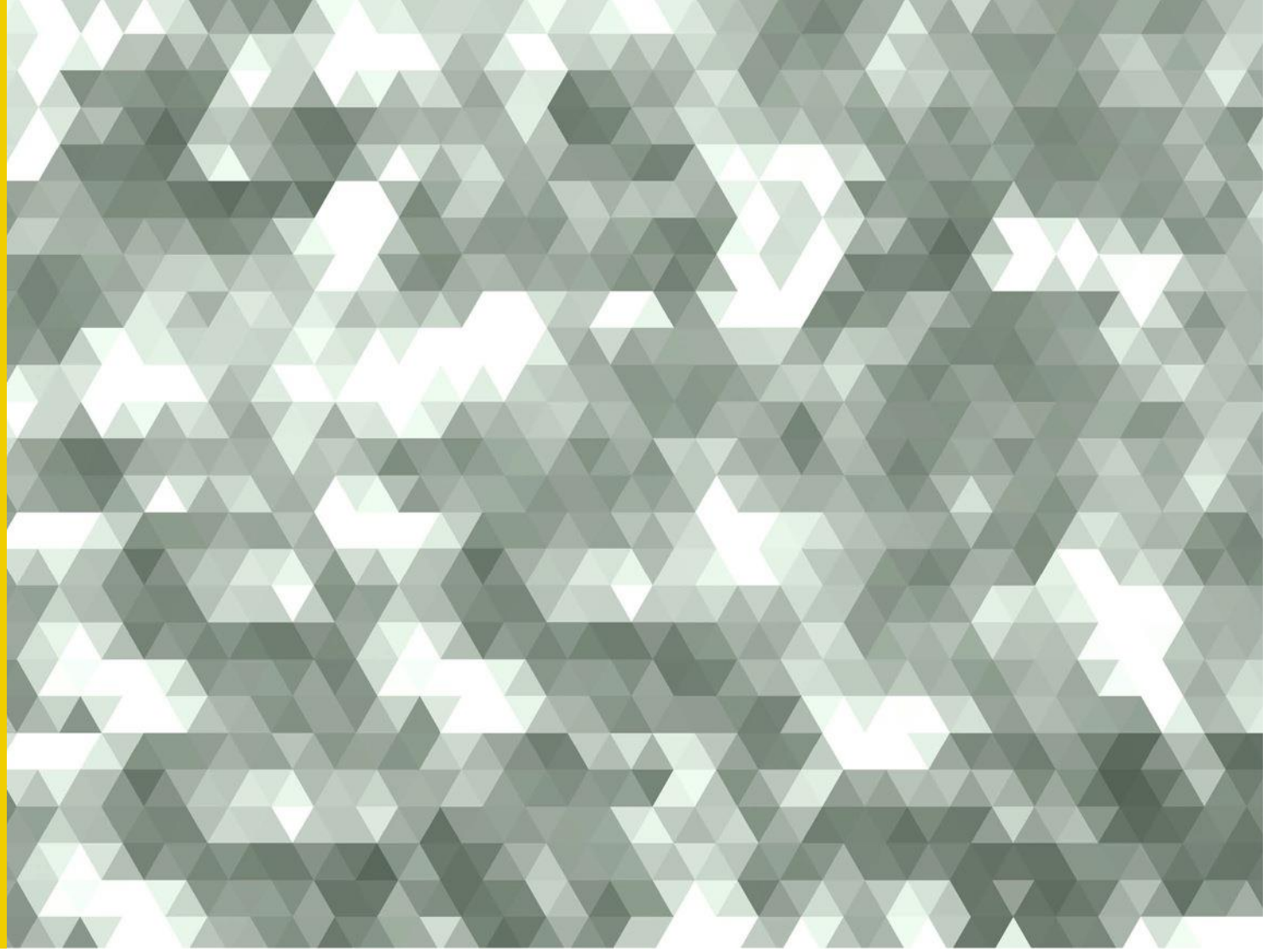

Audit Report

Global Fund Grants to Ukraine

GF-OIG-18-003
24 January 2018
Geneva, Switzerland

The Global Fund
Office of the Inspector General

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Audit Report

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Table of Contents

1. Executive Summary

1.1. Opinion

Ukraine has made progress in accelerating the end of HIV and tuberculosis (TB) as epidemics. The number of people who know their HIV status increased by approximately 60,000 between 2014 and 2017; and the number of people on HIV treatment grew tenfold between 2003 and 2014. The numbers should increase further thanks to a reduction in the price of the main antiretroviral medicines as a result of more transparent and competitive procurements. The country has also achieved a high retention rate of 85% of people with HIV started on treatment after the first year. Furthermore, despite having one of highest multidrug-resistant tuberculosis (MDR-TB) burdens in the world, good progress has been made towards reducing overall TB incidence from 114 per 100,000 people in 2000 to 91 per 100,000 in 2015.[1] The government has also committed to increasing its financial support for HIV and TB programs by 25% in the next grant cycle, despite a difficult economic situation.

However, many challenges remain which limit the achievement of grant objectives. Detection yields have not been correctly measured. There is no proper mechanism for following up people diagnosed with HIV who are then lost before they can be put on treatment. Approximately 9,000 confirmed cases of people living with HIV have not started treatment due to a shortage of drugs, among other limitations. For MDR-TB, treatment success rates continue to be low. The Global Fund has supported a new approach which involves home visits for MDR-TB patients rather than clinic trips, which has had some success. However, the approach has not so far been extended to the majority of patients. Nor can its effectiveness be proved as there is no comparable data. Furthermore, material discrepancies exist in program data. Hence, program processes and controls **need significant improvement** to deliver quality services to beneficiaries and ensure data accuracy.

The OIG found administrative and efficiency challenges at the grant sub-recipient level. A comprehensive transition plan is needed to ensure that the Public Health Center (PHC), a government entity under the Ministry of Health, is able to effectively implement Global Fund-supported activities starting in 2018. The plan will need to take into account the impact of transition on access and the range of services available for key populations. Therefore, the OIG has rated the implementation and funding arrangements as well as the sustainability of programs as **partially effective**.

Antiretroviral (ARV) drug costs have gone down significantly thanks to civil society advocacy and negotiations with manufacturers. Some manufacturers have agreed not to enforce their patents in Ukraine and allow the import of generic products; and some have reduced their prices. However, some key drugs are still more expensive compared to the international generic reference prices, (although their prices are aligned with regional prices in other Eastern European countries). Government procurement delays, compounded by a funding crisis in 2014/2015, have resulted in consistent "borrowing" of drugs financed by the Global Fund or grant savings being used to procure drugs for government-supported patients. As Global Fund investments decrease over the next grant cycle, the risk of drug stock-outs in the HIV program increases. In addition, gaps in coordination have led to expiries of MDR-TB drugs as well as large quantities of drugs with a short shelf life. A concept to reform the procurement of health products has recently been approved by parliament. This should help develop a capacity-building plan for a national procurement agency and finalize future supply chain arrangements. Both are needed by mid-2018 as part of the envisaged transition to PHC under the next grant cycle. Overall, the procurement and supply chain systems are rated as **partially effective**.

[1] WHO Tuberculosis country profile

1.2. Key Achievements and Good Practices

Treatment effectiveness: AIDS-related deaths almost halved from 14,000 in 2010 to 7,900 in 2015.[2] Furthermore, 78% of people on ARV treatment had a suppressed viral load, making them less likely to transmit the HIV virus.

Scaling up HIV programs: In 2017, the government approved the UNAIDS 90-90-90 targets. A "test and treat" approach, which puts people who test positive for HIV on ARVs regardless of CD4 count, will increase the number of people on treatment if medication is available.

Major price reductions: Chiefly due to patent licensing terms, historically, unit costs to the program for some ARVs were up to 276% higher than the international generic reference prices. Concerted advocacy efforts by civil society organizations, and subsequent negotiations with manufacturers, have led to price reductions for the majority of ARVs, largely aligning them with international generic reference prices.

Increased commitment from the government: Despite conflicts in the east and an economic recession since 2014, the government increased the HIV budget in 2017 for the procurement of medicines and other key interventions by 171%; and the TB budget by 133% compared to 2016. The government also approved a four-year HIV strategy,[3] taking a patient-oriented approach, including improved access to prevention programs for key populations.

1.3. Key Issues and Risks

Treatment cascade challenges: While significant scale-up has been achieved in the last decade with the support of the Global Fund, the outreach program has difficulties in achieving better detection and treatment results for key populations. In particular, there is a low yield of HIV case findings; a significant loss of people between directly assisted self-testing and treatment enrolment; and a lack of appropriate follow-up mechanisms. A combination of limited drug availability and an overloaded health workforce hampers the ability to put people diagnosed with HIV on treatment. These issues will become even more critical when PHC takes over the Global Fund programs in 2018-2020.

Difficulties in improving MDR-TB treatment: Ukraine is one of the countries with the highest MDR-TB burdens in the world, ranking fifth in infection rates per capita. Global Fund grants finance 50% of MDR-TB treatment courses. The overall treatment success rate for the 2013 cohort was at 39% versus a target of 65%, increasing to 46% versus a target of 75% in 2014 cohort. However, improvements are needed in MDR-TB case management and the development of sustainable patient-centered TB services. The Global Fund has also supported an ambulatory treatment program, which includes food packages and directly observed treatment provision to encourage people to complete their treatment; however, the actual effectiveness of this approach is difficult to measure. This is because the results only take into account patients selected after completing a hospitalization phase of four to eight months.

Implementation and governance arrangements require improvements: The new funding cycle (starting in January 2018) aims to gradually transition activities and procurements from the current non-governmental organization Principal Recipients to PHC (20% in 2018, 50% in 2019 and 80% in 2020). In the absence of a detailed transition plan, capacity-building gaps may affect the ability of PHC to successfully take on its new responsibilities. The plan should evaluate the impact of the transition on activities targeting key populations and issues related to sub-recipient management.

[2] UNAIDS (2016) Prevention Gap Report.
3 Ukraine National HIV/AIDS Programme 2014-2018

Further improvements in procurements needed: Despite the price reductions mentioned above, Global Fund programs still purchase some ARV medicines at significantly higher costs than the international generic reference price. For example, Lopinavir/ritonavir 200/50 mg, a WHO-recommended second line medicine used in antiretroviral treatment, is 200% higher than the WHO-recommended first line treatment product. Currently this drug alone constitutes 46% of the total US$28 million used to procure ARVs in Ukraine. An additional concern is that this drug is used as a first-line treatment although this is not recommended by WHO.

Inherent challenges in government procurement and supply chain systems: Government procurements have been regularly delayed, increasing stock-out risks. This has led to continuous borrowing from Global Fund inventories, or using savings under Global Fund grants to bridge the government financing gaps and to procure drugs for government-supported patients. By 2020, the government will double the amount of ARV drugs it is currently buying. It will also take over most of the MDR-TB drug procurement (from the current 50%). As Global Fund investments in Ukraine decrease, there will be limited room for the government to address shortages using Global Fund grants. This is likely to increase the risk of stock-outs and treatment disruption.

The Ministry of Health procures health products for programs, including ARVs and TB medicines. The regions procure, store and manage all other health products. When centrally-procured health products arrive, they transit through a central warehouse before being distributed in full to the regions. As the central warehouse's capacity and conditions do not meet international standards, health products procured with grant funds are managed through private warehouses. This is a concern when the grants transition in 2018. A recently approved health sector reform should trigger the establishment of a national procurement agency with technical support from UNDP, WHO, and UNICEF. However, the Ministry of Health, together with partners (e.g. USAID-funded SAFEmed), must still decide how health products centrally procured by the agency will be stored, distributed, and managed throughout Ukraine.

1.4. Rating

- **Objective 1: adequacy of the implementation and funding arrangements in supporting the achievement of grant objectives and sustainability of programs.**

OIG rating: Partially effective. The government has committed to a 25% increase in its budget for HIV and TB in the next grant cycle. Implementation arrangements at sub-recipient level have been simplified but more administrative and efficiency improvements are needed. The new funding cycle accompanies the gradual transition of procurement, supply chain and other functions to PHC, enhancing long-term sustainability. However, although this transition starts in early 2018, the first steps to build capacity for the government procurement agency, and for finalizing future supply chain arrangements, have been initiated after the recent approval of the procurement mechanism reform.

- **Objective 2: effectiveness of the program processes and controls for delivering quality services to beneficiaries, including the availability of accurate and timely data to aid decision-making.**

OIG rating: Needs significant improvement. The combination of limited drug availability and an overloaded health workforce has hampered treatment for people diagnosed with HIV; these issues could be exacerbated when the government takes over a significant proportion of the Global Fund programs in 2018- 2020. For HIV, in the sampled regions, a 25% variance was detected between the reported number of people on treatment and the number of patients in the adherence records. Discrepancies of 5% - 15% were also identified between the TB reports, registers and patient cards. The two non-governmental Principal Recipients currently operate segregated patient data systems, with patients having two separate unified codes, although work is ongoing to harmonize the systems.

- **Objective 3: efficiency and effectiveness of procurement and supply chain processes and systems to ensure the timely availability of quality medicines, health and non-health products.**

OIG rating: Partially effective. ARV drugs costs have been significantly reduced through advocacy and negotiations, although some key drugs are still more expensive compared to the global average. Supply chain arrangements have included private sector warehousing arrangements at central level, avoiding any major supply disruptions. However, post-transition arrangements need to be finalized.

1.5. Summary of Agreed Management Actions

The Secretariat will put in place a number of corrective actions in collaboration with the Principal Recipients, the Government of Ukraine and other partners including an optimization plan to increase treatment impact; and better coordination between government and the donors to avoid any future overstocking or stock outs. The Secretariat and partners will also put in place a detailed action plan for transitioning from donor funding to government funding of TB and HIV programs to ensure satisfactory quality and access of services by key populations after transition.

2. Background and Context

2.1. Overall Context

Ukraine is classified as a lower middle-income country with a population of approximately 45 million (World Bank 2016). It ranked 84th out of 188 countries in the United Nations Development Programme's 2016 Human Development Index. The country has been politically unstable since its independence in 1991 with a turnover of 16 Prime Ministers, four acting Prime Ministers and twenty-two health ministers. This political instability has contributed to delays in improvements needed in public health approaches. Major health reforms, recently endorsed by the Ukrainian parliament, should lead to more focus and financing for HIV and TB and a more decentralized public health approach. These reforms do not yet have implementation timelines.

Since 2014, the Ukrainian economy has shrunk on average 8-10% annually due to the loss of its largest trading partner, Russia, following the annexation of Crimea and the conflict in the eastern regions of Donetsk and Luhansk. The conflict has resulted in more than one million internally displaced people and emergency assistance, including for HIV and TB care. Between 2014 and 2016, the national currency, the hryvnia, lost about 200% of its value against the U.S. dollar. This difficult economic situation has led to major fiscal challenges for the government.

The Ukrainian health system has largely retained its legacy structure. A total of 80% of overall government health funding is allocated to hospital-based care compared to 15% for outpatient services and 5% for primary care and prevention.[4] Budget allocations and staff deployments are based on inputs and fixed schedules rather than on performance or quality of care standards.

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 classified into two crosscutting 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.

Ukraine is:

	Focused: (Smaller portfolios, lower disease burden, lower mission risk)
x	**Core: (Larger portfolios, higher disease burden, higher risk)**
	High Impact: (Very large portfolio, mission critical disease burden)

x	**Challenging Operating Environment**
	Additional Safeguard Policy

[4] PEPFAR-Ukraine Country Operational Plan FY 2014

2.3. Global Fund Grants in Ukraine

The Global Fund has signed over US$555 million and disbursed overUS$547 million in Ukraine since 2003.[5] There are currently four active grants in the country:

Principal Recipient	Grant Number	Component	Grant period	Grant Signed Amount (US$)
Alliance for Public Health ('Alliance')	UKR-C-AUA	TB/HIV	January 2015 - December 2017	66,268,901
All-Ukrainian Network of People Living with HIV/AIDS ('Network')	UKR-C-AUN	TB/HIV	January 2015 - December 2017	63,279,884
Public Health Center of the Ministry of Health of Ukraine ('PHC')	UKR-C-UCDC	TB/HIV	January 2015 - December 2017	3,373,393
UNICEF (Emergency funds)	UKR-H-UNICEF	HIV/AIDS	July 2015 - June 2018	7,988,841
Total				**140,911,019**

The active grants are managed by two non-governmental organizations: the Alliance for Public Health (Alliance) and the All-Ukrainian Network of People Living with HIV/AIDS (Network); one government agency, the PHC of the Ministry of Health of Ukraine, previously called the Ukrainian Center for Socially Dangerous Disease Control; and one UN agency, the United Nations International Children's Education Fund (UNICEF). The two civil society Principal Recipients currently work with 108 sub-recipients.[6] They provide HIV/ TB services across the country, including in the non-government controlled areas of Donetsk and Luhansk. These non-government controlled areas receive medication from UNICEF through an emergency grant. Current PHC grant focuses on coordination and health systems strengthening.

For the 2018-2020 grant cycle, a concept note has been submitted and grant-making is scheduled for November- December 2017. Total disease allocation has been reduced to US$119 million. The majority of grant activities will transition to PHC gradually.

Approximately 59% of current Global Fund grants finance the procurement of medicines and health products. The procurements of TB and HIV medicines and health products financed by the grants are managed by Alliance and Network respectively. The government continues to outsource its procurements to international agencies. The next grant cycle envisages a gradual transition of grant procurements to the government (50% in 2019 and 80% in 2020) through the national procurement agency planned to be established by 2019.

[5] The Global Fund- Ukraine country profile
[6] This excludes five sub-recipients in Crimea.

2.4. The Two Diseases in Ukraine

HIV and AIDS: Ukraine has the second biggest HIV epidemic among the Eastern European and Central Asian countries and accounts for 25% of AIDS-related deaths in the those countries.[7] Ukraine is also one of the 30 fast track countries that account for 89% of all new HIV infections worldwide.[8]

Regional concentration: 50% of officially registered HIV positive people live in three regions: Donetsk, Dnepropetrovsk and Odessa regions. The highest HIV prevalence indicators are registered in Odessa (861.8 per 100,000 people), Dnepropetrovsk (827.0 per 100,000 people), Donetsk (670.5 per 100,000 people) and Mykolaiv (755.0 per 100,000 people) regions.[9]

Conflict zones: 24% of all registered new HIV cases (33,235), 21% of people receiving antiretroviral (13,435) and the highest number of HIV positive people who inject drugs (45,000) live, or have lived, in the Donetsk and Luhansk regions.[10]

Ukraine is considered to have a concentrated epidemic within key populations.

Cumulative numbers between 1987 and 2017 of HIV cases:
306,295[11]

AIDS cases:
97,584[11]

AIDS-related deaths:
43,206[12]

As of July 2017 there are **136,965 people[13] officially registered** as living with HIV under medical supervision of the Health Care Facilities

82,860 people are on antiretroviral therapy as of July 2017[14]

Tuberculosis: TB is an epidemic in Ukraine. MDR and XDR-TB are widespread, there is relatively high mortality from untreated or inappropriately treated TB, and there is increasing TB/HIV co-infection.

Ukraine is No 5 for MDR-TB rate per capita among the top 10 high-MDR-TB burden countries in the world.[15]

Ukraine has a high TB/HIV burden and is part of the 41 high TB/HIV burden countries; TB is also the main cause of death among 65% of the total number of people living with HIV.[16]

TB cases notified:
35,304[17]

MDR/RR-TB incidence among notified pulmonary TB cases:
12,000[18]

TB incidence:
91 per 100,000[19]

MDR/RR-TB incidence:
49 per 100,000[20]

[7] Public Health Centre 'Ukraine Country Progress Report 2015'
[8] UNAIDS fast truck report 2014
[9] UNGASS-country progress report 2015
[10] http://www.unaids.org/sites/default/files/country/documents/UKR_narrative_report_2015.pdf .
[11] Public Health Centre routine reporting https://phc.org.ua/uploads/documents/83da57/8597cb94ebb5c0c006c328d159f86d7d.pdf
[12] Public Health Centre routine reporting https://phc.org.ua/uploads/documents/83da57/8597cb94ebb5c0c006c328d159f86d7d.pdf
[13] Public Health Centre routine reporting July 2017
[14] Public Health Centre Ukraine https://phc.org.ua/uploads/documents/85ec49/959a48b562073497787 11e4047b4d342.pdf
[15] Public Health Centre routine reporting https://phc.org.ua/uploads/documents/83da57/8597cb94ebb5c0c006c328d159f86d7d.
[16] http://www.euro.who.int/__data/assets/pdf_file/0004/194071/Evaluation-report-on-HIV-AIDS-treatment-and-care.pdf
[17] WHO- Ukraine Tuberculosis profile
[18] WHO- Ukraine Tuberculosis profile
[19] WHO- Ukraine Tuberculosis profile
[20] WHO- Ukraine Tuberculosis profile

3. The Audit at a Glance

3.1. Objectives

The audit sought to provide reasonable assurance on the following aspects of the Global Fund grants to Ukraine:

- the adequacy of implementation and funding arrangements in supporting the achievement of grant objectives and sustainability of programs;
- the effectiveness of program processes and controls for delivering quality services to beneficiaries, including the availability of accurate and timely data to aid decision-making; and
- the efficiency and effectiveness of procurement and supply chain processes and systems to ensure the timely availability of quality medicines, health and non-health products.

3.2. Scope

The audit took place in accordance with the methodology described in Annex B and covered the period from January 2015 to June 2017. The audit covered grants implemented by three of the four Principal Recipients: Alliance, Network, PHC and their sub-recipients.

The OIG visited six regions (oblasts), including twenty health facilities, three warehouses and 22 sub-recipients. This audit did not cover the prevention activities as well as the emergency fund grant to UNICEF, which is designed to ensure the continuity of essential HIV-related commodities and services to the Donetsk and Luhansk regions. This scope limitation was due to the lack of security clearance to visit the affected regions.

3.3. Progress on Previously Identified Issues

Previous relevant OIG audit work

Audit of the Global Fund grants to Ukraine (August 2012)

The OIG audited grants in Ukraine in November 2010 and released the report in August 2012. The risks identified from the previous audit have been materially mitigated, including:

- Programmatic Challenges: The audit noted delays in releasing goods from customs and tax exemption for the goods and services procured using Global Fund resources. The issues were resolved by obtaining tax and customs exemption from the Ministry of Health that also expedited the release of goods from customs.
- Institutional capacity: The audit identified a need for an internal auditor at the Principal Recipient level and better compliance with Global Fund grant terms and conditions. As a result, both Principal Recipients recruited internal auditors and lawyers to ensure that their operations comply with the Global Fund terms and conditions and Ukrainian law.
- Financial management: The audit recommended aligning staff salaries at the Principal Recipient level with market levels. Both Principal Recipients contracted an independent consultant to conduct a salary survey, which was subsequently approved and adopted by the Global Fund Secretariat as the basis for salaries.
- Procurement and supply management: The audit recommended that all procurements should go through a designated department with rotating staff. Both Principal Recipients comply.

The above issues were corrected by the recipients by the time the final report was released in 2012 as acknowledged in the audit report itself.[21] The OIG considered all the issues above at the planning and fieldwork stages of the 2017 audit. No major reoccurrence of previously identified issues was noted.

[21] Please refer to Annex 2 in the report

4. Findings

4.1. Challenges in achieving current HIV targets and proposed scale-up

Ukraine has accelerated the enrollment of people on treatment in recent years. The number of people living with HIV put on treatment increased from 64,360 to 82,860 between 2015 and 2017.[22] The country shows a strong commitment in its response to HIV as demonstrated by its will to scale up the number of people on ARV from 82,860 to 194,400 over the next grant cycle in 2018-2020. This is in line with UNAIDS Fast-Track targets.[23] To achieve these goals, the government has committed to an increase of US$4.8 million in HIV and TB funding annually over that cycle.[24]

However, the following programmatic and financial bottlenecks have contributed to historically moderate detection and treatment outcomes:

Detection Challenges

PHC reported 136,965[25] people living with HIV who are under medical supervision.[26] This represents 55% of the total number of people estimated to have HIV in the country. To reach the new country target, the HIV program will need to identify an additional 79,000 cases by 2020.[27]

Whilst the HIV epidemic in Ukraine is concentrated in key populations, current outreach programs yield low test results from them. The latest estimated prevalence figures are 7% for sex workers, 8.5% for men who have sex with men and 21.9% for people who inject drugs.[28] For the three regions reviewed in the audit, outreach programs focusing on key populations had identified approximately 2-3% positive cases from the total number of people tested for HIV in the period under review.[29]

Those numbers included repeated cases, i.e. people who have been already identified as HIV-positive and registered in a health center. The average number of these repeat cases in the visited regions was 17%. Thus, if this rate of duplication is extrapolated, the real percentage of newly detected cases through outreach programs is likely be 1.7-2.5%. This low rate may be the result of weaknesses in the design of the outreach programs. For example, the current programs do not generally include tracing people who may have come into contact with newly-diagnosed cases.

Due to legal restrictions on who can perform HIV testing, many cases are detected through directly assisted self-testing, with assistance from the outreach workers who provide the kits. However, approximately 50% of these cases detected through self-testing kits are lost before reaching the treatment stage. The sub-recipients do not currently have a mechanism to find those who have been lost to follow up.

Treatment Challenges

The country reports approximately 83,000 HIV-positive people on ARV treatment and plans to enroll another 111,000 before 2020.[30] However, there are challenges associated with putting the currently identified people on treatment and reaching the new targets:

[22] Public Health Centre form 56- 2015- 2017.
[23] Ukraine funding request 2017-2020.
[24] Ukraine funding request 2017-2020.
[25] https://phc.org.ua/uploads/documents/c21991/1489e96901f2c3c26f4210ba6a9698cc.pdf
[26] Data reported by Public Health Centre (PHC) for July 2017.
[27] This is based on the denominator of 240,000 persons living with HIV according to UNAIDS 2016 estimates, with at least 90% of the population being detected as per 90-90-90 approach.
[28] http://www.unaids.org/en/regionscountries/countries/ukraine
[29] Routine reports from the NGOs to Alliance 2016.
[30] According to the 90-90-90 plan with estimated number of cases 240,000

- **Resource constraints affecting the initiation of treatment:** PHC reported more than 9,000 people currently eligible for treatment but who do not have access to medicines.[31] The number eligible for treatment should increase by approximately 54,000 by January 2018[32] after adopting the new UNAIDS targets. The main obstacle to getting those people on treatment is the limited budget allocated for the procurement of medicines. For example, in 2017, the Government of Ukraine, the Global Fund and the US President's Emergency Plan for AIDS Relief together funded drugs for approximately 85,000 people in aggregate.

  The depreciation of the hryvna has resulted in grant budget foreign exchange savings of approximately US$2.9 million over the period 2015-2017. The Global Fund has not approved a request by Alliance to use the savings to buy additional MDR-TB drugs. The Secretariat has not yet established a systematic process for evaluating potential reprogramming using foreign exchange savings, especially for life-saving treatment.

The country and the Secretariat are currently finalizing grant conditions and performance framework targets for the next grant cycle. These aim to address the bottlenecks and progressively scale up the number of people on ARV to 195,625 by 2020. A 2017-2021 national TB strategy is also being finalized, which will capture the actions needed to deliver the improved results.

Agreed Management Action

Based on the expectation that current drafts of grant conditions and performance frameworks for 2018-2020 will address the risks noted above, no further agreed management action is needed.

[31] https://phc.org.ua/uploads/documents/85ec49/959a48b562073497787l1e4047b4d342.pdf
[32] 137,000 PLWHIV registered – 83,000 on treatment

4.2. Improvements needed in MDR-TB treatment approach and coordination with HIV program

To improve low MDR-TB treatment success rates and reduce new infections, the country needs to implement better infection control and to increase collaboration between HIV/TB interventions.

The national TB program conducted the first country-wide survey from November 2013 to May 2014 to identify MDR-TB levels and risk factors. MDR-TB was detected in 24% of new patients and 58% of previously treated patients. This is higher than the international averages of 4% and 21%, respectively, for those groups.[33]

The following issues are the main contributing factors of the high disease burden and new infections:

Cross infection across TB patients: Ukraine continues to largely rely on an in-patient treatment approach for TB. Patients are hospitalized for treatment, potentially increasing the risk of cross-infection. In four out of the eight facilities visited, the OIG found poor ventilation; a high density of patients (up to eight in one ward); high risks of cross-infections between smear positive and smear negative MDR-TB patients; and an insufficient number of masks and U.V. lamps.

Proposed revisions in health reform aim to change the financing model of regional hospitals from one that incentivizes the number of beds in TB hospitals to one that considers the number of patients treated. If implemented effectively, this should reduce the incentives for physicians and regions to seek more patients in hospital in order to obtain higher budget allocations. This change in treatment approach is part of an overall health reform agenda that was recently endorsed by the parliament.

Low MDR-TB treatment success: Global Fund grants purchase 50% of the MDR-TB treatment courses. The overall treatment success rate is 39% versus a target of 65% for the 2013 cohort. This low success rate is due, in part, to MDR-TB case management issues; a lack of sustainable patient-centered TB services based on outpatient case management; and insufficient patient support.

To improve results, the current grant has supported an ambulatory treatment program with patient motivational packages and directly observed treatment to increase the success rate. This program has so far covered 7,700 patients out of its overall coverage target of 9,300.[34] The program intervention starts for the selected patients after a hospitalization phase of four to eight months. The treatment success rate started improving with the 2014 cohorts and reached 46% in October 2017. However, in the absence of comparable data for the patients who were not part of the program, its actual effectiveness cannot be measured.

There is a need for improvements in TB/HIV collaboration: There has been a constant growth of co-infected patients. Indeed, Ukraine is one of the 41 high TB/HIV co-infection burden countries. As a result, TB remains one of the leading causes of death of people with HIV.

Collaboration between the HIV and TB vertical programs has improved with TB patients tested for HIV, and vice versa. However, many planned activities to support TB/HIV interventions are still facing challenges. For instance, for all the facilities visited in the audit, there was no data on the number of HIV-positive people who receive TB preventive therapy. The indicator tracking TB/HIV[35] collaboration (preventive therapy for people living with HIV) records a rate of 49.7% compared to a target of 82%.

There are also difficulties with the implementation of preventive therapy for TB patients living with HIV;[36] limited implementation of minimal standards for TB infection control at sites visited by HIV

[33] http://www.who.int/tb/challenges/mdr/mdr_tb_factsheet.pdf
[34] The targeted number of MDR-TB patients to begin treatment is approximately 12,300 people.
[35] 1.Percentage of HIV-positive new and relapse TB patients on ART during TB treatment and TB/HIV and 2.Percentage of people living with HIV newly enrolled in HIV care started on TB preventive therapy
[36] co-trimoxazole

positive people, including HIV centers; and outreach worker TB symptoms testing is still suboptimal with no sputum collection and testing by Rapid Diagnostic Tests (GeneXpert) at HIV sites.

As mentioned before, the country and the Secretariat are aware of these challenges, and are currently finalizing grant conditions and performance framework targets for the next grant cycle.

Agreed Management Action

Based on the expectation that current drafts of grant conditions and performance frameworks for 2018-2020 will address the risks noted above, no further agreed management action is needed.

4.3. Procurement inefficiencies and gaps in supply chain processes

As mentioned above, Ukraine has managed to reduce the cost of most ARV medication. However, some key drugs are still more expensive compared to the international generic reference price. This is because of Ukraine's market size and purchasing power; inefficiencies in procurement practices; intellectual property rights; and trade issues. Despite some simplifications, there are still multiple HIV treatment regimens procured using Global Fund grants, contributing to procurement and administrative inefficiencies. Government procurement delays have resulted in consistent borrowing from the Global Fund drug stocks, with higher stock-out risks as Global Fund reduces drugs investments in the next grant cycle. Gaps in coordination led to expiries and large quantities of MDR-TB drugs with a short shelf life. The government has not yet developed plans to build the capacity of a procurement agency and future supply chain arrangements. Both of these are needed by mid-2018 for the transition to PHC under the next grant cycle.

Pricing policies by manufacturers and/or patent-right holders in the Ukrainian market has meant that, historically, unit costs for some ARVs were up to 276% higher than the international generic reference prices. This is consistent with regional prices in other Eastern European countries, as reported in the Price & Quality Reporting database.[37]

Concerted efforts and negotiations by civil society organizations starting in 2014 have resulted in the willingness of manufacturers to include Ukraine under voluntary licensing agreements, or to waive their patent rights in Ukraine. This has resulted in a broader set of health products being available, as well as price reductions for the majority of ARVs. This included the main HIV regimen that covers 40% of Global Fund-supported patients recently in 2017.[38]

In a separate initiative, the government of Ukraine has also outsourced all its procurements to international partners.[39] This has enhanced competitiveness and transparency, as well as reduced prices. This change has also brought prices and costs down in line with international averages. UNDP estimated and reported procurement cost reductions of US$16 million for 2015-16.[40] However, outsourcing is an interim arrangement until a national procurement agency is set up that will take over procurements by mid-2018.

Despite the above successes, the following gaps and challenges will need to be addressed to improve procurement efficiencies:

Maximizing the use of Global Fund resources: The country is currently using Lopinavir/ritonavir 200/50 mg as a first-line medicine although this is not recommended by WHO. Furthermore, it costs approximately 200% more than for the WHO-recommended first line treatment product. Currently this drug alone constitutes 46% of the total of US$28 million used for the procurement of ARVs under the existing grant cycle in Ukraine.

While the government purchases of these second-line drugs used for first-line treatment decreased by 6% between 2015 and 2017, their procurement using Global Fund grants has increased by 34% during the same period.

Cost savings and improved program sustainability would result from optimizing regimens to be more cost-effective and increase the number of people on ART.

Procurement delays and weak supply coordination for government procurements need to be resolved: Government funding and procurement processes have historically had consistent delays. The government has an annual budgeting and fund allocation process which is

[37] Darunavir was higher by 286% per pack than international average (USD $604.88 vs $156.84); Efavirenz+Emtricitabine+Tenofovir by 231% ($30.00 vs $9.06); Lopinavir+Ritonavir tablets by 161% ($60.80 vs $23.28); Abacavir+Lamivudine by 111% ($28.99 vs $13.71); Abacavir by 106% ($23.86 vs $11.58); Lopinavir+Ritonavir oral liquid by 86% ($60.80 vs $32.70); Raltegravir by 38% ($350 vs $253.56); NfevirapineNevirapine by 14% ($2.47 vs $2.16); and Lamivudine by 9% ($2.03 vs $1.86).
[38] This main regimen is TDF/FTC+EFV
[39] UNDP, UNICEF and Crown Agents.
[40] http://www.ua.undp.org/content/ukraine/en/home/operations/projects/democratic_governance/Medicine_procurement.htm

generally approved around the start of the year. As a result, government-financed procurements cannot go through before the budgets are made available. The procurement process then takes another 12 to 18 months before the drugs are actually delivered. For example, 2016 procurements were only delivered in late 2017. This results in a significant backlog for government-supplied drugs.

In the future, the government is planning to triple the amount of ARVs by 2020 and take over most of MDR-TB order (up from the current 50%). This will increase the risks associated with government procurement issues. For example, in case of delayed government supplies, it will become difficult to continue treatment by borrowing from other stocks. In addition, regional supply chain systems will receive higher quantities making it difficult to manage them through their existing warehouse space.

Future procurement and supply chain arrangements need to be finalized and developed: Ukraine is currently in the process of creating a national procurement agency, which is expected to take over all government procurements and part of Global Fund-financed procurements from 2019. The importance of this institution will further increase in coming years as the government share of drug procurements for HIV and TB increases. As the existing outsourcing arrangement ends in 2019, a robust national procurement agency will also be essential to ensure long-term transparency and cost effectiveness of procurement arrangements.

Funds have been earmarked from the government and various partners to build the capacity of the national procurement agency. For example, the concept note for the 2018-2020 Global Fund grants has budgeted capacity-building costs of approximately US$300,000. However, details on the activities for the agency have not yet been costed and an implementation strategy is in the process of being developed.

Currently, centrally procured health products transit through a central warehouse before being distributed in full to the regions. The capacity and conditions of the central warehouse do not meet international standards. Therefore, health products procured with grant funds are managed through private warehouses. PHC has concerns about continuing this arrangement with private sector partners after the transition, due in part to regulatory requirements. The gradual transition of procurement to PHC will start in 2019. In the absence of a plan to evaluate the actual capabilities of government warehouses and to address the potential gaps, the transition from private sector arrangements to public facilities may introduce significant risks to the delivery of grant services.

Agreed Management Action 1

The Secretariat will, in collaboration with the Principal Recipients, the Government of Ukraine and Partners:

- ensure that the drugs procured with Global Fund grants are only WHO-recommended regimens, and establish an optimization plan to increase treatment impact;
- establish an effective procurement coordination mechanism between government and the donors to avoid any future overstock or stock-outs; and
- discuss and agree with PHC the supply chain arrangements for Global Fund grants in the next grant cycle, including plans for any capacity building initiatives needed for national supply chain arrangements.

Owner: Head of Grant Management
Due date: 31 July 2018

4.4. Data quality challenges affecting decision-making

There are challenges with data quality which affect decision-making. The OIG noted issues related to assurance mechanisms, the accuracy of TB registers, and duplicative registration codes for HIV and MDR-TB patients.

Lack of reliable assurance mechanisms concerning the number of people on ARVs: Ukraine is currently in the process of developing a national health information system that will automate case recording and reporting. However, there is no mechanism to confirm the current number of people on ARV treatment except through limited site visits. In the regions sampled for the audit, the auditors compared the current number of people reported on treatment to the total number of people alive and actually receiving ARV treatment according to the adherence monitoring reports. An average variance of 25% was found between these two data sets.

Discrepancy between patient cards, patient register and reported data for MDR-TB patients: In four regions, constituting 50% of the TB burden in Ukraine, the OIG noted discrepancies in data between the reports submitted to the national level, the TB registers and the patient cards at the health facilities. For eight out of ten facilities visited, the discrepancies ranged between 5% and 15%.[41] The contributing factors for these discrepancies are the lack of reconciliation between the registers and the absence of sufficient monitoring visits.

Different registration numbers given to people with HIV: The two main Principal Recipients currently operate segregated patient data recording and reporting systems, with different registration codes. This means a person with HIV would have two different codes provided by the two Principal Recipients. This could hamper data consolidation and Principal Recipient collaboration. The Ministry of Health is currently establishing a national health management information system. One of the main challenges is the inability to reconcile the data from the two isolated systems.

Agreed Management Action 2

The Secretariat will, in collaboration with the Principal Recipients and other partners ensure that the costed Monitoring and Evaluation plans for TB and HIV are developed, and will include plans for:

- strengthening the reporting systems covering but not limited to the harmonization of patients identification codes;
- strengthening the monitoring and supervision systems for TB and HIV programs; and
- performing evaluations and surveys.

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

[41] TB 01 (patient cards), TB 03 (patient's register) and TB 08 (report to the next level)

4.5. Need for effective planning of transition in grant implementation arrangements

Global Fund programs will undergo a major transition in the next grant cycle. These include changes in the roles and budgets of Principal Recipients, changes in sub-recipients, consolidation of data systems, and improvements in governance processes. Implementation challenges exist that require careful analysis planning for a successful transition. The risks associated with access to services and patients' rights also need to be adequately managed.

Capacity building requirements for PHC: The concept note for the next grant cycle envisages major changes in the implementation structure. There will be a gradual transfer of key program activities and procurements from the two main NGO implementers, Alliance and Network, to PHC. These changes will ensure material transition of the implementation of the programs, including the HIV prevention program, from civil society to the Government of Ukraine. This is consistent with the objective of ensuring the long-term sustainability of these interventions, even after the country transitions from Global Fund support.

The PHC grant will increase from US$3.3 million in the current grant cycle to approximately US$40 million in the next cycle. PHC will also have major new responsibilities, taking over key program activities like prevention, outreach, and procurement of pharmaceuticals and other health products. Overall, PHC will take over 20% of implementation activities starting from January 2018, gradually increasing to reach 80% by 2020. These changes require a detailed analysis of PHC's new roles and responsibilities in comparison to its current ones. This is in order to identify relevant capacity gaps that should addressed through capacity building plans that are costed, budgeted, with execution milestones defined. A capacity assessment was started in September 2017 and will need to be refined as the specific implementation arrangements are further defined for the new grant cycle.

Possible impact of transition on access to services needs careful management: During interviews with representatives from key populations, including people who inject drugs, female sex workers and men who have sex with men, they expressed concerns about the possible adverse impact on access to services when the prevention activities move to PHC. These concerns arise from multiple factors including:

- All these key populations are criminalized according to the law in Ukraine, which is likely to affect their confidence in seeking services from government employees or facilities. As a result, government agencies may find it difficult to reach them.

- There are reservations about the government's commitment and in-depth understanding of these interventions as well as a risk that efficiency considerations will take precedence over the delivery of comprehensive programs. For example, after the Ministry of Health took over the methadone program, a psychological support component was considered unnecessary and removed.

OIG discussions with PHC representatives indicate an awareness of these risks. The new concept note also identifies some of these challenges, and the need for adequate mitigation measures to ensure easy access to services. The Secretariat is also in the process of including conditions in new grant agreements requiring effective action planning for a smooth transition. PHC also highlighted the likelihood of engaging NGOs as sub-recipients through a competitive process, to maintain the quality of outreach while optimizing cost efficiencies. However, a final decision has not yet been reached on measures to mitigate the above-mentioned risks.

Sub-recipient management challenges: the current grant reduced the number of sub-recipients from 225 to 108. However, although the initial process selected fewer sub-recipients, there has not been a detailed review to map the technical capacity, regional presence, or administrative costs.

The audit reviewed 71 grant budgets for sub-recipients and sampled 22 sub-recipients in six regions (Kiev, Donetsk, Dnipro, Mykolaiv, Kherson and Odesa) in a detailed field review. The following issues were identified:

- **Cases of appointment of sub-recipients:** After completing the initial sub-recipient selection process at the beginning of the grant, both Principal Recipients added twelve additional sub-recipients. Ten of them were chosen through an alternative "sub-grant selection" mechanism rather than through an open tender process. This poses the risk of ineffective implementation due to the increased risk of selecting sub-recipients with insufficient capacity.

- **Ratio of indirect human resources and administrative costs:** A financial analysis of sub-recipient grant budgets highlighted an average of 27% allocated to indirect human resources and administrative expenses (excluding direct program-delivery human resources costs). Out of these, six grant budgets had more than 40% (up to 49%) indirect human resources and administrative expenses. There is no Global Fund standard range for guiding or benchmarking the percentage of indirect costs in grant budgets. The Principal Recipient uses a benchmark of 20% for administrative costs in grants for assessing their reasonableness. The current costs indicate room for further efficiencies in administrative costs.

- **Duplication of activities:** The audit found cases where multiple sub-recipients were delivering the same activities for the same target populations in the same regions or cities. For instance, in Dnepropetrovsk, two sub-recipients deliver identical outreach activities for the same group in the same health facilities. Similar cases were found in Dnipro region (Nikopol), Mykolaiv, Odesa and in the Donetsk region (Mariupol).

- **Conflicts of interest:** In two cases following visits to the sub-recipients, the head of the organization and the chief accountant were direct family members. In another case, three staff members of the accounting department were also family members. In a third case the director was performing the duties of the store keeper as well (i.e. no control over the movement of goods). There was also one case where the director of a sub-recipient contracted himself for several consultancies for approximately US$39,000.

- **Effectiveness of Internal controls:** the audit identified several instances of expenses with no or insufficient supporting documents. For a sample of expenses totalling US$486,000 in aggregate, supporting documentation was missing for US$23,358 (approximately 5% of the sampled transactions). Controls were also not effectively implemented over expense categories such as nutritional support, with a general lack of documents concerning procurement and distribution of the food items. For example, the name of the person receiving the goods and the contact details of the beneficiaries were not recorded properly for verification purposes.

  The issues above have been referred to the OIG Investigations Unit for further review.

Agreed Management Action 3

The Secretariat will, in collaboration with the Principal Recipients and other partners, ensure that:

- A detailed action plan to transition from donor funding to government funding of TB and HIV programs with the rate 20%-50%-80% is developed, which includes measures to ensure satisfactory quality and access of services by key affected population after transition.
- The ongoing sub-recipient selection process systematically considers administrative costs, geographical locations and control gaps in the existing cycle, to explore further implementation improvements and efficiencies.

Owner: Head of Grant Management
Due date: 31 August 2018

5. Table of Agreed Actions

Agreed Management Action	Target date	Owner
The Secretariat will, in collaboration with the Principal Recipients, the Government of Ukraine and Partners: • Ensure that the drugs procured with the Global Fund grants are only WHO recommended regimens, and establish an optimization plan to increase treatment impact; • Establish effective procurement coordination mechanism between government and the donors to avoid any future overstock or stock outs; • Discuss and agree with PHC the supply chain arrangements for the Global Fund grants in the next grant cycle, including plans for any capacity building initiatives needed for national supply chain arrangements.	31 July 2018	Head of Grant Management
The Secretariat will, in collaboration with the PRs and other partners ensure that the costed M&E plans for TB and HIV are developed, and will include plans for: • Strengthening the reporting systems covering but not limited to the harmonization of patients identification codes; • Strengthening the monitoring and supervision systems for TB and HIV programs; and • Performing evaluations and surveys.	30 September 2018	Head of Grant Management
The Secretariat will, in collaboration with the PRs and other partners, ensure that: • A detailed action plan for transitioning from donor funding to government funding of TB and HIV programs with the rate 20%-50%-80% is developed, which includes measures to ensure satisfactory quality and access of services by key affected population after transition; • The ongoing sub-recipients selection process systematically considers administrative costs, geographical locations and control gaps in the existing cycle, to explore further implementation improvements and efficiencies.	31 August 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 documents 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 at the Global Fund as well as in country, 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.