

rGLC report format
TECHNICAL ASSISTANCE REPORT

Country:	Bangladesh
Dates of TA provision:	15 October- 6 November 2021
Consultant(s):	Dr. Maria Imelda Josefa Quelapio
Clearance of the report	The content of the report is for clearance by the National Tuberculosis Program- Bangladesh and WHO-Bangladesh.
Sharing of the report	This report will be shared with the NTP-Bangladesh, WHO-country and WHO-SEAR.
TA coordination	rGLC/SEAR Secretariat and WHO Country office Bangladesh
Summary of the TA provided	<p>The terms of reference of the technical assistance for the NTP in Bangladesh include conducting a remote capacity building workshop, and providing a review of the Standard Operating Procedures (SOPs) for the clinical management component of active TB drug safety monitoring and management (aDSM).</p> <p>A. Conduct of the aDSM capacity building workshop: a preparatory meeting was held on 1 November with the NTP, WHO and partners to discuss the content, intended audience, date and time of the aDSM workshop. During the preliminary meeting, a brief background was provided regarding the current MDR-TB regimens and aDSM practices in the country. The actual aDSM workshop was held on 15 November 2021.</p> <p>Background: Currently, the identification and management of adverse events (AE) are done <i>ad hoc</i> in the DR-TB facilities. An aDSM training was recently conducted for the introduction of the all-oral Bedaquiline (Bdq)-containing regimen, and will be followed with an aDSM reporting and causality assessment training in December 2021 by G. Hill which will tackle the AE report forms, reporting route from the field in the context of a Memorandum of Understanding between the NTP and the Directorate General of Drug Administration (DGDA), the national Pharmacovigilance Center. Bangladesh implements the core aDSM package for which only serious AEs are reported. The new drugs, Bdq and Delamanid (Dlm) are well-tolerated but not Linezolid (Lzd); hence, the importance of the focus on clinical adverse events identification and management in this training.</p> <p>Contents: The contents that were agreed to be included in the aDSM workshop are in Annex 1, the Agenda with inclusion of appropriate regimens used in special conditions (pregnancy and extrapulmonary DR-TB), and aDSM in TB preventive therapy using Rifapentine, 3RH, 6H. The topic on Programmatic aDSM implementation in Bangladesh supposedly by the NTP was omitted as requested by the country team as this was just recently presented to the attendees. Instead, a copy of the presentation was sent to the consultant to serve as background prior to the workshop.</p> <p>The presentations that were delivered during the workshop included a) the aDSM Framework; b) Identification of AEs; c) Clinical management of AEs; and d) aDSM for TB preventive therapy. There was active participation from the participants during the</p>

	<p>question and answer sessions after each main presentation. The questions asked were on a) color vision testing of illiterate patients; b) objective way to grade peripheral neuropathy; c) aDSM for TB preventive therapy (TPT); d) recommended drugs for pregnancy; and e) appropriate regimen for extrapulmonary TB. The responses to the questions were provided in a powerpoint presentation sent after the workshop. Copies of all presentations have been provided to the NTP and WHO-country.</p> <p><i>References:</i> The main references used in the workshop presentations were the 2020 WHO Consolidated Guidelines and Operational Handbooks for the treatment of DR-TB, the WHO aDSM Framework for Implementation (2015), and the Clinical and Programmatic Guide for patient management with new TB drugs, ver 4.0 of the End TB Consortium (January 2018). Country documents such as the National Guidelines and Operational Manual for the Programmatic Management of Drug-resistant TB, 3rd edition (Dec 2020) and the aDSM presentation by WHO-country (N Arefin) given during the Stakeholders' workshop for aDSM SOP development on 9-11 November 2021 served as important country references for the workshop.</p> <p><i>Audience:</i> The meeting was attended by members of the NTP who conduct trainings on DR-TB, the medical doctors from the 10 MDR-TB facilities and partners such as WHO, Damien Foundation, USAID-IRD, BRAC and ICDDRDB (Annex 2- the list to be provided by the NTP).</p> <p>B. Review of the SOPs for the clinical management of aDSM: A draft of the aDSM SOPs (Oct 2021) is still being finalized by the country and will be shared with the consultant for comments as soon as ready.</p>
Summary of the recommendations to follow up	<p>The aDSM workshop was a venue to clarify questions not only pertaining to aDSM but also on the appropriate regimens for special conditions such as pregnancy and extrapulmonary TB and aDSM in TPT. Responses were provided to the team based on what are recommended in the available WHO guidelines. These questions and responses were provided in a separate powerpoint presentation.</p>

ANNEXES

Annex 1 – aDSM WORKSHOP AGENDA

WORKSHOP ON ACTIVE DRUG SAFETY MONITORING AND MANAGEMENT FOR DRUG-RESISTANT TB

NATIONAL TB PROGRAM, MINISTRY OF HEALTH and FAMILY WELFARE, BANGLADESH

15 November 2021 @10:00 AM -4:00 PM

Time	Topic/ activity	Facilitator/ Speaker
10-10:15	Registration	Organizers
	Opening and welcome	NTP
	Introductions of Facilitators and participants	Organizers
10:15-10:20AM	Rationale and Objectives of the Workshop	Organizers
10:20- 10:40AM	Programmatic aDSM implementation in Bangladesh	NTP
10:40-11:00 AM	WHO aDSM framework for implementation	Mamel Quelapio PMDT Consultant
11:00-11:50 NN	Identification of adverse events Specific procedures for the identification of AEs <ul style="list-style-type: none"> - Brief Peripheral Neuropathy Screen (BPNS) - Visual acuity check: Snellen Eye Chart - Color discrimination check: Ishihara Chart - QTcF calculation 	Mamel Quelapio
11:50-12:00 NN	<i>Q and A</i>	<i>All</i>
12:00-1:00 PM	Management of specific adverse events: <ul style="list-style-type: none"> - Introduction and principles - Peripheral neuropathy, Optic neuritis, myelosuppression, QT prolongation hepatotoxicity and gastric disturbances, psychiatric disorders 	Mamel Quelapio
1:00-1:45 PM	L U N C H B R E A K	
1:45-2:30 PM	Management of specific adverse events: <ul style="list-style-type: none"> - Arthritis and arthralgia, electrolyte abnormalities, ototoxicity, nephrotoxicity, hypothyroidism, other minor AEs 	Mamel Quelapio
2:30-2:40 PM	<i>Q and A</i>	<i>All</i>
2:40-3:15 PM	AE management in TB Preventive Therapy (TPT), special conditions (pregnancy); drug-drug interactions	Mamel Quelapio NTP
3:15-3:20	<i>Q and A</i>	<i>All</i>
3:25-3:30	Wrap up and Closing	NTP

Annex 2 – LIST OF PARTICIPANTS (to be provided by the country team)

Annex 3 - LIST OF PERSONS CONSULTED DURING THE DEVELOPMENT OF THE PRODUCT

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Name	Designation
Dr. Vineet Bhatia	Medical Officer, MDR-TB, Department of Communicable Diseases, WHO-South East Asia Region, rGLC SEAR Secretariat
Dr. Pronab Kumar Modak, MBBS, MPH*	Deputy Program Manager (Training), Focal Person, MDR-TB, NTP
Dr. Arefin Nazis Saki*	National Professional Officer (Tuberculosis), WHO-Bangladesh
Dr. Manzur*	Deputy Director, Interactive Research and Development (IRD)
Dr. Anupama Hazarika*	Medical Officer, Communicable Diseases, WHO-Bangladesh

*Present during the preliminary meeting to discuss the details of the aDSM Workshop