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.