

REPUBLIC OF KENYA



MINISTRY OF HEALTH

DR-TB Patient Treatment Log Book

Patient Name:

Patient Reg. No.:



February 2023

MOH/DPPH/DNTLD/ DRTBPTTreat.LOGBOOK/002

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1. DEFINITION OF TREATMENT OUTCOMES

Outcome	Definition
Cured	Treatment completed as recommended by the national policy without evidence of failure AND three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase
Treatment Complete	Treatment completed as recommended by the national policy without evidence of failure BUT no record that three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase
Treatment Failed	<p>Treatment terminated or need for permanent regimen change of at least two anti-TB drugs because of:</p> <ul style="list-style-type: none"> – Lack of conversion by the end of the intensive phase, or – Bacteriological reversion in the continuation phase after conversion to negative, or – Evidence of additional acquired resistance to fluoroquinolones or second-line injectable drugs, or – Adverse Drug Reactions (ADRs)
Lost to Follow Up	A patient who started treatment and interrupted for 2 consecutive months or more
Died	A patient who dies for any reason before starting or during the course of TB treatment

2. PRE TREATMENT EVALUATION /ASSESSMENT

2.1. Vital Signs

Vital Signs	Functional status:	
BP ____/ ____	Able to conduct normal activity, No special care needed	
Pulse rate ____/ min	Unable to conduct normal activity, Some assistance needed	
Temp ____oC	Unable to care for self, requires hospitalization	
Resp. rate ____/ min		
SpO2 ____.(%)		

2.2. Drug Susceptibility Test (Genotypic/Phenotypic) Results (microbiology)

Test	Diagnostic specimen (tick)		Result (tick / indicate all applicable)							Date
	Sputum	Other (specify)								
Xpert RIF/UL-TRA /TrueNat (mandatory)			No MTB	MTB/Rif Sen.	MTB/Rif Res.	MTB/Rif Indeter- minate	MTB Trace	Not done		
1 st line LPA			No MTB	MTB detected ()	Rif Sen.()	Rif Res.()	INH Sen.()	INH Res.()		
2 nd Line LPA			No MTB	MTB detected ()	FQN Sen.()	FQN Res.()				
Culture			Growth	No Growth	MOTT	Contaminated	Other			
DST 1 st Line R=Resistant S=Sensitive			Isoniazid	Rifampicin	Streptomycin	Ethambutol	Pyrazinamide			
DST 2 nd Line R=Resistant S=Sensitive			FQN (Lfx/Mfx)	Linezolid	Bedaquiline	Delamanid	Clofazimine	Pretomanid		
Histology (if performed indicate report/ result)										

2.3. Baseline Lab Test Results & Imaging

Baseline lab test results					
Test	Date	Results	Comment		
Creatinine					
Bilirubin					
AST					
ALT					
Potassium					
Full Hemogram					
TSH					
Pregnancy test					
Magnesium					
RBS					
Albumin					
HIV test					
CD4					
Viral Load					
Other Baseline tests			IMAGING TESTS		REMARKS
Test	Date	Results	CXR	OTHERS	
ECG (QTCF)					
Audiometry(Normal/ Abnormal)					
Visual testing	Remarks				
Ishihara test					
Snellen's test					

2.4. Obstetrical and Gynecology History

Obs/ Gyn history

Last menstruation date ____/ ____/ __ (dd/mm/yy)

Parity _____ Gravidity _____

Contraceptive use: YES _____ Specify _____ NO _____

2.5. Review of Systems

Systemic examination	
Fill in the findings on systemic examination	
Lymph nodes	
Cardiovascular system	
Respiratory system	
Abdomen	
Skin	
Urogenital system	
Musculoskeletal exam	
Neurological exam	
Other	

2.5. Anthropometric Assessment

[illegible]

2.6. Social Status Screening

Assessed by social worker () Yes () No

Family support available () Yes () No

(describe).....

Work Status:() Paid work: () Self-employed: () None paid work:() Student/scholar: () Retired:() Unemployed: () Other

Indicate the work address and contact person

Linked to Social Support (medical insurance, monthly stipend and nutritional support) () Yes () No

Specify if yes/No: if no specify why:.....

2.7. Disability and Rehabilitation Assesment

Interview date:	Initial Phase:		End of treatment			
Name of interviewer:	Initial Phase:		End of treatment			
Do you have difficulties performing the following tasks:	None		Need some assistance		Cannot do	
	Intensive Phase	End of treatment	Initial phase	End of treatment	Initial Phase	End of treatment
1. Standing/ walking for long periods (e.g 30 min)						
2. Concentrating on doing something for 10 min						
3. Washing your whole body						
4. Getting dressed						
5. Going to toilet						
6. Your day-to-day work/school						
Remarks:						
Referral: (for any ticks in the grey area please refer to rehabilitation professional)						

3. CONTACT SCREENING AND MANAGEMENT

Contacts are defined as persons living in the same household, or spending many hours together in the same indoor living space. Screen the contacts for symptoms and obtain a chest X-Ray at baseline. Close contacts of DR TB are at high risk of DR TB. Close contacts with TB should be treated as DR TB. Refer to the DR TB guidelines. Screen contacts for symptoms every 0 months(at time of diagnosis of the index case), 3 months, 6 months, 12 months, 18 months and 24 months. If a contact is found to have TB symptoms, obtain a chest X-Ray, genexpert/TRUE-NAT, FL LPA, SL LPA, and culture and DST. (Document this in the clinical notes section

					Date __ / __ / __	Date / / / __	Date / / / __	Date / / / __	Date / / / __	Date / / / __	Date / / / __	Date / / / __	Date / / / __	
No.	Name	Age	Sex	Mobile No.	Are there TB symp-toms? (Y/N)	CXR	Gen-eXpert Results	Are there TB symp-toms? (Y/N)	Are there TB symp-toms? (Y/N)	Are there TB symp-toms? (Y/N)	Are there TB symp-toms? (Y/N)	Are there TB symp-toms? (Y/N)	Are there TB symp-toms? (Y/N)	Out- come TB/ No TB
						Key 1.Normal 2.Abnormal (Sugges- tive of TB) 3.Abnormal Others 4.Not done								

4. REGIMEN FORMULATION GUIDE

For all TB patients with resistance to rifampicin, by Gene Xpert / TrueNat or conventional DST (please tick in box)			
Check	Ask	Yes	No
A	A1- Has the patient been previously treated for DR-TB for >1 month?		
	A2- Does the patient have extra-pulmonary disease?		
	A3- Is there any reason to suspect that the patient has or will develop intolerance to any of the 2 nd Line medicines?		
	A4- Does the patient have severe lung damage (on CXR), such as multiple bilateral cavities, extensive parenchymal damage or lung collapse?		
	A5- Is the patient pregnant?		
	A6- TB? Does the patient have a close contact who: <ul style="list-style-type: none"> a. Had XDR TB? b. Had resistance to fluoroquinolone c. Failed or is failing treatment for DR-TB? d. Died while on treatment for DR-TB? 		
	If there is YES to any of the 6 questions above, the patient is eligible for individualized regimen, go to C below If NO to all the above 6 questions, the patient is eligible for standardized regimen, go to B below		
B	Trace results for 2 nd Line LPA and conventional 2 nd Line DST		
	B1- Is there resistance to any group A drugs (FQ, Bdq, Lzd) If YES to the question above the patient requires individualized regimen, go to D below If the response to question above is NO, or results unavailable, start on standard MDR regimen		
C	Trace results for 2 nd Line LPA and conventional 2 nd line DST		
	C1- Is there resistance to fluoroquinolone or any other group A drugs C2- Is there any YES on the answer to Question A6 (above) C3- Is there suspected intolerance to 2 nd Line medicines?		
	If YES to any to any of the C-3 questions above, go to D below If the response to all 3 questions is NO, constitute the PMDT team and start patient on treatment for uncomplicated disease		
D	Consult the National PMDT Technical Advisory team for regimen design		

5. CONSENT FORM

Level	Information provided	Agreement			
	Is the patient willing to receive DOTs?	Yes		No	
	Does the patient fully understand the duration of treatment?	Yes		No	
Agree between HCW and patient	Does the patients understand that the health care worker will maintain confidentiality?	Yes		No	
	Does the patient understand the consequences of stopping/refusing treatment to himself/herself?	Yes		No	
	Does the patient understand the consequences of Stopping/refusing treatment to their close contacts and general public?	Yes		No	
	Does the patient understand that one of the consequences of Stopping/refusing treatment is involuntary isolation for the duration of treatment?	Yes		No	
Arrange with the patient	Does the patient understand the need to organize his/her priorities in order to better cope with changes and interruptions in social life	Yes		No	
	Does the patient have a treatment supporter (caregiver or family member) that will participate in the education/ counselling sessions and help in treatment management	Yes		No	
	Does the patient have daily schedule for taking his medication and treatment plan for DOT	Yes		No	
Health care workers responsibility	Have you helped the patient to evaluate the factors likely to interfere in the treatment and their solutions?	Yes		No	
	Will you be available for the patient to express his emotions and other psychological reactions?	Yes		No	
	Will you assist the patient to anticipate barriers to implementing treatment plan and identify strategies to overcome them?	Yes		No	
	Have you applied the PHQ9 and CAGE form to the patient?	Yes		No	
	Is there a history of mental illness or substance abuse? (If yes, refer to appropriate care providers)	Yes		No	1

Patient/Guardian, Next of Kin/Guardian and Health Care Workers Memorandum of Understanding for DR TB Treatment

I.....(patient identified to have DR TB/Guardian) And.....(who is the Next of kin/Treatment supporter) have been explained about DR-TB, the medicines to be used and associated adverse/side effects, the need to complete treatment and the duration of treatment. We also understand the consequences of stopping/refusing treatment to self, close contacts and general public. We have agreed that the patient will be started on DR TB treatment and we undertake to ensure that the patient will present themselves to the health facility (or allow a health worker to visit them daily) for the stipulated treatment period as advised by the health care worker. We also undertake to ensure that the patient does not interrupt treatment under any circumstances. In case of interruption of treatment, we understand the applicable consequences, including involuntary isolation treatment for the patient in a health facility.

Patient:

Sign:.....

Name:.....

Tel.....

Next of Kin:

Sign:.....

Name:.....

Tel.....

Witness (HCW):

Sign:.....

Name:.....

Reviewed:

CTLC

Sign:.....

Tel.....

6. TREATMENT

Date treatment started	Date started (Intensive phase)		Date started (Continuation Phase)	
Short treatment regimen (>15yrs) <i>(Treatment duration 6months)</i> 6BPaLM	Drug	Dose per Day	Drug	Dose per Day
	Bedaquiline			
	Pretomanid			
	Linezolid			
	Moxifloxacin			
<15yrs (intensive 6 months, Continuation 3 months) <i>(BLLCC)..to discuss</i>	Bedaquiline		Levofloxacin	
	Linezolid		Cycloserine	
	Levofloxacin		Clofazimine	
	Cycloserine			
	Clofazimine			
	Bedaquiline			
	Delamanid			
	Levofloxacin			
	Moxifloxacin			
	Amikacin			
	Kanamycin			
	Capreomycin			
	Streptomycin			
	Clofazimine			
	Ethionamide / Prothionamide			
	Cycloserine			
	Linezolid			
	Rifampicin			
	Isoniazid			
	Pyrazinamide			
	Ethambutol			
	PAS			
	Imipenem/Cilastatin			
	Meropenem			
	Amoxicillin/Clavulanate			
	Thiacetazone			
	Pretomanid			
	Terizidone			
Additional treatment	Cotrimoxazole		Cotrimoxazole	
	Pyridoxine		Pyridoxine	
Antiretroviral treatment				
Other medicines				

7. ADHERENCE COUNSELING

Questions	Baseline	Day 14	Day 28	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	Month 13	Month 14	Month 15	Month 16	Month 17	Month 18	Month 19	Month 20
Date																						
Agreement between HCW and patient	****Tick appropriately****																					
Is the patient willing to receive DOTs?																						
Does the patient fully understand the duration of treatment?																						
Does the patients understand that the health care worker will retain confidentiality?																						
Does the patient understand the consequences of stopping/refusing treatment to themselves?																						
Does the patient understand the consequences of stopping/refusing treatment to their close contacts and general																						
Does the patient understand they can be put under involuntary isolation as a consequence of stopping/refusing treatment?																						
If the patient stopped/ refused TB treatment in the past, what will he/ she do differently this time in order to complete treatment?																						
Arrange with the patient																						
Does the patient understand the need to organise his/ her priorities in order to better cope with changes and interruptions in social life?																						
Does the patient have a treatment supporter (care-giver or family member) that would participate in the sessions and help in treatment management?																						
Does the patient have a daily schedule and treatment plan for DOT?																						
Health care workers responsibility																						
Have you assisted the patient to evaluate the factors likely to interfere in the treatment and their solutions?																						
Will you be available for the patient to express his emotions and other psychological reactions?																						
Will you assist the patient to anticipate causes of treatment interruption and identify strategies to overcome them?																						
Have you applied the PHQg form to the patient?																						
If mental or substance abuse history, have you referred to appropriate care providers?																						

8. DAILY OBSERVATION OF DRUG INTAKE

Month:																																Reason for missed drug
Date:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Bedaquiline (Bdq)																																
Levofloxacin (Lfx)																																
Moxifloxacin (Mfx)																																
Linezolid (Lzd)																																
Pretomanid (Pmd)																																
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Imipinem (Imp)																																
Amoxy-Clavulanic Acid (Amx/Clav)																																
Mark in the boxes						O	Daily Observed	Comments:																								
						N	Not Supervised																									
						X	Drug not taken																									

9. DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

		Month _____/Year _____																															Enter code from key below	
	Date:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Management	Outcome
	Side Effect__																																	
1	Nausea																																	
	Q-T prolongation																																	
	Myelosuppression																																	
	Peripheral Neuropathy																																	
	Anemia																																	
2	Vomiting																																	
3	Abdominal pain																																	
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13	Joint pain																																	
14	Rash																																	
15	Discoloration of skin and mucus membrane																																	
16	Depression																																	
17	Psychosis																																	
18	Constipation																																	
19	Decreased hearing																																	
20	Tinnitus																																	
21	Tremors																																	
	Others (list)__																																	
22																																		
23																																		
24																																		

Side effect grading		
Grade 0 - No side effect.	1 Drug withdrawn	1 Recovering/Resolving
Grade 1 - Mild symptoms that don't interrupt normal functioning but requiring reassurance.	2 Dose reduced	2 Recovered/Resolved
Grade 2 - Moderate symptoms causing greater than some interference in normal functioning. Requires monitoring and reassurance.	3 Dose not changed	3 Requires prolonged hospitalization
Grade 3 - Severe symptoms causing limitation in normal functioning. Requires clinical intervention including regimen modification.	4 Patient reassured	4 Causes congenital anomaly
Grade 4 - Potentially life threatening symptoms causing inability to perform. Requires hospitalization for management.	5 Patient hospitalized	5 Permanent disability/morbidity
		6 Not resolved
		7 Unknown

DAILY OBSERVATION OF DRUG INTAKE

Month:																																Reason for missed drug
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Kanamycin (Km)																																
Amikacin (Amk)																																
Capreomycin (Cm)																																
Imipinem (Imp)																																
Amoxy-Clavulanic Acid (Amx/Clav)																																

Mark in the boxes	O	Daily Observed	Comments:
	N	Not Supervised	
	X	Drug not taken	

DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

		Month _____/Year _____																															Enter code from key below	
Date:		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Management	Outcome
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Grade 4 - Potentially life threatening symptoms causing inability to perform. Requires hospitalization for management.	

1 Drug withdrawn

2 Dose reduced

3 Dose not changed

4 Patient reassured

5 Patient hospitalized

1 Recovering/Resolving

2 Recovered/Resolved

3 Requires prolonged hospitalization

4 Causes congenital anomaly

5 Permanent disability/morbidity

6 Not resolved

7 Unknown

DAILY OBSERVATION OF DRUG INTAKE

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Amoxy-Clavulanic Acid (Amx/Clav)																																

Mark in the boxes	O	Daily Observed	Comments:
	N	Not Supervised	
	X	Drug not taken	

DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

		Month _____/Year _____																															Enter code from key below	
Date:		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Management	Outcome
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	5 Permanent disability/morbidity
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	7 Unknown
	3 Dose not changed
	4 Patient reassured
	5 Patient hospitalized

8. DAILY OBSERVATION OF DRUG INTAKE

Month:																																Reason for missed drug
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						X	Drug not taken																									

DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

		Month _____/Year _____																															Enter code from key below	
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17	Psychosis																																	
18	Constipation																																	
19	Decreased hearing																																	
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21	Tremors																																	
	Others (list) __																																	
22																																		
23																																		
24																																		

Side effect grading		
Grade 0 - No side effect.	1 Drug withdrawn	
Grade 1 - Mild symptoms that don't interrupt normal functioning but requiring reassurance.	1 Recovering/Resolving	
Grade 2 - Moderate symptoms causing greater than some interference in normal functioning. Requires monitoring and reassurance.	2 Dose reduced	2 Recovered/Resolved
Grade 3 - Severe symptoms causing limitation in normal functioning. Requires clinical intervention including regimen modification.	3 Dose not changed	3 Requires prolonged hospitalization
Grade 4 - Potentially life threatening symptoms causing inability to perform. Requires hospitalization for management.	4 Patient reassured	4 Causes congenital anomaly
	5 Patient hospitalized	5 Permanent disability/morbidity
		6 Not resolved
		7 Unknown

DAILY OBSERVATION OF DRUG INTAKE

Month:																																Reason for missed drug
Date:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
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Capreomycin (Cm)																																
Imipinem (Imp)																																
Amoxy-Clavulanic Acid (Amx/Clav)																																

Mark in the boxes	O	Daily Observed	Comments:
	N	Not Supervised	
	X	Drug not taken	

DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

		Month _____/Year _____																															Enter code from key below	
Date:		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Management	Outcome
	Side Effect__																																	
1	Nausea																																	
	Q-T prolongation																																	
	Myelosuppression																																	
	Peripheral Neuropathy																																	
	Anemia																																	
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Side effect grading	
Grade 0 - No side effect.	1 Drug withdrawn
Grade 1 - Mild symptoms that don't interrupt normal functioning but requiring reassurance.	2 Recovering/Resolving
Grade 2 - Moderate symptoms causing greater than some interference in normal functioning. Requires monitoring and reassurance.	2 Recovered/Resolved
Grade 3 - Severe symptoms causing limitation in normal functioning. Requires clinical intervention including regimen modification.	3 Requires prolonged hospitalization
Grade 4 - Potentially life threatening symptoms causing inability to perform. Requires hospitalization for management.	4 Causes congenital anomaly
	5 Permanent disability/morbidity
	6 Not resolved
	7 Unknown
	3 Dose not changed
	4 Patient reassured
	5 Patient hospitalized

DAILY OBSERVATION OF DRUG INTAKE

Month:																																Reason for missed drug
Date:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
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Imipinem (Imp)																																
Amoxy-Clavulanic Acid (Amx/Clav)																																

Mark in the boxes	O	Daily Observed	Comments:
	N	Not Supervised	
	X	Drug not taken	

DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

		Month _____/Year _____																															Enter code from key below	
Date:		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Management	Outcome
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Grade 4 - Potentially life threatening symptoms causing inability to perform. Requires hospitalization for management.	4 Causes congenital anomaly
	5 Permanent disability/morbidity
	6 Not resolved
	7 Unknown
	5 Patient hospitalized

DAILY OBSERVATION OF DRUG INTAKE

Month:																																Reason for missed drug
Date:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
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Amoxy-Clavulanic Acid (Amx/Clav)																																
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						N	Not Supervised																									
						X	Drug not taken																									

DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

		Month _____/Year _____																															Enter code from key below	
Date:		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Management	Outcome
	Side Effect__																																	
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Side effect grading	
Grade 0 - No side effect.	1 Drug withdrawn
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Grade 3 - Severe symptoms causing limitation in normal functioning. Requires clinical intervention including regimen modification.	3 Requires prolonged hospitalization
Grade 4 - Potentially life threatening symptoms causing inability to perform. Requires hospitalization for management.	4 Causes congenital anomaly
	5 Permanent disability/morbidity
	6 Not resolved
	7 Unknown
	3 Dose not changed
	4 Patient reassured
	5 Patient hospitalized

DAILY OBSERVATION OF DRUG INTAKE

Month:																																Reason for missed drug
Date:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
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Amoxy-Clavulanic Acid (Amx/Clav)																																
Mark in the boxes						O	Daily Observed	Comments:																								
						N	Not Supervised																									
						X	Drug not taken																									

DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

		Month _____/Year _____																															Enter code from key below	
	Date:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Management	Outcome
	Side Effect__																																	
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Side effect grading		
Grade 0 - No side effect.	1 Drug withdrawn	1 Recovering/Resolving
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Grade 3 - Severe symptoms causing limitation in normal functioning. Requires clinical intervention including regimen modification.	4 Patient reassured	4 Causes congenital anomaly
Grade 4 - Potentially life threatening symptoms causing inability to perform. Requires hospitalization for management.	5 Patient hospitalized	5 Permanent disability/morbidity
		6 Not resolved
		7 Unknown

DAILY OBSERVATION OF DRUG INTAKE

Month:																																Reason for missed drug
Date:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
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Amoxy-Clavulanic Acid (Amx/Clav)																																

Mark in the boxes	O	Daily Observed	Comments:
	N	Not Supervised	
	X	Drug not taken	

DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

		Month _____/Year _____																															Enter code from key below	
Date:		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Management	Outcome
	Side Effect__																																	
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Side effect grading	
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Grade 4 - Potentially life threatening symptoms causing inability to perform. Requires hospitalization for management.	4 Causes congenital anomaly
	5 Permanent disability/morbidity
	6 Not resolved
	7 Unknown
	5 Patient hospitalized

DAILY OBSERVATION OF DRUG INTAKE

Month:																																Reason for missed drug
Date:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
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Mark in the boxes						O	Daily Observed	Comments:																								
						N	Not Supervised																									
						X	Drug not taken																									

DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

		Month _____/Year _____																															Enter code from key below	
Date:		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Management	Outcome
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	5 Permanent disability/morbidity
	6 Not resolved
	7 Unknown
	5 Patient hospitalized

DAILY OBSERVATION OF DRUG INTAKE

Month:																																Reason for missed drug
Date:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
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DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

		Month _____/Year _____																															Enter code from key below	
Date:		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Management	Outcome
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	7 Unknown
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DAILY OBSERVATION OF DRUG INTAKE

Month:																																Reason for missed drug
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Mark in the boxes	O	Daily Observed	Comments:
	N	Not Supervised	
	X	Drug not taken	

DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

		Month _____/Year _____																															Enter code from key below	
Date:		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Management	Outcome
	Side Effect__																																	
1	Nausea																																	
	Q-T prolongation																																	
	Myelosuppression																																	
	Peripheral Neuropathy																																	
	Anemia																																	
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	Others (list) __																																	
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Side effect grading	
Grade 0 - No side effect.	<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> 1 Drug withdrawn 2 Dose reduced 3 Dose not changed 4 Patient reassured 5 Patient hospitalized </div> <div style="width: 45%;"> 1 Recovering/Resolving 2 Recovered/Resolved 3 Requires prolonged hospitalization 4 Causes congenital anomaly 5 Permanent disability/morbidity 6 Not resolved 7 Unknown </div> </div>
Grade 1 - Mild symptoms that don't interrupt normal functioning but requiring reassurance.	
Grade 2 - Moderate symptoms causing greater than some interference in normal functioning. Requires monitoring and reassurance.	
Grade 3 - Severe symptoms causing limitation in normal functioning. Requires clinical intervention including regimen modification.	
Grade 4 - Potentially life threatening symptoms causing inability to perform. Requires hospitalization for management.	

DAILY OBSERVATION OF DRUG INTAKE

Month:																																Reason for missed drug
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Imipinem (Imp)																																
Amoxy-Clavulanic Acid (Amx/Clav)																																
Mark in the boxes						O	Daily Observed	Comments:																								
						N	Not Supervised																									
						X	Drug not taken																									

DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

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Grade 4 - Potentially life threatening symptoms causing inability to perform. Requires hospitalization for management.	5 Patient hospitalized	5 Permanent disability/morbidity
		6 Not resolved
		7 Unknown

DAILY OBSERVATION OF DRUG INTAKE

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DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

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	5 Permanent disability/morbidity
	6 Not resolved
	7 Unknown
	5 Patient hospitalized

DAILY OBSERVATION OF DRUG INTAKE

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	N	Not Supervised	
	X	Drug not taken	

DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

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DAILY OBSERVATION OF DRUG INTAKE

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DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

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DAILY OBSERVATION OF DRUG INTAKE

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DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

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DAILY OBSERVATION OF DRUG INTAKE

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DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

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DAILY OBSERVATION OF DRUG INTAKE

Month:																																Reason for missed drug
Date:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Bedaquiline (Bdq)																																
Levofloxacin (Lfx)																																
Moxifloxacin (Mfx)																																
Linezolid (Lzd)																																
Pretomanid (Pmd)																																
Clofazimine (Cfz)																																
Cycloserine (Cs)																																
Delamanid (Dlm)																																
Isoniazid (Inh)																																
Rifampicin (Rif)																																
Ethambutol (Emb)																																
Pyrazinamide (Pza)																																
High Dose Isoniazid (Hh)																																
Prothionamide (Pto)																																
Ethionamide (Eto)																																
Para-Aminosalicylic Acid (PAS)																																
Kanamycin (Km)																																
Amikacin (Amk)																																
Capreomycin (Cm)																																
Imipinem (Imp)																																
Amoxy-Clavulanic Acid (Amx/Clav)																																
Mark in the boxes						O	Daily Observed	Comments:																								
						N	Not Supervised																									
						X	Drug not taken																									

DAILY DR-TB DRUG SIDE EFFECT MONITORING FORM

		Month _____/Year _____																															Enter code from key below	
Date:		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Management	Outcome
	Side Effect__																																	
1	Nausea																																	
	Q-T prolongation																																	
	Myelosuppression																																	
	Peripheral Neuropathy																																	
	Anemia																																	
2	Vomiting																																	
3	Abdominal pain																																	
4	Palpitation																																	
5	Diarrhea																																	
6	Headache																																	
7	Fatigue																																	
8	Dizziness																																	
9	Fever																																	
10	Jaundice																																	
11	Vision changes																																	
12	Oedema																																	
13	Joint pain																																	
14	Rash																																	
15	Discoloration of skin and mucus membrane																																	
16	Depression																																	
17	Psychosis																																	
18	Constipation																																	
19	Decreased hearing																																	
20	Tinnitus																																	
21	Tremors																																	
	Others (list) __																																	
22																																		
23																																		
24																																		

Side effect grading	
Grade 0 - No side effect.	1 Drug withdrawn
Grade 1 - Mild symptoms that don't interrupt normal functioning but requiring reassurance.	2 Recovering/Resolving
Grade 2 - Moderate symptoms causing greater than some interference in normal functioning. Requires monitoring and reassurance.	2 Recovered/Resolved
Grade 3 - Severe symptoms causing limitation in normal functioning. Requires clinical intervention including regimen modification.	3 Requires prolonged hospitalization
Grade 4 - Potentially life threatening symptoms causing inability to perform. Requires hospitalization for management.	4 Causes congenital anomaly
	5 Permanent disability/morbidity
	6 Not resolved
	7 Unknown
	5 Patient hospitalized

10. MONITORING FOR QUALITY OF CARE

10.1. Sputum Monitoring and Follow Up

Month No.	Date	Serial No.	Test result				Comment(s) / Action
			Smear Microscopy (Tick appropriately)		Culture (Tick appropriately)		
			Positive	Negative	Growth	No Growth	
Baseline							
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
11.							
12.							
13.							
14.							
15.							
16.							
17.							
18.							

10.2. Laboratory and Clinical Follow Up

RESULTS

[illegible]

10.3. Monitoring Schedule for Patients on Injectable Free Regimen

Month	Baseline	1	2	3	4	5	6	7	8	9	10	11	12	15	18
Patient Counselling	X	X	X	X	X										
Screening for substance abuse	X				X										
Review by a Clinician	X	Every 2 weeks	Monthly until treatment completion												
ADR screening	X	Monthly until treatment completion													
Weight/ BMI/ Z-Score	X	Monthly until treatment completion													
Smear microscopy	X	Monthly until treatment completion													
Culture	X	Monthly until treatment completion													
1 st line DST	X			X (if still smear positive)			X (if any reversion to positive culture in the continuation phase)								
2 nd line DST	X			X (if still smear positive)			X (if any reversion to positive culture in the continuation phase)								
ALT/ AST/ Bilirubin	X	Repeat if patient is vomiting, has abdominal pain, jaundice or any evidence of liver injury													
Serum Albumin	X														
Creatinine	X	Do monthly if on an injectable drug. Otherwise repeat only if the baseline creatinine was abnormal or if clinically indicated.													
Potassium, Magnesium	X	Do monthly if on an injectable drug. Otherwise repeat if vomiting, diarrhoea, if QTcF is prolonged or if clinically indicated.													
Full Hemogram	X	X	X	X	X	X	X	Monthly if on Linezolid							
HIV Test	X	As per HTS guidelines													
CD4	X*	As per ART guidelines													
Viral Load	X*	As per ART guidelines													
RBS	X														X
Review Contraception	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Pregnancy Test	X														
CXR	X														X
TSH	X		X												
Audiometry†	X														
ECG (QTcF monitoring)††	X	Every 2 weeks	X	X	X	X	X			X			X	X	X
Visual test (Ishihara & Snellen)	X	X	X	X	X	X	X	Test monthly each month that the patient is on LZD							

†If baseline CD4 <200

* If not done in the last 3 months. Otherwise, use the most recent Viral load

††At baseline and monthly in the intensive phase. Continue monthly if on Bedaquiline or Delamanid. Otherwise, ECG should be done every 3 months while on CFZ.

† Audiometry monthly if on an injectable drug. If any abnormality is detected, stop the injectable and consult the clinical team

10.4. DR TB Treatment Adjustment

Drug	Treatment Start date	Initial Dosage	Date of Dose adjustment	Adjusted Dose	Reason for adjusting dosage	Date drug substituted	Reason for drug substitution
Bedaquiline (Bdq)							
Levofloxacin (Lfx)							
Pretomanid (Pmd)							
Moxifloxacin (Mfx)							
Linezolid (Lzd)							
Clofazimine (Cfz)							
Cycloserine (Cs)							
Delamanid (Dlm)							
Isoniazid (Inh)							
Rifampicin (Rif)							
Ethambutol (Emb)							
Pyrazinamide (Pza)							
High Dose Isoniazid (Hh)							
Prothionamide (Pto)							
Ethionamide (Eto)							
Para-Aminosalicylic Acid (PAS)							
Kanamycin (Km)							
Amikacin (Amk)							
Capreomycin (Cm)							
Imipinem (Imp)							
Amoxy-Clavulanic Acid (Amx/Clav)							
Indicate type of contraception (for females)							

10.5. Nutritional Intervention

Nutrition support	Code
Nutritional Counselling	NC
Therapeutic feeds	RUTF
Supplementary Feeds	FBF
Vitamin A	
Pyridoxine	
Not Done	ND

12. MONTHLY DR TB CLINICAL REVIEW TEAM CHECKLIST

1. To be filled by the chair of the review team
2. Confirm and put a tick against each variable carried out

		Base line	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
1	Date																									
2	Record age in years																									
3	Record weight at current visit																									
4	Record BMI at current visit																									
5	Nutrition support given Y/N																									
6	Record follow up tests reviewed at visit depending on month of treatment (audiometry, hgm, LFTs, UECs, CXR, LFTs, CD4, repeat																									
7	Blood drawn for Lancet Labs Y/N																									
8	Screen for clinical symptoms of common ADRs (and complete the daily DR TB side effect monitoring form) Y/N																									
9	ADR forms filled and reported to county pharmacist Y/N																									
10	Drug adjustments made Y/N																									
11	Record reasons for drug adjustment e.g. weight gain, weight loss, ADR																									
12	Record date drugs adjusted																									
13	Record results of latest monthly smear microscopy																									
14	Record results of latest monthly culture																									
15	Where applicable, any ART adjustments made to dosage? Y/N																									
16	Record date adjustment made																									
17	Record reason for ART adjustments e.g. ADR, ART Resistance																									
18	Patients received monthly support Y/N																									
19	Has the patient been enrolled with NHIF?																									
20	Where applicable DOTS nurse received monthly transport support Y/N																									
21	DR TB Tx Counselling done? Y/N																									

13. DR-TB TREATMENT OUTCOME

Outcome	Mark One	Date of Outcome
Cured		
Treatment Complete		
Treatment Failed		
Lost to Follow Up		
Transferred Out Not outcome (consider deleting)		
Died		

14. POST DR-TB TREATMENT FOLLOW UP

Patients will be followed up for a period of 2 years after treatment completion to assess for any relapses/re-infection and post TB treatment complications that may arise.

Refer to table below for guidance

Post TB treatment follow up							
Patients will be followed up for a period of 2 years after treatment completion to assess for any relapses/re-infection and post TB treatment complications that may arise. Refer to table below for guidance							
Indicate Month <i>(after treatment completion)</i>		3	6	12	18	24	Remarks
Review by clinician <i>(evaluate for symptoms including TB and other lung conditions and record at every visit)</i>							
Weight/BMI (Done at each follow up visit)							
Screening for substance abuse <i>(type findings)</i>							
Imaging: CXR , CT scan (Done for any presumptive Post TB Lung Disease patient (PTLD) on follow up)							
Diagnostic tests for Presumptive TB							
TEST	TEST RESULT <i>(indicate date)</i>						
XPRT MTB/RIF/ ULTRA							
TRUENAT							
LPA (1st & 2nd Line)							
Culture & DST,1st & 2nd Line							
Spirometry (Done as clinically indicated (When there is impairment of lung function)							
Diagnosis (See Key below for options of diagnosis)							
1. Tuberculosis 2. Asthma 3. Lung scarring (fibrosis) 4. Bronchiectasis 5. Chronic Obstructive Pulmonary Disease (COPD) 6. Lung abscess 7. Aspergillus-related lung disease 8. Spontaneous Pneumothorax 9. Interstitial lung diseases 10. Lung cancer 11. Other specify							



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