

AUDIT REPORT

Global Fund Grants in the Republic of Kenya

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GF-OIG-22-005
11 March 2022
Geneva, Switzerland

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1. Executive Summary

1.1 Opinion

Despite a difficult and challenging period, Kenya has made progress in its fight against the three diseases. HIV prevalence declined from 4.9% in 2018 to 4.5% in 2020, and the HIV incidence rate reduced from 0.27% in 2016 to 0.14% in 2020. Progress has also been made for TB, with the incidence rate falling by 11% between 2018 and 2020.

Further progress is being severely hampered, however, by inefficient processes that delay procurements and affect medicine availability across the supply chain. While the Kenya Medical Supplies Authority (KEMSA)¹ is procuring quality-assured commodities at competitive prices, long turnaround times are resulting in delays, hurting programs. Warehousing and distribution controls are not effective, impacting data quality and commodity traceability, as well as the availability of medicines at central and health facility levels. There is no robust system to monitor, track and report commodities delivered to health facilities which cannot fully account for drugs received. Procurement and supply chain management systems are rated as **ineffective**.

Despite COVID-19 severely disrupting Global Fund programs in 2020 and 2021, grants are mostly performing reasonably well, with a positive trend in key impact indicators. Approximately 96% of the 1.5 million people living with HIV know their status, 89% are on treatment and 94% had viral load suppression in 2020.² New infections have decreased by 44% over the last 10 years. Malaria prevalence has reduced as well as TB incidence. However, not all programmatic aspects are on track. Delaying the planned 2020 distribution campaign of long-lasting insecticidal nets, a decision taken due to COVID restrictions, is likely to increase disease prevalence, morbidity and mortality. Failing to reduce the number of missed TB cases will increase disease incidence and prevalence. Programmatic interventions in Kenya are rated as **partially effective**.

Kenya's ability to absorb COVID funding in a timely manner remains low, at 51% at the end of the grant, mainly due to protracted procurements. Low utilization of funds limits the country's ability to quickly respond to the pandemic. The management of COVID funds, including grant flexibilities, needs **significant improvement**.

1.2 Key Achievements and Good Practices

HIV, TB and Malaria programs have achieved good results

Between 2018 and 2020, the TB incidence rate fell by 11% as per the WHO TB report, from 292 to 259 cases per 100,000 population. In 2019, the HIV program adopted a more targeted testing approach, which has contributed to test yield increasing from 1.5% in 2016 to 2.3% in 2020. These achievements have led to grants meeting their targets: in June 2021, the TB program under the National Treasury was rated A2 (meeting expectations), and the HIV program implemented by Kenya Red Cross was rated A1 (exceeding expectations). The country experienced an overall reduction in Malaria prevalence from 8% to 6% between 2015 and 2020.³ Additionally, the Malaria Program successfully undertook a 2020 Malaria Indicator Survey despite pandemic-related challenges.

Centralized supply chain arrangements have enhanced country ownership

KEMSA undertakes last mile distribution to health facilities, and provides procurement and warehouse services for the disease programs. KEMSA is also responsible for procurement, storage and distribution of medicines and health products financed by the US and Kenyan governments. This has enhanced both accountability and country ownership of the three programs, and has created efficiencies for all three major funders.

Governance and supply chain challenges are being tackled by a newly constituted Reform Committee

In January 2021, the Ministry of Health took prompt action in response to supply chain challenges identified by the Kenya Auditor General OAG around KEMSA's utilization of COVID-19 funds, by establishing a 32-member reform committee.⁴ A new five-member Board was appointed in April 2021, with a mandate to enhance efficiency and continue the reforms.

¹ KEMSA is the National Treasury procurement agent for grants, responsible for procurement, storage and distribution of medicines and health products.

² UNAIDS 2021 Global AIDS Update (https://www.unaids.org/sites/default/files/media_asset/2021-global-aids-update_en.pdf) (Accessed 31 August 2021)

³ 2020 Kenya Malaria Indicator Survey Summary Report

⁴ WHO 2021 Global TB Report – [Kenya profile](#) (Accessed 1 November 2021)

KEMSA is procuring HIV and Malaria commodities at competitive prices

The Global Fund Secretariat has a mechanism to request Local Fund Agent (LFA) pre-award reviews to oversee the transparency, competition and value for money of the KEMSA procurement process. LFA reviews were introduced to mitigate procurement risks and ensure compliance with policies and guidelines.

1.3 Key Issues and Risks

Long turnaround timelines for procurement are resulting in delays, impacting program implementation

KEMSA procures most HIV, TB, Malaria, and COVID-19 commodities for Global Fund Programs. COVID-19 Response Mechanism (C19RM⁵) procurements take on average 349 days from initiation by the Ministry of Health to delivery, with Malaria procurements taking 406 days on average, HIV 278 days, and TB 348 days. In-country procurement and distribution processes are not adequately ensuring that C19RM-funded commodities are procured and delivered on time. Only half of C19RM funds were spent by the end of the grant in June 2021, and the distribution of procured commodities was very slow compared with the initial timelines agreed with distribution providers. Due to gaps noted in advanced planning and turnaround timelines, long procurement delays are impacting program implementation and leading to stock-outs and non-availability of KEMSA commodities at almost all health facilities visited. The two other Principal Recipients, Amref and Kenya Red Cross, have also experienced delays procuring COVID-19 commodities: up to 182 days for Amref and over 180 for Kenya Red Cross.

Inadequate supply chain controls have worsened, largely due to inefficiencies and pandemic disruptions

KEMSA has poor internal controls on warehousing and inventory management, resulting in 16% differences in batch numbers verified, and discrepancies of 908,000 long-lasting insecticidal nets (LLINs) between actual and expected stock balances. KEMSA does not have an adequate system to ensure commodities distributed via third-party logistic companies (3PLs) arrive at health facilities on time and in the correct quantity. Only 31% of commodity receipt documents (Proof of Deliveries) were delivered to KEMSA by 3PLs on time in 2021. A limited market survey found Global Fund-financed commodities, including some which KEMSA had reported as not being distributed, on sale in four of seven sampled pharmacies spread across four counties; this issue has been referred to the OIG investigation unit for further analysis. We also noted weak internal controls over the accuracy of health facility data in KEMSA's inventory system, which have led to discrepancies between the Ministry of Health's list of approved facilities and KEMSA's system. Poor controls over IT systems are compromising data reliability and contributing to poor stock management.

COVID-19 has impacted programs and exacerbated pre-existing programmatic challenges

The pandemic has impacted programmatic performance in Kenya, especially during 2020. Through adapting and innovating, TB and HIV programs were able to resume during H2 2020, albeit with challenges, such as a lack of personal protective equipment to support community activities. For malaria, the planned 2020 mass distribution campaign of long-lasting insecticidal nets was delayed by a year due to COVID-19, but was underway at the time of the audit. Several program challenges that existed prior to COVID-19 persist, threatening the strategic plan target in 2023; these include reducing the number of missing TB cases (estimated at 40%) and inefficiencies in the HIV testing approach.

Risk management and assurance arrangements do not adequately mitigate emerging and known risks

The Global Fund has mature processes for risk management at the portfolio level. This is a continuous process, performed by the Country Team with support from various support and monitoring functions and the Risk Department. The design of assurance mechanisms to oversee grant implementation is adequate, but mitigation measures to address known and emerging risks either do not fully address issues or are improperly implemented.

Improvements needed in terms of financial controls and absorption of C19RM funding

Financial management controls could be improved for better accountability. While program absorption rates improved in the last semester of grant implementation, the country's capacity to use its COVID-19 funding allocation on time, including C19RM and government counterpart funding, remains comparatively low.

⁵ C19RM helps countries mitigate the pandemic's impact on HIV, TB and malaria programs, and initiates urgent improvements in health and community systems.

1.4 Objectives, Ratings, and Scope

The Audit's overall objective was to provide reasonable assurance on the adequacy, effectiveness, and efficiency of Global Fund Grants to the Republic of Kenya.

Specifically, the Audit assessed:

Objective	Rating	Scope
Controls and assurance over the procurement and supply chain management systems are sound to deliver and account for quality-assured medicines and health products.	Ineffective	Audit period: January 2018 to April 2021
Effectiveness of Global Fund COVID 19 response in maintaining and scaling up TB and HIV screening and testing and LLINs interventions, including adaptation during the COVID 19 period.	Partially Effective	Grants and implementers: NFM2 grants implemented by the National Treasury, KRCS and AMREF
Effectiveness of the financial assurance framework/mechanism during the pandemic including absorption capacity, C19-RM funding utilization and co-financing mechanism.	Needs significant improvement	Scope exclusion: None

The auditors visited 21 health facilities at the national and county level, as well as KEMSA warehouses. Remote audit methodology and techniques were deployed where necessary. Details about the general audit rating classification can be found in [Annex A](#) of this report.

2. Background and Context

2.1 Overall Context

A low-middle-income country, Kenya is considered the regional economic hub for East and Central Africa. Public health care delivery is devolved; the 2010 Constitution gives Kenya's 47 counties responsibility for delivering most health services while the national Government retains leadership in developing health policy and regulation, and in managing national referral facilities.

The national health system comprises over 13,000 health facilities. 46% are government-owned, 43% private-owned, and the rest are either faith-based organizations or NGO-owned facilities. The private sector is a key player in delivering health care services in the country.

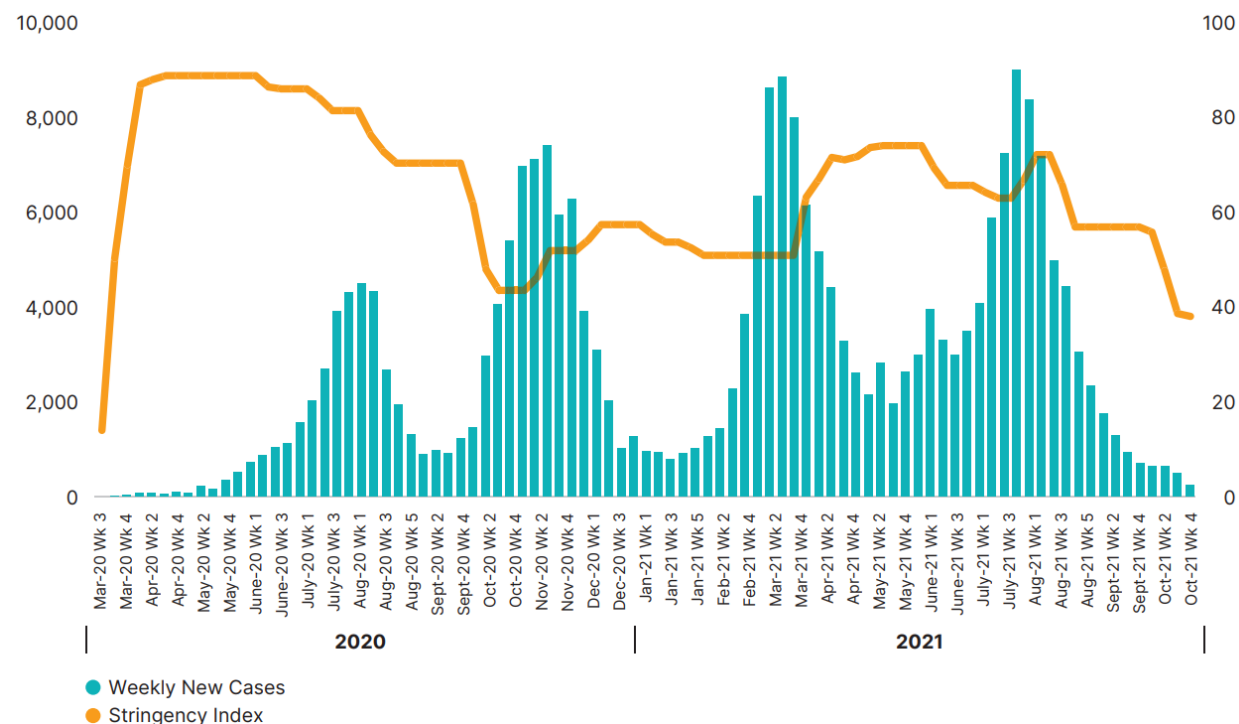


Country data ⁶	
Population	53 million (2019)
GDP per capita	US\$1,879 (2020)
TI Corruption Perception Index	128 of 180 (2021)
UNDP Human Development Index	143 of 189 (2020)
Health expenditure (% of GDP)	2.1% (2019)

2.2 COVID-19 situation

Since March 2020, the Country has taken stringent containment measures to slow the spread of the virus, including lockdowns and dusk-to-dawn curfews.

Figure 1: COVID-19 cases and stringency index in Kenya⁷



COVID-19 statistics

(17.11.21)

- Cases – **254,453**
- Active cases – **7,031**
- Recovered – **247,791**
- Deaths – **4,864**

⁶ Sources: population, GDP, Health expenditure from data.worldbank.org <https://www.transparency.org/en/countries/kenya>; <https://hdr.undp.org/sites/default/files/Country-Profiles/KEN.pdf>; all accessed 23 Feb 2022

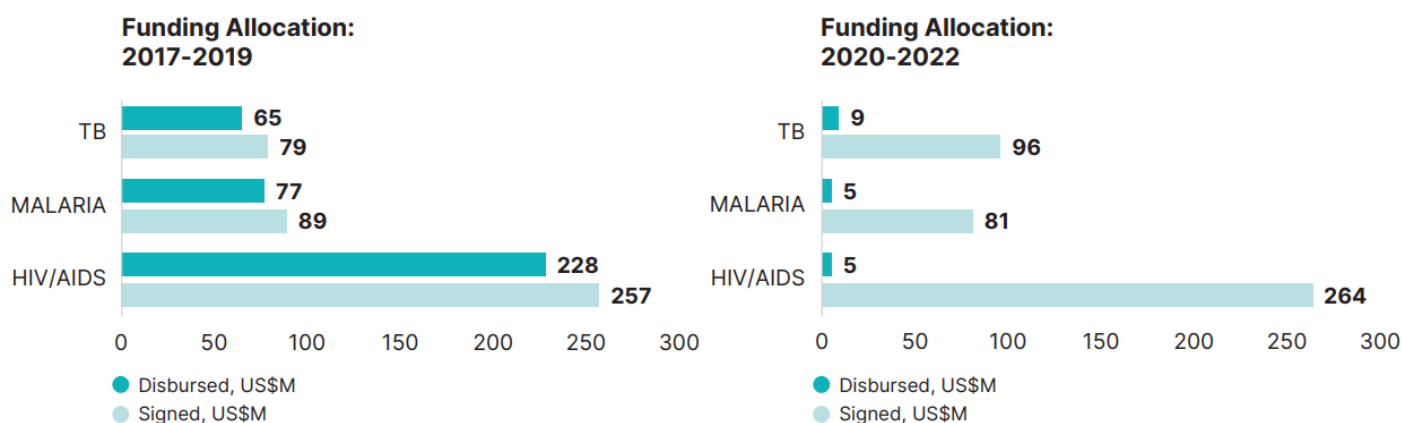
⁷ [University of Oxford Blavatnik School of Government](https://www.oxfordblavatnikschool.org/)

2.3 Global Fund Grants in Kenya

Since 2003, the Global Fund has signed over US\$1.8 billion and disbursed over US\$1.4 billion to Kenya. Active grants total US\$444 million for the 2020-2022 Funding Allocation (July 2021 to June 2024 implementation period). Full details on the grants can be found at [the Global Fund's Data Explorer](#).




The National Treasury, Kenya Red Cross Society and Amref Health Africa are grant Principal Recipients. The Ministry of Health implements grants on behalf of the National Treasury through the national programs for the three diseases. Each disease program is implemented by a government implementer and a non-governmental organization.

Figure 2: Funding allocations, prior and current funding cycles (as of August 2021)⁸



Approximately 60% of grant funding goes towards procuring medicines and health products. The National Treasury has contracted the Kenya Medical Supplies Authority (KEMSA), a government entity, as its procurement agent for the grants. KEMSA is responsible for procuring, storing, and distributing medicines and health products.

2.4 The Three Diseases

HIV/AIDS		MALARIA		TUBERCULOSIS	
<p>1.5 million people are living with HIV, of whom 96% know their status. Among identified PLHIV, 89% were on treatment and 94% had viral load suppressed in 2020.⁹</p> <p>Annual new infections decreased by 44% from 75,000 in 2010 to 41,416 in 2019.¹⁰</p> <p>AIDS-related deaths decreased by 59% from 51,000 in 2010 to 20,997 in 2019.¹⁰</p>	<p>4.5 million malaria cases treated in 2020.⁸</p> <p>Due to travel related and other pandemic disruptions, 194K LLINs were distributed in 2020 against a target of 12.9 million.¹¹</p>	<p>Kenya is among the 30 high TB and TB/HIV burden countries.</p> <p>In 2021, Kenya transitioned out of the 30 high MDR/RR-TB burden countries.¹²</p> <p>TB incidence of 426 cases per 100K.¹³</p> <p>TB case notifications decreased by 14% from 81,518 in 2015 to 70,387 in 2020.</p> <p>TB treatment success rate was 84% for new cases in 2018.</p>			

⁸ Global Fund's Data Explorer, Kenya profile (<https://data.theglobalfund.org/location/KEN/overview>) (Accessed 31 August 2021)
⁹ UNAIDS 2021 Global AIDS Update (https://www.unaids.org/sites/default/files/media_asset/2021-global-aids-update_en.pdf) (Accessed 31 August 2021)
¹⁰ Kenya AIDS Strategic Framework II 2020/21-2024/25 (https://nacc.or.ke/wp-content/uploads/2021/01/KASFII_Web22.pdf) (Accessed 26 July 2021)
¹¹ GF Program data
¹² WHO press release, June 17 2021: [New global lists of high-burden countries for TB, HIV-associated TB and drug-resistant TB](#) (Assessed 26 July 2021)
¹³ Kenya TB Prevalence Survey Report (<https://www.nltp.co.ke/download/kenya-tb-prevalence-survey-report/>) (Accessed 26 July 2021)

3. Portfolio risk and performance snapshot

3.1 Portfolio Performance

GLOBAL FUND GRANTS IN KENYA							GRANT RATINGS						
Grant number	Principal Recipient	Grant Period	Total Budget Amount (USD)	Absorption Dec 2020 (%)	Absorption Jun 2021 (%)	Jun 2018	Dec 2018	Jun 2019	Dec 2019	Jun 2020	Dec 2020	Jun 2021	
HIV	KEN-H-TNT	The National Treasury	1 Jan 18 – 30 June 2021	190,295,823	79.6%	85.5%	A2	A2	A2	A2	B1	B1	B1
HIV	KEN-H-KRCS	Kenya Red Cross Society	1 Jan 18 – 30 June 2021	76,852,690	82.8%	94.9%	B1	B1	A2	A1	B1	A1	A1
TB	KEN-T-TNT	The National Treasury	1 Jan 18 – 30 June 2021	46,603,938	79.8%	83.1%	A2	B1	B1	B1	A2	A2	A2
TB	KEN-T-AMREF	AMREF Health Africa Kenya	1 Jan 18 – 30 June 2021	40,324,780	89.6%	85.4%	B1	A2	B1	B1	B1	B1	B1
Malaria	KEN-M-TNT	The National Treasury	1 Jan 18 – 30 June 2021	74,063,824	39.5%	73.9%	B1	B1	B1	B1	B2	B1	B1
Malaria	KEN-M-AMREF	AMREF Health Africa Kenya	1 Jan 18 – 30 June 2021	16,059,470	76.8%	81.2%	B1	A2	A2	A2	B1	B1	B1
TOTAL				444,200,525	73%	85%							

Kenya has received US\$45 million through the newly created C19RM mechanism and grant flexibilities to fight COVID-19's impact on the three diseases. These amounts are included in the grants presented above totalling US\$444.2M.

3.2 Risk Appetite

The OIG compared the Secretariat's aggregated assessed risk levels for the key risk categories covered in the audit objectives for the Kenya portfolio, with the residual risk that exists based on OIG's assessment, mapping risks to specific audit findings. The full risk appetite methodology and explanation of differences are detailed in [Annex B](#) of this report.

AUDIT AREAS	RISK CATEGORY	SECRETARIAT AGGREGATED ASSESSED RISK LEVEL (April 2021)	ASSESSED RESIDUAL RISK, BASED ON AUDIT RESULTS	RELEVANT AUDIT ISSUES
Procurement and supply chain management	Procurement	High	High	Findings 4.1 & 4.3
	In-country supply chain	Very High	Very High	Findings 4.2 & 4.3
Program quality and COVID's impact on program implementation	Program quality – TB, HIV, and Malaria	High	High	Finding 4.4
Financial assurance framework /mechanism	Grant-related fraud and fiduciary risks	Moderate	Moderate	Finding 4.5
	Accounting and financial reporting	High	High	Finding 4.5

More details about Risk Appetite are presented in Finding 4.3 of this report.

4. Findings

4.1 Inefficient processes are delaying procurements and affecting medicine availability across the supply chain

KEMSA is procuring quality-assured health commodities at competitive prices, however insufficient coordination and procurement planning among stakeholders creates inefficiencies and bottlenecks, delaying their availability. Our audit noted irregularities in procurements, weak contract management, and inadequate assessment of vendor performance.

KEMSA Global Fund procurements are guided by the Country Public Procurement Act¹⁴ and by the Public Procurement and Asset Disposal Regulation.¹⁵ There has been good collaboration between the National Programs, KEMSA (in the technical evaluation of tenders) and the Global Fund (in setting up measures to review bidding processes and ensure fair competition and transparency for procurements).

Due to gaps in planning of health commodity procurements, purchases in Kenya consistently result in long completion times. This affects the availability of health commodities at all levels, resulting in stock-outs and shortages of key HIV, Malaria, TB and COVID-19 commodities at central (KEMSA) and lower (health facility) levels. The protracted procurement process is due to insufficient coordination among the many stakeholders in the procurement process, and to KEMSA's limited planning and oversight. Rigorous planning is critical, as KEMSA procures on behalf of three main partners – Kenyan Government, U.S. Government, the Global Fund – and therefore any delayed or halted procurement from one partner affects drug availability across the supply chain. Global Fund procurement safeguards mainly focus on tender transparency, price competitiveness and compliance with procurement policies, with inadequate monitoring of implementation to ensure procurements happen on time (detailed in Finding 4.3).

Procurement delays due to ineffective planning, coordination and execution

Inefficiencies and bottlenecks in procurement initiation and execution

KEMSA's procurement processes are complex, and involve many stakeholders to ensure that procurements are programmatically relevant and that oversight mechanisms are in place. National Disease Programs within the Ministry of Health (MoH) raise procurement requests which are reviewed and authorized by the MoH Principal Secretary before their submission to the National Treasury (within the Ministry of Finance and Planning) for approval. Finally, the National Treasury instructs KEMSA to initiate procurements. The Local Fund Agent pre-reviews bids to ensure competition and transparency when awarding tenders. Review timelines for each stakeholder's input are neither defined nor tracked, resulting in process inefficiencies and bottlenecks. With no clear review accountability for each stakeholder involved, it took on average 345 days from initiation of a procurement to delivery of commodities for sampled Malaria, HIV, TB and COVID-19 commodities.¹⁶ Amref and the Kenya Red Cross Society face similar delays (up to 180 days) in procuring COVID-19 commodities, caused in part by delays in sharing specifications from sub-recipients and long response times from the Kenya Bureau of Standards.

Gaps in procurement planning & coordination affect the supply of commodities

The Ministry of Health, National Treasury and KEMSA do not coordinate effectively to establish procurement plans, procurement initiation dates, procurement methods to be used, review timelines or planned delivery dates. Planning and coordination is critical, given the scale of commodities procured by Kenya, the involvement of other partners (including the U.S. and Kenyan Governments) in procuring HIV and malaria commodities, and the different procurement plans of these partners (annual vs three years). The lack of effective coordination between various

¹⁴ Public Procurement and Asset Act, 2015 (<http://ppra.go.ke/ppda/>) (Accessed 13 September 2021)

¹⁵ Public Procurement and Asset Disposal Regulations 2020 (<https://www.treasury.go.ke/wp-content/uploads/2020/11/Public-Procurement-and-Asset-Disposal-Regulations-2020.pdf>) (Accessed 13 September 2021)

¹⁶ OIG procurement sample indicate that it takes (from procurement initiation to delivery of commodities) on average 349 days for COVID 19 , 406 days for Malaria, 278 days for HIV and 348 days for TB.

partners, coupled with the lengthy procurement process for Global Fund and Government of Kenya-funded commodities, has adversely affected the supply of HIV and Malaria commodities.

Delays in securing tax exemptions

For the 2017-2019 funding cycle, tax waiver procedures require programs to obtain both a General Tax waiver and a specific tax exemption for each order. The General Tax waiver for grants was only approved fifteen months after the start of the grants.¹⁷ In addition, specific tax exemptions need to be obtained for each purchase order issued. On average, it takes almost four weeks to secure these exemptions (in one instance it took 216 days for anti-retroviral drugs), at which point suppliers can ship goods. A contributing factor for delays in obtaining the general tax exemption for the 2017-2019 grant cycle has been the development of new guidelines for processing tax exemptions by the National Treasury. U.S. Government-funded health commodities encounter identical challenges.

Lack of standard specifications for commodities to be procured

While the Ministry of Health and the National Treasury have developed a consolidated specification/catalogue for malaria commodities, the document is yet to be approved and is still in draft form. There is no similar consolidated standard specification for HIV, TB or COVID-19 commodities. Based on the sampled procurements reviewed by the OIG, tender cancellations due to inaccurate specifications for COVID 19 commodities and delays in issuing solicitation documents are also a major cause of delays.

Ineffective procurement controls have resulted in unmitigated operational risks

Non-compliance with policies has resulted in non-competitive procurements

Implementers do not always follow procurement policies and guidelines. The audit identified instances where competitive tendering was not undertaken, in favour of direct awards. For instance, KEMSA did not seek approval from the National Treasury before contracting a logistics provider (Postal Corporation of Kenya – PCK) as per the terms of its MoU with the National Treasury. Additionally, PCK, which was initially meant to provide services for three months to allow for a competitive procurement process, had its contract extended by 33 months without competitive tendering, in spite of poor performance. PCK distributed a quarter of KEMSA's deliveries between 2018-2021 and is the biggest 3PL provider in the 1 and 1.5 tonnes categories, transporting 64% of the total commodities distributed by KEMSA in this category between January 2020 and May 2021.

Between 2018 and June 2021, the Kenya Red Cross Society (KRCS) awarded 69% of procurements for conference facilities (valued at US\$836,000) to Boma Inn Hotel, a subsidiary of KRCS, without a competitive procurement process. Furthermore, a framework agreement for the provision of conferencing facilities was only issued to Boma Inn, rather than to the three lowest bidders, as stipulated in the KRCS procurement manual.

Weak contract management is hindering the effectiveness of contract execution

Improvement is required in the way that KEMSA manages contracts with commodity providers, which is leading to suppliers cancelling contracts and deliveries due to inconsistent or delayed information. For the mass LLIN distribution campaign, the Malaria Program increased the number of required drop-off points for nets from eight in the tender phase to 45 in the signed contract, and then sought to increase it further to 87 after the contract was signed. KEMSA did not however adjust the contract price accordingly, as requested by the supplier, and the contract expired during negotiations, with 86% (6 million of 7 million) of the ordered LLINs not having been delivered.

Inadequate assessment of vendor performance causes poor quality of service

Neither KEMSA, Amref nor KRCS have a defined procurement performance monitoring framework to analyze supplier performance. While KEMSA rolled out a performance measurement tool in 2020/21, there was no supplier performance appraisal documentation on file, or evidence of corrective actions taken against poor performers, who continue to be contracted, contributing to delays in delivering health commodities. None of the procurements sampled in 2018 were delivered On Time and In Full (OTIF). Only 8% were OTIF in 2019, 5% in 2020, and 25% in 2021, against a 60% target for Global Fund procurements. For the logistic provider PCK, in 2021, only 31% of Proofs of Delivery¹⁸

¹⁷ Since the completion of OIG fieldwork, there has been improvement on this issue as the general tax exemption master list for the NFM 3 grants (starting 1 July 2021) was issued on 10 November 2021 (only four months after the signature of the grants).

¹⁸ Based on OIG samples for four months for 2021 transactions

reached KEMSA within five days (27% from Hospitals and 36% from Regional Health Facilities) against a target of 98%. Only 17% of MDR TB orders between January and April 2020 were delivered within the agreed two-day timeline. KRCS's procurement manual stipulates that supplier performance be assessed every six months. However, the last assessment was undertaken in 2018. At Amref, supplier delivery dates are documented but without any analysis of OTIF, limiting insight into supplier performance.

Delayed procurement processes and inadequate procurement plans have led to sub-optimal budget absorption rates for the Malaria program (74% at the end of the grant) and for COVID-19 funding (51% at the end of the grant) and contributed to the delay of the 2020 mass LLIN distribution campaign that was also affected by the pandemic. The delayed procurement also had a significant impact on the stock-outs identified at all levels, as detailed in Finding 4.2.

Agreed Management Action 1:
The Global Fund Secretariat will work with the Principal Recipients to develop a framework document that outlines all the different steps throughout the procurement process and that makes clear the responsible stakeholders, the deliverables they are responsible for to move to the next step, and the reasonable time / KPI within which the steps can be reached.
OWNER: Head of Grant Management Division
DUE DATE: 30 June 2023



4.2 Poor controls over critical health products at central and health facility levels cause unmitigated traceability and availability risks

Ineffective controls at KEMSA's warehousing and distribution systems are affecting commodity traceability, and inadequately ensuring the accountability of commodities received and distributed. There is no robust system to monitor, track and report commodities delivered to health facilities, and health facilities cannot fully account for received drugs.

The Global Fund has aligned its investments to support Kenya's supply chain. A new KEMSA warehouse to store health and non-health commodities has been built in Nairobi, funded by the government of Kenya, KEMSA, the Global Fund and partners including the United States Government. KEMSA carries out last-mile distribution of Global Fund-supported medicines and commodities to all health facilities, in line with orders reviewed by the national disease programs. Our audit noted ineffective controls across the supply chain at all levels, which seriously compromise the achievement of grant objectives.

Sub-optimal inventory management and data inconsistency lead to lack of traceability at central level

KEMSA controls over inventory systems are ineffective, and do not provide appropriate visibility of stock levels. KEMSA's Nairobi warehouse was overcrowded with commodities during our visit, making it difficult to trace commodities. For example, in a physical sample count, KEMSA could not locate three of eight batches of TB medicines (worth US\$91k of a total US\$570k). Data inconsistencies in KEMSA's information system included unexplained adjustments amounting to US\$544k. This was in addition to adjustments of US\$5.6 million due to anomalies in commodity unit prices: prices for expired drugs were overstated by 100 times. There were discrepancies between actual and expected stock balances for sampled HIV (1.1 million fewer condoms) and Malaria commodities (908K fewer LLINs). COVID-19 commodities procured through the Global Fund's Pooled Procurement Mechanism were marked as donations (unconnected to any specific donor) in the Warehouse Management System, making it difficult to track and trace them in future.

Ineffective controls over deliveries limit assurance over commodity availability at facility level

Weak Proof of Delivery (POD) and third-party logistics (3PL) monitoring are resulting in limited assurance of timely, in-full deliveries to health facilities. KEMSA requires 3PL delivery trucks be fitted with GPS trackers which KEMSA can access. However, at the time of the audit, KEMSA did not access this GPS tracking system to track commodities in transit. Furthermore, 3PL service providers return POD documents with delays (e.g. taking on average nine days for Bulito and eight days for Postal Corporation of Kenya against a five-day target). In addition, 23% of returned PODs were not entered into the system.

KEMSA's lack of oversight over commodity distribution has resulted in poor operational practices that were pervasive across our sample, such as: duplicate PODs issued three months after initial dispatch after being reported as missing by the 3PL; no signature acknowledging receipt of commodities by 3PL officers; no signature by health facility officers acknowledging receipt of commodities.

Inadequate controls to ensure facilities receiving drugs are legitimate and approved by the Ministry of Health

OIG noted 122 duplicate entries for health facilities in the KEMSA management system. Of the around 11,000 facilities on the KEMSA system, 14% (1,626) did not have a MOH Kenya Master Health Facility List code. Of those 1,626 entities, 300 were supplied with Global Fund funded commodities worth US\$9.1 million between Jan 2019 and April 2021. The OIG has sampled 21 of those facilities and confirmed their existence. In addition, 153 of 10,001 health facilities with standard codes on the KEMSA master facility system were not on the MOH approved list. As the two lists are maintained by KEMSA and MOH using two different systems, it is vital to ensure appropriate controls are in place when health facilities are migrated from one system to another.

Poor commodity accountability at health facilities creates risk of stock-outs

19/21 (90%) of health facilities visited had unexplained stock count variances of sampled commodities, culminating in a net unreconciled difference of US\$265K. These were due to unjustified adjustments following stock counts, and variances between physical and stock card balances on the day of the visit.

A poor IT control environment at KEMSA results in unmitigated risks and vulnerabilities

KEMSA's IT general controls are inadequately designed and implemented. IT admin users have unlimited access to operational level modules, and there is no regular review of the audit trail/logs and system access permission granted to users. We also noted gaps in the IT disaster recovery plan, a weak offsite backup management facility, and no comprehensive back-up procedures to validate the restoration of data when required. Poor application controls are affecting the integrity and accuracy of data recorded in the KEMSA inventory system, and creating duplicate records. For instance, we identified 165 long outstanding/undelivered Local Purchase Orders (LPOs) valued at US\$14.5 million.¹⁹ The high number of LPOs without an attached delivery notes poses the risk of fake suppliers or diverted procurements.

These control weaknesses mean that traceability and availability risks go unmitigated. For example:

- The OIG sampled seven private pharmacies in four counties and found Global Fund-financed commodities for sale at four pharmacies spread across the four sampled counties. Although this is not a representative sample, meaning we cannot derive a definitive conclusion from the small sample, the matter has been referred to the OIG Investigation unit, who are assessing the source and the extent of the product diversion. We also noted a discordance between drugs dispensed and the number of confirmed cases tested at Health Facility level.
- There are stock-outs or low stocks of health commodities at all levels. For example, there were central-level stock-outs for more than two months for LPV/r 100/25mg, NVP Oral Suspension, INH 300mg, Artemether/Lumefantrine and Artesunate Injections. There were stock-outs at a large number of health facilities visited (at 12/21 facilities for Malaria commodities, 12/21 HIV commodities, and 8/21 for TB commodities). A summary of stock-outs noted at the central level and at the 21 health facilities visited is contained in [Annex C](#) of this report.

Agreed Management Action 2:
The Global Fund Secretariat will work with the National Treasury, the Ministry of Health, and KEMSA to develop an action plan to provide enhanced assurance oversight of in-country distribution of Global Fund commodities. The action plan should cover both (i) existing supply chain controls that are in place but require corrective action, and (ii) any new controls that should be established - with SOPs for implementation within set timelines.
OWNER: Head of Grant Management Division
DUE DATE: 31 December 2023

¹⁹ Following the presentation of these findings, KEMSA has indicated it is in the process of undertaking a data clean up exercise.



4.3 Gaps in Secretariat risk management and assurance mechanisms for procurement and supply chain risks

Secretariat risk management and assurance arrangements do not adequately mitigate emerging and known risks. Mitigation measures to address known risks either did not fully address risks or were improperly implemented.

The Global Fund categorizes Kenya as a High-Impact Country. There are active grants of over US\$440 million for the 2020-2022 allocation cycle, with approximately 60% of grant funds going towards procuring medicines and health products. Kenya is one of a few countries not using the Global Fund’s Pooled Procurement Mechanism, instead procuring health commodities using its own country systems. Warehousing and distribution of Global Fund-financed commodities is performed by KEMSA on behalf of the grant Principal Recipient, the National Treasury.

The Global Fund has mature processes for risk management at the portofolio level. This is a continuous process, performed by the Country Team with support from various support and monitoring functions and the Risk Department. Country Portfolio Reviews (CPRs), conducted by the Portfolio Performance Committee (PPC), serve as the primary forum for decision-making on risk acceptance and risk trade-offs for country-level risks. The CPRs evaluate programatic, financial, procurement and supply chain, and governance risks. Decisions are made on a country-by-country basis, through a combination of full and executive sessions. The Country Team, with support from a Risk Specialist, prepares a Country Risk Management Memorandum (CRMM) for CPR sessions, and there is clear guidance on its minimum content.

All High-Impact Countries are expected to prepare a CRMM annually, unless the PPC agrees to less frequent reviews. The 2020 PPC CPR schedule was approved by the PPC leadership in October 2019. As a result of COVID-19, various routine risk assurance and monitoring processes were reasonably deprioritized, such as country portofolio reviews and follow up on key mitigation actions for on-going grants. As a result, in September 2020, the PPC leadership decided to deprioritize PPCs not performed at that point – 20 out of 27 scheduled CPR sessions, including 15 High-Impact countries. Countries that did not undergo through a CPR session in 2020 were required to “invest their efforts towards detailing a comprehensive Risk Tracker per grant for NFM3 grants”.

Limited risk assessment and ineffective risk monitoring for procurement and supply chain risks

Kenya did not benefit from a full PPC in 2020 or 2021, despite procurement and supply chain risk levels having increased significantly between 2019 and 2021. The increased risk was due to a number of factors, such as declining performance following a change of CEO at KEMSA, and widely reported corruption allegations over KEMSA’s PPE procurements. The Secretariat performed a risk assessment for the Kenya portofolio, adjusting the ratings upwards: Procurement risk moved to High, and In-Country Supply Chain risk to Very High. On 13 April 2021, during the grant making stage, this assessment was documented in the Integrated Risk Management module which records all grant-related risks.

RISK CATEGORY	2019 CPR ASSESSED RISK LEVEL	2020 ASSESSED RISK LEVEL	2021 REVIEW ASSESSED RISK LEVEL
Procurement	Moderate	No assessment performed in 2020	High
In-country supply chain	Low	No assessment performed in 2020	Very High

While a formal risk assessment was not performed for Kenya, various discussions between the Country Team and senior management, including the Executive Director, happened in late 2020. This included a memo submitted by the Country Team to the Chief Risk Officer and the Head of Grant Management, highlighting the key risks and mitigation measures in place. In addition, a PPC executive session held on 30 March 2021 looked specifically at “Global Fund Oversight & Risk Mitigation for Kenya Medical Supplies Authority (KEMSA)”. Contrary to a standard PPC, PPC executive sessions do not require minimum measures (as per the CRMM guidelines approved in March 2019) to be followed. Hence a number

of the ordinarily mandatory elements were not tabled at the meeting, such as (i) the country profile, (ii) the portfolio risk heat map, (iii) the assessment of country performance against outcome indicators, (iv) prioritized risks for PPC review and acceptance, (v) detailed grant risks and (vi) the portfolio risk acceptance summary. Key procurement risks were highlighted by the assurance providers in 2019 but were not promptly escalated.

While the PPC did not review a comprehensive risk assessment by type of risk and sub-risk, it did acknowledge the general increased risk levels at KEMSA due to (i) the change in KEMSA leadership and prolonged key vacant positions and (ii) investigations and audits performed on KEMSA by various national and donor oversight functions.

While the Secretariat has designed robust processes for risk assessment at the country level, their implementation has been significantly affected, largely due to pandemic-related disruptions and pressures, including Country Teams' inability to travel. As a result, despite a need for prioritized and focused action, mitigations were not well executed.

In response to the increased risk level, the Country Team presented 13 mitigation measures to the Executive PPC on 30 March 2021: six have been implemented, four have not yet started and three have been ineffectively implemented.

MITIGATING MEASURE	OIG COMMENT	OIG COMMENT
Review of KEMSA inventory management and last-mile distribution	Partially implemented	The review was completed but not all risks have been identified. There is limited follow-up on the recommendations.
Periodic spot checks of health products stock and procurement & supply management status	Not started	No spot checks have been undertaken. The Secretariat approved the ToRs for spot checks in November 2021 and spot checks will be performed for NFM3 grants from 2022.
Increased oversight on procurement and supply chain management	Partially implemented	A procurement review was completed but there has been limited follow-up on its recommendations.
Increased oversight on National Treasury and KEMSA to improve monitoring of suppliers' performance	Not started	No appraisal of supplier performance has been undertaken. It is scheduled for NFM3 grants from 2022.
Other ad-hoc and on-spot assessments/verifications as required	Not started	No ad-hoc/on-spot assessments have been undertaken. The ToRs for a fraud risk review at CSO PRs were approved in November 2021.
Joint GF/USAID assessment of KEMSA in 2019 (periodic capacity assessment)	Partially implemented	A joint report was issued in December 2019, however identified risks/gaps remain and are highlighted in this report. The Secretariat decided to follow up on these recommendations as part of the KEMSA reform project.
Use of PPM / WAMBO as option to mitigate delays and/or risks for some procurements	Partially implemented	All 2020 HTM and C19RM procurements were locally sourced, with the exception of 6 million LLINs which were procured using PPM in February 2021 to mitigate procurement delays. 37% of C19RM 2021 procurements will be sourced using PPM. 63% of C19RM 2021 procurements (mainly relating to Oxygen equipment and supplies) will be non-PPM procurements.

The Secretariat relies on in-country assurance mechanisms but has not remedied their findings

The Global Fund has invested heavily in assurance mechanisms for Kenya, spending over US\$2.5 million in the last three years (2019 -2021). Some mitigation measures have been effectively implemented; pre-award reviews of procurements, and key procurement and supply chain reviews have been performed. However, overall in-country assurance for procurement and supply chain has been limited in its effectiveness. This is due to ineffective follow-up on Local Fund Agent (LFA) recommendations, but also due to the structural changes needed at the country level to address the highlighted risks. Some of the recommendations meant to be addressed as part of the KEMSA reform project have been significantly delayed.

For example, at the instruction of the Global Fund, the LFA performed a review of "Procurement processes" of health products undertaken by the Principal Recipient (the National Treasury) through the procurement agent (KEMSA). The report was sent to the Global Fund in December 2019, and a Management Letter, with recommendations to mitigate

the identified risks, was sent to the country in February 2020. The LFA review identified almost all the key procurement risks highlighted in section 4.1 of this report, including long procurement processes and poor supplier performance. While proposed mitigations were sent to the country as part of the Management Letter, our audit noted no progress, and identified similar issues.

Agreed Management Action 3:
The Global Fund Secretariat should perform a comprehensive risk assessment for the Kenya portfolio and assess the status of the current mitigation measures in place. If needed additional assurance arrangements should be included as part of the then current assurance plan, which should also be updated to capture any additional mitigation measures emanating from AMA 1 and AMA 2.
OWNER: Head of Grant Management Division
DUE DATE: 31 December 2022



4.4 Actions taken to mitigate COVID's impact on program activities, but challenges remain for TB and Malaria interventions

COVID-19 severely impacted Global Fund Programs in Kenya during 2020. While programs managed to recover thanks to adaptations and reprogramming, further effort will be needed if grants are to reach strategic targets by 2023. A number of issues noted during the previous OIG audit in 2018 remain.



Tuberculosis: failure to tackle missing cases will increase incidence, prevalence, mortality and morbidity

Tuberculosis is the leading infectious disease killer in Kenya. While the incidence rate fell by 11% between 2018 and 2020, and Kenya is no longer one of the 30 countries with the highest MDR/RR-TB burdens, it remains in the top 30 for TB and TB/HIV burdens. Of the estimated 169,000 TB cases annually, 40% go missing.²⁰

TB notifications declined from 97,164 confirmed cases in 2018 to 85,522 in 2019 and 73,060 in 2020. COVID-19 largely impacted the 2020 decline due to movement restrictions, reduced patient facility attendance, disruption of community-level contact tracing/case identification, repurposing of health facilities and health workers, and stigma related to symptom similarity between COVID-19 and TB. Other reasons for the overall decline since 2018 include:

- **Delay in updating TB screening guidelines.** Kenya still screens for TB by testing for the four major symptoms, which contributes to missing TB cases.²⁰ Active case-finding in 2020 only achieved a 73,310 yield against a target of 111,062 (66%). Results registered in 2020 were lower than for 2019, at 83% (86,963 against the target of 104,704). New TB screening guidelines were issued in June 2021 to update facility-based screening as required by WHO.
- **Low utilization of GeneXpert machines.** Machines ran at only 46% and 47% of capacity in 2019 and 2020, respectively. Several machines in the public sector were not functional due to a lack of maintenance. A one-year maintenance contract for GenXpert equipment was signed in April 2021, the previous one having expired in March 2019. Other reasons for the low utilization include: a shortage of Community Health Volunteers (CHVs)²¹ performing contact tracing and referral for testing; poor linkages of facility-based services with CHVs; lack of Personal Protective Equipment (during the COVID-19 pandemic) due to delayed procurement and distribution; inefficient deployment of machines; not procuring a sputum transportation service provider under the TNT TB grant; and disruptions in cartridge supply. The OIG's 2018 audit already highlighted a number of challenges relating to GeneXpert, including low utilization and maintenance issues. However, the mitigation measures established have not been able to address these.
- **Operational challenges** such as delays in start-up, late engagement with Civil Society Organizations/Counties, or difficulties in contracting sample transportation services for the three critical strategic initiatives (Kenya Innovation Challenge TB Fund, Pay-for-Performance and Public-Private Mix) designed to help find missing TB cases.



Malaria: delays in distributing nets pose the risk of increased prevalence, morbidity and mortality, especially among pregnant women and infants

The malaria prevention strategy is focused on the mass distribution of LLINs. The objective is to achieve universal coverage, reaching pregnant women and children under five through maternal and child health clinics. The most recent distribution targeted all 23 counties in malaria-endemic and epidemic-prone zones, plus five sub-counties with irrigation areas.²²

²⁰ Kenya TB Prevalence Survey Report (<https://www.nltc.co.ke/download/kenya-tb-prevalence-survey-report/>) (Accessed 26 July 2021)

²¹ Community Health Volunteers (CHVs) are recruited and deployed by the county governments

²² Some studies have blamed the increase of malaria risk on the creation of favorable breeding sites in irrigation projects like Kenya' Mwea Rice Irrigation.

For 2020, 15.9 million LLINs²³ were to be procured and distributed at a cost of US\$61.7M. However, the campaign was delayed due to:

- **Inadequate procurement planning, impacting LLIN availability.** In addition to the Global Fund, the President's Malaria Initiative (PMI) also funds LLIN procurement. The Malaria Working group agreed that PMI funds would be used first, followed by Global Fund procurement. Procurements under the Global Fund grant were initiated but faced delays of 405 days (the average time taken from MOH initiation to delivery) at planning and approval and tendering, as detailed in section 4.1 of this report.
- **Delayed adaptations to COVID-19, impacting LLIN distribution.** Only 194,960 (1.5%) of the original target of 12.9 million Global Fund-financed LLINs were distributed in 2020. Following the pandemic outbreak, the Malaria program adapted its distribution strategy and the 2020 mass distribution plan was revised. An amended plan was issued in August 2020, and a pilot mass distribution campaign undertaken in October 2020. During this pilot, 194k LLINs were distributed against the target of 12.9 million by Dec 2020. The results of the pilot were assessed and a countrywide LLIN distribution was under way at the time of the audit. Unlike other countries which successfully adapted to the pandemic by moving to a door-to-door distribution approach of LLINs, Kenya opted to pilot its LLIN campaign strategy, ultimately opting to adopt a fixed point based distribution, rather than door to door.



More progress needed on testing and yield for HIV interventions

Kenya has made commendable progress in its HIV response (see Section 2.4). However, the country is still lagging behind in achieving targets for HIV testing. There was a **significant decline in testing in Q2 of 2020** due to COVID-19: testing volumes fell by 33% between March and April 2020, and facility testing by 28% over the same period. Community testing decreased by 47%: 630,000 tested in 2020 compared to 1.1 million people in 2019.

While most patients who received a positive HIV result were enrolled on ARV treatment, a high percentage (between 28 to 51%) of Key Populations reached were not tested. For example, in 2020, for Female Sex Workers (FSW), men who have sex with men (MSM) and People who inject drugs (PWID) who were reached with prevention packages, only 49%, 54% and 72% respectively were tested. This is mainly due to the fact that not all clients reached with a prevention intervention are eligible for testing at that point, and to testing not being included in peer intervention services.


There is an opportunity to increase testing yield for key populations, based on current positivity rates versus the latest prevalence results. For example, in 2020, the positivity rate versus the related prevalence results were: FSW 6% versus 29%, MSM 5% versus 18%, and PWID 1% versus 19%.

In addition to pandemic-related disruptions, reasons for the low testing performance in 2020 include the high percentage (50-60%) of repetitive testing, reduced testing by nurses,²⁴ industrial action by health workers, stigma and discrimination towards key populations, and limited availability of HIV rapid diagnostic tests.

Agreed Management Action 3:
The Global Fund Secretariat will support the Principal Recipients, the MOH, and technical partners, under CCM, to:
a. Tuberculosis: Undertake an in-depth desk review analysis to identify the reasons for sub-optimal TB case notification rates. An action plan should subsequently be developed with strategies to address the challenges identified in the desk review, including building on ongoing implementation of TB case finding strategic initiatives.
b. HIV: Evaluate implementation of targeted testing strategy (2018) and use lessons learnt to inform development of an action plan to address existing gaps.
OWNER: Head of Grant Management Division
DUE DATE: 30 June 2023

²³ 12.9 million LLINs were to be Global Fund funded and 3 million LLINs were to be funded by the US Government.

²⁴ Refer to the Constitutional Petition No.282 of 2017 (<http://kenyalaw.org/caselaw/cases/view/174230/>) which banned non-lab personnel from performing tests.



4.5 Limited utilization of COVID-19 funds. Improvement needed in the design and implementation of financial controls.

While program absorption rates improved in the last semester of grant implementation, the country's capacity to use its COVID-19 funding allocation on time, including C19RM and government counterpart funding, remains low. Financial management controls could be improved for better accountability.

Low utilization of Covid-19 funds has impacted program effectiveness

The Global Fund designed and implemented the COVID-19 Response Mechanism (C19RM) to support countries in their fight against COVID and to mitigate the pandemic's impact on disease programs. C19RM along with grant flexibilities was designed to provide countries with resources to enable them to respond quickly to the pandemic. Three C19RM awards totalling US\$36.9 million were approved between June and December 2020: US\$16.6 million in June, US\$8.3 million in August and US\$12 million in December. In addition, US\$8.3 million in grant flexibilities were approved in April 2020. Two thirds of the total COVID 19 funds were directed towards reinforcing the national COVID-19 response, and the remainder towards mitigating the pandemic's impact on TB, HIV and Malaria programs.

The utilization of these funds has however been low, affecting key program activities. Eight months after the first COVID-19 funds were awarded (31 December 2020), only 15% had been utilized, rising to 17% by 31 March 2021. At the end of the grant date (30 June 2021) the utilization rate was 51% for both C19RM funds and grant flexibilities.²⁵ US\$17.5 million (47%) in unutilized C19RM funds for 2020 were approved and rolled over to C19RM 2021, bringing the total C19RM award for Kenya to US\$139.2 million.

The low utilization rate stems from delayed approval processes between the various stakeholders, and from inefficient procurement processes (see Finding 4.1). There were significant delays in effecting payments for delivered commodities; it took on average 134 days and 148 days for Global Fund and government counterpart funding procurements respectively. It took on average 149 days between the Global Fund notifying the Kenya Coordinating Mechanism of the C19RM funding allocation and the Ministry of Health raising a request to the National Treasury. As a result, critical program activities were adversely affected. For example, community-based TB activities were also disrupted due to restrictions on movement, lack of access to TB services and the non-availability of Personal Protective Equipment during the COVID-19 pandemic.

Failure to maximize the use of government financing has impacted the availability of health commodities

During 2018-2021, the Government of Kenya met its first two annual commitments for counterpart funding, but not for the 2020/2021 financial year, due to the economic recession prompted by COVID.²⁶ Kenya counterpart funds are provided exclusively for procuring health commodities. Between July 2018 and June 2021, the Government allocated approximately US\$90 million for this purpose, however only 57% (US\$38.5 million) of the committed funding was actually available for spending. The rest was foregone/unavailable due to pending bills,²⁷ a consequence of limited planning and delays in the procurement process (see Finding 4.1).

Treasury management and other financial controls could be improved for better accountability

The National AIDS Control Council, a sub-recipient under the National Treasury HIV grant, had a US\$3.2 million cash balance in February 2021, representing 47% of its total budget (US\$6.8 million) for the grant period Jan '18 – June '21. This was a consequence of receiving a US\$1.8 million disbursement in February 2021 (four months before grant-end), which exceeded its budgetary requirements. We found unexplained variances in M-Pesa bank accounts, a consequence of the National Treasury, the national Malaria and HIV disease programs not preparing monthly bank reconciliations for their respective M-Pesa bank accounts, despite this being a requirement in the 2012 Public Finance Management Act and the Country Team flagging the issue.

²⁵ The final absorption for Grant Flexibilities was 41% whereas for C19RM it was 53%.

²⁶ World Bank press release, June 08 2020: [COVID-19 to Plunge Global Economy into Worst Recession since World War II](#) (accessed 25 August 2021);

²⁷ Pending bills carried forward from preceding periods are not payable from the respective year's commitment but are deducted from future commitments.

Annex A: Audit rating classification and methodology

Effective	No issues or few minor issues noted. Internal controls, governance and risk management processes are adequately designed, consistently well implemented, and effective to provide reasonable assurance that the objectives will be met.
Partially Effective	Moderate issues noted. Internal controls, governance and risk management practices are adequately designed, generally well implemented, but one or a limited number of issues were identified that may present a moderate risk to the achievement of the objectives.
Needs significant improvement	One or few significant issues noted. Internal controls, governance and risk management practices have some weaknesses in design or operating effectiveness such that, until they are addressed, there is not yet reasonable assurance that the objectives are likely to be met.
Ineffective	Multiple significant and/or (a) material issue(s) noted. Internal controls, governance and risk management processes are not adequately designed and/or are not generally effective. The nature of these issues is such that the achievement of objectives is seriously compromised.

The OIG audits 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 audits may be specific or broad, depending on the context, and covers risk management, governance and internal controls. Audits test and evaluate supervisory and control systems to determine whether risk is managed appropriately. Detailed testing is used to provide specific assessments of these different areas. Other sources of evidence, such as the work of other auditors/assurance providers, are also used to support the conclusions.

OIG audits typically involve an examination of programs, operations, management systems and procedures of bodies and institutions that manage Global Fund funds, to assess whether they are achieving economy, efficiency and effectiveness in the use of those resources. They may include a review of inputs (financial, human, material, organizational or regulatory means needed for the implementation of the program), outputs (deliverables of the program), results (immediate effects of the program on beneficiaries) and impacts (long-term changes in society that are attributable to Global Fund support).

Audits cover a wide range of topics with a particular focus on issues related to the Impact of Global Fund investments, procurement and supply chain management, change management, and key financial and fiduciary controls.

Annex B: Risk appetite and risk ratings

In 2018, the Global Fund operationalized a Risk Appetite Framework, setting recommended risk appetite levels for eight key risks affecting Global Fund grants, formed by aggregating 20 sub-risks. Each sub-risk is rated for each grant in a country, using a standardized set of root causes and combining likelihood and severity scores to rate the risk as Very High, High, Moderate, or Low. Individual grant risk ratings are weighted by the grant signed amounts to yield an aggregate Current Risk Level for a country portfolio. A cut-off methodology on high risks is applied (the riskiest 50% of grants are selected) to arrive at a country risk rating.

OIG incorporates risk appetite considerations into its assurance model. Key audit objectives are generally calibrated at broad grant or program levels but OIG ratings also consider the extent to which individual risks are being effectively assessed and mitigated.

OIG's assessed residual risks are compared against the Secretariat's assessed risk levels at an aggregated level for those of the eight key risks which fall within the Audit's scope. In addition, a narrative explanation is provided every Time the OIG and the Secretariat's sub-risk ratings differ. For risk categories where the organization has not set formal risk appetite or levels, OIG opines on the design and effectiveness of the Secretariat's overall processes for assessing and managing those risks.

Annex C: Stock-outs of health commodities noted during the audit

A. Stock-outs at Central Level

HIV	<ul style="list-style-type: none"> ● LPV/r 100/25MG was stocked out centrally in March '19, whereas in April and May '19 the stock balance was 56 Packs (0.01 MoS), too low to meet Health Facility (HF) needs. ● NVP Oral Suspension - 10MG/ML was stocked out centrally in April & Oct '19. Low stock levels were registered in March '19 (18 packs (< 1 MoS); 2 packs (< 1 MoS) from July to Sept '19. ● Stock levels of TLD were consistently below recommended minimum stock levels of 6 MoS from Jun '19 (4MoS) to Jan '20 (2MoS) and from Nov '20 (5 MoS) to April '21 (2 MoS). Stock levels stagnated at 2MoS from April '21 to Jun'21.
TB	<ul style="list-style-type: none"> ● INH 300mg 28s was stocked out centrally for 16 consecutive months from March '20. Whilst INH 300mg 672s was available, the stocks were too low to meet the HF needs as stock levels gradually reduced from 1 MoS in Feb '20 to 0.01 MoS in April '21 before stocking out in May '21.
Malaria	<ul style="list-style-type: none"> ● All pack sizes of Artemether/ Lumefantrine were stocked out centrally for 3 consecutive months from Aug to Oct '19. ● Malaria RDTs were stocked out centrally for 3 consecutive months from July to Sept '18 and for 6 months from Jun to Nov '19. ● Artesunate Inj was stocked out centrally for 4 consecutive months July to Oct '19. ● 10% (n=2) of HFs experienced stock-outs of this product during the same period.

B. Stock-outs at Health Facilities

	No. of sampled facilities that were stocked out (%)	Overall average of stock-out days	Highest # of days for an individual stock-out
Malaria Drugs and Commodities			
ACT – Artemether + Lumefantrine (AL) 20+120 mg (6)	12 (57%)	154	485
ACT – Artemether + Lumefantrine (AL) 20+120 mg (12)	9 (43%)	131	445
ACT – Artemether + Lumefantrine (AL) 20+120 mg (18)	5 (24%)	92	258
ACT – Artemether + Lumefantrine (AL) 20+120 mg (24)	13 (62%)	135	418
Artesunate injection	7 (33%)	98	489
mRDT (Malaria Rapid Test Kits 25 Tests)	2 (9.5%)	65	210
HIV Drugs and Commodities			
Tenofovir/Lamivudine/Dolutegravir (TLD) 300mg/300mg/50mg 30s	8 (38%)	30	86
Tenofovir/Lamivudine/Dolutegravir (TLD) 300mg/300mg/50mg 90s	6 (28.6%)	52	129
Tenofovir/Lamivudine/Efavirenz (TLE) 300mg/300mg/400mg - 30s	7 (33%)	92	354
Atazanavir/Ritonavir (ATV/r) 300mg/100mg	3 (14%)	12	31
Nevirapine Oral Suspension - 10mg/ml	5 (24%)	39	106
Zidovudine/Lamivudine - 300/150mg	3 (14%)	52	184
Lopinavir/Ritonavir 100/25mg	3 (14%)	125	494
Abacavir/Lamivudine 120mg/60mg	5 (24%)	150	401
HIV Test Kits (Determine)	9 (43%)	12	36
HIV Test Kits (First Response)	10 (47.6%)	35	113
Oral HIV Self-test Kits	12 (57%)	69	373
TB Drugs			
RHZE 150 mg/75mg/400mg/275 mg	8 (38%)	168	540
RHZ(75/50/150) 3FDC RHZ D.S	2 (9.5%)	54	163
Isoniazid 300mg	9 (43%)	270	933