



Audit Report

Global Fund Grants in the Kingdom of Lesotho

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Geneva, Switzerland

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Audit Report

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OIG investigations examine either allegations received of actual wrongdoing or follow up on intelligence of fraud or abuse that could compromise the Global Fund's mission to end the three epidemics. The OIG conducts administrative, not criminal, investigations. Its findings are based on facts and related analysis, which may include drawing reasonable inferences based upon established facts.

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1. Executive Summary

1.1. Opinion

The Global Fund is a key partner to Lesotho in the fight against HIV and TB, with cumulative investments of over US\$300 million since 2003.

The country has made noteworthy progress against HIV, evidenced by a 15% decline in AIDS-related deaths and a 35% reduction in new infections since 2010. TB deaths have decreased by 17%, and incidence by 35%, since 2010. Notwithstanding these achievements, the country continues to have the second highest HIV prevalence in the world at 23.6%, reaching 71% in key and vulnerable populations. The country's TB incidence rate, at 611 per 100,000 population, is the highest in the world.¹ As such, Global Fund investments are heavily invested in HIV prevention to reduce the number of new infections and control the epidemic, and in HIV/TB collaboration for active TB case finding and treatment. These areas account for approximately 59% of the grant in the past two funding cycles, NFM 1 and NFM 2.

Various exceptions were identified for the performance of TB screening and testing, and of contact tracing, contributing to the high percentage of missing cases in the country. Inadequate mechanisms are in place to identify and treat MDR-TB. Duplications in prevention activities and geographic locations were noted in HIV prevention programs implemented at sub-recipient level. In addition, there is a lack of coordination between implementers promoting HIV prevention services such as Voluntary Medical Male Circumcision and those providing the services, with substantial gaps between the number of patients referred for HIV prevention services and those actually receiving the service. The adequacy and effectiveness of controls to ensure access to quality services, including prevention programs, are therefore **partially effective**.

Multiple challenges exist around governance and oversight. The audit identified a number of issues related to the Government of Lesotho fulfilling its commitments towards procuring HIV and TB medicines and funding Human Resources for Health. This has contributed to stock-outs of key commodities and a failure to initiate HIV patients on preventive therapy for TB. Critical vacancies exist in the HIV and TB programs, as well as the Supply Chain Directorate, within the Ministry of Health. This has a direct impact on programmatic activity and implementation of grant activities. In consequence, Global Fund grants have a low absorption rate (68% under NFM 1 and 57% under NFM 2) with key activities not being undertaken. Lack of stability in leadership and ownership for the HIV and TB response in the country, as well as challenges at the Country Coordinating Mechanism were contributing factors. The adequacy and effectiveness of program governance and grant oversight therefore **need significant improvement**.

1.2. Key Achievements and Good Practices

Ongoing initiatives to address challenges in TB

The country has already identified most of the weaknesses noted by OIG in the TB program; a number of mitigating actions were in progress at the time of the audit. For example, the World Health Organization has deployed technical assistance to support the development of a revised case finding strategy, which will be supported by clear and detailed standard operating procedures. Through the Southern Africa TB Health System Strengthening Support Project, the country is endeavouring to engage with non-government organizations to conduct community TB screening using mobile X-ray machines in two high-burden districts. Under the Ministry of Health, strengthening of monitoring and evaluation has been commissioned to improve reporting for TB cases and treatment. The project is also leading the efforts to integrate MDR-TB into the District Health Information System (DHIS2).

¹ WHO Global Tuberculosis Report, 2019. Table A4.1, pages 263 - 266.

Progress achieved against the 90-90-90 HIV/AIDs cascade

Notwithstanding Lesotho's high HIV incidence and prevalence, the country has made significant progress in the fight against HIV. Overall, 86% of people living with HIV are aware of their status, of whom 71% are receiving HIV treatment, and 93% are virally suppressed. The country's test and treat policy is well integrated in the health system, with 93% of patients tested positive initiated on treatment in the facilities visited. There has been a three-fold increase in the number of people tested for HIV through widened access to Provider Initiated Testing and Counselling. The Prevention of Mother to Child Transfer Program is well integrated and delivered in the Maternal and Child Health platform. As a result, 95% of pregnant women know their HIV status during the first antenatal visit. In 2018, the country revised its HIV testing strategy to address challenges with the low testing yield despite the high number of tests performed. The strategy is supported by implementation guidance, and a draft costed operational plan is in place to embed the new strategy throughout the health system.

1.3. Key Issues and Risks

Bottlenecks in active TB case finding and linkage to care for MDR-TB hindering achievement of TB grant objectives

Substantial improvements are required for supervision and oversight on adherence to TB screening and testing guidelines, to address gaps in active TB case finding. TB screening guidelines were inconsistently applied in 90% (9/10) of the TB health facilities visited. Some cases with one or more symptoms were not flagged as presumptive, and therefore not referred for testing. In addition, 38% of presumptive TB cases were not tested for TB. The contribution of non-national TB program providers to TB screening and case notification is not recorded and reported through any mechanism. Contact tracing for TB remains in its infancy, with no recording and reporting on contact tracing for children under five. Over 41% of contacts of confirmed adult TB patients were not traced and screened for TB. MDR-TB continues to be a challenge for the country, with only 25% of estimated cases diagnosed and enrolled into treatment.² The country achieved 64% and 63% of its MDR-TB case notification and treatment targets respectively.³

Uncoordinated implementation arrangements for HIV prevention programs impacting service delivery

HIV prevention programs are critical to addressing the high number of new HIV infections in Lesotho. HIV prevention activities accounted for approximately 30% of Global Fund grants under NFM 1 and NFM 2. Weaknesses exist in their implementation arrangements. Multiple sub-recipients perform the same outreach and mobilization for HIV prevention services, in the same districts, for the same target population. In addition, there is inadequate coordination and linkages between the sub-recipients who perform outreach and mobilization activities to create demand for HIV prevention services activities, and those implementers who perform services. In consequence, there are extensive time lags between outreach and service provision, contributing to gaps between patients referred for HIV services and those who receive services. For example, there was a 42%⁴ gap between patients who were referred, and those who received HIV testing services. Similarly, there was an 85% gap between patients who were referred for, and those who received, voluntary medical male circumcision. Weaknesses were also identified for the implementation of Pre-exposure prophylaxis (PrEP) as a preventive measure against HIV. National targets for Key Populations on PrEP and implementation guidance are yet to be defined, despite PrEP being offered to patients at facility level and being included in HIV prevention packages. This has led to a low uptake of PrEP and low adherence rates for completion of the service.

² Data Records at the Partners in Health MDR – TB for January 2018 – December 2018

³ LSO-C-MOF PUDR for period ended June 2019

⁴ Pact Lesotho data for PrEP uptake (October 2017 to September 2019)

Weak country ownership, governance and oversight impacting continuation of services and grant implementation

The Government of Lesotho (GoL) has failed to meet several of its commitments relating to procurement of HIV and TB medicines and investments in Human Resources for Health. These are critical for the on-going activities and sustainability of the National HIV and TB programs. In 2018, the government failed to meet 84% of its procurement commitments for INH 300mg, contributing to widespread stock-outs and negatively impacting the implementation of preventive therapy for HIV patients. As of June 2019, 38% of the government's procurement commitments for anti-retroviral (ARVs), TB and opportunistic infection medicines were not met. The Lesotho Country Coordinating Mechanism has since put forward a Prioritized Above Allocation Request (PAAR) to the Global Fund for additional funding to cover the ARV funding gap that will arise due to GoL's inability to meet its procurement commitments in 2020.

Frequent leadership changes, in particular at the levels of Minister and Principal Secretary for Health, have impacted policy-making and the implementation of HIV and TB programs, including the fulfillment of financing commitments. This has contributed to on-going challenges for the CCM to operate effectively and provide adequate oversight of grant implementation. The CCM's role in addressing key grant bottlenecks is critical, particularly when the Principal Recipients are not involved in implementation. Key issues relating to grant implementation and financial absorption have been repeatedly flagged at CCM meetings, however no agreed mitigating actions and monitoring plans have been put in place to resolve them. Most important is the failure to operationalize investments of US\$1.4 million for health infrastructure and persistent absorption challenges (due to the Ministry of Health's failure to meet its commitments).

1.4. Ratings

	Objective 1: The adequacy and effectiveness of controls to ensure access to quality services including prevention programs OIG rating: Partially Effective
	Objective 2: The adequacy and effectiveness of program governance and grant oversight including assurance mechanisms to ensure efficient and sustainable achievement of grant objectives OIG rating: Needs Significant Improvement

1.5. Summary of Agreed Management Actions

The OIG and the Secretariat have agreed a set of actions and related deliverables to address the findings. Specifically, the Global Fund Secretariat and in-country stakeholders will work to:

- Perform an assessment and develop a plan to improve TB and MDR-TB cases.
- Develop a coordinated risk-based supervision plan for implementers and sub-implementers.
- Assess the current sub-recipient implementation arrangements and programmatic gaps for HIV prevention activities, to develop a coordinated implementation plan reflecting prevention and service delivery activities.
- Assess budgeted commitments for government financing of commodities, human resources for health and health systems to identify short, medium and long-term mitigating actions to address current program challenges. This will also serve as an input into the design of the next Global Fund investment/grant.

2. Background and Context

2.1. Overall Context

Lesotho is a constitutional monarchy, ruled by a King as Head of State, and governed by a 33-member Senate and a 120-member National Assembly. Administratively, Lesotho is divided into 10 districts, each headed by a district administrator. The districts are further subdivided into 80 constituencies and 78 local community councils.

Lesotho is classified as lower middle income by the World Bank. There is high income disparity, with 60%⁵ of the population living below the income poverty line.

A mountainous and landlocked country surrounded by South Africa, Lesotho is largely dependent on its neighbour. In recent years, Lesotho's economy has faced challenges emanating from political instability and a prolonged period of slow growth in South Africa, which has led to falling Southern Africa Customs Union (SACU) revenue and liquidity challenges.⁶

Population: **2.3 million**
(UNFPA, 2019)

GDP per capita: **US\$1,324**
(World Bank, 2018)

UNDP Human Development Index:
159 of 189 (2018)

Global Health Security Index:
144 of 195 (ghsindex.org, 2019)

Transparency International
Corruption Perceptions Index:
78 of 180 (2018)

2.2. Differentiation Category for Country Audits


The Global Fund has classified the countries in which it finances programs into three 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. Lesotho is classified as:

 Focused: (Smaller portfolios, lower disease burden, lower mission risk)

 **Core: (Larger portfolios, higher disease burden, higher risk)**

 High Impact: (Very large portfolio, mission critical disease burden)

 Challenging Operating Environment

 Additional Safeguard Policy

2.3. Global Fund Grants in Lesotho

The Global Fund has signed grants of over US\$300 million and disbursed over US\$256 million to Lesotho since 2003, with US\$67.8 million in current active grants. Lesotho was allocated matching funds from catalytic investments of US\$1.5 million for various adolescents and young people interventions. The Ministry of Finance of the Kingdom of Lesotho and Pact Lesotho, an international NGO, are the current Principal Recipients for the Global Fund grants for the 2018-2021 implementation period.

⁵ UNDP, Human Development Reports – Lesotho - <http://hdr.undp.org/en/countries/profiles/LSO>

⁶ The World Bank – Lesotho country overview - <https://www.worldbank.org/en/country/lesotho/overview#1>

2.4. The Two Diseases in Lesotho

HIV/AIDS: Lesotho has a high HIV prevalence among 15 to 49-year olds at 23.6%. Prevalence is even higher in female sex workers (71.9%), and men who have sex with men (32.9%)⁷.

340,000 people living with HIV, of whom 61% (206,000) are on treatment (2018)⁷.



The Global Fund funds approximately 9% of the funding need for HIV; 43% comes from other funding partners⁸ and 22% from domestic financing, with a funding gap of 26% (US\$153 million) for 2018-2021.⁹

AIDS-related deaths declined by 15% and new HIV infections declined by 35% from 2010 to 2018¹⁰. In 2018 there were 13,000 new HIV infections and 6,100 AIDS-related deaths⁷.



Tuberculosis: Lesotho is classified by WHO as one of the 30 highest TB burden countries. It has the world's highest TB incidence rate of 611, and TB mortality of 200 per 100,000 population.⁷ 15-49

7,027 TB cases notified (2018). TB treatment coverage is 55%. Treatment success rate is 76% (2017)¹²

The Global Fund funds approximately 40% of the funding need for TB; 43% is funded through domestic financing with a gap¹¹ of 17% (US\$5.8m) for 2018-2021.⁵

2.5. Portfolio Performance

Grants in the country are generally performing well, as shown by the achievement rate of key coverage indicators. However, performance for key TB and HIV prevention interventions is either not tracked or cannot be measured. For instance, the national targets for PrEP for key affected populations have not been finalized, therefore performance of the three PrEP indicators cannot be assessed. The active grants do not have indicators to track the percentage of eligible people living with HIV (PLHIV) on antiretroviral treatment who are initiated on TB preventative therapy. While the Global Fund does not fund INH for IPT, there is significant investment in demand creation activities through sub-recipients which includes TB testing and prevention. Results for TB contact tracing for children under 5 years and the contribution of non-national TB program providers to TB screening and case notification are also not tracked under the Global Fund Performance Framework. The National TB program does perform tracking of this key indicator, however national targets have not been defined. Currently, only 58% of children under 5 of TB contacts are initiated on TB preventative therapy. Despite the grant implemented by Pact being a TB/HIV combined grant, there are no TB/HIV indicators monitored through this grant. The audit identified several issues with service uptake for prevention interventions and gaps in TB active case finding interventions, the root causes of which are analyzed in sections 4.1 and 4.2 of this report.

Global Fund Key Indicator Achievements (June 2019) ¹³			
HIV/AIDS	Target	Result	Achievement
Number of people who were tested for HIV and received their results during the reporting period	449,591	468,614	104%

⁷ UNAIDS Data 2019 – Lesotho Country Data, page 48 to 51

⁸ PEPFAR is a major funder for the HIV response in Lesotho. Over the past few years, PEPFAR Lesotho's budget has significantly increased from US\$34 million in COP15 to US\$85 million in COP19 (https://www.state.gov/wp-content/uploads/2019/09/Lesotho_COP19-Strategic-Directional-Summary_public.pdf)

⁹ Funding Landscape Table (Funding request to the Global Fund May 2017)

¹⁰ <https://aidsinfo.unaids.org/>

¹¹ Lesotho has also benefited from a World Bank supported regional project (US\$15 million) targeting mining communities, high TB burden regions, high HIV/AIDS burden regions, transport corridors, and cross-border areas which complements GF and domestic funding.

¹² WHO Global Tuberculosis Report, 2019

¹³ Global Fund Grant Rating Tool for the two grants for the period January to June 2019; selected key grant performance indicators based on relevance and importance.

Global Fund Key Indicator Achievements (June 2019)¹³			
HIV/AIDS	Target	Result	Achievement
Number of medical male circumcisions performed according to national standards	25,000	17,834	71%
Percentage of other vulnerable populations that have received an HIV test during the reporting period and know their results	72.0%	34.0%	47%
Percentage of people living with HIV currently receiving antiretroviral therapy	86.7%	63.7%	73%
Percentage of newly diagnosed people linked to HIV care (individual linkage)	97.0%	94.9%	98%
Percentage of adolescent girls and young women (AGYW) reached with HIV prevention programs- defined package of services	15.1%	23.8%	120%
Percentage of other vulnerable populations that have received an HIV test during the reporting period and know their results	5.1%	3.2%	63%

TB	Target	Result	Achievements
Number of notified cases of all forms of TB (i.e. bacteriologically confirmed + clinically diagnosed), includes new and relapse cases	3,864	3,324	86%
Treatment success rate- all forms: Percentage of TB cases, all forms, bacteriologically confirmed plus clinically diagnosed, successfully treated (cured plus treatment completed)	83%	79%	95%
Number of TB cases with RR-TB and/or MDR-TB notified	137	88	64%
Number of cases with RR-TB and/or MDR-TB that began second-line treatment	137	86	63%

TB/HIV	Target	Result	Achievements
Percentage of people living with HIV in care (including PMTCT) who are screened for TB in HIV care or treatment settings	100%	74.7%	75%
Percentage of registered new and relapse TB patients with documented HIV status	83%	79%	95%

Exceeding Expectations	>100%
Meet Expectations	90-100%
Adequate	60-89%
Inadequate but potential demonstrated	30-59%
Unacceptable	<30%

2.6 Risk Appetite

Risk appetite has been developed at the organizational level using data from a cohort of 25 countries¹⁴ representing the majority of the global burden for the three diseases: 85% for HIV/AIDS; 80% for TB; 76% for malaria. The Global Fund's Risk Appetite Framework, operationalized in 2018, sets recommended risk appetite levels for eight key risks affecting Global Fund grants. Country Teams determine each risk at grant level using the Integrated Risk Management module. The ratings are reviewed by the second line functions and senior management from the Grant Management Division. Grant risk ratings are weighted using the country allocation amount to arrive at an aggregate risk level for the country portfolio. The aggregated risk levels, along with the mitigation plan and expected trajectory of risk levels, are then approved by the Portfolio Performance Committee¹⁵ during the Country Portfolio Review (CPR). For Lesotho, the CPR was finalized in October 2018. The OIG compared the Secretariat's aggregated assessed risk levels of the key risk categories covered in the audit objectives for the Lesotho portfolio with the residual risk that exists based on OIG's assessment, mapping risks to specific audit findings. Please refer to the table below.

Risk	Secretariat aggregated assessed risk level	Assessed residual risk, based on audit results	Relevant audit issues
Program Quality	Moderate	Moderate	Finding 4.1 & 4.2
National Program Governance and Grant Oversight	High	High	Finding 4.2 & 4.3

The audit noted systemic failures for TB screening and testing and weak linkages between demand creation for HIV prevention services and service uptake. However, as described in section 1.2 of this report, there are ongoing initiatives to address challenges in TB and the country has achieved significant progress against the 90-90-90 HIV/AIDs cascade. It is on this basis that the assessments of risk levels by the OIG and the Secretariat are aligned for both Program Quality and National Program Governance and Grant Oversight.

¹⁴ Bangladesh, Burkina Faso, Cameroon, Congo (DRC), Côte d'Ivoire, Ethiopia, Ghana, India, Indonesia, Kenya, Malawi, Mali, Mozambique, Myanmar, Nigeria, Pakistan, Rwanda, South Africa, Sudan, Tanzania, Uganda, Ukraine, Viet Nam, Zambia, Zimbabwe

¹⁵ The role of the Portfolio Performance Committee is to conduct country portfolio reviews and enterprise reviews

3. The Audit at a Glance

3.1 Objectives

This audit sought to assess the adequacy and effectiveness of:

- (i) controls to ensure access to quality services including prevention programs
- (ii) program governance and grant oversight including assurance mechanisms to ensure efficient and sustainable achievement of grant objectives

3.2 Scope and Methodology

The audit was in accordance with the methodology described in Annex B, covering the period from July 2017 to June 2019. Therefore, the audit covered both active and closed grants. Of the four grants audited, two ended on 30 June 2018 and the other two will end on 30 June 2021.

Grant No.	Principal Recipient	Grant component	Grant period	Budget amount (US\$)	Disbursed amount (US\$)
<i>Funding cycle 2016-2018</i>					
LSO-C-MOF	Ministry of Finance of the Kingdom of Lesotho	HIV and TB	July 2016 to June 2018	50,391,980	38,118,204
LSO-C-PACT	Pact Lesotho	HIV and TB	July 2016 to June 2018	8,261,040	7,609,071
Total				58,653,020	45,727,275

<i>Funding cycle 2018-2021*</i>					
LSO-C-MOF	Ministry of Finance of the Kingdom of Lesotho	HIV and TB	July 2018 to June 2021	55,499,451	13,077,500
LSO-C-PACT	Pact Lesotho	HIV and TB	July 2018 to June 2021	12,347,559	3,949,455
Total				67,847,010	17,026,955

*Disbursement amounts as at 30 June 2019

The auditors visited 16 health facilities in five districts (Maseru, Berea, Quthing, Thaba Tseka and Buthe Buthe), covering 19% of people on antiretroviral treatment and 28% of TB case notifications cases for the year ended June 2019. The auditors also visited the central warehouses, and storage facilities in Mafeteng and Berea districts.

3.3 Progress on Previously Identified Issues

This is the first OIG audit of grants in Lesotho.

4. Findings

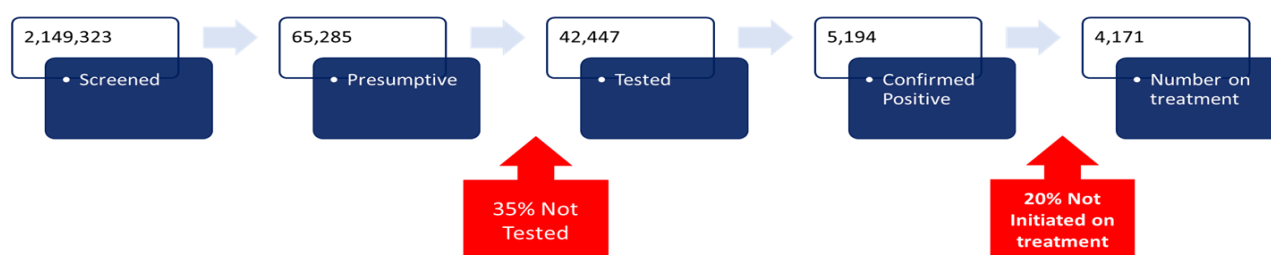
4.1 Bottlenecks in active case finding interventions and management of MDR-TB

Lesotho is classified as one of the 30 high burden countries for both TB and TB/HIV co-infection.¹⁶ TB treatment coverage increased by 7% between 2017 to 2018, but remains relatively low at 55%.¹⁷ The country's TB incidence rate, at 611 per 100,000 population, is the highest in the world.¹⁸ As such the Global Fund grant objectives and the country's National Strategic Plan focus on case finding, preventative therapy for eligible HIV patients, and treatment of drug-susceptible TB patients.

The country has taken several steps to improve case detection. This includes the adoption of ultra-GeneXpert testing cartridges, with 20% better sensitivity, in September 2018. Sample transportation mechanism has improved with the use of Riders for Health; sample turnaround time is two days and the sample rejection rate is 0.07%. TB-related deaths decreased by 17% between 2010 to 2017. In addition, the country has recently launched initiatives to address case finding, Technical Assistance being deployed to develop advanced strategies and standard operating procedures. Despite the progress made, TB case finding and management of MDR-TB remain a challenge for the country, contributing to its high TB incidence.

TB case finding: Lesotho is missing 45%¹⁷ of TB cases, in comparison to the global average of 31%¹⁹. TB is the 2nd leading cause of death, with estimated TB-related deaths of 200 per 100,000 annually.²⁰ Below is an illustration from the *DHIS2 data between July 2018 and June 2019* of the National TB Cascade.

National Level -Cascade View



Inadequate quality of TB screening and testing is a contributing factor to the gaps in TB case finding. TB screening guidelines were inconsistently applied in 90% (9/10) of the TB health facilities visited. There were multiple instances where cases with one or more symptoms were not flagged as presumptive, and therefore not referred for testing. There is also no effective mechanism to follow up all presumptive TB cases for testing. In health facilities visited by the OIG, 38% of presumptive TB cases were not tested for TB. Whilst all TB patients were systematically tested for HIV, the same was not the case for HIV patients. In 44% (7/16) of the health facilities visited, people living with HIV were not systematically screened for TB. Despite the Global Fund investment in an HIV/TB collaboration officer, this issue highlights major flaws in the HIV program for HIV/TB collaboration, with negative effects for finding TB cases.

Ineffective contact tracing and reporting on contacts for confirmed TB patients is another contributing factor. Over 41% of contacts (adults and children under 5) of confirmed TB patients were not traced and screened for TB at health facilities visited. The National TB Program Childhood TB Guidelines require routine enrolment on Isoniazid preventive therapy (IPT) for children under

¹⁶ WHO Global Tuberculosis Report, 2019. Table 2.4, page 23.

¹⁷ WHO Global Tuberculosis Report, 2019 – Lesotho Country profile, page 236.

¹⁸ WHO Global Tuberculosis Report, 2019. Table A4.1, pages 263 - 266.

¹⁹ WHO Global Tuberculosis Report, 2019 – Global profile, page 258.

²⁰ WHO Global Tuberculosis Report, 2019. Table A4.2, page 268.

five years who are screened negative for active TB. However, there is no specific recording tool for TB contact tracing for children under five. As a result, there is a varying approach to contract tracing at the health facility level, with some facilities not performing contact tracing at all, and others performing it and recording the results on existing recording tools, such as TB registers and screening and detection registers.

The TB program is failing to identify opportunities to leverage community-based interventions such as Community Health Workers to follow up and collect sputum samples from presumptive TB cases. Ineffective supervision and job mentorship are also contributing to the gaps in TB screening and contact tracing. 25% (4/16) of TB facilities visited were not supervised, and of the TB facilities that were supervised, 42% (5/12) did not receive written feedback.

MDR-TB case management: only 25% of estimated MDR-TB cases are diagnosed and enrolled into treatment.²¹ Under the Global Fund performance framework the country achieved 64% and 63% of its MDR-TB case notification and treatment targets, respectively.²² The suboptimal performance for MDR-TB is linked to a centralized treatment model, with no oversight and monitoring throughout the treatment cascade.

At Lesotho's only treatment center for MDR-TB patients there is limited capacity to provide other services for MDR-TB patients, given high co-morbidity. There is no palliative care such as pain management, treatment of side effects or HIV care for MDR-TB patients, and secondary complications such as psychiatric disorders are managed off site. Diagnostic infrastructure, including mobile and static X-ray machines, had been down for over one month at the time of the audit. There is a high discordancy rate of 10%²³ between district hospital laboratory results and repeat tests at the MDR-TB treatment hospital. As GeneXpert tests are used in both cases, there should be no discordancy. Whilst the discordancy could also be attributed to the poor quality of the sputum collection, External Quality Assurance and regular monitoring of performance at the district level remain key challenges and were observed to be the main contributors of the high discordance.

There is no formal mechanism supported by clear and documented guidelines to confirm that referred MDR-TB patients from districts and health facilities are initiated on treatment in timely fashion. Informal mechanisms such as phone calls are used at some facilities, however there were no records in place to support this. TB patient transfer/referral forms were not used in 88% (14/16) of facilities visited by the OIG. As a result, the number of patients enrolled for treatment is small, and declining²⁴ compared to the estimated number of MDR/RR- TB patients in the country.²⁵ In addition, patients seek care and treatment at the MDR-TB hospital very late; co-infected patients seek care with CD4 counts as low as one. There is no documented mechanism to track patients lost to follow-up. Only patients enrolled on MDR-TB treatment are reported as notified cases, leading to the number of cases reported being almost equal to the number of patients on treatment. There is no functional structure at the central level to oversee the management of MDR-TB in the country. MDR-TB cases are not reported in DHIS2 and there is no mechanism to report adverse drug reactions.

Overall, the issues for both TB and MDR-TB are influenced by the lack of governance, ownership and prioritisation for the disease in the country. For example, the approved TB program organogram and resources under the Ministry of Health are not aligned to the TB National Strategic Plan which is central to the Global Fund grant. Only four out of the 13 positions, of which one is vacant, are recognized in the government-approved organogram. The other positions are either being temporarily funded by donors or are vacant. As such, key positions such as TB/HSS coordinator, MDR- TB focal point, M&E specialist and TB information management systems coordinator are not filled.

²¹ Data Records at the Partners in Health MDR – TB for January 2018 – December 2018

²² LSO-C-MOF PUDR for period ended June 2019

²³ PIH Lab data July 2017 to July 2019

²⁴ Decline in MDR-TB patient enrolment: 2016 (250), 2017 (158), 2018 (191), 2019 (144) – MDR-TB Treatment hospital data

²⁵ WHO Global Tuberculosis Report, 2019 – Lesotho Country profile, page 236.

Agreed Management Action 1

a: The Secretariat will work with the Ministry of Health to finalize a plan to improve TB and MDR-TB case finding using available data reviews and assessment results.

b: The Secretariat will work with the Principal Recipient to develop a coordinated, risk-based sub-recipient supervision plan including timelines, responsibilities, and feedback and follow-up mechanisms.

Due Date: 31 December 2020

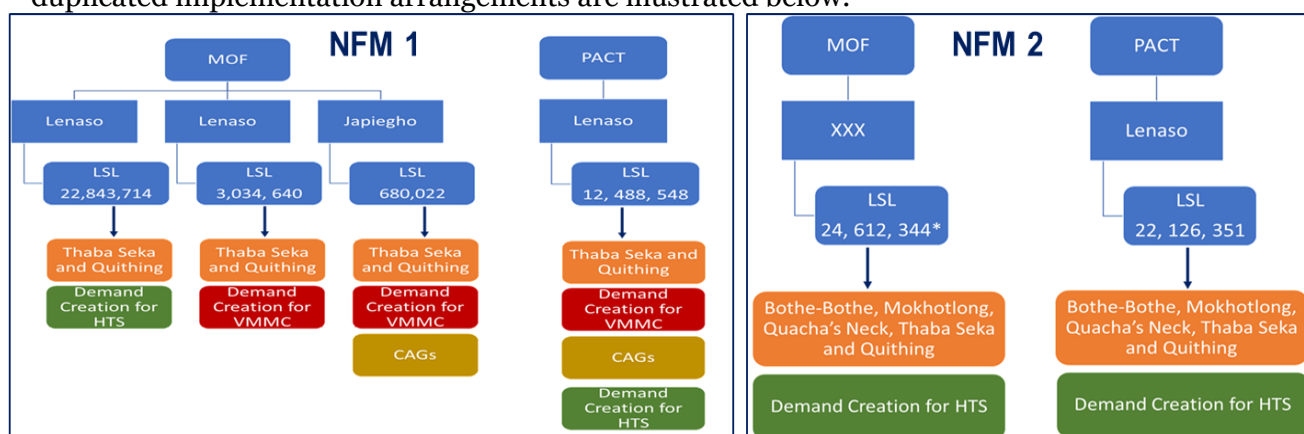
Owner: Head of Grant Management

4.2 Uncoordinated implementation arrangements for HIV prevention programs are impacting effectiveness of demand creation activities and service delivery

Lesotho has the second-highest HIV prevalence rate (23.6%)²⁶ and second highest HIV incidence rate (7.8 per 1000 population) in the world.²⁷ Prevention activities are therefore critical for the country to end HIV/AIDS as an epidemic. As such, the Global Fund has invested heavily in HIV prevention activities, as depicted in the table below. Despite the significance of the investments, inadequate implementation arrangements are in place for the combined HIV prevention programs, negatively impacting the effectiveness of demand creation activities and linkages to service delivery.

Module	NFM 1 (2016-2018) (USD)	NFM 2 (2018-2021) (USD)	Total (USD)
Prevention programs for general population	10,142,270	3,859,773	14,002,043
Comprehensive prevention programs for sex workers and their clients	440,436	776,920	1,217,356
Prevention programs for other vulnerable populations	1,032,487	312,889	1,345,375
Prevention programs for adolescents and youth, in and out of school	3,406,220	3,954,366	7,360,586
Comprehensive prevention programs for MSM	423,755	79,252	503,008
PMTCT	724,341	2,457,676	3,182,017
Total (USD)	16,169,509	11,440,876	27,610,385

Duplication of HIV demand creation interventions: during NFM 1, the two Principal Recipients, Ministry of Finance and PACT, utilized sub-recipients to undertake demand creation activities for the same HIV prevention services in the same geographical locations. While some of the activities might be specific to a community or key population, the audit noted that there were no supporting implementation plans to clearly demarcate the activities and locations to ensure that there was no duplication. A similar implementation arrangement was planned to be used for NFM 2, however the arrangement is still under discussion following the observations from the audit. The duplicated implementation arrangements are illustrated below:



XXX – SR yet to be signed by MOF

Orange - Duplicated Districts

Red – Duplicated Interventions for VMMC

Yellow – Duplicated Interventions for Community Art Groups

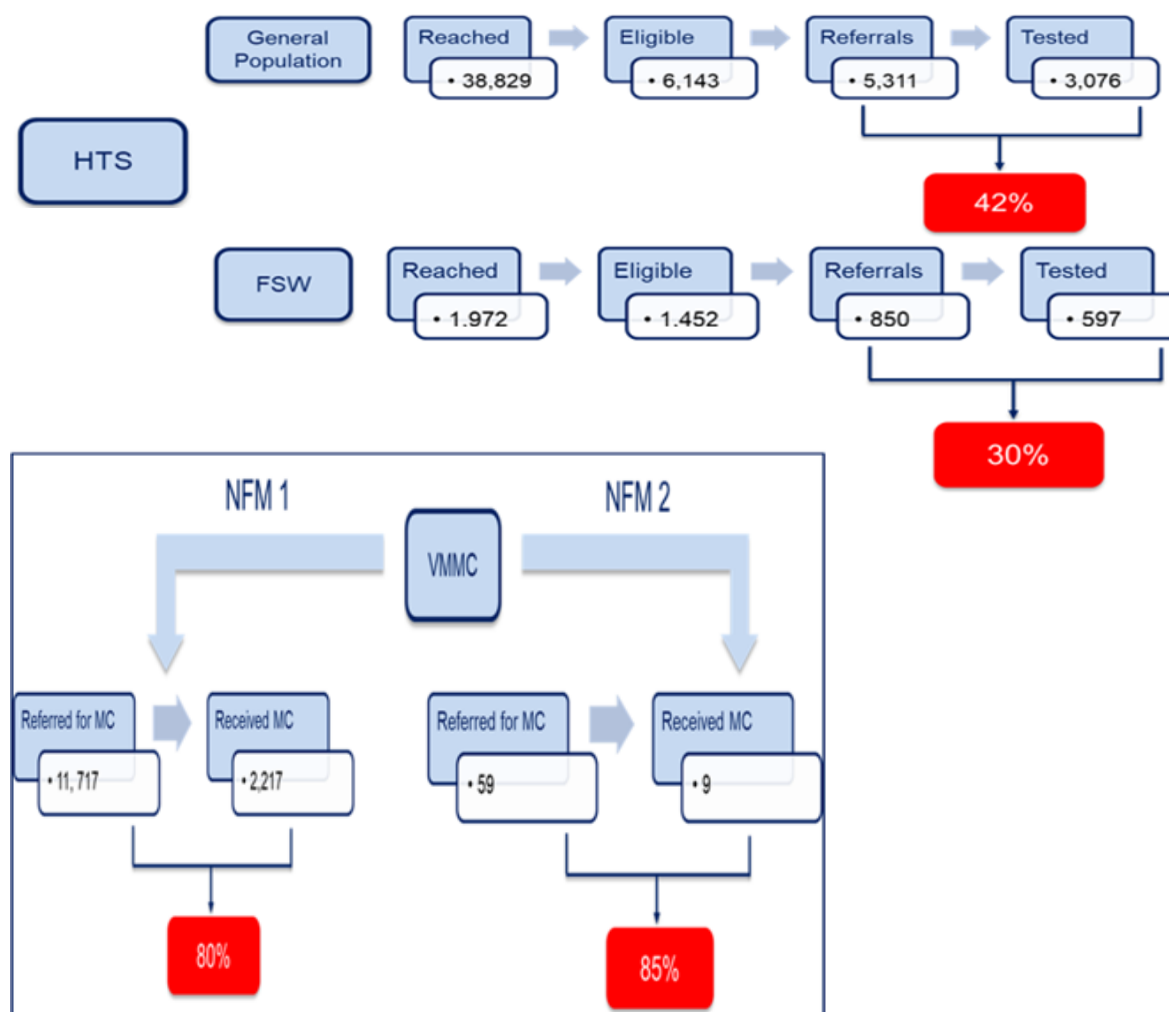
Green – Duplicated Interventions for HTS

²⁶ UNAIDS Data 2019, Lesotho Country Data – page 48

²⁷ HIV Incidence per 1000 population (National) - <https://aidsinfo.unaids.org/>.

Lack of coordination and linkages between demand creation activities and service delivery: the Principal Recipient, Pact, uses several sub-recipients (SRs) to create demand for HIV prevention services. However, these SRs do not provide most HIV prevention services such as HIV testing services (HTS), Voluntary Medical Male Circumcision (VMMC) and Pre-exposure prophylaxis (PrEP). Demand creation and service delivery should occur in close tandem (within 1-3 days) of each other. As such, the effectiveness of demand creation activities depends on the sub-recipients' ability to coordinate and plan with other service providers and link patients to services provided at health facility level or by Ministry of Finance SRs. Currently, there are no structures and processes in place to facilitate this coordination. Principal Recipients and sub-recipients do not meet regularly to discuss outreach and service plans. As a result, outreach activities are not coordinated with prevention service activities, limiting their effectiveness. For example, one SR performed VMMC outreach activities in a specific location in January 2019, however the SR performing the service was only going to that location in March 2019, and therefore had to reperform outreach and mobilization for the same target population before administering the service.

In addition, there are no supporting processes to ensure linkages to service for demand creation activities. For example, there is no Memorandum of Understanding between sub-recipients under Pact and the Ministry of Finance to coordinate and enable access to data, to ensure that patients who were eligible and referred for service actually received the service. In the context of patient data confidentiality, treatment supporters or peer navigators to accompany those consenting clients for the referred services are also not used to follow up on whether the service has been provided. Demand creation activities therefore stop once the patient is referred for the service, and targets for sub-recipients performing demand creation are measured on the number of people reached, not the number of people receiving the service. The current approach for HIV prevention programs does not allow for evaluation of the effectiveness of demand creation activities, and creates losses between patients referred and patients receiving the service, as depicted below:



PrEP implementation in its infancy: Lesotho has done well to update its national guidelines recommending PrEP for HIV prevention among high-risk population groups, including men who have sex with men, people who inject drugs, sero-discordant couples, and adolescent girls and young women. Limited progress has however been made to scale up the implementation of PrEP as a preventive measure against HIV. National targets for Key Populations on PrEP are yet to be defined. Roles and responsibilities between health facilities, community and civil society organizations have not been clarified, so far as implementation of PrEP is concerned. Although prevention packages include PrEP, the Technical Working Groups on prevention do not focus on PrEP. As a result, implementers have limited guidance on performing education and promotion of PrEP amongst key populations. This has contributed to low uptake of PrEP, with only 286 patients receiving this service across all 16 health facilities visited. PrEP uptake among female sex workers, men who have sex with men, and adolescents declined between 2018 and 2019 by 23%, 48% and 100% respectively.²⁸ In addition, there is low retention of patients on PrEP, with only a 34% retention rate at the health facilities visited. The OIG notes that subsequent to the audit, the Principal Recipient in coordination with the Ministry of Health has started a process to define national targets for PrEP.

Agreed Management Action 2

The Secretariat will work with the Principal Recipients to assess the current sub-recipient implementation arrangements and programmatic gaps for HIV prevention activities, considering duplications, program implementation gaps and linkages between demand creation and service delivery.

Following the assessment, a coordinated implementation plan will be developed, reflecting prevention and service delivery activities and the accountabilities, roles and responsibilities for coordination between the principal and sub-recipients performing the various activities.

Due Date: 30 June 2021

Owner: Head of Grant Management

²⁸ Pact Lesotho data for PrEP uptake (October 2017 to September 2019)

4.3 Inadequate governance and country ownership impacting continuation of services and sustainability of Lesotho's HIV and TB programs

The Government of Lesotho is a major funder and implementer of HIV and TB programs in the country, with the Global Fund grants designed to complement Government investments. The Government procures 70% of HIV anti-retroviral medicines and all first-line TB medicines. The percentage of Government expenditure on health has been maintained close to the 15% Abuja declaration over the last five years. However, the non-fulfilment of government commitments, coupled with leadership and governance challenges at the Ministry of Health, may affect the sustainability of the country's response to HIV and TB. The Government through the Ministry of Health committed to perform various activities including the procurement of medicines and the recruitment of human resources to support implementation of the HIV and TB programs. These commitments remain to be fully fulfilled and are an important component to enable realization/absorption of Global Fund and other donor investments, scale up key programmatic interventions, address key program bottlenecks and ensure sustainability of the programs.

Procurement of HIV and TB medicines: the Government fell short of its commitments for anti-retroviral medicines, TB medicines and opportunistic infection medicines by 26%, 25% and 10% respectively in the last three years. In 2018, the Government was solely responsible for procuring TB medicines, including INH 300mg, but fell short of its commitments by 84%, which contributed to stock-outs of INH affecting effective implementation of preventive therapy for HIV patients (81% of eligible HIV patients were not put on preventative therapy for TB). In addition, during January to June 2019, the Government (which is responsible for procuring 70% of anti-retroviral medicines) fell short of its commitments by 38%. With the country continuing to face fiscal challenges and uncertainties on governments procurement commitments remaining, the Country Coordinating Mechanism has put forward a Prioritized Above Allocation Request (PAAR) to the Global Fund for additional funding, to cover the immediate ARV funding gap in order to prevent treatment disruption for people living with HIV. The funding from PAAR will cover needs up to June 2020, following which the Government is expected to resume its commitments.

Human Resources for Health (HRH): key positions at the national level remain vacant. 77% (10/13) and 64% (18/28) of the required positions at National TB Program and HIV/STI program respectively are vacant. In addition, three key managerial positions²⁹ at the supply chain department are also vacant, in addition to operational staff vacancies representing 94% of the department. The Government depends heavily on donors for funding the vacant positions: the Global Fund and the World Bank are temporarily funding 50% (5/10) of the positions at the National TB Program; Global Fund and PEPFAR are temporarily funding 33% (6/18) of the positions at the HIV/STI Program; and 68% of staff at health facilities are funded by donors. Despite the Global Fund grant requiring a commitment from the Government to transition from donor support and to submit an updated budget to the Global Fund to reflect increased investment in human resources by 1 January 2020, the Government currently does not have any HR plan in place to guide the fulfilment of this commitment or take over funding for these critical positions. The program is likely to be negatively affected if the Global Fund continues with its plan to reduce HR support in the current grant cycle (NFM 2) as set out in the grant agreement and in the table below.

Position	Global Fund Human Resources Support			
	Jul 2018 - Jun 2020	Jul 2020 - Jun 2021	Jul 2021- Jun 2025	Post June 2025
Data Clerks	83	53	To Be Finalized	
Laboratory Technologists	5	3		
Senior Counsellors	5	5		
TB Screening Clerks	71	71		
District Logistics Officers	5	5		
Microscopist	42	42		
NTRL Data Clerk	1	1		

²⁹ These are Supply Chain Operations; M&E and Quality Assurance; and Quantification Manager

Roles and Responsibilities: limited clarity in roles and responsibilities of key actors in the HIV and TB response is negatively impacting implementation of HIV and TB programs, including Global Fund-supported interventions. For example, the Ministry of Health (MOH) and National AIDS Commission (NAC) have similar Technical Working Groups (TWGs) for treatment and prevention, leading to duplicated efforts. On the other hand, key interventions such as pre-exposure prophylaxis (PrEP) and voluntary medical male circumcision are not covered under any of the TWGs. As a result, outcomes of the TWGs and key program information are not fully disseminated by the MOH from the central level to district and health facility levels. For example, guidance and action plans to address key issues relating to implementation of the recent HIV Testing Strategy, including approaches for Index Partner Testing and PrEP, are inconsistently or not applied at health facility and community levels.

The lack of clarity of roles and responsibilities has contributed to major delays in the development of key strategies and policies, including: National HIV and TB Strategic Plan, including District Operational Plan (over 18 months delay); National HIV policy (yet to be updated since 2006). NAC performed a Partner Indexing study to inform modes of HIV transmission, however the results are yet to be adopted by the Ministry of Health, impacting on the effectiveness of indexed partner testing performed at the facility level. Only 64% of index partners were identified for the health facilities visited, and of these only 21% of the identified indexes were tested for HIV.

In addition, the Supply Chain Directorate has no approved legal mandate to ratify roles, responsibilities and decisions within the Ministry of Health. This has contributed to key sub-TWGs such as Quantification and Forecasting of the Supply Chain Directorate not being operational. In consequence, there is currently no functioning governance and oversight mechanism for the commodity pipeline. This has contributed to the stock-outs of key commodities noted above.

The above challenges are influenced by the lack of stability in leadership and ownership for the HIV and TB response in the country. There have been frequent changes in the Ministry of Health, including the Principal Secretary to Health who has changed nine times since the commencement of Global Fund grants under NFM 1. As such there is no consistent leadership to drive the development of policies and ensure implementation from the central to the health facility level. This has also contributed to the ongoing challenges of the Country Coordinating Mechanism (CCM) to operate effectively, with multiple challenges related to adherence to Global Fund eligibility requirements and LCCM ByLaws. There have been seven CCM Chairs in the last three years. In addition, there is no consistent government leadership presence at CCM meetings. As such, the CCM is unable to provide adequate oversight of grant implementation. For the key issues identified from oversight activities performed in 2019, no mitigating actions were agreed with Principle Recipients. There is also no active monitoring of resolution of issues identified through oversight activities, or regular performance reports of the Principal Recipients presented to the CCM.

Agreed Management Action 3

The Secretariat will work with the Government of Lesotho and partners to do an assessment of:

- the budgeted commitments for financing of commodities and human resource for health and health systems;
- current structures, roles and responsibilities of disease programs, including their governance, management and funding flow structures.

The assessment will inform mitigating actions for the short, medium and long term to address current program challenges and will serve as an input into the design of the next Global Fund investment/grant.

Due Date: 30 June 2021

Owner: Head of Grant Management

5. Table of Agreed Actions

Agreed Management Action	Target date	Owner
<p>a: The Secretariat will work with the Ministry of Health to finalize a plan to improve TB and MDR-TB case finding using available data reviews and assessment results.</p> <p>b: The Secretariat will work with the Principal Recipient to develop a coordinated risk-based sub-recipient supervision plan including timelines, responsibilities, and feedback and follow-up mechanisms.</p>	31 December 2020	<p>Head of Grant Management</p> <p>Mark Edington</p>
<p>The Secretariat will work with the Principal Recipients to assess the current sub-recipient implementation arrangements and programmatic gaps for HIV prevention activities, considering duplications, program implementation gaps and linkages between demand creation and service delivery.</p> <p>Following, the assessment, a coordinated implementation plan will be developed, reflecting prevention and service delivery activities and the accountabilities, roles and responsibilities for coordination between the principal and sub-recipients performing the various activities.</p>	30 June 2021	<p>Head of Grant Management</p> <p>Mark Edington</p>
<p>The Secretariat will work with the Government of Lesotho and partners to do an assessment of:</p> <ul style="list-style-type: none"> the budgeted commitments for financing of commodities and human resource for health and health systems; current structures, roles and responsibilities of disease programs, including their governance, management and funding flow structures. <p>The assessment will inform mitigating actions for the short, medium and long term to address current program challenges and will serve as an input into the design of the next Global Fund investment/grant.</p>	30 June 2021	<p>Head of Grant Management</p> <p>Mark Edington</p>

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 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 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 may also assess how Global Fund grants/portfolios are performing against target for Secretariat-defined key indicators; specific indicators are chosen for inclusion based on their relevance to the topic of the audit.

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

Annex C: Risk Appetite and Risk Ratings: Content, Methodology and Implications

Risk appetite has been developed at the organizational level using data from a cohort of 25 countries³⁰ representing the majority of the global burden for the three diseases: 85% for HIV/AIDS; 80% for TB; 76% for malaria. The Global Fund's Risk Appetite Framework, operationalized in 2018, sets recommended risk appetite levels for eight key risks affecting Global Fund grants.

As accurate risk ratings and their drivers are critical to effective risk management and operationalization of risk appetite, a robust methodology was developed with clear definitions, granular risks, root causes as well as an extensive review process as detailed below.

The eight grant-facing risks for which risk appetite has been set represent an aggregation from 20 risks as depicted in the table on the following page. Each of these 20 risks is rated for each grant in a country using a standardized set of root causes and considers a combination of likelihood and severity scores to rate risk - Very High, High, Moderate or Low. Country Teams determine each risk at grant level using the Integrated Risk Management module. The ratings are reviewed by second line functions and senior management from the Grant Management Division.

The ratings at the 20-risk level are aggregated to arrive at the eight risks using simple averages, i.e. each of the component parts are assumed to have similar importance. For example, the risk ratings of *Inadequate program design (1.1)* and *Inadequate program quality and efficiency (1.3)* are averaged to arrive at the rating of Program Quality for a grant. As countries have multiple grants, which are rated independently, individual grant risk ratings are weighted by the grant signed amounts to yield an aggregate Current Risk Level for a country portfolio. As the ratings of grants often vary significantly and to ensure that focus is not lost on high-risk grants, a cut-off methodology on high risks is applied (the riskiest 50% of grants are selected) to arrive at a country risk rating. The aggregated risk levels, along with the mitigation plan and expected trajectory of risk levels, are then approved by the Portfolio Performance Committee³¹ during the Country Portfolio Review.

Leveraging Risk Appetite in OIG's work

As the Risk Appetite framework is operationalized and matures, OIG is increasingly incorporating risk appetite considerations in its assurance model. Important considerations in this regard:

- The key audit objectives that are in the scope of OIG audits are generally calibrated at broad grant or program levels (for example, effectiveness of supply chain processes, adequacy of grant financial management, quality of services, reliability of data, overall governance of grant programs, etc.) as opposed to narrower individual risk levels. Thus, there is not a one-to-one match between the overall audit rating of these broad objectives and the individual rating of narrower individual risks. However, in the absence of a one-to-one match, OIG's rating of an overall audit objective does take into consideration the extent to which various individual risks relevant to that objective are being effectively assessed and mitigated.
- The comparison of OIG's assessed residual risks against the Secretariat's assessed risk levels is done at an aggregated level for the relevant grant-facing risks (out of the eight defined ones) that were within the scope of the audit. This comparison is not done at the more granular level of the 20 sub-risks, although a narrative explanation is provided every time the OIG and the Secretariat's ratings differ on any of those sub-risks. This aggregated approach is designed to focus the Board and AFC's attention on critical areas where actual risk levels may differ from perceived or assessed levels, and thus may warrant further discussion or additional mitigation.

³⁰ Bangladesh, Burkina Faso, Cameroon, Congo (DRC), Côte d'Ivoire, Ethiopia, Ghana, India, Indonesia, Kenya, Malawi, Mali, Mozambique, Myanmar, Nigeria, Pakistan, Rwanda, South Africa, Sudan, Tanzania, Uganda, Ukraine, Viet Nam, Zambia, Zimbabwe.

³¹ The role of the Portfolio Performance Committee is to conduct country portfolio reviews.

For risk categories where the organization has not set formal risk appetite or levels, OIG focuses on the Secretariat's overall processes for assessing and managing those risks, and opines on their design and effectiveness.

Table of risks

Corporate Risks (8)	Operational Risks (20)
Program Quality	1.1 Inadequate program design and relevance
	1.3 Inadequate program quality and efficiency
M&E	1.2 Inadequate design and governance of M&E Systems
	1.4 Limited data availability and inadequate data quality
	1.5 Limited use of data
Procurement	3.3 Inefficient procurement processes and outcomes
In-Country Supply Chain	3.2 Unreliable forecasting, quantification and supply planning
	3.4 Inadequate warehouse and distribution systems
	3.6 Inadequate information (LMIS) management systems
Grant-Related Fraud & Fiduciary	2.1 Inadequate flow of funds arrangements
	2.2 Inadequate internal controls
	2.3 Fraud, corruption and theft
	2.5 Limited value for money
Accounting and Financial Reporting by Countries	2.4 Inadequate accounting and financial reporting
	2.6 Inadequate auditing arrangements
National Program Governance and Grant Oversight	4.1 Inadequate national program governance
	4.2 Ineffective program management
	4.3 Inadequate program coordination and SR oversight
Quality of Health Products	3.1 Inappropriate selection of health products and equipment
	3.5 Limited quality monitoring and inadequate product use