Here's all you need to know about additions to the Stop TB Partnership's Global Drug Facility (GDF)'s Catalog and latest missions to provide technical assistance to countries and support National TB Programs in managing procurement

- Latest additions and updates to the Stop TB Partnership's Global Drug Facility's Catalog

IGRAs
GDF has expanded its Diagnostics Catalog by adding an IGRA (interferon-gamma release assay) test for latent TB infection. The products required to run the Quantiferon-TB Gold Plus (QFT-Plus) IGRA are now available at a GDF-negotiated price of $15.90 per test by the manufacturer Qiagen (Hilden, Germany). This price is offered to any public sector or not-for-profit buyer in low- and middle-income countries when procuring through GDF. For the full listing of products, see the GDF Diagnostics Catalog. In addition to the QFT-Plus IGRA, GDF is expecting to soon be able to add a second IGRA test to its catalog, as well as generic products used to run the tests.

GeneXpert
The GeneXpert Edge has been added to the GDF Diagnostics Catalog. The Edge is a one-module GeneXpert system that comes with external batteries to allow for a full day of testing and a tablet instead of a laptop or desktop computer. It is priced at $8,945. The system’s batteries and a standard HEPA filter are expected to help overcome many of the challenges related to power outages and dust that have prevented GeneXperts from being used effectively in some peripheral settings. An optional larger battery can also be procured with the system to allow the Edge to be plugged into a wall socket, with the battery serving as a UPS. Note the Edge still requires an air-conditioned room, as it uses the standard GeneXpert modules. For more information, see the GDF Technical Information Note on Xpert and the GDF Diagnostics Catalog.

The shelf life of Ultra cartridges has been lengthened. Cepheid now provides GDF clients with a minimum of 11 months shelf life (up from a minimum of 6 months). The maximum available shelf life is 15 months.

- Stop TB Partnership’s Global Drug Facility’s participation to the Joint TB Program Monitoring Mission in Eswatini, 14-25 October 2019

The TB/HIV Joint Programme Review was conducted on 14-25 October 2019 with the goal being to review the country achievements in implementation of the 2015-2019 National Strategic Plan.

Eswatini is among the countries that are quick to adopt new tools and strategies. The country has already transitioned to the new WHO guidelines for DR-TB and is also implementing the new TPT option 3RH with plans to roll out 3HP in the long term. The new pediatric formulations for DR-TB are also available in country. There is capacity for use of QuanTB tool and generation of early warning system (EWS) reports. The government meets 100% funding for procurement of FLDs and SLDs with diagnostics being largely funded through the GF grant. There is adequate storage capacity with optimum storage conditions at the government owned central medical stores (CMS). The country has implemented active drug safety monitoring, though reporting remains low.

 Untimely disbursement of funds from government for procurement frequently disrupts supply planning. As a result, frequent stock outs and emergency situations are experienced across the country. The EWS
reports are not regularly utilized to monitor stock situation. Generation of real time inventory reports at CMS remains a challenge while pipeline visibility is limited due to largely manual LMIS. The country has limited capacity for medicines regulation and quality control testing. In addition, there are no facilities for disposal of damaged and/or expired medicines and other health products. The team recommended the NTP to review the minimum stock level maintained at CMS to cushion the country from procurement delays and regular generation and optimal use of EWS reports to monitor stocks. Additionally, the fast tracking of deployment of electronic LMIS to improve pipeline visibility and upgrade of the warehouse management system at CMS is necessary. The country should also strengthen the MRU to effectively undertake quality assurance functions. There is also a need to fast track the operationalization of the QC lab to support quality assurance and post marketing surveillance while making use of existing collaboration with external quality control lab for quality control testing in the short term.


From 11 to 22 November 2019, Stop TB/GDF participated in the Joint HIV/TB/PMTCT/STI Review of the progress made towards implementation of the National Strategic Plan for HIV/TB/STI 2017-2022 and Last Mile Plan for Elimination of Mother-To-Child Transmission 2016-2021 as well as a Situation Analysis of the Viral Hepatitis in South Africa.

One of the critical enablers to maximising the reach and impact of South Africa’s response to HIV, TB and STIs is strengthening the procurement and supply chain management systems to attain a “ready, uninterrupted access to essential prevention, diagnostic and treatment commodities.” This, to some extent, has been achieved as medicines were generally available but not without challenges in supply chain system affecting stock availability in some health facilities.

The mission observed that there were no standardized tools for quantification and early warning systems (EWS) at provincial level. In line with the objective, there is a need to strengthen quantification and EWS to ensure equitable distribution and monitoring of medicines across the provinces and health facilities. Supply chain linkage with the programme also needs to be strengthened and this could be attained by
embedding Pharmacist/ Supply Chain Professionals into the programme management team at National Department of Health to serve as the liaison between programs and various stakeholders at different levels including the Provincial Depot, suppliers, Funders, Partners, the Drug Regulatory Agency, and other government departments and parastatals.

Following frequent changes in diagnosis and treatment of TB, the importance of monitoring stock levels regularly cannot be over-emphasized. A good early warning system would help strengthen the procurement and supply management system exposing potential risk in time and averting stockouts.

Good storage organisation and display of medicines at Community Health Centre, Kagisho
Stop TB/GDF participated in the Namibia National TB and Leprosy Programme (NTLP) midterm external programme review led by WHO from 11 to 22 November 2019.

The observed key programme achievements include the availability of the new paediatric formulations for both first- and second-line treatment. Furthermore, the country is in the process of scaling up the use of Xpert MTB/Rif Ultra cartridge for TB diagnosis and the implementation of the new DR-TB guidelines started in December 2018.

The procurement systems for TB medicines and diagnostic commodities were assessed and inefficiencies were identified that are resulting in sourcing commodities at high prices. These include lack of long-term agreements with suppliers of TB medicines. As a result, multiple tenders with low volumes for the same products are conducted in a year. Discussions were on-going at the time of the review to move towards the use of international pooled procurement mechanisms for pharmaceuticals in order to reduce costs and improve reliability of supply. The country has been considering using GDF for the supply of both TB medicines and laboratory commodities. However, the current country’s procurement laws do not have provision for pre-payment. The NTLP was advised on the availability of the GDF flexible procurement fund and are engaging their procurement unit in this regard.

In addition, a stock status assessment was conducted identifying potential stock outs in the next 4 months for adult first line TB medicines. The NTLP has committed to engage the Central Medical Stores and the Executive Director of the Ministry of Health to initiate emergency orders for adult first line TB medicines with immediate effect to avert stock outs.
Stop TB Partnership’s Global Drug Facility’s participation to the Joint TB Program Monitoring Mission in India, 11-22 November 2019

Based on a request from the Government of India (GoI), WHO organized the 7th JMM from 11th to 22nd of November 2019 to review the country’s progress towards Universal access to TB care, challenges and plans for TB control efforts, and to advise the GoI and partners on the pathway towards strategies in line with End TB Strategy.

The participation and contribution of the members from the Stop TB/GDF were significant in the technical field, for inclusion of the affected community, advocacy to quickly transitioning to the newer regimen PAN India, engage newer diagnostics, consider the major private sector, speed up the LTBI intervention and to explore all the relevant activities including the reinforcement of the R&D activities to achieve the End TB in India by 2025.

Some final key takeaway points were made, including:

- Strengthening existing manpower with additional dedicated and skilled workers;
- Ensuring strong and accurate forecasting and employ direct and innovative contracting for drugs and diagnostics;
- Encouraging the entire private sector and Ayush providers to find the 3 million cases and successfully treat them;
- Establishing a surveillance system at National, State and District level for effective service delivery, monitoring performance and to assessment emerging priorities;
- Replacing sputum microscopy with decentralized molecular TB diagnosis and extend DST to adult, paediatric patients of both public and private sectors;
- Encouraging novel skin tests for latent TB, automated digital chest X ray and new drugs and regimen based on global evidence.
• **Stop TB Partnership’s Global Drug Facility’s Technical Assistance mission in Nigeria, 11-22 November 2019**

From 11 to 22 November 2019, Stop TB/GDF visited Nigeria as part of the GDF/Green Light Committee Joint technical assistance mission.

The mission made several observations, including progress made in the implementation of PSM transition plan for the new DR TB treatment guidelines. All the required second line TB medicines were already procured at the time of the mission. Nigeria is also likely to be one of the early adopters of the newly FDA approved six-month all-oral Bpal treatment regimen expected to be implemented under operational research together with the modified shorter MDR TB treatment regimen. However, implementation of the overall transition had been delayed from the initial date of October 2019 to quarter 1, 2020. There are also plans to roll out the new WHO LTBI guidelines which include 3HP.

To kick start the process, the country is considering reprogramming available GF funds to be able to procure Rifapentine which was initially not budgeted for. Additional support is expected from UNITAID through IMPAACT4 TB project to cover 20,000 patients in 2020. The government of Nigeria is also making efforts to allocate funds for procurement of other TB medicines; for 2019/2020, a total of USD 524,416.67 had been allocated, almost three times increase from USD 199,700.55 allocated in 2017. However, following GDF’s support in the review of TB medicines quantification data, a funding gap of approximately USD 2.29 Million was revealed, if the country meets the 2020 enrollment targets. A need to mobilize more resources for procurement of TB medicines was therefore highlighted.

Observed best practices: Nigeria has sustained the implementation of the kit distribution system for second line TB medicines and it is the only country in Anglophone Africa using this approach. This practice has helped to simplify the stock management process at DOT clinics as all the required SLDs are locally pre-packed in one kit and managed as one product. The country is also making progress in the integration of TB commodities into the existing electronic Logistic Management Information System and in harmonizing warehousing and distribution system for DR TB and DS TB commodities hence possible reduction of distribution cost. Previously, SLD used to be distributed through a parallel distribution system.
Stop TB Partnership’s Global Drug Facility’s participation to the Somalia LTBI guidelines development workshop in Kampala, Uganda, 18-20 November 2019

The main objective of this meeting was to assist Somalia to develop guidelines and operational plan on management of LTBI. The StopTB/Global Drug facility has been a strong partner to Somalia, providing technical assistance in managing an uninterrupted supply of anti-TB products. GDF has also in the past supported Somalia to transition to various tools, most recently the new DR-TB regimens and new DR-TB paediatric formulations.

Stop TB/GDF’s participation in this meeting was to; i) lead discussions on the procurement and supply chain management of LTBI pharmaceuticals and diagnostics modules of the guidelines, ii) support the development of the operational plan, and ii) provide technical input with emphasis on PSM aspects.

The main achievements of the meeting were:
- StopTB/GDF’s presentation on effective implementation of LTBI management, its PSM implications and the role of GDF in providing technical assistance and access to quality assured LTBI medicines and diagnostics;
- Review of the draft Somalia LTBI technical guidelines and operational plan;
- Development of TPT options to be rolled out by the country. The 3HP will be the main option for population above 5 years while 3RH is the main choice for children under 5 years;
- Development of quantification and supply plans for the transition to the new LTBI options;
- Discussions on funding availability to support implementation of the operational plan and procurement of medicines and diagnostics. The World Vision team who are the Global Fund Grant Recipients highlighted their support for roll out plan.

Participants of the workshop
Stop TB Partnership’s Global Drug Facility’s participation to the Eastern Mediterranean (EMR) Regional Green Light Committee (rGLC) Technical Meeting in Pakistan, 20-22 November 2019

From 20 to 22 November 2019, Stop TB/GDF participated in the eleventh meeting of the regional green light committee (rGLC) organized by WHO in collaboration with the Government of Pakistan in Karachi, Pakistan.

The purpose of the meeting was to brief the members of the newly established EMR rGLC about the scope of work, roles and responsibilities of the members. During the three days meeting, the progress of introduction of the new DR-TB policies, treatment regimens, progress on PMDT expansion and treatment outcomes in EMR countries were reviewed and discussed with a focus on high burden countries and the Global Fund supported member states (Afghanistan, Djibouti, Iraq, Jordan, Lebanon, Morocco, Pakistan, Somalia, Sudan, Syria and, Yemen). One day was dedicated to observing experiences of public and non-public PMDT programmes in Pakistan during which the team visited 3 PMDT sites for the rGLC experts and PMDT programs to share experiences on best practices around DR-TB implementation.

Based on three extensive days of work, different technical areas to support the EMR countries were identified which formed the basis for the development of an action plan for the technical support needed as well as a workplan for 2020.

Participants of the meeting
Stop TB Partnership’s Global Drug Facility’s participation to the Joint TB Program Monitoring Mission in DRC, 18-29 November 2019

StopTB /GDF participated in the DRC 2018-2020 PSN-TB mid-term review from 18 to 29 November 2019. The objectives of the mission were to: i) identify issues in the supply chain of TB drugs and laboratory commodities, ii) make recommendations for fluid supply chain, and iii) set directions for the new 2021-2023 TB Strategic Plan.

The main challenges identified by StopTB/GDF mission were:
- Absence of a clear budget line in the National Budget for the purchase of anti-tuberculosis drugs and laboratory inputs;
- Failure to implement interventions planned in the transition to the new reprocessing regimen and the use of paediatric RH for the prevention of TB in children under 5;
- Irregular meetings of the coordination committee for monitoring supplies (order situation, stock analysis, distribution plans and difficulties encountered during distributions);
- Long supply lead times at all levels resulting in stockouts.

In order to find adequate solutions to the shortcomings of the DRC supply chain, StopTB/GDF has proposed the following guidelines for the new 2021-2023 PSN-TB:
- Establish an automated electronic system (e-SiGL) for the control of drugs and laboratory inputs using computers at the Provincial and Bureau Zone levels and tablets at the health centers level;
- Put in place drones for the distribution of drugs and laboratory inputs at the level of health zones and/or health centers;
- Make the Provincial Directorates of Health (DPS) autonomous in the management of drugs and laboratory inputs (quantification with QuanTB, storage, distribution, reporting) with centralized purchases and direct delivery to DPS (1 or 2 times per year depending on capacity).

During this mission, a review of the quantification of the first and second lines was also conducted, which had made it possible to readjust the needs according to the real performances of the programme.

Stop TB Partnership’s Global Drug Facility’s participation to the Joint TB Program Monitoring Mission in Ethiopia, 18-29 November 2019

The Ethiopia NTLP conducted the end term review of their 2013/14 to 2020 Strategic plan between November 18 to 30, 2019. The main goal was to review the achievements made and provide recommendations for the next strategic plan to align it with the global END TB strategy. STOP TB/GDF was among stakeholders participating in recognition of their PSM expertise.

Ethiopia is already implementing the new WHO DR TB treatment guidelines and LTBI guidelines. The country has an established supply chain system with a functional TWG at national level, good storage conditions at Ethiopia Pharmaceutical Supplies Agency central and hubs which have a networked inventory management using Health Commodity Management Information System (HCMIS). There is adequate
regulatory and quality assurance capacity at the Ethiopia Food and Drug Authority with system to fast-track registration, conduct risk-based PMS and testing at the national quality control laboratory, including for medicines procured through the Global Fund.

Among the challenges observed was erratic supply of Xpert Cartridges and stock out of key reagents at the National TB Reference Laboratory due to procurement delays and funding challenges. DR TB patient enrollment data adequately disaggregated by regimen and age was not readily available which is key for accurate quantification. There is also lack of quality data on actual enrolment on TB preventive therapy. The Logistic Management Information System (LMIS) data from the regional level down to health facilities is also delayed and of inadequate quality. A lack of standardized tools for quantification for lab commodities was also observed.

The need to ensure consistent and adequate funding for TB commodities, especially Xpert cartridges and other diagnostics, and to ensure timely procurement were highlighted. There is also a need for nationwide trainings and capacity building on integrated pharmaceutical logistics system and TB commodity management and ensuring regular feedback upon data quality checks. The review team also recommended to implement a lab commodity LMIS or expansion of the current HCMIS to include all lab commodities and provision of tool and support for quantification of Lab commodities.

One of the Ethiopia Pharmaceutical Supplies Agency Cluster hub