, April-June, July-September, October-December) tallies and reporting system. Reporting aggregated data to NTP is important for good program management. This should occur on at least a quarterly basis. Reported analyses include (*1*): • Number of suspect cases (lab registry)=A • Number of sputum samples examined (lab registry)=B • Number of positive sputum smears (lab registry)=C • Number of 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 patients smear-negative in last month of treatment divided by those with newly diagnosed smear-positive TB (>85% is global cure rate target) or divided by those alive at end of treatment (survivors) in same period of time. • **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 (>85% is global cure rate target) or divided by those alive at end of treatment (survivors) in same period of time.
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.

Part 3: Data Management Explanation Worksheet

Item No.	Explanation
	Default Tracing
12-14	Aggressive education about adherence throughout treatment process and home visits to trace nonadherent 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 (less than 5 years of age) compared with total cases imply good rates of contact tracing and case ascertainment for a program. Over 40% (33%-50%) of household contacts can be infected (*5*), with children having a greater risk of progressing to disease.
	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.

References

1. Connolly MA, Gayer M, Ottmani, editors. Tuberculosis care and control in refugee and displaced populations: an interagency field manual. 2nd ed. Geneva, Switzerland: World Health Organization Press; 2007 [accessed 2 June 2008]. Available from URL: http://whqlibdoc.who.int/publications/2007/9789241595421_eng.pdf.
2. Medecins Sans Frontieres. Refugee health: an approach to emergency situations. Paris: Médecins Sans Frontières; 1997.
3. Boerma T, Chopra M, Evans D. Health system performance assessment in the Bulletin. Bull WHO 2009;87:2 [accessed 7 January 2009] Available from URL: http://whqlibdoc.who.int/publications/2007/9789241595421_eng.pdf.
4. World Health Organization. Acid-fast direct smear microscopy training package [accessed 2 October 2008]. Available from URL: http://wwwn.cdc.gov/dls/ila/acidfasttraining/.
5. International Union against Tuberculosis and Lung Disease. Technical guide: sputum examination for tuberculosis by direct microscopy in low income countries. 5th ed. Paris: International Union against Tuberculosis and Lung Disease; 2000.
6. World Health Organization. Definition of a new sputum smear-positive TB case. [accessed 27 March 2009]. Available from URL: http://www.who.int/tb/dots/laboratory/policy/en/index1.html.
7. Kam KM. Recommended tools for quality assurance in TB laboratories. WHO, Western Pacific Region, National TB Program and Laboratory Managers Meeting, 3-6 December 2002 [accessed 27 March 2009]. Available from URL: http://www.wpro.who.int/internet/files/stb/cebu/2_implementing_quality_assurance_in_tb_lab.pdf.
8. Department of Health and Human Services/Centers for Disease Control and Prevention. Goals for working safely with Mycobacterium tuberculosis in clinical, public health, and research laboratories. [accessed 27 March 2009]. Available from URL: http://www.cdc.gov/od/ohs/tb/tbdoc2.htm.
9. Zaleskis R. Adverse effects of anti-tuberculosis chemotherapy. Eur Resp Dis 2006. Available from URL: http://www.touchbriefings.com/pdf/2006/Zaleskis.pdf.
10. Centers for Disease Control and Prevention. Self-study modules on tuberculosis. Contact investigations for tuberculosis. Atlanta: U.S. Department of Health and Human Services; 1999 [accessed 2 October 2008]. Available from URL: http://www.cdc.gov/tb/pubs/ssmodules/pdfs/6.pdf.
11. Centers for Disease Control and Prevention. Core curriculum on tuberculosis. 5th ed. Atlanta: U.S. Department of Health and Human Services; 2004 [accessed 2 October 2008]. Available from URL: http://www.cdc.gov/tb/pubs/corecurr/index.htm.
12. Variane F, editor. Tuberculosis. 4th ed. Paris: Médecins Sans Frontières; 2005.
13. World Health Organization. Treatment of tuberculosis: guidelines for national programmes. 3rd ed. Geneva, Switzerland: World Health Organization; 2003 [accessed 2 October 2008]. Available at: http://whqlibdoc.who.int/hq/2003/WHO_CDS_TB_2003.313_eng.pdf.
14. World Care Council. The Patients' Charter for Tuberculosis Care [accessed 2 October 2008]. Available at: http://www.nationaltbcenter.edu/international/index.cfm.
15. Arbeláez MP, Kenrad E Nelson KE, Muñoz A. BCG vaccine effectiveness in preventing tuberculosis and its interaction with human immunodeficiency virus infection. Intern J Epidemiol 2000;29:1085-91[accessed 2 October 2008]. Available from URL: http://ije.oxfordjournals.org/cgi/content/full/29/6/1085.

16. Colditz GA, Brewer TF, Berkey CS, Wilson ME, Burdick E, Fineberg HV, et al. Efficacy of BCG vaccine in the prevention of tuberculosis. Meta-analysis of the published literature. JAMA 1994;271:698–702.
17. Rodrigues LC, Smith PG. Tuberculosis in developing countries and methods for its control. Trans R Soc Trop Med Hyg 1990;84:739–44.
18. Centers for Disease Control and Prevention. Tuberculin skin testing. Atlanta: U.S. Department of Health and Human Services; 2007 [accessed 2 October 2008]. Available from URL: http://www.cdc.gov/tb/pubs/tbfactsheets/skintesting.htm.
19. World Health Organization. Laboratory biosafety manual. Second edition (revised). Interim guidelines. [accessed 10 June 2009]. Available from URL: http://www.who.int/csr/resources/publications/biosafety/who_cds_csr_lyo_20034/en/.
20. World Health Organization, Stop TB Department. Planning framework: monitoring and evaluation system and impact measurement. 2006 [accessed 2 October 2008]. Geneva, Switzerland: World Health Organization. Available from URL: http://www.who.int/tb/dots/planningframeworks/monitoring&evaluationplanningframework_may06.doc.
21. Daviaud E, Chopra M. How much is not enough? Human resources requirements for primary health care: a case study from South Africa. Bull WHO 2008;86:46–51 [accessed 2 October 2008]. Available from URL: http://www.who.int/bulletin/volumes/86/1/07-042283.pdf. 11.9.

Online Resources

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 and HIV/AIDS
- TB Can Be Treated
- Testing for TB
- You Can Prevent 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
- A guide for tuberculosis treatment supporters, 2002: http://whqlibdoc.who.int/hq/2002/WHO_CDS_TB_2002.300.pdf
- Community TB care in Africa project: http://www.who.int/tb/people_and_communities/commcare/background/en/index1.html
- Revised TB recording and reporting forms and registers - version 2006: http://whqlibdoc.who.int/hq/2006/WHO_HTM_TB_2006.373_eng.pdf
- A guide to monitoring and evaluation for collaborative TB/HIV activities, 2009: http://whqlibdoc.who.int/publications/2009/9789241598194_eng.pdf

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

Sputum Collection

Health education poster that staff can put on walls in lab or clinic to remind themselves, and make patients aware, of proper method for collecting sputum. Available in PDF form for printing 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.

Mild Side Effects and Their Management

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 CD-ROM. The evaluator may want to print some out before traveling to TB control program for distribution to augment existing educational materials.

TB Admissions Talk

Health education posters that the staff can use to remind themselves what to tell the patients. Available in PDF form for printing 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

Mild Side Effects of TB Drugs and Their Management

Drug	Side Effect	Management
Rifampicin	No appetite, nausea, stomach pain	Eat small meals and before bedtime
	Rash	Take antihistamines, if worsens see health officer
	Orange/Red Urine	Reassure patient—an expected effect of drug
Pyrazinamide (PZA)	Joint pain	Take ibuprofen or aspirin (if not a child)
	No appetite, nausea, stomach pain	Eat small meals and before bedtime
	Rash	Take antihistamines, if worsens see health officer
Isoniazid (INH)	Burning/tingling in hands/feet	Take vitamin B6/ Pyridoxine 100mg
	No appetite, nausea, stomach pain	Eat small meals and before bedtime
	Rash	Take antihistamines, if worsens see health officer
Ethambutol	Eye problems	Stop medicaton and see health officer immediately

TB Admission Talk Patients Must Know:

- **TB can be cured** *and disease symptoms go away with treatment*
- **TB can be easily spread;** *learn how to stop the spread*
- **Always cover your mouth when coughing or sneezing**
- **If you default (stop taking your drugs) your family could get TB;** *and you could possibly die*
- **If a dose is missed, take it as soon as you remember** *but not within 8 hours of the next dose*
- **DOT (Directly Observed Therapy) works** *when it lasts for at least 2 months*
- **Be patient: TB drugs take a while to work;** *learn about the two different phases*
- **If pregnant, tell your doctor,** *you should not take streptomycin injections*
- **Bring in children** *less than 5 years old to be examined, because of high risks of TB*
- **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*
- **Report side effects and if they are severe come to the clinic immediately**
- **Take no alcohol** *while on treatment because of 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 tick 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 from 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 and avoid 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 tick 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:	Date:

Appendix C: Program Implementation

Program Implementation Evaluation Tool

Why the program implementation tool?

Use this section when the healthcare implementing partner is asked whether it is appropriate to start a TB control program in a resource-poor, post-conflict, or refugee setting. TB control is not considered a part of responding to the acute stage of a humanitarian emergency. However, TB among refugees and other migratory populations is an important public health problem and as conflicts become protracted and more camps become long-term settlements, the need for TB control programs increases.

Who should do this evaluation?

This tool should be used by program managers for stable camp settings.

Further explanation of tool

There are 3 parts:

1. Evaluation worksheet for evaluator to complete
2. Scoring guide that provide suggested scores and possible time for reevaluating for implementation, if not currently
3. Explanation worksheet that explains the importance of each item scored, including references

These items have been adapted from Tuberculosis Care and Control in Refugee and Displaced Populations: an Interagency Field Manual (*1*) among other references (see explanations).

Program Implementation Evaluation Worksheet

Site _____ Country _____ Date _____
dd/mm/yy

Write the item's score in the last column (if yes met, give 1 point; if not met, give 0 points)

Item No.	Description	Score Yes = 1 No = 0
	Criteria for Implementation	
1	Foresee security and stability for at least 6 months	
2	National data indicate TB is an important problem	
3	Acute or emergency phase is over (mortality is <1 per 10,000 population per day)	
4	Basic water, shelter, food and sanitation needs are met	
5	Essential clinical services and basic drugs for common illnesses are available	
6	Health services are accessible to enough of the population so that persons with symptoms suggestive of TB can be identified and appropriately investigated or referred	
7	Sufficient funding is available for 12 months	
	Components Needed	
8	Received political commitment at relevant levels of leadership	
9	Developed memorandum of understanding with implementing partner's TB program coordinator and lead health agency (e.g., MOH, WHO, or UNHCR)	
10	Raised awareness in and received support from both host and displaced community	
11	Used National TB Program as a resource in TB programming	
12	Estimated staffing and training requirements (job descriptions, recruitment, training needs)	
13	Plannned for patient accommodation, such as for intensive phase and other patients that require hospitalization as per determined criteria	
14	Assessed lab resources	
15	Defined supervision system	
16	Assessed physical infrastructure	
17	Established recording system	
18	Established monitoring and evaluation of the program	
	Financial Needs	
19	Estimated number of patients requiring TB treatment in the first year (plus 6 months)	
20	Determined health staff salaries	
21	Estimated drugs and other medical supply requirements and costs	
22	Estimated laboratory equipment and reagents requirements and costs	
23	Estimated transport requirements for staff and supplies	
24	Estimated physical infrastructure costs including housing for patients and pharmacy	
25	Estimated generator and fuel costs (if not already in place)	
26	Identified training infrastructure needs and estimated costs	
27	Identified needs and estimated costs of recording system	
	Drug, Reagent, and Equipment Needs	
28	Identified drug and materials procurement officer	
29	Identified potential suppliers and costs	
30	Estimated time from placing the order to arrival of drugs	
31	Procured suitable storage facilities	
32	Purchased drugs and supplies, including lab supplies	
33	Put in place drug stock management system	
A	**Total Score**	

Program Implementation Scoring Guide

	Score/Rating Guide		
	Total Score from previous page (A)		
Range		**Rating**	**Suggested Time Until Implementation**
30-33 (>=90%)		Excellent	Implementation now
25-29 (75%-89%)		Good	Reevaluate for implementation in 3-6 months
17-24 (50%-74%)		Poor	Reevaluate for implementation in 6-11 months
<=16 (<=49%)		Failed	Reevaluate for implementation in 12-18 months

Program Implementation Explanation Worksheet

Site _____ Country _____ Date _____
dd/mm/yy

Item No.	Explanation
	Criteria for Implementation
1-7	Because of concern about creating drug-resistant cases of TB and length of treatment, a TB control program should not be implemented unless stability in security, funding, basic needs of daily living, and basic clinical services are already implemented. Funding for 12 months is needed to complete treatment for the starting cohort; however, a total commitment of at least 18 months is better (*1, 20*).
	Components/Needed
8-10	Political commitment and awareness at all levels are critical and a memorandum of understanding or agreement can help ensure this as well as ensure completion of therapy in the event of repatriation or other movement.
11	The National TB Program (NTP) of the host country should be involved and contribute to the development and implementation of the TB control program. In addition, staff should be familiar with the regimen of the country of origin with the hope of repatriation if clinical conditions are suitable in country of origin (if not, complete therapy in host country).
12	Estimates of staffing and training requirements (job descriptions, recruitment, training needs): • 1 TB coordinator per 50,000 population served A 2008 article from South Africa cited in the methods for a health center (21): • 1 full-time professional nurse or nurse assistant • 1 doctor available at any point during clinic hours • 1 half-time general clinic assistant • 1 clerk available at any point during clinic hours.
13	A small number of very ill patients and a potentially large number of patients living at a distance will need accommodations or during intensive phase of treatment.
14-16	Determine human, material, and laboratory resource needs and cost. A source of quality control for the laboratory is also important (contact the NTP about this possibility).
17-18	Use the STOP TB strategy or other standardized templates (*20 and WHO online resources, page 43*). Use NTP counterparts for monitoring and evaluating.
	Financial Needs
19-27	Assessing TB burden among the population, using incident data from the population's country of origin if possible, will provide a baseline for staffing, drug, supplies, laboratory, logistics, and other needs. If country-of-origin data are not available, use host-country data. TB incidence rates will provide an idea of numbers of staff, drugs, supplies, etc. needed.
	Drug, Reagent and Equipment Needs
28-33	Drug and materials procurement officer has been identified. Use TB burden among the population to estimate baseline amount of drugs and other supplies. Besides an adequate lab, drug procurement, storage, and stock management are essential to a well-functioning program.