DR-TB Patients' Clinical Management

Quality Improvement Tool

Acknowledgments

This "Quality Improvement Tool" (QI Tool) was developed as an output of the "Core Bedaquiline Coordination Project" for Challenge TB Project (CTB) under the APA4 workplan.

The project team adapted the earlier tools developed by the European Respiratory Society (ERS), European Centre for Disease Control (ECDC), and CTB Indonesia on the clinical management of tuberculosis (TB) patients. This QI Tool was upgraded for use by a new target group, namely: supervisors and monitoring specialists working at the National TB programs and partner organizations.

This QI Tool was pilot-tested in countries in Central Asia Region, Eastern Europe, South East Asia and Africa, at the district and facility levels. Health professionals (from NTPs, KNCV, PATH) in the countries, where the QI Tool was pilot-tested, made a huge contribution to improve the initial draft versions of the tool. Their enthusiastic participation during the pilot tests gave the QI Tool the benefit of their ideas and experience and helped to keep it focused on the practical needs and challenges of health providers who manage patients with drug-resistant TB (DR-TB).

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Introduction to the Quality Improvement Tool

The objective of this Quality Improvement (QI) Tool is to assess patients' diagnostic and treatment pathways in order to identify potential bottlenecks leading to an optimization of the daily clinical practice for all DR-TB patients being managed at the respective health facility.

This QI Tool is to be used to document patients' clinical management, to facilitate on-the-job training of staff, and informing discussions on quality improvement of the daily clinical practice.

The tool consists of three parts:

PART 1 collects general information on the respective health facility and indicates what diagnostic and monitoring services are available at the respective health facility.

PART 2 collects information from files and patients' treatment cards/charts to give an insight into the day-to-day clinical management of the patients (from diagnosis to completion of treatment) in order to initiate a discussion with staff leading to agreed next steps and timelines to improve the quality of patient clinical management at the respective health facility. Each worksheet can collect data about five patients. If you have time and need to assess more than five patients, additional worksheets developed for PART 2 accordingly can be used.

PART 3 provides recommendations for on the job training and improvements.

The QI Tool is designed as a participatory job aid- "learning through doing", e.g. systemic analysis of the current situation and identified issues, discussions, problem solving, and planning and taking actions. Users learn through interaction with each other and conducting immediate on-the-spot discussions amongst themselves in small groups. It is designed to move from learning to action(s) for improving the quality of the clinical management of the DR-TB patients at the respective health facility.

Quality Improvement Tool

PART 1: HEALTH FACILITY

[DD/MM/YEAR] of the **PREVIOUS** ASSESSMENT	NAME/ POSITION Auditor	PHONE NUMBER/EMAIL Auditor
[DD/MM/YEAR] of the **CURRENT** ASSESSMENT	NAME/ POSITION Auditor	PHONE NUMBER/EMAIL Auditor

FACILITY	FACILITY ADDRESS/ PHONE NUMBER
NAME/ POSITION contact person of the facility	PHONE NUMBER/EMAIL contact person of the facility

1.1. FACILITY CHARACTERISTICS Pls tick [**X** or **√**] to indicate what type of a health facility is assessed		
Facility	☐ general	☐ TB facility
Type of services	☐ out-patient	☐ in- patient
For which age group services are provided	☐ adults	☐ children

1.2. AVAILABILITY OF TB DIAGNOSTIC LABORATORY SERVICES Pls tick [**X** or **√**] to indicate what type of tests are available	
Smear microscopy ☐ Yes, at the facility ☐ Not available ☐ Yes, transferred (transported) to another facility	**Xpert MTB/RIF** ☐ Yes, at the facility ☐ Not available ☐ Yes, transferred (transported) to another facility
Comments: *Describe the transportation system*	Comments: *Describe the transportation system*
1st-line LPA ☐ Yes, at the facility ☐ Not available ☐ Yes, transferred (transported) to another facility	**2nd- line LPA** ☐ Yes, at the facility ☐ Not available ☐ Yes, transferred (transported) to another facility
Comments: *Describe the transportation system*	Comments: *Describe the transportation system*
Culture on solid media (L-J) ☐ Yes, at the facility ☐ Not available ☐ Yes, transferred (transported) to another facility	**Culture on liquid media (MGIT)** ☐ Yes, at the facility ☐ Not available ☐ Yes, transferred (transported) to another facility
Comments: *Describe the transportation system*	Comments: *Describe the transportation system*
1st-line pDST MGIT ☐ Yes, at the facility ☐ Not available ☐ Yes, transferred (transported) to another facility	**2nd-line pDST MGIT** ☐ Yes, at the facility ☐ Not available ☐ Yes, transferred (transported) to another facility
Comments: *Describe the transportation system*	Comments: *Describe the transportation system*
1st-line pDST L-J ☐ Yes, at the facility ☐ Not available ☐ Yes, transferred (transported) to another facility	**2nd- line pDST L-J** ☐ Yes, at the facility ☐ Not available ☐ Yes, transferred (transported) to another facility

1.2. AVAILABILITY OF TB DIAGNOSTIC LABORATORY SERVICES	
Pls tick [**X** or **√**] to indicate what type of tests are available	
Comments: *Describe the transportation system*	Comments: *Describe the transportation system*
Other: …… ☐ Yes, at the facility ☐ Yes, transferred (transported) to another facility ☐ Not available	
Comments: *Describe the transportation system*	

1.3. AVAILABILITY OF MONITORING TESTS				
Pls tick [**X** or **√ if YES**] to indicate what tests are available				
Tests	Yes, at the facility	Yes, transferred (transported) to another facility	Not available	Comments
Full blood count				
Liver enzymes				
Serum creatinine				
Potassium				
Magnesium/ Calcium				
Uric acid				
Thyroid stimulating hormone				
Blood glucose				
Serum albumin				
Lipase/amylase Lactic acid				
HIV test				
Viral load				
CD4				
Hepatitis virus panel				

1.3. AVAILABILITY OF MONITORING TESTS				
Pls tick [**X** or **√ if YES**] to indicate what tests are available				
Pregnancy test				
Audiometry				
ECG/ QTc calculation				
Visual acuity				
Color vision				
X-Ray				
Comments: *If partially available, e.g. no FBC but rapid test for Hb only, put in comments*				

1.4. ***INFECTION CONTROL MEASURES IMPLEMENTED AT THE FACILITY***			
Pls tick [**X** or **√**] to indicate measures indicated			
Are DS-TB patients separated from DR-TB patients? **In- patient** ☐Yes ☐No **Out-patient** ☐Yes ☐No	Are RR-/ MDR-TB separated from pre-XDR-TB/XDR-TB patients? **In- patient** ☐Yes ☐No **Out-patient** ☐Yes ☐No	Are there isolation rooms available for respiratory infection patients (in the ward)? ☐Yes ☐No	Are respiratory infectious patients supplied with surgical masks? **In- patient** ☐Yes ☐No **Out-patient** ☐Yes ☐No
Comments:			

1.5. ***DRUG STOCKS AT THE HEALTH FACILITY***	
Pls tick [**X** or **√**] to indicate measures indicated	
Has there been a stock out drugs used for DR-TB treatment during last 3 months? ☐Yes ☐No	Has there been a stock out of Bdq, Dlm, and repurposed drugs (Mfx, Lfx, Cfz, Lzd) during last 3 months? ☐Yes ☐No

Comments:

Part 2: Patients

Pls. fill in the UNIT or DEPARTMENT of the FACILITY, where information is being collected:

Introduction

From the DR-TB patients currently on treatment in this facility, randomly select 5-10 patients, and ask the assisting facility staff to pick out patients' treatment cards files. The number of patients will depend on the amount of time you have to review their information, but the minimum should be five. Enter the patient's registration no. in the in the table below, so that the answers and conclusions in the subsequent sections can be traced back to the individual patient. It is possible that the information requested may also be in the DR-TB Register.

To randomly select patients, use the function RANDBETWEEN in Excel. For instance, if there are 100 patients in the *Masterlist* and they are numbered 1 to 100, type: "=RANDBETWEEN(1,100)". It will give you a random number between 1 and 100. You can repeat the RANDBETWEEN function 10 times and take the numbers that are indicated. If the numbers are 6-36, type "=RANDBETWEEN(6,36)". If you copy the content of the cell to another cell, it will give you another random number.

**Please note that the RANDBETWEEN return value changes every time you change anything in the Excel file. Should you want to store the randomly returned numbers, then please copy them to Word. If you want to copy them to Excel, then make sure that you choose the Paste Special > Past Values option.*

Example

Suppose that there are 100 patients and you want to review 10 patient files, then, on average, 1 in 10 patients should be selected. You can either repeat the RANDBETWEEN function 10 times and take the numbers that are returned (in case of duplicate numbers you will need to repeat), or (simpler), ask for a random number between 1 and 10 and add 10 to it several times. So, if the number 3 is returned, then the 3rd, 13th, 23rd, etc. patients' files should be reviewed.

Patients For each selected patient (1-5), pls. write down the ID or registration number						
	Patient 1 (P1)	Patient 2 (P2)	Patient 3 (P3)	Patient 4 (P4)	Patient 5 (P5)	Notes
Registration number						
Gender (M/F)						
Age						

2.1. DIAGNOSIS AND TURN-AROUND TIME OF RESULTS AT TREATMENT INITIATION

Please compare results jotted down in patients' cards/charts with source documents, e.g., laboratory test results, etc.

To fill in the data below, pls. **DATE**, **0=Unknown** in case the information is missing in the patients' file **or N/A= not applicable** not applicable for any reason.

		P1	P2	P3	P4	P5	Comments
Date registered as presumptive DR-TB or date of 1st consultation (last episode)							
Date Xpert MTB/RIF sample collected (last episode)							
Date Xpert MTB/RIF results	reported by laboratory						
	received by clinician						
Turn-around-time (T-A-T) (days) Xpert MTB/RIF*							
Date of referral from peripheral to treatment initiating center							
Date of the treatment initiation							
Date of baseline SL LPA sample collected							
Date of baseline SL LPA results	reported by laboratory						
	received by clinician						
Turn-around-time (T-A-T) SL LPA*							
Date of baseline culture sample collected	MGIT						
	LJ						
Date of baseline culture result reported by laboratory	MGIT						
	LJ						
Date of baseline culture result received by clinician	MGIT						
	LJ						
Turn-around-time (T-A-T) baseline culture*	MGIT						

2.1. DIAGNOSIS AND TURN-AROUND TIME OF RESULTS AT TREATMENT INITIATION

Please compare results jotted down in patients' cards/charts with source documents, e.g., laboratory test results, etc.

To fill in the data below, pls. **DATE**, **0=Unknown** in case the information is missing in the patients' file **or N/A= not applicable** not applicable for any reason.

	LJ						
Date of baseline sample collected for 1st line DST**)**	MGIT						
	L-J						
Date of baseline 1st line DST results reported by laboratory	MGIT						
	L-J						
Date of baseline 1st line DST results received by clinician	MGIT						
	L-J						
T-A-T baseline 1st line DST*****	MGIT						
	L-J						
Date of baseline sample collected for 2nd line DST	MGIT						
	L-J						
Date of baseline 2nd line DST results reported by laboratory	MGIT						
	L-J						
Date of baseline 2nd line DST results received by clinician	MGIT						
	L-J						
T-A-T baseline 2nd line DST *****	MGIT						
	L-J						
Date of DR-TB treatment initiation							
Time from presumptive DR-TB or Xpert MTB/RIF result to initiation of DR-TB treatment **							

Comments:

P1:

P2:

P3:

2.1. DIAGNOSIS AND TURN-AROUND TIME OF RESULTS AT TREATMENT INITIATION
Please compare results jotted down in patients' cards/charts with source documents, e.g., laboratory test results, etc.
To fill in the data below, pls. **DATE**, **0=Unknown** in case the information is missing in the patients' file **or N/A= not applicable** not applicable for any reason.
P4:
P5:
**TAT can be calculated by number of days between sample collection date and reported result.*
***Number of days between "registered as presumptive DR-TB or date confirmed RR-TB by XpertMTB/RIF and date start of treatment"*

2.2. TREATMENT PRESCRIPTION AND ADMINISTRATION						
To fill in the data below, please indicate **Yes, No, 0** (no data in the patients' clinical records) **or N/A= not applicable** in case not applicable for any reason (e.g. not needed or not applicable at this moment).						
	P1	**P2**	**P3**	**P4**	**P5**	Comments
Correct regimen choice (triage to STR or ITR)						
Correct regimen design. STR Standard. ITR contains at least 5 (intensive phase) TB drugs deemed active						
Right administration of drug as per label (dosage, frequency), according to the country guidelines						
Adequate intensive phase STR: intensive phase 4-6 months ITR injectable (if included in the regimen) = 8 months						
Adequate continuation phase* **STR:** 5 months **ITR:** minimum 12 months						
Treatment adjusted according to the DST results or intolerance of drugs						

2.2. TREATMENT PRESCRIPTION AND ADMINISTRATION

To fill in the data below, please indicate **Yes, No, 0** (no data in the patients' clinical records) **or N/A= not applicable** in case not applicable for any reason (e.g. not needed or not applicable at this moment).

Comments:

Pls. indicate in the comments if patient's regimen is without injectable, and borders of phases are difficult to distinguish

P1:

P2:

P3:

P4:

P5:

*Duration of the treatment should be according to the national guidelines and sputum results (check the completion date).

2.3. TREATMENT RESPONSE MONITORING (BASELINE AND FOLLOW-UP TESTS)

To fill in the data below, please indicate **Yes, No, ?** (if data are incomplete), **0** (no data in the patients' clinical records), **or N/A= not applicable** in case not applicable for any reason (e.g. not needed or not applicable at this moment).

B= baseline, F= follow-up

	P1		**P2**		**P3**		**P4**		**P5**		Comments
	B	F	B	F	B	F	B	F	B	F	
Weight											
Body Mass Index											BMI = (weight in kilograms)/ height in meters²

2.3. TREATMENT RESPONSE MONITORING (BASELINE AND FOLLOW-UP TESTS)

To fill in the data below, please indicate **Yes, No, ?** (if data are incomplete), **0** (no data in the patients' clinical records), **or N/A= not applicable** in case not applicable for any reason (e.g. not needed or not applicable at this moment).

B= baseline, F= follow-up

Smear											
Culture											
Repeated SL LPA/pDST											If smear/culture positive > 4 months or suspect failure
Chest X-ray											
Comments: P1:											
P2:											
P3:											
P4:											
P5:											

2.4. TREATMENT SAFETY MONITORING (BASELINE AND FOLLOW-UP TESTS)

To fill in the data below, please indicate **Yes, No, ?** (if data are incomplete)**, 0** (no data in the patients' clinical records) **or N/A= not applicable** in case not applicable for any reason (e.g. not needed or not applicable at this moment).

B= baseline, F= follow-up

	P1		**P2**		**P3**		**P4**		**P5**		Comments
	B	F	B	F	B	F	B	F	B	F	
Full blood count (FBC)											
Liver enzymes											

2.4. TREATMENT SAFETY MONITORING (BASELINE AND FOLLOW-UP TESTS)

To fill in the data below, please indicate **Yes, No, ?** (if data are incomplete)**, 0** (no data in the patients' clinical records) **or N/A= not applicable** in case not applicable for any reason (e.g. not needed or not applicable at this moment).

B= baseline, F= follow-up

Serum creatinine											
Potassium											
Magnesium, Calcium											If potassium is abnormal
Uric acid											
Thyroid stimulating Hormon (TSH)											
Blood glucose											
Serum Albumin											
HIV test*											Pls indicate [+] or [-]
Hepatitis B											According to the country protocol
Hepatitis C											According to the country protocol
Pregnancy test											
Audiometry											
ECG / QTcF											
Visual acuity											
Color vision test											
Other tests*											

Pls indicate other tests (only if patient has specific clinical condition or specific treatment choices (e.g. patient is on Lzd or other options)

Comments:

P1:

P2:

P3:

P4:

2.4. TREATMENT SAFETY MONITORING (BASELINE AND FOLLOW-UP TESTS)

To fill in the data below, please indicate **Yes, No, ?** (if data are incomplete)**, 0** (no data in the patients' clinical records) **or N/A= not applicable** in case not applicable for any reason (e.g. not needed or not applicable at this moment).

B= baseline, F= follow-up

P5:

2.5. ADVERSE EVENTS

To fill in the data below, please indicate **Yes, No, ?** (if data are incomplete)**, 0 (no data in the patients' clinical records) or N/A= not applicable** in case not applicable for any reason (e.g. not needed or not applicable at this moment).

	P1	**P2**	**P3**	**P4**	**P5**	Comments
Serious adverse events detected						
Serious adverse events managed properly						
Ancillary drugs are available for serious adverse						
Severe adverse events reported accordingly *						According to the country protocol: facility→ to national level→ to global level

Comments:

P1:

P2:

P3:

P4:

P5:

* In case of a SAE a copy of the report should always be kept in the patients' file.

Please fill section 2.6 for TB/HIV co-infected patients only, if they are HIV+, see section 2.4 otherwise indicate as N/A.

*2.6. MANAGEMENT TB/HIV CO-INFECTION **

To fill in the data below, please indicate **Yes, No, ?** (if data are incomplete), **0 (no data in the patients' clinical records) or N/A= not applicable** in case not applicable for any reason (e.g. not needed or not applicable at this moment).

B= baseline, F= follow-up

	P1	**P2**	**P3**	**P4**	**P5**	Comments
Viral load						
CD4 count						
Cotrimoxazole preventive therapy given						
Correct timing of ART start						
Correct ART regimen/ BDQ compatible						
Correct Management of virological failure, timely switch ART						
Comments: P1:						
P2:						
P3:						
P4:						
P5:						

2.7. PATIENT SUPPORT

To fill in the data below, please indicate **Yes, No, ?** (if data are incomplete), **0 (no data in the patients' clinical records) or N/A= not applicable** in case not applicable for any reason (e.g. not needed or not applicable at this moment).

	P1	**P2**	**P3**	**P4**	**P5**	Comments
Counselling and education on DR-TB done						
Psychological assessment done						
Social support assessment done						
The individual support plan is developed, followed-up and updated						
Comments: P1:						
P2:						
P3:						
P4:						
P5:						

PART 3: RECOMMENDATIONS FOR ON THE JOB TRAINING AND IMPROVEMENTS

Number	Recommendation	Responsible	Date [dd/mm/yy]	Implemented Yes/ No
1.				
2.				
3.				
4.				
5.				