AFRO GLC & GDF MONITORING MISSION

REPORT

Tanzania

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DATE OF THE NEXT GLC MISSION: (GIVE PLEASE THE 2 MAIN TOPIC)

DATE:

TOPICS: MDR-TB DIAGNOSIS AND TREATMENT

SIGNATURE/DATE: ……

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Acronyms/Abbreviation

aDSM	-	Active Drug Safety Monitoring and Management
AIDS	-	Acquired Immunodeficiency Syndrome
ART	-	Anti-Retroviral Therapy
CPT	-	Co-trimoxazole Therapy
DR-TB	-	Drug Resistant Tuberculosis
EQA	-	External Quality Assurance
FLDs	-	First Line Anti-TB Drugs
GDF	-	Global Drug facility
HIV	-	Human Immunodeficiency Virus
LPA	-	Line Probe Assay
MDR-TB	-	Multi Drug Resistant-Tuberculosis
MGIT	-	Mycobacteria Growth Indicator Tube
MoHCDGEC	-	Ministry of Health, Community development, Gender, Elderly and Children
MEML	-	National Essential Medicines List
PEPFAR AIDS Relief	-	The United States of America President's Emergency Plan for
PPM DOTS	-	Public-Private Mix Directly Observed Treatment short-course Strategy
PSM	-	Procurement and Supply Management
PV	-	Pharmacovigilance
QA	-	Quality Assurance
QC	-	Quality Control
rGLC	-	Regional Green Light Committee
RR-TB	-	Rifampicin Resistant Tuberculosis
SLDs	-	Second Line Anti-TB Drugs
SQRT	-	Safety and Quality Reporting Tool
TMDA	-	Tanzania Medicines and Medical Devices Authority
WHO	-	World Health Organization

XDR-TB	-	Extensively Drug Resistant Tuberculosis
Xpert MTB/RIF	-	Molecular test for the diagnosis of TB and Rifampcin Resistance.

Acknowledgement

We are grateful to the WHO Regional Office for Africa for the opportunity and privilege to participate in the regional Green Light Committee (rGLC) mission in Tanzania. Our gratitude also to the WHO country office in Tanznia, Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) and the National Leprosy and TB Control Programme for the support to ensure a successful the mission. Our appreciation also goes to the following institutions and organizations for their cooperation during the mission: Tanzania Medicines and Medical Devices Authority (TMDA); Central TB Reference Laboratory (CTRL); Temek Regional Reference Hospital and Kibong'oto Infectious Disease Hospital (KIDH). We also acknowledge District and Regional TB and Leprosy Coordinators and facility-based health workers for the insightful information shared during the mission. The DR-TB patients at Kibong'oto IDH are appreciated for accepting to share their perspectives on the quality of care being received.

We give glory to God Almighty for a fruitful mission.

Executive Summary

Background

TB has remained to be a disease of public health importance in Tanzania. The 2021 Global TB report categorizes Tanzania among the 30 high burden countries for TB as well as for TB/HIV. In 2019, an estimated incidence of 133,000 TB cases was notified, 26,800 TB deaths occurred, with deaths among HIV-negative and HIV-positive TB patients accounting for 63% (17,000) and 37% (9,800) respectively. The main drivers of the TB burden in the country (in order of risks) are undernourishment, HIV, alcohol use, smoking and diabetes mellitus. Furthermore, specific occupations such as miners are associated with high incidence of TB disease and likewise people confined in the congregate settings.

The 2020 Global TB report estimated 1,700 RR/MDR-TB cases occurred in 2019. Review of routine data (during the mission) showed that the proportion of new and relapse cases among RR/MDR-TB has increased from 28% in 2015 to over 80% in 2020. This is shows that transmission of resistant strains of TB is driving the DR-TB burden in the country. This has implication for strengthening infection prevention and control practices and measure at all levels, especially in the community and health care settings. The need for early detection and prompt treatment with effective medicines, cannot be over-emphasize. No case(s) of Extensively Drug Resistant TB (XDR-TB) have been notified in the country.

TB prevention and control in the country is based on the WHO End TB Strategy and the country has made tremendous progress in the attainment of 2020 milestones of the strategy related to reduction in TB mortality and incidence of TB relative to the 2015 benchmark. However, 45% of TB patients and/or household members suffer catastrophic cost due to TB.

Impact of COVID-19 on TB: TB case finding, and notification was not diminished consequent on the global COVID-19 pandemic in 2020 (see section on TB case finding and notification). Instead, Tanzania is among four 30 high burden countries for TB (Democratic Republic of the Congo, Nigeria, and Zambia) that recorded increase in TB notification compared other high burden countries that recorded decline in TB notification according to the WHO 2021 Global TB Report. This may have been due to the fact the country did not implement a lockdown. Most importantly, the Government has continued to provide guidance by adapting and/or adopting WHO-recommended guideline and building capacity to implement infection prevention and control measures. Government also leveraged $112 million from the Global Fund to support the Government's COVID-19 response

This report

The joint Regional Green Light Committee (r-GLC) and Global Drug Facility mission in Tanzania took place from 8th to 17th November 2021. The mission was primarily to monitor the status of implementation of the programmatic management of drug-resistant TB (PMDT), the laboratory and drug quality and management support system. Other thematic areas included the implementation of active drug safety monitoring and management (aDSM) and infection prevention and control (IPC). The key findings are presented as follows:

Political commitment and strategy to end TB

The draft 2021 – 2026 Health Strategic Plan recognizes TB along with other diseases like HIV, Hepatitis and Malaria as public health threats to the country. Government adopted the End TB Strategy (which is aligned to the Sustainable Development Goal 3.3) with free access to TB diagnosis and treatment. 65% of TB funding needs met with domestic and international sources of 22% and 40% respectively in 2019/2020. The Government also committed to support TB PSM-Funds provided to cover 5.6% of in-country warehousing and distribution of TB commodities and for custom clearance when need arise. There is a well-established and operational joint governance structure for the implementation for the prevention and control of TB in the country with an. established partner engagement and coordination. However, the challenge has remained an inadequate funding for programme development and implementation. A funding gap of 38% was documented in the 2021 Global TB Report for the country.

Status of the TB epidemic:

- Programmatic - Overall TB Control:

There exist robust guidelines, standard operating procedures and algorithms for the effective prevention and control of TB and leprosy, including bi-directional testing for TB, COVID-19, Diabetes Mellitus, and other non-communicable diseases. Also observed is the improved TB access to TB diagnostic services including the use of the molecular technology: there are 334 GeneXpert machines across 315 sites and TB microscopy sites. Innovative TB case finding strategies based on the intra-facility Quality Improvement model of systematically screening of all health facility attendees for TB as well as community-based outreaches. Innovative deployment of strategies for the diagnosis of childhood TB are also in place. Increased treatment coverage from 38% (62,180 TB cases) in 2015 to 64% (85,597 cases) in 2020. Childhood TB notification also has upward trajectory reaching 14% in 2020.

Patient-centred decentralized model of care with over 90% of TB patients being managed in the community. Increasing and sustained high treatment success rates (TSR) over 90%. In 2019, 94% TSR was attained which is over and above the national target of 90%. Death rate was below 4% while loss to follow up was 1% in the 2019 treatment cohort. Uninterrupted availability of WHO pre-qualified first and second-line anti-TB medicines: no stock out reported in the previous 12 months. The following gaps was observed in the overall TB control effort of the country:

- *Sub-optimal testing with Xpert MTB/RIF assay*: only 34% of bacteriologically confirmed TB were tested with Xpert MTB/RIF. Attributable in part to stock out of catridges and modular failures.
- *Case finding gap of 36%:* under-diagnosis may be attributable to inadequate access to Xpert MTB/RIF assay. Also, according to the preliminary report of a research by the National Institute of Medical Research (NIMR), the missing cases are in part attributable to under reporting by about 5-10% of cases that are not notified by the laboratories and facilities in the DHIS2 and electronic TB and Leprosy (e-TL) register.

Trend of presumptive TB not captured as a monitoring indicator of expansion in TB case finding activities.

- *There is incomplete cascade analysis of the ongoing case finding interventions*. The implication is that there is there is inadequate tracking of the of the performance of the variables in the cascade for appropriate programmatic interventions. No tool to facilitate the complete cascade analysis of the various case finding interventions. Current TB notification tool does not track trend of presumptive TB
- Access to free x-ray services is encumbered by bureaucracy as presumptive TB have to go through the process of exemption. Those who do not get the exemption or perceive any delay pay out of pocket. This process could lead to lead to missed opportunity for diagnosis or add to the already high Catastrophic Cost due to TB.
- 2021 Global TB Report estimates that of the 26,800 *TB mortality*, 17,000 (63.4%) occurred in HIV negative TB cases. This may be attributable to other co-morbidities like Diabetes Mellitus and other non-communicable diseases (NCDs).
- No form of *social package* for TB patients and/their treatment supporters.
- Limited geographic *cross-border coverage* for the surveillance of TB.

- TB/HIV Collaborative Services:

There is an optimized screening for of TB cases for HIV (100%) and 100% access to ART and 94% access to Co-trimoxazole preventive therapy.

- Programmatic - Drug-Resistant TB:

A draft update of the National Guidelines for the management of Drug-Resistant TB in place with recent WHO recommendations already adopted in the guidelines. There is a well-functioning Centre of Excellence at the Kibong'oto Infectious Disease Hospital with trained and dedicated staff; good patient care; impressive record keeping and organization. Also observed, is an expanding and well-functioning decentralized model of care in 177 sites (as of June 2021). Increasing DR-TB notification from 178 in 2015 to 534 in 2019 (peak), although this declined to 423 cases in 2020. Timely and increasing high enrollment of diagnosed DR-TB cases on treatment and care. In 2020, 95% of diagnosed cases were enrolled for care. Ongoing implementation of the fully oral regimens for the treatment DR-TB since 2019. Package of care for in-patients: free feeding, diagnosis, baseline & follow up investigations and treatment. Monthly transport support for ambulatory patients. Conduct of quarterly cohort meetings: high culture conversion rate of over 85%. Programme quality improvement system also in place. High treatment success of 80% attained in the 2018 cohort.

Ongoing implementation of active Drug Safety Monitoring and Management (aDSM) related to the use of the modified all oral STR and new MDR-TB treatment regimens. Cross Border and other initiative for TB prevention and control: Implementation of cross-border disease surveillance, including TB at the borders of Tanzania with Rwanda and Kenya. Existing regional integration platforms such as the East, Central and Southern Africa Health Community (ECSA-HC) provide opportunity for leveraging support for the effective implementation of Cross-Border TB prevention and control. The following gaps was observed in the overall DR-TB control effort of the country:

- Despite the annual increase in notification, there is still a *huge case notification gap* of 75% (n= 1,277) compared to the estimated incidence at the end of 2020. The gap may even be more at the end of 2021, given the cases notified so far. The huge gap between notification and estimated RR/MDR-TB is attributable to the sub-optimal testing with Xpert MTB/RIF assay. The trend of notified cases shows that the proportion of new and relapse among RR/MDR TB has increased exponentially from 48% in 2015 to over 80% in 2018 and subsequent years till date. This smacks of ongoing transmission in the community due to delayed detection and inadequate infection prevention and control practices.
- *Baseline culture/DST* was not available in many treatment cards reviewed: discordance in smear and culture results observed at the Kibong'oto Infectious Hospital and Temeke Regional Referral Hospital. Long TAT of LPA results and culture/DST to guide clinical decisions as part of good clinical practice and good quality of care. Increasing death rate due to late presentation of some cases, severe disease, and co-morbid conditions. The 2018 cohort showed death rate of 15%.
- *Institutionalization of mortality* audit is yet to be done. At the Kibong'oto Infectious Disease Hospital, a quick review of the possible cause of death were done for 10 of the deceased cases during the mission: 5 patients (50%) died within one week of treatment; 3 others died within two weeks of treatment while the remaining 2 died after a month on treatment. The deaths within the first two weeks are mostly due to severe disease and late presentation. Further analysis showed that 3 of the patients died due to severe aneamia; 4 due to severe acute malnutrition and HIV (stage 4) co-infection, 2 died due to extensive lung destruction secondary to silicosis and one was attributable to liver failure. Patients on ambulatory treatment may not easily access ancillary medicines because of bureaucratic processes of getting exemption from payment through the welfare scheme. The WHO recommended SR is not in use; the country is only using a modified SR under operational research
- *Active Drug Safety Monitoring and Management(aDSM):* Inadequate reporting of all deaths in KIDH in 2020 and 2021. No feedback from TMDA on analysis of causality.
- *Implementation of Infection Prevention and Control*: Lack of N-95 respirators in the hospitals at the time of the mission. Variable compliance in the consistent use of face mask by Health Care Workers. Lack of TB surveillance among HCWs: no periodic TB screening for Health Care Workers. No evidence of regular or effective monitoring and evaluation of IPC activities.

Laboratory Support System:

A very well-established structured Laboratory Network, which consists of the Central TB Reference Laboratory (CTRL); 5 Zonal TB Culture Laboratories, Zonal TB Culture, 303 GeneXpert sites and 1,613 microscopy sites. There is ongoing Culture, Line Probe Assay (LPA), and DST services. The CTRL and other laboratories have been accredited on 2 scopes, namely, GeneXpert and Smear Microscopy section by KENAS since 2012. The CTRL has Signed a Memorandum of understanding (MOU) with the Supra-national Reference Laboratories in Antwerp and Uganda to provide Quality assurance of samples. CTRL management has signed the service level agreement on behalf of all GeneXpert sites in the

country and uses the Medical Engineers from the Ministry of health to service and calibrate the other Laboratory. equipment such as Freezers, Biosafety cabinets, and Centrifuges.

2 staffs from the CTRL are being trained (14th – 26th /11/2021) at the SRL Uganda to conduct DST for new and repurposed second line anti-TB medicines, namely, bedaquiline, delamanid, linezolid and clofazimine. The CTRL is conducting verification on Xpert Ultra for possible adoption and roll out in the country. Also, the use stool sample to be adopted soon the for the diagnosis of TB in children using the Xpert MTB/RIF assay. Sample referral has been integrated thou not really optimized which is supported by Management development for health (MDH) through the hub and spoke model. A New Laboratory complex being built ay Kibong'oto Infectious Disease Hospital provides opportunity for a laboratory centre of excellence when it is completed and commissioned.

The 2016 – 2021 National TB Laboratory strategic plan is due for review. Abysmally Low GeneXpert utilization rate as follows: 14.8% (2018); 23% (2019); 23.9% (2020) and 19% in 2021 (January to September). Performance by the end of 2021 likely to far lesser than the preceding years. Stock out of consumables for MGIT/LPA reported by the laboratories. Prolonged TAT for LPA /Culture results. Inadequate technical oversight for regional culture laboratories e.g., Discordant results between baseline smear and culture results. Inadequate quality improvement and quality assurance system to address to identify discordant results e.g., smear vs Culture at baseline. There are different laboratory reporting platforms such as TB Laboratory Information System, GX Alert, DHIS and Laboratory net. There is need for streamlining.

Health System Support:

Established and well-functioning electronic TB and Leprosy (e-TL) register at the hospitals, district, regional and national levels. The paper-based reporting is at the level of the dispensaries and uploaded into the e-TL register by the District TB and Leprosy Coordinator. Updated national guidelines on infection prevention and control and observed implementation of IPC measures including:

- Functional Hospital IPC Committees in KIDH and Temeke RRH; IPC policy also available
- Capacity building and sensitization for HCWs
- Handwashing stations in various parts of the facilities.
- Available IPC IEC materials
- Spacious and well-ventilated waiting areas in the facilities; triaging of patients; handwashing or use of sanitizers in the facilities; (variable) use if face masks by HCWs and clients/patients
- Good waste management practices in the laboratories visited.

Several areas of strengths were observed including the ongoing efforts to roll out of the all-oral DR-TB treatment regimens in line with the latest WHO DR-TB treatment guidelines. The modified all-oral shorter DR-TB regimen is being implemented since early 2020 under operational research. The new child-friendly DR-TB formulations are also being scaled up though the uptake of both mSTR and the new child-friendly DR-TB formulation was slow at the time of the mission. The roll out of the shorter LTBI treatment regimens has yet to

commence, but progress has been made to establish technical working group to inform the Ministry of Health on the transition process. The need to expedite development of the transition plan to the new WHO recommended shorter LTBI regimens was emphasized including establishing the required budget and mobilizing resources for procurement of the related products- 3HP and RH75/50mg once approved

TB medicines and supplies management

With regard to TB procurement and supply management, the government of Tanzania has continued to show commitment to support TB PSM component. Funds are provided for warehousing and in-country distribution of TB commodities and for custom clearance when need arises. Currently, the Medical Stores Department (MSD) charges 11.6% of the total procurement costs to cover warehousing and in-country distribution of which 5.6% is covered by the government and the remaining 6% by the Global Fund. The mission highlighted the need to closely follow up on timely disbursement of funds for storage and distribution and for procurement of laboratory TB commodities via MSD particularly for products which are not in the GDF Catalogue

Overall, the country has been able to maintain a steady supply of quality assured first line and second line TB medicines in the past 12 months and funds have been secured for procurement of TB medicines and laboratory commodities to cover 2021-2023 through the Global Fund grant: USD 18,755,345.01 for TB medicines and USD 15,720,752.06 for laboratory commodities. Additional support is available through USAID/PEPFAR for procurement of Isoniazid for TPT and Cartridges. However, there is need to mobilize additional resources to bridge the funding gap of approximately USD 4.3Millioins for procurement of GeneXpert cartridges for the year 2022 and strengthen the country's capacity for quantification of TB laboratory commodities to address the observed erratic supply of some laboratory commodities. At the time of the mission, there was a shortage of Cartridges (0.7 months of stock), Sputum containers (3 months of stock) at the central level and stock out of N95 respirators at MSD store and visited DR TB sites. Stock levels were also low for some SLDs, but no potential stock out was anticipated to occur as new shipments were expected to arrive a month after the mission.

The logistic management information system (LMIS) has continued to be implemented which has helped to improve recording, reporting, and ordering of FLDs. The country has continued to implement e-LMIS for FLDs up to the district level. The roll out of health facility level e-LMIS has started in 5 regions and optimized supply chain system for management of DR-TB medicines has been developed to align with the mainstream country`s supply system for other commodities.

Adequate in-country capacity has also been maintained to ensure regular monitoring of quality of TB medicines through the WHO pre-qualified laboratory located at the Tanzania Medicine and Medical Devices Authority (TMDA). Based on the study on quality surveillance of TB medicines conducted by TMDA from 2012 to 2018 and published in March 2021, TB medicines were found to be of acceptable quality and no TB medicine failed quality test in the past 12 months. Additionally, pharmacovigilance system is in place including spontaneous ADR reporting system and active drug safety monitoring and management (aDSM) system.

PV tools have been developed both paper- based and electronic and are used to monitor safety of new medicines and other TB medicines. However, ADR reporting is still very low suggesting the need for the country to mobilize additional resources and train more health care workers on aDSM and pharmacovigilance system in general,

Funding gap of approximately USD 4.3M for procurement of Cartridges for 2022 At the time of the mission, there was a shortage of Cartridges (0.7 months of stock), Sputum containers (3 months of stock) at the central level and stock out of N95 respirators at MSD store and visited DR TB sites. Stock levels were also low for some SLDs, but no potential stock out was anticipated to occur as new shipments were expected to arrive a month after the mission. Ancillary medicines not included in the available GF budget for procurement of TB commodities except Pyridoxine

Provided through general supply chain system: accessing it could be cumbersome. DR TB patients pay due to inability to follow the required procedure for payment exemption. Low ADR reporting rates despite ongoing efforts to strengthen PV system. Inadequate funding to support training of HCWs on the new integrated electronic Safety and Quality Reporting Tool (SQRT)-aDSM included

Progress towards recommendations of previous missions and End TB strategy

- Summary of Implementation of Recommendations of 2019 rGLC Mission:
- 46.3% (31/67) of recommendations were fully implemented.
- 41.8% (28/67) of the recommendations were partially implemented.
- 11.9% (8/67) of the recommendations were not implemented.
- Summary of Implementation of DR-TB related Recommendations of the 2020 Joint External Review of National TB and Leprosy Programme:
- 11.9% (8/67) of the recommendations were not implemented 28.6% (4/14) of the recommendations were fully implemented.
- 50% (7/14) of the recommendations were partially implemented
- 21.4% of the recommendations were not implemented.

The country has made tremendous progress in the attainment of 2020 milestones of the strategy related to reduction in TB mortality and incidence of TB relative to the 2015 benchmark. However, 45% of TB patients and/or household members suffer catastrophic cost due to TB. The recommendations in the body of the report should be able to improve programme implementation in the course of time.

Limitations of the mission:

The team lead arrived late for the mission due to delay in approving his release and subsequent delay in securing the Tanzanian visa. Secondly, the mission covered limited number of health facilities and institutions.

1.0. Background

The United Republic of Tanzania is a union of Tanganyika mainland and the Island of Zanzibar, which was formed in April 1964, after attaining independence in 1961. It is the largest country in East Africa, occupying an area of about 945,087 square kilometers of land surface. It shares borders with eight neighboring countries, namely: Kenya and Uganda to the north; Rwanda, Burundi and Democratic Republic of Congo to the west; and Zambia, Malawi and Mozambique to the South. Tanzania is an ethnically and culturally diverse nation with an estimated 54 million population spread in 31 regions and 184 councils. The general age structure of the society demonstrates that 63% of the population is aged 24 years and younger. The country is a low-income with Gross National Income per capita of USD 1,020 in 2018, and nearly 70% of Tanzanians are farmers, fishermen and pastoralists. Over 75% of the population live in rural areas. Figure 1: United Republic of Tanzania, Administrative boundaries Note: Figure 1 summarizes important demographical information.

1.1. Health and Health System

The Health Sector in the country is guided by Tanzania Development Vision 2025 which identifies health as one of the priority sectors. Among its objectives is the achievement of a high quality of life for all Tanzanians. The Health sector is also informed by the National Strategy for Growth and Poverty Reduction in Tanzania Mainland (MKUKUTA) provides the national direction for achievement of the global Sustainable Development Goals (SDGs). The country is now updating its national Health Policy -2007 and revising its fourth Health Sector Strategic Plan – (2020 - 2025). The Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) is comprised of various departments and special units and in collaboration with President's Office – Regional Administration and Local Government is the supervisor of the implementation of the National Health Policy. The Ministry is responsible for the development, supervision, coordination of the policy and, related laws, regulations, guidelines, and standards of health services at all levels of health service delivery in Tanzania. The health service delivery structure in Tanzania follows an administrative governance structure in form of a hierarchy. The system complies with a pyramid on top, where there are central hospital and zonal hospitals. Regional referral hospitals are at all 29 administrative regions and in each district council, there is a district hospital. The health centers are found at ward level and dispensaries are found in every village. The country has a total of 8215 Health Facilities in which public health facilities are 6882 of which only 240 are hospitals.

1.2. Health and Socio-Economic Indicators

Indicators	Rates/Status
Projected population based on 2012 census	55.8 million
Annual	2.7%
Totality Fertility Rate	Declined from 5.2 to 4.9 children per woman (TMIS) 2017)
Life Expectancy at Birth	Increased from 51 years in 2002 to 62 years by 2012 (2012 census) and projected increase to 65.5 years by 2019 (NBS - Tanzania in Figures 2019)
Infant Mortality Rate	Decreased from 45 per 1000 in 2015 live birth to 43 per 1000 live births in 2019
Neonatal Death Rate	Decreased from 26 per 1000 in 2015 live birth to 25 per 1000 live births in 2019
Under-5 Mortality Rate	decreased from 81 per 1000 live births in 2015 to 67 per 1000 live births in 2019
Maternal Mortality Ratio	546 deaths per 100,000 live births
HIV Prevalence	
Literacy rate (people 15 years and above)	63 years for Males, 68 years for Females
Human Development Index	95th out of 117 Countries
GDP growth rate	7.0 % in 2018
Gross National Income (GNI) per capita	Increased $1,020 in 2018 to $1,080 in 2019

Sources: MoHDCGEC Health Sector Strategic Plan July 2021 – June 2026 (HSSP V).

Tanzania Demographic Health Survey and Malaria Indicator 2015-16.

https://countryeconomy.com/demography/literacy-rate/tanzania

2.0. Epidemiology of TB, DR-TB, and TB/HIV in Tanzania

2.1. Tuberculosis Burden: TB has remained to be a disease of public health importance in Tanzania. The 2021 Global TB report categorizes Tanzania is among the 30 high burden countries for TB as well as for TB/HIV and estimated an incidence of 133,000 TB cases occurred in 2019. It was also estimated that 26,800 TB mortality occurred in 2019, with 17,000 occurring among HIV-negative and 9,800 HIV-positive persons. According to the report, the main drivers of the TB burden in the country (in order of risks) are undernourishment, HIV, alcohol use, smoking and diabetes mellitus. Furthermore, specific occupations such as miners are associated with high incidence of TB disease and likewise people confined in the congregate settings.

2.2. Drug Resistant Tuberculosis Burden: The 2020 Global TB report estimated 1,700 RR/MDR-TB cases occurred in 2019. Review of routine data (during the mission) showed that the proportion of new and relapse cases among RR/MDR-TB has increased from 28% in 2015 to over 80% in 2020. This is shows that transmission of resistant strains of TB is driving the DR-TB burden in the country. This has implication for strengthening infection prevention and control practices and measure at all levels, especially in the community and health care settings. The need for early detection and prompt treatment with effective medicines, cannot be over-emphasize. No case(s) of Extensively Drug Resistant TB (XDR-TB) have been notified in the country.

2.3. TB/HIV: According to a 2020 UNAIDS data (https://www.avert.org), Tanzania has a HIV prevalence of 4.8% among adults 15 – 49 years, with 1.7 million people living with HIV. Based on routine data, the TB/HIV co-infection rate reduced from 36% in 2015 to 21% in 2020. The proportion of TB cases with known HIV status also increased from 93% to 100% in the same period.

3.0. Terms of Reference

3.1. Introduction: Multidrug resistance Tuberculosis (MDR TB) remains a public health problem and a threat towards achieving a world free of TB. To address it, the Green Light Committee for the WHO African region (r-GLC) was established in response to intensify Programmatic Management of MDR-TB (PMDT). The r-GLC is an independent advisory committee to WHO AFRO, Member states, donor agencies and partners. The central coordination of the r-GLC is done at WHO through Global Fund support. One of the important tasks of the r-GLC is to conduct PMDT missions to countries to monitor and advice on the implementation of control programmes for drug resistant TB.

The rGLC mission to Tanzania was also conducted jointly the Global Drug Facility (GDF) mission. The latter is a mechanism developed by the Stop TB Partnership in 2001 to expand access to, and availability of, high quality TB drugs to facilitate expansion of Directly Observed Treatment short course strategy (DOTS) expansion. The mission took place from 7th to 17th November 2021. The National Professional Officer for South West Zone (Nigeria) was the team lead and worked with a Laboratory Consultant and a GDF Consultant.

3.2. Objectives of Mission:

- To assess implementation of the Programmatic Management of Drug resistant -TB (PMDT).
- To assess the situation with drug procurement and supply management.
- To identify needs for additional support and technical assistance.

3.2.1. Specific Objectives:

- MDR-TB Interim and final treatment outcomes.
- Case finding strategies for RR-/MDR-TB.
- Treatment strategies including use of all DR TB regimens and follow-up of RR-/MDR-TB cases.
- Management system for second-line TB drugs in terms of quantification method. procurement, importation, storage, distribution, and delivery to the patients.
- Current status of TB laboratory network in providing MDR/RR/XDR-TB services.
- Health Management Information System and Data Management for MDR-TB.
- Active Drug Safety Monitoring and Management (aDSM).

3.3. Method and Scope of Work:

- Courtesy calls/briefing meeting the WHO Country Office and National TB/Leprosy Control Programme.
- Desk reviews: programme policy guidelines; strategic plans, National Health Policy supervision/minoring reports and triangulation of information.
- Briefing and planning meeting with National Leprosy and TB Programme (NLTP) team.
- rGLC/GDF team received briefing and updates from the NTLP on the status of clinical and programmatic management of drug resistant TB (PMDT).
- Review of the status of implementation of the recommendations of the 2019 rGLC mission as well as the recommendations for the DR-TB component of 2020 Joint External Review of the Tanzania National TB and Leprosy Programme.
- Participatory involvement of NLTP staff; staff of health facilities, regional and district TB coordinators.
- Interaction with Director of Kibong'oto Infectious Disease Hospital with DR-TB patients.
- Monitoring/review visits to regulatory institution and health facilities: Tanzania Medicines and Medical Devices Authority; Central TB Reference Laboratory, Kibong'oto Infectious Disease Hospital and Temeke Referral Regional Hospital
- Debriefing sessions.

3.4. Outputs/Outcomes of Mission:

- Reviewed the status of implementation of the recommendations of the 2019 rGLC mission as well as the recommendations for the DR-TB component of the 2020 Joint External Review of the Tanzania National TB and Leprosy Programme.

- Reviewed the implementation of the clinical and programmatic management of TB/DR-TB including a rapid review of the DR-TB mortality at the Centre of Excellence at Kibong'oto Infectious Disease Hospital.
- conducted visit to and interacted wit critical stakeholders: Programme Manager and Staff of National TB and Leprosy Programme; Tanzania Medicines and Medical Devices Authority; Central TB Reference Laboratory; Director and Staff of Kibong'oto Infectious Disease Hospital; a Regional and three District TB and Leprosy Coordinators; DOTS staff at Temeke Regional Referral Hospital and DR-TB patients.
- Debriefed WHO and National TB and Leprosy Programme on key findings and recommendations.
- Overall, the objectives of the mission were met.

4.0. Review of Implementation of Recommendations of Previous

4.1. Status of Implementation of Recommendations of rGLC Mission

S/No	Recommendations	Status
	Thematic Areas	
1.0.	**TB Program performance**	
1.1.	Expand Active case finding in the community and target the Key populations	
1.2.	Optimise Contact tracing and ensure follow ups are done	
1.3	Strengthen sample referral system to ensure more samples are transported to Xpert sites-integration with Tutume is assisting in other districts e.g Meru	
1.4	Ensure follow up sputa are collected at month 2,5 and 6 to increase cure rate for drug susceptible TB cases.	
1.5	Continue Expanding TB/HIV collaborative and ensuring a one stop shop and early ART initiation.	
2.0.	**Overall DR-TB Program performance**	
2.1.	Continue expanding GeneXpert machines and improve sample transport system to ensure second sample from microscopy sites reach GeneXpert sites	
2.2.	Consider implementing quality improvement projects and expand to all DR-TB sites so as to improve conversion rate, documentation of culture results and probably high deaths rate.	
2.3	To improve treatment success rate, there is need to reduce **Case fatality rate** and maintain the decline in **lost to follow up.**	
2.4.	**DR-TB Case Fatality Rate**	15% (2018)
2.4.1.	The program with support from partners should investigate the actual causes of TB deaths and implement targeted interventions or quality improvement projects.	
2.4.2.	This can be done through mortality audits/reviews in all the DR-TB sites or retrospective data review.	

2.4.3.	Invite the referral or follow up site during the mortality review discussions or use the existing Tele-echo platform.	
2.4.4.	Monitor implementation of mortality audits, collect data monthly/quarterly at district, regional and national level and provide feedback to health care workers on the progress.	
3.0.	**Role of partners in delivery of TB and MDR-TB care**	
3.1.	Avail more funding support to the TB program to ensure that all priority activities are implemented according the new Strategic plan.	
3.2	Improve GeneXpert utilization by optimizing sample transportation system which will ultimately increase case detection and notification.	
3.3.	Prioritize and Optimize Contact tracing to increase the case notification and treatment coverage which is currently at 53%, target is 90%	
3.4	Use the same modalities for Childhood DS-TB contact tracing to improve childhood DR-TB contact tracing which is currently at 2.4% vs 14% for DS-TB.	
3.5.	Support NTLP to advocate for more funding for comprehensive patient support package for DR-TB patients which include food package, transport allowance and stipend for community treatment supporters.	
3.6.	Use both community and family treatment supporters to strengthen DOT for DR-TB patients as we transition from injectables to all oral medications as patients might not visit the facility more often.	
	Continue supporting with monitoring tests as active pharmacovigilance is a priority in the recent WHO recommendations with the introduction of new drugs for both DR-TB and HIV.	
4.0.	**Case Finding Strategies and Laboratory**	
4.1.	**Contact Tracing:** Prioritize and Optimize Contact tracing to increase the DR-TB case notification and treatment coverage which is currently at 24% when compared with WHO estimate and 66% when compared with NSP target. The overall target is 90%. ○ Monitor follow-up contact tracing during supportive supervision and also support with transport.	
4..1.2	Improve childhood DR-TB case detection by ensuring that follow up of contact tracing is conducted consistently. ○ Capacity building of clinicians on DR-TB childhood TB diagnosis Ensure training slides include the rationale and literature for clinical diagnosis in children	
4.2 4.2.1.	**Xpert testing** Expand GeneXpert laboratory network to increase access to GX-testing, at all levels of service provision, for TB & RR/MDR TB diagnosis. Ensure all Xpert machines are connected to GXalert system.	
4.2.2.	Redistribution and mapping of Xpert sites	

	○ Consider Meru district hospital as it has high case notifications, consider getting one GeneXpert machine from Kibong'oto hospital	
4.2.3.	Pursue the Surcharge option with Cepheid to ensure that all geneXpert have maintenance plan in place	
4.2.4.	Procure UPS for Xpert machines that do not have	
4.2.5.	Invest in integrated specimen transport system to ensure more samples are transported to Xpert sites-integration with Tutume is assisting in other districts e.g Meru.	
4.2.6.	Consider another transport system from community to facility-e. g Bodaboda (suggested by AMREF).	
4.2.7.	Capacitate CTRL and Zonal labs to prepare samples for GeneXpert PT internally	Confirm
4.2.8.	Finalise the laboratory strategic plan with budget for New GX systems and Cartridges, to be procured. Leverage resources from other national programs as GeneXpert is a disease cross-cutting platform (e.g HIV 1 EID).	
4.3. 4.3.1.	**Phenotypic DST** Expand 2nd line DST (phenotypic) for new DR-TB drugs, as planned for (Bedaquiline, Linezolid, Clofazimine, Delamanid).	
4.3.2.	Capacity building of CTRL and Zonal labs staff on DST for new drugs and LPA WHO Technical support for both LPA and DST for new drugs	
4.3.3.	Consider tracking TAT for LPA and phenotypic DST results from both clinical and laboratory side to monitor progress as well as comparison ○ Can be included in the indicators for supportive supervision This could also improve documentation of results in both electronic and paper-based system.	
4.3.4.	Strengthen Clinical-laboratory interphase and also consider conducting cascade analysis to follow up a patient from screening, diagnosis and treatment enrollment so that laboratory confirmed cases are traced into the treatment registers.	
4.3.5.	Acquire and Functionalize the NGS/WGS platform at CTRL for Predicting molecular drug resistance for all drugs used in TB/DR-TB treatment, as a long term solution (follow WHO guidance.	
5.0.	**Kibong'oto National DR-TB Referral Hospital**	
5.1.	Consider adding food packages with basic items as part of the patient support package for all your DR-TB patients. *Adopt from experiences from other countries (Eswatini), MSF supported countries and others.*	
5.2.	Consider adding community treatment supporters (CTS) instead of relying on family treatments supporters alone for DOT as we move to all oral regimens as some patients might not come to the facility more often. *Therefore, include a stipend for the CTS in the patient support package.*	

5.3.	Identify some DR-TB sites (starting with zones) that can be upgraded to admit patients with DR-TB.	
5.4.	To consider in future outpatient initiations for stable patients in a phased approach as numbers increase.	
5.5.	Consider minimal days of admission for mothers with uninfected babies or have separate isolation rooms for the babies with less contact with the mothers o Treatment supporters can be proposed for these babies during the admission period. Could also consider DR-TB preventive therapy for such unique cases: Adopt some experiences from other countries.	
5.6.	Mobilize more resources to fund the Cohort review meetings with transition of challenge TB.	
5.7.	DTG use should be the preferred regimen for all DR-TB patients and should be included in both HIV and DR-TB guidelines.	
6.0	**DR-TB Decentralized sites**	
6.1.	Continue training on all oral regimens to cover all DR-TB sites.	
6.2.	Onsite training and mentorship for ECG as we transition to injectable free regimen	
6.3.	Procurement of visual monitoring tools (Snellen charts, ishihara charts and ophthalmoscopes) and include the practical in the training package.	
6.4.	The DR-TB staff should document Visual monitoring tests results after referral to Eye clinic.	
6.5.	Ensure Vitamin B6 is part of the DR-TB regimen especially with the new regimen which has both Cycloserine and Linezolid.	
6.6.	Prioritize Meru district when redistributing geneXpert and consider taking one from Kibong'oto hospital.	
6.7.	Improve documentation of referral forms from Kibong'oto to decentralized sites and also consider attaching another blank sheet with comprehensive information.	
6.8.	Ensure baseline serum electrolytes (K+ and Mg2+) are requested and reviewed before initiating patients on new drugs (QTc prolonging drugs).	
7.0	**Pharmacovigilance/aDSM**	
7.1.	Possibility of using tele-echo platform to engage the clinician who submitted the adverse events report to TFDA and NTLP.	

7.2.	During mentoring and supportive supervision ensure documentation of LPA, Phenotypic DST and monitoring tests. Also verify use of these results.	
7.3.	Consider procurement of monitoring reagents under GF for back up in other sites. Possibilities of having one main partner supporting TB program.	
7.4.	Onsite training and mentorship for ECG as we transition to injectable free regimen.	
7.5.	Procurement of visual monitoring tools (Snellen charts, ishihara charts and ophthalmoscopes) and include the practical in the training package *Visual monitoring tools have become important in all DR-TB sites with the transition to injectable free regimens (one of the drugs LZD causes optic neuritis).*	
7.6.	Training package/slides should emphasize common tests that need to be done and rationale. o These should be aligned to the proposed all oral new regimens *Ensure KCL is part of the ancillary drugs.*	
7.7.	DTG use should be the preferred regimen for all DR-TB patients and should be included in both HIV and DR-TB guidelines. o Therefore, active pharmacovigilance should be strengthened Incorporate DTG adverse events in the list of adverse events of special interest for DR-TB.	
8.0	**Drug Management**	
8.1.	Fast track the order for Clofazimine and redistribute the current stock to other sites that are almost stocked out. Important for the country to continue implementing all the recommandations by GHSC and LFA.	
8.2.	Fast track the orientation of health care workers on the revised facility reporting system.	
8.3.	Train MSD staff on basic DR-TB management and orient them on the new regimens.	

8.4.	Capacitate the laboratory personnel on the ordering system for laboratory commodities especially the cartridges.	
8.5.	Consider the small unit of measure when ordering the second-line TB medicines since distribution will be done directly to the DRTB sites and some sites have small numbers.	
9.0	**Recording and Reporting Systems**	
9.1.	Support all RTLC and DTLC with internet bundles and should be standard.	
9.2.	Facilities to dedicate one day per week to review both systems and complete any documentation Mentoring and supportive supervision should prioritize this activity.	
9.3.	The classification of DR-TB regimen will need to be revised to allow the clinician to click each drug-since the regimens have become more individualized.	
9.4.	Consider adding Regimen change/ drug changed tab. This information will assist with quantification of the TB drugs.	
9.5. 9.6. 9.7.	NTP to discuss with TMDA on few variables that can be added to ETR from paper based aDSM tool. Important to also compare with vigiflow variables. Discuss with developer on possibilities of exporting adverse event data to vigiflow and provide access to TFDA on that page only.	
10.0	**PMDT Funding Source**	
10.1.	Increase domestic funding to ensure sustainability.	
10.2.	Mobilise more resources to cover the gap in funding.	

4.2. Status of Implementation of DR-TB related Recommendations in the 2020 TB Programme Review

S/No	Recommendations	Status
1.0	**To address the gaps identified**	
1.1	Improve GeneXpert utilization and an integrated sample referral/results feedback	
1.2	Ensure universal DST to increase RR/MDR case finding, currently coverage is low i.e. 37% among New patients and 50% in previously treated patients.	
1.3	Transition to GeneXpert Ultra cartridges that have better sensitivity for better case finding.	

1.4	Functionalize GXAlert implementation for real time reporting of result at all GeneXpert hub	
1.5	Improve TAT for culture and DST results using e-TL register	
1.6	Build lab capacity to perform SL DST for new drugs – BDQ, DLM, LZD, and CFZ.	
1.7	Introduce full Genomic sequencing.	
1.8	Putting DR-TB patients' care record forms in booklet form will go a long way to easy case clinical reviews and storage of records.	
1.9	Provide social support to both hospitalized and ambulatory DR-TB patients. These may include food, laboratory testing, transport and specialized services through obtaining running service contracts with private provider.	
1.10	Strengthen community TB systems for DR-TB case finding and case holding.	
1.11	Conduct MDR-TB Mortality audits and studies to delineate causal factors so as to design mitigation measures	
1.12	Draw Long term servicing contracts with Cepheid for prompt GeneXpert Maintenance	
2.0	**Recommendations based on Global perspective**	
2.1	Operational Research (OR) is recommended during use of full oral shorter drug regimen (STR) that conform to WHO recommendation. The Country has received funds to conduct OR on two regimens, viz; 6 Bdq-Lzd-Lfx-Cfz-Cs-Z/3-5 Lfx-Cfz-Cs-Z and 6 Bdq- DlmLfx-Cfz-Cs-Z/3-5 Lfx-Cfz-Cs-Z. And the country is ready for OR implementation. HOWEVER, there is need to obtain and use standardized OR tools to allow pooling of data into WHO global data base.	
2.2	Build capacity for Whole Genomic sequencing and DST for new SL drugs	
2.3	Need to adopt and closely monitor implementation of UNHLM recommendations and targets	

Keys:

Fully Implemented	
Partially Implemented	
Not implemented	

Summary of Implementation of Recommendations of 2019 rGLC Mission:

- 46.3% (31/67) of recommendations were fully implemented.
- 41.8% (28/67) of the recommendations were partially implemented.
- 11.9% (8/67) of the recommendations were not implemented.

Summary of Implementation of DR-TB related Recommendations of the 2020 Joint External Review of National TB and Leprosy Programme:

- 28.6% (4/14) of the recommendations were fully implemented.
- 50% (7/14) of the recommendations were partially implemented
- 21.4% of the recommendations were not implemented.

5.0. Summary of Recommendations of the 2021 rGLC Mission

S/No	Recommendations	Responsible	timeline
	Thematic Areas		
1.0.	**Implementation of Recommendations of Previous Missions**		
1.1.	Establish action tracker for monitoring the timeliness and status of implementations of recommendations of missions.	NTLP/WHO/Partners	Immediately.
1.2.	NTLP should work with partners to ensure full implementation of recommendations that are either partially or not implemented.	NTLP/WHO/Partners	Immediately/Ongoing
2.0.	**Programme Policy and Guidelines**		
2.1.	Finalize all draft guidelines for printing and dissemination to the field.	WHO/NTLP	Quarter 1, 2022
3.0.	**Drug Susceptible TB case finding and Notification**		
3.1.	Improve sample transportation and linkage of all samples to Xpert MTB/RIF assay: Immediately.	NTLP/CTRL	Immediately
3.2.	Review and/or update, finalize and operationalize NTLP tools to: ❖ Track the cascading of the various active case finding strategies to facilitate complete cascade analysis for the purpose of effective monitoring and evaluation of the interventions. ❖ Track the number/proportion of diagnosed TB cases for the purpose of understanding and addressing under reporting of TB cases from the laboratories and health facilities. ❖ Track for trend of presumptive TB over time and impact on TB diagnosis and notification. This should guide the planning process for	NTLP/WHO	Quarter 1, 2022

	procurement & deployment of diagnostic consumables.		
3.3.	Streamline the process of accessing free x-rays for the clinical diagnosis of TB:	NLTP/ MOHCDGEC	Quarter 1, 2022.
4.0.	**TB/COVID-19 Bi-directional Screening**		
4.1.	Document and share country experience(s) on the impact of bi-directional screening for TB and COVID-19 on programming in the context of health emergency.	NTLP, WHO and Partners	Quarter 2, 2022
5.0.	**Drug Susceptible TB Treatment and Care**		
5.1.	Institutionalize treatment cohort analysis for children (0 – 4) to identify and mitigate any peculiar challenge that may be masked	NTLP	Quarter 1, 2022
5.2.	Strengthen bi-directional screening for TB and NCDs as part of integrated and holistic care to improve health outcomes.	NLTP/Partners	Immediately
5.3.	Mobilize resource for minimal support package for TB patients: Q1 2022	NLTP	Quarter 1, 2022
6.0.	**TB/HIV Collaborative Services**		
6.1.	Sustain the high access to HIV screening and ART and work towards optimal access to CPT	NTLP/Partners	Ongoing.
7.0.	**Cross-Border TB Initiatives**		
7.1.	NTLP should generate data to drive the expansion of the Cross Border Initiative. NTLP to operationalize the Cross Border	NTLP	Quarter 2, 2022.
	Expand Cross-Border activities as contained in the 2020 – 2025National TB and Leprosy Strategic Plan.	MoHCDGEC/NTLP	Quarter 1, 2022
8.0.	**DR-TB Case Finding and Notification**		
8.1.	Strengthen access to Xpert MTB/RIF for samples from all presumptive TB.	NTLP	Immediately
8.2.	NTLP should work with partners to promote IPC practices in the community and also promote early health seeking through sustained awareness creation in the community: Q1 2022.	NTLP/Partners	Immediately
9.0.	**DR-TB Treatment and Care**		
9.1.	Provide adequate oversight for the laboratories to address the issue of	CTRL	Immediately

	long TAT for LPA and Culture/DST to ensure clinical validity and guidance for clinical decisions in patient management.		
9.2.	Identify and address the causes of late presentation of DR-TB cases at point of diagnosis/treatment: Q1 – 4 2022.	NTLP/WHO/Partners	Quarter 1, 2022
9.3.	KIDH MDR-TB committee to institutionalize mortality auditing with a view to identifying and addressing preventable causes of death like aneamia and severe acute malnutrition among MDR-TB patients and hence improve the overall clinical management of patients.	KIDH/NTLP	Quarter 1, 2022
9.4.	NLTP should ensure that all needy DR-TB patients have access to ancillary medicines as part of quality of care and hence favourable health outcomes for the patients.	NTLP	Immediately
9.5.	Conduct six-monthly interim analysis of treatment outcomes for the modified Shorter Regimen as well as the Longer Regimen as part of programmatic monitoring and evaluation of the regimens.	NTLP	Ongoing
9.6.	Consider introducing the WHO recommended Shorter Regimen as a comparator to the modified Shorter Regimen being given under operational research conditions.	NTLP	Quarter 2, 2022
10.0.	**Active Drug Safety Monitoring and Management (aDSM)**		
10.1.	NTLP and TMDA should sensitize clinicians, pharmacists and nurses in the MDR unit to report all cases of death, Serious Adverse Events and Adverse Events of Special Interest and submit same to appropriate referring sites.	NTLP/TMDA	Immediately
106.2.	Routinely provide regular feedback on causality analysis to all reporting sites.	TMDA	Quarter 1, 2020
11.0.	**Laboratory Network and Services**		
11.2.	Review/update the TB Laboratory strategic plan and operationalized in line with the NLTP Strategies**.**	NTLP	Quarter 1 2022
11.2.	NTLP should conduct a thorough assessment of health facilities to guide the strategic deployment of GeneXpert machines for the purpose of ensuring optimization: operational	NTLP	Quarter 1 2022

	considerations should include power supply.		
11.3	Consider the procurement of other molecular diagnostics like the Trunat for strategic deployment, e.g., to hard-to-reach or under-served areas	NTLP	Quarter 1, 2022
11.4.	Ensure adequate stock of catridges and consumables.	NTLP	Q1 2022.
11.5.	NTLP should improve sputum referral linkages to molecular diagnostic sites based on the hub and spoke model and as well put in place a tracking system for the movement of samples. Ensure all samples are tested with molecular diagnostics.	NTLP	Immediately.
11.6.	Strengthen demand creation activities including the Sensitization of clinicians, more community engagement/ mobilization and enhancing public enlightenment e.g. Jingles on Radio and TV, social media, pamphlets to improve, celebrity endorsement model: Immediately.	NTLP	Immediately.
11.7.	Identify and address the causes of the reported delay or the prolonged TAT for LPA/Culture/DST results	NTLP/CTRL	Immediately.
11.8.	Develop a mitigation plan to avoid procurement delays in future.	NTLP	Immediately.
11.9.	Provide regular supportive supervision and Mentoring of the laboratory staff, especially in the sites performing cultures and molecular tests.	CTRL	Immediately.
11.10.	Work with the peripheral laboratories to put in place the Quality Improvement system to improve services.	CTRL	Immediately
	Harmonize all existing TB Laboratory reporting systems for more effective and efficient data and information management	NTLP/CTRL	Quarter 2 2022
	Facilitate the enrollment of the regional culture laboratories for ISO certification for LPA, Culture and DST for FLD /SLD	CTRL	Quarter 4 2022
12.0	**Infection Prevention and Control**		
12.1.	Ensure the availability and use of N-95 respirators for HCWs in high-risk units in the facilities, especially laboratories and MDR-TB units. Leverage available stock at Medical Supply Department (MDS).	NLTP	Immediately

12.2.	IPC Focal Point to work with health facilities to ensure continuous sensitization of HCWs on IPC compliance.	NLTP/Health Facilities	Ongoing
12.3.	IPC Focal Point to liaise with Health facility managers to institutionalize periodic screening of HCWs for TB.	NLTP/Health Facilities	Immediately
12.4.	IPC Focal Point to work with facility IPC focal points to ensure regular and systematic monitoring and evaluation of IPC practices and mitigate observed lapses.	NLTP /Health Facilities	Immediately
13.0.	**Programme Information and Data Management**		
13.1.	Review and/or update, finalize and operationalize NTLP tools (by Q1 2022) to: ❖ Track the cascading of the various active case finding strategies to facilitate complete cascade analysis for the purpose of effective monitoring and evaluation of the interventions. ❖ Track the number/proportion of diagnosed TB cases for the purpose of understanding and addressing under reporting of TB cases from the laboratories and health facilities. ❖ Track for trend of presumptive TB over time and impact on TB diagnosis and notification. This should guide the planning process for procurement & deployment of diagnostic consumables.	NTLP/WHO/Partners	Q1 2022
14.0	**Summary of GDF Recommendations**		
14.1.	Need to mobilize additional resources to bridge the funding gap for procurement of Xpert Cartridges, ancillary medicines and ensure timely procurement to avoid interrupted supply.	MOHCDGEC/NTLP	Quarter 1, 2022
14.2.	Follow up on disbursement of funds for storage and distribution and for procurement of laboratory TB commodities initiated via MSD. Procurement process needs to be fast tracked.	MOHCDGEC/NTLP	Immediately
14.3.	Improve quantification of TB laboratory commodities, engage all relevant stakeholders in setting realistic targets and assumptions.	NTLP	Immediately

14.4.	Fast track the roll out of optimized system for management of DR TB medicines to ensure pipeline visibility and reduce distribution cost	NTLP/Partners	Quarter 1, 2022
14.5.	Expedite the roll out of health facility level e-LMIS for FLDs, identify and address factors affecting effective roll out of e-LMIS for TB laboratory commodities: Quarter 2, 2022 by NTLP/Partners	NTLP/Partners	Quarter 2, 2022
14.6.	Need to initiate all future procurements based on the actual program performance/enrollment trends. Targets should only be used for planning and budgeting purposes.	NTLP	Quarter 2, 2022
14.7.	Ensure effective use of EWS alerts generated by the QuanTB tool in making timely supply chain decisions: ongoing by NTLP.	NTLP	Ongoing
14.8.	Initiate new procurement of FLDs immediately to avoid stocks out and ensure stock levels are always maintained within recommended min-max stock levels	NTLP	Immediately b
14.9.	Optimize the use of e-LMIS in tracking of key TB supply chain indicators including reporting rates, completeness of reports and medicines availability: ongoing by NTLP and Partners.	NTLP/Partners.	Ongoing
14.10.	Mobilize resources for training of HFs on aDSM implementation. ➢	NTLP	Quarter 1, 2022
14.11.	Intensify supportive supervision to ensure that treatment guidelines for managing childhood DS TB are followed by all HCWs to avoid expiries.	NTLP	Ongoing
14.12.	Need to improve recordkeeping practices and ensure AC is functional at Temeke dispensing unit.	RTLC/MOI Temeke	Immediately
14.13.	**Consider introduction of patients' kit pack/kits to** prevent treatment interruptions for patients already on treatment and simplify stock management process. ➢ Conduct quantification exercise to establish the required budget ➢ Develop a training plan to cover pharmacy staff and TB Health workers at	NTLP	Quarter 3 2022

	storage dispensing points ➢ Review/update LMIS tools ➢ Mobilize resources		
14.14.	Expedite the roll out of the new WHO recommended LTBI regimens-3HP and 3RH: ➢ Conduct quantification exercise and establish the required budget for procurement of the new LTIB products to inform the transition process ➢ Develop LTBI transition plan ➢ Mobilize resources for procurement and other related activities	NLTP	Immediately

5.1. List of Technical Assistance Required

Aspect	TA needed (Y/N)	Time frame
MDR scale-up planning, resource mobilization and management	N	
Laboratory network development	N	
Drug procurement	N	
Training and human resource development	N	
TB Infection Prevention and Control	N	
Palliative care	N	
Data management / ICT support	N	
Collaboration private sector	N	
Collaboration prison sector	N	
ACSM	N	
Other: DRS	N	

6.0. Tanzania National TB and Leprosy Programme

The National Tuberculosis and Leprosy Programme (NTLP) was launched by the government in 1977 as a single combined Programme to effectively control TB and leprosy in the country. The mission of the programme is to provide high-quality, effective interventions for TB and leprosy care and control in Tanzania, with a focus on gender mainstreaming, equity, accessibility, and those most at risk.

6.1. Structure and Organization of the Programme: The NTLP is functions at the national, regional, district, community, and health facility levels

6.1.1. National level: The TB and Leprosy central unit (TLCU) at national level is headed by the Programme Manager. This unit responsible for:

- developing policy guidelines, planning, M&E, resource mobilization, and financial management at the national level, and
- overseeing efficient use of allocated TB and Leprosy resources at the regional and district levels.
- coordinating training of staff, quality assurance, and operational research.
- The central unit comprises of TB unit coordinators who advises RHMTs and other partners on all matters pertaining to the control of TB, TB/HIV, and leprosy.
- It is also responsible for mentorship of RTLCs, DTLCs, and TB/HIV officers and other staff during supervision visits and programme meetings.

6.1.2. Regional Level: Management of TB and leprosy control at this level is under the purview of the Regional TB and Leproy Coordinator (RTLC), who works closely with other members of the Regional Health Management Team (RHMT). The responsibilities at this level include planning, implementing, and monitoring of TB and leprosy activities. The RTLC receive technical guidance from the NTLP, and he is responsible for the TB, TB/HIV, and leprosy activities in the region.

6.1.3. District Level: The District TB and Leprosy Coordinator, collaborates with the other members of the CHMT in addressing, implementing and monitoring the TB, TB/HIV, and leprosy control agenda in the CCHP. The coordinator also liaises with local TB implementing partners to ensure TB, TB/HIV, and leprosy activities are given priority within the district. Area based on the evidenced need. The DTLC receive guidance from the RTLC and the NTLP

6.1.4. Community and Health Facility Levels: At the community level, TB, TB/HIV, and leprosy care and control are implemented as part and parcel of routine NTLP activities to expand DOTS activities beyond health facilities and to involve communities. HCWs at the health facility level are responsible for providing and sustaining the quality of TB, TB/HIV, and leprosy services.

They are responsible for overseeing all advocacy, communication and community TB, TB/HIV, and leprosy activities. All CHWs, including social support groups for TB, TB/HIV, and leprosy care and control, work with the guidance and support of HCWs.

6.2. Inventory and Status of Programme Policies and Guidelines

TB control in Tanzania is within the context of the 2020 7th edition of the Manual for the Management of TB and Leprosy. There is also an updated draft Guidelines for the Management of Drug-Resistant TB that has adapted recent WHO recommendations and rapid advice. Tools and standard operating procedures exist for childhood TB and other thematic areas. The status of programme guidelines are follows:

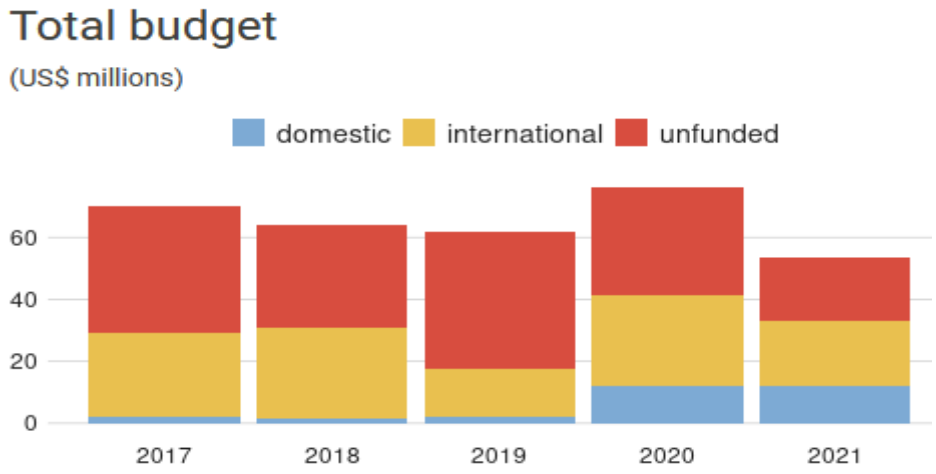
- Draft National TB and Leprosy Strategic Plan 2020 – 2026: need to finalize and disseminate to stakeholders to guide programme planning and implementation.
- Draft National TB Laboratory Strategic Plan 2016 – 2021: due for review/update for verification and approval for dissemination.
- Electronic copy of Active Drug Safety Monitoring and Management (aDSM) guidelines: need to print and disseminate.
- Enhancing Quality of TB and Leprosy Services In The Context of COVID- 19 Pandemic: A Practical Guide.
- Finalized Quality Improvement for TB Case Detection – Toolkit for HFs 2021: already printed and disseminated to the health facilities.
- Manual for Management of TB/Leprosy 7th edition (April 2020): Need to update/align with current definitions in the DR-TB guidelines.
- Updated draft National DR-TB Guidelines: need to finalize and disseminate to stakeholders.
- Updated draft of National Guidelines for TB infection prevention and Control (IPC): need to finalize and disseminate to stakeholders.

6.3. Governance Commitment and Partnership and Funding

The Government in its 2021 – 2026 Health Strategic Plan V, prioritizes TB with other communicable diseases like HIV/AIDS, Hepatitis, and malaria as public health importance. However, the historical trend shows that TB as a public health programme in the country is and still donor driven. The Government of Tanzania, however, continue to provide the right policy environment for effective programme implementation and impact. The government continues to leverage on the support of partners, particularly, the Global Fund and the United States of America President's Emergency Plan for AIDS Relief (PEPFAR) to achieve its set goals and targets The governance structure for TB operates at the national, regional, district, community and health facility levels. The NTLP implements activities across these levels in collaboration with Implementing Partners. There is also engagement of the private-for-profit and faith-based health through the public-private mix (PPM) DOTS initiative. Programme implementation is guided by the various NTLP guidelines. A Parliamentary TB Caucus established to push for more government support for programme development and implementation. As mentioned above, funding for TB programme is mainly from either the Global Fund or PEPFAR. As shown in figure 1, the 2021 Global TB Report states that of the total USD 53 million budgeted

for TB, domestic funding and international funding 22% and 40% respectively with a funding gap of 38%.

Figure 1: Trend of Funding Landscape for TB in Tanzania.



Source: WHO 2021 Global TB Report

6.3.1. Challenges:

- TB programme is still largely donor driven.
- Funding gap for programme implementation.
- 45% of TB patients facing catastrophic total costs

6.3.4. Recommendations:

- NTLP to work with the Parliamentary Caucus for TB to improve Government funding for TB/DR-TB prevention and control – **Ongoing**.
- NTLP to work with MOHCDGEC to improve access to diagnostic processes like x-rays and treatment/care services like access to ancillary medicines for DR-TB patients – **Quarter 1, 2022**.

6.4. Progress toward the 2020 Milestones of the SDG and End TB Strategy: based on the 2021 Global TB report, Tanzania has made good progress and surpassed the targets for the 2020 milestone in two of the indicators.

- Reduction in TB deaths compared to 2015: HIV-negative mortality reduced from 59/100,000 in 2015 to 29/100,000 in 2020, i.e., a 48.2% decline. Similarly, HIV-positive mortality reduced from 47/100,000 to 16/100,000, i.e., a 66% decline in the same period.

- Reduction in TB incidence to 2015: from an incidence of 306/100,000 in 2015, this reduced to 222/100,000 in 2020, representing a 37.8% compared to expected target of 35% reduction.
- However, progress towards a zero Catastrophic Cost to TB patients and households due to TB is 45%.

7.0. Case Finding and Notification of Drug Susceptible TB

7.1. Overview: Since 2016, TB case finding strategy has been based on the Quality Improvement (QI) model. This new approach utilizes facility entry points for systematic TB screening of all facility attendees irrespective of what has brough the client to the facility. This provides the opportunity for every client utilizing facility services to undergo TB screening with an ultimate goal of increasing overall TB case detection in the country. Additionally, contact tracing and community-based screening for TB is ongoing. Both private for profit and faith-based health institutions and prison health care are also engaged for TB case finding and treatment.

7.2. Progress and Achievements:

- TB case finding is guided by guidelines and job aids for systematic TB screening. Prioritized diagnostics techniques are based on the use the GeneXpert technology, Microscopy & use of x-rays. Other new molecular techniques, like the Trunat, Urine based Lateral flow lipoarabinomannan assay (LF-LAM) are considered for acquisition and deployment.
- TB microscopy increased from 1,122 in 2015 to 1,613 in June 2021, while GeneXpert coverage increased from 62 in 2016 to 315 in June 2021.
- The treatment coverage increased from 38% (n= 62,180) in 2015 to 64% (n= 85,597) in 2021: a 38% increase. See figure 2.
- TB case finding in children is based on different strategies and method, including systematic screening of children for TB in OPDs, paediatric wards, building of the capacity of health workers at district health centres to conduct gastric lavage and use of x-rays. Health Care Workers leverage available Childhood TB guidelines, desk guide, score chart, revised IMCI guidelines and appropriate algorithms for the diagnosis of childhood TB. All these have impacted positively childhood TB notification, which increased from 8,004 in 2015 to 12,124 in 2020. See figure 3

Figure 2: Trend of TB Notification vs. Target

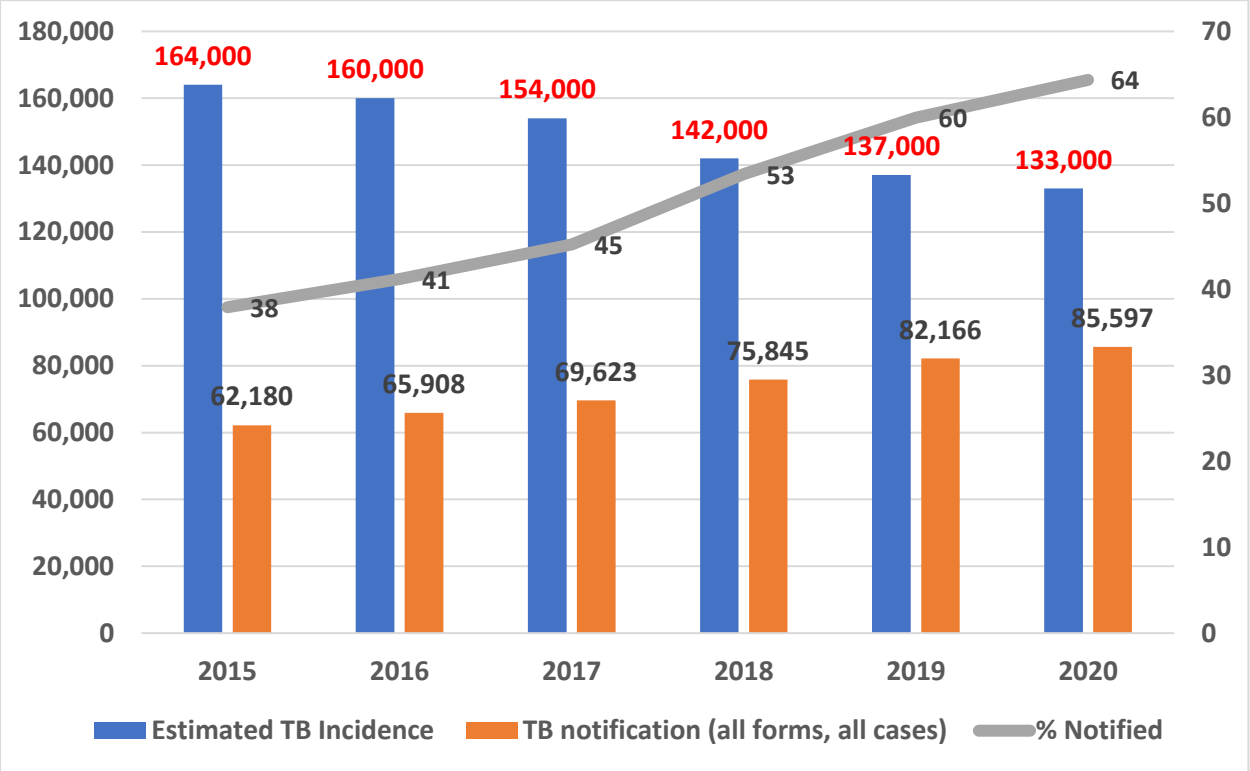
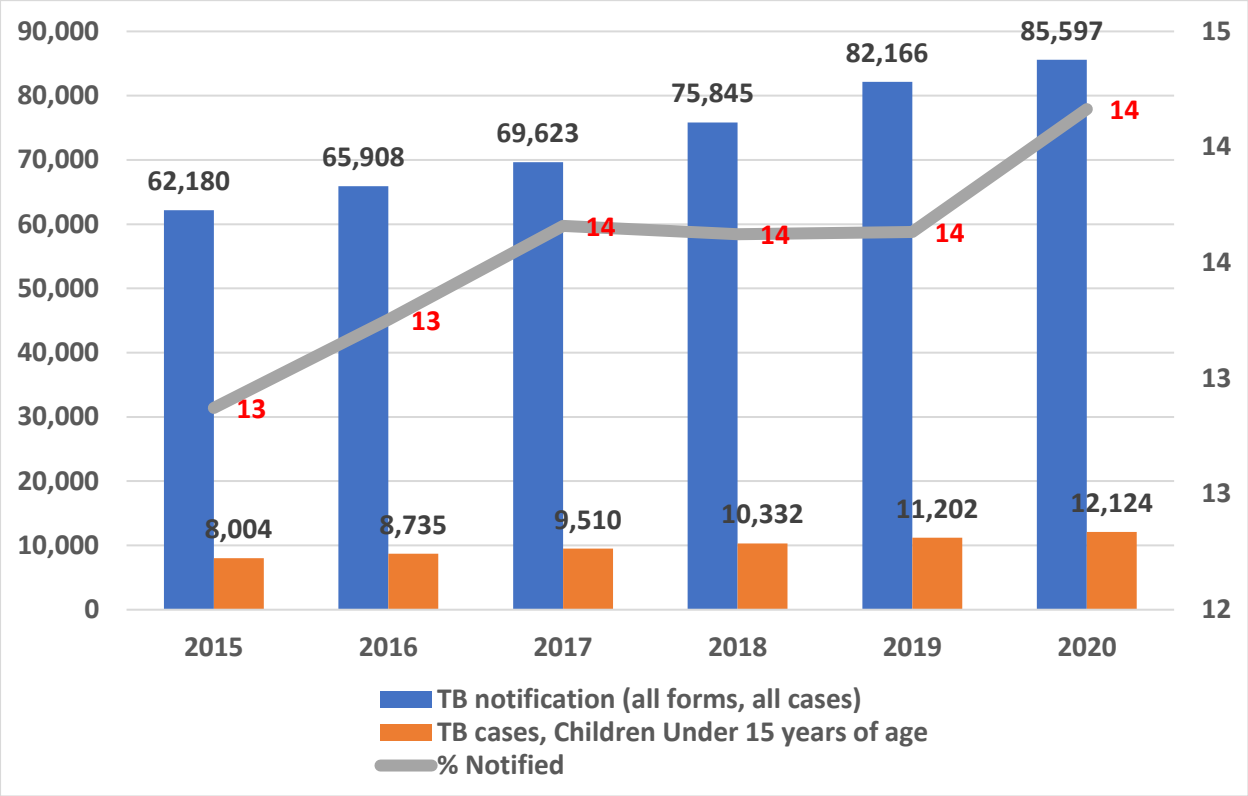


Figure 3: Trend of Childhood TB Notified among All forms of TB



7.3. Challenges and Issues to Address

- Sub-optimal testing with Xpert MTB/RIF assay: only 34% of bacteriologically confirmed TB tested with Xpert MTB/RIF. Attributable in part to stock out of catridges and modular failures.
- Case finding gap of 36%: under-diagnosis may be attributable to inadequate access to Xpert MTB/RIF assay. Also, according to the preliminary report of a research by the National Institute of Medical Research (NIMR), the missing cases are in part attributable to under reporting by about 5-10% of cases that are not notified by the laboratories and facilities in the DHIS2 and electronic TB and Leprosy (e-TL) register.
- Trend of presumptive TB not captured as a monitoring indicator.
- There is incomplete cascade analysis of ongoing case finding interventions, which implication for lack of understanding of the effectiveness of the various elements of the cascade and hence appropriate programmatic interventions.
- Access to free x-ray services is encumbered by bureaucracy as presumptive TB have to go through the process of exemption. Those who do not get the exemption or perceive any delay pay out of pocket. This process could lead to lead to missed opportunity for diagnosis or add to the already high Catastrophic Cost due to TB.

7.5. Summary of Discussions: The Tanzania NTLP has made good progress towards reducing the incidence of TB. However, as observed, the case notification gap of 36% has been attributable to both under diagnosis and under reporting. More so, the challenges of sub-optimal utilization of GeneXpert tests need to be addressed. Sputum referral linkages should be given urgent and adequate attention. The recommendations proffered below should substantially mitigate the challenges observed.

7.6. Recommendations:

- Improve sample transportation and linkage of all samples to Xpert MTB/RIF assay: **Immediately**.
- Review and/or update, finalize and operationalize NTLP tools – **(Quarter 1, 2022)** to:
    - ❖ Track the cascading of the various active case finding strategies to facilitate complete cascade analysis for the purpose of effective monitoring and evaluation of the interventions.
    - ❖ Track the number/proportion of diagnosed TB cases for the purpose of understanding and addressing under reporting of TB cases from the laboratories and health facilities.
    - ❖ Track for trend of presumptive TB over time and impact on TB diagnosis and notification. This should guide the planning process for procurement & deployment of diagnostic consumables.
    - ❖ NLTP to work with the MOHCDGEC to streamline the process of accessing free x-rays for the clinical diagnosis of TB: **Quarter 1, 2022**.

8.0. Treatment and Care for Drug-Susceptible TB

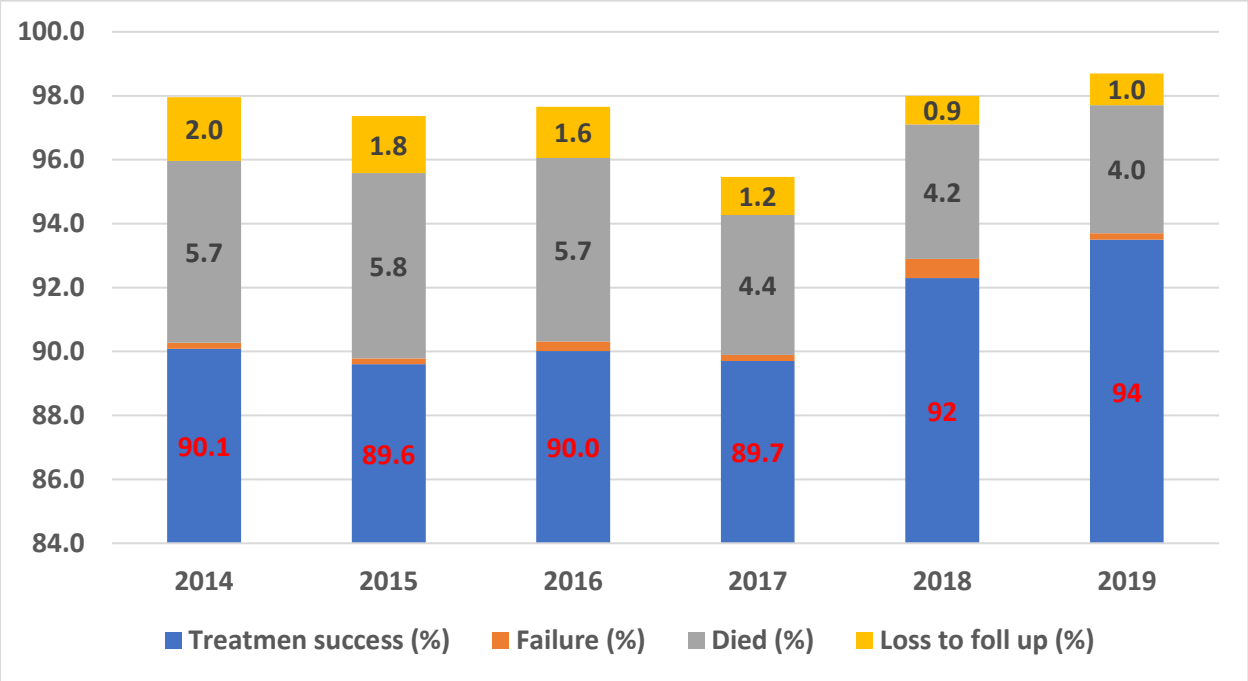
8.1. Overview: Early diagnosis and treatment are the cornerstone of TB prevention and control in the country. The patient-centred approach allows the patient to decide he or she takes treatment. The directly observed treatment (DOT) ensures that patients are supported to adhere to treatment. DOT is based on two models, namely, Health Facility-based DOTS (where patients come daily for treatment under the watch of a health care worker) and community-based DOT, where a patient chooses a family or community member to supervise his or her treatment. The treatment is based on the WHO-recommended six-month fixed dose combinations of drugs, comprising of 2 months of four fixed combination of rifampicin, isoniazid, pyrazinamide and ethambutol in the intensive phase and 4-month two fixed combination of rifampicin and isoniazid in the continuation phase.

8.2. Progress and Achievements:

- There are 3,600 DOTS centres across the country.

- Quick turn-around time between diagnosis and initiation of treatment: mostly within 24 hours.
- Effective DOT strategy in place: HCW and Community-based treatment supporters ensure adherence to treatment.
- Adequate stock of WHO pre-qualified FLDs: no stock out reported in the previous six months
- The case holding has been generally impressive. The trend of treatment success rate has increased from 92% in 2018 to 94% in 2019, which is above the national target of 90%. The unfavourable (negative) treatment outcomes have remained low and within acceptable limits, e.g., loss to follow up (LTFU) rate remained very low and the death rates have remained below 5% for the 2017, 2018 and 2019 cohorts. This impressive case holding and treatment outcomes attributable to the effectiveness of the DOT strategy. See Figure 4.

Figure 4: Trend of DS-TB Treatment Outcomes



8.3. Challenges and Issues to Address:

- NTLP does not routinely conduct treatment cohort analysis for childhood TB cases and other sub-populations.
- 2021 Global TB Report estimates that of the 26,800 TB mortality, 17,000 (63.4%) occurred in HIV negative TB cases. This may be attributable to other co-morbidities like Diabetes Mellitus and other non-communicable diseases (NCDs).
- No form of social package for TB patients and/their treatment supporters.

8.4. Summary of Discussions: the patient-centred approach and effective DOT models of the NTLP has ensured the impressive trend in the case holding and treatment outcomes. This is further strengthened by the uninterrupted supply of WHO pre-qualified first line anti-TB drugs. No stock was reported in the previous 12 months. The recommendation should address some of the challenges observed.

8.5. Recommendations:

- NLTP should institutionalize treatment cohort analysis for children (0 – 4) and other sub-populations to identify and mitigate any peculiar challenge that may be masked: **Quarterly1, 2022**.
- NLTP to strengthen bi-directional screening for TB and NCDs as part of integrated and holistic care to improve health outcomes: **Immediately**.
- NLTP to mobilize resource for minimal support package for TB patients: **Quarter 1, 2022.**

9.0. TB Service Implementation in the Context of COVID-19:

Tanzania reported its first imported case in March 2020. The MoHCHGEC immediately put in place measures to reduce the impact of COVID-19 on TB control and vice versa. A practical guide was developed to ensure continuity in the provision of TB, Leprosy, and other services with focus on differentiated service delivery models that encourage longer prescription and shorter clinic stay to reduce congestion and effective use of person protective equipment (PPE) and institutionalization of bi-directional screening for TB and COVID-19.

9.1. Impact of COVID-19 on TB: TB case finding, and notification was not diminished the COVID-19 pandemic in 2020 as shown in the section on TB case finding and notification. According to the WHO 2021 Global TB Report, Tanzania is among four 30 high burden countries for TB (Democratic Republic of the Congo, Nigeria, and Zambia) that recorded increase in TB notification compared other high burden countries that recorded decline in TB notification. This may have been due to the fact the country did not implement a lockdown because according to Sayoki G Mfinanga et al (2021)," *that would have restricted public access to health services, especially for patients with chronic conditions like tuberculosis and HIV infection, which, in settings like Tanzania with large burdens of infectious and non-infectious disease, would have had severe effects. Lockdown might have also prevented citizens from working, affecting households' ability to afford food or health care, pushing more people into poverty*". Most importantly, the Government has continued to provide guidance by adapting and/or adopting WHO-recommended guideline and building capacity to implement infection prevention and control measures. Government also leveraged $112 million from the Global Fund to support the Government's COVID-19 response

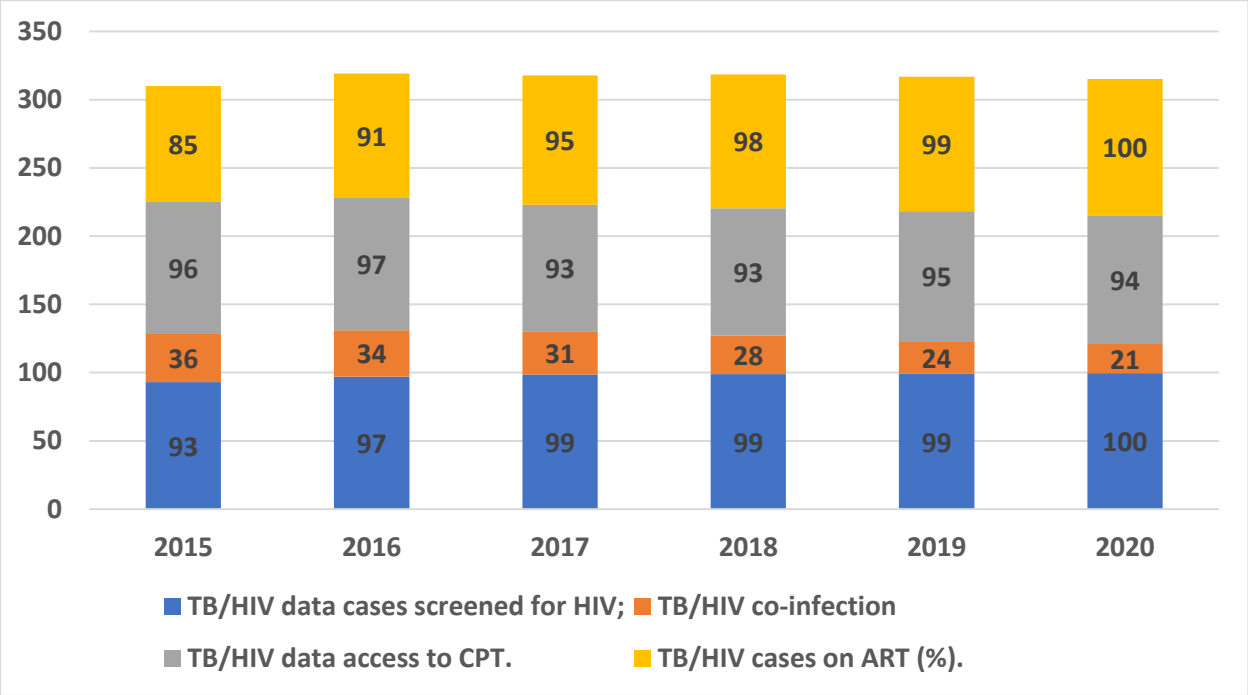
(https://www.theglobalfund.org/en/news/2021-08-17-global-fund-tanzania-deepen-partnership-to-fight-covid-19-accelerate-end-of-hiv-tb-malaria).

9.2. Recommendations:

- NTLP should Document and share country experience(s) on the impact of bi-directional screening for TB and COVID-19 on programming in the context of health emergency – **Quarter 2, 2022**.

10.0. TB/HIV Collaboration: this is well structured and integrated into routine service delivery. Provider-initiated HIV counselling and testing is provided as a routine package to all TB patients. TB/HIV collaboration as an intervention has achieved increasing and tremendous achievements in the country. The HIV status of all the registered TB patients in 2020 was known. Access to ART for TB/HIV co-infected cases attained the set target of 100%, while access to CPT was 94%, which is rightly in the upward trajectory towards the set target of 100%.

Figure 5: Trend of Access to TB/HIV Collaborative Services



10.1. Challenges:

- Sub-optimal access to CPT.

10.2. Recommendations:

- NTLP should sustain the high access to HIV screening and ART and work towards optimal access to CPT: **Ongoing**.

11.0. Cross Border TB prevention and Control: As mentioned earlier, Tanzania is the largest country in East Africa and shares borders with eight countries. The NTLP recognizes that infectious disease outbreaks is fuelled by intensive patterns of regional migration due to economic integration, socio-cultural practices like pastoralism, and insecurity. In response, the Cross Border Initiative (CBI), a partnership platform for improving surveillance of infectious disease at the borders was established in the previous six years. Now, limited cross border TB prevention and control activities were conducted at the Tanzania and Rwanda border at the Rusumo area and Tanzania and Tarakea). In the current draft National Strategic Plan 2020 – 2025, the NTLP plans to expand the Cross Border to the initiative to more borders. A Framework for Cross Border and Regional Programming in TB prevention and Control for East, Central and Southern Africa (ECSA) was developed in 2012, this has not been fully operationalized.

11.2. Recommendations:

- NTLP should generate data to drive the expansion of the Cross Border Initiative: **Quarter 2, 2022**.
- NTLP to operationalize the Cross Border Initiative activities as contained in the 2020 – National TB and Leprosy Strategic Plan: **Quarter 1, 2022**.

12.0. Organization, Management and Coordination of Programmatic Management of Drug-Resistant TB

12.1. PMDT Governance and Coordination: PMDT is integrated into the NTLP structure. PMDT is coordinated by a Focal Person within the NTLP. There is functional Consilium of Expert that meets every Monday using the ECHO platform to link with all the DR-TB treatment centres in the country. The consilium reviews cases presented by the peripheral sites and provides guidance on the management of the cases.

12.2. DR-TB Case Finding and Notification

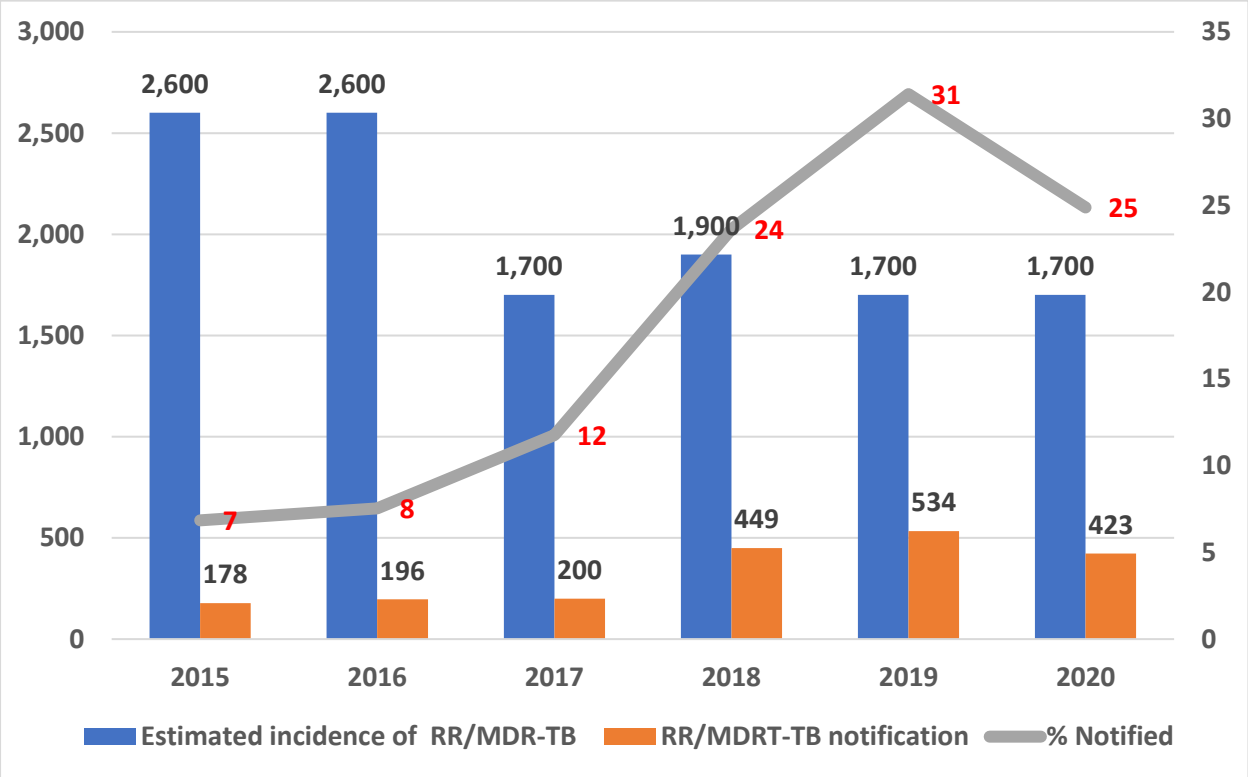
12.2.1. Overview: DR-TB case finding is integrated into the overall TB case finding strategies. However, for the purpose of surveillance, the NTLP and DR-TB guidelines have well defined priority and high-risk groups for DR-TB. These are: Treatment failure after using first-line anti-TB medicines; close contact of a known DR-TB case; patients who remain sputum smear-positive at month two or five of a first-line anti TB drug regimen; relapse and return after loss to follow-up, without recent treatment failure; healthcare workers presenting with TB symptoms and vulnerable groups in congregate settings (prisoners, urban poor, miners, PWIDs). High-risk groups for extensive drug resistant TB are also well defined. Case finding and diagnosis of DR-TB is guided by an algorithm.

12.2.2. Progress/Achievements:

- There is an updated draft PMDT guidelines based on recent WHO recommendations.
- Recording and reporting both paper-based and integrated into the electronic TB and Leprosy (e-TL) register. Documentation was good in all the centres visited.
- There is laboratory capacity for Initial diagnosis of at least rifampicin resistant TB (RR-TB) is supported through a network of 315 GeneXpert sites. About 90% of GeneXpert sites have functional GX Alert system that notify diagnosed RR-TB to the District and Regional TB/Leprosy Coordinators.
- There is also laboratory capacity for mycobacterial culture; culture-based drug susceptibility testing (DST), first- and second-Line Probe Assay.

- The notification of RR/MDR-TB increased slowly from 178 cases in 2015 to 534 cases in 2019 (with a drop in 2020 due to inadequate access to Xpert testing and perhaps the impact of COVID-19). Between January and September 2021, a total of 243 cases. The trend of notified cases shows that the proportion of new and relapse among RR/MDR TB has increased exponentially from 48% in 2015 to over 80% in 2018 and subsequent years till date. This smacks of ongoing transmission in the community due to delayed detection and inadequate infection prevention and control practices.

Figure 6: Trend of RR/MDR-TB Notification versus estimated incidence



12.2.3. Challenges and Issues to Address:

- Despite the annual increase in notification, there is still a huge case notification gap of 75% (n= 1,277) compared to the estimated incidence at the end of 2020. So far in 2021 (between January and September), only 307 DR-TB cases have been notified. The notification may therefore be at end of 2021.
- The relatively low case diagnosis and notification is attributable to the sub-optimal testing with Xpert MTB/RIF assay.
- As shown on table 1, the trend of notified cases shows that the proportion of new and relapse among RR/MDR TB has increased exponentially from 48% in 2015 to over 80% in 2018 and subsequent years till date. This smacks of ongoing transmission in the community due to delayed detection and inadequate infection prevention and control practices.

- Baseline culture/DST was not available in many treatment cards reviewed: discordance in smear and culture results observed at the Kibong'oto Infectious Hospital and Temeke Regional Referral Hospital.

Table1: Trend of Patient Category Notified

Patient Category	**Notification Period**						
	2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021 (Jan - Sept**
Total Reported	178	196	200	449	534	423	307
New & Relapse	50	89	107	276	442	362	224
%	**28**	**45**	**59**	**61**	**83**	**86**	**73**
After Failure	61	61	50	59	34	33	9
%	**34**	**31**	**25**	**13**	**6**	**8**	**3**
After LTFU	9	8	6	8	7	9	8
%	**5**	**4**	**3**	**2**	**1**	**2**	**3**
Others	0			2	3	3	2
%	**0**	**0**	**0**	**0**	**9**	**1**	**1**
Gap	58	38	27	104	48	16	64
%	**33**	**19**	**14**	**23**	**1**	**4**	**21**

12.2.4. Summary of Discussions: There is still a huge gap of 75% between the notified and estimated DR-TB cases in the country. This is mainly attributable to under diagnosis due to sub-optimal utilization of the GeneXpert test. It should also be noted that the relatively increasing trend in the proportion of new and relapses among notified RR/MDR-TB cases shows that the burden of DR-TB in the country is possibly being driven by ongoing transmission of the resistant strains of the bacilli. Infection prevention and control measures have to be strengthened at all levels.

12.2.5. Recommendations:

- NLTP should strengthen access to Xpert MTB/RIF for samples from all presumptive TB: **Immediately**.
- NTLP should improve sputum collection/referral: create referral networks based on the hub & spoke model and put in place methods for tracking sputum movement by couriers: **Immediately**.
- CTRL should work with the peripheral culture laboratories to institutionalize a quality improvement and assurance system the quality and reliability of tests: **Quarter 1, 2022**.
- NTLP should work with partners to promote IPC practices in the community and also promote early health seeking through sustained awareness creation in the community: **Quarter 1, 2022**.

12.3. DR-TB Treatment and Care

12.3.1. Overview: The treatment of DR-TB is integrated into the NTLP service delivery structure. The country adopted and commenced the implementation of the fully oral Shorter and Longer regimens for the treatment of DR-TB in 2019. Treatment is free and patient care is based on both in-patient and decentralized model. Emphasize is placed on early detection and prompt and appropriate treatment with effective drug regimens.

12.3.2. Progress and Achievements:

- The Kobong'oto Infectious Disease Hospital is maintained as the country's Centre of Excellence. Decentralized sites for the initiation of treatment increased from 145 in 2020 to 177 in 2021. In-patient care is based on criteria, e.g., patients who are seriously ill or presents with HIV and other forms of co-morbidities.
- Functional and supportive National Consilium of Experts. The consilium meets evry Monday and uses the ECHO video platform to discuss difficult DR-TB cases and provides guidance on appropriate management of such cases.
- The turn-around time (TAT) from diagnosis to initiation of treatment is 1 – 2 weeks
- 95% of diagnosed RR/MDR-TB were initiated on treatment in 2020. The trend of diagnosed versus enrolled patient is presented in figure 5.
- The NTLP has adopted the WHO-recommended all oral Bedaquiline-based treatment since 2019: However, the WHO Shorter Regimen is not in use, rather is a modified regimen being given under operational research condition. The regimens in use are as follows:
    - ❖ Modified Shorter Regimen: 6Bdq – Lfx – Lzd – Cfx – Cs - Z/ 3 Lfx – Cfx – Cs – Z under Operational Research conditions.
    - ❖ Longer Regimen: 6 6Bdq – Lfx – Lzd – Cfx – Cs / 12 Lfx – Cfx – Cs
- Baseline investigations are done as required and consent form signed by patients in the facilities visited. The follow up investigation are done accordingly. The quality of care is generally good. Patients interviewed at the KIDH expressed satisfaction with the level of care.
- Package of care for in-patients: free feeding, diagnosis, baseline & follow up investigations and treatment. Monthly transport support for ambulatory patients.
- As part of the programmatic governance and quality assurance system, quarterly DR-TB cohort review meetings are conducted. Patients' progress and treatment outcome are monitored, and difficult or challenging cases are discussed. The meeting is also used to build the capacities of the participants, among whom are DR TB care providers from KIDH and sites, Laboratory personnel from CTRL and zonal laboratories, NTLP, Regional and District TB and Leprosy Coordinators, regional aDSM focal person, invited specialists and representatives from implementing partners.

- Review of the cohort reports for Quarters 1 and 2 shows that culture conversion was 88 and 92% respectively. The unfavorable outcomes, i.e., death, loss to follow up and noted evaluated for the two the quarters were within acceptable limits. Summary is shown in table 2. The nutritional status and drug toxicity are comprehensively reviewed.

Table 2: Six-month Interim Outcome for Quarter 1 and 2 2020

Reporting period	**Percent of Patients on Treatment at 6 months**			**Unfavourable Outcomes, i.e. Percent of all Patients Not on Treatment at 6 months**		
Quarter 1 2020	92 (92%)			8 (8%)		
	Culture Negative	**Culture Pos**	**Culture Unknown**	**Died**	**Lost to Follow Up**	**Not evaluated**
	81 (88.1%)	1 (1.1)	10 (10.9%)	5 (5%)	3 (3%)	0
Quarter 2020	**Percent of Patients on Treatment at 6 months**			**Unfavourable Outcomes, i.e. Percent of all Patients Not on Treatment at 6 months**		
	88 (88%)			12 (12%)		
	80 (91.9%)	0	8 (9.1%)	9 (9%)	3 (3%)	0

- Comprehensive DR-TB programme quality improvement issues are also identified for follow up. Some of these include:
  - ❖ Inconsistency/Delay of DR-TB drugs to treatment sites from KIDH and EMS delivery
  - ❖ Some of patients are not enrolled, transferred/referred thorough ETL
  - ❖ Most sited has challenges in performing baseline and monitoring tests due unavailability and no funds to cover the costs in private facility
  - ❖ Under reporting of AE/SAE but not reported due to knowledge gap of aDSM focal persons
  - ❖ Most patients initiated on treatment in decentralized sites has no DST done
  - ❖ Lack of LPA/phenotypic DST tests at Bugando zonal Laboratory
- The case holding has been high with increasing treatment success rates of 83% and 80% respectively in the 2017 and 2018 treatment cohorts as shown in figure 6.

Figure 7: Trend of Diagnosed versus Enrolled Patients

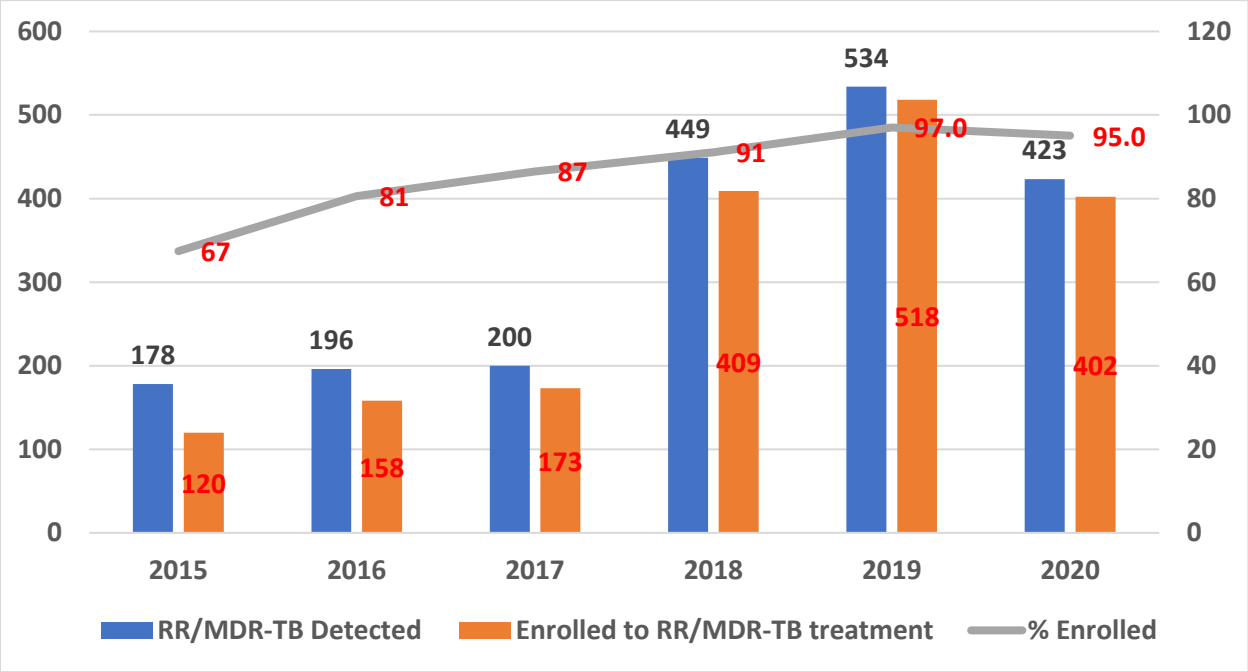
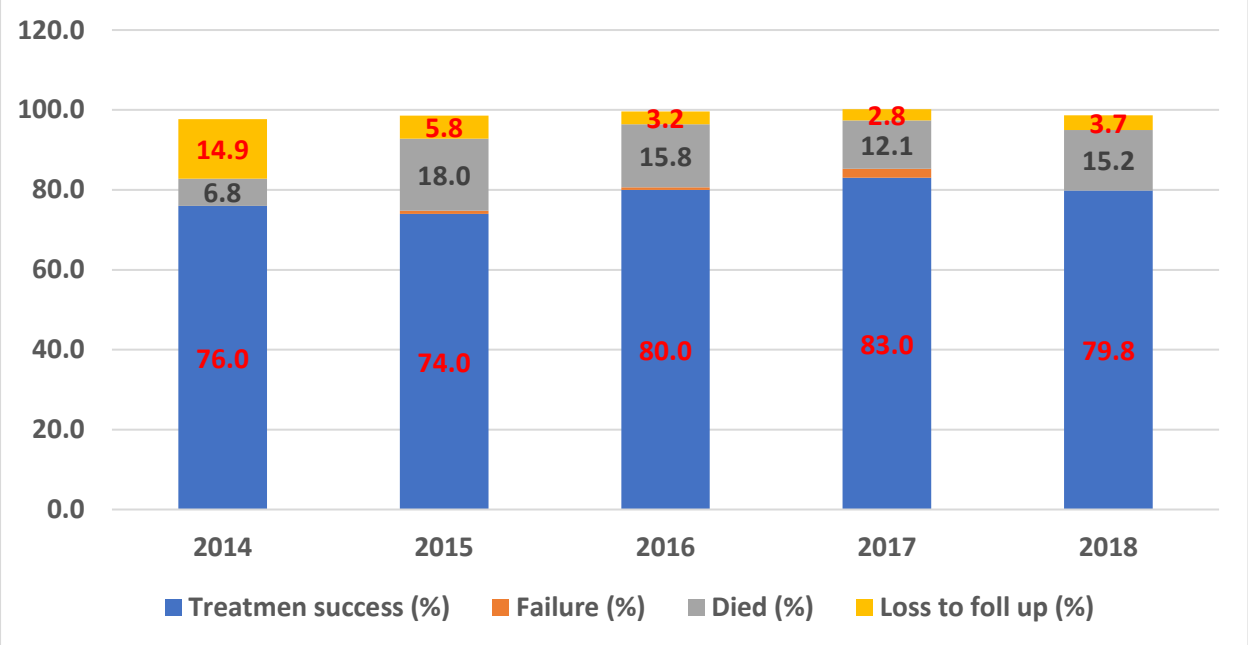


Figure 8: Trend of DR-TB Treatment Outcomes



12.3.3. Challenges and Issues to Address:

- Long TAT of LPA results and culture/DST to guide clinical decisions as part of good clinical practice and good quality of care.
- Increasing death rate due to late presentation of some cases, severe disease, and co-morbid conditions. The 2018 cohort showed death rate of 15%.

- Institutionalization of mortality audit is yet to be done. At the Kibong'oto Infectious Disease Hospital, a quick review of the possible cause of death were done for 10 of the deceased cases during the mission: 5 patients (50%) died within one week of treatment; 3 others died within two weeks of treatment while the remaining 2 died after a month on treatment. The deaths within the first two weeks are mostly due to severe disease and late presentation. Further analysis showed that 3 of the patients died due to severe aneamia; 4 due to severe acute malnutrition and HIV (stage 4) co-infection, 2 died due to extensive lung destruction secondary to silicosis and one was attributable to liver failure.
- Patients on ambulatory treatment may not easily access ancillary medicines because of bureaucratic processes of getting exemption from payment through the welfare scheme.
- The WHO recommended SR is not in use; the country is only using a modified SR under operational research.

12.3.4. Summary of Discussions: the high treatment success rates over the years are commendable and should This is variously attributable to the patient-centred approach, strategic decentralization, patient education and counselling, the model of DOT in place, uninterrupted availability of free second-line anti-TB medicines and provision of minimum package of financial support. The observed high death rates warrant the need for routine mortality audit and leverage on critical lessons to improve the clinical management to prevent preventable causes of death.

12.3.5. Recommendations:

- CTRL should provide adequate oversight for the laboratories to address the issue of long TAT for LPA and Culture/DST to ensure clinical validity and guidance for clinical decisions in patient management: **Immediately**.
- NLTP should work with WHO and other partners to identify and address the causes of late presentation of DR-TB cases at point of diagnosis/treatment: **Quarter 1 – 4, 2022**.
- KIDH MDR-TB committee to institutionalize mortality auditing with a view to identifying and addressing preventable causes of death like aneamia and severe acute malnutrition among MDR-TB patients and hence improve the overall clinical management of patients: **Q1 2022**.
- NLTP should ensure that all needy DR-TB patients have access to ancillary medicines as part of quality of care and hence favourable health outcomes for the patients: **Immediately**.
- NTLP should conduct six-monthly interim analysis of treatment outcomes for the modified Shorter Regimen as well as the Longer Regimen as part of programmatic monitoring and evaluation of the regimens: **Ongoing**.

- NTLP should consider introducing the WHO recommended Shorter Regimen as a comparator to the modified Shorter Regimen being given under operational research conditions: **Q2 2022**.

13.0. Side Effects, Monitoring and Management Development of aDSM

13.1. Overview: The implementation of aDSM is based on a concise guideline adopted from the WHO guidelines on aDSM. The Tanzania Medical and Medical Devises Authority (TMDA) act of 2018 provides the overarching guidance and regulation.

13.2. Achievements and Progress:

- Strong collaboration between NTLP and TMDA in strengthening PV system.
- aDSM system has been linked to TMDA reporting platform, i.e., Safety and Quality Reporting (SQRT).
- Ongoing TA support from partners, Pharmacovigilance Africa, (PAVIA project).
- Pharmacovigilance trainings including aDSM are being conducted using the e-blended ADR training methodology in use and TOT conducted for 36 trainers. The roll out of aDSM trainings to TB clinics has started and as of June 2021, a total of 172 health care workers working at TB Clinics were already trained and are expected to become ambassadors of ADR reporting at their workplaces including aDSM implementation
- aDSM being implemented in the facilities visited, i.e., Kibong'oto Infectious Disease Hospital (KIDH) and Temeke Regional Referral Hospital (RRH): forms are filled and transmitted electronically to the NLPT Pharmacist and thence to the TMDA.
- In KIDH, review of the forms showed that the following:
    - ❖ In 2019: 4 SAE cases – on clinical trial with Bedaquiline-Moxifloxacin and Pretomanid died of liver toxicity; 2 patients on the Shorter Regimen died (liver failure and respiratory distress) and the 4th patient had prolonged QTc.
    - ❖ In 2020: 2 on the Shorter Regimen developed SAEs and both died.
    - ❖ So far in 2021: 5 SAE cases – 4 on the Longer Regimen and 3 died variously due to aneamia/severe acute malnutrition or drug-induced liver toxicity; the 5th patient on the Shorter Regimen died due to severe respiratory syndrome.
- Similarly, in Temeke RRH, the aDSM forms were filled for five patients, who variously had grade 3 renal failure, hepatoxicity, grade 3 prolonged QTc, prolonged QTc, depression and myelosuppression. There was clear attribution of the possible causes of the SAEs/AEIs and appropriate clinical management instituted for each of the cases. Two of the cases were already resolved and patients cured while three of the cases were said to be resolving.

- Implementation of aDSM in other facilities has been slow because of lack funds to conduct training for the facility staff.

13.3. Challenges:

- There is a funding gap to cover trainings on the new electronic reporting system therefore not yet rolled out to the peripheral level. Currently, manual aDSM reporting tools are in use.
- Low ADR reporting rates despite ongoing efforts to strengthen PV system
- Inadequate reporting of all deaths in KIDH in 2020 and 2021.
- No feedback from TMDA on analysis of causality.

13.4. Summary of Discussions: the aDSM system has been set up and there is strong collaboration between the NTLP and TMDA. The technical support by PAVIA provides great opportunity for strengthen pharmacovigilance (PV) in the country. Based on observations in the facilities visited, the coverage of aDSM needs to firmed up to ensure that all patients with reportable ADRs are documented and notified accordingly.Tthe feedback loop from TMDA to the facilities also requires strengthening.

13.5. Recommendations:

- NTLP should Mobilize resources for training of more health facilities on aDSM implementation.
- NTLP and TMDA should sensitize clinicians, pharmacists, and nurses in the MDR unit to report all cases of death, Serious Adverse Events and Adverse Events of Special Interest and submit same to appropriate level: Immediately.
- TMDA to routinely provide regular feedback on causality analysis to all reporting sites: Q1 2020.

14.0. Laboratory Services Support

14.1. Overview of Tuberculosis Diagnostic Services

The main Objective of the rGLC mission was to assess the implementation of diagnostic service delivery and identify the Progress/Achievements, Challenges and recommendations. This was guided by the National Strategic Laboratory plan (2016-2021) which is a draft and needs review. This was guided by the following strategic interventions; Strengthening 50% of underperforming diagnostic centers; Increase EQA coverage from 50%- 95%; Expansion of new TB diagnostic technologies (xpert) for detection of Drug Resistant Tuberculosis; strengthen the sample referral and efficient feedback system and Establish Laboratory quality management system.

Table 3: Implementation dashboard for TB Laboratory services

S/no	Indicator	Target 2022	Baseline 2017	Results 2019	Achievements
Objective 1: Increase access to quality assured AFB Microscopy					
1	Revive the non-functional microscopy sites from 300 in 2007 to zero by 2022	300	0	0	
2	Increase the coverage of EQA Program from 63%in 2017to 95%by 2022	95%	63%	85%	
Objective 2: Improve the diagnosis of TB among AFB-negative cases especially among people living with HIV					
1	Increase the number of laboratories performing rapid testing with the use of GeneXpert MTB/RIF technology from 83 in 2017 to 300 by 2022	300	83	213	
2	Establish reliable specimen referral system at all levels by 2022				
Objective 3: Increase access to rapid laboratory diagnosis of drug-resistant TB among presumptive and TB patients considered at risk of M/XDR-TB					
1	Increase the number of laboratories performing rapid testing with the use of GeneXpert MTB/RIF technology from 83 in 2017 to 300 by 2022	300	83	210	
Objective 4: Establish Laboratory Quality Management Systems					
1	Increase the number of zonal TB laboratories implementing QMS in order to be accredited from 1 in 2017 to 6 by 2022	6	1	5	

14.2. Key Findings and Observations**:** NTLP through the CTRL has decentralized the TB laboratory diagnostic services through the Laboratory network system organized within the four tier. The laboratory network consists of the apex which is the Central TB Reference Laboratory (CTRL) with 6 Zonal TB Reference Laboratory, thirty-two Regional referral hospitals and 188 district hospital laboratories, 1392 Peripheral TB diagnostic centers which comprises of Health centers and dispensaries. The network is

technically coordinated from the CTRL which is based in Dar es Salaam while the NTLP is in the New established capital Dodoma.

Laboratory Tuberculosis Diagnostic Services: This is well organized at the visited facilities with spacious, neat and well-equipped air-conditioned rooms to take care of both Gene xpert, Culture /DST and the LPA and power back up supply (UPS) and running water.

The diagnostic platform includes 1 Culture/ DST, 4 LPA, 303 Gene xpert hubs (334 machines) and 1613 Microscopy centers by 2021 inclusive of both faith-based and private. Gene xpert is the recommended first test for all presumptive cases. Most of these facilities are linked to treatment sites and in areas the diagnosis is not done they have a sample referral system.

During the Covid pandemic 2020 to date the TB laboratory services were not disrupted in facilities where this gene xpert machines are placed. The top leadership in the Ministry of health (MOHCDGEC) designated the National public health laboratory with staffs deployed to work there and none of the services suffered during the routine surveillance on early case detection TB drug resistant patient

TB Laboratory Coordination: There is coordination from CTRL to other TB labs within the existing network. There is also an established linkage of the CTRL and the Uganda SRL which serves as a supra reference laboratory and for networking. All policy guidelines, algorithms and the strategic plan on TB diagnostic activities are available (e.g. National Standards for Medical Laboratory, Standard Medical Laboratory Equipment Guidelines, Draft National TB Lab strategic plan 2018-2022, (xpert MTB/Rif Implementation & Roll-out Plan etc.). There is a technical Working Group (TGW) for TB diagnostic, which holds quarterly meeting, involving stakeholders, implementing partners and TB focal persons from regional, district and facility level TB diagnostic centers.

TB Laboratory Diagnostic: The diagnostic guideline outlines that Gene xpert MTB/RIF is the initial test for TB diagnosis and smear microscopy for follow up during treatment. The patient produces two sputum samples i.e., spot and early morning sample. Other Samples / specimen for EPTB are also done smear microscopy, LPA, Culture and Drug susceptibility test (DST).

Standard Operating Procedures (SOP), for all TB diagnostic, procedures, and testing algorithms were available at the Central TB labs., all other laboratory facilities that were visited.

Laboratory Information system: All Culture results are transmitted through electronic system (eTL) as well as paper based through the transport courier that is supported by Management Development for health (MDH). While 80% of all Gene xpert machines are connected to Gx Alert platform, others are transmitted through paper-based i.e. the AFB microcopy results through the sub contracted courier Tutume, Boda boda to the TB coordinators. The Laboratory Information System (LIS) is well established at the CTRL and NTLP but not linked to other TB labs in the network.

In addition, the National system has the DISA LIS is used in all zonal, and Lab Net in regional laboratories, but not yet linked and/or integrated with CTRL system. The current Epi Data at CTRL lacks the link with TB laboratories network within the country, and the patient-based data that is captured with other non-laboratory tools i.e. clinical patient based data-paper based at facility level and electronic at district, regional and national level (DHIS2).

Laboratory Quality Management System (LQMS): There is a functional External Quality Assessment Scheme (EQAS) in place for all functional TB microscopy laboratories, Gene Xpert hubs and culture and DST Labs and continue to be decentralized to lower levels of the health system including the private sector. The EQA methods used to monitor AFB microscopy test include blinded rechecking and onsite supervision. TB culture laboratories were successfully enrolled in EQA in NEQAS scheme but the EQA.

1. Gene Xpert hub received Proficiency Testing Panels
2. AFB microscopy centers
3. All functional DST and LPA sites are enrolled in EQA with a concordance rate 100%
4. **Laboratory Accreditation ISO:15189:** 24 laboratories at central and regional levels have attained international accreditation on specific scopes mainly Microscopy and gene xpert.

Sample referral systems for the TB laboratory network: The National guideline for laboratory sample referral system is available in draft 2019. They signed a service agreement for sample parcels transportation with the Tanzania post corporation May 2021. Sample collection and transportation are described in the guidelines. Sample collection manual is available at the CTRL and other health facilities i.e., Regional and District levels, Sample referral SOPs are available in the laboratories implementing Quality Management System visited. Currently, they have an Integrated Sample Referral System whereby it involves all other tests countrywide including TB with hubs /spokes.

Maintenance and validation of TB laboratory equipment: The MOHCDGEC through CTRL has signed a service level agreement (SLA) with Cepheid for all GeneXpert machine, they have also trained focal office are able to do minor maintenance services on Xpert machines. The Medical Engineers from the Ministry of health to service and calibrate the other Laboratory. equipment e.g. Freezers, Biosafety cabinets, and centrifuges.

Laboratory Workload

Central Tuberculosis Reference Laboratory

Year 2020				
Culture Samples (CTRL)	**Total**	Positive	Negative	Contamitated
	3042	**988**	**2018**	**36**
			Contamination Rate	1%
LPA 1	**Total**	Mono or Multdrug resistant	Sensitive to All	MTB Not Detected
	156	26	119	40
LPA 2	**Total**	Mono or Multdrug resistant	Sensitive to All	MTB Not Detected
	28	0	26	2

Year 2021 (Q1-Q3)				
Culture Samples (CTRL)	**Total**	Positive	Negative	Contamitated
	1936	**517**	**1252**	**67**
			Contamination Rate	3%
LPA 1	**Total**	Mono or Multdrug resistant	Sensitive to All	MTB Not Detected
	86	15	22	49
LPA 2	**Total**	Mono or Multdrug resistant	Sensitive to All	MTB Not Detected
	8	0	4	4

Genexpert					
Target	**2018**	**2019**	**2020**	**2021**	
968924	**143465**	**223589**	**231853**	**96868**	**Total**
utilization rate	**14.80%**	**23%**	**23.90%**	**9.90%**	
	19959	17063	17840	7379	T
	120038	182487	188785	74480	N
	758	633	671	377	RR
Positivity Rate	0.50%	0.20%	0.20%	0.30%	
	7081	11616	12628	6104	ERROR
	2036	3932	2930	1156	INVALID
	4315	7395	8259	3059	

14.3. Progress & Achievements:

- A very well-established structured Laboratory Network, which consists of the Central TB Reference Laboratory (CTRL); 5 Zonal TB Culture Laboratories, Zonal TB Culture, 303 GeneXpert sites and 1,613 microscopy sites.
- Ongoing Culture, LPA and DST services
- 2 Staff going to SRL for capacity building on DST for new SLDs: Bdq; Dlm; Lzd and Cfx.
- Ongoing verification method on Xpert Ultra for possible adoption and roll out in the country.

- Stool sample to be adopted soon for Xpert for the diagnosis of TB in children.
- New Laboratory complex being built ay Kibong'oto COE for MDR TB

14.4. Challenges and Issues to Address:

- The 2016 – 2021 National TB Laboratory strategic plan is due for review.
- Abysmally Low GeneXpert utilization rate as follows: 14.8% (2018); 23% (2019); 23.9% (2020) and 19% in 2021 (January to September). Performance by the end of 2021 likely to far lesser than the preceding years.
- Stock out of consumables for MGIT/LPA reported by the laboratories.
- Prolonged TAT for LPA /Culture results.
- Inadequate technical oversight for regional culture laboratories e.g., Discordant results between baseline smear and culture results.
- Inadequate quality improvement and quality assurance system to address to identify discordant results e.g., smear vs Culture at baseline.
- There are different laboratory reporting platforms such as TB Laboratory Information System, GX Alert, DHIS and Laboratory net. There is need for streamlining.

14.4. Recommendations:

- NTLP should review/update the TB Laboratory strategic plan and operationalized in line with the NLTP Strategies: **Quarter, 1 2022.**
- NTLP should conduct a thorough assessment of health facilities to guide the strategic deployment of GeneXpert machines for the purpose of ensuring optimization: operational considerations should include power supply: **Quarter 1, 2022.**
- NTLP should also consider the procurement of other molecular diagnostics like the Trunat for strategic deployment, e.g., to hard-to-reach or under-served areas: **Quarter 1 2022**
- NTLP Ensure adequate stock of catridges and LPA consumables: **Quarter 1, 2022**.
- NTLP should improve sputum referral linkages to molecular diagnostic sites based on the hub and spoke model and as well put in place a tracking system for the movement of samples. Ensure all samples are tested with molecular diagnostics: **Immediately**.
- NTLP should strengthen demand creation activities including the Sensitization of clinicians, more community engagement/ mobilization and enhancing public enlightenment e.g. Jingles on Radio and TV, social media, pamphlets to improve, celebrity endorsement model: **Immediately**.
- NTLP to work with the CTRL to identify and address the causes of the reported delay or the prolonged TAT: **Immediately**.

- NTLP should develop a mitigation plan to avoid procurement delays in future: **Immediately**.
- CTRL to provide regular supportive supervision and Mentoring of the laboratory staff, especially in the sites performing cultures and molecular tests: **Immediately**.
- CTRL to work with the peripheral laboratories to put in place the Quality Improvement system to improve services: **Immediately**.
- NLTP should work with the CTRL to harmonize the reporting and integrate the TB data: **Quarter 2, 2022**.
- CTRL should facilitate the enrollment of the regional culture laboratories for ISO certification for LPA, Culture and DST for FLD /SLD.

15.0. Health System Support

15.1. Infection Prevention and Control:

15.1.1. Overview: There is an integrated infection prevention and control guidelines that focuses on building the capacity of health facilities to handle the threat of communicable diseases like Ebola Virus Disease, TB, COVID-19, etc. The guidelines spell out the fundamentals and processes of infection prevention and control, including prevention in special settings.

15.1.2. Progress & Achievements:

- National IPC Focal Point
- Updated National IPC guidelines (2018 edition).
- Functional Hospital IPC Committees in KIDH and Temeke RRH; facility IPC policy also available.
- Ongoing capacity building and sensitization for HCWs.
- Handwashing stations in various parts of the facilities.
- Available IPC IEC materials in the facilities visited.
- Spacious and well-ventilated waiting areas in the facilities; triaging of patients; handwashing or use of sanitizers in the facilities; (variable) use if face masks by HCWs and clients/patients
- Good waste management practices in the laboratories visited.

15.1.3. Challenges:

- Lack of N-95 respirators in the hospitals visited though we told that these were available in the Medical Supply Department.
- Variable compliance in the consistent use of face mask by HCWs.
- Lack of TB surveillance among HCWs: no periodic TB screening for HCWs.
- No evidence of regular or effective monitoring and evaluation of IPC activities.

15.1.4. Recommendations:

- NLTP should ensure the availability and use of N-95 respirators for HCWs in high-risk units in the facilities, especially laboratories and MDR-TB units. Leverage available stock at Medical Supply Department (MDS): Immediately.
- IPC Focal Point to work with health facilities to ensure continuous sensitization of HCWs on IPC compliance: Ongoing
- IPC Focal Point to liaise with Health facility managers to institutionalize periodic screening of HCWs for TB: Ongoing
- IPC Focal Point to work with facility IPC focal points to ensure regular and systematic monitoring and evaluation of IPC practices and mitigate observed lapses: Immediately.

15.2. Information System and Data Management

15.2.1. Overview: The NTLP has a functional integrated monitoring and evaluation (M&E) system that monitor TB/DR-TB and leprosy case detection and treatment outcomes. The system generates and provides information required for critical decision-making at all levels of care and management. Both paper-based and an electronic TB and leprosy register are in place.

15.2.2. Progress and Achievements:

- NLTP has a functional M&E unit with a Desk Officer
- Electronic TB and Leprosy (e-TL) register fully operational in the hospitals (district, regional referral, specialist, zonal and national) and the District, Regional and National levels. The peripheral health facilities (dispensaries) use the paper-based recording and reporting tools. The District TB and Leprosy Coordinator has the responsibility for uploading data at this level of health car into the e-TL register.
- All the NLTP thematic areas of TB programming (drug-susceptible and drug-resistant TB, childhood TB, PPM-DOTS, TB in prisons, contact investigation and community-based TB) are integrated into the e-TL register

- Paper-based recording and reporting system done at the PHC facilities
- Quality Assurance activities include:
    - ❖ Quarterly Regional M&E meetings.
    - ❖ Bi-annual data review meetings.
    - ❖ Annual NLTP review meeting provides the platform for all partners.

15.2. 3. Challenges:

- No tool to facilitate the complete cascade analysis of the various case finding interventions.
- Current TB notification tool does not track trend of presumptive TB.

15.2. 4. Recommendations:

- Review and/or update, finalize and operationalize NTLP tools (by Q1 2022) to:
    - ❖ Track the cascading of the various active case finding strategies to facilitate complete cascade analysis for the purpose of effective monitoring and evaluation of the interventions.
    - ❖ Track the number/proportion of diagnosed TB cases for the purpose of understanding and addressing under reporting of TB cases from the laboratories and health facilities.
    - ❖ Track for trend of presumptive TB over time and impact on TB diagnosis and notification. This should guide the planning process for procurement & deployment of diagnostic consumables.

16.0. Global Drug Facility Report: Drug Quality and Management

16.1. Overview**:** Presently, Tanzania procures TB medicines through GDF with 100% of the FLDs and SLDs budget being covered by the Global Fund. To ensure uninterrupted supply of quality assured TB commodities at all levels, the TB program is implementing various interventions aimed at improving procurement, in-country distribution, stock management and TB supply chain management in general. The introduction of TB eLMIS which was done under the previous NSP helped the country to successful transition from push to pull inventory control system for FLDs. The country is currently implementing the new NSP for the period 2020–2025 where the need to ensure integration of SLDs and laboratory commodities within the existing supply chain to improve data visibility and continue building capacity of health care workers on the management of TB have been identified as some of key areas of focus.

16.1. Programme Management

16.1.1. Progress and Achievements:

- There is continued government's commitment to support TB PSM component. Funds are provided for warehousing and in-country distribution of TB commodities and for custom clearance when need arises. Currently, the MSD charges 11.6% of the total procurement costs to cover warehousing and in-country distribution of which 5.6% is covered by the government and the remaining 6% by the Global Fund.

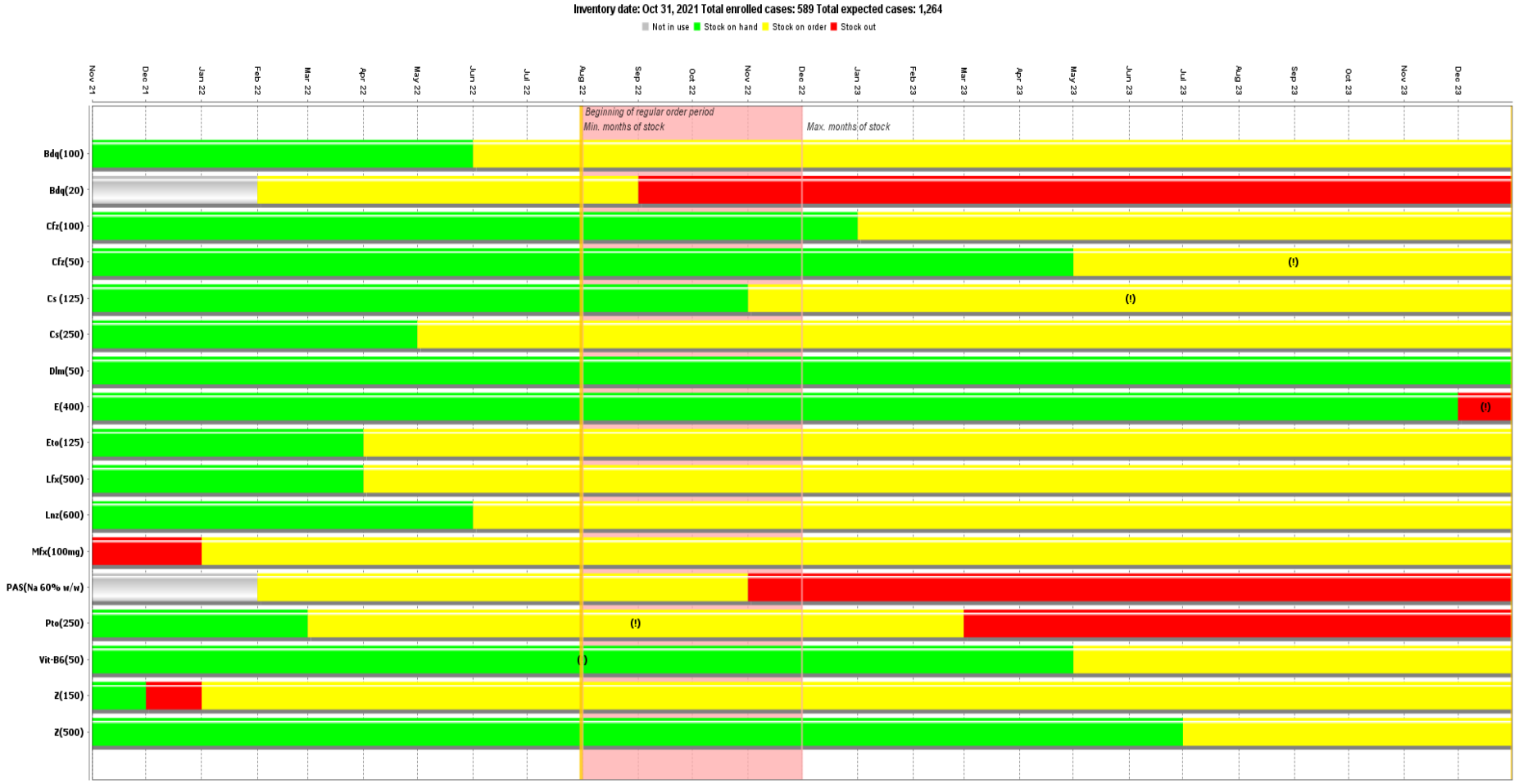
- The country has also maintained a strong collaboration and coordination among NTLP, MSD, TMDA, HIV program, PEPFAR/USAID and WHO in the implementation of TB PSM activities, aDSM and TPT related interventions. There is also on-going TA support from partners mainly USAID funded Global Health Supply Chain (GHSC) project in strengthening TB supply chain system

- There are two full time PSM staff at NTLP dedicated to support the management of TB PSM component. Adequate capacity has also been maintained within the NTLP for quantification of TB commodities, procurement and managing other TB supply chain interventions. Quantification reviews are conducted biannually using Quan TB tool followed by quarterly stock status reviews.

- All-oral DR-TB treatment regimens have been rolled out in line with the latest WHO DR-TB treatment guidelines including the modified all-oral shorter DR-TB regimen currently being implemented under operational research from early 2020. The new child-friendly DR-TB formulations are also being scaled up though the uptake was slow at the time of the mission. The roll out of the WHO recommended shorter LTBI treatment regimens has yet to commence, but progress has been made to establish technical working group to inform the Ministry on the transition process. Currently, the country is considering introducing 3HP for adults PLHIV and 3RH for under five years children TB contacts.

- Overall, the country has been able to ensure a steady supply of quality assured first line and second line TB medicines. No stock outs of TB medicines were reported in the past 12 months despite the COVID-19 pandemic. Funds have been secured for procurement of TB medicines and laboratory commodities to cover 2021-2023 through the Global Fund grant: These include USD 18,755,345.01 for TB medicines and USD 15,720,752.06 for laboratory commodities.

SLD Stock Status as of 31 October 2021



16.1.2. Challenges:

- There is funding gap of approximately USD 4.3M for procurement of Xpert Cartridges despite the increase in the Global Fund investment in Tanzania: The total Cartridges needs for 2022 are estimated to be close to 12,000 packs of 50 based on the current GeneXpert utilization rate. Out of those, funds have been allocated for procurement of 5067 packs under the year two budget of TB GF grant for 2021-2023. NTLP is yet to receive confirmed commitments under the HIV GF grant component and from the USAID/PEPFAR which have been additional sources of funds for procurement of Cartridge.
- Ancillary medicines are currently not included in the available Global Fund budget for procurement of TB commodities except Pyridoxine. DR-TB patients are required to access the respective medicines through the general supply chain system. However, most DR-TB patients end up paying due inability to follow the required procedures for payment exemption.
- Delayed disbursement of funds for storage and distribution under government support is also a challenge.
- Inadequate number of PSM staff at KIDH. 7 staff are currently available instead of the required 16 PSM staff in line with the government of Tanzania scheme of services.
- Slow uptake of the modified STR and new pediatric SLD formulations than earlier planned. The initial plan was to enroll 55% of DR-TB patients on mSTR in 2021 and increase the proportion to 65% in 2022. From quarter 1 to 3, 2021, the country only managed to enroll 33% of the notified DR-TB cases on mSTR. However, enrolling more DR-TB cases on longer all oral DR-TB treatment regimens than earlier planned could have positive effect on consumption of adult SLDs stock which may be overstocked once new shipment arrives due low DR-TB enrollment trends compared to the target used to inform procurement. Slow uptake of pediatric SLDs has contributed to potential expiry of Cycloserine 125mg and potential overstocks of Ethionamide 125mg and Pyrazinamide 150mg.

16.2. Pharmaceutical Management

16.2.1. Progress and Achievements:

- The National Essential Medicines List (NEML) is in place updated in July 2021 where almost all WHO-recommended TB medicines have been added, including the newer TB medicines (bedaquiline and delamanid) and repurposed medicines (such as linezolid though Clofazimine is still indicated for Leprosy only). However, the child-friendly DR-TB formulations have yet to be added except for Ethionamide 125mg. The mission also noted that phased out TB medicines such as Capreomycin injection, Kanamycin injection, Rifampicin+Isoniazid+Pyrazinamide+Ethambutol (RHE) and Ethambutol400mg +Isoniazide100mg (EH) are still captured hence suggesting the need to immediately update the new version to align with the current WHO recommended TB treatment guidelines.

- There is on-going monitoring of the quality of TB medicines including post-marketing surveillance through the WHO pre-qualified and ISO Certified quality control laboratory located at TMDA. Based on the study on quality surveillance of TB medicines conducted by the TMDA from 2012 to 2018 and published in March 2021, all samples of TB medicines which were collected from different supply chain areas during the respective review period were found to be of acceptable quality. In addition, no TB medicine reported to have failed quality test in the past twelve months.

- Efforts are being made to ensure timely submission of ADR reports though there is still low ADR reporting rate. A merged online Safety and Quality Reporting tool (SQRT) was recently developed and electronic aDSM reporting tool has also been integrated and linked to this new reporting platform. Plans are underway to sensitize all DOT clinics (over 3000 facilities) on the developed electronic aDSM reporting.

- Good storage practices at the MSD and KIDH SLD storage hub: There is adequate space at the visited MSD warehouse, well arranged and fully equipped. Good record keeping practices and optimal temperature conditions were also observed at both sites. Progress has been made to improve stock management practices at the MSD. The warehouse inventory management system has been upgraded from EPIC0R 9 to 10.2 since July 2020. This has further improved stocks visibility across MSD warehouses

- The existence of functional logistic management information system (LMIS) has helped to improve recording, reporting, and ordering of FLDs. The country has continued to implement e-LMIS for FLDs up to the district level. The roll out of health facility level e-LMIS has started in 5 out of 27 regions since end of 2020 where 150 health care workers have been trained on the new optimized system for FLDs during the financial year 2020/2021.

- Optimized supply chain system for management of DR-TB medicines has also been developed with support from the USAID/GHSC Project to align with the mainstream country`s supply system for other commodities. TOT has been conducted involving 30 trainers to allow rapid roll out of the developed system. Once implemented, storage and distribution of SLDs will be decentralized from KIDH to zonal MSD warehouses in line with the ongoing efforts to decentralize MDR-TB treatment services. The new system will help to enhance visibility of SLDs stocks available at health facility level and of DR-TB patients' enrollment data by regimen for easy stocks monitoring. Furthermore, it will reduce distribution cost for SLDs which are currently stored at KIDH and distributed to other treatment sites using a parallel distribution system through postal express mail services (EMS).

16.2.2. Challenges:

- Erratic supply of some laboratory commodities. At the time of the mission, there was a shortage of Xpert Cartridges (0.7MOS) and Sputum containers (3MOS) at the central level as well as stock out of N95 respirators at the central level and visited facilities. Erratic supply of Cartridges and Sputum containers can be attributed to inadequate coordination among NTLP and partners in rolling out the intensified case finding interventions. According to the NTLP, additional 37 Xpert machines have been procured with financial support from partners. However, these together with the related active case finding targets and assumptions were not factored in during the forecasting process for Xpert

Cartridges. The observed shortage has been further affected by delays in initiating procurement under the new Global Fund grant currently being processed.

- Prolonged procurement lead time for TB laboratory commodities via MSD for products that are currently not in the GDF's products catalogue. A 4-month delay in the disbursement of funds was observed at the time of the mission based on the procurement request which was submitted in July 2021. Additionally, some orders for laboratory commodities are small in quantity contributing to tender failure and the need for readvertisement hence further delays.
- Recurring back orders/emergency distribution from MSD headquarters to zonal stores leading to extra distribution costs. This mainly occurs when stock levels are low for some TB commodities at the MSD headquarters. As a result, MSD makes efforts to distribute outside the normal distribution cycle once new shipments arrive which has cost implication.
- Delayed roll out of the developed optimized supply chain system for DR-TB. Storage, and distribution of SLDs is still managed by the KIDH.
- Inadequate funding to support training of health care workers on the new integrated electronic Safety and Quality Reporting Tool (SQRT) including aDSM.

14.3. Recommendations:

- Need to mobilize additional resources to bridge the funding gap for procurement of Xpert Cartridges, ancillary medicines and ensure timely procurement to avoid interrupted supply: **Quarter 1, 2022 by MOHCDGEC/NTLP**.
- Follow up on disbursement of funds for storage and distribution and for procurement of laboratory TB commodities initiated via MSD. Procurement process needs to be fast tracked: **Immediately by MOHCDGEC/NTLP**.
- Improve quantification of TB laboratory commodities, engage all relevant stakeholders in setting realistic targets and assumptions: Immediately by NTLP.
- Fast track the roll out of optimized system for management of DR TB medicines to ensure pipeline visibility and reduce distribution cost: Quarter 1, 2022 by NTLP/Partners.
- Expedite the roll out of health facility level e-LMIS for FLDs, identify and address factors affecting effective roll out of e-LMIS for TB laboratory commodities: **Quarter 2, 2022 by NTLP/Partners**.
- Need to initiate all future procurements based on the actual program performance/enrollment trends. Targets should only be used for planning and budgeting purposes: **Quarter 2, 2022 by NTLP**.
- Ensure effective use of EWS alerts generated by the QuanTB tool in making timely supply chain decisions: **Ongoing by NTLP**.
- Initiate new procurement of FLDs immediately to avoid stocks out and ensure stock levels are always maintained within recommended min-max stock levels: **Immediately by NTLP**.

- Optimize the use of e-LMIS in tracking of key TB supply chain indicators including reporting rates, completeness of reports and medicines availability: **Ongoing by NTLP and Partners**.
- Mobilize resources for training of HFs on aDSM implementation: **Quarter 1, 2022 by NTLP**.
- Intensify supportive supervision to ensure that treatment guidelines for managing childhood DS TB are followed by all HCWs to avoid expiries: Ongoing NTLP
- Need to improve recordkeeping practices and ensure AC is functional at Temeke dispensing unit: immediately by RTLC/MOI Temeke
- **Consider introduction of patients' kit pack/kits to** prevent treatment interruptions for patients already on treatment and simplify stock management process: **Quarter 3 2022 by NLTP**
    - Conduct quantification exercise to establish the required budget
    - Develop a training plan to cover pharmacy staff and TB Health workers at storage dispensing points
    - Review/update LMIS tools
    - Mobilize resources
- Expedite the roll out of the new WHO recommended LTBI regimens-3HP and 3RH: **Immediately by NLTP**:
    - Conduct quantification exercise and establish the required budget for procurement of the new LTIB products to inform the transition process.
    - Develop LTBI transition plan.
    - Mobilize resources for procurement and other related activities.

17.0. Summary Report of Visits to Health Facilities

17.1. Visit to Kibong'oto Infectious Disease Hospital

- The facility is the main infectious disease hospital in the country and srves as the Centre of Excellence for Drug-Resistance TB management. The retinue of staff include 20 medical doctors (inclusive of specialists); 2 pharmacists; 5 pharmacists' technicians and one assistant pharmacy technician, 21 laboratory staff and many nurses.
- There is a ward with 56 beds for inpatient management of drug susceptible TB: a total of 34 patients were on admission at the time of the GLC mission. Also, there 79 bedded wards for the in-patient management of drug resistant TB.
- The hospital also provides general out-patient services, mycobacterial and other laboratory services. A gigantic regional (zonal laboratory complex is being built through the effort of Government and Global Fund.
- Though primarily an infectious disease hospital, integrated health services are provided. The entry point for all clients/patients is the registration unit, where cards are obtained and thence to the OPD for checking of vital signs and triaging. Clients with chronic cough or

observed to be coughing are referred to the DOTS clinic for capturing in the facility register for presumptive TB as well as in the electronic medical records. The clinicians then review and sends the patient to the laboratory for TB bacteriology. Bacteriologically positive patients are placed on treatment with 24 hours of diagnosis. Bacteriologically negative patients further evaluated and clinical diagnosis made with the use of x-rays and other investigations. Overall, TB management is based on the NLTP guidelines. Patients are mostly managed on ambulatory basis but seriously patients are admitted into the ward for for drug-susceptible TB patients until patients are stabilized and discharged home to continue treatment. There is adequate

- NTBLP tools like SOPs, recording and reporting materials, desk for data capturing in the electronic TB and Leprosy register, were available and being utilized appropriately.
- X-ray services are not free, and this adds to the direct cost by patients or relations.
- There is no facility-based register for contact management.

Infection Prevention and Control practices: the hospital has a standing infection prevention and control committee and members have been trained appropriately. There is a also a hospital IPC policy. Observed IPC practices included:

- Handwashing stations in various units; however, soap or sanitizer not necessarily available in all the stations.
- Spacious, open, and well-ventilated waiting areas.
- Variable use of face masks by health workers; many clients/patients were seen with face masks.
- There is no systematic surveillance of TB among the health care workers, especially among the staff working in the risk areas like the DOTS clinic, DR-TB ward, and TB laboratory.

DR-TB Management: the hospital serves a referral treatment centre for DR-TB patients from other parts of the country. The DR-TB unit has three wards with a total of 79 beds (48 for males and 31 for females). A total of 57 patients were on admission (42 males and 15 females). Admission and management are based on the National PMDT guidelines:

- Baseline tests, including ECG, clinical, haematological and bacteriological (first- and second-line LPA and culture) are conducted; and patients are enrolled on treatment within 3 – days of admission; length of admission is variable depending on the patients' clinical and social conditions until they are clinically stable or social issues addressed; averagely patients spend two to three weeks while other spend their entire treatment in the hospital;
- Allocation is treatment regimen is criteria based: most patients are enrolled on the modified Shorter Regimen (being provided under operational research conditions) while a few are placed on the individualized Longer Regimen.
- Cumulatively, 121 patients were admitted in 2020 of which, co-morbidities included 32 HIV/DR-TB co-infected; 4 with silicosis (of which two died) and 3 with diabetes mellitus;

overall 21 died. So far in 2021, 85 patients were admitted with 20 being HIV/DR-TB co-infected, 3 with diabetes mellitus and 3 with silicosis (1 died). A total of 10 patients died so far in 2021.

- There is no systematic mortality auditing to profile the cause of death. However, a quick review of the possible cause of death were done for 10 of the deceased cases during the mission: 5 patients (50%) died within one week of treatment; 3 others died within two weeks of treatment while the remaining 2 died after a month on treatment. The deaths within the first two weeks are mostly due to severe disease and late presentation. Further analysis showed that 3 of the patients died due to severe aneamia; 4 due to severe acute malnutrition and HIV (stage 4) co-infection, 2 died due to extensive lung destruction secondary to silicosis and one was attributable to liver failure.
- Random review of patients' records showed that there is discordance between the baseline smear and culture results with the former being positive and the latter being negative in most cases. This smack of specimen quality issues and/or laboratory processes like decontamination processes. The need for a quality improvement and assurance be instituted and a more regular and oversight provided by the Central TB Referral Laboratory.
- Drugs are available and no stock out reported in the previous six months.
- Patients expressed satisfactory with the quality of care including the meals being provided. No serious adverse drug effect was reported by the patients.
- Nurses use face mask but N-95 respiratory was acutely in short supply. Again, there is systematic surveillance of TB/DR-TB among the nurses, doctors or other health workers.

Pharmacovigilance and Active Drug Safety Monitoring and Management (aDSM): Both routine PV and aDSM are being conducted. The latter focuses mostly on Serious Adverse Effects as well as Adverse Event of Special Interest. The aDSM forms are filled as required and transmitted electronically to the Tanzanian Medicines and Devices Authority (TMDA). Review of the forms showed that the following:

- In 2019: 4 SAE cases – on clinical trial with Bedaquiline-Moxifloxacin and Pretomanid died of liver toxicity; 2 patients on the Shorter Regimen died (liver failure and respiratory distress) and the 4th patient had prolonged QTc.
- In 2020: 2 on the Shorter Regimen developed SAEs and both died;
- So far in 2021: 5 SAE cases – 4 on the Longer Regimen and 3 died variously due to aneamia/severe acute malnutrition or drug-induced liver toxicity; the 5th patient on the Shorter Regimen died due to severe respiratory syndrome.
- No feedback on the causality assessment has been received from TMDA.

Department of Community and Occupational Health and Safety: this unit of the hospital involved in community-based activities with focus on:

- Following with DR-TB patients discharged from the hospital to facilitate family support for the patient. This includes the provision of health education and identification of special needs and linkage to organizations/institutions to address the needs. This intervention has been quite helpful in reducing stigma and fear directed at the patient by the family and community members. Treatment adherence is also promoted/facilitated.
- Conducting mobile clinic outreaches and screening of small-scale miners to identify presumptive TB and silicosis and appropriate referral and linkages to nearby health facilities for treatment and care.
- Advocacy and Sensitization on TB among the Masai Communities.

Drug Management: The pharmacy unit has a retinue of 2 pharmacists, 5 pharmacy technicians and an assistant pharmacy technician. First line anti-TB drugs (FLDs) are managed through the web-based Logistics Management Information System (LMIS). Drug ordering is based on the pull system and supplies from the Central Medical Store in Dar es Salam consist of 3 months stock plus a buffer of 3 months. This is routinely on a quarterly basis. The lead time of supply is 5 to 6 days.

Drugs are dispensed to the patients at the pharmacy based on prescription from the DOTS clinic: drug are supplied to patients on a weekly or fortnightly basis. No stock out was reported in the previous six months.

The drug store is fitted with shelves. The air conditioner was fully functional maintaining an ambient temperature of 20 ^{0}C. Stocks cards are maintained for all the drugs and other commodities and updated: the physical stock was consistent with the stock record.

The management of second line anti-TB drugs (SLDs) have been integrated into the LMIS but yet to be rolled out. All the SLDs for the country are for now domiciled in the KIDH store and then supplies are made to the MDR-TB intake and decentralized sites based on request. Two weekly supplies are made to the patients on ambulatory treatment.

Challenges:

- Space constraint in the store.

TB Laboratory Services: The laboratory is within the Kibong'oto hospital complex. The laboratory provides integrated laboratory services. TB microscopy and Xpert MTB/RIF assay are housed at the main laboratory while the TB culture and LPA is housed in a different building within the facility next to the MDR TB Wards. The laboratory has a retinue of 7 Laboratory Scientist, 10 Laboratory Technologist/Technician, 3 Laboratory Attendant and 1 Data Clerk. There is a 16-module GeneXpert machine as well as a 4-module version with three functioning modules.

Summary of Achievements:

- The laboratory has Xpert, LPA and it performs Culture and sensitivity
- The laboratory is enrolled in in an EQA for Smear, LPA and Culture which is provided by CDC, CTRL.
- The laboratory is ISO certified for Xpert scope.
- The Staffs working at the TB Lab are screened yearly by testing sputum with Xpert MTB/RIF assay.
- They work in collaboration with community engagement thus a lab staff is attached to the mobile facility with a nurse and Radiologist
- Through the support of partners, they have done an improved BSL3 LAB for TB culture laboratory.

Summary of Strengths and Good Practices:

- Integrated health services in the facility. clients other than TB and other infectious diseases cases are catered for.
- Good quality of care for both DS-TB and DR-TB patients: the treatment success for patients in quarter 3 2020 was
- Effective utilization of the Logistic Management Information System: no drug stock out recorded in the previous six months.
- Regular conduct of both routine PV and aDSM and reporting to TMDA.
- Evolving use of Electronic Medical Records. Need to fully integrate TB information into the system.
- Functional Hospital Infection Prevention and Control committee. IPC policy also available.
- A laboratory complex being built by the Government provides opportunity for the implementation of best practices for TB bacteriology and other

Key Issues and Recommendations

S/No	Challenges/Issues to Address	Recommendations	Timelines
1	Payment for chest x-ray by presumptive TB	Provide free x-ray services as part of diagnostic process for TB diagnosis	Immediate/ongoing
2	There is no facility-based contact register for the tracking of the activities of contact tracing.	NTBLP should introduce a facility-based contact register as a management tool for triangulating contact tracing activities in the community.	Quarter 1 2022
3	Weak cascade analysis of contact tracing and	NLTP should develop and provide standard operating procedures on the complete	April 2022

	investigation and other TB screening interventions.	cascade analysis for the effective monitoring and evaluation of key active TB case finding interventions.	
4	Observed variable use of face masks by health workers in OPDs/wards	Hospital IPC committee should institutionalize M&E to ensure compliance with use of face masks and other IPC practices	Immediate/ongoing
5	Non-availability of N-95 respirators in the MDR-TB and laboratory	Procurement of adequate stock of N-95 respirators and prioritize for staff in high-risk units like the MDR-TB wards and TB laboratory	Immediate/ongoing
6	Lack of routine mortality auditing	Hospital MDR-TB committee to institutionalize mortality auditing with a view to addressing preventable causes of death like aneamia and severe acute malnutrition among MDR-TB patients.	Immediate/ongoing
7	Not all deaths in the MDR unit captured by aDSM reporting	Pharmacist in-charge to sensitize the nurses to report all cases of deaths in the MDR-TB unit	Immediate/ongoing
8	Limited storage space in the pharmacy unit	Hospital management should provide a more spacious accommodation for the storage of drugs and other commodities.	6 – 12 months
9	TB culture lab is experiencing stock for both MGIT and LPA	NTLP and CTRL to ensure adequate forecasting and quantification to avoid stock out in the immediate future.	Immediate
10	No ISO certification for other scopes like LPA, Culture/DST	NTLP and CTRL to facilitate the SIO certification for LPA, Culture/DST.	Quarter 4 2022

17.2. Visit to Temeke Regional Reference Hospital

TB Services:

- The DOTS clinics is well-ventilated; staff are trained, knowledgeable and skillful in patients management and documentation. Record keeping and organization is impressive. Paper-based records and maintained while the DTLCOs periodically upload patient information and data into the e-TL register. The serves two districts, namely Wailes 1 and 2.

- There is ongoing screening of facility attendees for TB and identified presumptive TB are referred to the DOTS clinic for documentation and collection of sputum samples. The samples are sent to the laboratory testing with Xpert MTB/RIF assay. The turn-around time for the results is 24 – 48 hours.
- The nurse in-charge of the DOTS clinic and the DTLCOs are trained to conduct gastric lavage in children. There is no national policy in place (at the time of the mission) on the use of stool for the diagnosis of TB in children.
- There is no policy for free chest x-ray for presumptive TB except exemption is granted by the social welfare office, which can be a bot cumbersome.
- Both drug susceptible and drug resistant TB cases are managed in the clinic on ambulatory basis. All patients are linked to a treatment supporter, who accompanies the patient to the clinic for the refill of drugs. There was adequate stock of first- and second-line anti-TB drugs and stock out was reported in the previous six months.
- Total TB cases detected in Quarter 3, 2021 were 326 comprising of 157 bacteriologically positive and 167 clinically diagnosed cases. There were 28 childhood TB cases.
- In 2020, a total of 24 DR-TB cases were detected and enrolled on treatment and between January and time of the mission, 16 cases were detected and enrolled on treatment. The quality of care is generally satisfactory: time enrollment of cases on treatment (within a week of diagnosis) and both baseline and follow up investigations ((ECG, haematology and clinical chemistry) are done as required. after diagnosis.
- Contact tracing and investigation is done for over 70% of bacteriologically positive index and confirmed DR-TB patients.
- Active drug safety monitoring and management (aDSM) was being done and documented for some patients: the aDSM forms were filled for five patients, who variously had grade 3 renal failure, hepatoxicity, grade 3 prolonged QTc, prolonged QTc, depression and myelosuppression. There was clear attribution of the possible causes of the SAEs/AEIs and appropriate clinical management instituted for each of the cases. Two of the cases were already resolved and patients cured while three of the cases were said to be resolving.

Challenges:

- There was adequate stock However, LPA results delay for up to 2 to three weeks. Baseline culture and drug susceptibility was documented for most of the cases.
- Review of patients' records (as observed at KIDH) also showed discordance between the baseline smear and culture results with the former being positive and the latter being negative in most cases. This smack of specimen quality issues and/or laboratory processes like decontamination processes. The need for a quality improvement and assurance be instituted and a more regular and oversight provided by the Central TB Referral Laboratory.

Recommendations:

- CTRL should work with the regional laboratories to improve the turn-around time for LPA results and put in place a quality improvement system.

Laboratory Services: Temeke regional laboratory is an integrated laboratory serving as a referral facility both for patients and for sputum samples from the peripheral facilities. The laboratory has 5 laboratory scientists, 9 laboratory technologist/technician and a laboratory attendant and is ISO certified for the GeneXpert, Viral load, HIV rapid diagnostic test and CD4. The laboratory receives samples for proficiency testing and quality assessment from the CTRL, CDC and SRL Uganda.

Achievements:

- Temeke hospital has a 16 module GeneXpert and has utilization rate of 52% with a turn-around time for results of 24 hours.
- The laboratory participates in the QA system coordinated by the CTRL. The laboratory has a sample referral linkage with the CTRL for TB culture.
- Management Development for Health supports the laboratory in the area of training, procurement and technical assistance on sensitization of the clinician on Xpert, early infant diagnosis, viral load and calibration of the machines in the laboratory.

Challenges:

1. Inadequate observation of IPC measures at the sputum sample collection at the reception
2. Sub-optimal utilization of Xpert MTB/RIF assay.

Recommendation:

1. Strengthen IPC practices at the site of specimen collection.
2. The Regional TBL coordinator with the lab staffs to sensitize the clinician to improve on the referral of presumptive TB for Xpert MTB/RIF testing as the first platform for the diagnosis of TB.

SLECTED PICTURES DURING THE MISSION

Nursing station in KIDH

Drug tray at KIDH

Female MDR ward at KIDH

Male MDR ward at KIDH

MDR-TB patients at KIDH recreating

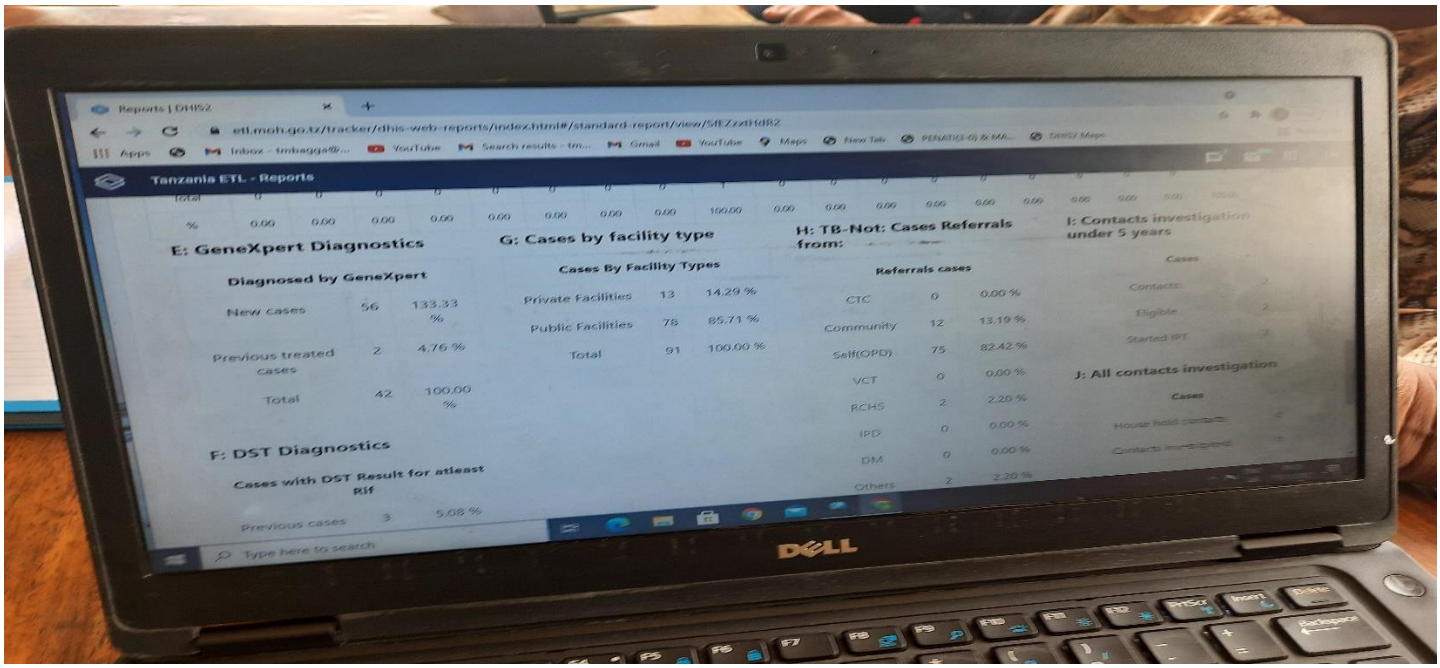
MDR-TB patients in KIDH Sun-bathing

Ultra-modern integrated laboratory complex under construction at KIDH

Front view of Kemeke Regional Hospital

GLC team at TB/DR-TB Clinic at Kemeke Regional Hospital

Screenshot of Electronic TB/Leprosy Management System



Well ventilated waiting area at KIDH

Well ventilated waiting area at Kemeke Regional Referral Hospital

Debriefing NTBLCP team

Debriefing NTBLCP team

At WHO Office Tanzania

Debriefing WHO team

Annex 1: List of Persons Met

S/No	Name of Person	designation	Contacts
	National TB and Leprosy Programme/MoHCDGEC		
1	Dr Kisonga Riziki	Programme Manager	kisongariziki@gmail.com +255 755 659206
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6	Edgar Luhanga	Laboratory Advisor	edgarluhanga@gmail.com
	Central TB Reference Laboratory		
7	Amri Miraji Kingalu	Laboratory Manager	amrikingalu@gmail.com +255 789 545422
	World Health Organization		
8	Dr Christine Chiedza Musanhu	Medical Officer, HIV/TB/Hepatitis	musanhuc@who.int +255763812308
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	Temeke Region		
11	Dr. Mary Chiyamkibi	Regional TB and Leprosy Coordinator	rosechagama@gmail.com
12	Silvester Ngow	Co-DTLC Wailes 1 District	ngusilver@gmail.com
13	Toulikifri Mbaga	Co-DTLC Wailes 2 District	tmbagga@gmail.com
	Temeke Regional Reference Hospital		
14	Dr. Kimaru	Director of the Hospital	
15	Venana Martin Mlowe	Laboratory Manager	
16	Wilson Simon	Microbiology section	
17	Dickson	Quality assurance Manager	
	Siha District		
18	Dr Jackson Kileo	District TB and Leprosy Coordinator	
	Kibong'oto Infectious Disease Hospital		
19	Dr. Subi	Director	
20	Dr Happy Mvungi	Medical Specialist in-charge MDR-TB	happinesscornel@gmail.com
21	Athumani Mohamed Ngoma	Pharmacist in-charge	Athmazan3@gmail.com
22	Dr Alexander William Mbuya	Medical Specialist in-charge OHS Unit	Kiletsa13@gmail.com

23	Richard Kihyala	Head, Microbiology	
24	Samson Mushi	Deputy Laboratory Manager	
25	Mpoki Jonas	Microbiology Unit	
26	Faith Musangi	Head, Serology	

Annex 2: Reference Materials/Documents

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