



Audit Report

Global Fund Grants to the Republic of Malawi

GF-OIG-16-024
11 October 2016
Geneva, Switzerland

Table of Contents

- I. Background3
- II. Scope and Rating6
- III. Executive Summary7
- IV. Findings and Agreed Management Actions..... 10
- V. Table of Agreed Actions.....26
- Annex A: General Audit Rating Classification 27
- Annex B: Methodology.....28

I. Background

Malawi is a low-income country in the southern part of Africa with an estimated population of approximately 16.7 million, with the majority (85%) living in rural areas.¹ The country's estimated gross domestic product (GDP) per capita in 2015 was US\$381.40. Approximately 50% of the population lived below the national poverty line in 2010.^{2,3} Malawi is ranked 174 out of 188 countries in the 2014 Human Development Index. There are high rates of unemployment and few natural resources. Malawi's economy is predominantly reliant on agriculture, which represents 38.6% of GDP and 80% of all exports.

Progress on development goals has been constrained by macro-economic instability, regular humanitarian crises caused by droughts and floods, high inflation rates and significant corruption. Transparency International's 2015 Corruption Perception Index ranked Malawi 112 out of 167 countries.

Malawi is facing severe staffing shortages in the health sector and has few resources to meet a minimal level of health care. Health worker to patient densities are respectively 0.019 physicians and 0.283 nursing and midwifery personnel per 1,000 population with ongoing vacancies across all nursing and clinical cadres. The World Health Organization's (WHO) standard is 2.5 physicians per 1,000 population.⁴ Health worker migration into private, urban, tertiary facilities and implementing partners is undermining the provision of appropriate rural and primary care.

The three diseases in Malawi

Malawi's HIV prevalence is one of the highest in the world, with 9.1% of the population living with HIV (11% among women and 7% among men).⁵ Although its population is relatively small, Malawi is one of the 10 countries that account for 81% of the total number of people living with HIV in sub-Saharan Africa.⁶ HIV prevalence among adults aged 15-49 years declined from 16% in 1999 to 10.6% in 2010.⁷ However, the decline in prevalence has been offset by the rapid population growth in Malawi, resulting in a fairly stable number of people living with HIV, from 1.1 million in 1999 to 1.0 million in 2013.⁸ The total number of people receiving antiretroviral therapy increased from 3000 people in 2003 to 595,186 by December 2015, with a twelve month retention rate above 85%. Malawi has implemented the new Integrated Clinical HIV Guidelines including "Option B+" for Prevention of Mother to Child Transmission.⁹ This resulted in a seven-fold increase in the number of HIV-positive pregnant women starting antiretroviral therapy by December 2012.¹⁰ In spite of this progress, the disease still accounts for about 27% of deaths in the country.¹¹

HIV is one of the most important risk factors for developing active tuberculosis (TB) in Malawi, and 56% of TB patients also tested positive for HIV in 2013.¹² TB continues to be a significant public health problem in Malawi. Preliminary findings from a national TB prevalence survey conducted in 2013/2014 indicated a TB prevalence almost twice as high as previous estimates. Prevalence of TB (all forms) is now estimated at 334/100,000 in the general population (all ages) and at 452/100,000 among adults based on the survey. The survey also indicated that case detection for TB is low in the country at only 43%. In 2014, 16,267 new and relapsed cases of TB

¹ World Bank 2014 data, <http://data.worldbank.org/country/malawi>

² <http://data.worldbank.org/indicator/NY.GDP.PCAP.CD>

³ World Bank 2014 data

⁴ http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_mwi_en.pdf

⁵ <http://www.unaids.org/en/regionscountries/countries/malawi>

⁶ UNGASS Country Progress Report 2015 Malawi

⁷ UNGASS Country Progress Report 2015 Malawi

⁸ UNAIDS. The GAP Report. Geneva, 2014.

⁹ "Option B+" offers lifelong antiretroviral treatment to pregnant and breastfeeding women irrespective of CD4 count with the aim of preventing HIV transmission.

¹⁰ Action Aid Grant Confirmation Document, 2016

¹¹ <http://www.theglobalfund.org/en/portfolio/country/?loc=MWI>

¹² <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4497634/>

were notified in Malawi.¹³ WHO estimates an annual multi-drug resistant TB (MDR-TB) case load of 154 but only 106 of these cases in 2014 were notified confirmed cases, with 64 of them initiated on MDR-TB treatment.¹⁴ Routine TB symptom screening is in place at antiretroviral therapy clinics, and HIV testing in TB cases has been maintained at over 90% since 2007.

Malaria is among the major causes of morbidity and mortality in Malawi. The disease is endemic and the entire population lives in high transmission areas.¹⁵ Malaria is responsible for: approximately four million suspected cases annually; 40% of all hospitalizations of children less than five years old; and 30% of all outpatient visits across all ages.¹⁶ Reported malaria cases show a decrease since 2009, from 484 cases per 1,000 population reported in 2009 to 239 per 1,000 population in 2013.¹⁷ Despite the progress made, total malaria deaths accounted for 25% of total in-patient deaths in 2015.¹⁸

Global Fund support in Malawi

The Global Fund has been a partner in Malawi since 2003. Nine grants amounting to US\$1.2 billion have been signed since the inception of Global Fund investment in the country with 69% (US\$837 million) of the grants disbursed for HIV/AIDS, malaria, TB and Health Systems Strengthening interventions. The country received a total envelope of US\$574 million (including existing funding of US\$278 million and additional funding of US\$296 million) under the Global Fund's new funding model for the period ending December 2017.

Global Fund investments in Malawi to date have contributed to significant results across all three diseases, with over 590,000 people on antiretroviral therapy, 7.74 million insecticide-treated nets distributed to protect children and families from malaria, and over 17,000 people tested and treated for TB.

During the period under review (2014 -2015), Global Fund programs were implemented by the Ministry of Health (malaria and TB grants) and the National AIDS Commission (HIV/AIDS grant). Under a dual-track financing arrangement, the Malawi Country Coordinating Mechanism nominated the Ministry of Health (MOH) to be the Government Principal Recipient, and ActionAid and World Vision to be the non-government Principal Recipients for the joint TB/HIV grant and the malaria grant, respectively, starting January 2016 to December 2017.¹⁹ ActionAid is responsible for TB/HIV interventions at community level, and World Vision Malawi is accountable for Integrated Community Case Management implementation at the community level.²⁰

In the past decade, disease control programs in the country have established parallel procurement, storage and distribution systems, due to the existing constraints of the government's central warehouses called the Central Medical Stores Trust (CMST). The MOH/Health Technical Support Services Pharmaceuticals (HTSSP), with the HIV, TB and malaria programs, co-ordinate key procurement and supply chain functions such as quantification, procurement planning and monitoring for essential medicines, HIV, TB and malaria program commodities. Procurement, central level warehousing and national distribution are outsourced to third party procurement agents.

In 2012, the Government of Malawi and development partners developed a joint strategy for integrating the parallel supply chains into one supply chain managed by CMST.²¹ Reforms at CMST are ongoing to create the necessary capacity and expertise to enable it to procure, store and distribute all essential medicines through one integrated supply chain system. The Global Fund has

¹³ WHO Tuberculosis report 2015

¹⁴ WHO Tuberculosis report 2015, Global TB Database

¹⁵ WHO World Malaria Report 2015

¹⁶ United States President Malaria Initiative Malaria Operational Plan, 2015 and http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_mwi_en.pdf

¹⁷ WHO World Malaria Report 2015

¹⁸ Malawi DHIS data, 2015

¹⁹ The initial grant period was 2014 to 2016 but due to delays in: finalizing the National Strategic Plans, drafting the concept notes and determining the implementation arrangements and PRs selection, grant period was changed to 2016 - 2017

²⁰ Integrated Community Case Management is a strategy to extend case management of childhood illness beyond health facilities

²¹ Malawi TB/HIV Concept Note, 2015

contracted a fiscal agent to perform financial and fiduciary functions to safeguard grant funds in the country. The Ministry of Health has also contracted a service provider for the payment of allowances at the district and facility levels.

In April 2016, the Office of the Inspector General (OIG) of the Global Fund launched a campaign called 'I Speak Out Now!' in Malawi. The campaign was designed to encourage people to speak out about wrongdoing in programs financed by the Global Fund and specifically to fight drug theft in Malawi. It was launched in parallel with a USAID campaign and in partnership with the Ministry of Health.

The OIG last reviewed this portfolio in 2010 with a full scope audit, published in August 2012. The audit identified weaknesses in financial management, sub-recipient management, procurement and supply chain management. This year's audit noted improvement in the financial management of the portfolio. However, management of sub-recipients, data quality assurance arrangements and inventory management, particularly at the facility level, remain inadequate.

II. Scope and Rating

01 Scope

The OIG assessed whether the implementation arrangements of Global Fund grants to Malawi are adequate, efficient and effective in achieving the grant objectives in the country. Specifically, the audit aimed to assess the effectiveness and efficiency of the:

- mechanisms in place to ensure quality of services;
- supply chain systems in place to store, deliver, account for and quality assure medicines and health products; and
- implementation arrangements for Global Fund supported programs in ensuring efficient absorption of grant funds and achievement of grant objectives.

As Global Fund new funding model grants had just started in January 2016, the audit focused on the previous grants (malaria and TB) implemented by the MOH, and the HIV/AIDS grant implemented by the National AIDS Commission and their sub-recipients, from January 2014 to December 2015. In certain cases, it was necessary to review activities and transactions prior to 2014 based on the results of the OIG's testing. In addition, the audit looked at the design of implementation arrangements under the new funding model grants.

The audit included site visits to four warehouses and 30 health and storages facilities. The 30 health facilities included urban, rural, faith-based, private and public facilities in 11 out of the 28 districts accounting for 60% of the population of Malawi.

02 Rating

Operational Risk	Rating	Reference to findings
Effectiveness and efficiency of the mechanisms in place to ensure quality of services.	Needs significant improvement	1.1, 1.2, 1.3
Effectiveness and efficiency of the supply chain systems in place to store, deliver, account for and quality assured medicines and health products.	Needs significant improvement	2.1, 2.2, 2.3
The implementation arrangements for Global Fund supported programs in ensuring efficient absorption of grant funds and achievement of grant objectives.	Partially effective	3

III. Executive Summary

Malawi is a key portfolio for the Global Fund in its mission to end the epidemics of AIDS, TB and malaria. Nine grants amounting to US\$1.2 billion have been signed since 2003, of which 69% (US\$837 million) have been disbursed for the three diseases and Health Systems Strengthening interventions.²²

Due to large investments and good collaboration between partners in-country, significant progress has been made over the last 12 years in the HIV program. For example, the total number of people receiving antiretroviral therapy increased from 3000 in 2003 to 595,186 by December 2015, with a 12-month retention rate above 85%. Malawi has implemented the new Integrated Clinical HIV Guidelines, including “Option B+” for Prevention of Mother to Child Transmission.²³ Since December 2012, there has been a seven-fold increase in the number of HIV-positive pregnant women starting antiretroviral therapy. HIV infection rates among infants are estimated to have declined by 71% between 2009 and 2015. Progress has also been made in the TB and malaria programs, with the TB treatment success rate reaching 83% by the end of 2014 and a steady decrease in reported malaria cases.

In this audit, the OIG assessed the mechanisms in place to ensure quality of services; the supply chain systems in place that deliver, account for and quality assure medicines and health products; and the implementation arrangements that ensure the absorption of grant funds.

A. Mechanisms to ensure quality of services

While significant progress has been made in the fight against the three diseases, important components of activities, funded by both the Global Fund and the US President’s Emergency Plan for AIDS Relief (PEPFAR), have not been implemented, affecting the availability and quality of key services to beneficiaries. For example:

For the **HIV program**, there is room for improvement to comply with the national HIV guidelines on testing²⁴ and effective monitoring of people on treatment. Currently there is a low proportion of HIV exposed infants and children tested within the recommended timeframes; and inadequate monitoring of CD4 counts and viral load testing for HIV patients.

For the **TB program**, case notification targets are not met, due to a lack of training and human resources capacity, sub-optimal utilization of GeneXpert diagnostic machines, and lack of screening for children. Inadequate measures to address TB infection control increase the risk of health facility-based transmission. These shortcomings are critical in fighting TB when taken in the context of the 2014 TB prevalence survey which indicated that prevalence had doubled compared to previous estimates.

The **malaria program** has significant weaknesses related to vector control and case management. Significant delays in a mass distribution campaign of insecticide-treated nets, which were delivered after the peak season, limited the effectiveness of the campaign in preventing malaria. The delays may have contributed to an increased number of cases, requiring treatment and further contributing to stock-outs at the national level. Malaria is treated without confirmed diagnosis in health facilities and in communities. 60% of patients treated for malaria at health facilities are not tested²⁵, and suspected malaria cases are reported and treated through the country’s integrated Community Case Management program without a confirmed diagnosis. Data quality limitations in the Health Management Information System and the District Health

²² This is mainly disbursements as at 31 December 2015 but include disbursement of US\$12.8m in 2016

²³ Option B+ commits to provide life-long ART treatment for all HIV-positive pregnant and breastfeeding women, regardless of their CD4 count.

²⁴ The MOH has established and staffed a Quality Management Unit and revised the HIV testing guidelines to address the issues with testing

²⁵ Round 12 of the PMI supported Outreach Training and Support Supervision (OTSS) program (Sept/October 2015).

Information System compromise decision-making, quantification and forecasting. The OIG concludes that **significant improvement** is needed to address quality of services issues in the country.

B. Supply chain system to effectively store, deliver, account for and quality assure health products

Effective procurement and supply chain controls are critical for the Malawi portfolio as drug procurement represented more than 80% of expenditures in the period from 2009 to 2015. The Secretariat²⁶ and the Principal Recipients have put in place mechanisms to safeguard commodities at the central level, including pooled procurement of health and non-health commodities, adequate storage space at the central level, and a multi-tier distribution system directly from the central level to end-user facilities. The HIV program has a centrally coordinated program planning, storage, distribution and stock transfer system that has helped improved the management of HIV commodities. The Ministry of Health, with the support of partners, has put in place measures including the establishment of a drug theft investigation unit. In addition, the Ministry of Health, in partnership with the National Pharmacy and Poisons Board, has developed draft legislation that imposes strong penalties for the theft and diversion of health commodities.

However, there are gaps in the supply chain system at the facility level which affect the country's ability to effectively store, account for and quality assure health commodities. Poor record-keeping, inadequate facility-level storage, and weak accountability lead to variances and unreliable stock controls. Malaria medicines financed by international donors can be openly procured in public markets as a result of drug theft. Causes include inadequate supervision of the malaria program, a lack of human resources capacity and significant delays in the enactment of legislation in Parliament to address the diversion and pilferage of health commodities.

Other issues noted include the absence of pharmacovigilance systems and weak monitoring of the quality of medicines and commodities. Stock-outs of malaria commodities and expiries of TB drugs remain a significant challenge, presenting the risk of potential treatment disruptions. At the time of the audit, the country was facing a severe stock-out of anti-malaria medicines at the facility level. This was caused by the weak quality of data to inform quantification and forecasting as well as challenges in addressing drug theft. As a result, donors have decided not to hold buffer stocks. At the same time, some anti-TB medicines, funded by the Global Fund, have expired due to inadequate data analysis, lack of inventory monitoring and facility-level deliveries that are not based on consumption patterns. The national program has put in place measures to guide supply planning and monitor stock status to address this issue.

The measures put in place at the central level have helped to address supply chain issues especially with HIV and malaria commodities at that level. The OIG concludes that **significant improvement** is needed to ensure that quality assured products are effectively stored, delivered and accounted for in a timely manner especially at the facility level.

C. Absorption of Global Fund grants and achievement of grant objectives

The overall absorption rate of Global Fund grants to Malawi, which were mainly concerned with the procurement of pharmaceuticals and health products from 2009 to 2015, was 82%. However, ineffective program management by implementers and inefficiencies in managing the portfolio by the Global Fund Country Team have resulted in a low use of funds²⁷ dedicated to in-country²⁸ activities and delays in the implementation of those activities. Only 30% (US\$36m) of funds available for in-country activities (US\$124m) were spent by the Principal Recipients from 2009-

²⁶ For the purposes of this report, Secretariat refers to the Global Fund Secretariat and not Malawi CCM Secretariat

²⁷ This excludes funds for procurement of health commodities through the Global Fund's Pooled Procurement Mechanism

²⁸ In-country activities refer to all activities in the grant budget except funds for activities that are directly disbursed by the Global Fund Secretariat to service providers on behalf of the country. These activities include procurement of health commodities under the pool procurement mechanism (PPM) and procurement of non-health product through UNOPS in Kenya.

15.²⁹ There is also a low absorption rate of the new grants and the funds committed by the Government of Malawi.³⁰ The national disease programs have limited resources to implement activities that are critical to the overall success of the programs, although funding is available. In addition, inefficiencies in the Global Fund Country Team's management of the portfolio and in fiscal agent processes also contribute to delays and ineffective implementation of key local activities.

Despite the low absorption of funds available for in-country activities, the Principal Recipients were able to achieve grant objectives with the support of USAID, PEPFAR and the US President's Malaria Initiative (PMI). The last Global Fund performance rating for the malaria and HIV grants was "A2" and that of the TB grant was "B1".³¹ The OIG concludes that mechanisms to ensure efficient absorption of grant funds and achievement of grant objectives are **partially effective**.

²⁹ These are Global Fund grants to the country excluding direct disbursement under the Global Fund's Pool Procurement Mechanism (PPM)

³⁰ Less than 1% of the new grant, which started in January 2016, had been absorbed at the time of the audit

³¹ Global Fund performance rating of the grants range between A1 (highest rating) and C (poorest rating)

IV. Findings and Agreed Management Actions

01. Effectiveness and efficiency of the mechanisms in place to ensure quality of services

Sub optimal implementation of activities under Global Fund supported programs affects the quality of services provided.

Global Fund investments in Malawi have significantly contributed to the scaling-up of key interventions across the three disease programs. However, important components of these interventions have not been implemented as designed, affecting the availability and quality of key services to beneficiaries.

1.1 Compliance with National HIV guidelines

The HIV/AIDS program has robust policies, guidelines and good data quality assurance systems in place. The total number of people receiving antiretroviral therapy increased from 3000 people in 2003 to 595,186 patients by December 2015 with a 12-month retention rate of above 85%. However, inconsistencies remain in the adherence to the national HIV guidelines. For example:

a) HIV exposed infants and children are not tested within the timeframes recommended in national guidelines, impeding timely access to antiretroviral therapy

Malawi has made significant progress in eliminating mother-to-child transmission. HIV infection rates among infants are estimated to have declined by from 32% in 2010 to 8.7% in 2015.³² Despite this progress and depending on the quarter in question, between 88% and 99%³³ of HIV positive infants did not receive their HIV test results before they were eight weeks old, delaying their access to life-saving antiretroviral therapy.

The underlying causes of this issue include delays in collecting, processing, dispatching, receiving results from the laboratories, and timely communication of results to mothers. Median time between sample collection and processing at laboratories until dispatch to health facilities³⁴ ranged from 19 days to 44 days depending on the quarter under review. Significant investments by the US Government have strengthened the transportation of laboratory samples, however its reach is not universal and gaps were noted in coordination.³⁵ However, there is no centrally managed real time tracking and allocation system for samples sent to laboratories. This has contributed to sub-optimal utilisation of the testing capacity in some laboratories and over-utilisation in others.

b) Inadequate laboratory monitoring of people living with HIV on treatment

Guidelines for the clinical management of HIV in children and adults in Malawi recommend routine CD4 counts every three months for patients with confirmed HIV infection who are not otherwise eligible for antiretroviral therapy as well as routine scheduled viral load testing at specific intervals after antiretroviral therapy initiation.³⁶ However, laboratory monitoring for CD4 count and viral load testing has been sub optimal. A total of 201,496 CD4 count tests were performed during the audit period against an estimated minimum of 336,000 (60%). Similarly,

³² UNAIDS 2016 report "On the fast-track to an AIDS-free generation"

³³ Q1 2014 and Q3, 2015 quarterly program data (MOH)

³⁴ also known as the Turn Around Time (TAT)

³⁵ The service provider, Riders for Health Malawi had over 14 contracts with various PEPFAR Implementing Partners (IPs) that did not provide complete coverage of all facilities providing services. In addition, we noted gaps in service provision due to delays in concluding contracts or availability of funding by the IP contracting Riders for Health Malawi. The Riders program covered 637 sites, whilst 131 sites are not covered.

³⁶ Malawi National HIV treatment guidelines, 2013 (intervals of 6, 24, 48 months and every 24 months thereafter)

viral load testing coverage ranged from 17% to 39% of the target, depending on the quarter in question. This is also significantly below expected target levels of patients estimated to require a viral load test. Underlying causes to explain the poor CD4 and viral load coverage include:

- inefficient sample transportation system;
- sub-optimal utilization of existing laboratory capacity dedicated to support viral load testing;³⁷
- gaps in laboratory Human Resources capacity (85% of senior and 65% of laboratory technicians are not in post);
- insufficient viral load testing results management;
- sub-optimal deployment, functionality and utilization of existing viral load platforms and CD4 machines (e.g. out of the 27 facilities with a CD4 machine, seven were not being used due to lack of reagents and staff with the skills to use them); and
- a weak laboratory logistics management system that resulted in frequent stock-outs of laboratory commodities.³⁸

The country has developed a plan to phase out CD4 monitoring in favour of viral load monitoring which will provide timely and correct diagnosis of treatment failure as the country transitions to “test and treat”.³⁹

c) Inconsistent compliance with guidelines related to HIV testing

Malawi’s national HIV guidelines recommend routine confirmatory testing of all people living with HIV prior to their initiation on antiretroviral treatment to rule out potential misdiagnosis. Although confirmatory testing rates have been steadily improving, 61% of the 211,622 people initiated on antiretroviral therapy during the period audited had not been re-tested prior to treatment initiation, as required. This increases the risk of patients starting antiretroviral therapy inappropriately, with adverse implications for both the health of the individuals and the efficient use of drugs in the program. Root causes for inconsistent compliance with HIV testing guidelines include:

- i. ***Proficiency Testing not implemented consistently:***⁴⁰ All HIV testing services providers are required to undergo proficiency testing twice a year.⁴¹ However, participation in proficiency testing nationally by providers ranged from 1%-65%. In the facilities visited by the OIG, 33% of providers had not undergone any proficiency testing in the past 12 months. Recommended corrective actions are not followed up consistently as the National HIV Reference Laboratory has neither the work force nor the funding to follow up recommendations from proficiency tests conducted.
- ii. ***Remedial actions for HIV testing not consistently implemented:*** The OIG’s review of the HIV services quality improvement reports indicate that repeated recommendations proposed for the same facilities during quarterly supervision visits by the program over time have not been consistently implemented.⁴² Although the Government has committed funds to strengthen quarterly supportive supervision to monitor compliance with approved standards, they have not been utilised.
- iii. ***High turnover among HIV testing services providers:*** The national program established ambitious targets for antiretroviral therapy enrolment, resulting in a doubling of

³⁷ Laboratory service supervision reports 2014-2015

³⁸ Laboratory service supervision reports 2014-2015

³⁹ Test and Treat interventions are built around two main components: HIV counselling and testing of all to identify those already infected with HIV or diagnosed but not yet linked to treatment and initiation of life-long antiretroviral treatment as soon as possible after HIV diagnosis, regardless of CD4 count,

⁴⁰ Proficiency Testing is where the National HIV Reference Laboratory external provider sends unknown samples for testing to HIV testing providers, and the results from the providers are analysed, compared, and reported to the testers

⁴¹ Malawi HIV Testing Services Guidelines (2013 and 2016), National HIV treatment guidelines, 2013

⁴² The Q1 2014 to Q4 2015 of the HIV National program quality improvement report indicate that: 30% of all the facilities supervised in Q1 of 2014 had the same recommendation in Q2 of 2014 quality improvement reports. In Q1 of 2014, 689 facilities were supervised and in Q2 of 2014, 697 facilities were supervised. The figure ranges between 33% to 38% the following quarters.

the number of people tested for the first time, during the period under review. However, the program did not consider adequately the number of required HIV testing providers available to support the scale-up. Between 15-38% (depending on the district) of certified HIV testing providers were no longer active at the time of the audit, leading to the remaining providers being overburdened and compromising the quality of testing. With support from PEPFAR, 713 HIV Diagnostic Assistants have been recruited to support the large testing load in PEPFAR supported districts. However, the numbers are insufficient to support HIV counselling and testing needs at the standards required.⁴³

Agreed Management Action 1

The Secretariat, in collaboration with the Ministry of Health and partners, will facilitate the development of an action plan to strengthen the quality of testing and laboratory services across HIV and TB programs in Malawi. Specifically, this plan will include:

- Training of relevant health workers on HIV counselling and testing;
- A mapping of existing investments in laboratory systems strengthening for HIV and TB;
- Measures to fill remaining gaps, with a focus on optimizing the use of existing infrastructure and staffing; strengthening management of laboratory commodities; and improving sample transportation.

Owner: Mark Edington, Head Grant Management Division

Target date: 31 December 2017

⁴³ The National Strategic Plan for HIV 2015-2020 identifies 3,000 HDAs as the minimum required.

1.2 TB case finding and transmission prevention

There has been a steady increase in the proportion of TB patients successfully treated, which reached 83% by the end of 2014.⁴⁴ With support from the Global Fund, the country undertook a population-based TB prevalence survey in 2014 to get a more accurate estimate of the TB burden. The findings from the survey indicated that TB prevalence was significantly higher, twice the previous estimates. However, routine program data indicates that case notification⁴⁵ rates have declined consistently since 2005. The following factors have contributed to ineffective case notification and transmission prevention:

a) Ineffective case finding

The National TB program has robust case findings guidelines. However, the OIG noted that:

- 50% of the positive TB patients identified in the survey had sought care in a health facility but had not been screened or diagnosed with TB;⁴⁶
- 60% of the facilities visited did not screen children who accompanied their parents for TB treatment;
- although 80% of the facilities visited reported that they had mechanisms to undertake contact screening, nearly all reported that contact screening was done inconsistently and coverage of screening was low; and
- 80% of the facilities reported that they did not systematically screen their health workers for TB on an annual basis.

The failure to meet case notification targets for both adult and pediatric TB has contributed to the expiration of TB drugs at central and health facility levels (refer to section on 2.3 of this report).

The following factors contribute to ineffective case findings in Malawi:

- i. **Passive case finding in health facilities/Sub-optimal case detection effort:** Less than 1% of clients seen at outpatient departments in health facilities nationally were screened for TB in 2014 and 2015.⁴⁷ Only 37% of health workers at the facilities visited by the OIG had received any training on TB diagnosis or treatment.
- ii. **Sub-optimal utilization of existing diagnostic capacity to support both TB and MDR-TB case finding:** Development partners and the Global Fund have procured 45 GeneXpert machines. However, capacity utilization for GeneXpert was sub-optimal at 35.5% at the end of September 2015. At the time of the audit, a plan had been developed to optimize the use of GeneXpert (including revising the algorithm), but this was yet to be implemented.
- iii. **Lack of commodities, equipment and technical capacity to screen children for TB at all levels:** 93% of the facilities visited by the OIG cited a lack of technical capacity to undertake sputum induction among children. Where capacity existed, a lack of commodities and equipment was an additional obstacle.

The new Global Fund grants include funding to address the gaps in case funding. However, due to the delay in signing the grant and selecting sub-recipients, many of the actions proposed, including complementary actions supported by the US Government through Challenge TB, were yet to be initiated at the time of the audit.

⁴⁴ National TB programme reporting system

⁴⁵ Case notification means that TB is diagnosed in a patient and is reported within the national surveillance system

⁴⁶ National TB prevalence survey draft report (2015)

⁴⁷ Malawi DHIS2 data for OPD cases (denominator), National TB program for TB case notification data (numerator)

b) Ineffective TB infection control measures

The National TB Program has developed and disseminated TB infection control guidelines. However, measures put in place to address TB infection control are inadequate. OIG's assessment in the 30 facilities visited found that, contrary to the guidelines:

- 80% of staff in the facilities had not received refresher training in infection control in 2015 and 73% had not assessed infection control in 2015;
- 60% did not have infection control plans, and 16% did not have a trained infection control focal point;
- 30% had no stock of particulate respirators that met or exceeded N95 standards;⁴⁸ and
- 38% did not have satisfactory measures in place to separate patients suspected with TB and facilitate sputum specimen production.

Several factors have created a conducive environment for TB to spread in health facilities among patients, health workers and the community. Over 595,000 HIV positive and other immune compromised patients visit the health facilities; appropriate infection control guidelines and practices are either absent or not adhered to. This can also have contributed to the country's high TB-HIV co-infection rate (56%).

The underlying causes for the inadequate infection control measures include the following:

- Insufficient human and financial resources are available at the national, district and facility levels to implement infection control interventions. This is because the TB program during the audit period was primarily funded through a Transitional Funding Mechanism that focused exclusively on providing treatment for TB and MDR-TB.
- There is inadequate dissemination of infection control guidelines and insufficient supervision for the implementation of infection control measures due to a lack of government funding.
- Although grant funds had been allocated to improve environmental controls (mechanical and natural ventilation), they were not available at the time of the audit as a condition pertaining to the release of these funds had not been met.

The current Global Fund TB grants include activities to improve TB case finding. These activities include trainings and strategies for community-based case finding.

Agreed Management Action

Please refer to Agreed Management Action 1

⁴⁸ N95 is a respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles and thus protect the user from airborne transmission of an infection.

1.3 Management of malaria control in Malawi

The country has made significant progress in controlling malaria. For example, reported malaria cases show a decrease since 2009, from 484 cases per 1,000 population reported in 2009 to 239 per 1,000 population in 2013.⁴⁹ However, management of the malaria program in Malawi needs further improvement.

a) Malaria is treated without confirmed diagnosis at health facilities and in communities

National treatment guidelines for malaria have been neither consistently enforced (in the case of health facilities) nor implemented (in the case of communities).⁵⁰ In the period under review, the OIG noted the following:

- 60% of patients treated for malaria were not tested.
- 31% of patients who tested negative for malaria, either through microscopy or malaria rapid diagnostic tests, were still given artemisinin-based combination therapy.⁵¹ In the facilities visited by the OIG, 58% of patients treated for malaria were not tested.
- All suspected malaria cases reported and treated through the country's Integrated Community Case Management programme are taken in the absence of confirmed diagnosis.⁵²

The OIG noted that some of the underlying causes of the country's inability to effectively diagnose malaria included:

- i. ***Delayed rollout of malaria rapid diagnosis tests to the community level:*** The Global Fund program quantified malaria rapid diagnosis tests to be used as part of the integrated Community Case Management program. However, due to protracted delays in undertaking the required training activity for the diagnosis tests in the community, this activity was moved to the new grant and had not been implemented at the time of the audit.
- ii. ***Insufficient supervision arrangements to ensure prescriber adherence to guidelines:*** 33% of health facilities visited had not received any malaria related technical supervision in the past 12 months. Although the funded program had allocated funding for supervision, these funds had not been accessed by the National Malaria Control Program (NMCP) at the time of the audit. The program relied on funding from US Government PMI to support the Outreach Training and Support Supervision program whose coverage was limited.
- iii. ***Sub-optimal utilization and training of staff:*** 38% of facilities visited by the OIG had not received any training in malaria diagnosis using rapid diagnostic tests in the past 12 months. In 13% of the facilities visited, malaria case diagnosis using the tests had been 'task shifted' to providers who had not been trained instead of those who had been trained. This results in risks of sub-optimal quality of rapid diagnosis testing, and loss of value-for-money related to training costs.
- iv. ***Delayed procurement of malaria rapid diagnosis tests funded under 'Willingness-to-Pay' by the national program:*** As part of its "willingness to pay" commitments, the Government of Malawi allocated US\$2.6 million to procure malaria rapid diagnosis tests for health facilities to support parasitological confirmation of malaria. However, at the time of the audit, the Ministry of Health had not procured the test kits, leading to treatment without confirmed diagnosis.

⁴⁹ WHO World Malaria Report 2015

⁵⁰ The national guidelines recommend testing all suspected malaria cases using an RDT prior to initiating treatment. Microscopy is recommended to: confirm diagnosis for hospitalized patients with severe malaria; monitor progress in severe malaria cases; and confirm first line treatment failures.

⁵¹ Round 12 of the PMI supported Outreach Training and Support Supervision program (Sept/October 2015).

⁵² Integrated Community Case Management is an equity-focused strategy that complements and extends the reach of public health services by providing timely and effective treatment of malaria, pneumonia and diarrhea to populations with limited access to facility-based health care providers, and especially to children under five.

Treating patients for malaria without a confirmed diagnosis increases risks of drug resistance in the population and loss of value-for-money due to a potentially excessive use of medicines.

b) Delayed mass distribution of insecticide treated nets limiting their utility and effectiveness in preventing malaria

Routine mass distribution and promotion of mosquito nets is the country's primary intervention to prevent malaria. The Global Fund supported mass net distribution in 2012, 2014 and in 2015/16. However, there were inefficiencies in Malawi's distribution as both the 2012 and the 2015/16 distribution campaigns took place during or after peak malaria transmission periods.⁵³ During peak transmission periods, there was an unplanned increase in the utilisation of antimalarial medicines and tests to diagnose and treat additional unexpected cases. The delays in the mosquito net distribution may have contributed to the increase in malaria cases during that period.

Grant funds allocated for other activities may also be reallocated to pay for the lease of additional storage space resulting from the delay in the net distribution. The OIG was not able to quantify this cost as it was being negotiated by the Principal Recipient and service provider at the time of the audit. The OIG noted that delays in the following areas contributed to the overall hold up in the mass campaign:

- finalization of detailed budgets for the mass campaign by the Principal Recipient and their subsequent review and approval by the Secretariat;
- procurement and contracting of a service provider for warehousing and distribution of the nets;
- review and approval of proposals by the Fiscal Agent;⁵⁴
- disbursement of payments for distribution related activities by G4S, the paying agent used by the national programs.

c) Limitations in the completeness, timeliness and accuracy of reports from facilities

The Global Fund and other partners rely on the national Health Management Information System for malaria routine data incorporated in the District Health Information System. There are significant limitations in the accuracy, completeness and timeliness of the reports from the facilities, which affects the availability of quality data for decision making by stakeholders for the malaria program:

- *Completeness:* Although the reporting rate for the malaria health facility reporting form has continued to improve, over 160 facilities still do not report into the system.⁵⁵
- *Timeliness:* Whilst the timeliness of reporting has improved, over 200 facilities do not provide reports on time and delays range from one to three months.⁵⁶
- *Accuracy:* In 73% of the facilities visited, the OIG noted inaccuracies between case management indicators that were reported in the district system and the facility data for the period under review.

⁵³ ITN distribution campaigns should be conducted prior to peak transmission periods to achieve the maximum efficiency.

⁵⁴ The Fiscal Agent changed the templates 3 times

⁵⁵ Malawi DHIS 2 Extract

⁵⁶ Malawi DHIS 2 Extract

At the time of the audit, the data management issues were yet to be fully addressed due to:

- i. ***Gaps in Health Management Information System human resource capacity at district and health facility level:*** 60% of statistical officers were not in post at the time of the audit.⁵⁷ Also, 10% of health management officers and malaria coordinators at the district level were not in post at the time of the audit.⁵⁸
- ii. ***Inadequate data quality assurance mechanisms:*** From the OIG's review of the district's Health Information System (DHIS) parameters for malaria data, the auditors noted that there are currently no data validation rules. Furthermore, although the funded program included an allocation for data quality assurance activities, including six monthly supervisions as well as data quality audits, these had not been performed at the time of the audit.

Agreed Management Action 2

The Secretariat in collaboration with the Ministry of Health will undertake an assessment of case management under the Continuous Quality Improvement work stream. The current practices will be benchmarked and assessment is expected to provide actionable information for improving case management.

Owner: Mark Edington, Head Grant Management Division

Implementation date: 30 June 2017

⁵⁷ Statistical officers are the cadre primarily responsible for supporting data management at health facilities.

⁵⁸ HMIS officers at the district level together with the District Malaria coordinators are responsible for entering monthly summary facility data into DHIS2.

02. Effectiveness and efficiency of the supply chain to deliver, account for and quality assure medicines and health products.

2.1 Systems at health facilities to store and account for commodities received

Ineffective systems at the facilities may affect the potency, efficacy and effectiveness of drugs, which may lead to drug resistance and loss of confidence in the program.

The Secretariat has put in place mechanisms to safeguard commodities funded by the grant at the central level. These mechanisms include pooled procurement of health and non-health commodities, outsourced contract for the provision of adequate storage space at the central level, and a multi-tier distribution system directly from the central level to end-user facilities that bypasses regional and district levels for HIV and malaria commodities. This is to mitigate the associated risks at those levels. However, the audit noted gaps in the supply chain system at the facility level affecting the country's ability to effectively store and account for health commodities.

The OIG identified weak record keeping, inadequate storage space and conditions and ineffective accountability systems at the facility level. The following were identified at the 30 facilities visited:

- 57% of facilities had inadequate storage conditions and practices (e.g: no temperature monitoring devices; no shelving and incorrect use of pallets; the use of First-to-Expire/First-Out policy not adhered to).
- 45% of the facilities had unexplained variances between the quantities of artemisinin-based combination medicines delivered and those recorded on stock cards.
- All facilities visited had unexplained variances between artemisinin-based combination therapy stock card balances and physical stock counts performed by the OIG audit team.
- 57% and 50% of the closing stocks for the Determine and Unigold HIV rapid diagnosis tests, respectively, were not mathematically correct.
- Across all 20 medicines, diagnostic products and commodities that were sampled for the audit, 93% of the facilities reviewed had variances between main pharmacy and dispensing units and 80% had variances between the main pharmacy and lab in at least one of the commodities reviewed.

While the above discrepancies are not financially material based on the sample assessed, they indicate internal control gaps relating to stock management at the facility level. Moreover, the OIG audit team was able to procure donated commodities at commercial outlets or community markets surrounding the facilities visited. The underlying causes of the inability of health facilities to effectively store and account for commodities received include the following:

- ***Lack of functional and effective accountability systems at the facility level for medicines and commodities:*** Although standard operating procedures have been distributed to all districts, the auditors noted that there were none in use at the facilities visited to ensure that medicines and commodities received are accounted for. In addition, there was also no evidence that stock counts and reviews were verified by management at the facility level, as required by the standard operating procedures. 43% of the facilities visited had not received any supervision from the district on pharmaceutical and health product management for malaria commodities in the last three months.
- ***Gaps in Human Resources capacity in pharmaceutical and health product management:*** Nationally, only 19% and 1% of pharmacy technicians and assistants, respectively, are in post.⁵⁹ Other employees, despite not being trained or experienced in pharmaceutical and health product management, are responsible for this area.
- ***Inadequate supervision arrangements:*** 43% of the facilities visited had not received supervision in malaria related pharmaceutical and health product management in the last 90

⁵⁹ Ministry of Health 2014-15 HR vacancy analysis

days as required by the national guidelines, and 97% had not received training in stock management in the past 12 months. 80% of the level of effort of the Local Fund Agent and the fiduciary agent was focused on financial and fiduciary risk whilst only 20% was on supply chain and programmatic activities. The level of efforts on procurement and supply chain management was mainly on procurement-related reviews and not supply chain issues; and

- ***Delay in the enactment of the Pharmacy Bill:*** The Pharmacy Bill, which is expected to strengthen regulations to address in particular the issue of drug theft and diversion, is yet to be sent to Parliament. Two years have passed since an initial draft was developed. A drug availability and security plan to address the theft and diversion of medicines and commodities had been developed but is yet to be fully implemented. The OIG identified some deficiencies in the plan, including a lack of clear responsibilities and timelines for the implementation of the proposed actions. Furthermore, the auditors noted that the actions in the proposed plan are focused primarily at the central and district levels and not at the facility level, where the most significant risk of theft and diversion lies.

At the time of the audit, a drug theft investigation unit had been established by the Ministry of Health. The unit had begun to undertake spot checks at facilities suspected to be involved in theft of commodities and medicines. In addition, the internal audit unit within the Ministry of Health has been resourced to undertake audits of facilities where theft or diversion of health commodities are suspected to have occurred. The Ministry of Health, with the support of partners, have also launched drug theft campaigns to address drug theft and diversion in the country.⁶⁰

Agreed Management Action 3

The Secretariat will follow-up with the Ministry of Health and partners to strengthen the oversight of the Drug Security and Availability plan that was developed in December 2015. The Secretariat will ensure that the implementation of the Action Plan is delegated to a focal person in the Ministry of Health who will be responsible for planning and coordinating the actions, monitoring progress, mobilizing resources, reporting and ensuring the overall success of all interventions.

Owner: Mark Edington, Head Grant Management Division

Implementation date: 30 June 2017

⁶⁰ The Global Fund and USAID Offices of the Inspector General recently launched the 'I Speak Out Now' and the 'Make a Difference' campaigns in the country to fight drug theft in Malawi.

2.2 Pharmacovigilance and monitoring of quality of pharmaceutical and health commodities

There are no systematic measures in place in the country to detect, assess, understand, report and prevent adverse drug reaction or other drug related problems. In addition to the absence of pharmacovigilance systems, the OIG noted that the quality of the funded commodities are not being monitored according to Global Fund requirements. Although there is some post market surveillance for some of the funded medicines and commodities, it is inadequate due to limited scope and coverage. In addition, the surveillance is not within Global Fund requirements.

The audit noted that although funds have been allocated in recent grants to procure external quality assurance services for medicines from a WHO pre-Qualified or ISO 17025 laboratory, an agency had not yet been contracted at the time of the audit. In addition, although the Government of Malawi has earmarked US\$0.7 million towards the establishment of a robust pharmacovigilance system, these funds had not been utilized at the time of the audit.

The Pharmacy Medicines and Poisons Board (PMPB) is working with the Global Fund Secretariat to make use of the Memorandum of Understanding between the United States Government Center for Pharmaceutical Advancement and Training (CEPAT) based in Accra, Ghana to enable CEPAT to provide technical assistance to the PMPB. This is in order to monitor the quality of products in the country and to use the expertise of CEPAT to help the PMPB attain WHO prequalification or ISO certification.

Agreed Management Action 4

The Secretariat will collaborate with the Pharmacy, Medicines and Poisons Board (PMPB) and USAID to enable the PMPB identify and contract a WHO prequalified or ISO 17025 certified laboratory to monitor the quality of medicines.

Owner: Mark Edington, Head Grant Management Division

Implementation date: 30 June 2017

2.3 Supply chain system affecting the stocks-outs and expiries of malaria and TB commodities

Global Fund grants to Malawi consist largely of procurement of pharmaceuticals and health products, accounting for 89% of grant funds between 2009 to 2015. The Global Fund Secretariat has put in place measures including procurement through the Global Fund's pooled procurement mechanism to ensure that health commodities are available to treat patients. However, stock-outs and expiries of health commodities, especially in the local facilities, continue to be a challenge.⁶¹

a) Stock out of malaria commodities

At the time of the audit, the country was facing a national stock-out of artemisinin-based malaria medicines at the facility level. 97% of the 30 facilities visited by the OIG reported stock-outs of artemisinin-based malaria medicines at some point during the audit period, with an average length of stock-out of 67 days. In light of the acute shortage of available stocks, the NMCP has been rationing commodities during the peak malaria transmission period. Contributing factors for the stock-out include:

- non-availability of accurate and reliable Logistic Management Information System /Health Management Information System data to inform accurate quantification and forecasting;
- lack of buffer stock, decided by donor partners including the Global Fund Secretariat to mitigate against unnecessary losses, monitor stock level, and minimize pilferage;
- quantification and forecasting for the new grant were based on the assumption that the mosquito nets mass campaign would be concluded prior to the peak malaria transmission season; however as previously noted, this assumption did not hold true, and may have contributed to increased malaria cases and the corresponding demand for unplanned and unquantified artemisinin-based combination therapy drugs.

At the time of the audit, the Global Fund Secretariat had agreed with the NMCP to procure additional stock of artemisinin-based combination medicine and malaria rapid diagnostic tests to improve critical commodity availability. In addition, the Secretariat is working with other partners in the country to mobilize additional resources to fill the national pipeline and build a modest buffer stock for the program.

b) Expiries of TB drugs

During the audit period, the OIG also identified expired anti-TB medicines funded by the Global Fund valued at US\$0.2 million at both the central level and in 50% of the facilities visited. The identified expiries could have provided treatment for 1,265 people.

These expiries were due to the inadequate review and analysis of both pipeline and TB service data to plan shipments or stagger deliveries based on consumption patterns. The lack of procurement and supply chain capacity within the national program was identified as a contributing factor. More resources would allow the national program to better monitor the stock and take appropriate preemptive actions like redistributing supplies to avoid expiries. Transition of regimen from previous dosing to the WHO recommended dosing also contributed to expiries of pediatric formulations. The program could not exchange the extra stock with other countries as a result of similar stock situation in neighboring countries.

At the time of the audit, an international procurement and supply management technical provider had been seconded to the program by USAID through the Challenge TB⁶² to address this issue.

⁶¹ Also identified in OIG 2012 audit

⁶² Challenge TB is the USAID's main mechanism for implementing its TB strategy as well as contributing to TB/HIV activities under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR)

Agreed Management Action

Please refer to Agreed Management Action 3

03 Effectiveness of the implementation arrangements in ensuring efficient absorption of grant funds and achievement of grant objectives

3.1 Absorption for in-country activities funds

Ineffective program management by implementers and inefficiencies in managing the portfolio by the Secretariat have resulted in low absorption of funds and delays in implementation of key activities.

Global Fund grants to Malawi are largely used to procure pharmaceuticals and health products and to pay for the related supply chain costs. The overall absorption rate of the grants from 2009 to 2015 was 82%, mainly due to Global Fund centralized procurements.

While this overall rate is relatively high, the absorption rate of funds available for in-country activities (excluding funds allocated through the centralized procurement mechanism) has been low. This affects the effective implementation of key activities and the quality of interventions supported by the Global Fund. Only 30% of funds for in-country activities (US\$36m out of US\$124m available) were absorbed by the Principal Recipients from 2009 to 2015.⁶³ Moreover, there is a risk of this trend persisting under the new funding model allocation period. An analysis of the new grants revealed that the Principal Recipients have absorbed less than 1% of the funds available for in-country activities (US\$58.5 million by end of March 2016), although the implementation of these grants started in January 2016.⁶⁴

In addition to the low absorption of grant funds, only 30% of the Year 1 (July 2015 to June 2016) “Willingness to Pay” commitment by the Government of Malawi had been utilized at the time of the audit in May 2016.

a) Ineffective program management

Principal Recipients in Malawi have contributed significantly to the fight against the three diseases, with significant gains registered in the country. However, further progress could have been made in the implementation of program activities.

There is limited capacity of the disease programs resulting in low implementation of activities critical to the overall success of the programs although funds were available. Some of these activities include: TB active case finding and MDR-TB activities (US\$3.3million); procurement of 4.4 million malaria rapid diagnostic tests (US\$2.9 million); expansion of medicines storage infrastructure for priority districts (US\$1.9 million); establishment of pharmacovigilance systems (US\$0.61 million); sample transportation for HIV and TB programs (US\$0.7 million) and all of the funded malaria interventions with the exception of the insecticide-treated nets mass distribution campaign. At the time of the audit, a WHO prequalified laboratory which was to have been contracted by June 2015 had not been finalized resulting in unutilized funds of US\$1.6 million.

A Program Implementation Unit was supposed to be established by the Ministry of Health before the start of the new grants to support the national programs in the implementation of the funded programs. However, the unit was not fully functional at the time of the audit, contributing to the non-implementation of key activities in the current grant by the national programs. In an attempt to address the capacity issues at the country level, the Technical Review Panel of the Global Fund requested the country to develop a human resource capacity development plan. The Global Fund Grant Approval Committee also recommended a detailed assessment of the current human resources for health capacity to develop a health work force capacity development plan. The

⁶³ These are Global Fund grants to the country excluding direct disbursement under the pool procurement mechanism (PPM)

⁶⁴ At the end of quarter one of 2016, only the non-governmental PRs had spent the funds under the new grants. The implementation of the new/current grants started in January 2016 and will end in December 2017

outcome of this assessment will result in the recruitment of up to 1,222 newly qualified health workers to support the implementation of TB/HIV and malaria grants.

b) Inefficiencies in portfolio management

The Global Fund Country Team for the Malawi portfolio has instituted innovative and proactive measures that have improved management of the portfolio and safeguards the Global Fund resources in the country. These measures include pooled procurement of health and non-health commodities at the central level; financial and fiduciary management at the Ministry of Health Principal Recipients, including the services of a fiscal agent; and payment of allowance by an independent service provider at the district and facility levels.⁶⁵ However, there is room for improvement in the Country Team's management of the portfolio as various inefficiencies are delaying the implementation of key activities:

- i. **Approval of requests by Malawi Global Fund Coordinating Committee and Principal Recipients:** The country submitted a request to the Country Team in March 2016 to use the updated donor harmonized daily subsistence allowance rate.⁶⁶ However, this rate had not been approved by the Country Team at the time of the audit, contributing to delays in the implementation of training and supervisory activities under the new grants amounting to US\$3.3 million. There were also delays in the approval of reprogramming requests submitted by the Principal Recipients to the Global Fund, resulting in the delayed implementation of these key activities;
- ii. **Signing and implementation of HIV/AIDS and TB grants managed by a civil society organization:** The implementation of these grants totaling US\$29.3 million was due to commence in January 2016. However, the Global Fund Secretariat only signed the grant in April 2016, several months after Board approval on 22 January 2016. The first disbursement under the grant was made in May 2016. Delays in signing the grant resulted in delays in the planning and implementation of the HIV/AIDS and TB community interventions, amounting to US\$5.3 million. These interventions were planned for the first half of 2016. The Principal Recipient had also not finalized the selection of its sub-recipients at the time of the audit, which impacted the implementation of not only grant activities, but also US Government funded activities that were meant to complement the activities funded by the grant.⁶⁷
- iii. **Significant interventions without detailed budget in the new grants:** At the time of the audit, contrary to the Global Fund Operational Policy Note on Grant-Making, funds amounting to US\$32.7 million have not been detailed, affecting effective planning and implementation of these activities.⁶⁸

In addition to the above, the OIG noted that **the fiscal agent processes, role and responsibilities do not favour effective grant implementation**. The Global Fund contracted the Fiscal Agent to mitigate the fiduciary risk and to improve the financial management of recipients. While the agent has contributed significantly to safeguarding the Global Fund resources, the following areas of improvement were noted by the auditors:

- In some instances, the Fiscal Agent went beyond his scope of work and made decisions that affected the effective implementation of activities. For example, the number of days for GeneXpert training in Lilongwe and an external quality assurance review meeting were reduced, although the expense line was in the approved budget.

⁶⁵ Pool Procurement Mechanism (PPM) is used for the procurement of pharmaceutical and health products at the central level; UNOPS is the procurement agent for non-health equipment; the Fiscal Agent is the financial and fiduciary agent at the central level for the government PRs; G4S is the payment agent for allowance at the district/facility level.

⁶⁶ Daily Subsistence Allowance is the per diem to cover costs for accommodation, meals and incidentals when travelling on missions inside or outside of the country.

⁶⁷ Several Challenge TB activities could not be implemented, pending the start of Global Fund activities from the HIV and TB grants

⁶⁸ Core Operational Policy Manual (clause 27, pg. 15) ...The grant will be submitted to the Board for approval only when it is disbursement-ready and all the required grant making inputs and outputs are in their final form and agreed with the PR...

- Some of the business processes put in place by the Fiscal Agent are lengthy and complex. This has resulted in program staff finding it difficult to adequately complete funding requests, and being reluctant to submit them. Incomplete requests and the time the Fiscal Agent takes to handle requests can result in delays. For example, in the period under review, the auditors noted an average of 17 days (with a maximum of 126 days) between the Fiscal Agent's reception and approval of the funding request. According to the Fiscal Agent's Terms of Reference, the turnaround time of a request should be a maximum of five days. Moreover, the Fiscal Agent approved some proposals but did not make funds available for the implementation of the activities. For example, a proposal for malaria microscopy outreach training and supervision of health workers was approved by the agent on 29 May 2015 but the funds had still not been made available at the time of audit in May 2016.

The Secretariat has put in place measures, including increasing the Country Team resources on the Malawi portfolio through a project called Differentiation for Impact. In addition, there is a Secretariat-wide project called Implementation Through Partnership⁶⁹ which is also aimed to address implementation bottlenecks. At the time of the audit, most of the action points in the work plan were on track although some have been delayed. The Implementation Through Partnership project has contributed to leveraging partner support and collaboration, but there are opportunities to further coordinate partner support to address bottlenecks at the country level to improve implementation.

Agreed Management Action 5

The Secretariat will complete a Risk and Assurance plan for the Malawi portfolio. This plan will consider a comprehensive review of mitigation measures (fiscal agents, logistics agent, PIU etc.) and assurance providers (LFA, external audit etc.) reflecting any changes in agents' contracts, manuals and working documents to ensure effective implementation of the programs.

Owner: Mark Edington, Head Grant Management Division

Implementation date: 31 March 2017

⁶⁹ Implementation Through Partnership is Global Fund initiative for increased technical cooperation through results-oriented support in 20 selected countries.

V. Table of Agreed Actions

#	Agreed Management Action	Target date	Owner
1	<p>The Secretariat, in collaboration with the Ministry of Health and partners, will facilitate the development of an action plan to strengthen the quality of testing and laboratory services across HIV and TB programs in Malawi. Specifically, this plan will include:</p> <ul style="list-style-type: none"> • Training of relevant health workers on HIV counselling and testing; • A mapping of existing investments in laboratory systems strengthening for HIV and TB; • Measures to fill remaining gaps, with a focus on optimizing the use of existing infrastructure and staffing; strengthening management of laboratory commodities; and improving sample transportation. 	31 December 2017	Mark Edington, Head Grant Management Division
2	The Secretariat in collaboration with the Ministry of Health will undertake an assessment of case management under the Continuous Quality Improvement work stream. The current practices will be benchmarked and assessment is expected to provide actionable information for improving case management.	30 June 2017	Mark Edington, Head Grant Management Division
3	The Secretariat will follow-up with the Ministry of Health and partners to strengthen the oversight of the Drug Security and Availability plan that was developed in December 2015. The Secretariat will ensure that the implementation of the Action Plan is delegated to a focal person in the Ministry of Health who will be responsible for planning and coordinating the actions, monitoring progress, mobilizing resources, reporting and ensuring the overall success of all interventions.	30 June 2017	Mark Edington, Head Grant Management Division
4	The Secretariat will collaborate with the Pharmacy, Medicines and Poisons Board (PMPB) and USAID to enable the PMPB identify and contract a WHO prequalified or ISO 17025 certified laboratory to monitor the quality of medicines.	30 June 2017	Mark Edington, Head Grant Management Division
5	The Secretariat will complete a Risk and Assurance plan for the Malawi portfolio. This plan will consider a comprehensive review of mitigation measures (fiscal agents, logistics agent, PIU etc.) and assurance providers (LFA, external audit etc.) reflecting any changes in agents' contracts, manuals and working documents to ensure effective implementation of the programs.	31 March 2017	Mark Edington, Head Grant Management Division

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 Office of the Inspector General (OIG) performs its audits in accordance with the global Institute of Internal Auditors' (IIA) definition of internal auditing, international standards for the professional practice of internal auditing (Standards) and code of ethics. These Standards help ensure the quality and professionalism of the OIG's work.

The principles and details of the OIG's audit approach are described in its Charter, Audit Manual, Code of Conduct and specific terms of reference for each engagement. These help our auditors to provide high quality professional work, and to operate efficiently and effectively. They also help safeguard the independence of the OIG's auditors and the integrity of their work. The OIG's Audit Manual contains detailed instructions for carrying out its audits, in line with the appropriate standards and expected quality.

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

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

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