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The programme has agreed with open sharing of this report



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Abbreviations and acronyms

aDSM	active TB drug-safety monitoring and management
ADR	Adverse drug reaction
AE	Adverse event
Am	Amikacin
Bdq	Bedaquiline
BSC	Biological safety cabinet
BSL	Biosafety level
C/DST	Culture and Drug Susceptibility Testing
Cfz	Clofazimine
Cm	Capreomycin
CMSD	Central Medical Supplies Department
CO	Country Office
Cs	Cycloserine
CTB	Challenge TB Project
CXR	Chest X-ray
DHIS	District health information system
Dlm	Delamanid
DM	Diabetes Mellitus
DRS	Drug resistance surveillance
DR-TB	Drug resistant TB
EQA	External quality assurance
E	Ethambutol
Eto	Ethionamide
FDA	Food and Drug Administration
FL	First line
FLD	First line anti TB drugs
FM	Fluorescent microscopy
FQ	Fluoroquinolones
GDF	Global Drug Facility
GF	The Global Fund
GMO	General Medical Officer
GXP	GeneXpert
H	Isoniazid
Hr	Isoniazid resistance
HR	Human resources
JMM	Joint Monitoring Mission
LC	Liquid culture
Lfx	Levofloxacin
LPA	Line Probe Assay
LTR	Longer treatment regimen
Lzd	Linezolid
MDR-TB	Multidrug-resistant TB
Mfx	Moxifloxacin
MMA	Myanmar Medical Association
MOHS	Ministry of Health and Sport
MNCH	Maternal, Neonatal and Child Health
MSF-H	Medecins Sans Frontieres – Holland
NCCA	National Core Committee for aDSM
ND	New drugs
NIRT	National Institute for Research in TB

NSP	National Strategic Plan
(I)NGO	(International) Non-Governmental Organisation
NHP	National Health Plan
NIMU	National Health Plan Implementation and Monitoring Unit
NTP	National TB Programme
NTRL	National TB Reference Laboratory
OPD	Out-patient department
Open MRS	Open Medical Record System
PHS-II	Public Health Supervisor-II
PIDM	Program for International Drug Monitoring
PMDT	Programmatic Management of Drug resistant TB
Pre-XDR-TB	Pre-Extensively drug resistant TB
rGLC	Regional Green Light Committee
RR-TB	Rifampicin Resistant TB
SAE	Serious adverse event
SDG	Sustainable Development Goals
SEARO	South-East Asia Regional Office
SL	Second line
SLD	Second line anti TB drugs
SLI	Second line injectables
SL-LPA	Second line Probe Assay
SNRL	Supra-National TB Reference Laboratory
STR	Shorter treatment regimen
TSR	Treatment success rate
UHC	Universal Health Coverage
WHO	World Health Organization
XDR-TB	Extensively drug resistant TB
Z	Pyrazinamide
ZN	Ziehl-Neelsen

I. Executive summary

i) TORs of the mission

The authors provided technical support for the review of drug-resistant tuberculosis (DR-TB) and laboratory related activities during the Joint Monitoring Mission (JMM) of Myanmar's National TB Programme from 11 to 21 August 2019 as part of the annual regional Green Light Committee (rGLC) mission, organized by the South-East Asia Regional Office (SEARO), the World Health Organization (WHO).

Terms of Reference (Dr DF Wares)

1. Review progress against the recommendations made in the last JMM;
2. Review existing nation-wide DR-TB guidelines and policy documents to check their alignment with latest WHO recommendations;
3. Evaluate the readiness to start the newly WHO recommended regimen, phasing out of the previous ones;
4. Provide assistance on provision of individualized treatment regimen. Discuss on the options of systems to provide good quality and quantity medicines on time, and drug supply management to minimize expiry and prevent stock out;
5. Evaluate the requirements to start DR-TB treatment, discuss and find solutions to reduce delay in starting treatment because of inflexible requirements; and
6. Provide recommendation of policy system that can accommodate changing of regimen following the latest drugs invention and knowledge.

Terms of Reference (Dr Rajesh Kumar Mondal and Dr Siva Kumar Shanmugam)

1. Review progress against the recommendations made in last JMM;
2. Review existing diagnostic algorithms and policy documents to check their alignment with latest WHO recommendations;
3. Evaluate the readiness of laboratories to support start of new recommended regimen;
4. To assess feasibility and way forwards to expand culture, DST and new diagnostics; and
5. Provide recommendations to improve access to laboratory and strengthen laboratory network.

ii) Findings and observations

Achievements

- Programmatic Management of DR-TB (PMDT) services cover all 330 townships since 2016. There are currently 59 DR-TB Treatment Initiation Centres across the country, with most district capital townships with GeneXpert (GXP) having an DR-TB centre.
- Since the last JMM in 2014, there has been a steady increase in the number of multidrug-resistant TB (MDR-TB) cases notified (2,631 in 2014 to 3,479 in 2018) and cases placed on treatment (1,537 to 2,802).
- Currently there is a network of 104 GXP machines in 79 sites across the country. The total number of GXP tests done in 2018 was 126,326 (in 2017, it was 93,072). The country has a plan of providing molecular diagnostics in all districts in a phased manner by 2019.

- 477 microscopy centres using either Ziehl-Neelsen (ZN) or fluorescent microscopy (FM) have been established at township level and are included in a national external quality assurance (EQA) system.
- A new Biological Safety Level (BSL) 3 laboratory for Yangon has been constructed adjacent to the old National TB Reference Laboratory (NTRL) building, and was built with funding through UNOPS and 3MDG. There are three culture and drug susceptibility testing (C/DST) laboratories in Mandalay, Taunggyi (Shan State South) and Yangon. Three functional line probe assay (LPA) testing laboratories are available in Yangon and Mandalay. LPA has now also been introduced in the laboratory in Taunggyi.
- There is clear and expanded criteria (dependent on whether the township has a GeneXpert test site or not) set out by the National TB Programme (NTP) on who is defined as a “presumptive MDR-TB case” and who are to be further tested for drug resistance. Since late 2017, all registered TB patients in the Yangon Region are being tested by GXP for rifampicin resistant TB (RR-TB).
- Ministry of Health and Sports (MOHS)/NTP now procures “quality-assured” TB medicines using government funds (100% of first line drugs [FLD] and 40% of second line drugs [SLD]).
- No stock out of TB medicines, ancillary medicines and key laboratory supplies for the past 2 years
- The new drugs (bedaquiline and delamanid) and regimens (shorter treatment regimen - STR) have been introduced in the Yangon and Mandalay Region for eligible DR-TB patients under the NTP and the endTB Project
- High treatment success rates (>80%) amongst initial cohort of DR-TB patients treated with the STR, and amongst those treated earlier (>70%, 2016 cohort) with the “conventional” longer treatment regimen (LTR).
- For the DR-TB patients a support package, both financial and nutritional, is in place.
- System for monitoring patient’s progress, drug safety, serious adverse event reporting, and causality assessment (i.e. active TB drug safety monitoring and management –“aDSM”) in place for DR-TB patients and functioning. National Core Committee for aDSM (NCCA) established and functioning.

Challenges

- Large gap between the estimated country burden (14,000 for 2018) and number placed on treatment (2,802). In addition, the National Strategic Plan for TB (NSP) 2018 target (4,905) for notification of RR-TB and/or MDR-TB cases was not met (3,479).
- Sub-optimal utilization of GeneXpert at all levels – still used only for detection of rifampicin resistance and not to detect TB.
- Nationally, there is limited laboratory capacity for C/DST and LPA (first-line [FL] and second-line [SL]). Though facilities are available, trained manpower is a challenge for the 2nd line DST.
- “Delay” between RR-TB diagnosis by GeneXpert and initiation on the STR was observed, and in Shan State, substantial barriers for patients to access DR-TB treatment services were seen.
- Care of patients treated with the STR is currently “centralized” at the two higher level TB Centres in Mandalay (Regional TB Centre) and Yangon (Regional TB Centre).
- Issues with infrastructure (service capacity) and patient pathways at and between TB Hospitals, Regional TB Centres and Township facilities.
- Unexpectedly high levels of hypokalemia reported amongst DR-TB patients treated with STR (in the 2018 cohort), including amikacin (Am) as the second line injectable.
- Initial cohort results of patients (n=38) treated with new drug (ND) containing regimens poor, with only a 58% treatment success and a 29% death rate.

- From MDR-TB patients and ex-patients - generally satisfied with the care that they receive, but wish the use of the second line injectable (SLI) to be stopped asap, and that the patient support package is insufficient to replace lost household income and leading to major problems in maintaining family life.
- From discussions with DR-TB DOT providers (Midwives) - limited understanding of potential adverse events in DR-TB patients and action to be taken, especially amongst those on the ND-containing regimens.
- Policy for isoniazid resistant (Hr) cases (identification, detection and treatment) unclear.
- Human Resource issues continue
- Recording and reporting remains primarily manual; electronic systems need to be improved and expanded.
- Need for NTP to be actively engaged in the ongoing dialogue in relation to the restructuring of the health services in Myanmar, development of the next NSP and ensuring access to TB services is included in the Universal Health Coverage (UHC) agenda of the country

Priority recommendations of the mission (max 10):

Recommendation	Responsible persons/agency	Timeline	Support required to fulfill the recommendation
1. Develop a national TB laboratory plan to expand Xpert sites to the majority of townships, with priority given to address the MDR-TB crisis in Yangon	NTP/NTRL/ WHO Country Office (CO)/ Partners/ Supra-National TB Reference Laboratory (SNRL – NIRT)	By Q2 2020	Technical assistance (TA) of laboratory expert(s)
2. A transition plan to provide Xpert testing as the initial diagnostic test for all presumptive TB cases is needed as a priority	NTP/NTRL/WHO CO/Partners/SNRL	By Q2 2020	TA of laboratory expert(s)
3. C/DST and LPA capacity to be urgently expanded	NTP/NTRL/WHO CO/Partners/SNRL	On-going	TA from SNRL
4. Suggested modifications to the new NTRL to be undertaken urgently	NTP/NTRL/WHO CO/Partners/Bio-medical engineering expert(s)/SNRL	By Q1 2020	TA from bio-medical engineering expert(s)/SNRL
5. Introduce and transition to the all oral DR-TB regimen as planned and scale-up it up nationwide as rapidly as possible. In the interim, scale-up nationwide the STR, with the care of the patients decentralized to all DR-TB Treatment Initiation Centres	NTP/WHO CO/ Partners	Initiate scale-up of STR by Q2 2020. Introduce all oral DR-TB regimen from Q2 2020, by Q2	TA from PMDT expert(s)

		2021 have completed transition	
6. Expand aDSM to cover all DR-TB patients. The observation of the high levels of hypokalaemia in patients treated with the STR needs further analyses urgently	NTP/NCCA/WHO CO and Regional Office/Partners	As soon as possible	TA from PMDT expert(s)
7. Shift from “full hospitalization” care model to a more ambulatory care model for those on ND-containing regimens, via the network of DR-TB Treatment Centres	NTP/WHO CO/ Partners	By Q2 2020	
8. Update the “Guidelines for the management of DR-TB in Myanmar”	NTP/WHO CO/ Partners	By Q2 2020	TA from PMDT expert(s)
9. Patient support package needs to provide enablers and incentives to meet the needs of the DR-TB patients, with the financial burden effectively addressed by appropriate social protection intervention, including consideration of income replacement	MOHS/Ministry of Social Welfare/WHO CO/Partners	By Q3 2020	TA of an expert in social protection interventions
10. Conduct/complete the planned Drug Resistance Surveillance (DRS) survey as soon as possible	NTP/WHO CO and Geneva/Partners/ SNRL	By Q4 2020	TA from WHO Geneva and SNRL

Status of Priority recommendations of previous mission (2018):

Recommendations	Responsible agency/person	Status
1. Fill all vacant posts (including Laboratory Technicians) related to programme implementation and management at various levels, and train them on the latest guidelines	NTP/MoHS/WHO CO/Partners	Limited number of staff appointed, particularly in higher level laboratories. Training mostly still pending
2. Identify the missing TB cases, enhance the case finding through improved sputum transport, actively engaging with partners, improve notification from private sector, target high-risk population and expansion of laboratory services	NTP/Myanmar Medical Association (MMA)/Other Partners	Focus on quality of sputa collection and transportation by NTP. GeneXpert network expanded, however still used for RR-TB detection and not as primary diagnostic test. Engagement with partners ongoing. Various active case finding activities introduced. Mandatory notification of TB cases introduced from January 2019.

3. Enhance and optimize the laboratory capacity for 1 st and 2 nd Line DST including use of SL-LPA as initial test for FQ and SL injectable resistance	NTP/NTRL/ WHO CO/Partners	2nd line LPA has been initiated but still no phenotypic SL DST being performed currently. Not all detected RR-TB cases are having a SL LPA test performed at baseline
4. Strengthen patient counseling to reduce diagnostic delays, develop better linkage with the private providers and other partners in order to reduce the gap between diagnosis and treatment	NTP/MMA/ Other Partners	Patient counselling has been strengthened particularly in the Yangon Region, where a counsellor has been placed at every DR-TB treatment initiation centre. Further improvement is required, particularly in Upper
5. Scale up shorter MDR-TB Regimen (remove Ethambutol as exclusion criteria) and expand the use of newer and repurposed drugs	NTP/DR-TB Expert Committee	Exclusion criteria of E removed. The STR yet to be expanded outside of Mandalay and Yangon Regions
6. Decentralize ART availability and ensure its early initiation, facilitate TB screening amongst PLHIV	NTP/National AIDS Control Programme	Screening for TB amongst PLHIV and ART provision increasing
7. Ensure funding sustainability beyond 2020	MoHS/NTP/WCO/ In-country Partners	Increased Government funding. NSP for 2021-2025 being developed. On-going discussions within MOHS regarding UHC and health insurance schemes. On-going discussions with varied external funding agencies
Achieved		
Some progress/ ongoing		
No change		

Review of DR-TB related recommendation from 2014 JMM Report

1. Ensure that all treatments for MDR-TB available for 2015 and beyond are utilised in a swift and efficient manner. For the longer term, start a debate on how stakeholders will provide access to treatment.

The recommendation has been partially implemented. The NTP is now offering the conventional LTR, the STR and ND-containing regimens. However implementation of the newer regimens and drugs has taken time, and their availability is still geographically limited. The number of patients detected and enrolled on treatment need to be increased asap.

2. Request technical assistance, in coordination with the rGLC, to assess how much and in what way the management of MDR-TB is disturbing good practice at Basic Health Service level, and to recommend ways of alleviating any problems.

It is not clear whether this analyses had been conducted, or not

Review of laboratory related recommendation from 2014 JMM Report

Recommendations	Responsible agency/person	Status
1. Field staff needs to be trained in proper sputum collection as most of the samples received are salivary, which contributes for poor culture recovery rates	NTP/NTRL/WHO CO	Ongoing, the peripheral centres still have problem in collection of sputum as there is no dedicated staff in town ship level microscopy centers
2. Current policy for doing two sputum samples each time during follow up to be modified to single sample as per WHO recommendation.	NTP/NTRL/WHO CO	Achieved
3. Microbiologist and Laboratory Technicians position to be filled up in the new BSL3 lab in Taungguyi which started functioning from May 2018	NTP/NTRL/WHO CO	The position is yet to be filled in Taungguyi
4. One additional MGIT machine for NTRL and two GT Blots-48 one each for NTRL & Mandalay respectively to be procured to meet the additional work load due to change in criteria	NTP/NTRL/WHO CO	Achieved
5. Retrain all the staff on liquid culture (LC) DST and start performing second line LC DST with no further delay.	NTP/NTRL/WHO CO	2 nd line DST is not performed yet, at Mandalay this is due to lack of trained staff. A training has been scheduled on 9 th September at SNRL-NIRT for 2 nd line and newer drugs
6. EQA from SNRL, Bangkok which has been discontinued since 2016 to be resumed from same or another Laboratory in SNRL network.	NTP/NTRL/WHO CO	An MOU has been put in place with SNRL-NIRT, Chennai for EQA and Training.
7. Perform liquid culture for all follow up samples and discontinue solid culture, this will result in reduced work load of laboratory personal	NTP/NTRL/WHO CO	Ongoing, due to budget constrain both solid and liquid on different months as follow for patients.
8. Strengthen the EQA of Smear Microscopy and expand LED FM services to more microscopy sites	NTP/NTRL/WHO CO	Achieved

Achieved	
Some progress/ ongoing	
No change	

Review of “Summary of approaches” in the “Short summary of 2016-2020 NSP document”

1.1 Accelerate appropriate diagnosis (page 9)

- Expand the diagnostic network to include chest X-Ray (CXR) in all townships, microscopy in all station health units, GeneXpert in all districts, and culture & first line DST in 6 states and regions and second line DST in Yangon and Mandalay. Introduce district designed sputum transport systems to cover all remote populations.

This has been partially achieved and should be continued.

- Ensure sufficient and qualified human resource capacity within the expanded diagnostic network (Training).

This remains appropriate and should be implemented with utmost urgency as the In Mandalay laboratory the trained technician is absent from duty and there is no technician to perform 2nd line DST

3. Accelerate the communication of results between diagnostic and treatment sites, enhancing the recording and reporting system(s) for laboratories to align with the treatment monitoring systems, including for PMDT facilities, and introducing electronic systems. (covered upto district level)

This has been partially achieved and should be continued.

4. Design and introduce an EQA system for X-Ray interpretation, while expanding access to digital X-Ray nationwide.

This remains appropriate and should be implemented asap

5. Ensure biosafety and infection prevention control measures in all TB laboratories and sputum collection sites.

This has been partially achieved and should be continued.

6. Guarantee a regular supply of laboratory commodities, including centralized supply procurement.

This remains appropriate and should be implemented asap

7. Update and disseminate guidelines and Standard Operating Procedures (SOPs).

This has been partially achieved in the NTRL laboratories in Yangon and Mandalay and should be continued for all the TB laboratories in Myanmar.

1.2 Identify and treat all cases

1.2.2. MDR-TB (page 10)

1. Expand implementation of essential services for PMDT to all districts and townships – ensuring appropriate and timely provision of care as close to patients' homes as possible

This remains appropriate and should be continued. See recommendations from this mission.

2. Expand MDR-TB diagnostic capacity, decentralizing the availability of GeneXpert, DST and RR screening

This remains appropriate and should be implemented asap. See recommendations from this mission.

3. Improve treatment outcomes; bolstering patient and provider education and ensuring the consistent provision of a patient support package

This remains appropriate and should be continued. See recommendations from this mission.

4. Update communications, diagnosis-to-treatment completion tracking, and recording and reporting systems

This remains appropriate and should be continued.

5. Ensure full engagement of all providers

This remains appropriate and should be continued.

6. Systematize contact tracing for all household contacts of MDR-TB patients

This remains appropriate and should be implemented asap. See recommendations from this mission.

7. Pilot and adopt new tools, including treatment regimens (e.g. PAS) and diagnostic tests

This remains appropriate and should be continued. See recommendations from this mission.

II. Detailed report

A. Introduction

Myanmar, with a population of 53 million, is amongst the 30 high-burden countries as defined by WHO for TB, MDR-TB and TB/HIV co-infection. WHO estimates (Global Report 2018) the incidence of all forms of TB as 358 per 100,000 population and TB mortality, excluding TB-HIV, as 51 per 100,000. The current estimated TB incidence is about the same as the earlier incidence rate of 365 per 100,000 in 2009-10 and there is an overall gap of about 32% in the case detection.

The country has developed a National TB Strategic Plan 2016-2020, which proposes key interventions in order to achieve the Sustainable Development Goal (SDG) targets of the End TB Strategy. These are summarized in the figure below:

Strategic Directions and Key Interventions of National Strategic Plan (2016-2020)

Strategic Direction I: Integrated, Patient-centered Care and Prevention	Strategic Direction II: Bold Policies and Supportive Systems
1.1. Accelerate the appropriate diagnosis of TB	2.1. Secure human and financial resources for implementation of the NSP
1.2. Identify and treat all forms of TB, among all ages and including drug-resistant and drug-sensitive	2.2. Promote a coordinated and multi-sectoral response and policy development
1.3. Prevent transmission and the emergence of active TB	2.3. Ensure inclusion of TB in UHC and wider economic development plans and activities (social protection)
1.4. Intensify targeted action(s) to reach marginalized and at-risk populations	2.4. Ensure a stable and quality-assured supply of drugs, diagnostic tests and commodities
1.5. Implement a robust communication strategy, extending from policy makers to patient education	2.5. Human resources for health
1.6. Engage all care providers, including NGOs and the private sector, in appropriate TB diagnosis and care	Strategic Direction III: Intensified Research and Innovation
1.7. Promote and strengthen community engagement	3.1. Implement the prioritized research agenda
1.8. Joint TB and HIV programming to enable decentralized and integrated services for TB and HIV	3.2. Enhance evidence-based programme monitoring and implementation

The 2016-2020 NSP aims to reduce the TB incidence to 317 per 100,000 population and TB mortality to 34/100,000population by the year 2020 (Table 1). The country also aims to increase the notifications of drug susceptible TB cases to 285 per 100,000 population by 2020, while maintaining treatment success rates of at least 85% (Table 2).

WHO estimates (Global Report 2018) the MDR-/RR-TB incidence to be 26 (15-39) per 100,000 population in 2017, equating to a total of 14,000 (8-21) cases. Amongst the notified pulmonary TB cases, an estimated 8,700 (6,200 – 11,000) cases of MDR-/RR-TB existed. The third nationwide drug resistance surveillance (DRS) survey of 2012-2013 found that 5.1% of new cases and 27.1% of previously treated cases respectively had MDR-/RR-TB.

In relation to DR-TB, the 2016-2020 NSP (Tables 1 and 2) aims to:

1. reduce the prevalence of MDR-/RR-TB amongst new TB cases by 20% by 2020, compared to 2015) i.e. from 5% to 4%;
2. Increase the notification of RR-TB and/or MDR-TB cases from 4,494 in 2014 to 5,115 in 2020 (2018 target was 4,905);
3. Increase the treatment success rate amongst RR-TB and/or MDR-TB cases from 79% in 2014 to 82% in 2020 (2018 target was 82%); and
4. Reduce the affected families who face catastrophic costs due to TB by 2020.

Table 1. NSP 2016-2020 Impact Indicator Targets

Impact Indicators	Baseline	Targets				
		2016	2017	2018	2019	2020
Reduce the TB incidence by 15% by 2020 compared to 2015 baseline (per 100,000 population)	369	358	348	337	327	317
Reduce the mortality due to TB by 35% by 2020, compared to the 2015 baseline (per 100,000 population)	53	48	45	43	41	34
MDR-TB prevalence among new cases reduction by 20% by 2020, compared to 2015 baseline	5%	4.8%	4.6%	4.4%	4.2%	4%

Table 2. NSP 2016-2020 Outcome Indicator Targets

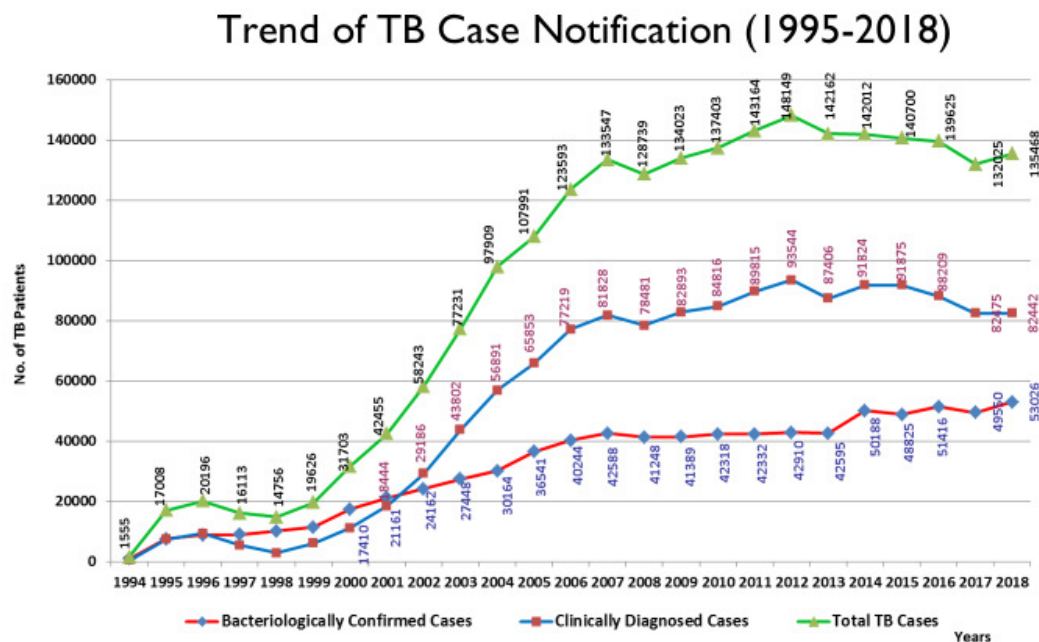
Outcome Indicators	Baseline	Targets				
		2016	2017	2018	2019	2020
Case notification rate per 100,000 population (bacteriologically confirmed+ clinically diagnosed)	276	294	292	290	288	285
Case notification rate per 100,000 population (bacteriologically confirmed)	97	106	108	110	112	114
Treatment success rate (bacteriologically confirmed)	85%	≥85%	≥85%	≥85%	≥85%	≥85%
Notification of RR-TB and/or MDR-TB cases	2793	4662	4787	4905	5014	5115
Number of RR-TB and/or MDR-TB cases to be treated	2207	3130	3297	3380	3510	3580
Treatment success rate RR-TB and/or MDR-TB	79%	81%	81%	≥82%	≥82%	≥82%

However the recently completed 2017-2018 TB prevalence survey has shown that there has been a significant decline in TB prevalence over the last 10 years in Myanmar (Table 3). The decline in prevalence is of the order of 50% over these years, and a reduction of over 20% in TB Incidence expected from 2015 to 2020 which will mean that Myanmar will achieve the End TB and SDG milestone targets for 2020.

Table 3. Results of 2009 and 2018 TB prevalence surveys

Prevalence per 100,000	2009	2018
Culture positive	520 (415 - 624)	256 (173 - 339)
Smear positive	195 (143 - 247)	57 (25 - 88)
Smear : Culture ratio	38%	22%

The graph below shows the trends in TB case notification in Myanmar from 1994 to 2018. Taking into consideration the results of the 2017-2018 TB prevalence survey, the case detection rate is probably higher than has been previously estimated. Also the RR-/MDR-TB situation might also be better than has been estimated.



The Ministry of Health and Sport remains the major provider of comprehensive health care, with the TB control services being provided through the regional/state and the district/township level hospitals and health centres (330). Under the current National Health Plan (NHP) for 2017-2021, a major restructuring

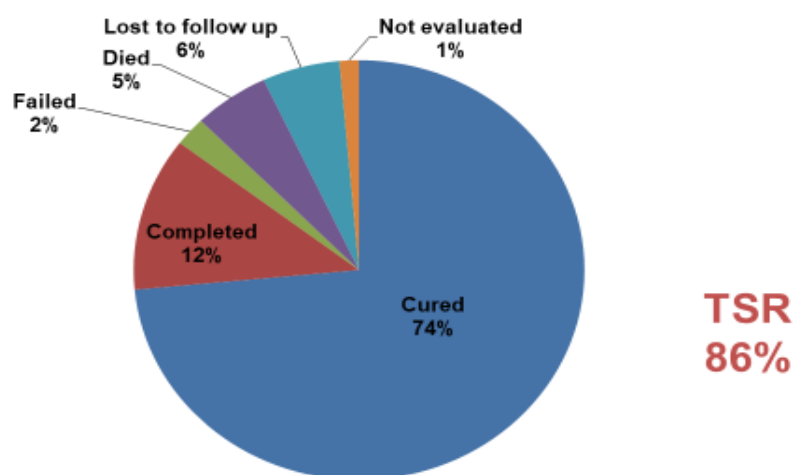
of the provision of health care is on-going within Myanmar. Also from 2015 onwards, the Department of Health was divided into the Departments of Medical Services and of Public Health, with the care packages of clinical services and public health services separated within the health system, with health care workers especially at the township and sub-township levels, being given new job descriptions. By 2021, the whole country is to be covered by the basic essential package of health services, and a new NHP for 2021-2025 will be developed. The country aims for Universal Health Coverage by 2030. The NTP needs to be actively engaged in all discussions and development of related health plans and care packages.

The private sector is also contributing to health care, mainly in the larger cities of Myanmar, especially in Mandalay and Yangon. The NTP also work with key partners such as the Myanmar Medical Association and PSI Myanmar, on TB care and control activities. The private, for non-profit, run by Community Based Organizations and Faith Based Organizations, are also providing ambulatory care, though some also provide institutional care.

Myanmar maintained the treatment success rate for bacteriologically confirmed TB cases for the 2017 cohort at 86% as shown in figure below:



Treatment Success Rate (TSR)(Bacteriologically confirmed), 2017 Cohort



26.6.19

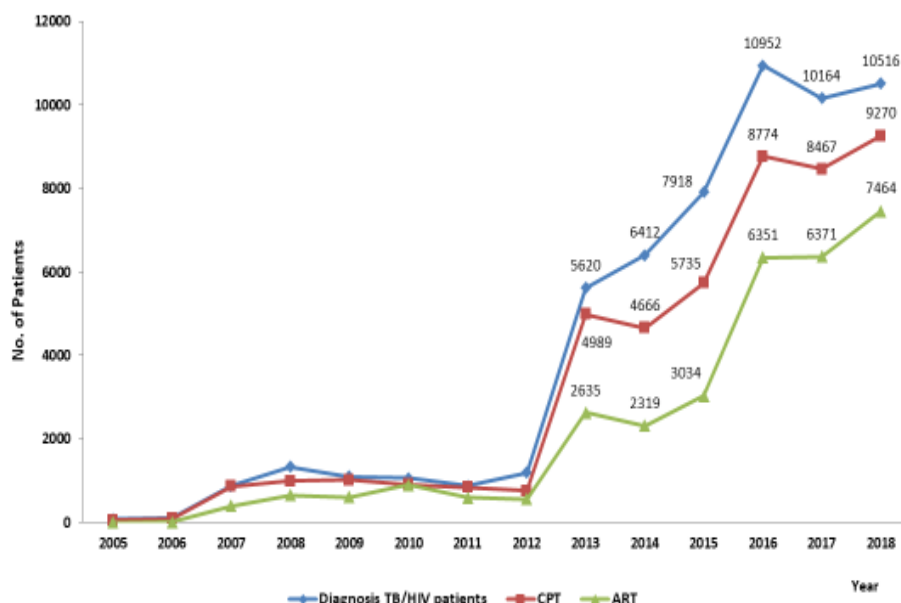
Annual TB Evaluation Meeting(2018)
Dr. Cho Cho San

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As per HIV sentinel surveillance data, the prevalence of HIV among new TB patients in 2016 was reported to be 8.5%. TB/HIV collaborative activities were initiated in 7 townships in 2005 and had expanded to cover all 330 townships by 2016. The graph below shows the achievements in the TB-HIV collaborative activities (2005-2018). Testing of TB patients for HIV has been improving in Myanmar with a rate of 90% of the 132,025 registered cases in 2017, of which 9% (10,164) were HIV positive. In 2018, 88% Of co-infected TB patients received cotrimoxazole preventive treatment. The number of co-infected patients who received anti-retroviral treatment increased in 2018, however it still remains low at 71%.



Trend of TB/HIV Collaborative Activities



26.6.19

Annual TB Evaluation Meeting(2018) Dr.
Cho Cho San

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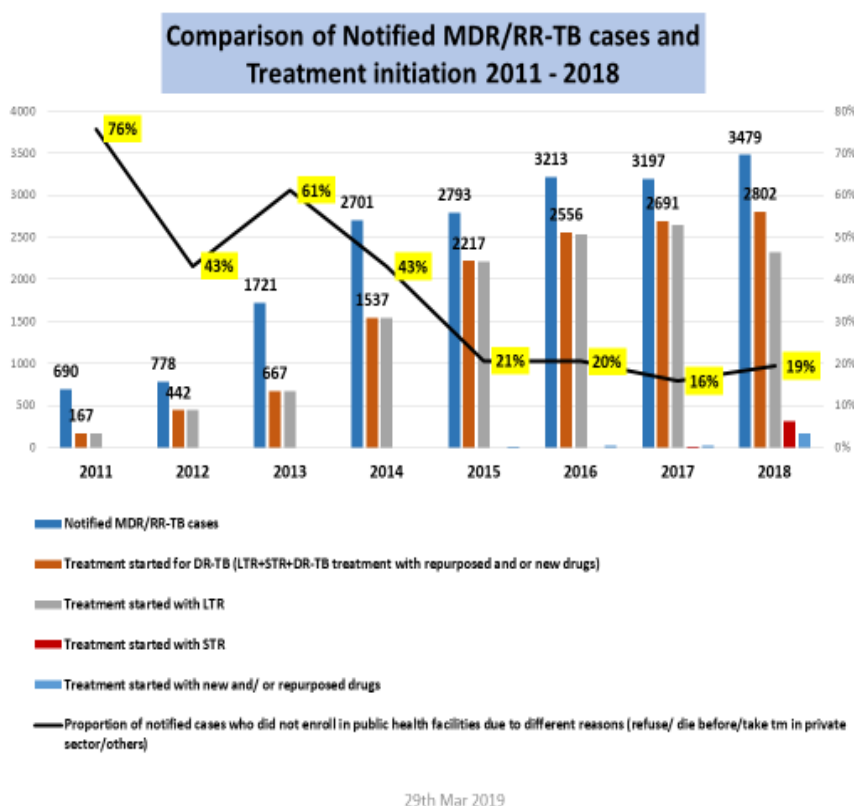
B. Overall programme performance (DR-TB)

Following experiences learnt from the DOTS Plus pilot project in 10 townships (5 each in Yangon and Mandalay Regions), programmatic management of drug-resistant TB was initiated in 2011 and expanded to cover all 330 townships from early 2016. There are currently 59 DR-TB Treatment Initiation Centres across the country, with most district capital townships with Xpert having an DR-TB Centre.

Since the last JMM in 2014, there has been a steady increase in the number of MDR-TB cases notified (2,631 in 2014 to 3,479 in 2018) and cases placed on treatment (1,537 to 2,802). However, although the number of DR-TB patients being placed on treatment is increasing, there is a large gap between the WHO estimated country burden (14,000 for 2018) and number placed on treatment (2,802). In addition, the NSP target for 2018 of an increase in notification of RR-TB and/or MDR-TB cases to 4,905 was not met (3,479).

Also, although again much improved from 2014 and earlier years, the national “gap” between the notified DR-TB cases (3,479) and those placed on treatment (2,802) for 2018 was 19% (see below figure). This has remained between 16% - 21% from 2015 onwards. In Shan State, substantial barriers for patients to access DR-TB treatment services (e.g. limited treatment sites resulting in access issues) were

observed, with ≈15% of patients who were detected with RR-TB not being enrolled on treatment. However in the Yangon Region, the figure is lower at 11%.



One reason provided for the “gap” between patients diagnosed and initiated on treatment was due to patient refusal with the need for injections, length of treatment, side effects and lack of access to care i.e. patient delay. However health system issues were identified and are discussed further in “Section E. Treatment strategy.”

The Yangon urban area has a much DR-TB higher caseload than anywhere else in the country – almost half of all the treated cases, with only 8 of 59 DR-TB Treatment centres and an over-burdened TB Hospital (Aung San Hospital). It is a “close to crisis situation” – please see respective chapter in the 2019 JMM Report for further details.

The latest “Guidelines for the management of drug-resistant tuberculosis in Myanmar” is from February 2017.

Recommendations

- Explore the barriers to accessing DR-TB care after RR-TB detection and undertake the necessary steps in reducing the enrolment gap, including by strengthening pre-treatment counselling.
- Urgently mount a response to the Yangon close-to-crisis situation - please refer to respective chapter in the 2019 JMM Report for further details.
- Update the “Guidelines for the management of drug-resistant tuberculosis in Myanmar”. The changes in global policies and in-country experiences since February 2017, need to be reflected in an updated guideline.

C. Case finding strategy

There has been an increase in the number of GeneXpert machines over the years with an increase in the number of GXP tests performed, with an expansion in the MDR-TB presumptive criteria (see figure below and table 4). Even though the number of tests performed has increased considerably. However, there is not a proportionate increase in the detection of DR-TB primarily due to the fact that there is a disproportionate increase in the testing of new cases vis-à-vis the other groups and we would not expect a large yield of DR-TB patients from the new cases until 100% are being tested.

Expansion of GXP machines by Year

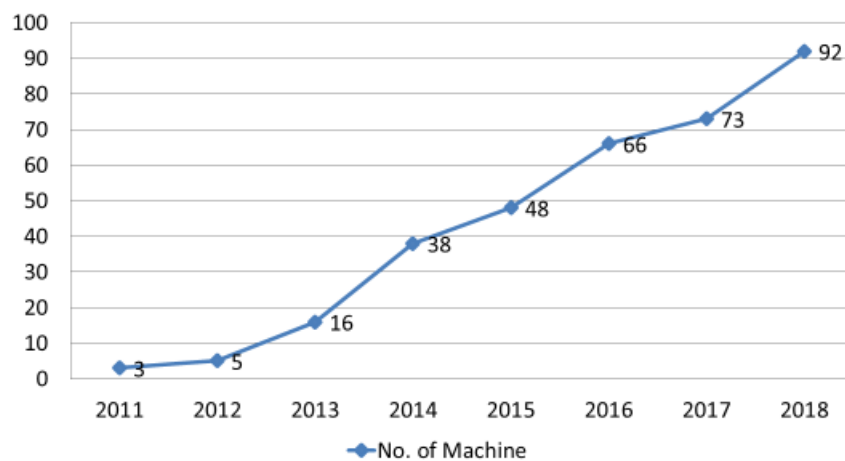


Table 4. GeneXpert test results 2017 to Q1 2019

Year	Total Tests	MTB Detected	MTB Detected & RR	MTB NOT Detected	Invalid/Error
2017	98,757	41,610	3,175*	46,565	6,569
2018	132,363	59,259	3,479*	67,069	6,035
Q1 2019	3,2742	15,378	765*	16,922	1,442

There is clear and expanded criteria (dependent on whether the township has a GeneXpert test site or not) set out by the NTP on who is defined as a “presumptive MDR-TB case” (includes retreatment cases, close contacts of MDR-TB patient who develop active disease, all patients and presumptive TB cases living with HIV/AIDS, patients who are sputum smear positive at the end of the intensive phase of treatment [non-convertor and positive convertor], patients residing in areas with high MDR-TB prevalence [>10% MDR-TB among new patients], patients with diabetes mellitus [DM], all smear positive

new cases, other cases to be considered individually as determined by the MDR-TB Committee, and all pulmonary cases) and who are to be further tested for drug resistance (see below figure).

Criteria for Gene X-pert test at Township with Gene X-pert installed

- All retreatment cases
- TB/HIV coinfecting patient and PLHIV with presumptive TB
- MDR TB contact
- Sputum positive at 2nd month sputum examination
- All new sputum smear positive and smear negative case at the time of Diagnosis (all pulmonary)
- TB/DM comorbid patient

Criteria for Gene X-pert test at Township with Gene X-pert not existed

- All retreatment cases
- TB/HIV coinfecting patient and PLHIV with presumptive TB
- MDR TB contact
- Sputum positive at 2nd month sputum examination
- All new sputum smear positive case at the time of Diagnosis (only positive case)

Remark

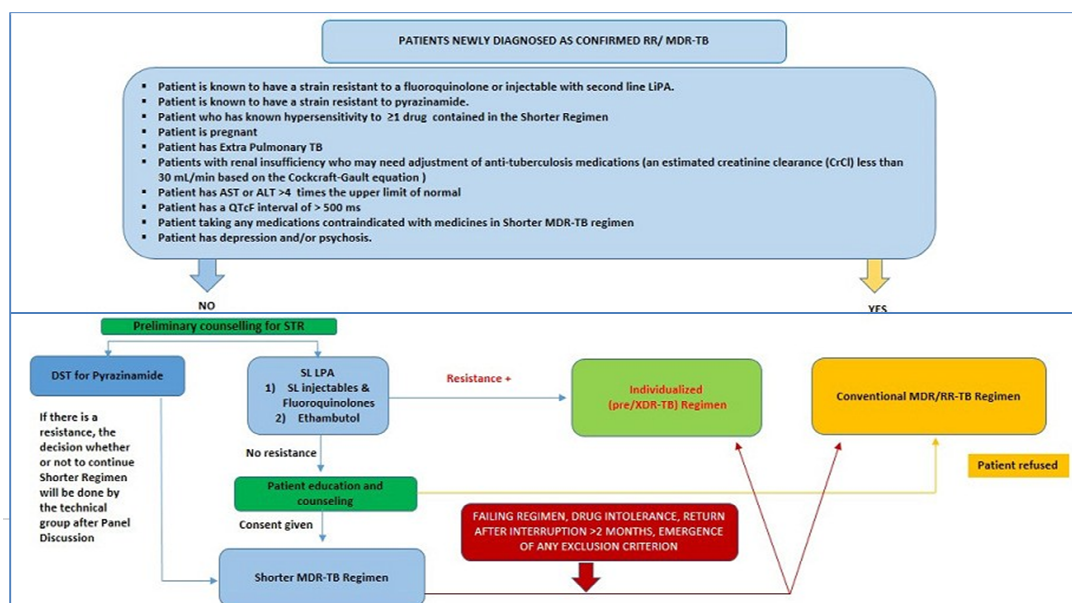
To test all register TB cases by Gene X-pert in Yangon region

Currently there is a network of 104 GXP machines in 79 sites across the country. The total number of GXP tests done in 2018 was 132,363 (in 2017, it was 98,757). The country has a plan of providing molecular diagnostics in all districts in a phased manner by 2019. However currently the GXP is still only used to detect RR-TB in already detected TB cases, and not as a primary diagnostic tool.

Since late 2017, all registered TB patients in the Yangon Region are being tested by Xpert for rifampicin resistance. However the JMM found sub-optimal utilization of GeneXpert at all levels.

The following flow chart was developed to identify eligible patients for the “pilot project” of the STR for MDR-TB patients (Figure 1).

Figure 1. Algorithm for selection of patients to be enrolled on the STR



Recommendations

- Develop a national TB laboratory plan to expand GeneXpert sites to the majority of townships, with priority given to address the MDR-TB crisis in Yangon.
- Increasingly use Xpert as the frontline test replacing smear microscopy for the diagnosis of TB among persons with symptoms and/or radiological abnormalities; promote same-day CXR reading and Xpert testing to create a one-stop diagnosis.
- Establishing an efficient sputum transportation system to increase access to TB diagnostic services at sub-townships and villages. Community TB care and prevention with community health workers for the identification of presumptive TB cases needs to be expanded.
- In the interim, ensure adherence to the criteria set for GeneXpert testing and expand it further, and by strengthening contact tracing.
- Mobilize resources and ensure adequate human resources for detection and management of DR-TB patients.

D. Laboratory services and expansion plan

The laboratory network

The TB laboratory network in Myanmar comprises four functional culture and DST facilities and another culture facility has been established but not yet operational at Mawlamyaing, Mon State due to challenges with utilities and human resources. The functional laboratories are located: two in Yangon, one in Mandalay, and one in Taunggyi, Shan State. Two liquid culture facility is located one at NTRL, Yangon and one in Mandalay. Three functional LPA laboratories are available in Yangon (two) and Mandalay (one) that were established under in EXPAND TB project in 2010. LPA has now also been introduced in the lab in Taunggyi. 104 Xpert sites have been established at District level, including two 16 module instruments in Yangon and Mandalay. 477 microscopy centres using either ZN or FM microscopy have been established at township level and are included in a national EQA system. A drug resistance survey is being planned for 2020 using DNA sequencing.

Smear microscopy has a relatively low sensitivity, whilst chest radiography has a high sensitivity but lower specificity (false positives). Microscopy can be replaced through the combined use of CXR as a screening tool to identify symptomatic persons accessing care who should be tested with GeneXpert. This approach will increase the number of bacteriologically confirmed TB cases and increase the number of new RR-TB cases. Human resource needs can be reduced and case finding increased. WHO has recommendations for the use of Xpert Ultra as an alternative test to Xpert MTB/RIF as it has much higher sensitivity for TB detection, especially among PLHIV and children. A list of the sites visited and persons met is provided in Annex 1.

The NSP-2016-2020 calls for expansion of the use of present GeneXpert facility, especially for the testing of children, people living with HIV and health workers. Revised GeneXpert diagnostic and referral algorithms have been developed by NTP as part of NSP and will be disseminated as the number of sites expands. Refresher training is planned annually at R/S and district levels. Advocacy among clinicians and programme officers will accompany the addition of new sites. Plans are included to enable districts to design and introduce sample transport systems for ensuring access to GeneXpert testing by all townships and station health units.

Nationally, there is limited laboratory capacity for C/DST and LPA (FL and SL). Not all detected RR-TB have “routine baseline” SL-LPA conducted. Hence it is difficult to gauge how prevalent resistance to fluoroquinolones and SLI is amongst MDR-/RR-TB patients. FQ resistance was reported to be between 5% and 13%, and SLI 1% - however the composition of the patient group and respective denominators were unclear.

National TB Reference Laboratory, Yangon

A visit to the NTRL was conducted with Dr Wint Wint Nyunt, Microbiologist, Dr Tin Tin Mar, Head of NTRL, The laboratory is staffed with a total of 27 staff including three microbiologist and 16 laboratory technicians and eight support staff. Only 12 staff members are government employees, 15 staff members are supported by other partners.

Laboratory infrastructure

The BSL-3 current facility was established through the EXPAND TB project and now serves as the primary diagnostic facility for performing culture, DST and LPA since the end of the project. The ventilation system appears to be functioning optimally, the biological safety cabinets (BSC) had been serviced and a biomedical engineer has been hired to oversee the function of the ventilation system. Both the culture area and the LPA laboratory were clean and well organised. As the new laboratory has been constructed there should be plans to transition all routine diagnostic testing performed at the NTRL to the new facility although there are a number of concerns with the new laboratory area that must be addressed before the routine work can be transferred.

New NRTL facility

A new BSL3 level laboratory for Yangon has been constructed adjacent to the old NTRL building and was built with funding through UNOPS and 3MDG. Although the facility was officially opened in March 2018, the laboratory has not been fully commissioned. The majority of the workload continues to be performed in the old NTRL and only a limited number of specimens are being processed for culture on solid media in the new facility.

The new TB laboratory is located on the ground floor of the new facility and the laboratory is accessed through double door leading to a large open space outside the laboratory that has the potential to be developed as a specimen reception and/or laboratory administration area. There are no windows on the ground floor level of the building and hence there is no natural light in any of the laboratory areas which will present challenges for staff working in the laboratory. There are separate BSL-2- and BSL3 laboratories.

The BSL-3 laboratory is accessed from an outer corridor via an ante-room. The anteroom leads into another small room called the “Equipment Alcove” which allows access to two separate BSL-3 laboratory spaces. A smaller room, referred to as the “Incubation room” and a larger area for TB culture which contains, two BSCs, a MGIT and centrifuge for processing specimens. The only exit from the main BSL-3 culture laboratory is via three separate doors leading to the outer laboratory space. There is an emergency exit from the main laboratory area in the new BSL-3 lab and there is no viewing panel into the BSL-3 culture laboratory to allow laboratory staff to be observed from outside the BSL-3 laboratory. This represents a major safety issue. Another major concern is the noise currently being generated by the ventilation system that makes it uncomfortable for staff to work in the laboratory for extended periods of time. The combination of no natural light into the laboratory, noise from the ventilation

system and no emergency exit from the main BSL-3 culture area means that it will not be possible to fully commission the laboratory until some modifications are made

The smaller “incubation room” is used to incubate the solid culture media and to read the cultures on a weekly basis. This room has the potential to be developed as a DST laboratory which would allow separation of the highest risk activities from routine culture and inoculation of specimens in the culture room. The highest risk activities are those associated with the manipulation of cultures for identification and DST. As such these activities should be performed in a separate area away from the culture processing area of the BSL-3 lab.

The BSL-2 laboratory, has been designed for performing molecular tests and is divided into three adjacent rooms (mastermix, amplification and hybridization) accessed by a common outer corridor that separates the BSL-3 and BSL-2 areas. Each of the rooms are sufficiently large for performing both first- and second-line LPA testing as well as other molecular tests such as DNA sequencing.

National TB Reference Laboratory, Mandalay: Upper Myanmar

The visit to the NTRL, Mandalay laboratory was conducted with Dr Kyi Kyi Swe, Microbiologist. A total of 21 Laboratory staff carries out the routine activity of the laboratory including one consultant microbiologist, one assistant Microbiologist and 18 technicians. Out of the 18 laboratory technicians eight are not working in the laboratory, either has been shifted out to other health laboratory or they have left the job. Presently 10 laboratory technicians are working in the laboratory.

The BSL-3 current facility was established through the EXPAND TB project and now serves as the TB diagnostic facility to cater the needs of the upper Myanmar for performing Smear, GeneXpert, culture, DST and LPA. The BSL3 facility has separate rooms to carry out culture and LPA activities. The ventilation system appears to be functioning optimally, BSCs had been serviced and a biomedical engineer has been hired to oversee the function of the ventilation system. The BSL3 facility has 3 BSCs and two MGIT machine to carry out culture and DST for 1st and 2nd line drugs using both solid and liquid culture. The BSL-2 laboratory, has been designed for performing molecular tests and is divided into three adjacent rooms (mastermix, amplification and hybridization) accessed by a common outer corridor that separates the BSL-3 and BSL-2 areas. Each of the rooms are sufficiently equipped for performing both first- and second-line LPA testing. Both the culture area and the LPA laboratory were clean and well organised.

A well-ventilated sputum collection area is available, and all the biomedical waste are incinerated after proper disinfection. State of art facility to carry out incineration is in place.

EQA activities

Laboratory technicians in both Mandalay and Yangon Regions participate in twice yearly panel testing for smear microscopy that is conducted by the National Health Laboratory. The performance was satisfactory for the 1st quarter of 2019 for the sites visited during the JMM but certain laboratories at the peripheral level where a single technician performs multiple laboratory tests in addition to microscopy were reported to have sub-optimal performance. Township and private station hospitals perform EQA using blinded slide rechecking assessed through the NRLs in Yangon and Mandalay.

EQA panels for GeneXpert are prepared and supplied annually to Myanmar by the NTRL in Vietnam. The performance of Xpert testing sites is monitored by Latha center in Yangon. GeneXpert sites visited during the JMM showed satisfactory results varying from 85 to 100%.

EQA for the 1st and 2nd line DST, 1st and 2nd line LPA is not in the place, last EQA performed was in 2013. A MOU with SNRL, NIRT, Chennai, has been carried out for EQA in all the above procedure. A summary of planned EQA activities in collaboration with the SRL in Chennai is provided in Annex 3.

Recommendations to the NTP

- In collaboration with NIMU and other stakeholders in the UHC infrastructure initiative, strengthen the capacity of CXR, giving preference to digital CXR, at townships
- Develop a national TB laboratory plan to expand Xpert sites to the majority of townships, with priority given to address the MDR-TB crisis in Yangon.
- Increasingly use Xpert as the frontline test replacing smear microscopy for the diagnosis of TB among symptomatic persons with radiological abnormalities; promote same-day CXR reading and Xpert testing to create a one-stop diagnosis.
- That the Xpert Ultra be procured as a replacement for the Xpert MTB/RIF assay for testing all symptomatic presumptive TB cases accessing health services and care.
- Consider routine CXR among high risk groups, such as PLHIV, contact, patients with cancer, on immunosuppressive agents, on dialysis, and diabetes with poor glycemic control, in facilities with CXR.

Recommendations for the diagnostic Network

- Eligible groups for Xpert as the initial diagnostic test has been expanded to include testing of all bacteriological confirmed cases. A transition plan to provide Xpert testing as the initial diagnostic test for all presumptive TB cases is needed as a priority.
- DST laboratories are currently not performing the 2nd line DST due to the lack of trained technicians. One or two technicians can be trained at SNRL, Chennai to carry out the DST for 2nd line and newer drugs.
- Capacity to implement DNA sequencing for surveillance purposes should be established in collaboration with the SRL in Chennai
- The 2nd line DST for the rifampicin resistant isolates should, at a minimum be carried out on all the 3rd month culture positive isolates if baseline DST is not performed. This will help to predict early failures and guide optimization of anti-tuberculosis therapy.

Recommendations to the NTRL, Yangon and Regional NRL, Mandalay

- Phenotypic DST for second-line agents is currently limited. Linkage with the SRL in Chennai provides a good opportunity to expand phenotypic DST testing to include the newer second-line agents, quality assurance for all diagnostic tests and support to implement the requirements for achieving ISO15189 laboratory accreditation.
- Diagnostic work performed in the NTRL should be moved to the new NTRL once building modifications have been completed. The existing NTRL facility should be maintained and developed for use as a training centre and for the evaluation of new TB diagnostic platforms such as DNA sequencing under operational research conditions
- Partial Documentation for the quality assurance for all diagnostic tests is in place. The linkage with SNRL Chennai can facilitate implementation of the requirements for achieving ISO15189 laboratory accreditation.
- The existing staff is over worked with the routine diagnostics and EQA smear microscopy activity. As part of smear microscopy EQA, a total of 72 laboratories including town ship, private station hospitals are maintained by the laboratory staff. Additional lab technicians can be recruited to carry out the smooth functioning of the laboratory

- Surge protectors and UPS is recommended for all the equipment's to increase the self-life of the equipment and uninterrupted laboratory functioning. Presently biological safety cabinets don't have UPS which presents a biosafety risk in the event of loss of power.

Recommendations for the new NTRL

The new BSL-3 laboratory has been established but not been fully commissioned and most diagnostic testing is being performed in the old NTRL building. There are concerns that there is no emergency exit from the main laboratory area in the new BSL-3 lab which presents a major safety issue;

- The noise in the ventilation system needs to be resolved through the company that installed the system -Myanmar Zircon Biomedical Engineering Group- through informing to PR UNOPS;
- An emergency exit door and viewing panel should be installed in the wall of the BSL-3 "Culture room" to allow access to the outer corridor in the event of a major accident or incident;
- Windows should be installed in the out walls to allow some natural light into the laboratory areas. Priority should be to install a window at the end of the corridor separating the BSL-2 and BSL-3 areas and in the outer laboratory area; and
- A specimen reception and administration area should be established in the outer laboratory area that would allow for the delivery of specimens directly to the new NTRL.

Other suggestions

- An incomplete laboratory information system provided by FHI 360 is in place with all the hardware. Using the available facility, the laboratory can adopt to District Health Information Software 2 (DHIS2) which is a free and open source health management data platform.
- Logistic system need to create for the exchange of TB strains with SNRL Chennai to carry out the EQA activities for DST and LPA activities.
- The para-nitrobenzoic acid used for the differentiation of the *M.tb* and NTM is expired and need to be replaced asap to carry out the routine diagnostic work up for the patients.
- To carry out the infection control measures, the laboratory decontamination needs to be performed quarterly.
- The Mandalay regional TB OPD at the Pyi Gyi Gan town Ship was visited to check the smear microscopy and GeneXpert facility. It was noted that the processing of the sputum and GenXpert is performed in a closed room without a proper ventilation system. It is recommended to have partition for the processing of the samples or have a Ventilated Workstation for AFB Smear Microscopy.

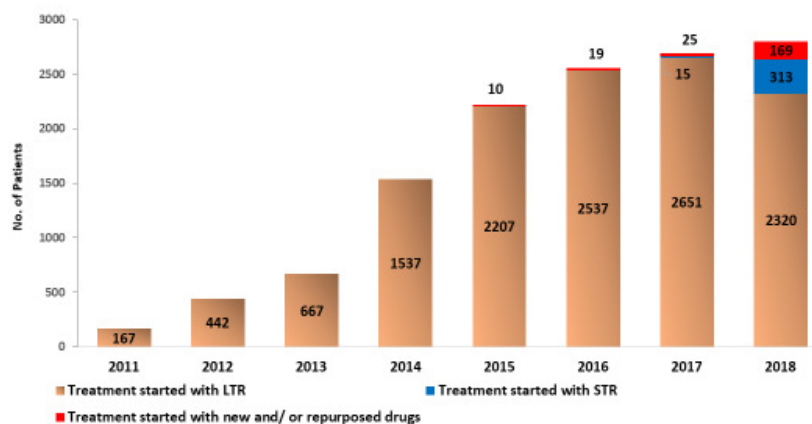
E. Treatment strategy

National coverage with PMDT services has been achieved since 2016, with all 330 townships in the country able to manage DR-TB patients. There are two major hospitals that care for DR-TB patients (Aung San TB Speciality Hospital in Lower Myanmar [Yangon] and Patheingyi TB Speciality Hospital in Upper Myanmar [Mandalay]) and every District has the capability to treat MDR-TB and refer for hospitalization, if necessary. Almost half of the DR-TB caseload is managed diagnosed in Yangon Region and an "MDR-TB crisis situation" has already been declared in the Yangon, the largest city, in Myanmar.

The gap between those DR-TB cases estimated to exist in the community and those placed on treatment has been discussed already on page 14. It is also to be noted that very few paediatric DR-TB patients are being diagnosed indicating that DR-TB is not being adequately diagnosed in the paediatric population, especially paediatric household contacts of infectious DR-TB patients.



Number of DR-TB patients started for Treatment (2011-2018)



Note: There were negligible number of patients who were included in LTR, failed and treatment started with new and repurposed drugs in the same year 2018.

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The “conventional” LTR being used for MDR-TB is 6Am-Pyrazinamide(Z)-Levofloxacin(Lfx)-Ethionamide(Eto)-Cycloserine(Cs)/18Lfx-Eto-Cs-Z. It appeared that the previous practice of including PAS in the LTR is no longer occurring.

The shorter treatment regimen for DR-TB patients has been introduced by the NTP. The “pilot” of the STR has been completed with 200 patients being enrolled, with enrolment of patients continuing (a total of 313 having been enrolled onto the STR by the end of 2018). The previous exclusion criteria for ethambutol (E) and/or Z resistance have been removed. The STR being used comprises 6 Am-Clofazamine(Cfz)-E-Eto-Isoniazid(H)-Moxifloxacin(Mfx)-Z/5Cfz-E-Mfx-Z

The new drugs - bedaquiline (Bdq) and delamanid (Dlm), for specific DR-TB patients have been introduced in the Yangon and Mandalay Region for eligible DR-TB patients under the NTP and the endTB Project. Regimens for pre-extensively drug resistant TB (pre-XDR-TB) and extensively drug resistant TB (XDR-TB) treatment, and for MDR-TB patients intolerant to SLD, approved by the National DR-TB Expert committee include the new drugs, are as follows: Bdq/Dlm-PAS-Z-Linezolid(Lzd)-Cfz-Amoxycillin/clavulanate (\pm capreomycin [Cm]). This regimen is being used through the endTB project which is an UNITAID funded joint project between the NTP, Aung San TB hospital and MSF-Holland (MSF-H), which was started in March 2016. MSF-H enrolled the target 50 patients in the first quarter of 2018. One hundred and sixty nine patients had been enrolled onto new and/or repurposed drug containing regimens in 2018, the majority under NTP.

Treatment delivery (DOT)/adherence and social support for patients

Community based programmatic management of DR-TB is in place with the majority of patients initiating and continuing treatment in the outpatient setting, except for patients on the STR and ND and/or repurposed drug containing regimens. DOT is provided daily generally by Basic Health Staff (mainly midwives, but the Public Health Supervisor-II (PHS-II) staff are now being involved) and sometimes by community volunteers who are adequately trained to provide DOT.

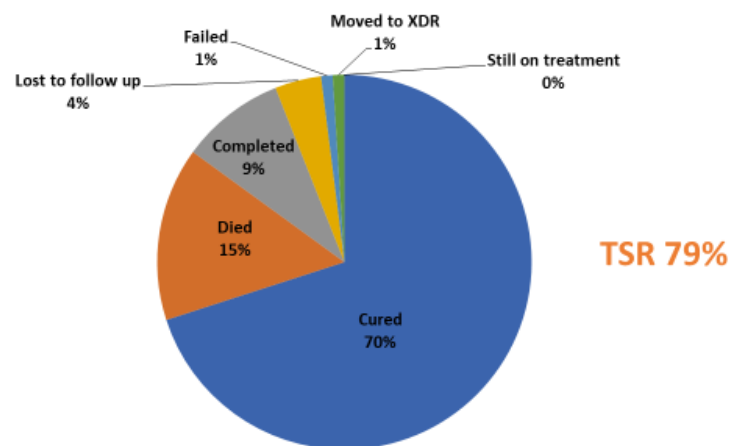
Patient counseling is provided by community volunteers and health care workers at diagnosis and at every visit. Social support is provided at the amount of 30,000 Kyat/month mainly for transportation. It was reported that nutritional support is provided for DR-TB patients, but it was not documented whether this was systematic or not.

High treatment success rates (>80%) amongst initial cohort of DR-TB patients treated with the STR, and amongst those treated earlier (>70%, 2016 cohort) with the “conventional” LTR are seen (see following figures). There is a very low level of Lost To Follow Up (<5%) – this can be explained by the presence of a strong community care network (e.g. in Yangon) and that a patient support package (all DR-TB patients are stated to receive a support package, both financial and nutritional) is in place.

LTR outcomes

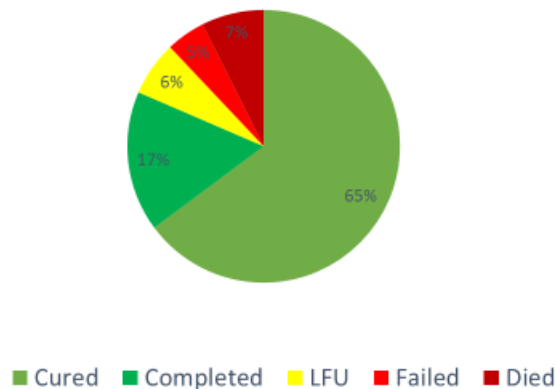


Treatment outcomes 2016 PMDT cohort
n=2529, TSR=79%



STR outcomes, Yangon Region

Outcome of 108 patients (Dec 2017-Aug 2018)
(excluding move to LTR)



However a “delay” of at least 3 weeks between RR-TB diagnosis by GeneXpert and initiation on the STR was observed. This was composed of a mixture of health systems delay (e.g. tracing of patient within the township after diagnosis, waiting for the SL-LPA result prior to initiating treatment, etc) and patient delay (e.g. delay in “accepting” diagnosis and treatment, time to return to the services once traced, death, etc). The care of patients treated with the STR is currently “centralized” at the 2 higher level TB facilities in Mandalay (Regional TB Centre) and Yangon (Regional TB Centre).

Issues with infrastructure (service capacity) and patient pathways at and between TB Hospitals, Regional TB Centres and Township facilities were observed. Namely:

- Patheingyi TB Hospital, Mandalay. This is a 200 bedded TB Speciality Hospital. However bed occupancy is only 25-30%, with the majority of patients being admitted for initiation of treatment;
- Mandalay Regional TB Centre is “split” on 2 sites, both having their own laboratories with GeneXpert capacity. The out-patient department (OPD) section was moved from inside the General Hospital in the middle of the city to a more remote area of the city, with poor public transport links. This has led to problems both for the General Medical Officers (GMO) and the patients. Previously the GMO could request a consultation from a “TB doctor” who was based in the same facility. Now they have to refer the patient to the OPD section of the TB Centre, which is at a distance with poor transportation links. An initial significant decrease in attendance numbers was seen, however it was reported that numbers had since “recovered” somewhat. Also the good training facilities available in the OPD section building are to date unused.
- The Aung San Hospital, Yangon. This is a >150 bedded TB Speciality Hospital. The hospital is said to be “over-burdened”, with the majority of admitted patients being either pre-XDR-TB or XDR-TB. Currently the hospital is receiving technical assistance from the MSF-H DR-TB project in Yangon. However the MSF-H project is scheduled to close in 2020.

The initial cohort results of patients (n=38) treated with ND-containing regimens is poor, with only a

58% treatment success (42% cure and 16% treatment complete), and a 29% death rate. Of the 11 deaths, only 1 was HIV co-infected, however 6 were XDR-TB cases. All cases were presented to the NCCA, where none of the deaths were “attributed” to the drugs used. All patients were deemed as cases of end stage TB disease (i.e. severe respiratory insufficiency), with other co-morbidities (DM, renal disease, etc).

The following table shows the varied treatment regimens agreed upon for the treatment of DR-TB in 2020 (Table 5). To ensure an adequate and timely supply of drugs will require close stock monitoring, frequent re-quantification and forecasting, and procurement (see Section G. Drug Management). Currently a second-line injectable, namely capreomycin, is still being used in pregnant DR-TB cases.

Table 5. DR-TB treatment regimens planned for 2020

	Treatment Regimens	Composition
1	Childhood MDR FQ resistance, 3 to 5 years	6 Cfz-Cs-Dlm-Eto-Lzd-Z/12 Cfz-Cs-Eto-Z
2	Childhood MDR, above 6 years	6 Bdq-Cfz-Lfx-Lzd-Z/12 Cfz-Lfx-Lzd-Z
3	Childhood MDR, less than 6 year FQ sensitive	6 Cfz-Cs-Eto-Lfx-Lzd/12 Cfz-Cs-Eto-Lfx
4	All oral new regimen	6 Bdq-Cfz-Lfx-Lzd-Z/8 Cfz-Lfx-Lzd-Z/4 Cfz-Cs-Lfx-Z
5	MDR-TB conventional for pregnant patients	7 Cfz-Cs-Lfx-PAS-Z/13Cfz-Cs-Lfx-PAS-Z
6	Pre-XDR-TB FQ resistance	6 Am-Bdq-Cfz-Cs-Lzd-Z/1 Am-Cfz-Cs-Lzd-Z/13 Cfz-Cs-Lzd-Z
7	Pre-XDR-TB SLI resistance	6 Bdq-Cfz-Lfx-Lzd-Z/14 Cfz-Lfx-Lzd-Z
8	STR MDR-TB regimen	6 Am-Cfz-E-Eto-H-Mfx-Z/ 5 Cfz-E-Mfx-Z
9	Standard MDR-TB regimen	7 Am-Cs-Eto-Lfx-Z/ 13 Cs-Eto-Lfx-Z
10	XDR-TB MDR/STR failure	3 Imi/Cis-Bdq-Cfz-Dlm-Lzd-Pas-Z/ 4 Imi/Cis-Bdq-Cfz-Dlm-Lzd-PAS-Z/ 2 Imi/Cis-Cfz-Lzd-PAS-Z/ 12 Cfz-Lzd-PAS-Z
11	XDR-TB primary resistance	1 Bdq-Cfz-Cs-Dlm-Lzd-Z/ 2 Bdq-Cfz-Cs-Dlm-Lzd-Z/ 4 Bdq/Cfz-Cs-Dlm-Lzd-Z/ 14 Cfz-
12	XDR-TB secondary resistance	1 Bdq-Cfz-Dlm-Lzd-Pas-Z/ 2 Bdq-Cfz-Dlm-Lzd-PAS-Z/4 Bdq-Cfz-Dlm-Lzd-PAS-Z/ 16 Cfz-Lzd-PAS-Z

From discussions with five MDR-/RR-TB patients and 2 ex-DR-TB patients at the Yangon DR-TB Treatment Centre:

- Generally they were satisfied with the care that they have received;
- However there was an unanimous and intense dislike of the use of the SLI (Am); and
- Although grateful for the patient support package that is being / was provided to them, they expressed that it is/was insufficient to replace lost household income and leading to major problems in maintaining life (e.g. inability to provide adequate food for the family, etc). NB: The

findings of the recently conducted catastrophic cost study which showed that 100% of households that had a DR-TB patient in it, suffered catastrophic costs due to this.

Currently the policy for isoniazid resistant cases (identification, detection and treatment) is unclear.

Recommendations

- The barriers and “delay” between RR-TB diagnosis by GeneXpert and initiation on to the STR need to be explored in order to reduce delay. Tools are available to support this activity.
- Introduce and transition to the all oral DR-TB regimen as planned and scale-up it up nationwide as rapidly as possible. In the interim, scale-up nationwide the STR, with the care of the patients decentralized to all DR-TB Treatment Initiation Centres.
- Initiate STR treatment within 5 days of RR-TB detection – do not wait for SL-LPA result prior to starting treatment.
- Use of SLI in pregnant patients should stop immediately, with an individualized regimen being designed for the patient.
- Shift from “full hospitalization” care model to a more ambulatory care model for those on ND-containing regimens, via the network of DR-TB Treatment Centres. To support this, clear hospitalization criteria need to be developed (to cover at start for treatment initiation; and during treatment if the patient develops any complication or adverse event).
- Rationalisation of service capacity / pathways at and between TB Hospitals, Regional TB Centres and Township facilities is required.
- The patient support package needs to provide enablers and incentives to meet the needs of the DR-TB patients. The financial burden needs to be effectively addressed by appropriate social protection intervention, including consideration of income replacement.
- Further analyses treatment outcomes (interim and final) of patients treated with ND-containing regimens, and review current eligibility criteria for treatment with ND-containing regimens.
- Consider introducing formal post-treatment follow up for all DR-TB patients, with active management of any post-TB sequelae.
- Consider conducting operational research on a modified STR.
- Consider introducing preventive treatment for the contacts of DR-TB patients– guidelines and regimen to be used will need to be discussed with international experts.
- Policy for H-resistant TB cases (identification, detection and treatment) needs to be more clearly defined and disseminated to staff.

F. Pharmacovigilance/aDSM

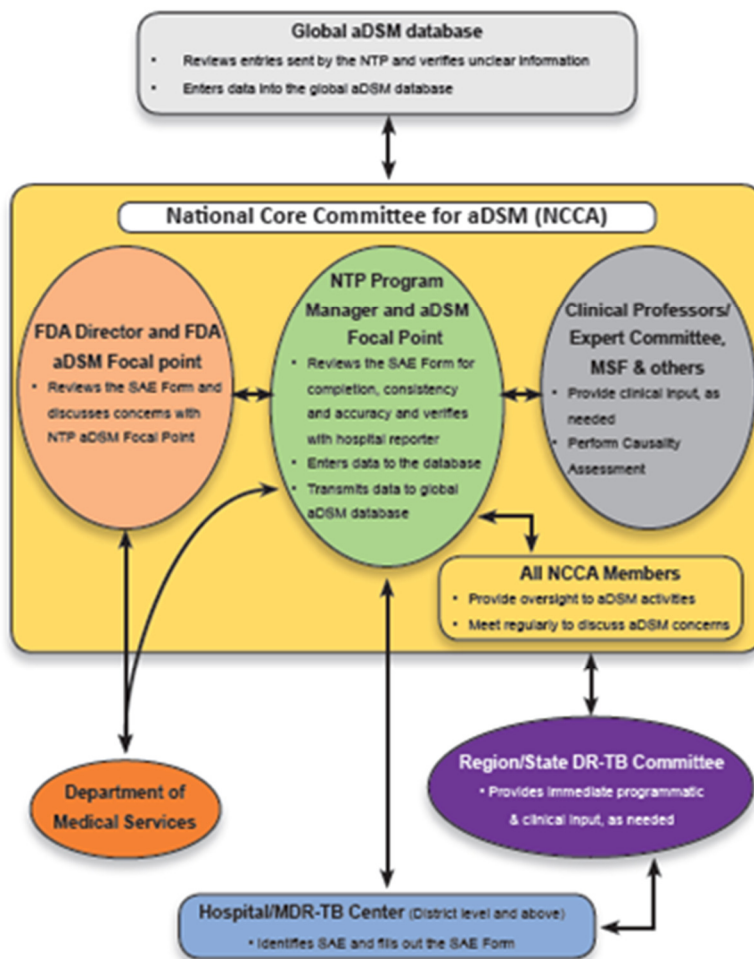
A system for monitoring patient’s progress, drug safety, serious adverse event reporting, and causality assessment (i.e. active TB drug safety monitoring and management) is in place for DR-TB patients and functioning, and a National Core Committee for aDSM established and active. A National aDSM guideline document was issued in August 2017.

Initially aDSM was implemented through the endTB Project primarily for patients on new drugs (Bdq and Dlm), then expanded to cover patients enrolled on the STR. MSF doctors report serious adverse events (SAE) for the endTB project patients. From January 2018, MoHS doctors report adverse drug reactions (ADRs) and SAEs to the NCCA (by medical officers, NTP for STR cases in MDR-TB clinics [OPD] and by doctors from 2 TB hospitals for STR and patients on new and/or repurposed drugs).

Clinical monitoring for patient safety is now more accessible for patients with the provision of ECG machines and audiometers at the point-of-care, through the Global Fund and the Challenge TB (CTB)

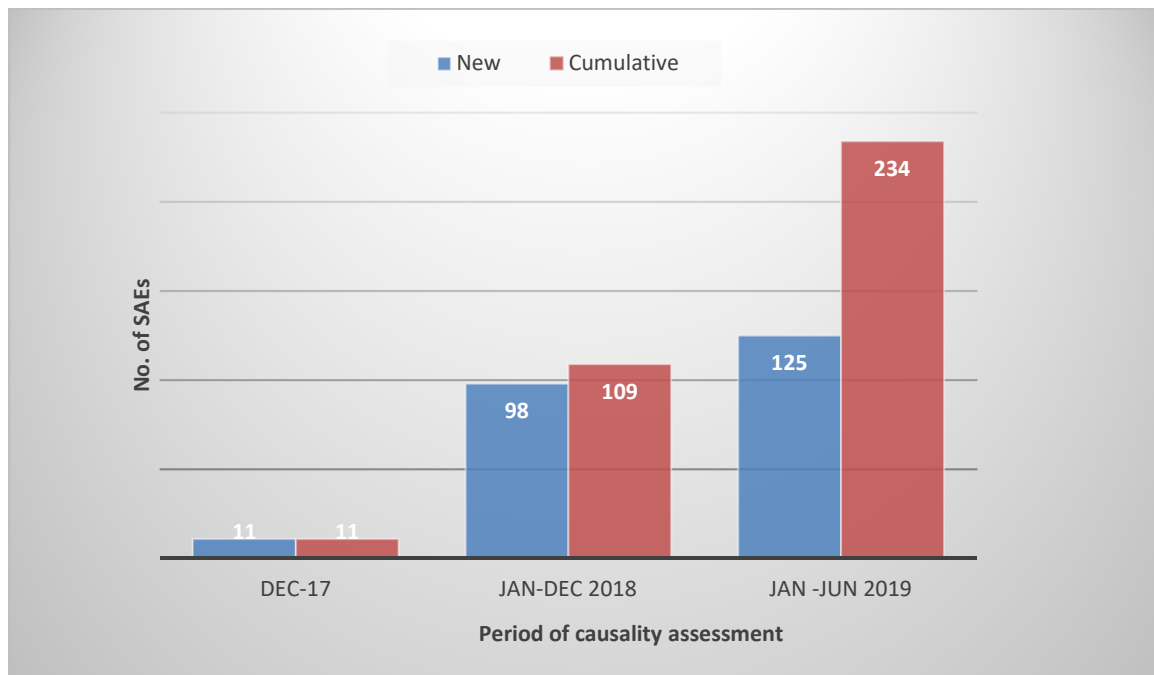
project. The programme's monitoring schedule is adhered to for the majority of the tests. It can be seen that health staff are applying the guidelines and inputs in clinical management obtained during trainings and workshops. There is an NTP form for reporting of SAEs and several patient monitoring tools, including the MDR-TB treatment card and the clinical, bacteriological and laboratory monitoring form. Reporting of SAEs under the aDSM core package has also been commendable with facilities having formed the habit of reporting SAEs to the NTP. The reports are routinely sent to the NCCA members and after entry to the electronic database, are forwarded to the WHO Global aDSM database based in Luxembourg.

Figure 4. Reporting Flow for SAE, Myanmar



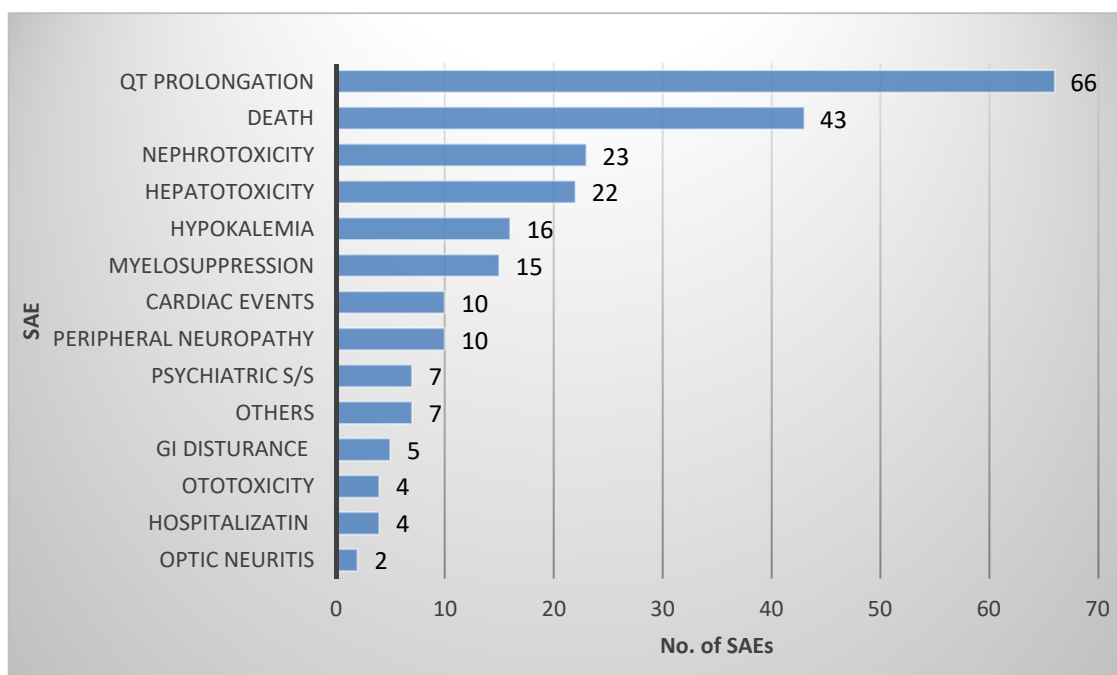
Expansion of the STR to all the townships of Yangon and Mandalay, and the decentralization of patients on new drugs to these townships after a period of hospitalization have resulted to a remarkable increase in the number of adverse events (AEs) identified in patients on treatment, adverse events (AEs) being managed according to standards, and SAEs reported to the national level and global level. A total of 687 RR-/MDR-TB patients have been covered by aDSM up to July 2019, and a total of 234 SAEs were reviewed with causality assessment done and WHO-recommended aDSM indicators analyzed (Figure 2).

Figure 2. Number of SAEs with causality assessment, Dec 2017- June 2019, N=234



The top five SAEs that were reported to have occurred from December 2017 to June 2019 were QT prolongation (28%), death (18%), nephrotoxicity (10%), hepatotoxicity (9%) and hypokalemia (7%) (Figure 3).

Figure 3. Frequency of SAEs (episodes), Myanmar, Dec 2017- June 2019, N= 234



With this considerable increase in reports received, more work is needed for causality assessment. More frequent meetings from quarterly to bimonthly have strengthened the implementation of aDSM including the conduct of causality assessment by the NCCA.

The Food and Drug Administration (FDA), the national pharmacovigilance centre in Myanmar has become an Associate Member of the WHO's Program for International Drug Monitoring (PIDM) through the Uppsala Monitoring Centre in September 2018 after the MoHS through the FDA signified interest to apply for membership. Efforts are now on the way for the FDA to become a full member of PIDM.

The main challenges are related to lack of human resource from both the FDA and the NTP side with the bulk of work and responsibility assumed by partners. Transition of technical assistance from the CTB project which ends in August 2019 to the NTP and other stakeholders has begun with NTP partners having taken up the funding and organization of NCCA meetings. Continuing support is crucial to sustain the gains made by aDSM in Myanmar.

Unexpectedly high levels (28-40%) of hypokalemia are being reported amongst DR-TB patients treated with STR (in the 2018 cohort), including amikacin (Am) as the second line injectable. The observation is similar in both Mandalay and Yangon sites.

Recommendations

- Expand aDSM to cover all DR-TB patients, with required strengthening of capacity (human and equipment) and database being provided.
- The observation of the high levels of hypokalaemia in patients treated with the STR needs further analyses urgently (including checking of the machines used for the tests and the methodology used for the test).
- Complete the process for the FDA to become a full member of PIDM, allowing opportunities for further capacity building in pharmacovigilance and aDSM to be available in-country.
- Sustainable funding for aDSM activities needs to be ensured, including submissions to Global Fund (GF) for support and FDA allocating funds.

G. Drug management

UNOPS, the principal recipient of the Global Fund is responsible for drug procurement from the Global Drug Facility (GDF), while the NTP is responsible for placing orders with UNOPS. The MOHS/NTP now procures "quality-assured" TB medicines using government funds (100% of FLDs and 40% of SLDs), including covering the procurement supply management costs.

The country uses QuanTB for quantification of drugs at the central level, and mSupply at the region/state level. Forecasting of drugs at the central level is based on the and the lead time for ordering is at least six months ahead. The Central drug store then distributes drugs to the Upper Myanmar Store (Mandalay) and the Lower Myanmar Store (Yangon) on a quarterly basis. Drugs are subsequently distributed to Regional/State drug stores also on a quarterly basis. TB hospitals and township sub-stores collect drugs from Region/State stores and supply to DOT providers on a monthly basis and townships request drug on a quarterly basis.

There have been no stocks out of TB medicines, ancillary medicines (provided free of charge to all

patients in need) and key laboratory supplies (including GXP cartridges) for the past 2 years. The paediatric dispersible FLD formulation is widely available. There is a plan for expansion and improvement of the central TB warehouse - currently in discussion with the GF. There is good drugs and diagnostic supplies management by pharmacists/drug point persons, with clear levels of organization, space is available, proper inventory is maintained, etc.

Although a National Drug Law (1992) exists governing pharmaceuticals in Myanmar, with antibiotics only meant to be issued on prescription, over-the-counter sale of antibiotics from private pharmacies exists, which may be contributing to the emergence of DR-TB and other anti-microbial resistance. There appear to an increasing number of TB suppliers in the country, with several TB drugs registered with FDA manufactured by Lupin (India), Macleods (India), United Labs (Philippines), and Myanmar Pharmaceutical Factory.

The Central Medical Supplies Department (CMSD) is supplying single dose FLDs and ancillary medicines from local suppliers that duplicates NTP's supply resulting in oversupply. CMSD supplies for the general services, while NTP procures 100% requirement of the TB Program. Some facilities (i.e. Patheingyi hospital) are getting ancillary meds from CMSD and not from NTP.

A quantity of expired medicines (mostly ancillary medicines) were found in the central warehouse, where they were awaiting approval for disposal.

Child-friendly second line drugs are absent, with at least two of the JMM teams meeting with untreated children with MDR-TB.

Quantification needs to review the assumptions currently used. The buffer used in quantification is only 3 months, but procurement lead time is at least 6 months, and some regimens may need to be reviewed.

Recommendations

- Enforce national law requiring prescription for antibiotics sale, via thorough market analysis, FDA strengthening and, enhancing implementation rules and drug stewardship. (FDA, MOHS, NTP)
- Streamline procurement of TB and ancillary medicines between CMSD and MOHS/NTP and review forecasting assumptions in order to avoid wastage. Consider 100% procurement of TB drugs by NTP and stop procurement of CMSD of TB drugs. For ancillary medicines, NTP may procure minimal quantities for facilities that are not under CMSD.(CMSD, NTP)
- Accelerate write off for disposal, aligned with plan of expansion and maximizing storage capacity of the central warehouse. (MOHS)
- Make available the SLD paediatrics from GDF. (NTP)
- Regular review of quantification assumptions (buffer, etc.), supply planning and timeline for patients kits and also SLDs particularly for the transition phase.(NTP)

H. Recording and reporting, and data management

Recording and reporting is still largely paper-based and sometimes incomplete. Hence the recommendation of previous rGLC missions to expedite the piloting and roll out of an electronic recording and reporting system for DR-TB and then DS TB, linking program management, treatment facilities, laboratories, drug stores and beneficiaries remains to be implemented. It is difficult to assess the completeness, accuracy and timeliness of reporting in a paper-based system as there is no good way of tracking the process systematically. Not having an electronic surveillance system at the National level makes it extremely difficult to track the epidemiology of DR-TB for purposes of program improvement,

to track patients for outcomes monitoring and aDSM, and trouble shoot problems in program management as they arise. Although the Open MRS system for MDR-TB management is used, its full potential is not currently being used and/or widely implemented.

Mandatory notification of TB cases was introduced from January 2019. Although numbers of cases reported from non-governmental private institutions have been modest to date (>150 cases), this intervention needs time and active support to see results.

Recommendations

- Establish an electronic surveillance system from the township to Regional/State to national level; the current system which is implemented as a pilot should be rapidly expanded.
- Consider expanding the Open MRS system for case management of DR-TB patients

I. Human resource, training and technical support strategy

The almost intractable human resource challenge remains and needs to be addressed to the benefit of NTP and general health services. This however needs to be contextualised. Hence:

- In April 2015, the MOHS divided the Department of Health into the Department of Medical Services and the Department of Public Health (reform). TB care and control are, jointly with HIV/AIDS, Leprosy, Trachoma and Vector-borne Diseases, under the Department of Public Health also responsible for Primary Health Care, Maternal Neonatal and Child Health (MNCH), school health, nutrition, and health promotion.
- The NSP 2016-2020 identifies 6 key strategic approaches and interventions for Human Resource Development: (i) fill authorized sanctioned posts and establish integrated AIDS/TB/Malaria disease control teams in all townships; (ii) strengthen pre-service training and ongoing training and establish centres of excellence starting with diagnosis and treatment of MDR-TB; (iii) e-Based and on-the-job learning; (iv) engage in strategic partnerships for health workforce development for comprehensive TB control; (v) contribute to an integrated personnel management system to foster adequate workforce planning, recruitment, hiring, deployment and retention; and, (vi) monitor and supervise health worker performance.
- The National Health Plan (NHP) 2017-2021, with its annual operational plans to strengthen Human Resources (HR), Infrastructure, Service delivery and Health Financing. Basic Public Health Services are to be defined by 2020 (11 areas, including TB) and delivered nationwide through existing infrastructure. Gradual expansion and improvement towards UHC by 2030 with the aim to improve health and reduce poverty. Standard operating procedures for clinical packages are nearly finalized and a costings exercise will be initiated soon.
- In March 2018, Myanmar published a Human Resources for Health Strategy 2018-2021, with annual operational plans.

The reform has contributed to strengthening of basic health services including outreach and clear organization of hierarchical public health system (diagnosis at township level and above; DOT below and strong referral down for patient centred care). The upper levels more vertical and lower more integrated services. Despite a high workload and limited access to new tools, the JMM members met very committed and dedicated health workers. The MOHS is making efforts to fill sanctioned positions (one third of sanctioned posts of all categories at different levels could be filled since previous JMM). The provision of training and supervision happen regularly. All townships (330) received tablets from NTP for recording, reporting and surveillance as well as distribution of new and updated guidelines related to TB. Strategic partnerships are being established. And the majority of people are diagnosed

and treated by the public sector (even if first contact is in the private sector) and particularly at township level and below.

However, since the reform process started, there has been some lack of clarity in the roles and responsibilities of staff during the transition from TB teams to public health teams. For example, the contribution of the PHS-II cadre, who were recruited to enable the midwives to focus on MNCH, are not yet clear. The midwives seem to still do household contact investigation, sputum transportation, and DOT for the DR-TB patients. From discussions with DR-TB DOT providers (Midwives) at the Yangon DR-TB Treatment Centre, there appeared to be limited understanding of potential adverse events in DR-TB patients and action to be taken, especially amongst those on the new drug containing regimens. And hence there is a great need for (re-)training of the basic health staff.

There is difficulty in filling vacancies and a high staff turn-over. Trained staff often join (international) non-governmental organisations ([I]NGOs) or in the private sector where salaries are higher. Where vacancies/gaps exist, either general health staff do the work or WHO, NGOs and partners tend to step in using donor funding e.g. for PMDT.

Recommendations

- Maintain 'categorical' technical leadership from the Ministry of Health level, Regional/State level, to the township level
- At township level and below, innovative approaches to integrated delivery of services should be scaled up nationally

Reform

- NTP to further clarify roles and responsibilities in the new public health system (develop clear job descriptions and ensure implementation of/adherence to job descriptions)
- Ensure TB specific tasks are well represented in revisions of basic training programmes of all health staff categories, as well as in supervision check lists
- Further strengthen collaboration with hospitals above township level organizations
- TB under Public Health - need to diagnose and treat disease but also avoid disease (more emphasis on prevention including infection control and TB preventive treatment). Needs a change in mindset to move away from providing direct clinical care in separate, standalone facilities and towards public health tasks

Filling vacancies and retention

- Explore community service as a requirement for medical/nursing registration
- NTP to prioritize vacancies to be filled and strengthen collaboration with partners, NGOs, and health workers of Ethnic Health Organizations
- Explore outsourcing of certain tasks e.g. transportation as well as use partner organizations in hard to reach areas to increase coverage of services
- Request more budget share for HR to fill the "priority" vacancies -> couple request with evidence on the impact of vacancies in terms of disease burden and reduced performance

Training and capacity building

- Update the "Guidelines for the management of DR-TB in Myanmar" – draft of updated guidelines was not available to the consultant during the JMM
- Consider expansion of new, less time consuming ways of updating guidelines and provision of training e.g. expand use of methodologies suited for fast changing environment (e.g. different learning approaches, online training, webinars)

Next NSP 2021-2025

- In this "transition period" with declining TB disease burden, ageing population and a trend to put emphasis on Non Communicable Diseases, the next NSP needs to include both short-term as

well as medium/longer-term sustainable strategies in line with the NHP towards UHC (with a mix of realistic and ambitious targets) and clearly show the funding gap for Human Resource Development.

- Encourage donors to help the NTP to strengthen the public system at least in the short term/medium term (as opposed to project funding), especially in areas such as PMDT.
- NTP to discuss/jointly work with the National Health Plan Implementation and Monitoring Unit (NIMU) to explore further opportunities for integration or collaboration with general health services and sharing of resources (increase efficiencies). Jointly define a proper balance between separate NTP/TB staff and general health services capable of delivering quality TB prevention and care, including PMDT.

J. Supervision of the programme

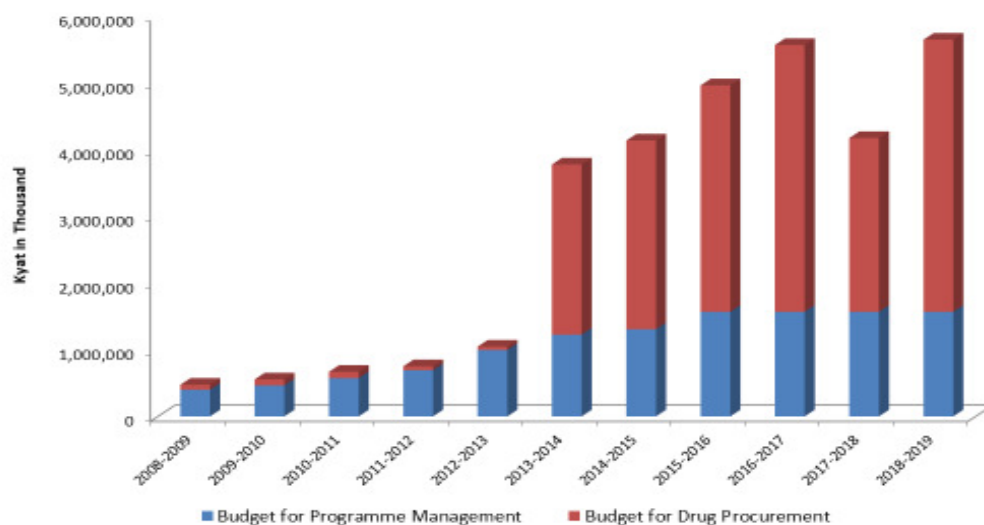
Supervision of the NTP activities will be determined greatly by the outcomes of the ongoing health reform process. Hence this will be impacted by what has been described and discussed under Section “I. Human resource, Training and Technical support strategy”.

K. PMDT plan including funding source

In 2017, the current PMDT plan included enrollment (including drug procurement) of 2200 patients (including 200 patients on the STR pilot) under GF funding and 1200 patients under government funding in 2017. The budget for the NTP has increased gradually over the years with a substantial increase from the year 2013-14 as shown in the figure below.



National Response: Government Budget for NTP (2008-2009 to 2018-2019)



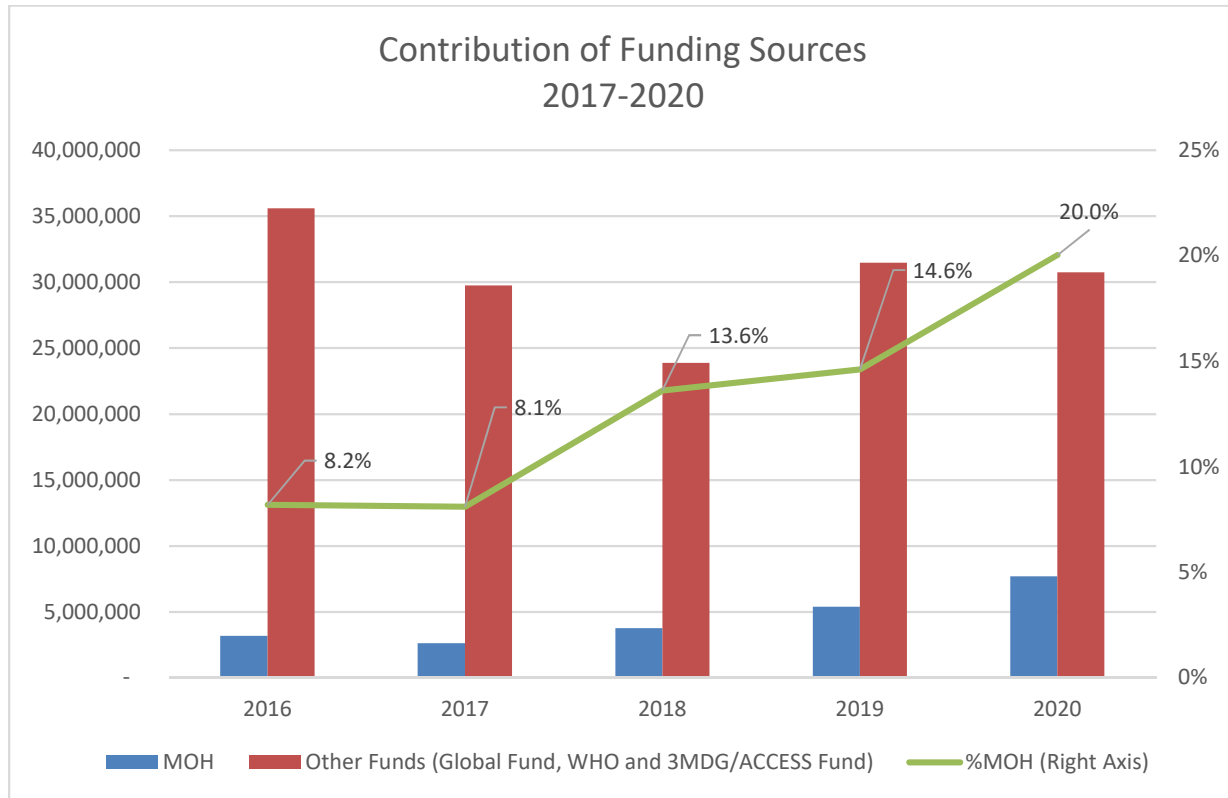
26.6.19

Annual TB Evaluation Meeting(2018)
Dr. Cho Cho San

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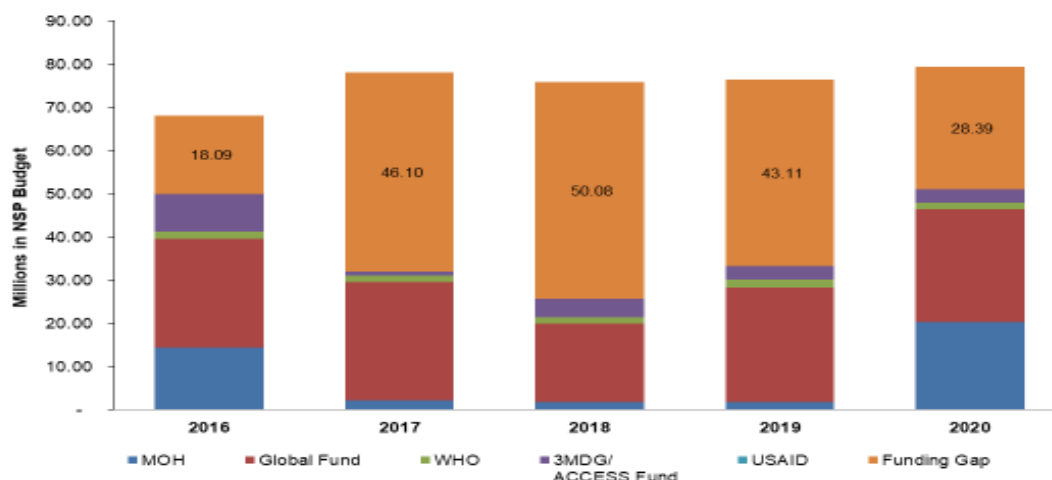
It will be observed that the budget for programme management activity has shown a gradual rise, whereas that for drug procurement has increased steeply. This is due to the expenditure on SLD.

The DR-TB related targets under the NSP 2016-2020 are presented in Tables 1 and 2 on page 11 of this report. On a macro-level, even by 2020, the Government budget will however only be contributing one-fifth of the total budget required, with the majority of current funding coming from the GF. Current financing is insufficient to meet committed targets, and external funding will not be sufficient to reduce the financing gap.





Estimated contributions of major fund agencies and funding gap against NSP budget (2016-2020)



26.6.19

Annual TB Evaluation Meeting(2018)
Dr. Cho Cho San

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On the micro-level, from the discussions with the MDR-TB patients and ex-patients, they were generally satisfied with the care that they receive, but wished the use of the SLI to be stopped asap, and that the patient support package is insufficient to replace lost household income and leading to major problems in maintaining family life. Hence social protection for TB patients and their families needs to be ensured.

Recommendations

The NTP needs to be actively engaged with the broader health sector in the ongoing dialogue in relation to the restructuring of the health services in Myanmar, development of the next NSP and ensuring access to TB services is included in the UHC agenda of the country. Hence:

- Integrate planning process for future sustainability: To escape standalone planning, include some government budget for TB activities; locate TB staff with overall health administration for coordinated planning of activities of integrated health workers at lower levels; align GF plans accordingly, with greater partner coordination at subnational levels
- NTP to engage with NIMU on TB access needs in the UHC agenda
- In collaboration with NIMU and other stakeholders in the UHC infrastructure initiative, develop a comprehensive framework of social protection for both DS- and DR-TB families facing catastrophic costs in particular with some urgency for Yangon region
- Engagement of Ministry of Labor (prevent unemployment, income loss compensation) and Ministry of Social Welfare to alleviate non-medical cost (transportation)
- Increased proportion of domestic funding is imperative for expanding and sustaining the TB response
- Conduct/complete the planned Drug Resistance Surveillance (DRS) survey as soon as possible. The results of the DRS survey will lead to a re-estimation of the DR-TB burden in the country and guide future interventions.

Annex 1. Itinerary of mission

Sunday 11 August 2019 Arrive in Naypyitaw (Dr Wares) and Yangon (Drs Mondal and Shanmugam)

Monday 12 August Briefing of JMM team in Naypyitaw
(pm) Travel to Yangon

Tuesday 13 August Visit to Yangon Regional Health Department, Lower Myanmar TB Office/
Yangon Regional TB Centre, National TB Reference Laboratory, Aung San TB
Specialty Hospital

Wednesday 14 August Visit to National TB Reference Laboratory, MSF-Holland Yangon DR-TB Project
Site, North Okkalapa District TB Centre, Yangon Region

Thursday 15 August (am) Travel to Mandalay
Visit to Mandalay Regional Health Department, Upper Myanmar TB Centre and
Laboratory

Friday 16 August Visit to TB Reference Laboratory - Patheingyi, Patheingyi TB Speciality Hospital,
and OPD Section, Upper Myanmar TB Centre

Saturday 17 August (pm) Travel to Yangon

Sunday 18 –
Tuesday 20 August Team debriefings and presentations, thematic presentations and discussions,
and preparation for debriefing meetings with MoHS, NTP, and partners

Tuesday 20 August (pm) Travel to Naypyitaw

Wednesday
21 August (am) Debriefing with Minister of Health, NTP and representatives of other
Ministries in Naypyitaw
(pm) Debriefing with partners in Naypyitaw
Depart from Naypyitaw

Annex 2. Persons met during the Joint Monitoring Mission, 11-21 August 2019

13th August 2019 (Yangon Regional Health Department, Lower Myanmar TB office, NTRL, Aung San TB Specialty Hospital)

Dr Tun Myint, Regional Health Director, Yangon Region
Dr Zaw Myint, Regional TB Officer, Yangon Region
Dr Asif Mohammad, MDR-TB Advisor to NTP
Dr Tin Tin Mar, Senior Consultant Microbiologist, NTRL
Dr Thynn Le Swe, Consultant Microbiologist, NTRL
Dr Wint Wint Nyunt, Consultant Microbiologist, NTRL
Mr Zayar Win, Engineer (Laboratory Equipment), WHO
Dr Thandar Hmun, Senior Medical Superintendent, Aung San TB Specialty Hospital
Dr Nway Nway Win, Medical Superintendent, Aung San TB Specialty Hospital
Dr Mar Mar Htay, Senior Consultant/ TB Specialist, Aung San TB Specialty Hospital
Dr Khin Aye Myint, Senior Consultant/ TB Specialist (retired), Aung San TB Specialty Hospital

14th August 2019 (North Okkalarpa District TB Centre)

Dr Ohanmar Seinn, Township Medical Officer, North Okkalarpa Township Health Department
Dr Saw Nwae Nwae Myint, Assistant Director/TB team leader, North Okkalarpa District TB Centre
Dr Tayzar Tun, Medical Officer (MDR-TB), MHAA
Mrs Daw Moe Moe Ei, Lady Health Visitor, TB Coordinator of North Okkalarpa District TB Centre
Mr Su Thaug, Laboratory Technician Grade I

15th and 16th August 2019 (Mandalay Regional Health Department, Upper Myanmar TB Centre, Reference Laboratory-Patheingyi, Patheingyi TB Speciality Hospital)

Dr Than Than Myint, Regional Health Director, Mandalay Region
Dr Yu Yu Wai, Deputy Regional Health Director, Mandalay Region
Dr Thandar Thwin, Regional TB Officer, Mandalay Region
Dr Kyi Kyi Swe, Microbiologist, Reference Laboratory-Patheingyi
Dr Kyaw Min, Medical Officer (NTP)
Dr Hla Myo Tun, Medical Officer (NTP)
Dr Mon Min Han, Medical Officer (MDR-TB), The Union
Mr Aung Aye Phy, Logistic Assistant, WHO
Mr Sao Kyaw Zeya, Engineer (Laboratory Equipment), WHO
Dr Moe Zaw, Medical Superintendent, Patheingyi TB Specialty Hospital
Dr Moe Lwin, Senior Consultant Physician, Patheingyi TB Specialty Hospital
Dr Khin Moeh Moeh Aung, Consultant Physician, Patheingyi TB Specialty Hospital
Dr Ye Thiha, Medical Officer, Patheingyi TB Specialty Hospital

Annex 3. Proposed External Quality Assurance and Training activity by SNRL-ICMR-NIRT Chennai

Timely and accurate diagnosis of active TB is a prerequisite for any successful TB control program and an essential part of the action framework to eliminate TB. The laboratory plays a key role in TB diagnosis both at individual and programmatic level through detection of active TB cases and drug susceptibility testing, contributing to administering optimal treatment regimens and prevention of transmission.

Myanmar initially was associated with SNRL Thailand for all the EQA activities for the diagnosis of TB and MDR TB. Now a MOU has been signed with SNRL-NIRT, Chennai in India to reinstate the EQA activities. We propose the following activities as part of SNRL-NIRT, Chennai support to TB laboratory activities in Myanmar. All the activities proposed will be carried out for the reference laboratories at Yangon and Mandalay. We propose similar activity in future, can be performed by trained individual to carry out the EQA activities in country for other culture and DST laboratory in Myanmar.

External Quality Assurance for 1st and 2nd line DST

Retesting: To reinstate the EQA program we will ask for a list of 100 culture on which 1st line DST have been performed and the SNRL will choose 20 to be shipped to SNRL Chennai for rechecking. For the 2nd line DST a list of 50 cultures will be requested and SNRL will choose 20 to be shipped to SNRL Chennai for rechecking. SNRL will carry out the DST on these cultures and send the feedback to the respective culture laboratories in Myanmar.

Panel Testing: A panel tests containing 20 strains will be sent to both NTRL Yangon and Mandalay for 1st line and 2nd line DST every year.

EQA for 1st and 2nd line LPA

Panel Testing: A panel tests containing 20 strains will be sent to both NTRL Yangon and Mandalay for 1st line and 2nd line LPA every year.

Training of laboratory personnel

There is an acute shortage of trained laboratory personnel to carry out DST for 2nd line and newer drugs in both NTRL's at Myanmar, we propose to carry out training activities at SNRL, NIRT, Chennai. We propose to support the laboratory to develop documentation and in country quality control activities to acquire international ISO-15189 accreditation for the TB reference laboratory and also SNRL, Experts will visit NTRL yearly for monitoring TB diagnostic and quality control activities carried out in the country.

Molecular epidemiology

We also propose to provide molecular epidemiology service (Spoligotyping, MIRU-VNTR and Whole Genome sequencing) and carry out training individuals in these techniques to determine the transmission dynamics of tuberculosis in the country. A drug resistance survey has been planned in the country for 2020 and we propose to provide targeted resequencing service for prediction of drug resistance for this survey and to assess the prevalence of drug resistance among new and previously treated patients in the whole country/high burden Yangon region.