#StepUpforTB 2020
A survey of national policies for TB prevention, diagnosis, treatment and care in 43 high TB burden countries

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Survey questionnaire

INFORMATION SHEET

INTERVIEWER: PLEASE READ OUT THE POINTS BELOW TO THE RESPONDENT BEFORE STARTING THE QUESTIONNAIRE.

1. THE PROJECT AND OBJECTIVES

MSF and Stop TB Partnership are jointly conducting this survey among the NTPs of 43 countries to assess if, and to what extent, international best practices (for example WHO recommendations) for TB diagnostics, treatment, models of care, prevention and drug procurement and regulation have been formally adopted at national level. **This aims to highlight successes as well as identify gaps and areas that need more attention to reach the EndTB goals, both at national and global level.**

2. THE DEFINITION OF 'ADOPTED NATIONAL POLICIES'

This survey asks for policies that are formally adopted by the government **by the end of December 2019**. Criteria for formal policy adoption are:

- A formal written document is published with the government's title or logo on it, and/or signed by a Minister or other national government official, for example: national policy documents, frameworks or statements, technical manuals, guidelines or protocols.

OR

- A written communication has been issued and/or circulated by the national government (e.g. MoH or NTP) to a range of national stakeholders with an accompanying statement of guidance or action required, including through prikazes, gazettes, memorandums, issuances, Essential Medicines Lists, circulars and/or MoH letters or emails.

3. IN THE EVENT OF NOT KNOWING THE ANSWER TO A QUESTION

If the respondent **does not know** the answer or they are unsure, select "Don't know". **However, it is possible to follow up and provide us with an answer at a later date, but no more than two weeks after the interview (i.e. two weeks from today).** If no response is received, the "Don't know" response will be included in the final data analysis.

4. HOW THE DATA WILL BE ANALYSED AND PUBLISHED

The study team will not modify any responses received from the respondents. After we receive the completed questionnaires, our technical specialists will check the answers for completeness, internal consistency and quality using official national documents as reference. This is standard procedure to prevent the publication of mistakes due to misunderstandings or processing errors. **Should we find missing answers or discrepancies with the national documents, the study team will seek clarification from the respondent.** Should it not be possible to clarify a discrepancy, e.g. because no response was received by the respondent, the study team may exclude the answer from the analysis. This will only happen in exceptional circumstances.

The results of the survey will be published in a joint report by MSF and Stop TB Partnership, which will present the individual answers provided by each country, as well as some aggregated results. We aim to launch the report at the UN General Assembly in September 2020.

5. CONSENT TO BE INTERVIEWED AND TO PUBLISH THE RESPONSES
Every respondent is formally asked to consent to the interview and to the publication of responses. The respondent may decline or withdraw consent for participating in this interview at any time, even after the interview. The respondent may also choose to decline answering a specific question at any time, without giving any reasons. Declined answers will be shown in the report as "Declined answers".

Section 0: Administration & Approval

To be filled by the interviewer at the beginning of the interview

Administration		
0.1	Date of interview	
	Name & affiliation of interviewer	
	Email address of interviewer	
	Name & affiliation of respondent	
	Country	

Approval		
0.2	Dear interviewer, did you read out the Information Sheet on the previous page to the respondent?	☐ YES ☐ NO
	Did the respondent consent to participate in the interview?	☐ YES ☐ NO
	Did the respondent approve the publication of responses?	☐ YES ☐ NO ☐ Conditional, please define_____
	Comments/notes to the study team	

Section 1: TB Diagnostics

Rapid Molecular Testing

1.1

Question	Which of the following rapid molecular diagnostic tests are indicated in the national policies for routine TB diagnosis?
Explanation	• This question concerns routine diagnostics only, please do not include tests that are used only under research conditions. • Please select the tests indicated in the national policies for routine diagnosis, regardless of algorithms.
Instruction	Please select ☑ **ALL** that apply.
Answers	☐ Xpert MTB/RIF ☐ TB LAMP ☐ TrueNAT ☐ Other rapid molecular TB diagnostic tests (please specify name and manufacturer): _____ ☐ None of the above tests are indicated in the national policies ☐ Don't know ☐ Decline answer
Comments	

1.2

Question	Please indicate the number of facilities that offer routine TB diagnostic testing using any of the technologies listed below.
Explanation	• Please answer for facilities in place as of the end of December 2019. • Please only include facilities where the test instrument(s) are physically installed. • Please answer regardless of algorithms or ownership of facilities/instruments (i.e. public and/or private), as long as facilities offer routine TB diagnostic services. • For the calculation of total no. of facilities (5th and 6th answer): Provide the sum. If a facility offers, for example, both Xpert and TB LAMP, please count this facility only once.
Instruction	Enter no. of facilities in table below. If unknown, please write "unknown". If NO facilities, please write "0".

Answers

No. of facilities offering:	
	Xpert MTB/RIF
	TB LAMP
	TrueNAT
	Smear microscopy
	Any rapid molecular diagnostic test (Xpert/TB LAMP and TrueNAT)
	Any TB diagnostic test (incl. Xpert/TBLAMP/TrueNAT/ smear, culture, LPA)

Comments

1.3

Question	According to the national policies, which groups of people are eligible for a rapid molecular diagnostic test as **initial diagnostic TB test**?
Explanation	• "Initial diagnostic test" means that the clinician orders it as initial test, regardless of subsequent lab procedures. For example: in some laboratories, staff also conduct microscopy prior to Xpert testing from the same sample. If this is done, Xpert/TB LAMP/TrueNAT are still initial diagnostic tests, as long as smear testing does not introduce a delay for returning the Xpert/TBLAMP/TrueNAT result and if Xpert/TB LAMP/TrueNAT is still done on all samples, regardless of smear result. • The definitions of "at risk for DR-TB" vary across countries. Here it refers to "however it is defined in the national policies". • "Other risk factors" could be defined in national policies based on socio-demographic characteristics or locations, please specify accordingly.
Instruction	Please select ☑ **ALL** that apply in the table below.

	Patients eligible for initial testing with:	Xpert MTB/RIF	TB LAMP	TrueNAT	Comments
	Adults at risk for DR-TB	☐	☐	☐	
	Children at risk for DR-TB	☐	☐	☐	
	Adults at risk for HIV-associated TB	☐	☐	☐	
	Children at risk for HIV-associated TB	☐	☐	☐	
	Adults with other risk factors, please specify_____	☐	☐	☐	
	Children with other risk factors, please specify _____	☐	☐	☐	
	All adults with presumptive TB	☐	☐	☐	
	All children with presumptive TB	☐	☐	☐	
	Test not indicated in national policies	☐	☐	☐	
	Don't know	☐	☐	☐	
	Decline answer	☐	☐	☐	

1.4	Question	If the use of rapid molecular tests for all people with presumptive TB is recommended by national policies, do these policies indicate a limitation to certain facilities?	
	Explanation	• This question only needs to be answered if you indicated that a rapid molecular test (either Xpert/TB LAMP or TrueNAT) is initial diagnostic test for all adults and all children with presumptive TB in Q1.3. If that is not the case, please skip this question. • In many countries, for example, Xpert testing for all people with presumptive TB is limited by the policies to facilities which have the GeneXpert installed, and countries have two different algorithms depending on Xpert on/off-site. In this case, please select the first answer. • But if all sites without a GeneXpert instrument refer specimen from all people with presumptive TB for Xpert testing to GeneXpert sites, this is *not* a limitation. In this case, please select the third answer (NO).	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, the policies indicate that rapid molecular tests for all people with presumptive TB is limited only to facilities which have the test instrument physically installed ☐ YES, the policies indicate that rapid molecular tests for all people with presumptive TB is limited only to facilities following other criteria (please specify) _____ ☐ NO, the policies do not indicate any limitations to certain facilities ☐ Don't know ☐ Decline answer	Comments

Urinary LAM Testing

1.5	Question	Do the national policies indicate the use of the urinary Lateral Flow LAM (LF LAM) test in the diagnosis of TB?	
	Explanation	• This is regardless of diagnostic algorithm and eligibility criteria.	
	Instruction	Please select ☑ **ALL** that apply.	
	Answers	☐ YES, LF LAM is indicated in the policies for routine use ☐ NO, LF LAM is not indicated in the policies for routine use but is exclusively used under research/pilot conditions ☐ NO, LF LAM is not indicated in the policies for routine use and no research/pilot is conducted ☐ Don't know ☐ Decline answer	Comments
1.6	Question	If the LF LAM is currently not indicated in the national policies, are there plans to introduce it **for routine** use in the coming 12 months?	
	Explanation	• This is regardless of diagnostic algorithm and eligibility criteria. • Please answer this question only if the response to Q 1.5 was NO, otherwise please skip.	
	Instruction	Please select ☑ **ALL** that apply.	

	Answers	☐ YES, there are plans to include it in the coming 12 months ☐ NO, there are no plans to include it in the coming 12 months ☐ Don't know ☐ Decline answer	Comments
1.7	Question	If the LF LAM is currently not indicated in the national policies, what are the reasons in your opinion?	
	Explanation	• Please answer this question only if you answered "NO" in Q1.5, otherwise, please skip.	
	Instruction	Please select ☑ **ALL** that apply. • **Note for the interviewer: Please do not prompt (i.e. do not read out the answers to the respondent but match the respondents' answers with the options given below).**	
	Answers	☐ Lack of funding for procurement of the test ☐ Lack of funding for the practical implementation (e.g. for policy revision or training) ☐ National regulations do not allow the use of this test ☐ National regulations are time consuming and delayed the implementation ☐ The LF LAM test is not in the mandate of the TB program ☐ No time to plan and prepare for the LF LAM implementation ☐ Test not relevant for the country given the epidemiological context ☐ Not aware of the LF LAM test ☐ Not aware of WHO recommendations for the LF LAM ☐ Evidence review presented by WHO is not convincing ☐ Do not believe the LF LAM test will have any value ☐ Waiting for a more accurate (sensitivity/specificity) version of the LF LAM test ☐ Awaiting results of our own research/pilot projects ☐ Other, please specify _____ ☐ Don't know ☐ Decline answer	Comments
1.8	Question	If the LF LAM is indicated in the national policies, what are the eligible patient groups, according to the policies?	
	Explanation	• Please specify eligible groups for LF LAM testing, based on their characteristics using: HIV status, age category (adults/children), presence/absence of TB symptoms, CD4 count threshold, category of HIV disease staging, presence/absence of danger signs, as well as location of the patient i.e. IPD or OPD).	
	Instruction	Please **describe.**	
	Answers	According to the policies, the following groups of people are eligible for LF LAM testing: _____ _____ _____ _____ ☐ Don't know ☐ Decline answer	Comments
1.9	Question	If the LF LAM is indicated in the national policies, do these indicate a positive LAM result to be used to initiate TB treatment?	
	Explanation	• Note for the interviewer: Treatment should be initiated based on a positive LF LAM result and there is no need to wait for bacteriological information. WHO recommends that, whenever possible, a sample is sent for Xpert testing for the purpose of a RIF result but a bacteriological confirmation (either by Xpert, smear or culture) is not required for treatment initiation. • A repeat LF LAM test is not considered a bacteriological confirmation.	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, according to the policies, a positive LAM result can be used for treatment initiation and waiting for bacteriological confirmation is not required	Comments

		☐ YES, according to the policies, a positive LAM result can be used for treatment initiation, but only for specific sub-groups, or under certain conditions/locations, please specify_____ ☐ NO, the policies indicate that a positive LAM result cannot be used for treatment initiation because bacteriological confirmation is required ☐ The policies are not clear on that ☐ Don't know ☐ Decline answer	
1.10	Question	How many LF LAM tests have been ordered in 2018 and 2019?	
	Explanation	Only tests ordered for routine use, not for operational research.	
	Instruction	Please enter **"0"** if **NO** tests were ordered.	
	Answers	Number of LF LAM tests ordered in 2018 _____ Number of LF LAM tests ordered in 2019 _____ ☐ Don't know ☐ Decline answer	Comments
1.11	Question	If the LF LAM is already practically implemented for routine use, in which type of facilities or settings?	
	Explanation	• If the LF LAM is not practically implemented for routine use yet, please skip the question.	
	Instruction	Please select ☑ **ALL** that apply.	
	Answers	☐ In-patient departments ☐ Out-patient departments ☐ Peripheral health facilities or clinics ☐ Other, please specify _____ ☐ Don't know ☐ Decline answer	Comments
Universal DST			
1.12	Question	Do the national policies indicate that bacteriologically confirmed TB cases should be tested at least for RIF resistance?	
	Explanation	• If the national policies indicate that Xpert/TrueNat is initial diagnostic test for all presumptive TB cases, everyone will automatically receive a RIF resistance result and the answer should be YES (first answer). • If Xpert/TrueNAT is not the primary diagnostic test for all presumptive TB cases, the answer here should be YES if, for example, all people with TB who were bacteriologically confirmed with other TB diagnostic tests (microscopy, TB LAMP or culture) should be tested for RIF resistance (second answer). • This includes RIF testing by any method, i.e. molecular diagnostic tests or phenotypic DST. • "Selected groups" could be based on certain socio-demographic characteristics or locations.	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, Xpert or TrueNAT are initial diagnostic test for **all** people with presumptive TB, therefore all bacteriologically confirmed TB cases will automatically receive a RIF result ☐ YES, **all** bacteriologically confirmed TB cases, diagnosed with tests other than Xpert/TrueNat, should also be tested for RIF resistance ☐ YES, bacteriologically confirmed TB cases, diagnosed with tests other than Xpert/TrueNat, should also be tested for RIF resistance but only selected groups of patients or under certain conditions/locations (please specify): _____ ☐ NO, the policies do not indicate RIF resistance testing for bacteriologically confirmed cases with TB ☐ Don't know ☐ Decline answer	
		Comments:	

1.13	Question	Do the national policies indicate that people with RR-TB should be further tested for resistance to at least FLQs (and SLIDs)?
	Explanation	• This includes testing by any method, including molecular or phenotypic DST. • For countries that are still using Km or Am for treatment, the answer should be YES if both, at least one FLQ and at least one SLID is tested. As long as any SLID is routinely used for treatment, the DST must include a SLID as well. • "Selected groups" could be based on certain socio-demographic characteristics or locations.
	Instruction	Please select ☑ **ONE** ANSWER only.
	Answers	☐ YES, **all** RR-TB cases should be tested for resistance to FLQ and SLID ☐ YES, RR-TB cases should be tested for resistance to FLQ and SLID, but only selected groups of RR-TB patients or under certain conditions/locations (please specify): _____ ☐ NO, the policies do not indicate FLQ- and SLID- testing for RR-TB cases ☐ Don't know ☐ Decline answer
		Comments

DST Methods

1.14	Question	Please indicate from the list below, which DST methods are available for routine use in country.
	Explanation	• Each DST method must be available (i.e. practically implemented) in at least one laboratory in country, not only at the SRL overseas. • The DST method must be practically available for clinicians for routine diagnostics, not only for research settings. We are not asking whether the country has the theoretical means to do it, we are asking if it is already there. • Phenotypic DST includes DST methods on any culture media. • Note for the interviewer: Just because we are asking for DST methods for certain drugs, it does not suggest the country is supposed to implement DST methods to all the drugs this survey asks for. There are drugs on this list for which no globally standardized, recommended methods exist. We still ask about these in order to gather evidence of whether or not these are available in countries in order to develop a high-level message.
	Instruction	Please select ☑ **ONE** answer for each row.

Molecular DST methods

	Available	Not available	Don't know	Decline answer
HAIN MTBDR Plus LPA for first-line drugs	☐	☐	☐	☐
HAIN MTBDRsl LPA for second-line drugs	☐	☐	☐	☐
Any other LPA for drug resistance, please specify name and brand _____	☐	☐	☐	☐
Next generation sequencing	☐	☐	☐	☐

Phenotypic DST methods

	Available	Not available	Don't know	Decline answer
Amikacin	☐	☐	☐	☐
Bedaquiline	☐	☐	☐	☐
Capreomycin	☐	☐	☐	☐
Clofazimine	☐	☐	☐	☐
Cycloserine	☐	☐	☐	☐
Delamanid	☐	☐	☐	☐
Ethambutol	☐	☐	☐	☐
Ethionamide	☐	☐	☐	☐

Comments

Gatifloxacin	☐	☐	☐	☐	
Imipenem-cilastatin	☐	☐	☐	☐	
Isoniazid – high dose	☐	☐	☐	☐	
Isoniazid – low dose	☐	☐	☐	☐	
Kanamycin	☐	☐	☐	☐	
Levofloxacin	☐	☐	☐	☐	
Linezolid	☐	☐	☐	☐	
Meropenem	☐	☐	☐	☐	
Moxifloxacin – high CB	☐	☐	☐	☐	
Moxifloxacin – low CC	☐	☐	☐	☐	
Ofloxacin	☐	☐	☐	☐	
P-amino salicylic acid (PAS)	☐	☐	☐	☐	
Pretomanid	☐	☐	☐	☐	
Protionamide	☐	☐	☐	☐	
Pyrazinamide	☐	☐	☐	☐	
Rifampicin	☐	☐	☐	☐	
Streptomycin	☐	☐	☐	☐	
Terizidone	☐	☐	☐	☐	
Other (please specify) _____	☐	☐	☐	☐	

Section 2: TB and DR-TB Treatment

WHO DR-TB treatment guidelines

2.1	Question	What is the current status of implementing the WHO DR-TB guidelines as of end December 2019?	
	Explanation	• This question concerns the WHO consolidated DR-TB guidelines first issued in December 2018 (final version published in March 2019). This question does not concern implementation of the Rapid Communication issued in December 2019. • This question concerns only the sections on composition of the MDR-TB treatment regimen in the WHO guidelines, not sections concerning INH mono-resistant TB, surgery or care and support for people with MDR-TB.	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ The national policies have been updated and were approved ☐ The national policies have not been updated, but a strategic plan (transition plan) has been developed ☐ The national policies have not been updated, and no strategic/transition plan has been developed ☐ The adoption of the WHO DR-TB treatment guidelines has not yet been addressed at all ☐ Other _____ ☐ Don't know ☐ Decline answer	Comments

Standardized shorter DR-TB treatment regimen

2.2	Question	Do the national policies indicate the use of the standardized shorter regimen for treating RR/MDR-TB <u>for adults</u>?
	Explanation	• The standardized shorter regimen includes 4-6 (Am/Kan/Cm)-(Mfx/Gfx/Lfx)-(Pto/Eto) -Cfz-Z-INH(high) / 5 Mfx-Cfz-Z-E, also known as the "Bangladesh regimen". • Please answer YES even when it is an option among other regimens for treatment of RR/MDR-TB. • This is regardless of specific eligibility criteria for people with TB defined in the national policies. • Operational research in this case is defined as programmatic research that is done by the MoH and/or a partner, has an approved ethics protocol and is not a clinical trial.

	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, the standardized shorter regimen may be used routinely for RR/MDR-TB treatment according to national policies ☐ NO, the standardized shorter regimen is not indicated in the national policies as routine treatment option for RR/MDR-TB, but is exclusively used under operational research/pilot conditions ☐ NO, the standardized shorter regimen is not indicated in the national policies for routine treatment and not used under operational research/pilot conditions ☐ Don't know ☐ Decline answer	Comments
2.3	Question	According to the national policies, which is the preferred injectable and the preferred FLQ drug in the standardized shorter regimen?	
	Explanation	• Answer this question only if the answer of Q 2.2 is YES, otherwise, please skip it. • "Preferred drug" means that the drug is indicated in national policies as first choice for treatment to clinicians unless there are (clinical) contraindications or the drug is not available.	
	Instruction	Please select ☑ **ONE** ANSWER for injectables and **ONE** ANSWER form FLQs.	
	Answers	**Preferred injectable drug** ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Other, please define_____ ☐ Don't know ☐ Decline answer	**Preferred FLQ drug** ☐ Moxifloxacin ☐ Gatifloxacin ☐ Levofloxacin ☐ Other, please define _____ ☐ Don't know ☐ Decline answer
		Comments:	

Modified shorter DR-TB treatment regimen

2.4	Question	Do the national policies indicate the use of a modified all-oral shorter regimen for treating RR/MDR-TB <u>for adults</u>?	
	Explanation	• This question and the following two questions concern the use of additional modifications to 4-6 (Am/Kan/Cm)-(Mfx/Gfx/Lfx)-(Pto/Eto) -Cfz-Z-INH(high) / 5 Mfx-Cfz-Z-E, beyond the two drug substitutions allowed by WHO (Pto or Eto, Mfx or Gfx or Lfx). These modifications may include, but are not limited to, for example, regimens in which the injectable has been replaced with BDQ. • Below, there are options for up to three modified regimens. For each modified regimen version, we ask you to outline the regimen, then we ask about the status of implementation (Q2.5) and in a third question (Q2.6), we ask how widely the respective regimen is available. Please answer for each modified regimen individually. • Of note, this question concerns both routine use and operational research – but only for adults.	
	Instruction	Please indicate drugs & length for each regimen. If you have more than three regimen options for these three questions (Q 2.4, 2.5 and 2.6), please continue in the additional answer sheet (ANNEX 2).	
	Answers	☐ YES, the national policies indicate the use of the following modified all-oral shorter regimen, either for routine use or operational research: _____ (regimen option 1) _____ (regimen option 2) _____ (regimen option 3) ☐ NO, the national policies do not indicate the use of any modified all-oral shorter regimen ☐ Don't know ☐ Decline answer	Comments

2.5	Question	Please indicate how the above defined all-oral short regimen options 1-3 are used, as of end December 2019.
	Explanation	• Operational research/pilot in this case is defined as research that is done by the MoH and/or a partner, has an approved ethics protocol and is not a clinical trial.
	Instruction	Please select ☑ **ALL** that apply for each regimen option.

	Regimen 1	**Regimen 2**	**Regimen 3**	Comments
Operational research or pilot has been completed	☐	☐	☐	
Operational research or pilot has started, but not completed	☐	☐	☐	
Operational research or pilot is planned but not started	☐	☐	☐	
Operational research or pilot is not planned	☐	☐	☐	
Implementation for routine use has been completed	☐	☐	☐	
Implementation for routine use has started, but not completed	☐	☐	☐	
Implementation for routine use is planned but not started	☐	☐	☐	
Implementation for routine use is not planned	☐	☐	☐	
Don't know	☐	☐	☐	
Decline answer	☐	☐	☐	

2.6	Question	What percentage of patients have started / will be started on this regimen, in 2019 and 2020?
	Explanation	• Denominator = all patients started on RR/MDR-TB treatment in the respective reporting year. • Please answer this question if routine use and/or operational research has been started, is planned or is completed. Skip the question if there are no plans for routine use or operational research. • If both routine use and operational research take place in the same year, please combine the estimated percentage of patients for both.
	Instruction	Please answer for each regimen option.

Regimen 1	**Regimen 2**	**Regimen 3**
Percentage for 2019: _____	Percentage for 2019: _____	Percentage for 2019: _____
Estimated percentage for 2020: _____	Estimated percentage for 2020: _____	Estimated percentage for 2020: _____
☐ Don't know	☐ Don't know	☐ Don't know
☐ Decline answer	☐ Decline answer	☐ Decline answer

Comments:

Longer DR-TB treatment regimen

2.7	Question	Do the national policies indicate the use of a longer all-oral regimen for treating RR/MDR-TB for adults?
	Explanation	• This question refers to longer regimens that are either standardized or individualized and based only on the use of oral drugs recommended by WHO. • These longer regimens do not include historic, standardized longer regimens with an injectable agent, previously commonly called a 'conventional regimen' or a 'standardized MDR regimen'. • Below, there are options for up to three all-oral long regimens. For each regimen version, we ask you to outline the regimen, then we ask about the status of implementation (Q 2.8) and in a third question (Q 2.9), we ask how widely the respective regimen is available. Please answer for every modified regimen individually. • Of note, this question concerns routine use and operational research – but only for adults.
	Instruction	Please indicate drugs & length for each regimen, if you have more than three regimen options for these three questions (Q 2.7, 2.8 and 2.9), please continue in the additional answer sheet (ANNEX 2).

	Answers	☐ YES, the national policies indicate the use of the following all-oral long regimen, either for routine use or operational research: _____ (regimen option 1) _____ (regimen option 2) _____ (regimen option 3) ☐ NO, the national policies do not indicate the use of any all-oral long regimen ☐ Don't know ☐ Decline answer	Comments

2.8	Question	Please indicate how the above defined all-oral long regimen options 1-3 are used, as of December 2019.
	Explanation	• Operational research/pilot in this case is defined as research that is done by the MoH and/or a partner, has an approved ethics protocol and is not a clinical trial.
	Instruction	Please select ☑ **ALL** that apply for each regimen option.

	Regimen 1	**Regimen 2**	**Regimen 3**	Comments
Operational research or pilot has been completed	☐	☐	☐	
Operational research or pilot has started, but not completed	☐	☐	☐	
Operational research or pilot is planned but not started	☐	☐	☐	
Operational research or pilot is not planned	☐	☐	☐	
Implementation for routine use has been completed	☐	☐	☐	
Implementation for routine use has started, but not completed	☐	☐	☐	
Implementation for routine use is planned but not started	☐	☐	☐	
Implementation for routine use is not planned	☐	☐	☐	
Don't know	☐	☐	☐	
Decline answer	☐	☐	☐	

2.9	Question	What percentage of patients have started / will be started on this regimen, in 2019 and 2020?
	Explanation	• Denominator = all patients started on RR/MDR-TB treatment in the respective reporting year. • Please answer this question if routine use and/or operational research has been started, is planned or is completed. Skip the question if there are no plans for routine use or operational research. • If both routine use and operational research take place in the same year, please combine the estimated percentage of patients for both.
	Instruction	Please select ☑ **ALL** that apply for each regimen option.

Regimen 1	**Regimen 2**	**Regimen 3**
Percentage for 2019: _____	Percentage for 2019: _____	Percentage for 2019: _____
Estimated percentage for 2020: _____	Estimated percentage for 2020: _____	Estimated percentage for 2020: _____
☐ Don't know	☐ Don't know	☐ Don't know
☐ Decline answer	☐ Decline answer	☐ Decline answer

Comments:

BPaL Regimen

2.10	Question	What is the current status of implementing the BPaL regimen at country level?
	Explanation	• BPaL regimen: bedaquiline, pretomanid, and linezolid 1200mg. • Regardless of indication of use.
	Instruction	Please select ☑ **ALL** that apply.

	Answers	☐ Clinical trial(s) are completed or ongoing ☐ Operational research or pilot has started, but not completed ☐ Operational research or pilot is planned but not started ☐ Operational research or pilot is not planned in the coming 12 months ☐ Implementation for routine use has started, but not completed ☐ Implementation for routine use is planned but not started ☐ Implementation for routine use is not planned in the coming 12 months ☐ Don't know ☐ Decline answer	Comments
2.11	Question	If BPaL implementation for routine use or operational research is planned or has started, please list the indication of use.	
	Explanation	• If there are no plans for routine use or operational research in the coming 12 months, please skip this question. • If the BPaL composition and drug dosing differs from (bedaquiline, pretomanid, and linezolid 1200 mg), please specify this in the respective answer option below. If there is no difference, please list the indication of use and leave regimen composition blank.	
	Instruction	Please **specify**.	
	Answers	Regimen composition (drugs and drug dosing):_____ Indication (XDR, pre-XDR, MDR intolerant/non-responsive, other): _____ ☐ Don't know ☐ Decline answer	Comments
New drugs - treatment duration			
2.12	Question	According to the national policies, is the use of bedaquiline or the use of delamanid limited to a specific duration in the routine treatment of DR-TB?	
	Explanation	• This question concerns only regulations for routine use of the drug, not operational research projects. • In some countries, the duration of use may be extended following case-by-case approval from a formal medical board. Please only indicate the duration of use that is allowed without individual/exceptional approval.	
	Instruction	Please select ☑ **ONE** ANSWER for bedaquiline and ☑ **ONE** ANSWER for delamanid.	
	Answers	**Bedaquiline** ☐ YES, bedaquiline use is limited to a duration of (please specify in weeks) _____ ☐ NO, bedaquiline use not limited to a specific duration ☐ Bedaquiline is not indicated in the national policies for routine treatment ☐ Don't know ☐ Decline answer	Comments
		Delamanid ☐ YES, delamanid use is limited to a duration of (please specify in weeks)_____ ☐ NO, delamanid use is not limited to a specific duration in national policies ☐ Delamanid is not indicated in the national policies for routine treatment ☐ Don't know ☐ Decline answer	
New drugs - youngest allowable patient age			
2.13	Question	According to the national policies, what is the youngest allowable patient age for the use of bedaquiline and the use of delamanid in the routine treatment of DR-TB?	
	Explanation	• This question concerns only regulations for routine use of the drug, not operational research projects.	
	Instruction	Please select ☑ **ONE** ANSWER for bedaquiline and ☑ **ONE** ANSWER for delamanid.	

	Answers	**Bedaquiline** ☐ Bedaquiline may be used for treating patients aged _____ (years) and above ☐ Age limits for the use of bedaquiline are not specified in the national policies ☐ Bedaquiline is not indicated in the national policies for routine treatment ☐ Don't know ☐ Decline answer	Comments
		Delamanid ☐ Delamanid may be used for treating patients aged _____ (years) and above ☐ Age limits for the use of delamanid are not specified in the national policies ☐ Delamanid is not indicated in the national policies for routine treatment ☐ Don't know ☐ Decline answer	

The combined use of bedaquiline and delamanid

2.14	Question	Please indicate the national policies for the combined use of bedaquiline and delamanid.	
	Instruction	Please select ☑ **ALL** that apply.	
	Answers	☐ The combined use of bedaquiline and delamanid is allowed for routine DR-TB treatment ☐ The combined use of bedaquiline and delamanid is allowed under operational research settings ☐ The combined use of bedaquiline and delamanid is not indicated in national policies or research protocols ☐ The combined use of bedaquiline and delamanid is not allowed and a negative statement is given in the national policies ☐ Don't know ☐ Decline answer	Comments
2.15	Question	If combined use of bedaquiline and delamanid is allowed for routine DR-TB treatment, is it limited to a certain duration?	
	Explanation	Please answer only if the combined use of delamanid and bedaquiline is allowed for routine DR-TB treatment, otherwise please skip.	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, bedaquiline and delamanid used in combination is limited to a duration of (please specify in weeks) _____ ☐ NO, bedaquiline and delamanid used in combination is not limited to a specific duration in the national policies ☐ Don't know ☐ Decline answer	Comments

Drugs used for TB and DR-TB treatment

2.16	Question	Please indicate from the list below, which drugs are routinely used for TB and/or DR-TB treatment in country (as of end of December 2019).	
	Explanation	• This question asks whether or not the drugs are used for routine treatment of TB and/or DR-TB treatment in country. "In use" here means that clinicians routinely prescribe the drug for TB and/or DR-TB treatment and not only under operational research or pilot conditions.	
	Instruction	Please select ☑ ONE ANSWER for every drug.	

	In use	Not in use	Don't know	Decline answer
Amikacin	☐	☐	☐	☐

Comments

Amoxicillin-clavulanic acid	☐	☐	☐	☐	
Bedaquiline	☐	☐	☐	☐	
Capreomycin	☐	☐	☐	☐	
Clofazimine	☐	☐	☐	☐	
Cycloserine	☐	☐	☐	☐	
Delamanid	☐	☐	☐	☐	
Ethambutol	☐	☐	☐	☐	
Ethionamide	☐	☐	☐	☐	
Ertapenem	☐	☐	☐	☐	
Gatifloxacin	☐	☐	☐	☐	
Imipenem-cilastatin	☐	☐	☐	☐	
Isoniazid – high dose	☐	☐	☐	☐	
Isoniazid – low dose	☐	☐	☐	☐	
Kanamycin	☐	☐	☐	☐	
Levofloxacin	☐	☐	☐	☐	
Linezolid	☐	☐	☐	☐	
Meropenem	☐	☐	☐	☐	
Moxifloxacin – high dose	☐	☐	☐	☐	
Moxifloxacin – low dose	☐	☐	☐	☐	
Ofloxacin	☐	☐	☐	☐	
P-amino salicylic acid (PAS)	☐	☐	☐	☐	
Pretomanid	☐	☐	☐	☐	
Protionamide	☐	☐	☐	☐	
Pyrazinamide	☐	☐	☐	☐	
Rifampicin	☐	☐	☐	☐	
Rifapentine	☐	☐	☐	☐	
Streptomycin	☐	☐	☐	☐	
Terizidone	☐	☐	☐	☐	
Other (please specify) _____	☐	☐	☐	☐	

DR-TB treatment follow-up

2.17	Question	According to the national policies, what are the regulations for culture-testing for follow-up of DR-TB treatment?	
	Explanation	• This question is regardless of regimen.	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ The national policies indicate that people on DR-TB treatment should receive a monthly culture for the full duration of treatment ☐ The national policies indicate that people on DR-TB treatment should receive culture for follow-up of treatment, but not monthly and/or not for the full duration of treatment ☐ The culture follow-up is indicated in the national policies but either frequency or duration or both are not defined ☐ Culture follow-up is not indicated in the national policies for routine follow up of DR-TB treatment at all ☐ Don't know ☐ Decline answer	Comments

Diagnosis and treatment of mono-INH resistant TB

2.18	Question	Do the national policies indicate INH-resistance testing for patients starting on DS-TB treatment?
	Explanation	• INH susceptibility testing can be done with any method, including molecular or phenotypic DST methods. • This question concerns INH resistance testing to be done at baseline for DS-TB treatment, i.e. before or shortly after starting DS-TB treatment.

		• If INH resistance testing is only indicated for certain groups of people, for example based on any risk factors, socio-demographic characteristics or locations, or based on TB treatment history, please specify this in answer option 2.	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, the national policies indicate INH-resistance testing at baseline for all ☐ YES, the national policies indicate INH-resistance testing at baseline, but only certain groups of people (please define) _____ ☐ NO, the national policies do not indicate INH-resistance testing at baseline ☐ Don't know ☐ Decline answer	Comments
2.19	Question	Is 6(RZE,Lfx) the preferred regimen for treatment of mono-INH resistant TB?	
	Explanation	• Mono-INH resistance TB (Hr TB). • "Preferred treatment regimen" means that the regimen is indicated in national policies as first choice for treatment for clinicians unless there are (clinical) contraindications. • Only for people with TB who have been diagnosed with Hr TB. • Note for the interviewer: In WHO documents, the regimen is often outlined to include (H), which was done to account for the use of FDCs that contain INH. For simplicity, that aspect is not reflected in this question/answers. The national policies of your country might follow the same principle; please answer the question regardless of whether INH is indicated or not.	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ The national policies indicate that the 6(RZE,Lfx) regimen is the preferred treatment regimen for (Hr) TB. ☐ The national policies do not indicate 6(RZE,Lfx) as preferred treatment regimen for (Hr) TB, but it is indicated as optional among other regimens. Please specify other regimen(s) _____ ☐ The 6(RZE,Lfx) regimen not indicated in the policies at all, only other regimens for treating (Hr) TB. Please specify _____ ☐ The policies do not indicate any regimen for (Hr) TB at all ☐ Don't know ☐ Decline answer	Comments
Pediatric TB			
2.20	Question	Is the fixed-dose-combination RHZ (75/50/150) indicated in the national policies for treating pediatric DS-TB?	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, the national policies indicate the use of the pediatric FDCs ☐ NO, the national policies do not indicate the use of the pediatric FDCs ☐ Don't know ☐ Decline answer	Comments
2.21	Question	If RHZ (75/50/150) is indicated in the national policies, has it already been practically implemented?	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, the FDC is routinely used by clinicians for treating pediatric TB ☐ NO, the FDC has been ordered but is not yet routinely used by clinicians ☐ NO, the FDC hasn't been ordered yet ☐ Don't know ☐ Decline answer	Comments

2.22	Question	Are the new pediatric second-line drug formulations indicated in the national policies for routine treatment of pediatric DR-TB?	
	Explanation	• The new pediatric second-line drug formulation may include one or more of the following: Pyrazinamide 150 mg DT, Ethionamide 125 mg DT, Levofloxacin 100 mg DT, Moxifloxacin 100 mg DT, Cycloserine 125 mg capsules.	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, the national policies indicate the use of new pediatric drug formulations ☐ NO, the national policies do not indicate the use of new pediatric drug formulations ☐ Don't know ☐ Decline answer	Comments
2.23	Question	If new pediatric second-line drug formulations are indicated in the national policies, have they already been practically implemented?	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, these are routinely used by clinicians for treating pediatric TB ☐ NO, these have been ordered but are not yet routinely used by clinicians ☐ NO, these haven't been ordered yet ☐ Don't know ☐ Decline answer	Comments
2.24	Question	Do the national guidelines indicate the routine use of an injectable-free regimen for children with mild RR-/MDR-TB disease?	
	Explanation	• Disease severity, defined from mild to severe, is based on national guideline definitions.	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, the national documents indicate the routine use of an injectable-free regimen for children with mild RR-/MDR-TB disease (please indicate drugs, length, and indication for all regimen) _____ ☐ NO, the national policies do not indicate the use of any injectable-free regimen for children with mild RR-/MDR-TB disease ☐ Don't know ☐ Decline answer	Comments

Section 3: TB Models of Care

Treatment Initiation		
3.1	Question	According to the national guidelines, does initiation of drug-sensitive TB treatment require hospital admission?
	Explanation	• Hospital admission for treatment initiation is defined as **mandatory** admission for one day or longer. • This question concerns only treatment initiation of clinically stable people with TB but excludes admission based on clinical needs. • "Specific patients" example: if admission is only required for SSM positive patients, please select the second YES option and indicate "SSM+ve". Proceed the same way for other specific groups of people with TB.

	Instruction	Please select ☑ **ONE** ANSWER.	
	Answer	☐ YES, treatment initiation requires admission to a hospital for all DS-TB patients, regardless of clinical or bacteriological status ☐ YES, treatment initiation requires admission to a hospital, but only for specific DS-TB patients, (please specify) _____ ☐ NO, the policies do not indicate a requirement of hospital admission for DS-TB treatment initiation of clinically stable patients ☐ Don't know ☐ Decline answer	Comments
3.2	Question	According to the national guidelines, does initiation of drug-resistant TB treatment require hospital admission?	
	Explanation	• As for Q3.1.	
	Instruction	Please select ☑ **ONE** ANSWER.	
		☐ YES, treatment initiation requires admission to a hospital for all DR-TB patients, regardless of clinical or bacteriological status ☐ YES, treatment initiation requires admission to a hospital, but only for specific DR-TB patients, (please specify) _____ ☐ NO, the policies do not indicate a requirement of hospital admission for DR-TB treatment initiation of clinically stable patients ☐ Don't know ☐ Decline answer	Comments
3.3	Question	According to the national policies, can DR-TB treatment be initiated at a primary health care facility?	
	Explanation	• Treatment initiation is defined as all the administrative/clinical processes that are necessary for a person to start taking their TB treatment. (Example: If a person with TB may, for example, start treatment at primary health care level but first has to get a prescription for the medication from a higher-level facility, the answer here must be "NO"). • Primary health care level facilities: these are facilities that offer a basic health care package and typically include (but are not limited to) a health post, primary care centers in rural or urban areas, or outpatient units.	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, according to the policies, treatment for DR-TB may be initiated at a primary health care facility ☐ YES, according to the policies, treatment for DR-TB may be initiated at a primary health care facility, but only for specific patients (please define) _____ ☐ NO, the policies do not indicate that this is allowed, or do not allow ☐ Don't know ☐ Decline answer	Comments
3.4	Question	If DR-TB treatment cannot be initiated at a primary health care facility, at which level up from primary level may DR TB treatment be initiated?	
	Explanation	• Answer this question only if you answered "NO" in Q3.3, otherwise please skip.	
	Instruction	Please specify.	
	Answers	☐ Health care facility level_____ ☐ Don't know ☐ Decline answer	Comments
DR-TB treatment follow-up			
3.5	Question	According to the national policies, can people with TB receiving DR-TB treatment be followed-up at a primary health care facility?	

	Explanation	• Treatment follow-up here means regular clinical consultations with a healthcare worker to, for example, assess potential side effects, collect sputum samples and/or provide drug refills. • Example: If a person with TB is usually followed-up at primary health care facility but has to go once or more to a higher-level facility, for example, for medical review, the answer here must be "NO". • Primary health care level facilities: these are facilities that offer a basic health care package and typically include a health post, primary care centers in rural or urban areas, or outpatient units.	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, according to the policies, treatment for DR-TB may be followed-up at a primary health care facility ☐ YES, according to the policies treatment for DR-TB may be followed-up at a primary health care facility, but only specific patients (please define) _____ ☐ NO, the policies do not indicate that this is allowed, or do not allow ☐ Don't know ☐ Decline answer	Comments
3.6	Question	According to the national policies, can people with TB take their daily DR-TB medications at home?	
	Explanation	• This refers to DOTs and may include digital adherence technologies (such as Video DOTs) as long as they provide direct treatment observation.	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, people with DR-TB are allowed to take their daily TB medications at home, including those taking oral medication and those receiving injections ☐ YES, people with DR-TB are allowed to take their daily TB medications at home but only specific patients (please define) _____ ☐ NO, taking medication at home is not indicated in the policies or is not allowed ☐ Don't know ☐ Decline answer	Comments
3.7	Question	Do the national guidelines indicate that people with <u>drug-sensitive</u> TB can take their daily TB medication as self-administered therapy (SAT)?	
	Explanation	• Self-administered therapy (SAT) is defined as allowing people with TB to take (swallow) their TB medication without having to be supervised by another person (including family members, community members, healthcare workers or others). This excludes DOTs. • "Specific circumstances" under which patients are allowed to take their medication as SAT may, for example, include specific times of the week (e.g. weekends/national holidays), or if the patient has demonstrated good adherence under DOTs.	
	Instruction	Please select ☑ **ONE** ANSWER.	
	Answer	☐ YES, according to the national policies, people with DS-TB can take their medication as SAT ☐ YES, according to the national policies, people with DS-TB can take their TB medication as SAT, but only specific circumstances (please specify) _____ ☐ NO, the national policies do not indicate that SAT is allowed for people with DS-TB or do not allow SAT ☐ Don't know ☐ Decline answer	Comments
3.8	Question	Do the national guidelines indicate that people with <u>drug-resistant</u> TB can take their daily TB medication as self-administered therapy (SAT)?	
	Explanation	• As for Q 3.7.	
	Instruction	Please select ☑ **ONE** ANSWER.	
		☐ YES, according to the national policies, people with DR-TB can take their medication as SAT	Comments

	Answer	☐ YES, according to the national policies, people with DR-TB can take their TB medication as SAT, but only specific circumstances (please specify) _____ ☐ NO, the national policies do not indicate that SAT is allowed for people with DR-TB, or do not allow SAT ☐ Don't know ☐ Decline answer	

Social Support

3.9	Question	Do the national policies indicate special social support for people receiving DR-TB treatment?	
	Explanation	• In this question, "social support" focuses only on the provision of extra food and transport (either as direct cash, direct food baskets, voucher or reimbursement systems).	
	Instruction	Please select ☑ **ALL** that apply.	
	Answers	☐ YES, the policies indicate the provision of extra food support for all people receiving DR-TB treatment ☐ YES, the policies indicate the provision of extra food support, but only for certain people with DR-TB or locations (please specify) _____ ☐ YES, the policies indicate the provision of extra transport support for all people receiving DR-TB treatment ☐ YES, the policies indicate the provision of extra transport support, but only for certain people with DR-TB or locations (please specify) _____ ☐ NO, the national policies do not indicate food or transport support for people receiving DR-TB treatment ☐ Don't know ☐ Decline answer	Comments
3.10	Question	What challenges do you have in the provision of social support for people with DR-TB?	
	Explanation	• In this question, "social support" focuses only on the provision of extra food and transport (either as direct cash, direct food baskets, voucher or reimbursement systems).	
	Instruction	Please select ☑ **ALL** that apply. **Note for the interviewer: Please do not prompt (i.e. do not read out the answers to the respondent but match the respondents' answers with the options given below).**	
	Answers	☐ Inconsistent funding or difficulties in releasing funding for social support strategies ☐ Inconsistent availability of a partner to provide implementation of social support strategies ☐ Poor reporting on the impact of social support service provision ☐ Implementation challenges, such as distribution of currency, expiry of food supplies, inconsistent reimbursements ☐ Other, please specify: _____ ☐ None ☐ Don't know ☐ Decline answer	Comments

Section 4: TB Prevention

Investigation for signs and symptoms of TB

4.1	Question	Which of the following strategies and interventions are indicated in the national policies?
	Explanation	• "People with other co-morbidities or other specific target groups" may include (but are not limited to): people with diabetes, prisoners, people receiving dialysis, migrants, miners, people with silicosis or health care workers.

	Instruction	Please select ☑ **ALL** that apply.	
	Answers	☐ All HIV positive children (age < 5 years) should be investigated for signs and symptoms of TB at every contact with a health service provider ☐ All HIV positive children (aged > 5 years and above), adolescents and adults should be investigated for signs and symptoms of TB at every contact with a health service provider ☐ People with other co-morbidities or other specific target groups should be investigated for signs and symptoms for TB at contact with a health service provider (please specify) _____ ☐ None of the above are indicated in the national policies ☐ Don't know ☐ Decline answer	Comments
4.2	Question	According to the national policies, an investigation for TB signs and symptoms should be conducted for the following household contacts:	
	Instruction	Please select ☑ **ALL** that apply.	
	Answers	Household contacts of drug-sensitive TB cases (bacteriologically confirmed), including: ☐ **All** children (aged <5 years) ☐ **All** children (aged 5 years and above), adolescents and adults Household contacts of drug-resistant TB cases (bacteriologically confirmed), including: ☐ **All** children (aged <5 years) ☐ **All** children (aged 5 years and above), adolescents and adults Household contacts of drug-sensitive TB cases (clinically diagnosed), including: ☐ **All** children (aged <5 years) ☐ **All** children (aged 5 years and above), adolescents and adults Household contacts of drug-resistant TB cases (clinically diagnosed), including: ☐ **All** children (aged <5 years) ☐ **All** children (aged 5 years and above), adolescents and adults ☐ Others (please specify) _____ ☐ None of the above are indicated in the national policies ☐ Don't know ☐ Decline answer	
		Comments	
LTBI			
4.3	Question	Which of the following groups are indicated in the national policies as target populations for LTBI treatment?	
	Explanation	• Treatment of latent TB infection (LTBI) is also often called "TB preventative therapy" or TPT. • Target groups are people who are considered at risk for TB infection as per national policy, and should be considered for LTBI treatment after ruling-out active TB disease. • Ruling-out active TB may follow any procedures defined in the national policies, including symptom screening and/or testing for TB/LTBI; the detailed procedures for further evaluation are not relevant for this question.	
	Instruction	Please select ☑ **ALL** that apply.	
	Answers	People living with HIV: ☐ **All** HIV positive children (age < 5 years) ☐ **All** HIV positive children (aged 5 years and above), adolescents and adults Household contacts of drug-sensitive TB cases (bacteriologically confirmed), including: ☐ **All** children (aged <5 years)	Comments

☐ **All** children (aged 5 years and above), adolescents and adults

Household contacts of drug-sensitive TB cases (clinically diagnosed), including:
☐ **All** children (aged <5 years)
☐ **All** children (aged 5 years and above), adolescents and adults

Other special groups
☐ **All** people with diabetes
☐ **All** prisoners
☐ **All** migrants
☐ **All** people receiving dialysis
☐ **All** miners
☐ **All** people with silicosis
☐ **All** healthcare workers

☐ Others (please specify) _____
☐ None of the above are indicated in the national policies
☐ Don't know
☐ Decline answer

4.4 Question: According to the national policies, which tests for latent TB infection are indicated for which patient groups prior to treatment of LTBI?

Explanation:
- Regardless of which other methods are recommended by the national policies to be conducted to rule-out active TB disease at the same time.
- If a test is for example indicated for all PLHIV, please select both: HIV positive children and HIV positive adults.
- Diaskin or C-Tb skin tests are based on the injection of MTB ESAT6/CFP10 proteins.

Instruction: Please select ☑ **ALL** that apply, for each latent TB test separately.

Answers

	TST	IGRA	Diaskin or C-Tb
Test is indicated for everyone prior to starting treatment of LTBI	☐	☐	☐
Test is indicated prior to starting treatment of LTBI only for specific groups, such as:			
HIV positive children (aged <5 years)	☐	☐	☐
HIV negative children (aged <5 years)	☐	☐	☐
HIV positive children (aged 5 years and above), adolescent & adults	☐	☐	☐
HIV negative children (aged 5 years and above), adolescent & adults	☐	☐	☐
Any other groups	☐	☐	☐
The test is not indicated in national policies for anyone prior to starting treatment of LTBI	☐	☐	☐
Don't know	☐	☐	☐
Decline answer	☐	☐	☐

Comments

Regimen for LTBI treatment

4.5 Question: Do the national policies indicate the use of a short regimen for treatment of LTBI?

Explanation:
- "Short" regimen: <6 months. "Long" regimen: 6 months or more.

Instruction: Please select ☑ **ALL** that apply.

YES, the national policies indicate the use of the following LTBI short regimen:
☐ 3HP
☐ 3RH

Comments

	Answers	☐ 4R ☐ 1HP ☐ NO, the national policies do not indicate the use of any of the above mentioned short LTBI regimens, but other short regimens are indicated, (please specify) _____ ☐ NO, the national policies do not indicate the use of any short LTBI regimen. Only long regimens, such as 6/9/36 month IPT, are indicated ☐ NO, the national policies do not indicate the use of any LTBI regimen at all ☐ Don't know ☐ Decline answer	
4.6	Question	If none of the above listed short LTBI regimens (3HP, 3RH, 4R, 1HP) are indicated in the national policies, what are the reasons in your opinion?	
	Explanation	**Note for the interviewer: Please do not prompt (i.e. do not read out the answers to the respondent but match the respondents' answers with the options given below).**	
	Instruction	Please select ☑ **ALL** that apply.	
	Answers	☐ Drugs are too expensive ☐ Lack of funding for procurement ☐ Lack of funding for implementation such as training, policy and document revision ☐ Not enough time to plan and prepare for implementation ☐ National regulations for procurement, import or use are prohibitive ☐ Not aware about these shorter regimen ☐ Not aware of WHO recommendations for shorter regimen ☐ Other, please specify _____ ☐ Don't know ☐ Decline answer	Comments
4.7	Question	Do the national policies indicate an LTBI regimen for contacts of DR-TB patients?	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, the national policies indicate the following LTBI regimen for DR-TB contacts (please specify drugs, duration and indication of use): _____ ☐ NO, the national policies do not indicate any LTBI regimen for DR-TB contacts ☐ Don't know ☐ Decline answer	Comments
"HIV test and treat"			
4.8	Question	Do the national policies indicate that all PLHIV should be started on ART, regardless of CD4 count ("HIV test & treat")?	
	Explanation	• This question concerns all PLHIV, not only those with TB co-infection or suspicion of TB co-infection. • "HIV test and treat" means that all people who test HIV positive are started on ART as soon as possible regardless of CD4 count.	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, the national policies indicate that all PLHIV should be started on ART regardless of CD4 count ☐ NO, the national policies indicate a certain CD4 threshold for starting PLHIV on ART. Please state_____ ☐ NO, the national policies indicate other criteria to start PLHIV on ART ☐ NO, the national policies do not specify any criteria to start PLHIV on ART ☐ Don't know ☐ Decline answer	Comments

Section 5: TB Drug Regulation and Procurement

TB Drug Regulation and Procurement			
5.1	Question	Does the national drug law allow early access provision mechanisms for TB drugs?	
	Explanation	• In the context of this question, "early access provisions" are defined as programs that aim to enable patients in need to access a drug that is likely to be effective but still not yet registered locally and/or under clinical development. • This is regardless of the specific TB drug, formulation, patient groups or specific patient conditions.	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, the national drug law allows early access provisions ☐ NO, the national drug law does not allow early access provisions or does not indicate that this is allowed ☐ Don't know ☐ Decline answer	Comments
5.2	Question	Do the national procurement policies for TB drugs require SDRA approval and/or WHO PQ for the importation of TB drugs purchased with domestic funding?	
	Explanation	• SDRA = Stringent Drug Regulatory Authority. • WHO PQ = WHO Pre-Qualification. • Please answer YES if either SDRA approval or WHO PQ, or both are required. • This concerns only TB drugs that are imported for routine use using domestic funding, and not operational research projects or donor-funding regulations. • There might be an SDRA approval/WHO PQ required only for "certain drugs", including but not limited to DR-TB drugs, DS-TB drugs or drugs for LTBI - please specify accordingly.	
	Instruction	Please select ☑ **ALL** that apply.	
	Answers	☐ YES, national procurement policies indicate that SDRA approval and/or WHO PQ are required for all TB drugs ☐ YES, national procurement policies indicate that SDRA approval and/or WHO PQ are required, but only for certain TB drugs, please define _____ ☐ NO, the national procurement policies do not indicate that SDRA approval or WHO PQ are required for any TB drugs ☐ Don't know ☐ Decline answer	Comments
5.3	Question	In cases where TB drugs are manufactured in the country, do the national procurement policies for the locally-manufactured TB drugs require SDRA approval and/or WHO Prequalification for the purchase of TB drugs with domestic funding?	
	Explanation	• As in Q 5.2.	
	Instruction	Please select ☑ **ALL** that apply.	
	Answers	☐ YES, national procurement policies indicate that SDRA approval and/or WHO PQ are required for all TB drugs manufactured in the country ☐ YES, national procurement policies indicate that SDRA approval and/or WHO PQ are required, but only for certain TB drugs manufactured in the country, please define_____ ☐ NO, the national procurement policies do not indicate that SDRA approval or WHO PQ are required for any TB drugs manufactured in the country ☐ No procurement of locally manufactured drugs ☐ Don't know ☐ Decline answer	Comments

5.4	Question	Do the national procurement policies for TB drugs require, for their importation, that these medicines are recommended by WHO and/or US-CDC?	
	Instruction	Please select ☑ **ONE** ANSWER only.	
	Answers	☐ YES, WHO and/or US-CDC clinical recommendation is required ☐ YES, WHO or US-CDC clinical recommendation is generally required, but an exemption is in place for selected TB medicines, please define: _____ ☐ NO, the policies do not indicate that WHO or US-CDC clinical recommendation is required ☐ Don't know ☐ Decline answer	Comments
5.5	Question	In national tenders for TB drugs, which of the following procedures are indicated in the national regulations?	
	Instruction	Please select ☑ **ALL** that apply.	
	Answers	☐ Publication of tender selection criteria ☐ Publication of the winning bidding company ☐ Publication of the final pricing ☐ None of the above ☐ Don't know ☐ Decline answer	Comments
5.6 **POLICY**	Question	In national tenders for TB diagnostics, which of the following procedures are indicated in the national regulations?	
	Instruction	Please select ☑ **ALL** that apply.	
	Answers	☐ Publication of tender selection criteria ☐ Publication of the winning bidding company ☐ Publication of the final pricing ☐ None of the above ☐ Don't know ☐ Decline answer	Comments

ANNEX 1: ACRONYMS

Am	Amikacin
ART	Antiretroviral Therapy
Bdq	Bedaquiline
BPaL	Regimen composed by Bedaquiline, Pretomanid, and Linezolid
C-Tb	Skin test based on the injection of MTB ESAT6/CFP10 proteins (Statens Serum Institut)
CB	Clinical Breakpoint
CC	Critical Concentration
Cfz	Clofazimine
Cm	Capreomycin
Diaskin	Skin test based on the injection of MTB ESAT6/CFP10 proteins (Generium)
Dlm	Delamanid
DOT	Directly-Observed Therapy
DR-TB	Drug-Resistant Tuberculosis
DS-TB	Drug-Sensitive Tuberculosis
DST	Drug Susceptibility Testing
DT	Dispersible Tablets
E	Ethambutol
Eto	Ethionamide
FDC	Fixed Dose Combination
FLQ	Fluoroquinolone
Gfx	Gatifloxacin
GX	GeneXpert (Instrument)
HIV	Human Immunodeficiency Virus
Hr-TB	Isoniazid-Resistant and Rifampicin-Susceptible Tuberculosis
IGRA	Interferon-Gamma-Release Assay
INH	Isoniazid
INH(high)	Isoniazid high dose
IPD	Inpatient Department
IPT	Isoniazid Preventive Therapy
Km	Kanamycin
LF LAM	Lateral Flow Urine Lipoarabinomannan Assay

Lfx	Levofloxacin
LPA	Line Probe Assay
LTBI	Latent Tuberculosis Infection
Lzd	Linezolid
MDR-TB	Multidrug-Resistant Tuberculosis
Mfx	Moxifloxacin
MoH	Ministry of Health
NGS	Next Generation Sequencing
OPD	Outpatient Department
PAS	P-aminosalicylic Acid
PLHIV	People Living with Human Immunodeficiency Virus
Pto	Prothionamide
RIF	Rifampicin
RR-TB	Rifampicin-Resistant Tuberculosis
SAT	Self-Administered Therapy
SDRA	Stringent Drug Regulatory Authority
SLID	Second-Line Injectable Drug
SSM	Sputum Smear Microscopy
SSM+ve	Sputum Smear Microscopy positive
TB	Tuberculosis
TB LAMP	TB Loop-Mediated Isothermal Amplification
TPT	TB Preventative Therapy
TrueNAT	Rapid molecular diagnostic tests for TB and RR TB (Molbio Inc)
TST	Tuberculin Skin Test
US-CDC	United States Center for Disease Control
WHO	World Health Organization
WHO PQ	World Health Organization Pre-Qualification
XDR-TB	Extensively Drug-Resistant Tuberculosis
Xpert	Xpert MTB/RIF, Rapid Molecular Diagnostic Tests for TB and RR-TB (Cepheid)
Z	Pyrazinamide

ANNEX 2: ADDITIONAL ANSWER SHEET - Please use this sheet to continue your responses to these questions if needed.

2.4a

Question	Do the national policies indicate the use of a modified all-oral shorter regimen for treating RR/MDR-TB for adults?
Explanation	• This question and the following two questions concern the use of additional modifications to 4-6 (Am/Kan/Cm)-(Mfx/Gfx/Lfx)-(Pto/Eto) -Cfz-Z-INH(high) / 5 Mfx-Cfz-Z-E, beyond the two drug substitutions allowed by WHO (Pto or Eto, Mfx or Gfx or Lfx). These modifications may include, but are not limited to, for example, regimens in which the injectable has been replaced with BDQ. • Below, there are options for up to three modified regimens. For each modified regimen version, we ask you to outline the regimen, then we ask about the status of implementation (Q2.5a) and in a third question (Q2.6a), we ask how widely the respective regimen is available. Please answer for each modified regimen individually. • Of note, this question concerns both routine use and operational research – but only for adults.
Instruction	Please indicate drugs & length for each regimen.
Answers	☐ YES, the national policies indicate the use of the following modified all-oral shorter regimen, either for routine use or operational research: _____ (regimen option 4) _____ (regimen option 5) _____ (regimen option 6) ☐ NO, the national policies do not indicate the use of any modified all-oral shorter regimen ☐ Don't know ☐ Decline answer
Comments	

2.5a

Question	Please indicate how the above defined all-oral short regimen options 4-6 are used, as of end December 2019.
Explanation	• Operational research/pilot in this case is defined as research that is done by the MoH and/or a partner, has an approved ethics protocol and is not a clinical trial.
Instruction	Please select ☑ **ALL** that apply for each regimen option.

	Regimen 4	**Regimen 5**	**Regimen 6**
Operational research or pilot has been completed	☐	☐	☐
Operational research or pilot has started, but not completed	☐	☐	☐
Operational research or pilot is planned but not started	☐	☐	☐
Operational research or pilot is not planned	☐	☐	☐
Implementation for routine use has been completed	☐	☐	☐
Implementation for routine use has started, but not completed	☐	☐	☐
Implementation for routine use is planned but not started	☐	☐	☐
Implementation for routine use is not planned	☐	☐	☐
Don't know	☐	☐	☐
Decline answer	☐	☐	☐

Comments

2.6a

Question	What percentage of patients have started / will be started on this regimen, in 2019 and 2020?
Explanation	• Denominator = all patients started on RR/MDR-TB treatment in the respective reporting year. • Please answer this question if routine use and/or operational research has been started, is planned or is completed. Skip the question if there are no plans for routine use or operational research. • If both routine use and operational research take place in the same year, please combine the estimated percentage of patients for both.
Instruction	Please answer for each regimen option.

Regimen 4	**Regimen 5**	**Regimen 6**
Percentage for 2019: _____	Percentage for 2019: _____	Percentage for 2019: _____
Estimated percentage for 2020: _____	Estimated percentage for 2020: _____	Estimated percentage for 2020: _____
☐ Don't know	☐ Don't know	☐ Don't know
☐ Decline answer	☐ Decline answer	☐ Decline answer

Comments:

2.7a	Question	Do the national policies indicate the use of a longer all-oral regimen for treating RR/MDR-TB for adults?	
	Explanation	• This question refers to longer regimens that are either standardized or individualized and based only on the use of oral drugs recommended by WHO. • These longer regimens do not include historic, standardized longer regimens with an injectable agent, previously commonly called a 'conventional regimen' or a 'standardized MDR regimen'. • Below, there are options for up to three all-oral long regimens. For each regimen version, we ask you to outline the regimen, then we ask about the status of implementation (Q2.8a) and in a third question (Q 2.9a), we ask how widely the respective regimen is available. Please answer for every modified regimen individually. • Of note, this question concerns routine use and operational research – but only for adults.	
	Instruction	Please indicate drugs & length for each regimen.	
	Answers	☐ YES, the national policies indicate the use of the following all-oral long regimen, either for routine use or operational research: _____ (regimen option 4) _____ (regimen option 5) _____ (regimen option 6) ☐ NO, the national policies do not indicate the use of any all-oral long regimen ☐ Don't know ☐ Decline answer	Comments

2.8a	Question	Please indicate how the above defined all-oral-long regimen options 4-6 are used, as of December 2019.	
	Explanation	• Operational research/pilot in this case is defined as research that is done by the MoH and/or a partner, has an approved ethics protocol and is not a clinical trial.	
	Instruction	Please select ☑ **ALL** that apply for each regimen option.	

	Regimen 4	**Regimen 5**	**Regimen 6**	Comments
Operational research or pilot has been completed	☐	☐	☐	
Operational research or pilot has started, but not completed	☐	☐	☐	
Operational research or pilot is planned but not started	☐	☐	☐	
Operational research or pilot is not planned	☐	☐	☐	
Implementation for routine use has been completed	☐	☐	☐	
Implementation for routine use has started, but not completed	☐	☐	☐	
Implementation for routine use is planned but not started	☐	☐	☐	
Implementation for routine use is not planned	☐	☐	☐	
Don't know	☐	☐	☐	
Decline answer	☐	☐	☐	

2.9a	Question	What percentage of patients have started / will be started on this regimen, in 2019 and 2020?	
	Explanation	• Denominator = all patients started on RR/MDR-TB treatment in the respective reporting year. • Please answer this question if routine use and/or operational research has been started, is planned or is completed. Skip the question if there are no plans for routine use or operational research. • If both routine use and operational research take place in the same year, please combine the estimated percentage of patients for both.	
	Instruction	Please select ☑ **ALL** that apply for each regimen option.	

Regimen 4	**Regimen 5**	**Regimen 6**
Percentage for 2019: _____	Percentage for 2019: _____	Percentage for 2019: _____
Estimated percentage for 2020: _____	Estimated percentage for 2020: _____	Estimated percentage for 2020: _____
☐ Don't know	☐ Don't know	☐ Don't know
☐ Decline answer	☐ Decline answer	☐ Decline answer

Comments: