

Value for Money Audit Report

Global Fund investments in

Health and Laboratory-related equipment

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The Office of the Inspector General (OIG) safeguards the assets, investments, reputation and sustainability of the Global Fund by ensuring that it takes the right action to end the epidemics of AIDS, tuberculosis and malaria. Through audits, value for money (VfM) audits, investigations and advisory work, it promotes good practice, enhances risk management and reports fully and transparently on abuse.

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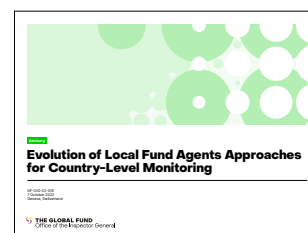
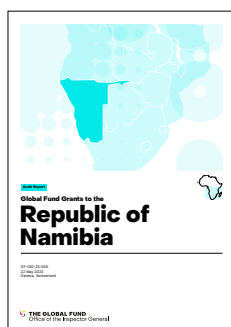


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1. Executive Summary

1.1 Opinion

Value for Money (VfM) audits conducted by the Office of the Inspector General aim to assess the extent to which grant investments are generating their intended results, according to the Global Fund defined VfM dimensions. The focus of this VfM Audit is on Global Fund investments in health and laboratory equipment.

Health and laboratory equipment plays a critical role in achieving programmatic objectives for the three diseases. This equipment ensures timely and reliable diagnosis, which supports improved access and quality of care to beneficiaries. Reflecting this, the Global Fund has invested nearly US\$2.3 billion in health and laboratory-related equipment during 2021-23.¹ The Global Fund continued to provide support to strengthen key enablers such as laboratory human resource capacity, specimen transportation and management systems. In a resource constrained environment, ensuring value for money for these investments is key to achieving the organization's mandate.

Value for Money framework at the Global Fund

To support the achievement of value for money (VfM), a Global Fund VfM framework was developed and presented to the Global Fund Board in November 2018.² It is comprehensive and well-tailored to the Global Fund's mission through the inclusion of five key dimensions, including *equity* and *sustainability* alongside *effectiveness*, *efficiency* and *economy*. A technical brief, updated in 2022, also provides an overview of the VfM framework with guidance for applicants when developing funding requests to the Global Fund.

However, the VfM framework is not fully operationalized or embedded in corporate and grant processes. There is a lack of clarity on the parameters to assess the five key dimensions for specific material investments, including health and laboratory equipment. In the absence of pre-defined and approved metrics, the OIG had to determine and assess the appropriateness and availability of existing data and data points which were used to assess VfM. While these may not align exactly with future metrics approved by the Global Fund, they were nevertheless based on existing and well-established metrics (such as priority indicators to monitor the implementation of the World Health Organization's End TB Strategy).³

Roles and responsibilities within the Global Fund for ensuring VfM are not well-defined and cascaded throughout the organization. A Secretariat-wide VfM Working Group (WG) was formed in 2022 to operationalize VfM at the corporate and grant level to increase the organizational focus on the value for money of material investments. Despite this, these issues have hindered effective tracking, monitoring, and managing in-country challenges in relation to investments in Cepheid's GeneXpert(r) System ("GeneXpert") and Chest X-rays.

GeneXpert platforms (\$800 million investment from Grant Cycles 4 to 6): Until 2020, the GeneXpert platform was the only WHO-approved rapid diagnostic tool to identify TB and drug resistant (DR) TB. It has been designed to improve the speed and accuracy of TB and DR-TB diagnosis compared to smear microscopy⁴ and culture. This speed and accuracy is a key enabler to support programs to improve the quality of service to beneficiaries, find more missing cases and reduce the opportunities for further transmission of the disease.

Effectiveness, efficiency, and equity for GeneXpert were constrained by operational factors at the implementation level including machine downtime, inadequate access to platforms for beneficiaries and COVID-19 disruptions.

1 From Grant Cycle 6 and C19RM funding, the figure includes all health and laboratory related equipment, cartridges, reagents, consumables and warranties.

2 Update on Value for Money (VfM) presented at the 40th Board Meeting in November 2018: https://archive.theglobalfund.org/media/8100/archive_bm40-15-updateonvalueformoney_report_en.pdf

3 WHO's Implementing the End TB Strategy: The Essentials 2022 Update (last accessed on 9 August 2023) recommends monitoring of percentage of notified new and relapse TB cases tested with a WRD as the initial diagnostic test (with a target of > 90% of cases by 2025) as one of the top 10 priority indicators to monitor the implementation of End TB Strategy.

4 WHO operational handbook on tuberculosis: module 3: diagnosis: rapid diagnostics for tuberculosis detection, 2021.

While the OIG noted positive trends in the absolute numbers of TB cases (both drug susceptible and drug resistant TB) identified through GeneXpert testing, as well as declines in mortality in all countries sampled, the percentage of notified TB cases identified through GeneXpert testing stands at or below 30% in three out of five⁵ countries as of 2021.⁶

One of the common causes is high machine downtime, caused by service and maintenance issues, inadequate sample transportation network, and stock-outs of cartridges. Importantly, the COVID-19 pandemic negatively impacted cases notified through GeneXpert testing; this was due to disruptions to accessing care, implementation challenges to find and treat people with the disease, supply chain issues and GeneXpert capacity being used to support testing for COVID-19. Lower efficiency due to operational challenges has also impacted *effectiveness* and *equity*.

A limited number of suppliers and adherence to the pre-existing buydown agreement, which guaranteed price stability, inadvertently hampered the Global Fund's ability to achieve the most economic price point and contributed to the acceptance of service and maintenance arrangements. *Sustainability* of GeneXpert investments is also impacted by limited progressive uptake of these investments through domestic financing and limited cross-program use of these instruments. The *equity* dimension, which focuses on equitable access, could not be fully assessed due to a lack of available data and analysis in this area. However, low geographical coverage as was noted in a few countries, which was linked to a limited number of GeneXpert platforms and challenges with regards to sample transportation networks.

Viral Load (VL) investments (\$635 million investment from GC4 to GC6): Value for money in terms of *effectiveness* and *efficiency* were largely achieved for Viral Load (VL) investments. This was due to high utilization of machines linked to robust supplier agreements that guarantee uptime with strong repair and maintenance support. There have been good efforts to optimize existing platforms through Diagnostic Network Optimization (DNOs), which has informed consolidation of VL laboratories, thereby ensuring increased capacity utilization and reduced resources. In-country partner implementation support and good donor coordination has also had a positive impact on the value for money achieved from these investments. For Early Infant Diagnosis (EID), low coverage was an unintended consequence of attempts to centralized testing and pooling of EID samples to optimize test runs with implications on *effectiveness*.

Chest X-ray investments (\$181 million investment from GC4 to GC6): Value for money was challenging to fully measure for Chest X-Ray machines because of limited data. In 62% of cases, significant delays (an average 12 months) for order placement, installation and site readiness have meant that either equipment has not arrived in the country or had only been used for less than six months as of November 2022. This period of lost implementation negatively impacted the value for money derived from these investments.

Overall, the achievement of value for money has been rated as **partially achieved**.

Although management actions were agreed for other risks identified, the Secretariat declined an action to mitigate risks identified with the efficient and effective use of Chest X-ray equipment (see finding 3.4). This was due to information on the use of Chest X-ray equipment not being consistently and systematically collected and reported by countries. Although the Secretariat's main focus is on measuring the access and quality of TB screening and testing, use of Chest X-ray equipment will not be monitored by the Global Fund which will limit more meaningful analysis.

5 Ethiopia is not included because the country has not tracked and reported the number of cases tested and diagnosed through WRD tests since 2015. In the absence of this indicator, the proxy indicator on bacteriologically confirmed TB cases was used and challenges with respect to GeneXpert network has been discussed as part of Finding 3.3.

6 Period for this comparison varies based on the countries in the sample. For the trend comparison, the OIG has used for the baseline year of each country the first year that met both criteria: A) the national testing algorithm was updated to allow for use of GeneXpert platforms to test for drug-sensitive TB, as well as resistant forms and B) Data was reported as the baseline year for comparison. 2021 was used as the latest year available in the most up-to-date WHO World TB report.



1.2 Key Achievements and Good Practices

The design of the Global Fund's VfM high level framework is comprehensive: the Global Fund's approach to VfM is comprehensive when compared to other organizations. Its approach is tailored to the organization's mission, taking into consideration *equity* and *sustainability* as additional cross-cutting themes in addition to *economy*, *efficiency* and *effectiveness*.

Increased organizational focus and capacity on Laboratory Systems Strengthening: The 2023-2028 Global Fund strategy has included a focus on strengthening of laboratory systems, supply chains and diagnostic capacity. A Secretariat-wide VfM Working Group (WG) was formed in 2022 to operationalize VfM at the corporate and grant level. Laboratory systems integration is one of the joint priorities of this group, increasing the organizational focus on the value for money of these investments. The technical capacity of the Global Fund Secretariat has been increased, with the Laboratory team within the Resilient and Sustainable Systems for Health (RSSH) unit of the Secretariat expanded from a single staff member to an eight-member team.

Strategic Initiatives for Laboratories is providing Technical Assistance (TA) to mitigate in-country gaps and improve effectiveness and efficiency: the initiative increases the TA provision available to strengthen laboratory governance, sample transportation networks and laboratory information systems. It is also supporting the implementation of the Global Laboratory Leadership Program (GLLP), which comprises tailored training courses to strengthen laboratory service delivery and management.

Good achievement of value for money in Viral Load equipment noted in sampled countries: this achievement was driven by a number of factors including: (1) effective donor coordination at grant level with partners with country presence playing a key role, (2) all-inclusive rental pricing agreements with suppliers that guarantee 95% equipment uptime and (3) adequate sample transportation coverage that was informed by Diagnostic Network Optimization (DNOs) assessments.



1.3 Key Issues and Risks

Efforts are needed to operationalize and embed the VfM framework in grant and corporate processes: Global Fund's VfM framework is comprehensive and tailored to the organization's mission, but the framework is not fully embedded in grant and institutional processes, and roles and responsibilities for monitoring, oversight, and reporting on VfM progress are not defined. This hinders securing and enhancing VfM of Global Fund investments.

Need to strengthen and leverage critical enablers of VfM to ensure continuous achievement and assessment of VfM in relation to laboratories: Lack of national laboratory strategies, limited involvement of national laboratory entities in the implementation of grants, limited information at the time of approving investments and lack of monitoring of processes at the Global Fund are hindering the value for money of investments in laboratory equipment.

Operational challenges in using GeneXpert platforms limit the attainment of effectiveness, efficiency and equity: Through Global Fund investments, countries have significantly increased GeneXpert platforms between 2016 to 2022. Positive trends in absolute numbers of drug susceptible and resistant TB cases diagnosed with GeneXpert platforms were noted in all countries. However, the percentage of notified TB cases identified through GeneXpert testing is at or below 30% in three out of five countries. This is mainly due to operational challenges causing low utilization of machines. These challenges include service and maintenance issues, inadequate sample transportation systems and stock-outs of cartridges. COVID-19 also had an impact on TB case notification and on the percentage of TB cases notified through GeneXpert testing, as well as on global supply chains. This impacts the *effectiveness* and *efficiency* of these investments, and access to diagnosis, which impacts *equity*.

Some of these challenges have been addressed through recent senior management efforts. In 2023, along with other TB partners, the Global Fund secured both improved service and maintenance arrangements for GeneXpert platforms and a 20% price reduction for cartridges as part of recent agreements with Cepheid.

Protracted procurement and delays in installation resulting in limited achievement of VfM from investments in Chest X-rays (CXR): There are significant delays in procurement and installation of CXR due to errors in the procurement process, delays in finalizing specifications, stalled site preparation for hosting this equipment, and human resources gaps. This has negatively impacted *effectiveness* and *equity*.

Objectives

This Value for Money (VfM) audit is part of the Office of the Inspector General (OIG) 2022 work plan. The overall objective of the VfM audit was to provide reasonable assurance to the Global Fund Board on whether the Global Fund has secured value for money in its investments in health and laboratory-related equipment. In particular, the VfM audit assessed the achievement of value for money in Global Fund investments in specific laboratory and health equipment.

VfM was assessed using the Global Fund defined dimensions of *Economy, Efficiency, Effectiveness, Equity & Sustainability* across the grant and product life cycle and value chain, focusing on the consideration and interdependencies of each dimension in achieving VfM.

The VfM audit included identifying in-country and Secretariat-level enablers and bottlenecks to maximizing VfM across all dimensions. This covered the Global Fund Secretariat's approach to VfM, including the people, systems, processes to strengthen, monitor and provide assurance on VfM at the country level.

Scope

The VfM audit covered:

- Global Fund Secretariat policies, structures, systems, processes, and tools for assessing and monitoring VfM.
- Global Fund investments in GeneXpert, Viral Load/EID and CXR machines in six countries (details in section 2.2).
- Global Fund's monitoring, assurance, and mitigation measures to effectively manage in-country challenges in relation to investments in health and laboratory-related equipment.

The VfM audit covered the period January 2018 to June 2022. The VfM audit also considered how investments prior to this period were factored into investment decisions. The VfM audit also leveraged findings from prior country audits (40) published between 2018 to September 2022.

The scope of the audit did not include an assessment of diagnostic accuracy (sensitivity, specificity, etc) of the selected equipment types, as these have already been pre-qualified by WHO and their efficacy confirmed by numerous scientific studies. The audit focused on Global Fund investments in the selected equipment types to determine to what extent these have achieved intended results across the five Global Fund VfM dimensions.

Methodology

The assessment of achieving value for money was based on the Global Fund-defined dimensions of *economy, efficiency, effectiveness, equity, and sustainability*, and conducted at the Secretariat and country level:

At the Secretariat level:

- Reviewing Secretariat guidance and processes to define, measure, monitor and report on VfM.
- Identifying Secretariat-level enablers and bottlenecks in maximizing VfM from investments across the five dimensions and their interdependencies.
- Interviewing Secretariat stakeholders, individual staff from Grant Management Division, Finance and the Strategic Investment & Impact Division.
- Performing benchmarking exercise on approaches with peer organizations that use a VfM approach.
- Assessing how the Secretariat has embedded the key dimensions of VfM across grant life-cycle processes and considered these dimensions for the product life cycle and value chain.

At the country level:

- Conducting six country “deep dive” reviews to assess the VfM of investments, focusing on how VfM has been considered in investment decisions and whether it has been achieved and monitored in each country.
- Identifying country-level enablers and bottlenecks in maximizing VfM from investments across the five dimensions and their interdependencies.
- Interviewing in-country stakeholders including local funding agents, Principal Recipients, implementers, and laboratory focal points.
- Conducting review of key strategic and operational documents.

Value for Money audits are optimally performed using existing, management-approved metrics to determine value for money across the various dimensions. However, as noted in finding 3.1, the Global Fund Secretariat has not defined a measurement framework. In the absence of Global Fund Secretariat-approved metrics for relevant investments covered in this audit, the OIG had to determine the appropriateness and availability of existing data to assess VfM. Although not specifically approved by management, these were existing and well-established metrics. For example:

Effectiveness:

- For GeneXpert - Trends in percentage of notified new and relapse TB cases tested with a WHO Recommended Rapid Diagnostic (WRD) as the initial diagnostic test⁷ and trends in number of installed GeneXpert instruments
- Molecular platforms for Viral Load /Early Infant Diagnosis - Trends in Viral Load testing coverage and suppression,⁸ trends in Early Infant Diagnosis coverage⁹ and trends in number of installed platforms.
- Chest X-rays - Trends in total people screened, number of people with abnormal CXR, number of people with abnormal CXR referred for further diagnosis and number of people diagnosed with TB.¹⁰

Efficiency: For all equipment types the following metrics were leveraged.

- Operational usage and availability factoring the procurement and installation, service, repair and maintenance of equipment, availability of cartridges/reagents, trained human resources, laboratory information systems and cross-program use of equipment.

Economy: For all equipment types the following metrics were leveraged.

- The use of appropriate procurement mechanisms and existence of favourable supplier agreements to ensure best quality for the lowest sustainable prices.

Equity: For all equipment types the following metrics were leveraged.

- Equitable access to screening and diagnostic services.
- The geographical coverage and key population achieved.
- The consideration of equity in placement plans of equipment.

Sustainability: For all equipment types the following metrics were leveraged.

- The progressive uptake of equipment, reagents, cartridges, consumables etc. through domestic financing
- The materialization of specific domestic commitments relating to this equipment, if any.

7 WHO's [Implementing the End TB Strategy: The Essentials 2022 Update](#) (last accessed on 9 August 2023) recommends monitoring of percentage of notified new and relapse TB cases tested with a WRD as the initial diagnostic test (with a target of > 90% of cases by 2025) as one of the top 10 priority indicators to monitor the implementation of End TB Strategy. Note that this is the main indicator in the list of priority indicators focused specifically on TB diagnosis. Global Fund has made this indicator mandatory for Grant Cycle 7 grants.

8 WHO's [Consolidated guidelines on person-centred HIV strategic information: strengthening routine data for impact](#) (last accessed on 9 August 2023).

9 Idem.

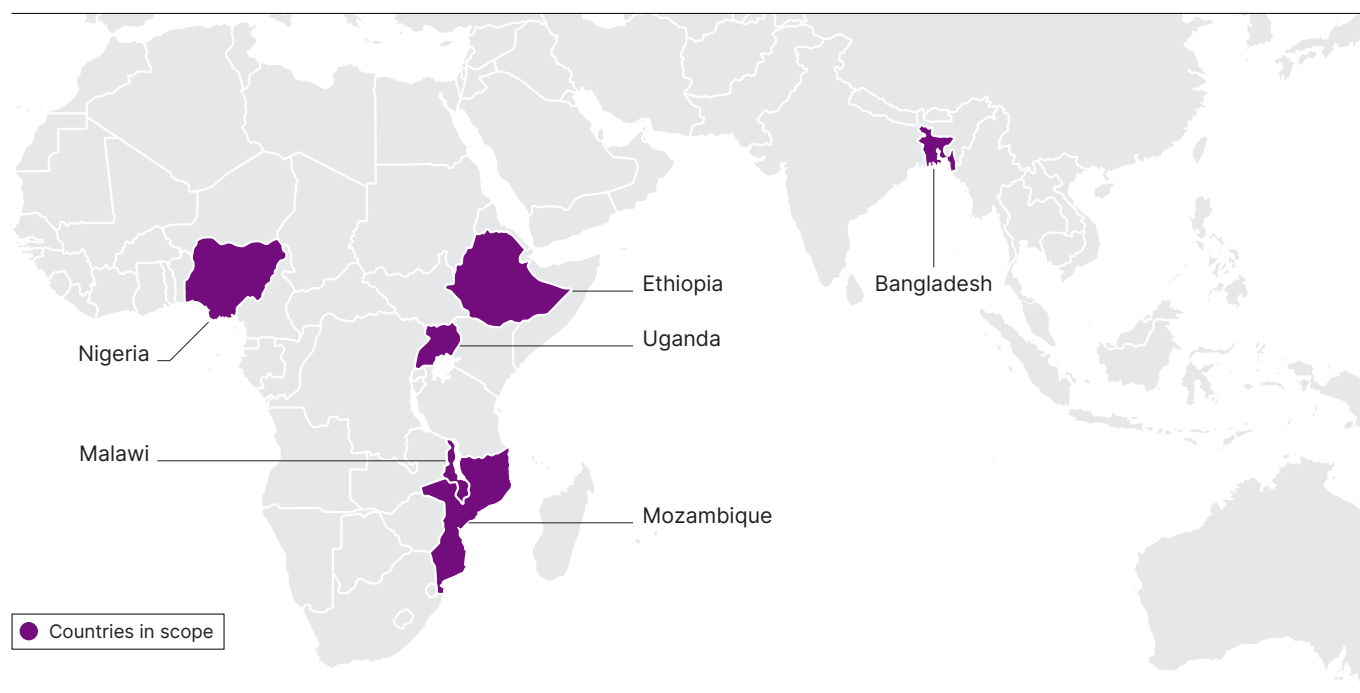
10 WHO consolidated guidelines on tuberculosis: module 2: screening: systematic screening for tuberculosis disease (last accessed on 9 August 2023).

Country Selection and coverage

The OIG selected a sample of six countries, which were selected on the basis that they represented material investments across the three equipment types. Together, the countries selected 37% of the investments made in Grant Cycle (GC) 6 in the selected equipment types.

Type of equipment	Bangladesh	Malawi	Mozambique	Nigeria	Ethiopia	Uganda	Total for Sampled countries	Total Investment in selected equipment types	% sampled of total GF investment
GeneXpert Equipment, cartridge and warranties	42	21	25	23	17	24	152	393	39%
Molecular platforms used for Viral Load and/or EID testing, reagents and warranties (apart from investments in GeneXpert, as already mentioned above)	-	42	-	8	7	18	75	212	35%
Chest X-ray Equipment and warranties	4	5	9	8	-	10	36	112	32%
Total	46	68	34	39	24	52	263	717	37%

(US\$ in millions)



Ratings

Objective	Rating	Scope
Achievement of VfM in Global Fund investments in specific laboratory and health equipment	Partially achieved	VfM audit period: January 2018 to June 2022

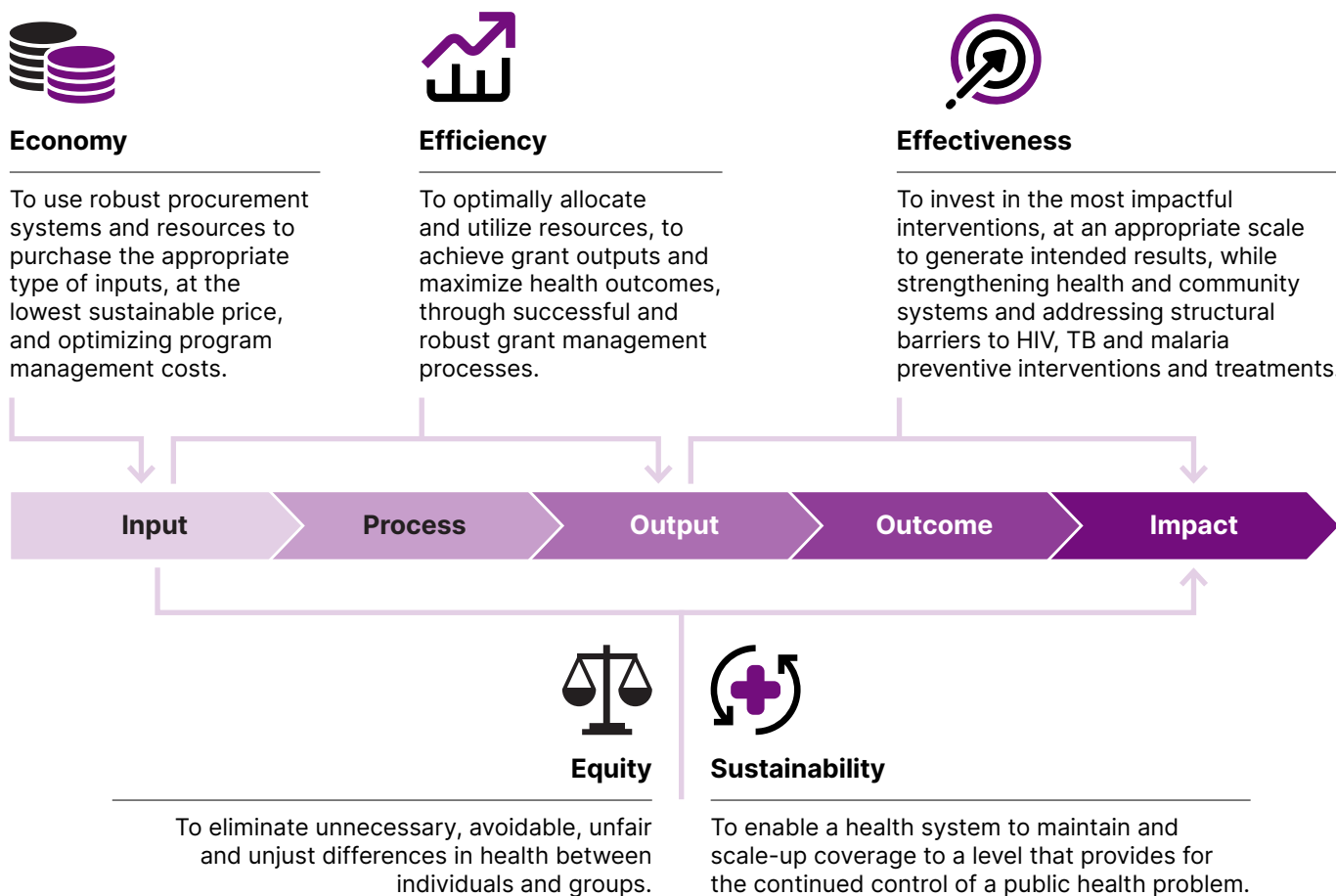
Details about the value for money audit rating classification can be found in Annex A of this report.

2. Background and Context

2.1 What is Value for Money at the Global Fund?

Value for Money (VfM) was introduced as a principle to guide Global Fund investments since 2011.¹¹ In the Global Fund Strategy for 2023-28, VfM is highlighted as a key component that underpins the Global Fund’s partnership model. VfM¹² is a concept that defines how to maximize and sustain equitable and quality outputs, outcomes or impact for a given level of resources. It entails understanding the cost-effectiveness of different investment options, as well as associated equity and sustainability implications to make sound investment decisions.

Figure 1:
The VfM framework across the health results chain



When describing the overall efforts to enhance VfM, applicants are encouraged to outline how investment decisions have been made to enhance all VfM dimensions. These dimensions complement each other, but in some cases, applicants will need to find a balance among them, given the country context, overall health strategies, epidemiological trends and gaps, health system capacity constraints, domestic budgets and other donor investments. Applicants are recommended to highlight and explain potential trade-offs made among VfM dimensions and the rationales behind them.

Technical Brief Value for Money Allocation Period 2023-2025. Date published: July 2019, Updated: October 2022

¹¹ [GF/B23/DP09](#) (last accessed on 27 November 2023).

¹² [Technical Brief on Value for Money](#) (last accessed on 27 November 2023).

2.2 Laboratory and Health Equipment in scope

The following equipment types were selected to be in the scope of this VfM audit, based on investment levels and criticality to the Global Fund mission. These equipment types are sourced from Pooled Procurement Mechanism (PPM)/WAMBO, Global Drug Facility (GDF) and/or through country's own procurement mechanisms.

Figure 2:
Investment value (US\$ in millions) in selected equipment (including associated consumables) from GC4 to GC6¹³



GeneXpert

The GeneXpert machine is a cartridge-based automated molecular test. It is approved by the World Health Organization (WHO) for the diagnosis and monitoring of several diseases including tuberculosis, HIV (Early Infant Diagnosis and Viral Load monitoring), SARS-CoV-2 (COVID-19) and other virological tests. Up until 2020, when new technologies were approved by the WHO,¹⁴ the GeneXpert machine was the only rapid diagnostic test recommended by the WHO for the testing of TB and drug resistant TB. In 2021, the GeneXpert machine was also recommended for the testing of COVID-19.

WHO Recommendations relating to GeneXpert use for TB:

- In 2010, WHO approved the use of Xpert MTB/RIF (GeneXpert) for diagnosing drug-resistant TB (RR-TB).
- In 2013, the WHO extended the recommendations to use GeneXpert as the initial diagnostic test for suspected pulmonary TB, paediatric TB and selected specimens of extrapulmonary TB.
- In 2020, the WHO recommended the new Xpert MTB/RIF Ultra assay (Ultra) for diagnosing TB and drug resistant TB due to improved sensitivity compared to MTB/RIF assay.
- In 2021, the WHO extended recommendations to use Xpert Xpress CoV_2 plus for COVID-19 testing.

¹³ The investment value includes equipment, cartridges, reagents, other related consumables and warranties.

¹⁴ In March 2023, the Global Fund, the United States Agency for International Development (USAID) and the Stop TB Partnership announced a new collaboration with Molbio Diagnostics that significantly reduces the price of the TrueNat® MTB, MTB Plus and MTB-RIF Dx tests (WHO-endorsed rapid molecular test for the initial diagnosis of TB and subsequent detection of rifampicin resistance in adults and children with signs and symptoms of pulmonary TB).

Chest X-ray (CXR)

CXR is recommended by the WHO as a tool that can be used to screen and triage target population groups at risk of developing TB. It supports the identification of potential people with TB who would need follow-on diagnosis. CXR machines come in several different categories including (1) analogue machines that require film processing, (2) indirect digital systems that use computer radiology cassettes and readers and (3) direct digital systems. The machines can also be either fixed machines, which are installed either in a health facility or a mobile vehicle, or a portable unit that can be transported and set up temporarily in a location used for screening.

WHO Recommendations relating to use of Chest X-ray for TB:

- In 2016, WHO recommended the use of screening and triage of target population groups at risk of developing TB.
- In 2021, the WHO recommended the use of computer aided detection (CAD) applications in chest radiography.

HIV Viral Load/EID platforms

Molecular platforms are used for Early Infant Diagnosis (EID) and Viral Load (VL) monitoring, consisting of two kinds of such platforms: 1) Laboratory-based machines and 2) Point-of-care machines.

WHO Recommendation for Early Infant Diagnosis (EID) and Viral Load monitoring:

- In 2021, WHO recommended use of point-of-care nucleic acid testing (NAT) to diagnose HIV in infants and children younger than 18 months of age. Birth testing is recommended for HIV-exposed newborns. If negative, test should be repeated at 4–6 weeks of age or if not tested previously. If HIV infection is not detected but the infant remains exposed or infants who were never tested but exposed during post-partum period, HIV testing is recommended at 9 months of age and if negative, testing at 18 months or 3 months after cessation of breast feeding, whichever is later.
- WHO recommends routine Viral Load monitoring for all People Living with HIV (PLHIV) at 6 months and 12 months after ART initiation and yearly beyond this if undetectable. If Viral Load count is more than 1000 copies/ml, PLHIV should undergo Enhanced Adherence Counselling (EAC) and viral load test should be repeated at 3–6 months.

3. Findings

3.1 Value for Money framework is comprehensive, but further efforts are needed to operationalize and embed it in grant and corporate processes for material investments

The Global Fund's 2018 Value for Money (VfM) framework is comprehensive and tailored to the organization's mission. However, the framework is not embedded in grant and corporate processes, and roles and responsibilities for those involved in the monitoring, oversight, and reporting on VfM progress are not defined.

The current Value for Money framework was developed and presented to the Global Fund Board in 2018 and the technical brief on Value for Money has been further revised to support GC7 grants starting in 2024. The Global Fund's VfM framework is more comprehensive than the frameworks of peer organizations and is well tailored to the organization's mission. It utilizes the commonly used dimensions of VfM (*economy, efficiency, and effectiveness*), but goes further by including two cross-cutting dimensions on *equity* and *sustainability* – see section 2. This ensures that VfM is more closely linked to the core mandate and strategic objectives of the organization.

VfM framework needs to be operationalized and further embedded in Global Fund processes to achieve VfM across the grant life cycle for material investments.

The VfM framework is focused on the funding request stage and is not fully embedded in grant implementation and closure processes. At these stages, there is no guidance around on-going monitoring of VfM or assessment on what has been achieved to date.

Various Secretariat departments play a key role in ensuring value for money. This includes key teams such as the Grant Management Division, Supply Operations, Finance, and Strategic Investment & Impact Division (Technical Advice & Partnership, Community Rights and Gender and Health Finance). However, the roles and responsibilities of these departments are not defined. Secretariat guidance states it is the role of all departments to secure VfM, and it's not clear how these responsibilities are shared or cascaded across all teams.

There is also a current lack of corporate-level key performance indicators to track achievement of the dimensions of VfM, and there is no coordinated and structured process for reporting on VfM at the corporate level. Lastly the framework does not highlight data limitations as a key challenge to monitor and report on VfM.

The guidance to apply the VfM framework to health & laboratory investments and to monitor the achievement of its various dimensions needs to be more specific to guide areas of material investment.

The VfM framework is a strategic framework that has not been translated into operational processes and guidelines towards applying the framework to specific investments. As a result, the approach to ensure all dimensions of VfM are applied and monitored to health and laboratory equipment has yet to be effective:

Economy: *Economy implies purchasing quality inputs at the lowest sustainable price, using robust procurement systems and managing financial flows through effective and integrated financial systems.*¹⁵

There is limited guidance to grant applicants on how to approach the most economical investment decisions. For example, in the context of investments in health and laboratory equipment, there is a lack of detailed guidance on the trade-offs and considerations between (i) investing in more lab equipment or in optimizing the existing investments by strengthening supporting infrastructure or (ii) buying equipment versus leasing/contracting diagnostic services.

¹⁵ See footnote 12.

Efficiency: Efficiency is about optimizing service delivery in a given context and enhancing scalability; it does not necessarily mean continuous reduction of costs.¹⁶

The VfM framework mainly refers to allocative and technical efficiency.¹⁷ However, for laboratory and health equipment, a measure of efficiency is utilization.¹⁸ There are no harmonized or regular reporting requirements on equipment utilization set at the country/grant level. As a result, the approach to tracking and monitoring use at the individual portfolio level has led to a fragmented understanding and inconsistent approach to assessing utilization (refer to Finding 3.3).

Effectiveness: Effectiveness is assessed by the extent to which the proposed interventions and activities achieve a set of defined outcome and impact targets, while removing structural barriers and strengthening resilient health systems.¹⁹

Performance measures have not been defined to assess whether the desired outcomes from investment in health and laboratory-related equipment have been achieved. There is no methodology to evaluate how the investments are directly contributing to intended impact (refer to Finding 3.3). For example, there is no metric to assess how investment in a particular technology has improved effectiveness or how different screening and diagnostic strategies can maximize the use of resources to achieve the desired outcomes.

Equity: Equity is achieved when unnecessary and avoidable differences in availability, utilization and outcomes of health services, which are unfair or unjust, are eliminated. This refers to the fair opportunity for everyone to attain their full potential for health and wellbeing, with no person disadvantaged due to social, economic, demographic or geographic differences. Equity is at the heart of the Global Fund and its vision of “a world free of the burden of AIDS, tuberculosis and malaria with better, equitable health for all.”²⁰

There is a lack of indicators to measure the extent to which equity is being achieved or not. Although the Global Fund's modular framework contains indicators on the number of cases notified among key affected population/ high-risk groups, these are often not tracked at the grant level with only two out of the six deep-dive countries tracking these indicators. This gap leads to an inability to assess equitable access to diagnostic services across the Global Fund portfolio.

Sustainability: The Global Fund's approach to sustainability focuses on the ability of a health system to maintain and scale up service coverage to a level that provides for the continued control of a public health problem and support efforts to eliminate the three diseases, even after funding from external donors comes to an end.²¹

There is a lack of VfM metrics for assessing the sustainability of investments. This is linked to a lack of a clear definition of what sustainability means for these investments, for example, whether to invest in bespoke equipment models with supplier support, investment in open platforms that do not lock countries into specific suppliers, or how investments transition from Global Fund support to being funded by national governments.

Trade-offs between dimensions: The VfM technical Brief²² also acknowledges that while the dimensions of the framework should complement each other, in some cases, there is a need to find a balance between them, given the country context, overall health strategies, epidemiological trends and gaps, health system capacity constraints, domestic budgets and other donor investments. Grant applicants are encouraged to highlight and explain potential trade-offs made among VfM dimensions and the rationales behind them.²³

However, there is limited guidance to assess VfM across the dimensions including trade-offs between components. For example, for GeneXpert efficiency (utilization) needs to be balanced with equity and access. As GeneXpert is recommended as an initial test to diagnose TB, universal access to the technology is promoted. But to reach all beneficiaries, full utilization of each individual machine may not be achieved.

¹⁶ See footnote 12.

¹⁷ As per Technical Brief on Value for Money, allocative efficiency at the disease program level refers to optimally allocating resource across interventions, geographies and population groups to maximize impact. At the system level, it implies allocating the total resources available, with due consideration of what proportion of resources should support strengthening the health system more broadly to overcome common bottlenecks across programs. At the disease program level, technical efficiency refers to minimizing the costs of service delivery along the care continuum while achieving the desired health outcomes. At the system level, it means to achieve the lowest costs in delivering quality services to meet different health needs so the total health benefit to the entire population is maximized.

¹⁸ For example, number of tests conducted, equipment downtime, number of patients screened with CXR machines, etc.

^{19, 20, 21, 22, 23} See footnote 12.

Ongoing work by the Secretariat to further operationalize VfM framework going forward:

The limitations above have been identified and acknowledged by the Secretariat. Specifically for health- and laboratory-related spend, there is ongoing work to enhance the approach to support and monitor investments for GC7. A working group was formed in 2022 with Secretariat-wide representation to operationalize VfM at the corporate and grant level, with laboratory systems being a key priority area for this group. A new sub-category of risks, focused on laboratory systems, is planned to be included in risk management systems, tools and processes with the aim of strengthening the identification, mitigation and monitoring of laboratory system-related risks including VfM.

The implementer capacity assessment template²⁴ will be expanded for GC7 to include laboratory-related capacity focusing on laboratory systems, structures, people, infrastructure at country-level, regulations, etc. This will enable better understanding of capacity and constraints of laboratory systems in-country. Secretariat technical briefs²⁵ and information notes²⁶ are updated, to provide enhanced guidance to implementing countries and Country Teams on achieving better effectiveness and efficiency. For example, there is now more robust guidance on network optimization for machines and integration of diagnostics across disease programs.

As part of the Agreed Management Action (AMA) below, the Secretariat aims to advance the Global Fund's approach to VfM through a phased approach. The resolution of the issues identified is dependent on the quality of the developed roadmap and the speed at which it is implemented. The OIG will review progress and include status in subsequent VfM audits conducted on an annual basis.

Agreed Management Action 1

The Global Fund Secretariat will progress the prioritization and operationalization of dimensions of the Value for Money Framework (with a focus on efficiency, equity and economy) in core grant processes, by developing and materially commencing implementation of a roadmap leveraging OIG VfM audit findings together with other VfM assessments conducted by the Secretariat.

OWNER: Marijke Wijnroks, Head, Strategic Investment & Impact Division

DUE DATE: 31 March 2026

²⁴ Capacity Assessment template is a tool to assess whether systems and capacities of grant implementers are adequate for effective management of the grant funds.

²⁵ See footnote 12.

²⁶ Information notes on [RSSH](#), [HIV](#) and [TB](#) (last accessed 08 February, 2023).

3.2 Need to strengthen and leverage key enablers to ensure continuous achievement and assessment of VfM for health and laboratory equipment

Lack of national laboratory strategies, as well as limited involvement of national laboratory entities in implementation, and lack of monitoring processes at the Global Fund are hindering the value for money of investments in laboratory equipment.

Through deep-dive reviews of six countries, the audit analyzed the critical enablers for achievement and continuous monitoring of VfM both at country and Global Fund level. These include strong in-country laboratory leadership and governance structures, a clearly articulated laboratory strategy, costed plans to guide and channel donor investments, robust assessment of VfM at the time of funding request, monitoring mechanisms at Global Fund and country-level to continuously assess and optimize investments, as well as coordination and alignment investments with other donor partners.

Lack of costed national laboratory strategies and limited involvement of National Laboratory entities in funding applications adversely impact effective grant-making and implementation.

In half of the six countries assessed, investments in laboratories are based on, and are guided by, disease NSPs rather than by National Laboratory Strategies and costed plans. In two out of six countries, the National Laboratory Strategy hasn't been finalized and in three out of six countries, National Laboratory costed plans do not exist to guide donor investments. For example:

- In **Malawi**, there is a National Laboratory Strategy (2017-2022), but it was not fully implemented. It refers to the creation of a laboratory directorate, but this has not occurred. Instead, a lower-level division exists under the Health Technical Support Services directorate with minimal visibility, resources and oversight.
- In **Nigeria**, the 2015-19 National Laboratory Strategy was not costed or implemented. There is now an unfinalized draft of the 2020-25 Strategy. This has resulted in continued fragmentation and overlap in responsibilities across two laboratory entities, impacting lab management, coordination and supervision.²⁷
- In **Bangladesh**, there is no coordinating entity for laboratories at the Ministry of Health and Family Welfare; the laboratory responsibility is split between disease programs. The National TB program developed a disease-specific laboratory strategic plan for 2021-2025, however, the costing for this plan is currently on-going.

GOOD PRACTICE: In **Ethiopia**, the National Laboratory Strategy is detailed, costed and up to date. It aligns with the overall health strategy for the country and provides a rational basis for Global Fund investments in health and laboratory equipment. The National Laboratory directorate – EPHI (Ethiopia Public Health Institute) plays a key role in coordinating Ethiopia's public health laboratory system.

EPHI actively participated in providing relevant input and guidance on laboratory components during the Country Dialogue and Funding Request stages of Ethiopia's GC5 & GC6 applications. Further, EPHI is an implementer under the current grants.

²⁷ The Federal Ministry of Health (FMOH) has proposed a new structure that places the Laboratory Directorate as the coordination point for laboratory activities. Through Global Fund grants this directorate is being strengthened with capabilities for supervision and oversight.

In half²⁸ of six countries assessed, National Laboratory entities were not involved in the Global Fund's Country Dialogue/funding request development. This was also highlighted in a survey conducted²⁹ by the Global Fund's RSSH laboratory team in 2021 – with only 33% (6/18) of laboratory directorates being actively involved in the preparation of Global Fund Funding Requests. The Global Fund CCM policy does include guidelines on government representation on CCM – while it places specific emphasis on representation from national disease programs, CDC, etc., it does not state National Laboratory representation.

Historically, Global Fund investments flow through disease programs, with National Laboratory entities seldom implementers under the grants, which usually result in having no direct relationship with Global Fund investments; this was noted in two out of five countries. This means they are not adequately incentivized or empowered to mobilize the financial resources to coordinate, implement and oversee activities outlined in National Laboratory Strategic Plans. To remediate this, the new Global Fund's RSSH information note reaffirms the role of national laboratory directorates in investment planning³⁰ and the Secretariat has conducted workshops with the national laboratory entities for several High Impact countries for GC7 to support better engagement. In addition, since the expansion of the Global Fund Laboratory team from one to eight members in 2021, there has been more focus on engaging and strengthening capacity of the National Laboratory directorates.

Limited visibility over information needed to assess VfM at the Funding Request stage.

Investments in health and laboratory equipment are not consistently based on an assessment of value for money considerations. In all deep-dive countries reviewed, the request for new equipment was not supported by a needs assessment, or by an analysis of current use of equipment already in the country, or prior challenges encountered to achieve VfM and corresponding mitigation measures. Countries were not required to submit deployment plans (including plans for contracting service providers for installation) or site readiness assessments prior to procurement of equipment, and this has downstream implications. For example, in Mozambique, 76 GeneXpert machines arrived in the country in April 2018, and were only deployed by December 2019 due to administrative hurdles in the contracting of service providers. Similarly, in Indonesia, 104 GeneXpert instruments had been at the warehouse for 1.5 years because facilities were not ready to receive them.

There is a need to take into consideration the entire laboratory ecosystem, including enablers such as infrastructure, maintenance, and human resources, so equipment can operate effectively following installation. In all the countries reviewed, while the Global Fund contributed to GeneXpert investments, there was no clarity on who would fund these supporting enablers, which can impact effectiveness, efficiency and equity.

GOOD PRACTICE: C19RM Funding Request Reviews

Under C19RM 2021 approvals for funding, management actions related to the purchase and use of equipment were specified in Notification Letters, and funds were not disbursed or could not be used until Principal Recipients fulfilled these conditions. For example, in the Bangladesh C19RM funding request, funds were approved for GeneXpert and CXR machines, but a management action specified that, prior to the use of funds, Principal Recipients needed to submit a deployment plan, utilization data for the existing network and an optimization plan. This was done to mitigate/minimize downstream risks and ensure decisions are based on factual information. However, for grants under GC5 and GC6, such conditions are not consistently specified.

²⁸ Nigeria, Malawi and Bangladesh.

²⁹ Laboratory Strategic Initiative Technical Working Group, August 2022.

³⁰ Information note on RSSH (last accessed 8 February 2023).

Ad-hoc processes to track and assess achievement of VfM throughout the grant life cycle.

In the Global Fund Secretariat, there is no process to ensure consistent monitoring of investments in health and laboratory-related equipment across countries, nor are there indicators to track efficiency of these investments. This results in ad hoc and inconsistent monitoring approaches by different Country Teams. The Nigeria Country Team requires Principal Recipients to submit quarterly reports on utilization, functionality, timely reporting of breakdown issues, etc. However, other Country Teams do not require the same level of tracking. Prior OIG reviews had noted gaps in monitoring and identifying issues. For example, GeneXpert machines remained in warehouses for up to one and a half years in Indonesia,³¹ missing critical opportunities to maximize impact.

At the country level, the Global Fund has not set up specific reporting structures for Principal Recipients to report on these investments, as such equipment utilization data is inadequate. For half³² of the countries analyzed, GeneXpert utilization rates are not tracked or calculated annually at the national level and fail to routinely measure use of individual equipment by regions, thereby leading to lack of optimization of investments, as detailed in Finding 3.3. In four³³ out of six countries, GeneXpert error rates are not systematically analyzed to reduce the number of failed tests. Similarly, equipment downtime and specimen referral performance indicators including Turn-Around-Time (TAT) are inadequately monitored (this may in turn require investment in underlying data systems).

The AMA below was developed considering the need to balance the urgent need to start reviewing GC7 funding requests versus the development of a longer-term approach. The Secretariat will aim to ensure a consistent approach to reviewing funding requests for investments in health and laboratory-related equipment across countries through a VfM lens. To mitigate the risks identified, it is important that the checklist developed as part of the AMA includes all the enablers identified in the audit finding and considerations are incorporated into investment decisions. The Secretariat declined further management actions to enhance the processes and roles and responsibilities in the longer term.

Agreed Management Action 2

The Global Fund Secretariat will review GC7 Funding Requests with proposed investments in molecular diagnostic platforms and Chest X-ray using a defined checklist for laboratory equipment and Chest X-ray.

OWNER: Marijke Wijnroks, Head, Strategic Investment & Impact Division (SIID)

DUE DATE: 31 March 2025

³¹ [Audit of Global Fund Grants in the Republic of Indonesia GF-OIG-20-001](#) (last accessed on 08 February 2023).

³² Malawi, Uganda and Ethiopia.

³³ Malawi, Nigeria, Uganda and Bangladesh.

3.3 Operational challenges in using GeneXpert platforms limit the attainment of effectiveness, efficiency and equity

With the support of Global Fund investments, countries have more than doubled GeneXpert testing sites between 2016 and 2022. This has led to an increase in absolute numbers of TB cases diagnosed using WHO-recommended rapid diagnostics in countries sampled by the OIG. However, the percentage of GeneXpert tested cases out of overall case notifications is at or below 30% in three out of five countries sampled by the OIG. This was linked to operational challenges with using GeneXpert platforms due to factors such as service and maintenance issues, inadequate sample transportation systems, stock-outs of cartridges and limited access to WHO-recommended rapid diagnostics.

When GeneXpert was introduced in 2010, it represented a paradigm shift in the diagnosis of TB and drug resistant TB. It simplified molecular testing by fully integrating and automating the diagnostic process, detecting not only TB but also resistance to rifampicin (first line anti-TB drug). The platform was the only WHO-approved rapid diagnostic tool to identify both TB and drug resistant TB until 2020, when additional technologies were approved.

The platform was designed to heavily decrease the time taken to provide a more accurate diagnosis of TB³⁴ and resistance to rifampicin (with return of result within two hours) compared to previous diagnostic methods, such as smear microscopy and culture. This is a key enabler to support programs in improving the quality of service to beneficiaries, finding more missing cases and reducing the opportunities for further transmission of the disease. This can in turn support programs to link patients more effectively to treatment and reduce overall mortality.

Global Fund supported investments in GeneXpert platforms.

The Global Fund has supported countries in scaling-up access to GeneXpert technology with a total investment of US\$800 million from GC4 to GC6. However, in terms of the broader funding landscape, funding for TB programs, even with the support from Global Fund and partners, is not sufficient to fully implement the National Strategic Plans (NSPs) for TB response. For example, across the six countries in the deep-dive, the total funding gap reported across the implementation of GC6 was US\$872 million (representing 47% of NSP needs), with the largest gaps reported by Nigeria, Bangladesh and Ethiopia³⁵ in absolute terms.

Funding gaps also exist specifically for the use of GeneXpert platforms, which require a regular supply of cartridges and financing for the broader enabling environment.³⁶ Because of this context, value for money is even more critical to inform investment decisions.

Trends in TB diagnosis and COVID-19 impact.

At the global level, there was a significant global decline in the number of notified TB cases during 2020 due to the COVID-19 pandemic. Despite this, 2.5 million (38%) of the 6.4 million people newly diagnosed with TB were diagnosed using a WHO-recommended rapid diagnostic test in 2021. This is a noteworthy achievement given the broader challenges for TB caused by COVID-19.

³⁴ WHO operational handbook on tuberculosis: module 3: diagnosis: rapid diagnostics for tuberculosis detection, 2021.

³⁵ Nigeria has a funding gap (US\$ 343 million), Bangladesh (US\$225 million) and Ethiopia (US\$134 million).

³⁶ This includes resources for sample transportation network, uninterrupted power supply, trained technicians, laboratory infrastructure etc.

In all the six deep-dive countries, significant progress has been noted in increasing TB case notifications using WHO recommended rapid diagnostics (WRD). In these countries, there has been an increase in the absolute number of cases diagnosed with WRD between 2016–2021 from 21,454 in 2016 to 283,624³⁷ in 2021. This is a positive trend in the context of the challenges posed by the COVID-19 pandemic, which impacted TB diagnosis rates in 2020–21. This was linked to the expansion of GeneXpert platforms and countries adopting the WHO recommendation for the use of GeneXpert as an initial diagnostic test for TB. Absolute number of cases detected with drug resistant TB also increased from 4,824 in 2016 to 7,001 in 2021. In addition, there was reduced TB-related mortality with a decline of 26%³⁸ in the same 2016–21 period. However, despite the investments made, there are still operational barriers to further maximize the positive impact of GeneXpert platforms as the initial diagnostic test, at country-level:

Effectiveness: Accurate diagnosis is a fundamental component of TB care. Rapid molecular diagnostic tests help to ensure early detection and prompt treatment. In line with this, across the deep-dive countries, investments in GeneXpert testing were made to ensure a scale up in case detection, as well as quality and speed of diagnosis. As previously stated in Section 1.4, the audit did not cover diagnostic accuracy of selected equipment types as these have already been pre-qualified by WHO and their efficacy confirmed by numerous scientific studies.

One of the key indicators as recommended by WHO³⁹ for monitoring the implementation of the End TB Strategy is percentage of notified TB cases tested with a WHO-recommended rapid diagnostic test as the initial test (regardless of test result). However, in three out of the five⁴⁰ deep-dive countries (see figure 3), the percentage of notified TB cases identified through GeneXpert testing is at or below 30% (note: no targets were established for this indicator to assess performance given the number of platforms in the country). However, increases in absolute cases⁴¹ notified and tested (both drug susceptible and resistant TB) using GeneXpert were noted in 5 out of 6 countries where it is tracked. *Effectiveness* has been impacted, in part, due to challenges with operational *efficiency* (discussed in more detail below), with COVID-19 playing a significant role.

In all the countries in the sample, the OIG noted that in addition to trends in testing, there were also other positive programmatic trends observed in the same period being assessed. These include several positive examples of decreases in estimated TB incident cases (Ethiopia and Malawi) and positive increases in TB case notification (Bangladesh, Mozambique, Nigeria, and Uganda).

37 Refer to footnote 36 for Mozambique.

38 WHO Global TB Report 2022, indicator on Estimated number of deaths from TB (all forms).

39 WHO's [Implementing the End TB Strategy: The Essentials 2022 Update](#) (last accessed on 9 August 2023) recommends monitoring of Percentage of notified new and relapse TB cases tested with a WRD as the initial diagnostic test (with a target of > 90% of cases by 2025) as one of the top 10 priority indicators to monitor the implementation of End TB Strategy.

40 For Ethiopia, please note that the country has not tracked and reported the number of cases tested and diagnosed through WRD tests since 2015. In the absence of this indicator, the proxy indicator on bacteriologically confirmed TB cases was used to assess achievement of effectiveness of investments.

41 See figure 3.

Figure 3:
Trends in increases in GeneXpert (GX) platforms vs tested cases in the sampled countries⁴²

Country	Time period assessed ⁴³	Increase in GX platforms ⁴⁴	Change in total absolute number of notified TB cases tested with WRDs	Latest reported % of notified TB cases tested with WHO Recommended Rapid Diagnostics (WRD) as initial diagnostic test (Top 10 priority indicator, WHO End TB Strategy) (2021)	Change in percentage of notified TB cases tested with WHO Recommended Rapid Diagnostics (WRD) as initial diagnostic test ⁴⁵	Change in total absolute number of DR-TB detected (2016-2021)	Percentage of missing DS-TB cases (2021)	Percentage of missing DR-TB cases (2021)
Bangladesh	2018-2021	135%	48,055 to 73,968	24%	6%	969 to 1,601	18%	64%
Mozambique	2016-2021	172%	10,840 to 25,802	26 ⁴⁶	11%	911 to 1,308	16%	73%
Malawi	2019-2021	36%	3,660 to 4,315	30%	8%	66 to 93	45%	87%
Ethiopia	2016-2021	168%	Not tracked	Not tracked ⁴⁷	Not tracked	703 to 518	27%	71%
Nigeria	2017-2021	5%	42,390 to 128,165	64%	23%	1,686 to 2,975	56%	80%
Uganda	2016-2021	144%	10,614 to 51,374	69%	45%	489 to 506	18%	66%

While there are many factors⁴⁸ that can affect contributions to increased TB case notification, the most common root cause in the OIG sample was the low utilization of the platforms due to operational challenges at the country level (see section below). This is hindering the ability for programs to attain the full benefits of the GeneXpert platforms. In **Bangladesh**, the utilization rate of GeneXpert platforms was 42%⁴⁹ due to service and maintenance related issues, stock-outs of cartridges and non-adherence to TB testing algorithm. COVID-19 also had an impact on TB case notification and on the percentage of TB cases notified through GeneXpert testing, which reduced in 2020 before recovering in 2021.

42 WHO TB datasets 2022 (last accessed on 8 February 2023).

43 See footnote 6.

44 Country-wise trend in increase in GeneXpert platforms: for Bangladesh 135% increase from 192 in 2018 to 451 platforms in 2021; for Mozambique 172% increase from 57 in 2016 to 155 platforms in 2021; for Malawi 34% increase from 108 in 2019 to 147 platforms in 2021; for Ethiopia 168% increase from 138 in 2016 to 370 platforms in 2021; for Nigeria 5% increase from 386 in 2017 to 405 platforms in 2021 and for Uganda 144% increase from 111 in 2016 to 271 platforms in 2021.

45 Country-wise trend in percentage cases notified and tested through WRD: for Bangladesh 6% increase (from 18% in 2018 to 24% in 2021); for Mozambique see footnote 37; for Malawi 8% increase (from 22% in 2019 to 30% in 2021); for Ethiopia see footnote 38; for Nigeria 23% increase (from 41% in 2017 to 64% in 2021) and for Uganda 45% increase (from 24% in 2016 to 69% in 2021).

46 For Mozambique, the country reported inaccurate data to WHO for inclusion in the 2022 WHO World TB report for number of notified TB cases tested and diagnosed with WRD. The country included number of cases tested and diagnosed through smear microscopy, as well as GeneXpert as part WRD testing. Due to this, the OIG did not leverage the WHO World TB report (for Mozambique only) and instead leveraged data directly reported to the OIG from the National TB Program in Mozambique. The National Program provided data on the number of positive results among the diagnostic tests performed using molecular WHO-recommended rapid diagnostics. The change in number of positive results among the diagnostic tests performed using molecular WHO-recommended rapid diagnostics shows an 11% increase over 2016 to 2021; in terms of number of cases notified 10,840 in 2016 to 25,802 in 2021.

47 For Ethiopia (not included in the three countries), please note that the country has not tracked and reported the number of cases tested and diagnosed through WRD tests since 2015. In the absence of this indicator, the proxy indicator on bacteriologically confirmed TB cases was used. However, this does not provide a fully accurate picture of trends in percentage of GeneXpert testing as initial diagnostic test to overall case notification. The change in bacteriologically confirmed cases (which includes positive cases through smear, culture and WRD testing) shows a 7% increase over 2016 to 2021; in terms of number cases notified 47,061 in 2016 to 46,720 in 2021.

48 Factors that can impact contribution to TB case notification, including demand generation activities to ensure prospective patients, are being identified for testing in the first instance. This also comprises factors that can impede effective active case finding, contact screening, community awareness, engagement, and testing.

49 For all GeneXpert machines in the country for January to September 2022 based on 3-cycle run.

Equity: *Equity* underpins the effectiveness of investments and their long-term impact, given that epidemic control and disease elimination efforts can only be successful if no one is left behind. Opportunities to increase equity include a continued scale-up of service coverage for key and vulnerable populations (KVPs), as well as an increased focus on other disadvantaged and left-behind groups, such as women and girls, the poorest and those living in remote or hard-to-reach areas.⁵⁰

A critical measure of *equity* for GeneXpert is maximizing accessibility to all beneficiaries. However, the VfM dimension on *equity* cannot be fully assessed due to a lack of available data and analysis in this area. For GC6 funding requests, there was a lack of detailed analysis on barriers to access diagnostic services and how those are being mitigated. There are also gaps in disaggregated data for case finding, with this being reported in only two out of six countries sampled. There was also a limited number of reviews/assessments conducted by the Global Fund Secretariat focusing on assessing and measuring the achievement of *equity* for the sampled countries.

Where applicable, when formulating the GC6 deployment plans for GeneXpert investments in the sampled countries, *equity* was considered through balancing the need to prioritize both high-burden as well as low-burden sites to support increased access. However, there is still low geographical coverage as was noted in three⁵¹ out of six countries. Key drivers for this are limited number of GeneXpert platforms and challenges with regards to sample transportation networks. To function optimally GeneXpert requires a level of infrastructure, which can impact implementation roll-out. For example, in **Mozambique**, GeneXpert sites cover only 58% of the population.⁵² *Equity* is also impacted due to operational challenges that can limit access to diagnostic services, these challenges have been highlighted in the prior sections.

Efficiency: One important measure of *efficiency* of GeneXpert machines is the utilization rate. The utilization rates of the deep-dive countries varied significantly from 42% to 74%. This indicates gaps in achieving *efficiency*. While the root causes of low utilization are numerous, the most common highlighted in the six country deep dives were, as noted below:

- **Lack of regular and timely maintenance of GeneXpert machines:** Gaps in servicing, repair and maintenance are a key challenge across the six deep-dive countries resulting in low utilization. There is support provided for repair and maintenance by a sole supplier⁵³ through warranties and an access care agreement. However, for the deep-dive countries with GeneXpert warranties, a high number of modules were non-functional and there were long turnaround times to repair modules. In **Mozambique**, between 30-40% of modules were faulty during 2020-22 and in **Bangladesh**, between 20-30% of modules were faulty during 2022, hindering access to TB diagnostic services. In **Ethiopia**, there were delays of up to four months to replace faulty modules, because there is no supplier service center in or around the region.
- **Lack of adequate sample transportation network:** Adequate sample transportation is key to ensuring samples can reach GeneXpert platforms for diagnosis and therefore lead to good utilization of platforms. However, in four⁵⁴ out of six countries, sample transportation networks were either fragmented or inadequate in coverage. In **Mozambique**, sample transportation has been fragmented with many different partners supporting provinces/districts in different ways.⁵⁵ In **Bangladesh**, limited sample transportation mechanisms exist in the sub-districts that do not have GeneXpert platforms.⁵⁶ This results in patients having to travel to testing centers, creating a geographic barrier to diagnosis that leads to reduced utilization. The cost of sample transportation differs according to each country context, meaning management judgements are required as to whether to invest in additional equipment or a sample transportation network.

50 [Technical Brief on Value for Money](#) (last accessed on 8 February 2023).

51 Mozambique, Bangladesh and Ethiopia.

52 This includes health facilities that send their samples and are located at a viable distance from the testing facility e.g., within a distance of 10 km.

53 The sole supplier is also the patent holder and manufacturer of the GeneXpert platform.

54 Mozambique, Nigeria, Bangladesh and Ethiopia.

55 [OIG Audit of the Global Fund grants in the Republic of Mozambique](#) (last accessed on 8 February 2023). A more consolidated partner supported transportation network has been implemented since 2022.

56 The country plans to scale-up molecular diagnostic technology to sub-district level.

- **Stock-outs of cartridges due to delayed shipments:** Stock-outs of cartridges due to delayed shipments from the supplier were noted in two out of six countries (**Bangladesh & Nigeria**). In **Bangladesh**, all shipments in 2021 and 2022 were delayed by an average of 300 days due to global production and distribution being negatively impacted by COVID-19, resulting in widespread stock-outs. As a result, the country reverted to reliance on smear-microscopy diagnosis of TB for much of 2021-22.

Previous OIG country audits have also highlighted similar issues related to stock outs of cartridges. In these instances, stock-outs were linked to delays in procurement, inadequate laboratory supply chain management, incorrect quantification, and lack of domestic funding to finance cartridges.

The Global Fund, through C19RM, has supported procurement of additional GeneXpert machines for conducting simultaneous testing for both TB and COVID-19 and to increase access. This increase in platforms increases the need to ensure adequate future financing for total cost of ownership of platforms including procurement of cartridges to minimize the risk of stock-outs. However, the impact of these additional machines was not assessed because at the time of the audit fieldwork most of these platforms had not been delivered and installed at country level.

- **Gaps in monitoring of utilization at site-level impacted the ability to resolve challenges in utilization:** As noted in Finding 3.2, in half of the six countries reviewed, GeneXpert machine utilization rates are not routinely tracked at the sub-national or GeneXpert site level. In countries sampled, a GeneXpert connectivity solution⁵⁷ was in place to support real-time monitoring of use at the platform level. However, its usefulness is limited due to broader issues with the strength of health systems and infrastructure development such as the availability of continuous power supply, internet access, HR capacity. This results in an inability to address utilization challenges in a timely manner.

This VfM audit and prior OIG country audits highlight other root causes of lower utilization, including a lack of sufficient training and shortage of human resources, non-adherence to testing algorithms, lack of uninterrupted power supply and stock-outs of cartridges due to gaps in supply chain management. These issues do not only affect GeneXpert platforms but can also negatively impact a broad range of health and laboratory investments.

It is important to note that while utilization is an important metric to monitor efficient use of GeneXpert platforms, attaining utilization needs to be balanced with the requirements of other dimensions. Trade-off decisions are required between achieving adequate utilization of GeneXpert and increasing access to the technology. For example, placing a GeneXpert platform in a remote/hard-to-reach area may not achieve adequate utilization due to lower volumes but may increase *equity*. Monitoring utilization is essential to identify bottlenecks early on and address any unintended inefficiencies and further optimize investments.

Economy: Factors influencing the ability to better achieve *economy* with GeneXpert investments including GeneXpert machines being manufactured by a sole supplier, and – until 2020 – it was the only WHO-approved rapid diagnostic tool for TB and drug resistant TB. To manage the risk of price volatility and support a continuous supply, in 2012, several health partners entered a buydown agreement with the supplier. This agreement resulted in a maximum ‘ex-works’ price for GeneXpert instruments and cartridges for a 10-year period. This pricing arrangement was followed by the original signatories, and subsequently the Global Fund until 2022. The buy-down agreement was instrumental in achieving an immediate reduction of cartridge prices in 2012. For the next 10 years cartridges were priced at US\$9.98 with no further price reductions agreed in this period. However, this cost in a broader resource constrained environment has had an implication on the volume of cartridges that could be acquired by TB programs to support an expansion of GeneXpert testing. Negotiations are ongoing for a new agreement for 2023 and onwards. In the meantime, in October 2023 the Global Fund and partners have announced a new 20% price reduction for cartridges going forward.⁵⁸

⁵⁷ Connectivity solutions supports monitoring of equipment operational performance by sending data to a server (in-country or cloud) and also facilitates instant and accurate transmission of patients results directly to clinicians as well as to laboratory information management systems or electronic registers.

⁵⁸ Global Fund, Stop TB Partnership and USAID Announce New Collaboration with Danaher to Reduce Price and Increase Access to Cepheid's TB Test (last accessed on 16 October 2023).

Existence of only a single supplier and the adherence to the pre-existing buydown agreement impacted how the Global Fund could influence the achievement of economy when compared to other equipment investments. It has also contributed to the acceptance of service and maintenance arrangements that limit the achievement of *economy* and have implications on *efficiency*. However, it did ensure a stable fixed price for cartridges regardless of orders placed, which demonstrated methodical planning and guarded against volatile price swings.

Limitations in the provision and planning for service and maintenance: To support ongoing servicing, repair and maintenance of platforms, GeneXpert platform purchases include a two-year warranty with the option to purchase further extensions through an extended warranty scheme. However, these warranties do not cover critical elements of repair and maintenance (e.g., in-country on-site visits by authorized service providers) limiting the added value of these contracts. This is despite Global Fund programs having paid more than \$17 million⁵⁹ in purchasing extended warranties in total.

As a result, countries engage in separate contracts with service providers or try to build internal capacity to service equipment. However, the total cost of ownership, including repair and maintenance is not always factored into investment decisions at the outset. As a result, many countries face challenges in keeping the instrument fleets running optimally. At the Global Fund Secretariat level, there is limited consolidated data on Service and Maintenance issues at the country level, which hinders the Global Fund's ability to hold suppliers to account and tackle issues strategically.

To mitigate the above, the supplier developed another support arrangement called "Access Care".⁶⁰ This is a Service Level Agreement covering maintenance needs. When performing a cost-benefit analysis comparing the extended warranty arrangement versus Access Care, it was noted that in several instances Access Care is cheaper and provides more service support at country level.⁶¹ However, only 10 countries (Nigeria, Uganda, Ethiopia and Malawi from OIG sampled countries) were offered Access Care and countries must negotiate individually to agree pricing resulting in varying terms and conditions being reached. This reduces the negotiating power of implementer counties for achieving optimal *economy*. To help address these problems, along with other TB partners, the Global Fund has secured improved service and maintenance arrangements with Cepheid as part of the revised GeneXpert package negotiated in 2023.

Sustainability: Key *sustainability* metrics for GeneXpert machines include the role of domestic financing to support costs, as well as the cross-functional use of machines to embed the investments in the broader health system. It was noted that most of the laboratory investments are heavily financed by the Global Fund and partners. The Technical Review Panel noted limited progressive uptake of laboratory commodities (equipment, reagents, cartridges, etc.) by domestic funding.⁶²

GeneXpert platforms are still primarily used for TB testing but can also be used for other purposes such as Viral Load testing. Most recently, the COVID-19 pandemic led to expanded use of platforms, with many countries leveraging the platforms for COVID-19 testing.

However, our review found cross-program use varied significantly. In **Mozambique & Nigeria**, there are plans to conduct a pilot to expand GeneXpert to HIV VL/EID testing, but this is not yet implemented. As noted previously, the Global Fund, through C19RM, invested in additional GeneXpert and cartridges for COVID-19 testing to expand diagnostic capacity.

59 Figure of US\$17 million could only be quantified from warranties purchased through GDF and Wambo from GC4 to GC6. Data is not available for countries that purchased warranties directly from the supplier.

60 It is funded in the form of a surcharge or top-up paid for each GeneXpert cartridge.

61 A cost-benefit analysis, conducted for comparing extended warranties with AccessCare, suggests extended warranties are costing much more than AccessCare (US\$2,898 vs. US\$2,040 for a 4-module GeneXpert) with the added coverage of AccessCare (preventive maintenance, on-site swapping of faulty modules, training & installation).

62 This was highlighted by the review of Technical Review Panel (TRP) lessons learned from 2020-22 allocation report "TRP's concerns on limited to no domestic financing for reagents and kits for laboratory diagnosis, indicating an extreme reliance on the Global Fund."

Investments in GeneXpert technology has led to the increase in accurate diagnosis of TB cases (including in pediatrics), as well as an increase in detection of Rifampicin Resistant -TB cases. Recognizing the criticality of this technology, the resolution of operational and implementation challenges together with increasing access to WHO-recommended rapid diagnostics are key to further enhance the impact of this investment.

Agreed Management Action 3

The Global Fund Secretariat will monitor progress in addressing operational challenges in using WHO rapid molecular diagnostic tests (mWRDs) in the 20 priority countries by including in the grant Performance Framework as a Group 1 indicator “Percentage of new and relapse TB patients tested using WHO recommended rapid diagnostic tests at the time of diagnosis” and report this at least once a year. Additionally, the coverage of rapid molecular diagnostics is part of the TB Program Essentials and will additionally be tracked on a semi-annual basis. This tracking and reporting will also include analyses to identify operational challenges impacting access to mWRDs by patients and recommendations for improvements.

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DUE DATE: 31 December 2025

3.4 Protracted procurement and delays in installing machines, resulting in limited achievement of VfM from investments in Chest X-rays (CXR)

There are significant delays in procurement and installation of CXR due to protracted procurement processes, delays in finalizing specifications, time required for site preparation for hosting this equipment, as well as obtaining regulatory approvals and recruiting radiologists. This has impacted *effectiveness* and *equity*.

CXR is a sensitive, accurate and efficient tool used to identify people in need of follow-on diagnostic testing. It can support a broad range of medical diagnoses including for TB. With a total investment of US\$181 million from GC4 to GC6, there is improved access to radiology services to intensify active case finding and to facilitate TB diagnosis. The use of CXR also plays a vital role in case notification for children who cannot produce a sputum sample. Most of the CXR investments have been made under GC6 and C19RM 2021 funding. As such, countries are either piloting, or in nascent stages of, developing comprehensive CXR implementation or scale-up plans.

Effectiveness: For 62% of all Chest X-rays procured in our deep-dive countries, operational barriers limited programmatic impact, resulting in negligible achievement of *effectiveness*. This is due to equipment not yet arriving in the country or being used for less than six months at the time of the VfM audit. This is a result of delayed order placement, procurement, deployment, and installation of CXR. There are multiple root causes for these delays across the five deep-dive reviews that had investments in CXR.⁶³

- Evolving requirements at country level have caused delays (e.g., late changes in technical specification) in three (Bangladesh, Nigeria and Uganda) out of five countries.
- Slow custom clearance processes and delivery to wrong port in one country (Bangladesh).
- Re-tendering linked to issues in Principle Recipient procurement processes in one country (Nigeria).
- Protracted renovation works of the designated health facilities linked to radiation safety concerns and COVID-19 disruption in two countries (Bangladesh and Nigeria).
- Delay in obtaining regulatory approvals for sites from radiology authorities in two countries (Bangladesh and Nigeria).
- Delays in recruiting/onboarding of radiologist/radiographers in two countries (Bangladesh and Nigeria).
- Delay in development comprehensive radiology plan to ensure appropriate deployment and usage in one country (Mozambique).

Furthermore, *effectiveness* cannot be assessed in cases where no data is being collected on progress and impact of CXR on screening. Fixed CXR are handed over to radiology departments or hospitals where these are placed, and National Tuberculosis Programs have limited visibility over their usage. For example, in Malawi 12 fixed digital CXR were procured, however the National Tuberculosis Program had no visibility on the number of patients screened and total yield from this investment, as these were handed over to the Radiology department. This highlights broader challenges with implementing CXR which required coordination and alignment across health actors beyond the National TB program. This is due to CXR use not always being specific for TB and the equipment is generally incorporated into the broader primary health system.

⁶³ Deep-dive review countries with investments in CXR include Bangladesh, Malawi, Mozambique, Nigeria, and Uganda.

GOOD PRACTICE: In **Uganda**, five portable digital CXRs were placed at five health facilities in high TB burden districts - a total of 5,262 individuals were screened for TB between June 2020 and August 2021 – out of which 802 had abnormal CXR and 79 (10%) were bacteriologically confirmed TB cases. The National TB program closely monitored the results of the CXR, and this informed the plans to scale-up the use of digital CXR with Computer Aided Detection (CAD) for TB screening at health facilities and in communities.

Efficiency: Due to the delays in procuring, deploying, and installing the majority of CXR machines, there is limited achievement of *efficiency*, as there has been limited use of these investments. The VfM audit noted that one out of five countries did not make provision for maintenance or purchase extended warranties. For example, in **Bangladesh**, where due to delays in installation, the original 12-month warranty elapsed by the time machines were installed. No additional or extended warranties were purchased and 28% (31/109) of machines malfunctioned shortly after installation with no service arrangement in place.

Economy: There were no material issues with the achievement of *economy* as adequate procurement processes were noted for these investments. In 61% of cases, CXR machines have been purchased using PPM/ Wambo, which ensures competitive prices and market terms. Where a local procurement mechanism has been adopted, Local Fund Agents (LFAs) undertake pre-procurement reviews, ensuring *economy* considerations are factored into procurements.

Equity: Countries have prioritized investment in CXR machines to reach key populations that do not have access to diagnostic services to ensure *equity*.⁶⁴ However, due to limited achievement on *effectiveness*, as noted above, *equity* has been impacted given that access to operational CXRs has been delayed. Furthermore, there is a lack of indicators to assess equitable access to CXR screening services, and this impacts how the achievement of equity can be measured.

Sustainability: As noted for GeneXpert, there is a heavy reliance on donor-financed investments for CXR machines, which limits the achievement of *sustainability* in these investments.

The Secretariat declined an action to mitigate risks identified with the efficient and effective use of Chest X-ray equipment. This was due to information on the use of Chest X-ray equipment not being consistently and systematically collected and reported by countries. Although the Secretariat's main focus is on measuring the access and quality of TB screening and testing, use of Chest X-ray equipment will not be monitored by the Global Fund which will limit more meaningful analysis.

⁶⁴ This was demonstrated through activities like organizing mobile chest camps in community, screening patients at mining communities, prisons, refugee camps etc.

3.5 Good achievement of VfM from investments in molecular platforms used for Viral Load testing due to donor coordination and all-inclusive pricing agreements with suppliers

Good achievement of VfM in Viral Load is driven by effective donor coordination at grant level and efficiencies obtained on reagent rental agreements with suppliers that guarantee 95% equipment uptime. However, for Early Infant Diagnosis, the coverage is low due to unintended consequences of pooling of samples to optimize test runs and heavy reliance on centralized testing.

The Global Fund has supported implementing countries on Viral Load/Early Infant Diagnosis (VL/EID) testing with an investment of US\$635 million from GC4 to GC6. In the deep-dive countries, good achievement of VfM was noted for VL/EID platforms. This is primarily due to support from donors that have an in-country presence. Efficiency has also been supported by multiple suppliers for VL/EID platforms that offer all-inclusive pricing agreements. In addition, VL/EID laboratories have been supported by adequate sample transportation coverage, which has been informed by Diagnostic Network Optimization (DNOs), leading to increased use of the equipment. This means that fewer HIV VL/EID testing laboratories require less resources and effort compared to the number of sites required for GeneXpert.

Effectiveness: Overall good VL coverage and suppression is being achieved in all sampled countries. However, EID coverage is low in almost all sampled countries:

Figure 4:
Country-level indicators on People Living with HIV on treatment who are virally suppressed and EID coverage in the six countries sampled⁶⁵

Countries	PLHIV on ART who are virally suppressed	EID coverage
Bangladesh	93%	N/A ⁶⁶
Ethiopia	96%	38%
Malawi	93%	79%
Nigeria	95%	15%
Uganda	92%	75%
Mozambique	N/A ⁶⁷	

In most of the countries, pooled testing of EID samples reduces testing frequency, meaning samples are accumulated and batched together to optimize testing levels on conventional platforms. Due to this, there were high turnaround times of more than three months, resulting in treatment delays.

⁶⁵ UNAIDS Country Factsheets for 2021 (last accessed on 8 February 2023).

⁶⁶ Out of the scope of VfM audit as EID coverage for Bangladesh is not supported by Global Fund grants.

⁶⁷ Out of scope of VfM audit as equipment and consumables are not funded by the Global Fund but by other partners.

Another root cause for low coverage is the heavy reliance on centralized EID testing. For example, in **Ethiopia**, EID Point of Care (POC) contributes only 16% of total EID tests performed despite a seven-fold increase in POC testing capability from 2016 to 2022. In **Nigeria**, low EID coverage is due to sub-optimal sample collection and referral systems, as well as an over-reliance on centralized testing with POC testing only beginning to scale-up in 2022. Programmatic root causes of low EID coverage include a limited awareness of the need for EID referral among providers, as well as the reluctance of HIV pregnant mothers to seek EID services. Lastly, weak linkages and integration of Maternal and Child Healthcare services with HIV treatments sites also contribute to low EID coverage.

Efficiency: A major contributor to high *efficiency* is that countries have transitioned from outright purchase of VL/EID equipment to equipment placement (reagent rental) arrangements, ensuring cost effectiveness and equipment optimization. Supplier agreements contain robust KPIs to ensure accountability, for example, more than 95% of 'uptime', more than 90% of orders delivered in full and on-time, less than 5% of failed tests due to machine or human error, etc.

Economy: Reagent rentals ensure *economy* in pricing by adequately covering preventive and break-down maintenance, replacement of old with new technology and 90% on-time order fulfilment. Several manufacturers exist for VL/EID platforms, providing competitive pricing and service offering. Through consolidation of global volumes, donors have established global reagent prices together with service pricing for selected countries. Overall, there is good donor coordination, with all the funding going towards the commitments made under single reagent-rental agreements per country.

Equity & Sustainability: In all the countries in the sample, VL coverage and suppression is lower in children (ages 0-14) than for adults (ages +15); this is due to inadequate community awareness and outreach activities. Furthermore, while HIV programs maintain disaggregated data on gender and age, VL coverage data on key affected populations is not available. This hinders assessment of equitable access to VL testing.

As with other equipment analyzed, there is a heavy reliance on donor funding for VL/EID platforms and reagents. This limits the achievement of sustainability.

Investments for this equipment class would be strengthened through the cross-cutting Agreed Management Action 1 under Finding 3.1. This action aims to positively impact all health and lab-related equipment investments.

Annex A: Value for Money (VfM) Audit Rating Classification and methodology

Rating Classification

Achieved	No issues or few minor issues noted in achieving value for money. All (or substantially all) dimensions have been fully considered for this investment area with appropriate trade-offs taken. There is reasonable evidence that VfM is being achieved overall.
Mostly achieved	Moderate issues noted in achieving value for money. Most VfM dimensions have been considered for this investment area with some appropriate trade-offs taken. One or a limited number of issues were identified that moderately limit the achievement of VfM.
Partially achieved	One or few significant issues noted in achieving value for money. Several VfM dimensions have not been sufficiently considered for this investment area with limited trade-offs appropriately considered. Several issues were identified that highly limit the achievement of VfM.
Not achieved	Multiple significant and/or (a) material issue(s) noted in achieving value for money. Most or all VfM dimensions have not been considered for this investment area with a few or no trade-offs considered across dimensions. Several material issues were identified that result in limited or no achievement of VfM.

Methodology and approach

All OIG audits, including VfM audits, are conducted in accordance with the Global Institute of Internal Auditors' definition of internal auditing, international standards for the professional practice of internal auditing and code of ethics. These standards help ensure the quality and professionalism of the OIG's work. The principles and details of the OIG's audit approach are described in its Charter, Audit Manual, Code of Conduct and specific terms of reference for each engagement. These documents help safeguard the independence of the OIG's auditors and the integrity of its work.

The scope of OIG VfM audits may be specific or broad, depending on the focus of the engagement. Other sources of evidence, such as the work of other auditors/assurance providers, are also used to support the conclusions.

Any mention of specific companies or the products they manufacturer does not imply that these products or their use are endorsed, recommended or, alternatively, discouraged by the Global Fund to Fight AIDS, Tuberculosis and Malaria.

OIG Value for Money (VfM) audits aim to assess the extent to which Global Fund investments are generating their intended results and achieving value for money through the Global Fund defined VfM dimensions of *Economy, Efficiency, Effectiveness, Equity & Sustainability* (refer to section 2.1 for more details on these dimensions) across the grant life cycle and value chain.

An OIG VfM audit differs from a standard Governance, Risk and Controls (GRC) audit as its primary purpose is to assess VfM and not to focus on the design, implementation and effectiveness of key controls, the broader risk environment and governance framework. However, issues with governance, risk management and controls can be key root causes impacting VfM and thus can still be reported upon in relation to the impact on achievement of VfM.

The OIG VfM audit assesses the achievement of VfM across all five dimensions as it cannot only be assessed through each dimension independently or in isolation of one another. A VfM audit provides a rating on the overall achievement of VfM, as well as agreed management actions to improve the achievement of holistic value for money.