rGLC COUNTRY SUPPORT MISSION REPORT

Country: Bhutan

Inclusive dates of mission: 7-14 October 2017

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Acknowledgments: The author would like to express his gratitude towards Ministry of Health, Government of Bhutan for the support extended for this mission. Special thanks to National Tuberculosis Control Programme (NTP), Medical Superintendent, Specialists and Pharmacists at JDW National Referral Hospital, and the team from Drug Regulatory Authority for providing the requisite information. Thanks to WHO country office for facilitating the visit. The team also thanks the doctors, nurses, health care staffs and patients at the sites visited for their hospitality and collaboration with the mission members.

The programme has agreed with open sharing of this report

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Abbreviations and acronyms

DOT Directly Observed Treatment

DOTS Directly Observed Treatment Short-course

DRS Drug Resistance Survey
DST Drug Susceptibility Testing

DVED Drugs, Vaccines and Equipment Division

EPTB Extra-Pulmonary Tuberculosis

EQAS External Quality Assurance Scheme

FDC Fixed-Dose Combination

FYP Five Year Plan

GDF Global (TB) Drug Facility
GDP Gross Domestic Product
GNH Gross National Happiness

HIV Human Immunodeficiency Virus

HRD Human Resource Development/Division

INH Isoniazid

JDWNRH Jigme Dorji Wangchuk National Referral Hospital

LPA Line Probe Assay

MDR-TB Multi-Drug-Resistant Tuberculosis

MO Medical Officer
MOH Ministry of Health

MSTF Multi Sectoral Task Force

NACP National AIDS Control Programme NGO Non-Governmental Organization

NSB National Statistical Bureau

NSP New smear Positive Tuberculosis

NTCP National Tuberculosis Control Programme

NTRL National TB Reference Laboratory

PHCB Population and Housing Census of Bhutan

PHL Public Health Laboratory
PLWHA People living with HIV/AIDS
PPE Personal Protection Equipment
rGLC regional Green Light Committee
RGOB Royal Government of Bhutan
RRH Regional Referral Hospital

SRL Supranational Reference Laboratory

TB Tuberculosis

TWG Technical Working Group

VCT Voluntary Counselling and Testing

VHW Village Health Worker WHO World Health Organization

XDR-TB Extensively Drug-Resistant Tuberculosis

Executive summary

i. TORs of the mission

- Conduct desk review of progress in PMDT activities
- Support update of guidelines for shorter regimen for MDR-TB
- Undertake training of medical officers/ specialists and pharmacists in shorter regimen

ii. Overall implementation status of PMDT compared to targets in NSP. Status of implementation of GF supported activities

- One national and two regional referral hospitals functioning as MDR-TB treatment sites
- Continuation phase treatment done in all district hospitals on case basis
- GeneXpert machines operating in 5 sites with one more to come in the next funding cycle of the GF grant

iii. Significant achievements since last visit

- 5 GeneXpert machines have been installed and made operational
- 2 staff at PHL have been trained and country is ready to start SL LPA testing
- Referral system and shipment of samples by all 32 TB reporting centers in place.
 Turnaround time is better

iv. Key challenges identified in this mission in relation to the ToRs

- a. Long lead times in procurements specifically lab consumable for SL LPA
- b. GeneXpert usage needs to be strengthened as no substantial increase in case notification has been observed after roll-out of the machines
- c. Innovative patient support mechanisms are required for those on second-line treatment

v. Priority recommendations of the mission:

Recommendation	Responsible persons/agency	Timeline	Support required to fulfil the
			recommendation
Finalise the updated PMDT guidelines	NTP	Mid-	Desk support
		November	from WHO SEARO
		2017	
Ensure that all drugs needed for shorter	NTP, DRA, MoH	End November	
regimen are part of the country EML		2017	
Place orders with GDF in consultation	NTP	Early	GDF to help
with focal point		December	quantify drugs
		2017	
Establish multi-stakeholder high level	NTP and MoH	January 2018	
national initiative in accordance with			
Delhi Call for Action			

Capitalise on the existing momentum	NTP and MoH	Ongoing	
and political commitment to mobilise			
domestic resources – both government			
and private sector			
Follow-up on pending	NTP	Ongoing	
recommendations made during			
previous rGLC mission			

vi. Status of priority recommendations of previous mission:

_		Time	Status
	agency/person	frame	
Scale up line probe assays for first-line (and introduce second-line) antituberculosis drug susceptibility testing. Consider linkage with Indian counterparts for training.		6 months	The LPA for first line has been already scaled up and started the testing of samples. While SL LPA has been established in the NTRL. Two NTRL officials have been trained on the second line LPA at SNRL. Further, NTCP with support from WHO CO and WHO SEARO will be conducting the training of lab technicians from GeneXpert sites and NTRL on rapid diagnostic test and second line LPA at National Institute of TB and Respiratory Disease in New Delhi from 20-28 November 2017.
Introduce MDR "Short Course" amongst a small cohort of patient to gain local experience. Consider partnering with "Centres of Excellence" of neighboring countries such as India (e.g., National Institute of Tuberculosis and Respiratory Diseases) and Bangladesh (International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) through onsite training and observation or through innovative distance learning technologies, such as Project ECHO	JDWNRT Supported by	12 months	
Conduct a nationally- representative	Support by: WHO, USAID,		With the joint monitoring mission conducted by programme in close coordination with WHO and CDC, it was recommended that there is no

to the prevalence of SLD amongst new and retreatment cases. Implementation and validation of LPA (see recommendation 1) could be streamlined as part of preparations			requirement of nationwide prevalence survey. NTRL/RCDC had been conducting routine MDR-TB surveillance report for the cohort years.
Expand, monitor and optimize all WHO endorsed rapid diagnostics (WRD) to rationalize use of technologies that complement each other for early and accurate diagnosis of all forms of TB	Supported by	6 months	NTCP has already implemented this recommendation and procured 5 GeneXpert machines. The machines had been placed in three referral hospitals and two other hospitals in strategic locations.
Decentralize PMDT diagnostic and treatment services to make it more accessible, convenient and friendly to the patient's needs		24 months	The PMDT diagnostic had been already decentralized to referral hospitals and selected district hospitals from National TB Reference Laboratory as recommended. It is not possible to decentralize PMDT services to all districts considering the facilities and the service standards present in respective hospitals. However, the treatment services for the MDR-TB patients during the continuation phase have been already decentralized to the respective reporting centers/hospitals in the districts.
Enhance interdepartmental collaboration within various departments of RGOB to mobilize or cross- utilize resources for TB services	MoH, NTCP Supported by WHO	6 months	As a part of recommendation, NTCP in close collaboration with various national programmes had been conducting joint meetings, trainings and the workshop to make best use of limited resources. NTCP have been collaborating with other relevant departments/divisions within the ministry to mobilize resources for TB services.

personal protective infection control measures in hospital settings with adequate HCW training while building capacity of architects and engineers in addressing engineering aspects of AIC under cold climate conditions	Supported by WHO, CDC		The administrative and the personal protective infection control measures in the hospital setting with adequate HCW training was conducted in close coordination with Infection Control Programme under the Department of Medical Services of the Ministry Programme had trained inflection control focal persons each from referral and district hospitals. To incorporate the infection control designs in the hospital constructions, program had trained two architects from the Health Infrastructures Development Division at Thailand with funding support from Global Fund. Further, the Ministry with funding support from Government of India has planned to train infection control focal persons (Nurse supervisors) to train on infection control for about one week at India.
address social	MoH, NTCP Supported by WHO	6 months	Programme, in close coordination with village health worker programme, Health Promotion Division, district health sectors had been involving the community based organizations like Village Health Workers, Multisectorial Task Force, Community Based Support Systems and the basic health units at the community level to address this issue in providing TB services. Moreover, the MDR-TB ward at the Gidakom Hospital is being refurbished with measures to improve infection control through redesigning of existing infrastructure through trained architects and medical experts.
Conduct operational research in focusing a several key areas (i.e., ageand gender-stratified analyses, border and binational TB epidemiology, extrapulmonary TB disease, molecular	Supported by WHO, UNION,	12 months	Program has been prioritizing operational research for evidence based planning and interventions. It has conducted an operational research workshop to the district health managers, medical officer in close collaboration with KGUMSB and

epidemiology transmission studies, evaluation of shorter within regimens the Bhutanese population, and evaluation of novel enhance initiatives to treatment compliance, such as 99DOTS

Research Unit of the Ministry. An EP-TB study under the SAARC funding, study on the factors to determine development of MDR-TB among new TB patients has been outsourced to KGUMSB in the current fiscal year with GF support, and an operational research on the implementation of GeneXpert machines has been ongoing with WHO TDR grant. National programme is in the process of developing proposal under the TB reach funding to adopt 99DOTS or Video Observed Treatments (VDOTS) to enhance treatment compliance and monitoring.

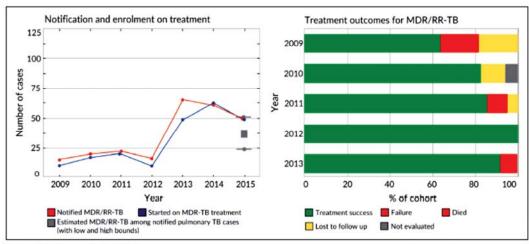
Achieved	
Some progress/ ongoing	
No change	

Detailed report

(Since the major focus of this mission was country capacity building and transition to shorter regimen, the background information and progress assessment is short and based on desk-review only)

A. Overall DR-TB programme performance

The programme demonstrated accelerated DR-TB case notification in 2013 but it has almost been static since then. It is expected that notifications will increase once there is optimal utililisation of GeneXpert machines that have already been installed. Treatment success rate so far has been good and consistent more than 80% for several years that may also be because the cohort size is relatively small and patients receiving individualised attention.



Source: http://www.who.int/tb/data

B. Case finding strategy

As per the existing programme policy, all sputum smear positive patients are screened for drugresistance using GeneXpert and conventional methods in addition to those considered at risk of drug resistance or those where there is a possibility of an unfavourable outcome because of comorbidities and hence at high risk of mortality due to drug-resistance. As per the guidelines being updated, following groups will be screened for resistance using rapid tests:

- 1. All TB cases starting on treatment will be screened with GeneXpert, if not already done at the time of diagnosis. However, in clinically diagnosed and extra-pulmonary (EP) TB cases, the testing will depend on availability of adequate specimen.
- 2. High Risk groups— Certain categories of patients are considered at high risk fordrug resistance TB and this group also includes vulnerable populations in whom, because of their immunity and co-morbidity, mortality could be higher if they have associated drug resistance. Therefore, the following groups will be subjected to Xpert test without undergoing sputum microscopy:

- All re-treatment TB cases both smear-positive and negative cases (Relapse, Failure and treatment after loss to follow-up cases)
- Symptomatic close contacts of MDR-TB cases including health care workers or
 those contacts who have suspicion of TB on physical examination by a physician.
 Non-symptomatic close contacts will be screened using chest X-ray. Patients
 with anomalies on Chest X-ray suggestive of TB will be screened using
 GeneXpert irrespective of symptoms;
- Non-converters at 2/3 months of TB treatment;
- Treatment failure cases of TB treatment;
- TB-HIV co-infected cases
- Diabetes, chronic kidney disease, drug users etc.

C. Laboratory services and expansion plan

	Methods and Technology	Year of establishment
1.	Solid Culture & DST using egg based	2010
2.	Liquid Culture & DST using BACTEC MGIT 960	2012
3.	Line Probe Assay for Rapid detection MDR-TB (Rifampicin and Isoniazid)	2014
4.	GeneXpert for Rapid detection MDR-TB – 5 machines installed as of date	Sept. 2016
5.	Second line drugs Line Probe Assay	Planned before end 2017

The programme aims to have at least one more machine in coming year for a mobile diagnostic unit to reach the difficult to reach populations because of geographical constraints.

D. Treatment strategy

The programme intends to transition to shorter regimen in a phased manner. The regimen to be used is in alignment with WHO recommendations
Intensivephase4-6 Km-Mfx-Pto-Cfz-Z-Hhigh-dose-E
Continuation-159 Mfx-Cfz-Z-E

The regimen can be used in all adult, children and PLHIV patients if they do not fall in any exclusion criteria (as in the guidelines).

In the initial phases of implementation, the shorter regimen will be used only in new RR/MDR-TB cases after checking for exclusion criteria as above. It is possible that around $^{\sim}30$ cases will be initiated on treatment in the first year of implementation. Based on developing evidence and further guidance of WHO, the regimen may be considered for all eligible cases in next year

For other cases, longer MDR-TB regimen will continue to be used

<u>Intensive phase</u>8Z+Ka+Lfx+Eto+Cs <u>Continuation phase</u>12Z+Lfx+Eto+Cs $Z-Pyrazinamide;\ Ka-Kanamycin;\ Lfx-\ Levofloxacin;\ Eto-\ Ethionamide;\ Cs-\ Cycloserine;\ H-\ Isoniazid$

The regimen can be individualized after receiving reports of the SL LPA

E. PMDT plan for shorter regimen

Sl.No.	Plans and programs	Status	
1.	Infrastructure	In place	
2.	National Strategic Plan	In place (2017-2023)	
3.	FL-LPA in NTRL	established in 2014	
4.	Training of Laboratory staffs on SL-LPA	2 staff trained in 2 nd quarter of '16	
5.	Procurement of LPA kits for SL-DST	Process initiated	
6. Develop guidelines, algorithms and SOPs		4th quarter of 2017	
7.	Training of HPs on shorter regimen	4th quarter of 2017	
8.	Drug forecast, logistics and supplies	4th quarter of 2017	
9. Arrival of drugs, logistics and supplies		1st quarter of 2018	
10.	Launch the implementation of shorter regimen	World TB Day 2018	
11.	Implementation of aDSM	Simultaneous with introduction of	
		shorter regimen	
12.	Enhanced supervision and monitoring	Simultaneous with introduction of	
		shorter regimen	

F. Training summary

A two days training of 33 experts, medical doctors and pharmacists from districts on shorter regimen was held in Paro. The topics covered were

- Case definitions and treatment outcomes
- Screening for DR-TB and diagnosing cases
- WHO guidelines for Laboratory network
- Treating MDR-TB and use of shorter regimen
- aDSM important definitions and implementation
- Treatment adverse effects and their management
- Drug needs for shorter regimen and transitioning from longer to sorter regimen
- Recording and reporting on MDR-TB

Each topic was followed by interactive exercises

Pre and post-tests was also conducted for all participants. All questions were objective in nature. Each question had 1 mark. If a question had multiple correct choices, marks were given only if all correct choices were chosen. Summary is as follows

In pre test

Minimum score	3	
Maximum score	14	2 participants
Average score	9	
Median score	8	
Maximum correct answers	Q 10	24 participants
Minimum correct answers	Q 11	0 participants

Q 10 pertained to managing QT prolongation in patients on second line drugs while Q 11 pertained to correct definition of 'treatment failure' in patients on second line drugs.

In post test: Significant improvement in scores was seen in post test

Minimum score	10	3 participants
Maximumscore	16	3 participants
Averagescore	14	
Medianscore	14	
Maximum correct answers	Q 6	32 particpants
Minimum correct answers	Q 7	11 participants

Q 6 pertained to clinical decision to be taken in case where a patient on shorter regimen is smear positive at 4 months of treatment and Q 7 to circumstances under which a DR-TB patient may receive medicines for self-administration. It is also to be noted that for Q 7 only 6 participants had correctly answered during the pre-test. Hence, despite being answered correctly by a low number of participants, it is improvement over the pre-test

G. Discussions on updating of PMDT guidelines

A meeting of experts was held on 13 October to further discuss adoption of WHO guidelines for diagnosis and management of MDR-TB. Some of the salient decisions were

- 1. The programme will move towards universal drug susceptibility testing using the available GeneXpert machines. With current capacity, around 3000 tests can be performed each year
- 2. The WHO recommended shorter regimen will be adopted as such without any modifications
- 3. As soon as the guidelines are finalized, the programme will approach Essential Medicines and Technology Division and Drug Regulatory Authority for inclusion of Moxifloxacin and Prothionamide in the essential drug list of the country. The process can be expedited for approval within a month of proposal from the National Drug Committee
- 4. The programme will sound GDF on its intention to introduce shorter regimen from first quarter of 2018 and make a formal procurement rest as soon as the necessary administrative processes are complete
- 5. Process of receiving consent from the patient specifically when initiating on shorter regimen will be formalized
- 6. A low-chart for information flow on adverse events will be prepared in coordination with the Pharmacovigilance department
- 7. Duties of persons responsible for adverse events reporting will be assigned and included in the guidelines
- 8. The programme will include bedaquiline and delamanid use in guidelines as options for patients where an effective regimen cannot be constituted with available drugs.

Annexure 1: Agenda for training on shorter regimen for DR-TB

Day 1 (11/10/2017)

Time	Program	Facilitators
08.30-09.00	Registration of participants	Facilitators plus
		participants
09.00-09.10	Introduction of participants and facilitators	NTCP
09.10-09.20	Objectives and expectations	NTCP
09.20-09.40	Pre-test	Dr. Vineet Bhatia
09.40-10.00	Current status of PMDT in the country and future	NTCP
	plans, including those for introduction of shorter	
	regimen	
10.00-10.30	PMDT programme performance – global, regional	Dr. Vineet Bhatia
10.00.11.00	and country	
10.30-11.00	Tea/coffee break	Dr. Vineet Bhatia
11.00-11.30	PMDT programme performance – global, regional and country	Dr. Vineet Bhatia
11.30-12.00	Case definitions and treatment outcomes	Dr. Vineet Bhatia
12.00-12.30	Screening for DR-TB and diagnosing cases	Dr. Vineet Bhatia
12.00-12.30	WHO guidelines for Laboratory network	Dr. Vineet Bhatia
12.30-13.00	Exercises on detection of MDR-TB followed by	Dr. Vineet Bhatia
	discussions	
13.00-14.00	Lunch break	
14.00-14.30	Treating MDR-TB and use of shorter regimen	Dr. Vineet Bhatia
14.30-15.00	Exercises on treatment of MDR-TB followed by	Dr. Vineet Bhatia
	discussions	
15.00-15.30	Tea/coffee break	
15.30-17.00	Continue Exercises followed by discussions	Dr. Vineet Bhatia

Day 2 (12/10/2017)

09.00-09.15	Recap of Day 1	Participants
09.15-10.00	Pharmacovigilance – current guidelines and policies	DRA, Bhutan
	in Bhutan	
10.00-10.30	aDSM – important definitions and implementation	Dr. Vineet Bhatia
10.30-11.00	Tea/coffee break	
11.00-11.30	Side effects and their management	Dr. Vineet Bhatia
11.30-13.00	Exercises on treatment of MDR-TB followed by	Dr. Vineet Bhatia
	discussions	
13.00-14.00	Lunch-Break	
14.00-14.30	Continue Exercises on treatment of MDR-TB f	Dr. Vineet Bhatia
14.30-15.00	Drug needs for shorter regimen and transitioning	Mr Alessio Mola/GDF
	from longer to sorter regimen	
15.00 15.30	Tea/coffee break	
15.30-16.00	Recording and reporting on MDR-TB	Dr. Vineet Bhatia
16.00-16.30	Exercises on R&R of MDR-TB followed by discussions	Dr. Vineet Bhatia
16.30-17.00	Post-test & End of the day	Dr. Vineet Bhatia

Annexure 2: Pre and post-test questionnaire

1.	Write a "T" for true or "F" for false by the following statements:
	A drug-susceptibility test (DST) is required to confirm a diagnosis of MDR-TB.
	Xpert MTB/Rif can be done for people presumed to have DR-TB even before smear test
	An HIV-positive patient with smear-negative TB does not need Xpert MTB/Rif test.
	All patients with confirmed MDR-TB have strains of TB that are resistant to at least isoniazidand rifampicin.
	If available, all patients starting on shorter regimen for MDR-TB should get a second line LPA done.
2.	Which of the following is correct WHO recommended shorter regimen for MDR-TB(tick 1)
	 a. 5 Km-Z-Cs-Lfx-PAS/ 5 Cs-Lfx-PAS b. 4-6 Km-Mfx-Pto-Cfz-Z-Hhigh-dose-E / 5 Mfx-Cfz-Z-E c. 8 Km-Mfx-Pto-Cfz-Z-Hhigh-dose-E / 8Mfx-Cfz-Z-E d. 4-6 Km-Z-Cs-Lfx-PAS/ 5 Cs-Lfx-PAS
3.	Which of the following is not a core MDR-TB regimen drug as per the recent regrouping of drugs by WHO a. Ethionamide b. Cycloserine c. p-aminosalicylicacid d. Linezolid e. Clofazimine
4.	Which of the following cases cannot be given shorter regimen for MDR-TB (tick all that apply) a. New case with no history of previous TB medications b. HIV positive individual c. EP-TB case with Rif resistance d. Pregnant females e. Patient who took Levofloxacin for chest infection for more than one month

5. What are the number of injections Kanamycin needed for intensive phase of shorter regimen

- a. 112
- b. 152
- c. 224
- d. 236
- 6. What is the clinical decision in case where a patient on shorter regimen is smear positive at 4 months of treatment
 - a. Declare as failure
 - b. Consider extension of intensive phase
 - c. Switch to continuation phase
 - d. Switch to longer regimen
- 7. Under which circumstances may a DR-TB patient receive medicines for self-administration? (Tick all that apply)
 - a. when the patient has to travel
 - b. when the patient cannot come to the health centre for directly observed treatment because she or he feels sick
 - c. when the patient has completed the intensive phase
 - d. when a patient has never missed a dose
 - e. none of the above
- 8. What are the critical aspects of directly observed treatment? (tick all that apply)
 - a. talking to the patient and giving support
 - b. providing medicine to the patient
 - c. watching the patient swallow the medicines
 - d. recording the treatment on the treatment card
- 9. What is the full form of aDSM
 - a. Active drug side-effects management
 - b. Active TB drug-safety monitoring and management
 - c. Acute drug side-effects monitoring
 - d. Absolute drug safety monitoring
- 10. What would you do in case you notice significant QT prolongation in a patient on second line anti-TB medicines
 - a. Stop QT prolonging drugs
 - b. Check for electrolytes
 - c. Repeat ECG

d. All of the above

- 11. Treatment failure in a case on second line treatment is defined as treatment terminated or need for permanent regimen change of at least two anti-TB drugs because of (tick all that are applicable):
 - a. Lack of conversion by the end of the intensive phase
 - b. Bacteriological reversion in the continuation phase after conversion to negative
 - c. Evidence of additional acquired resistance to fluoroquinolones or second-line injectable drugs
 - d. Adverse drug reactions

12. What is the definition of Cure in second-line treatment

- a. Treatment completed as recommended by the national policy without evidence of failure
- b. Three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase
- c. Treatment completed as recommended by the national policy without evidence of failure OR three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase
- d. 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

Annexure 3: Attendance list of training

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Registration for the training of medical officers/professionals on shorter regimen to treat MDR-TB Venue: Hotel Holiday Home, Paro 11th-12th October, 2017

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Registration for the training of medical officers/professionals on shorter regimen to treat MDR-TB 11th-12th October, 2017

Venue: Hotel Holiday Home, Paro

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Registration for the training of medical officers/professionals on shorter regimen to treat MDR-TB 11th-12th October, 2017

Venue: Hotel Holiday Home, Paro

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Registration for the training of medical officers/professionals on shorter regimen to treat MDR-TB Venue: Hotel Holiday Home, Paro 11th-12th October, 2017

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