

Audit Report

Global Fund Grants to Tanzania (mainland) Follow-up Audit

GF-OIG-18-006 21 March 2018 Geneva, Switzerland



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Audit Report

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1. Executive Summary

1.1. Opinion

With funding support from the Global Fund and other donors, Tanzania continues to make progress against the three diseases. Malaria mortality rate decreased by 76% between 2004 and 2016. Since 2015, antiretroviral treatment coverage has increased from 47% to 63% of people living with HIV while the tuberculosis (TB) treatment success rate has reached 90%. While these results demonstrate significant programmatic advances against the three diseases, quality of services continue to present significant challenges. This is notably the case for the HIV program which still has a significant proportion of patients (18%) lost to follow-up or non-traceable after starting treatment. Some key populations also continue to face major barriers regarding access to HIV prevention and treatment services. As a result, the OIG considers the overall quality of services as partially effective.

Global Fund grants to Tanzania are largely commoditized, with 73% of funds in the current grant cycle allocated to procure and distribute health products. Hence, effective mitigation of supply chain risks is essential. Commodities are now directly delivered from the warehouses of the central Medical Stores Department (MSD), the central agency responsible for procurement and distribution of drugs in Tanzania, to the health facilities. Stock-outs at central and zonal warehouses have been minimized. However, management of health commodities by the national disease programs remains a challenge. Approximately US\$9 million worth of HIV drugs procured through the Global Fund's Pooled Procurement Mechanism expired at MSD warehouses between January 2016 and September 2017.1 While these expiries represent only 4% of the Global Fund HIV drug procurements during the same period, their absolute values are high. At the same time, the risks of HIV drug stock-outs persist at the health facilities level. Furthermore, variances in excess of 36% exist between the estimated consumption based on the reported number of patients and the actual amounts of anti-malarial drugs consumed. Supply chain arrangements therefore still need significant improvement. The primary root causes are inadequate numbers and supply chain skills of the human resources at central to health facilities levels. This is particularly the case for forecasting the needs based on agreed targets and planning deliveries and inter-facilities stock transfers based on consumption and stock status reports.

Oversight and governance mechanisms are partially effective. Improvements have been made in governance and coordination, but some gaps still exist in oversight. In particular, weak management units within the ministries have limited the timely detection of issues, the adequacy of follow-up, and overall accountability for results.

1.2. Key achievements

Significant program achievement for the three diseases:

- HIV: Tanzania scaled up HIV testing services from 2.5 million people tested in 2014 to 7.5 million in 2016. The number of HIV-positive people receiving antiretroviral treatment increased from 846,527 in December 2016 to 935,228 in June 2017.
- Malaria: Mortality decreased from 41/100,000 people in 2004 to 10/100,000 in 2016. Treatment of malaria cases without a parasitological confirmed test decreased from 36% in 2014 to 14% in 2016, following the adoption of new treatment guidelines and the increased availability of malaria rapid diagnostic tests at the health facility level.
- Tuberculosis: Treatment success rates for tuberculosis are high at 90% (for the 2015 cohort) and detection improved with the number of tuberculosis cases notified in 2016 at 65,902, an increase of 3,580 over 2015.

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Success in implementing supply chain improvements: A strategic review of MSD was completed in February 2016. The review recommended improving MSD's financial situation; strengthening the collaboration with the Ministry of Health; enhancing the distribution of drugs to health facilities; and improving inventory data. Improvements have already been noted in the distribution arrangements. For example, in 2017, almost 90% of orders of malaria commodities were delivered directly to health facilities when, in the past, they were only delivered to the regional and district levels. As a result, stock-outs and expiries of malaria drugs at the health facilities have been relatively low.

Improvements in the timeliness of the Principal Recipient disbursements: Disbursements from the Principal Recipient, the Ministry of Finance and Planning, to key sub-recipients are significantly quicker. Whilst delays of up to one year were noted in 2015, the disbursement cycle was reduced to between 14 and 60 days in 2017.

Significant efforts since 2015: The Secretariat and in-country stakeholders have mitigated the risks previously identified in the 2015 audit by implementing the ensuing agreed management actions. This includes facilitating two assessments to improve effectiveness of the overall supply chain; establishing a key risk matrix; tailoring the process for completing and submitting key reports to include targeted spot checks by the Local Fund Agent; and improving coordination with the external and internal auditors. The Secretariat has also recovered all ineligible expenditures from the Government of Tanzania.

1.3. Key challenges

Expiry of HIV antiretroviral drugs: As noted above, MSD reported expired antiretroviral drugs worth approximately US\$9 million procured through Global Fund grant funding between January 2016 and September 2017.¹ The reasons behind were gaps in program management: inaccurate pediatric treatment target setting leading to overstock of pediatric drugs (31% of expiries); not managing stocks of old drugs formulations when executing changes in the antiretroviral regimens; and limited monitoring of stock levels due to human resources constraints.

Data quality issues: The OIG noted problems in existing information systems, resulting in significant discrepancies between the logistics management system, the health information system and the inventory records, as well as the following unexplained overconsumption of malaria drugs:

- For the period between July 2016 and September 2017, the new automated logistics system (LMIS) reported consumption of 37.9 million anti-malarial blisters. This exceeds the estimated number of available drugs of 21.2 million² based on MSD supplies. The logistics system data has only recently been put in place and staff have not yet received sufficient training.
- For 2016-17, based on manual inventory records which are more reliable than LMIS, the consumption of antimalarial blisters was estimated at around 15 million according to MSD supplies and inventory records. However, this was also 40% higher than the dispensed antimalarial drugs (11 million blisters) as per the District Health Information System (DHIS2) for the same period. The corresponding value of this difference of 4 million blisters is more than US\$1.2 million. The implementers identified health systems weaknesses as possible root causes but were unable to account for these significant discrepancies. Possible explanations include unreported expiries by facilities, under-reporting of malaria treatments in DHIS 2, or potential drug leakages. Understaffing at government health facilities is also a likely contributor to reporting errors. The OIG, the Secretariat, and in-country stakeholders have agreed that the discrepancy requires further investigation, which will be undertaken separately by the OIG.

¹ The total expiries during a **21-month period (January 2016 - September 2017)** from all sources of funding were approximately US\$ 11.3 million. The unit price used is the corresponded PQR price that reflect the actual paid price.

² In 2016, total stock available at facilities was estimated to be around 21.2 million ACT blisters: 7.6 million as opening stock balance as per e-LMIS and 13.6 million delivered by MSD.

Low HIV patient retention rate and treatment access risks: Tanzania has adopted an ambitious target to initiate 94% of people living with HIV on antiretroviral treatment by 2020, compared to the current 69%. This is above the UNAIDS Fast-track targets of treating 90% of people living with HIV. However, 18% of adults and 15% of children are currently lost to follow up, or become non-traceable due to inter-facility transfers, within one year after initiating treatment. In the context of the anticipated scale-up, significant improvement in patient retention is needed to ensure that future programmatic targets are reached.

Furthermore, in October 2016, following allegations of "homosexuality promotional activities", a government directive temporarily suspended HIV and AIDS services to key populations at the community level. Policies that restrict non-discriminatory access of key populations to counselling or testing services pose potentially significant risks to the effective implementation of HIV programs.

Supply chain funding gaps: Following significant supply chain gaps in 2015, Tanzania conducted a holistic supply chain review. The review detailed all the improvements needed requiring a total investment of US\$40.4 million.³ While the Global Fund committed to a contribution of US\$2.7 million, the government needs to develop a financing plan to fund the remaining gap.

Furthermore, although its debt has almost stopped growing, the government has not yet cleared long-outstanding payables to MSD, amounting to US\$65.6 million as of 30 June 2017. Approximately half of this amount was budgeted by the government to be repaid in 2016-17, but this commitment remains largely unmet.

Governance and oversight need further improvements: Despite multiple layers of governance and oversight, gaps still exist in the implementation of the grants in terms of program oversight, issue identification, or follow-up on corrective actions. Major remaining issues include delays in key portfolio decisions, low in-country absorption, and sustainability in the context of continued heavy reliance on donor financing. Existing governance mechanisms have not been able to effectively tackle these broad portfolio-level issues due in large part to an unclear definition of roles, responsibilities and accountability for various decisions, the lack of structured mechanisms for following up on corrective actions, and delays in submitting information needed for oversight and monitoring.

1.4. Rating

Needs significant improvement	Objective 1: Effectiveness of the supply chain arrangements to deliver and account for health products. Procurement and distribution arrangements have improved, particularly by MSD, and the current supply chain arrangements in country are able to deliver drugs to patients, with minimal stockouts. However, expiration of HIV drugs remains a significant issue. Material discrepancies, which cannot yet be reconciled, also exist between the reported volume of malaria drugs distributed and the reported levels of consumption. Supply chain reviews have determined ambiguity in roles and accountabilities of different entities involved, and health workforce and training issues as principal root causes. Supply chain arrangements therefore still need significant improvement.
Partially Effective	Objective 2: Effectiveness of the operational plans and actions in addressing quality of services issues, including malaria testing, HIV treatment and access to services. Patient access to treatment and quality of services have improved since the OIG 2015 OIG audit. However, broader issues, which are beyond Global Fund's control, have limited the effectiveness of the actions undertaken so far to improve quality of services. These issues include significant gaps in health workforce, weaknesses in

³ The budget excludes the fleet expansion cost for which the Global Fund already funded US\$ 10.8 million.

	regional supervision of health facilities, ineffective management of the co-payment mechanism, and risks related to key populations' access to HIV services. Overall, due to these broader constraints, the actions to improve quality and access to services remain partially effective.		
Partially Effective	Objective 3: Effectiveness of the governance and assurance arrangements. Since the last audit, significant improvements have been made in program oversight, timeliness of decision-making, and reduction of disbursement delays. However, due in part to the multi-layered and complex governance arrangements, there is still limited accountability and follow-up on outstanding issues such as in-country grant absorption orimplementation of management actions agreed with the Secretariat. Governance and assurance arrangements are therefore partially effective.		

1.5. Summary of Agreed Management Actions

The Secretariat will work with the government ministries and Principal Recipients to map out grant implementation structures, roles and accountabilities, for the ministries, President's Office, and various other government agencies and management units. In particular, roles relating to procurement, supply chain management, quality of services and grants oversight will be clarified. The holistic supply chain review action plan will also be critically reviewed and key activities will be prioritized.

The Secretariat will align the Global Fund resilient health systems grant funding with national human resource plan and budget, targeting vacancies in critical cadres, and planning their absorption into government public service system over the program term.

The Secretariat will also monitor and ensure the selection of an appropriate entity for managing a co-payment mechanism.

2. Background and Context

2.1. Overall Context

Economic and social overview

The United Republic of Tanzania (comprising of Tanzania mainland and the semi-autonomous islands of Zanzibar) is the largest and most populous country in East Africa. Tanzania is a low income country, with 46.6% of its 52 million population living below the income poverty line of US\$1.90 per day. It ranks 151th out of 188 in the UN Development Programme's Human Development Index and 116th out of 176 in Transparency International's Corruption Perceptions Index (2016).

Health sector structure

Tanzania mainland has 27 administrative regions, 133 districts and 162 councils. The councils (local governments) are the most important administrative and implementation units for public services. Tanzania has a total of 6,734 health facilities, which include private facilities, faith-based organizations and public institutions. They are managed by the councils under a decentralized setup. The President's Office (Regional Administration and Local Government) is responsible for the management and administration of public services at the regional and council level.

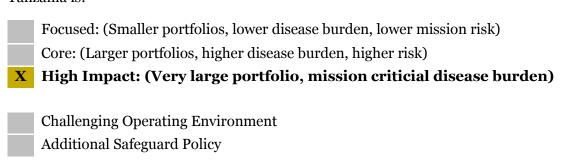
The Ministry of Health, Community Development, Gender, Elderly and Children has overall responsibility over health and social welfare services. Its roles include defining priorities for health services, providing technical guidance, defining quality standards and policy setting.

The financing of the health sector in Tanzania is heavily dependent on external donors. A total of 93% of HIV funding and 87% of tuberculosis funding came from external sources in 2015-2017.

2.2. Differentiation Category for Country Audits

The Global Fund has classified the countries in which it finances programs into three overall portfolio categories: focused, core and high impact. These categories are primarily defined by size of allocation amount, disease burden and impact on the Global Fund's mission to end the three epidemics. Countries can also be classed into two cross-cutting categories: Challenging Operating Environments and those under the Additional Safeguard Policy. Challenging Operating Environments are countries or regions characterized by weak governance, poor access to health services, and man-made or natural crises. The Additional Safeguard Policy is a set of extra measures that the Global Fund can put in place to strengthen fiscal and oversight controls in a particularly risky environment.

Tanzania is:



2.3. Global Fund Grants in the Country

The Global Fund has invested approximately US\$1.9 billion in Tanzania since 2002. Tanzania mainland is one of the most important countries in the Global Fund portfolio, representing almost 6% of total 2017-2019 allocation.

Global Fund grant funding is allocated separately between Tanzania mainland and Zanzibar. At the time of the audit, there were five active Global Fund grants in Tanzania mainland, all ending on 31 December 2017.

Grant component	Grant number	Principal recipient	Start date	End date	Signed amount (US\$)
HIV	TNZ-405- G06-H	Population Services International	1 April 2014	31 Dec 2017 (extended from 31 December 2016)	61,192,309
	TZA-H-MOF	Ministry of Finance and Planning of the United Republic of Tanzania	1 July 2015	31 Dec 2017	386,605,772
HIV/TB	TZA-C-STC	Save the Children Federation Inc.	1 July 2015	31 Dec 2017	13,059,126
ТВ	TZA-T-MOF	Ministry of Finance and Planning of the United Republic of Tanzania	1 July 2015	31 Dec 2017	21,377,285
Malaria/HSS	TZA-M-MOFP	Ministry of Finance and Planning of the United Republic of Tanzania	1 May 2016	31 Dec 2017	126,713,941

The Ministry of Finance and Planning is the Principal Recipient for three of the grants, one for each of the three diseases. The Ministry of Finance and Planning has established a Program Management Unit for the management of grant funds, which allocates funding to the implementing sub-recipients (the three National Disease Programs and the President's Office through a second Global Fund Coordinating Unit located in the Ministry of Health. The Ministry of Health acts as a lead Sub-Recipient in this implementation arrangement.

The grant managed by Populations Services International, initially projected to end in December 2016, was extended until December 2017. At the time of the audit, the country was going through a grant-making process for the funding allocation 2018-2020.

2.4. The Three Diseases



HIV/AIDS: Tanzania accounts for 4.6% of the global HIV burden, and ranks 7th in the world.

Tanzania has a mixed HIV epidemic. The most frequent mode of transmission is within heterosexual relationships but key populations have a higher risk of being infected.

846,572 people on antiretroviral therapy at the end of 2016⁴

Approximately 1.4 million people are living with HIV⁵

4.7% HIV prevalence (adults 15-49 years old)⁶

55,000 new HIV infections in 2016⁷

⁴ National Aids Control Program Tanzania in December 2016.

⁵ National Aids Control Program Tanzania.

⁶ UNAIDS Aidsinfo.

⁷ UNAIDS Aidsinfo.

Among key populations, the HIV prevalence of female sex workers is estimated at 26%; men who have sex with men at 25% and people who inject drugs at 36%.

Tanzania has adopted the WHO 'test and treat' guidelines, recommending that all diagnosed people living with HIV start antiretroviral treatment. This has brought a scale-up of testing and treatment services and the country is aiming to reach 95% of diagnosed people living with HIV who have initiated treatment by 2020.

33,000 AIDS-related deaths in 20168

84% coverage of pregnant women who receive antiretroviral treatment for prevention of mother to child transmission

40% coverage of early infant diagnosis



Malaria: Tanzania has the 4th largest population at risk of malaria in the world, and ranks 7th on disease burden.

Tanzania accounts for 2% of the global estimated malaria cases but 4% of total estimated malaria deaths in 2015.9

In 2015, 49 % of the population slept under a mosquito net the previous night. There was a decline in household mosquito bed net ownership from 91% in 2011-2012 to 66% in 2015-2016.

Malaria mortality decreased significantly from 41/100,000 population in 2004 to 10/100,000 population in 2016.

67.5. million insecticide-treated nets distributed.

5.5 million reported confirmed cases at health facility level in 2016

6,311 reported deaths in 2016

41% of the population live in high transmission areas



Tuberculosis: Tanzania is ranked 12th among the 22 high burden TB countries and has the 6th highest TB/HIV burden globally in 2015.

The estimated TB case detection rate ranges between 42% and 54% (below the Millennium Development Goals target of 70%). WHO revised down this detection rate to 36% in 2015.

Tanzania is also one of 41 TB/HIV high burden countries with a TB/HIV co-infection rate of 37-39% in the last three years. In 2016, 95% of all people diagnosed with TB were also tested for HIV. 91% of those co-infected were initiated on antiretroviral treatment.

65,908 total cases of TB notified in 2016

TB incidence rate (including HIV/TB co-infection): 287 per 100,000 population in 2016¹⁰

MDR-TB incidence rate : 4.7 per 100,000 population in 2016¹¹

TB mortality rate: 51 per 100,000 population in 2016¹²

⁸ UNAIDS Aidsinfo.

⁹ WHO World Malaria Report 2016.

¹⁰ Global Tuberculosis Report 2016.

¹¹ Global Tuberculoses Report 2016.

¹² Global Tuberculosis Report 2016.

3. The Audit at a Glance

3.1. Objectives

Given the significance of the issues identified in the 2015 audit and the importance of the Tanzania portfolio, the OIG followed up its audit to assess progress on the key risks identified.

The follow-up audit assessed the effectiveness of:

- supply chain arrangements to deliver and account for health products;
- operational plans and actions to address quality of service issues, particularly malaria testing, HIV treatment and access to services; and
- governance and assurance arrangements towards improving grant management and oversight.

3.2. Scope and Methodology

The audit covered the following active grants implemented by Ministry of Finance and Planning (MOFP) including its sub-recipients and governance arrangements:

Grant No. Grant		Grant period	Signed	Disbursed to
	component		amount	date
TZA-H-MOF	HIV	01/07/2015-31/12/2017	386,605,772	320,861,050
TZA-T-MOF	Tuberculosis	01/07/2015-31/12/2017	21,377,285	16,311,540
TZA-M-MOF	Malaria/HSS	01/05/2016-31/12/2017	126,713,941	95,369,236

The audit covered the active grants from July 2016 to June 2017. The audit included:

- collection and review of relevant documents and information;
- interviews with grant managers and relevant staff at the Secretariat, the Local Fund Agent, in-country partners; and
- in-country field work which included site visits, review of systems and process and substantive testing, where relevant.

3.3. Progress on Previously Identified Issues

In 2015, the OIG audited Global Fund grants to mainland Tanzania (GF-OIG-16-002) focusing on three objectives: (i) patients/clients have access to quality-assured drugs in a timely manner; (ii) accurate and timely data is available to support decision making; and (iii) available grant funds are spent in an economic, efficient and effective manner. Six Agreed Management Actions (AMAs) were issued, of which three have not yet been fully implemented and closed.

The main AMA, which has been implemented, targeted supply chain improvements. Two supply chain assessments have been performed, aimed at addressing ownership, coordination and accountability issues,

Previous relevant OIG audit work

GF-OIG-16-002 (8 February 2016), Audit of Global Fund Grants to the United Republic of Tanzania (mainland)

including overall MSD financial conditions. However, success is contingent on the availability of funding and the government commitment to execute the established action plan. The remaining persisting gaps in supply chain are detailed in Finding 4.1.

Another AMA required strengthening grant implementation arrangements, including the capacity of the Ministry of Finance and Planning to execute its mandate, and the effectiveness of it sub-recipient oversight. Some gaps remain in governance and oversight which are highlighted in Finding 4.2.

The third implemented AMA related to recovery of unaccounted funds, which has been completed.

One of the three outstanding actions requires improvements in quantification and forecasting, health workforce training to improve quality of services and the identification of a suitable entity for managing a co-payment mechanism.¹³ The components related to quantification, forecasting and training have been completed. However, the entity identified to manage the co-payment mechanism has not yet taken over this responsibility. Furthermore, a mechanism has not yet been developed to monitor subsidized anti-malaria drugs that are distributed in the endemic areas at the recommended prices.

The second outstanding action at the Secretariat level requires detailed analysis and planning to address funding gaps for reaching HIV fast track targets. A plan has not yet been developed. The last outstanding action involved the development of guidance on construction and renovation projects undertaken as part of the Global Fund Health Systems Strengthening programs. However, both these agreed actions have more long-term and portfolio-wide risk implications.

¹³ The private sector co-payment mechanism, launched in Tanzania in 2010, involves paying subsidies to manufacturers of malaria drugs in order to ensure the availability and affordability of subsidized antimalarial medicines in private health facilities. The 2015 audit identified ownership issues.

¹⁴ This agreed management action required the Secretariat, partners and governments for five countries, including Tanzania, to develop a plan for addressing additional funding requirements from test and treat approach for HIV.

4. Findings

4.1. Improved supply chain management but inefficiencies in stock utilization and poor drug traceability

The OIG audit in 2015 identified material supply chain issues. These included recurring stock-outs of commodities, drug expiries, poor inventory data quality, and the weak financial situation of MSD. In response to the findings, the country conducted two reviews aimed at identifying and addressing the main supply chain risks. The first, the MSD strategic review was completed in February 2016, and second, the holistic supply chain review was completed in June 2017.

The implementation of recommendations from these reviews already shows significant improvements in the MSD supply chain management, including the following:

- **Direct delivery of commodities to health facilities:** Under the new logistics system¹⁵, MSD has significantly increased delivering HIV and malaria commodities from its central warehouses directly to the health facilities. In 2017, almost 100% of orders to MSD zonal warehouses were directly delivered. This is a major improvement from 2015, when almost half of deliveries were indirectly routed through the District Medical Offices, resulting in recurring stock-out at the facilities. Under this mechanism, primary drugs are supplied on a quarterly basis. This frequency will improve after completion of a planned procurement of 200 new vehicles and trucks.
- Continuous availability of drugs: Major stock-outs have largely been avoided in 2016-17 for both HIV and malaria commodities, at the central and zonal levels (with a few exceptions, such as Unigold HIV tests- see below). Only 9% of health facilities¹⁶ experienced stock-outs of malaria ACTs and test kits in 2017, compared to pervasive stock-outs across facilities in 2015. The volume of malaria stock-outs was also low throughout 2016-2017 and remained consistently below 3%.¹⁷ These improvements resulted from direct and more frequent deliveries (explained above), reduction in delivery time from 65 days in 2015 to 21 days in 2016-17, and improvements in meeting order requests (the order fill rate is almost 85% compared to 60% in 2015).
- Improved stock data quality in MSD: The inventory management system Epicor 9 data at MSD is more accurate, reliable and readily available, compared to 2015. The issue of negative stock balances identified in the previous audit has been addressed, with only 1% discrepancy between the system records and the physical stock.
- Increased coverage of the Logistic Management and Information System (eLMIS): In 2017, the eLMIS reached a national coverage of around 95% of health facilities. In 2015, it was limited to district facilities and few health facilities outside the districts.
- Improved documentation of financial transactions at MSD: Contrary to 2015, all transactions funded through Global Fund grants at MSD were well supported. MSD has improved in collecting, filing and archiving supporting documents.

These improvements demonstrate progress in the management of the supply chain in Tanzania. However, two key risks identified in the OIG audit of 2015 still remain unmitigated or have only been partially addressed:

• **Expiries of health commodities:** The MSD reporting system provides detailed lists of all expiries countrywide, and shares those with the programs on monthly basis, with quarterly joint management meetings at the central level. As a result, for the fiscal year 2016-17, malaria

¹⁵ Integrated Logistics System Direct Delivery (ILS – DD).

¹⁶ As per stock-out status reported in eLMIS data.

¹⁷ Based on stock reports from Malaria National Program.

expiries were low at US\$143,085 worth of expired diagnostic tests (4% of the annual procurements) and less than US\$10,000 for drugs. The risk of expiries of anti-malarial drugs for next year is also low, with 92% of commodities in the current stock having a shelf life in excess of 12 months. These improvements were mainly attributed to longer shelf lives for commodities procured through the Global Fund Pooled Procurement Mechanism and active program management.

However, unlike for malaria, the trend has deteriorated for HIV where drug expiries were significantly higher than in 2014-15, despite regular MSD reporting to the program. Expiries of approximately US\$11.3 million were reported for antiretroviral drugs between January 2016-and September 2017, of which approximately 78% (US\$9 million) were procured through Global Fund grants. In 2014-15, Global Fund expired commodities at MSD were approximately US\$0.2 million. While these expiries constitute, in relative terms, a small percentage of the total Global Fund antiretroviral procurements for the same period, their absolute dollar value remains high and needs to be reduced in the future. The breakdown of the HIV expiries is as follows: adult drugs (52%), paediatric drugs (31%) and second line drugs (17%). The primary root causes for these expiries were high paediatric treatment targets leading to overstock; changes in drugs regimens, inadequate commodity pipeline monitoring; and not implementing the First-Expiry-First-Out method²⁰ at warehouses when phasing out old regimens; and weak monitoring of stock levels, indicative of poor oversight at the national disease program level.

In addition to the total reported expiries at the central MSD warehouse level, adult antiretroviral drugs worth US\$ 1.2 million were also at high risk of expiry at the facilities level, as of August 2017. These included one drug with 25 months of stock and another with 13 months of stock, with less than 6 months' maximum shelf life in February 2017. The National AIDS Control Program guidelines require stock levels to not exceed 15 months of stock for any drug. The updated stock status and any expiries had not been reported at the time of the audit. Similarly, another adult antiretroviral drug had 17 months of stock in September 2017, with less than 6 months of maximum shelf life, and US\$ 1.5 million worth of drugs at a high risk of expiry.

- **Risk of stock-outs of commodities at health facilities:** While minimized at central and zonal levels, the risk of stock-outs of HIV and malaria test kits, as well as HIV and TB drugs, remains in the health facilities as inventory management issues persist at that level of the supply chain:
 - An analysis of e-LMIS data for all facilities country-wide, for the fiscal year 2016-17, showed that the adequacy of stock levels varied greatly across facilities. Overall, when assessed against eLMIS guidelines, 20% of facilities had adequate stocks of antiretroviral medicines for HIV treatment throughout 2016-17 as per the program guidelines on inventory management,²¹ 18% of facilities were understocked, 30% were overstocked and 24% of facilities had stock-outs at least once. The average duration of stock-outs in each of the three-month reporting period could not be determined, because eLMIS does not capture the actual stock-out days. This information would be important to adjust average monthly consumption and individual facility orders in the future.
 - For TB, MSD data show concurrent stock-outs and overstocks of first line drugs. For instance, individual paediatric products have been overstocked at the central level while at the same time very low stock (less than one month) was observed at the zonal level. As a result, eLMIS data indicates that 16%-18% of District Medical Offices reported stock-outs and 34% were

¹⁸ OIG report related to the audit of Global Fund grants in the United Republic of Tanzania (GF-OIG-16-002 page 11).

¹⁹Total procurements during the 21-month period was US\$ 155,207,352

²⁰ The First-Expiry/First-Out is an <u>inventory management</u> approach used for perishable products, such as drugs, whereby the items with the closest future expiration date are dispensed first and the items with the longest remaining shelf life are dispensed last. This methodaims to minimize the risk of expiration for commodities in stock.

²¹ As per the eLMIS guidelines, stock out refers to zero stock, "understocked" means stock below 3 months, adequately stock is between 3-6 months, over stocks refer to stock above 6 months.

understocked in 2016-2017. For the first line tuberculosis drug RHZE, the analysis shows 17% of District Medical Offices experiencing stock-outs and 48% that were understocked.²²

- Some cases of central and zonal stock-outs have also been observed. For example, Unigold HIV tests went briefly out of stock eight times at zonal levels, and had an average stock of 0.3 months compared to required stock level of 3 months as per guidelines. At central level, its average stock was 1.4 months compared to the required level of 6 months. Since June 2017, Unigold test kits are out of stock at central and zonal levels.

The issues of stock-outs and expiries of drugs are due to the following:

- Understaffing of government health facilities and weak monitoring: Low staffing at district and facilities contributes to non-adherence to inventory re-order levels and weak monitoring/supervision of inventory positions by the districts. Furthermore, while the National AIDS Control Program has issued a useful standard template for the program to report months of stocks with remaining shelf lives, it would benefit from automatic warning functions for expiries, to ensure continuous monitoring.
- **Improved accountability:** Roles and responsibilities, as well as accountability for supply chain issues, need to be clarified. For instance, the recommendation from the MSD strategic review on the improvement of accountability of the Logistic Management Unit within the Ministry of Health is overdue since June 2017.
- **Inflated target setting:** In case of paediatric antiretroviral drugs, expiries were mainly due to overstocking resulting from unmet ambitious targets of paediatric HIV treatment, and poor adherence to the HIV treatment guidelines by health workers leading to low use of paediatric formulations in some instances.

• Data quality issue on eLMIS and unexplained overconsumption of ACTs

The number of malaria cases treated and drugs consumed (based on MSD inventory management system and the e-LMIS database) were triangulated to assess their consistency. The results indicated the following weaknesses:

- e-LMIS data on drugs consumed is not reliable. In 2016, e-LMIS reported a consumption of 37.9 million ACT blisters, which abnormally exceeded the estimated available drugs of 21.2 million²³ based on MSD supplies. Understaffing at government health facilities contributes to eLMIS data issues. Furthermore, the e-LMIS system has been recently rolled out country-wide, but users have not been fully trained nor have they developed the necessary software experience. Consequently, there is a high risk that many of the facilities were entering data incorrectly.²⁴ The consumption data reported by the e-LMIS was based on estimates and used different units of reporting (e.g. tablets or blisters). In some cases, different units of count were aggregated and no adjustments made when calculating total stocks.
- Unexplained variance on ACT consumptions: Based on MSD data related to its opening and closing stock balances, the consumption of ACT treatment courses for October 2016 to September 2017 was estimated at around 15 million. This was 114% higher than the reported malaria cases (7 million)²⁵ and approximately 36% higher than the people to whom ACTs were dispensed (11 million)²⁶ as per DHIS 2 for the same period. The identified discrepancies may be due to one or more of the following:

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²² Due to data limitation, OIG was not able to assess whether the stock-out at district level resulted in disruption of treatments at facilities level.

²³ In 2016, total stock available at facilities was estimated to be around 21.2 million blister of ACTs: 7.6 million as opening stock balance as per eLMIS and 13.6 million delivered by MSD.

²⁴ Possible errors are tablets entered instead of blisters and 3-months consumption entered as an average monthly consumption.

²⁵ Based on OPD/ IPD registers. These numbers are much lower than epidemiological trends in the country and the region.

²⁶ Based on dispensing registers.

- unreported expiries by facilities
- under-reporting of malaria treatments in DHIS
- potential drugs leakages

As the implementers were not able to identify the reasons for this discrepancy, the matter has been referred to the OIG Investigations Unit to investigate the reasons for the difference and any possible drugs leakages.

Furthermore, to address the patient data issues, the National Malaria Program has recently rolled out two initiatives, Malaria Service Data Quality Improvement and Malaria Dashboard within DHIS2. These initiatives will facilitate early identification and resolution of issues related to health commodities stocks.

• Inadequate coverage of assurance on traceability of ACTs- The above unexplained variance on ACTs consumption stresses the importance of assurance over the traceability of malaria commodities, especially ACTs. As requested by the Global Fund Secretariat, the Local Fund Agent carried out two separate reviews on the traceability of ACTs and the rational use of ACTs based on confirmed diagnosis, covering the period July 2015—September 2016. The reports concluded that there were significant improvements in the use and traceability of ACTs to dispensing points. However, the terms of reference of the traceability review did not cover the traceability of drugs from the dispensing points to the patients, which was a major cause of similar variances identified in the 2015 OIG audit. Further, the review could only carry out traceability tests in 13 out of 40 facilities that were sampled.

• Supply chain funding gaps

In 2015, after identifying major supply chain issues, Tanzania conducted a holistic supply chain review as mentioned above. This review identified the main causes impeding an effective and reliable supply chain. To implement the required improvements, the review recommended an investment of US\$40.4 million. At the time of the audit, the Global Fund had already committed to US\$2.7 million towards this investment. However, the government needs to develop a financing plan to funding the difference of US\$37.7 million.

Furthermore, while its debt has almost stopped growing, the government has not cleared long-outstanding payables to MSD, amounting to US\$65.6 million as at 30 June 2017. Out of this, US\$38.6 million had been committed for repayment by the government in 2016-17, but only US\$5 million (13% of the committed amount) was actually disbursed. For years 2017-18, the government has committed US\$30.8 million against its payables to MSD.

Agreed Management Action

Notes:

- Agreed action for review of health facilities staff is included after Finding 4.3.
- No agreed action required for ACTs variance and e-LMIS data, due to referral to Investigations.

Agreed Management Action 1: The Secretariat will:

• Obtain from the Ministry of Health and approve a sub-segment of the **grant implementation arrangements map** detailing forecasting and quantification, ordering, procurement and supply chain management of health products and equipment. This map will specifically define the roles and accountabilities for the national disease programs within the Ministry of Health, President's Office for Regional Administration

and Local Government, Pharmaceutical Services Unit, Logistics Management Unit, Medical Stores Department and the Global Fund program management units within the respective ministries.

• Request the Ministry of Finance and Planning, Ministry of Health and the Tanzania National Coordinating Mechanism (TNCM) to critically review, prioritize and update the holistic supply chain review action plan and budget taking into account the recommendations of the review, and indicating the activities currently earmarked for funding from all sources.

Owner: Head of Grant Management

Due date: 30 September 2018

4.2. Governance, oversight and accountability need to be improved for better results

Global Fund grants in Tanzania are managed through complex implementation arrangements. These involve program management and coordination units across three government departments: the Ministry of Finance and Planning (the Principal Recipient), the Ministry of Health, and a Health Department established under the President's Office (Regional Authorities Local Governments). These actors are all responsible for the oversight, coordination and monitoring of Global Fund grants. In addition, the Tanzania National Coordination Mechanism (TNCM) is also responsible for grant governance and oversight.

Despite these multiple layers of governance and oversight, there are gaps in the implementation of the grants. For example:

• **Delays in execution and reporting-** Progress update reports in 2016-17 have been submitted by the Principal Recipients with an average delay of 21 days over the prescribed deadlines as per the Global Fund policy, with delays of up to 60 days in some cases. Similarly, the Local Fund Agent's review of these reports took on average 96 days, and up to 177 days in some cases. In one instance, a reprogramming request took over six months from the date of the request submission until the final decision, and the revised implementation letter was not issued even after this period. This contributed to a pattern of disbursement delays, in turn affecting grant activities and in-country expenditures, as highlighted below. Similarly, quarterly cash reporting has been regularly delayed.

Gaps and missing information in the initial reports/ requests, and weak first-level quality checks, were the main reasons for these delays. The oversight mechanisms were ineffective in self-detecting the gaps and ensuring accurate initial submissions.

Similar delays exist in implementing agreed actions to address the gaps identified through progress updates reviews. For example, as of June 2017, 21 out of 24 agreed management actions were overdue for the HIV grant. These include actions to improve performance on certain key coverage indicators, and reconciling material outstanding advances.

- Low in-country grant absorption —As identified in the 2015 audit, the absorption of the Global Fund grants in the country continued to be low in 2017, especially for the malaria and the Health Systems Strengthening grants. As of June 2017, with six months remaining before the end of the grants, cumulative reported expenditures against the budgeted amounts, excluding expenditures incurred directly through the Global Fund's Pooled Procurement Mechanism, were 35% for malaria/HSS, 46% for HIV and 70% for TB, respectively.
- The reasons for low in-country grant absorption included general delays in decision-making in various areas including reprogramming budget, grant closure plans, training plans, disbursements, or procurement delays. The governance and follow-up mechanisms were not effective in addressing these issues in a timely manner.
- **Sustainability in program financing-** The 2015 audit identified challenges to mobilize domestic resources for long term funding and sustainability of the three diseases. Limited progress has been made to mobilize resources domestically and the three diseases continue to receive approximately 63% of total funding from external donors.²⁷ Tanzania's AIDS Trust Fund has been operationalized since the last audit, but it has not yet made material contributions, generating only US\$500,000 as of November 2017. Challenges related to the government's cumulative unpaid commitments to MSD have been highlighted in Finding 1.

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²⁷ Based on Concept Notes for TB/HIV and Malaria 2015-17.

The inability of governance and oversight mechanisms in successfully treating these issues is due to the following:

• **Gaps in accountability-** Roles, responsibilities and accountability for various decisions or timely actions have not been clearly identified and effectively implemented in many cases. For example, the review and approval lines of the multiple program management and coordination units in the different ministries are not clear. These units and the national disease programs have not been systematically reporting to senior management in the ministries, or effectively following up on identified issues. The fragmentation and complexity in reporting structures have also hampered accountability.

The terms of reference for each program management or coordination unit were developed in isolation. Some overlaps and gaps exist in the roles and responsibilities of these units across the Ministry of Finance and the Ministry of Health. The units do not have key performance indicators and there have not been any evaluations of the staff.

Oversight entities such as the TNCM do not have sufficient leverage, through decision-making and input in the evaluation of the implementers' performance, to ensure effective implementation of actions for improvement.

- Lack of structured follow-up mechanisms- The program management and coordination units and the national disease programs do not share the status and progress on remedial actions agreed with the TNCM. Action points are not effectively implemented. For example, in the case of grant absorption, the Principal Recipient does not systematically monitor grant expenditures against budgets. The monitoring is done mostly on an ad-hoc basis by PMUs/ GFCUs. The Principal Recipient also does not report follow-up progress on low absorption, despite the request by TNCM.
- Delays in submitting information needed for oversight and monitoring- Reports are not submitted on time by the national disease programs and PMUs/ GFCUs to TNCM, affecting its decision making and oversight function. Reports are required to be submitted 14 days prior to meetings, to allow sufficient time to understand and contextualize reported results; however, in some cases reports were submitted less than 24 hours before the start of the meeting.

Agreed Management Action

No additional action needed.

A time-bound action plan was developed in response to an AMA from the OIG 2015 audit, to streamline and strengthen the country's implementation arrangements to support the effective implementation of funded programs. This included strengthening the capacity of the Principal Recipient to effectively execute its mandate, and oversight of the delegated authority to subrecipients and sub-sub recipients (especially the Ministry of Health and Prime Minister's Office Regional Administration and Local Governments).

The plan is currently being executed and tracked by the Secretariat for effective implementation.

4.3. Improvements needed in quality of services and access to care

The 2015 OIG audit noted that the national disease programs faced challenges impacting the quality and access of patients to treatment. These included treatment of malaria patients without confirmed diagnosis; gaps in enforcing treatment guidelines; tracing and retaining people on HIV treatment; and gaps in ACT co-payment arrangements for private sector regarding drugs availability and affordability.

Significant progress has been registered in addressing those challenges:

- Malaria treatment without confirmed diagnosis- The National Guidelines for Malaria Diagnosis and Treatment were rolled out in 2016. These guidelines require malaria treatment based on confirmed diagnosis only. This is in line with the WHO recommendations of universal parasitological diagnosis of suspected malaria cases. This has contributed to a reported decrease of malaria cases diagnosed and treated without testing from 36% in 2014 down to 7% in 2017.
- HIV treatment initiation and retention- Tanzania adopted the World Health Organization 2015 guidelines for HIV treatment²⁸, which recommends treatment initiation for all people diagnosed with HIV, irrespective of their CD4 count. The country continues to scale up its HIV testing and treatment. More than six million people had been tested for HIV by 2016 compared to 2.5 million in 2014. At the end of 2016, 846,527 persons had initiated antiretroviral treatment, compared to 703,589 in 2015. Thus, 63% of the estimated 1.4 million people living with HIV in Tanzania are currently accessing treatment, compared to 47% in 2015. Tanzania plans to reach 95% anti-retroviral coverage by 2020.

However, the following challenges still exist:

- **Low retention on treatment for HIV-** The relatively high ART patients' attrition rate of 25% identified in 2015 has improved. However, 18% of patients were still reported as "lost to follow-up" over a 12-month period in 2016.²⁹ The continuing low retention on treatment is due to several factors:
 - In the absence of unique patient identifier codes, the attrition might be over-estimated because some patients who transfer from one facility to another are incorrectly treated as lost to follow up.
 - The gaps in sufficient, qualified health workforce at facilities level lead to risks of weak quality of care, insufficient patient follow-up and counselling, or improper recording of treatment such that treated cases may be counted as lost. The latest Service Availability and Readiness Assessment for the health sector outlines the shortage of skilled health care workers. Health facilities have on average only 40% of the healthcare staff that they need,³⁰ making it challenging to provide adequate quality of health care services to patients and maintain patient data records. Staffing issues affect Global Fund grants as well; all the six health care facilities visited for the audit experienced severe staff shortages, affecting services to patients as well as record-keeping.
 - At regional level, supervisions are not always conducted in a timely manner. For example, for the third quarter of 2016 (July-September 2016), 55 out of 144 planned supervisions from regional level to health facilities were not executed.
 - The rural areas, where over 70% of the population lives, are underserved with only 31% of national health care staff,³¹ although measures such as the provision of accommodation for health care personnel in rural areas have improved these ratios a little.

²⁸ http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/

²⁹ National Aids Control Program

³⁰ Tanzania Service Availability and Readiness Assessment 2013

³¹ Tanzania Service Availability and Readiness Assessment 2013

Most of these issues will also hamper effective scale-up in HIV treatment for reaching the programmatic target of 95% treatment by 2020.

- Ownership of co-payment mechanism- A private sector co-payment mechanism, launched in Tanzania in 2010, involves paying subsidies to manufacturers of malaria drugs in order to ensure the availability and affordability of subsidized antimalarial medicines in private health facilities. The 2015 audit identified issues regarding the roles and responsibilities for implementing this component. Although the mechanism was for the private sector, it was managed under the public sector (by the Ministry of Finance with some functions delegated to the National Malaria Control Program). This management of a private sector issue by the public sector impacted the effectiveness of the mechanism and the quality of its oversight. This issue of management structure has not yet been addressed. A new public sector custodian for the mechanism, the Pharmacy Council, has been identified but ownership has not yet been transferred. This new implementation mechanism is planned to be effectively implemented in the 2018-2020 grant cycle.
- **Risks on access to HIV services for key populations** Approximately 10% of Tanzanians belong to groups identified as key populations.³² The HIV prevalence rate is high for three categories of key populations: 25% in men who have sex with men, 26% in female sex workers and 36% in people who inject drugs. Without a tailored HIV program outreach for these populations, achievement of the testing and 95% treatment target is unlikely.

Effective community-level interventions are key to the success of the key population outreach programs. In October 2016, following allegations of "homosexuality promotional activities" taking place in the country, a government directive was issued to temporarily suspend HIV and AIDS services to key populations at the community level. Some of the grant activities related to key population HIV prevention and treatment program had been suspended in the HIV/TB grant ending in December 2017. Policies, legal directives or political measures that discourage the key populations from accessing health services such as condoms, counselling and testing, pose potentially significant risks to the effective implementation of HIV programs. They may also, in some cases, potentially lead to violation of the minimum human rights standards for programs supported by the Global Fund which require non-discriminatory access to services for all

In 2017, the Government of Tanzania revised its "National Guidelines for HIV Interventions among Key and Vulnerable Populations". The goal was to promote increased access to health and social services for these groups, in order to significantly minimise HIV transmission and to reduce HIV-related morbidity, stigma, and discrimination. However, the guidelines also envisage discontinuing drop-in centres supported by PEPFAR that were used by key populations to access services. HIV services for all patients, including key populations, are to be provided through government health facilities. In OIG interviews with representatives from key populations (men who have sex with men, people who inject drugs, and female sex workers), significant concerns were expressed about potential program disruptions and possible adverse impact on access if services are restricted to government health facilities. These concerns arise from multiple factors including:

- Some key population groups are criminalized by law in Tanzania. While patients are not required to disclose their behaviour or mode of transmission when accessing governmentled services, the criminalization can affect their confidence in seeking services from government employees or in government-run facilities.
- Reservations exist about the government's commitment to some interventions, sometimes
 due to political issues or ambiguity between access to services and promotion of disallowed

 $^{^{32}}$ https://www.pepfar.gov/documents/organization/272606.pdf . The 10% or 5,017,156 population comprises of 49,700 MSM (men who have sex with men and transgender women), 155,450 FSW (Sex Workers), 30,000 PWID (Person who inject drugs) and 4,782,006 AGYW (vulnerable adolescent girls and young women).

activities in Tanzania, as the concept of promotion of preventive services is not clearly defined under the existing policies. Furthermore, there are risks of stigmatization by government health workers. While public health facilities are mandated to provide HIV testing and antiretroviral treatment support to all clients without discrimination, health workers are yet to be adequately trained and sensitized on these issues and to the rights of key populations.

The OIG's discussions with government HIV program representatives indicated awareness of those risks. Various efforts have been made to address them, for example, by introducing methadone substitution program for drug users. However, risks remain high that barriers to key population access, particularly for men having sex with men, may lead to key population program disruptions. There is a need, under the current environment, for particular focus on execution of planned activities for prevention, stigma and discrimination reduction, training of health care providers, and improvement of legal literacy ("know your rights") of key populations.

Agreed Management Action

There is an outstanding AMA from the OIG 2015 for addressing gaps in ownership of co-payment mechanism (summarized below):

The Secretariat will ensure that the Principal Recipient identifies a suitable entity to manage the Co-Payment Mechanism.

Agreed Management Action 2:

The Secretariat will:

- Receive the updated national structure for management and coordination of Global Fund grants, including the human resources plan and budget;
- Align the Global Fund resilient health systems grant component funding with this plan, including targeting vacancies in critical cadres, and planning absorption into government public service system over the program term.

Owner: Head of Grant Management Due date: 30 September 2018

Agreed Management Action 3:

In collaboration with partners, the Secretariat will conduct an evaluation of the implementation of the national Key and Vulnerable Population Guidelines, the findings and recommendations of which will guide any required reprogramming of grant funds.

Owner: Head of Grant Management

Due date: 31 December 2018

5. Table of Agreed Actions

Agreed Management Action	Target date	Owner
 Obtain from the Ministry of Health and approve a subsegment of the grant implementation arrangements map detailing forecasting and quantification, ordering, procurement and supply chain management of health products and equipment. This map will specifically define the roles and accountabilities for the national disease programs within the Ministry of Health, President's Office for Regional Administration and Local Government, Pharmaceutical Services Unit, Logistics Management Unit, Medical Stores Department and the Global Fund program management units within the respective ministries. Request the Ministry of Finance and Planning, Ministry of Health and the Tanzania National Coordinating Mechanism (TNCM) to critically review, prioritize and update the holistic supply chain review action plan and budget taking into account the recommendations of the review, and indicating the activities currently earmarked for funding from all sources. 	30 September 2018	Head of Grant Management
 2. The Secretariat will: Receive the updated national structure for management and coordination of Global Fund grants, including the human resources plan and budget; Align the Global Fund resilient health systems grant component funding with this plan, including targeting vacancies in critical cadres, and planning absorption into government public service system over the program term. 	30 September 2018	Head of Grant Management
3. In collaboration with partners, the Secretariat will conduct an evaluation of the implementation of the national Key and Vulnerable Population Guidelines, the findings and recommendations of which will guide any required reprogramming of grant funds.	31 December 2018	Head of Grant Management

Annex A: General Audit Rating Classification

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.

Annex B: Methodology

The OIG audits in accordance with the global Institute of Internal Auditors' (IIA) definition of internal auditing, international standards for the professional practice of internal auditing (Standards) 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 help our auditors to provide high quality professional work, and to operate efficiently and effectively. They also help safeguard the independence of the OIG's auditors and the integrity of their work. The OIG's Audit Manual contains detailed instructions for carrying out its audits, in line with the appropriate standards and expected quality.

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 takes place across the Global Fund as well as of grant recipients, and is used to provide specific assessments of the different areas of the organization's' activities. 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.