

Risk & Assurance Toolbox

Objectives



The objective of Risk and Assurance Tool box is to provide the Local Fund Agents (LFAs) with a reference guide on the typology of mitigating actions and available assurance activities against the risks and mitigating actions.

Usage

The Risk & Assurance Toolbox is jointly developed by Technical Advisory and Partnership (TAP), Community Rights and Gender Department (CRG), Program Finance (PF), Supply Chain, Grant Portfolio Solutions and Support and Risk Departments. The Risk and Assurance Toolbox will be updated on an ongoing basis.



The Toolbox includes assurance activities that are provided by LFAs as well as other assurance providers.

Description inside each assurance activity provides only high level overview. Relevant terms of reference should be used for each assurance activity tailored to the country/implementer context and the needs of the Global Fund Country Team.

Overall structure

The Risk and Assurance Toolbox is structured as follows. 21 grant risks as per Intergrated Risk Module are categorized into four risk types:

Programmatic and M&E

Financial and Fiduciary

Health Product Management & Supply Chain

Governance, Oversight & Management

For each risk, there is a guidance on 1) typology of mitigating actions, 2) potential assurance activities, and 3) high leveldetails of each assurance activity. The assurance activity details include general definition, assurance area, frequency requirement/recommendations, guidance/ToR availability and link, providers and average duration.

Programmatic and M&E

List of assurance activities

	•				
1	Review of data systems (community/facility)	2	Program and/or data quality spot checks	3	Joint programmatic, financial and supply chain spot checks
4	Health facility assessments	5	Data quality reviews	6	Review of Laboratory systems
7	Program reviews	8	Partner reviews	9	Routine programmatic analysis
10	Population-based surveys	11	Country evaluations	12	Thematic reviews
13	Prospective Country Evaluation	14	Community based monitoring		
7 10 13	Program reviews Population-based surveys	5 8 11 14	Partner reviews Country evaluations	9	Routine programmatic analysis

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Risks		Typology of mitigating actions	Assuran	ce activities
1.1	Inadequate program design and relevance	Develop/update a costed National Strategic Plan. Coordination with stakeholders (donor and government) for funding programs around the NSP Improve human resources availability and training Use of country specific epidemiological context for interventions and targets. Specific activities to improve linkages between program design and supply chain	7 8 9 10 11 12	Program reviews Partner reviews Routine programmatic analysis Population-based surveys Country evaluations Thematic reviews Prospective Country Evaluation
1.2	Inadequate design and operational capacity of M&E systems	Ensure sufficient grant funding on M&E systems strengthening. Develop costed M&E strategy and Operational Plan. Coordination of donor and government funding for M&E, improve human resource availability and training around the national (and/or disease specific) M&E strategy and Operational Plan Institutionalize/improve data use culture and feedback into improving data quality as well as program quality. Address known gaps M&E Systems specific to the country context. Sufficient resources for planning, implementation, and TA of national HMIS (e.g. DHIS2) strengthening, scale-up, and maintenance, and linkages with other data sources. Improve linkages between HMIS design and supply chain/HPM information system design (e.g. LMIS, Lab systems)	1 7 8 11 11 13 13	Review of data systems (community/facility) Program reviews Partner reviews Country evaluations Prospective Country Evaluation

Inadequate program quality and efficiency

 Improve routine supervision and feedback (following approved) national/ WHO program guidelines of evidence based care).

• Data gap mapping to understand the epidemic and specific program quality issues; and resource mobilization Grant activities aimed to improve program quality and efficiency (for example activities included in PQE pilots) • Strengthen case detection, initiation on treatment and retention. Improve referrals and linkages (e.g. TB/HIV, EID)
 Improve the readiness to provide services at facilities and/or community sites (includes strong linkages with Lab, supply chain and

• RSSH activities focused on HRH- recruitment, retention, training. Institutionalize/improve in-country routine program quality

- HPM interventions).
 Specific grant related activities for monitoring and addressing drug resistance.
- Ongoing TA from partners
 Implement National Laboratory Strategic Plan; and specific activities for national quality standards for lab services, lab quality management, and integration of lab services.

1	Review of data systems (community/facility)
2	Program and/or data quality spot checks
3	Joint programmatic, financial and supply chain spot checks
4	Health facility assessments
5	Data quality reviews
6	Review of Laboratory systems
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8	Partner reviews
9	Routine programmatic analysis
10	Population-based surveys
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12	Thematic reviews
13	Prospective Country Evaluation

1.4	Limited data availability and inadequate data quality
1.5	Limited use of data

- \bullet Ensure sufficient grant funding on M&E systems strengthening.
- Institutionalize/improve in-country routine data quality assurance practices, e.g. routine review process of DHIS2 DQR app reports, programmatic results reported every month jointly between M&E officers and program officers and/or health facility staff.
- Sufficient resources for planning, implementation, and TA of national HMIS (e.g. DHIS2) strengthening, scale-up, and maintenance.
- Integrate/link disease specific and/or other data (e.g. key LMIS indicators) reporting within the national HMIS
- Improve routine supervision and feedback
- Institutionalize/improve the community health information systems (CHIS) and integrate/link the CHIS within the national HMIS
- Improve country's ability to report on disaggregated data and ability to report on outcome and impact indicators.
- Strengthen data use and analytical capacity at all levels of health system
- Develop national HMIS Strategy and Operational Plan.
- Coordination of donor funding for HMIS around the national HMIS Strategy and Operational Plan (and/or M&E Strategy).
- Improve human resources availability and training for HMIS, particularly in coordination with other donors and government.

Ensure sufficient grant funding on M&E systems strengthening.
Include data analysis and use component in the M&E strategy and

Coordination of donor funding for data use around the national (and/or disease specific) M&E strategy and Operational Plan. Institutionalize/improve in-country routine data use practices, e.g. routine review process of DHIS2 Dashboard reports, routine review process of programmatic results jointly between M&E officers and

program officers and/or health facility staff, etc.

RSSH activities focused on Human Resources for Health

recruitment, retention and training.

analytical capacity and data use, etc.

and gender-related barriers to services;

in the HMIS Strategy.

1	Review of data systems (community/facility)
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Increase investments in programs to reduce human rights-related

• Improve resources and linkages from local research and training institutions/universities etc. to the Ministry of Health. Courses in

- Leverage matching funds and other available resources to scale-up programs to remove human rights and gender-related barriers; ensure quality gender-responsive and transforming programs for AGW; and strengthen quality and innovative programs and approaches to address access barriers for key populations
- Conduct baseline assessments to assess human rights-related barriers and programs to address them
- Develop and implement 5-year action plans for comprehensive programs to remove human rights-related barriers;
 Leverage different resources to advocate for a more equitable
- Leverage different resources to advocate for a more equitable regulatory and cultural environment
 Strengthen capacities for programmatic responses to human rights-
- related barriers and disparities (among key national stakeholders and within the Secretariat)

 "Use Performance Frameworks to monitor progress towards removing human rights-related and gender and age-related barriers
- and disparities including through use of sex/age disaggregated data
 Develop standard operating procedures for pre-empting and responding to human rights-related crises in the frame of the response to the 3 diseases;
- Work with technical and community partners for enhanced coordination in relation to safety and security of key and vulnerable populations

1	Review of data systems (community/facility)
7	Program reviews
8	Partner reviews
9	Routine programmatic analysis
11	Country evaluations
12	Thematic reviews
13	Prospective Country Evaluation

Inadequate promotion of human rights and gender equality

Program and/or data quality spot checks
Thematic reviews
Community based monitoring

Review of data systems (community/facility)

There are different types of reviews that fall under this assurance option, but all have the characteristic of reviewing the status and functionality of the data systems (facility and/or community based in the country, paper-based and/or electronic. Key examples are: the review of M&E systems and capacity in the CAT, other independent or country-led data system reviews, or systematic data quality checks from routine data systems (e.g. reports from the WHO DHIS2 data quality review App).

The data system review results provide information on the status and functionality of the data system(s) used in the country, as well as recommendations for improving the design, functionality, efficiency and quality of the data systems. These reviews often also provide real-time data quality results for the whole data system (e.g. on completeness and timeliness)

This activity is therefore useful to assess, define mitigating actions for, and/or assure the M&E system design and capacity risk, particularly for Risk 1.2 Inadequate design and operation capacity of the M&E systems, as well as Risks 1.4 and 1.5.

As relevant

Standard global guidance and tools on M&E systems and/or HMIS assessment (e.g. WHO, UNAIDS, and Measure)

WHO DHIS2 Data Quality Review App

Usually conducted by a service provider contracted by the country to review its systems, but can also be provided by other service providers, including LFA, depending on the funding and implementation mechanism.

4 – 6 weeks; systematic data quality checks from routine data systems is immediate to run results/reports once set up in the system.

Program and/or data quality spot checks

Program and/or data quality spot checks are spot checks following standard TORs developed by GF to assess the program and/or data quality of specific programmatic services, particularly community services, at a targeted number of sites (ideally 20 - 40 sites).

- This activity provides targeted information at the output level on the program and/or data quality for specific programmatic services, especially communitybased services that are not traditionally covered in more facility-based surveys or assurance activities.
- Program and/or data quality spot checks can be used for assurance purposes either to assess a risk and/or to assure a mitigating action, particularly for risk 1.3: Inadequate program quality and efficiency and risk 1.4; Limited data availability and inadequate data quality
- The risk assessment and/or assurance that can be gained from this activity is limited to the sites that are visited usually 20 40 sites: i.e. the results cannot be inferred to a larger sample or wider context given the small sample size. Therefore the scope and goals of this activity should be targeted by the CT - e.g. to assess the program and/or data quality of a specific service for a new SR in a certain geographic area.
- When used in this targeted manner, this activity is useful for informing risk assessment and assurance of mitigating actions for specific program and/or data quality issues, and providing results that can be used for targeted discussions with the relevant PRs/SRs.

As relevant

There are 15 predefined Programmatic Spot Checks with standard TOR and data entry templates as listed below. Contact Country Teams for further guidance.

- o Community-based HIV testing services
- o Prevention services among key populations
- o Community-based malaria case management activities
- o Community TB activities (including MDR TB where appropriate) with focus on treatment
- o DHIS implementation and hospital data recording/coding system
- o Implementation of malaria vector control interventions (LLIN distribution and IRS)
- o Assessment of implementation of Opioid Substitution Therapy program o Assessment of supervision effectiveness in a given health program
- o Assessment of training activities and related expenses
- o HPM ACT Co-payment Mechanism First Line Buyers
- o HPM LMIS Implementation Review
- o HPM Procurement Review
- o HPM Quality Monitoring for Pharmaceuticals
- o HPM Supply Chain Management Review

ToRs are also available on LFA website

Providers LFA or other assurance providers

Average duration 4-6 weeks

Joint programmatic, financial and supply chain spot checks

This activity should be used when either the Program Quality verifications and spot checks and /or Data Quality verifications and spot checks assurance activity(ies) are being conducted jointly with other spot checks (e.g. Finance, Supply chain , Laboratory etc.) for effective triangulation.

Assurance areas

See guidance section for program, data, financial and/or supply chain spot checks as relevant

As relevant

See guidance section for program, data, financial and/or supply chain spot checks as relevant

Providers LFA

See guidance section for program, data, financial and/or supply chain spot checks as relevant

Health facility assessments

This activity refers to health facility assessments of service availability and readiness and quality of care either using a nationally representative sample (generally around 150-200 sites) or a targeted sample (generally 20-40 sites).

A health facility assessment is an assessment of the status of a country's health facility services, including but not limited to HTM programs. For each service, this includes 1) whether the service is offered, 2) whether the minimum staff, equipment, and medicines and communities to conduct the service are available, and 3) additional aspects of the quality of the service such as the process of care.

A health facility assessment is useful for assessing, defining mitigating actions for, and/or assuring program quality risks, (1.3 and 1.4).

1) nationally representative HFA

The results from a program quality health facility assessment provide extensive information at the output and outcome level on the state of services offered in health facilities across the country.

2) targeted HFA A targeted HFA provides targeted information at the output level on the state of services offered in health facilities.

The risk assessment and/or assurance that can be gained from a targeted HFA is limited to the sites that are visited - usually 20 - 40 sites; i.e. the results cannot be inferred to a larger sample or wider context given the small sample size. Therefore the scope and goals of a targeted HFA should be targeted by the CT - e.g. to assess the program quality of a certain facility profile for a certain SR in a certain geographic area.

When used in this targeted manner, this activity is useful for informing risk assessment and assurance of mitigating actions for program quality issues, and providing results that can be used for targeted discussions with the relevant PRs/SRs.

Recommended by WHO to be routinely conducted by a country to assess its health facilities' services as part of the national routine program monitoring and improvement cycle

Standard global guidance, TORs, and tools. Examples include WHO Service Availability and Readiness Assessment (SARA): service availability and readiness assessment: http://www.who.int/healthinfo/systems/sara_introduction/en/; the USAID / DHS Program Service Provision Assessment (SPA): https://dhsprogram.com/What-We-Do/Survey-Types/SPA.cfm; the World Bank Service Delivery Indicators (SDI): http://www.sdindicators.org/

For a targeted HFA, the WHO SARA is also used for the TORs, with adaptations for use with a small sample size. Contact Country Teams for further guidance.

- 1) national: Conducted by the country with strong TA from technical partners, QA from GF OPEX if needed
- 2) targeted: LFA or other assurance providers

- 1) national: ~6 months
- 2) targeted: 4-6 weeks

Data quality reviews

This activity refers to assessments using the WHO Data Quality Review Toolkit either using a nationally representative sample (generally around 150-200 sites) or a targeted sample (generally 20-40 sites).

A data quality review is an assessment of the quality of data reported through the national HMIS. This includes 1) a verification of the accuracy, completeness and timeliness of the data at each level of the system 2) an assessment of the M&E systems at each level 3) a further assessment of the data quality at the national

Data quality reviews are useful for assessing, defining mitigating actions for, and/or assuring data quality risks. (1.3 and 1.4).

1) nationally representative DQR

The results from a nationally representative DQR provide robust results at the output and outcome level on the quality of data reported through health facilities across the country.

2) targeted DQR

A targeted DQR provides targeted information at the output level on data quality, most commonly for facility based data, but can also be used for community data quality.

The risk assessment and/or assurance that can be gained from a targeted DQR is limited to the sites that are visited - usually 20 - 40 sites; i.e. the results cannot be inferred to a larger sample or wider context given the small sample size. Therefore the scope and goals of a targeted DQR should be targeted by the CT - e.g. to assess the data quality of a certain facility profile for a certain SR in a certain geographic area.

When used in this targeted manner, this activity is useful for informing risk assessment and assurance of mitigating actions for data quality issues, and providing results that can be used for targeted discussions with the relevant PRs/SRs.

Recommended by WHO to be routinely conducted by a country to assess its data quality as part of the national routine program monitoring and improvement cycle

Guidance/ToR availability and link

Standard WHO guidelines: the WHO Data Quality Review Toolkit: http://www.who.int/healthinfo/tools_data_analysis/en/

For a targeted DQR, the WHO Data Quality Review Toolkit is also used for the TORs, with minor adaptations for use with a small sample size. For further guidance, refer to the LFA Website (https://www.theglobalfund.org/en/lfa/guidelines-tools/ongoing-grant-management/) or contact Country Teams.

- 1) national: Conducted by the country with strong TA from technical partners, QA from GF OPEX if needed
- 2) targeted: LFA or other assurance providers

1) national: ~6 months 2) targeted: 4-6 weeks

Review of Laboratory systems

This activity is a full or partial review of the structure, functionality, availability and the quality of the medical Laboratory services and systems in the country.

The Laboratory system review findings provide information on the structure and functionality of the system(s) and the availability and quality of services in country, as well as recommendations for improving the national lab strategy, its performance, supply chain, efficiency and quality of services.

i. Assess the availability and quality of laboratory services required by the national programmes

- ii. Assess the adequacy of the supply chain management systems and testing protocols/methodology used for HIV, TB and Malaria including laboratory equipment, reagents, and consumables
- iii. Understand the environment in which laboratory services are provided
- iv. Estimate the testing coverage and gaps in services, by cross-checking with programmatic results
- v. Identify the PSM related challenges that could be overcome with appropriate intervention in order to ensure continuous availability of equipment, quality test kits, reagents and consumables
- vi. Assess, define mitigating actions for, and/or assure the Laboratory system development is based on a strategy, is effective, functional and coordinated in a tiered quality assured service delivery network.

As relevant

Based on standard global guidance and tools (e.g. WHO)

ToR available on LFA web pages

LFA webpages

Usually conducted by a service provider contracted by the country to review its systems, but may be also completed more independently as well, depending on the funding/implementation mechanisms.

It may conducted by the LFA with adequate expertise.

Average duration 4-6 weeks

Program reviews

National program reviews constitute periodic assessments of program activities and achievements against national strategic objectives and targets. National program reviews play crucial role in terms of informing the development and updating of national disease program strategic plans, which in turn, form the basis for resource mobilization, access to funding and strategic investment decisions.

The epidemiological review, the findings and the recommendations from the national program review provide robust information about the status of the national and/or disease program at the outcome and impact level.

These are useful to assess, define mitigating actions for, and/or assure the program design, relevance and quality risks, particularly risks 1.1, 1.3 and 1.4.

Once every 3 years, particularly for High Impact countries

Guidance/ToR ailability and link

 $Standard\ WHO\ guidelines.\ HIV:\ http://www.who.int/hiv/pub/toolkits/hiv-response-guide/en/;\ TB:\ http://www.who.int/tb/publications/framework-tb-programme$ reviews/en/; Malaria: http://www.who.int/malaria/publications/atoz/whomprmalariaprogramperformance manual/en/atorial m

Providers

Led by respective national health authorities and carried out jointly with WHO and other partners

Average duration ~3 months

Partner reviews

General Definition

This activity refers to any programmatic or M&E reviews conducted by other partners.

Partners will have many different reasons for conducting programmatic and/or M&E reviews, so this activity largely will provide opportunistic (only) risk and assurance information. However the independence, technical expertise and scope of these reviews is generally very high, so these can be well suited to risk and assurance purposes. This activity also provides a cost effective method to obtain risk assessment and assurance, albeit ad hoc.

Varies

Standard partner SOWs

Providers Providers selected by partners

Average duration Varies

Routine programmatic analysis

This activity refers to non-population based special studies or evaluations funded by the grants and/or other donors and conducted by the country with technical assistance from technical partners. Examples of these types of studies include TB pathway analysis. ART cohort analysis. HIV cascade analysis, etc.

These types of special studies or evaluations provide critical information at the outcome level about the country's specific epidemic that are needed to inform program design and effectiveness

These are particularly useful for assessing program design and program quality risks (1.1. Inadequate program design and relevance and 1.3 Inadequate program quality and efficiency), as well as for defining mitigating actions for these two risks. Triangulation of results from routine programmatic analysis can also be used as assurance for data quality risks

For example, a TB pathway analysis study will provide results showing where TB cases are being missed and informing where to better target interventions to reach these missing cases. As another example, HIV cascade analysis results are used to identify issues of retention of HIV patients and can inform the interventions to improve retention.

Some special studies can also be used for assuring program design and quality risk mitigating actions. For example, HIV cascade analysis repeated every year will show whether retention of HIV patients has improved over time.

Varies depending on the specific study

Varies depending on the specific study. In general, specific global guidance or tools are adapted to country context with strong TA and QA from technical partners are used for each type of special studies

Providers

Conducted by the country with strong TA and QA from technical partners

Average duration 4-6 months

Population-based surveys

Population-based surveys, such as the Demographic and Health Survey (DHS), AIDS Indicator Survey (AIS), TB Prevalence Survey, Malaria Indicator Survey (MIS) and Multiple Indicator Cluster Survey (MICS), are large surveys to generate nationally, sub-nationally and/or group-specific representative data on key measurements required for the program design, grant performance and impact progress tracking.

The results from a population based survey provide critical information on the status of the epidemic surveyed at the outcome and impact level.

These are useful for assessing, defining mitigating actions for, and/or assuring program design, relevance and quality risks (1.1. Inadequate program design and relevance and 1.3 Inadequate program quality and efficiency)

Varies depending on the specific survey

Varies depending on the specific survey. Some examples include DHS: https://dhsprogram.com/, MICS: https://www.unicef.org/statistics/index_24302.html, MIS: https://dhsprogram.com/what-we-do/survey-types/mis.cfm.

Conducted by the country with strong TA and QA from technical partners

Average duration 6-12 months

Country evaluations

This activity refers to evaluations of the program and/or data quality of the country programs. One key example are the Focus country evaluations commissioned by the Global Fund that are required once every three years per Focus country as part of D4I requirements.

Assurance areas

The program evaluations provide evidence on effectiveness, impact, program and data quality, and address issues around sustainability.

This evidence is useful for assessing, defining mitigating actions for, and/or assuring program and/or data design, relevance and quality risks (Risk 1.1-1.5)

As relevant: once every 3 years in Focus countries

Standard SOWs (MECA Team)

Depending on funding source. For Focus country evaluations, consulting firms have been selected via RFP to perform the evaluations

Average duration

~3 months

Thematic reviews

This activity refers to reviews that addresses special thematic issues across countries at a regional or global level. The results inform the further design, reprogramming and progress assessment of selected themes in any of three disease programs or cross-cutting aspects. Examples include HIV key population program globally, MDR-TB in EECA or iCCM for malaria in Africa, etc.

These thematic reviews generate evidence whether the Global Fund is investing in the right interventions in the right groups and right places for the themes This evidence is useful for assessing, defining mitigating actions for, and/or assuring program and/or data quality risks (Risk 1.1 and Risk 1.3 – 1.5) across countries Standard SOWs (MECA Team) Providers selected by GF through RFP

Prospective Country Evaluation

Average duration

This activity refers to an in-depth, country-level, prospective evaluation that utilizes a variety of methods to provide a detailed picture of the implementation, effectiveness and impact of Global Fund-supported programmes in selected countries.

PCEs are expected to support identifying outstanding risk and challenges (assessing and assuring)- related to both Global Fund practices and country contexts and practices that affect program performance - and opportunities that would strengthen programmatic outcome, in order to inform and improve program quality, impact, effectiveness, and value-for-money (defining mitigating actions), in the following 8 countries: Cambodia, Myanmar, DRC, Uganda, Mozambique, Sudan, Senegal and Guatemala.

Evaluation protocol (TERG)

Providers

Providers already selected by TERG

Average duration 3 years

3-6 months

Community based monitoring

Community Based Monitoring (CBM) is a process by which service users or local communities gather and use information on service provision or information on local conditions impacting on effective service provision, in order to improve the responsiveness, equity and quality of services and hold service providers to account. CMB in relation to health can be general (e.g. scorecards for a range of health services at community level), or disease specific, or even sub-programme specific (e.g. monitoring of HIV and/or TB treatment access or of human rights barriers for key populations).

CBM can be a critical component in efforts to strengthen program quality and impact. The model provides for rapid identification of a range of service and system related issues and bottlenecks including stock outs, retention in care and treatment, accessibility etc. CBM models contribute to the reduction in human rights and gender related barriers in access to services when data derived is strategically utilized to inform systems and service development as responsive and tailored to needs of different communities.

CBM is an ongoing program activity.

To be updated

Local community and civil society organization (in collaboration with MoH etc)

Average duration Ongoing

Financial and Fiduciary

List of assurance activities

1	Budget Review	2	Review of adequacy of the funds flow	3	Value for money reviews and analysis
4	Review of independence and effectiveness of the audit arrangement and function	5	Domestic funding and co-financing, willingness to pay verification and analysis	6	Review preparedness for reliance on country financial management systems/assurance mechanisms
7	Review design and/or effectiveness of the internal control environment	8	Financial data quality review	9	Expenditure verification and / or review of compliance
10	Validation of financial statements	11	Audit related activities (a,b,c,d)	12	Country Coordinating Mechanism expenditure verification
13	Review of reconciliations of imprests, SR/SSR advances and decentralized activities	14	Financial spot checks	M&E 3	Joint programmatic, financial and supply chain spot checks
15	Fraud specific review	16	Review of Financial Management Transition	17	Analysis of root causes of systemic/structural bottlenecks
18	Budget Variance Analysis	19	Fixed (non-health) Asset Verification		

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18 Budget Variance Analysis		19	Fixed (non-health) Asset Verification			
Mo	apping of m	nitigations & assurance against risks		Typology of mitigating actions		Assurance activities
					1	Budget Review
					2	Review of adequacy of the funds flow
					3	Value for money reviews and analysis
	2.1	Inadequate flow of funds arrangements		 Implement alternative fund transfer mechanism (mobile money, payment agent, etc) 	13	Review of reconciliations of imprests, SR/SSR advances and decentralized activities
		madequate now or runus arrangements		Review monthly the aging balance of advances to sub-recipients	17	Analysis of root causes of systemic/structural bottlenecks
					18	Budget Variance Analysis
					1	Budget Review
				Use of Fiscal/Fiduciary Agent to develop and ensure adherence to established policies and procedures Technical Assistance to improve control design and operating effectiveness	4	Review of independence and effectiveness of the audit arrangement and function
		Inadequate internal controls			6	Review preparedness for reliance on country financial management systems/assurance mechanisms
					7	Review design and/or effectiveness of the internal control environment
					9	Expenditure verification and / or review of compliance
	2.2				10	Validation of financial statements
				Exception reporting to management on internal control	12	Country Coordinating Mechanism expenditure verification
				weaknesses and actions to be taken to address the identified weaknesses and potential financial risks	16	Review of Financial Management Transition
					17	Analysis of root causes of systemic/structural bottlenecks
					18	Budget Variance Analysis
					19	Fixed (non-health) Asset Verification
					2	Review of adequacy of the funds flow
					3	Value for money reviews and analysis
						Review design and/or effectiveness of the internal control environment
				 Use of Fiscal/Fiduciary Agent Design of anti-fraud policy and fraud awareness 	8	Financial data quality review
	23			Reporting to Audit Committee or those charged with governance	9	Expenditure verification and / or review of compliance
		Financial fraud, corruption and theft		on instances of suspected or actual fraud incidents covering a defined period of time	11	Audit related activities (a,b,c,d)
				• Implement a whistle-blower policy e.g. OIG Speak Out Campaign	14	Financial spot checks
					M&E 3	Joint programmatic, financial and supply chain spot checks
					15	Fraud specific review
					19	Fixed (non-health) Asset Verification



- Change/upgrade implementer accounting system and map to donor reporting requirement

 Technical Assistance on financial management/recruitment of
- competent financial manager/clerk
- Use of Fiscal/Fiduciary Agent
- Established procedures to ensure management is presented with account reconciliations on a periodic basis, including explanations on variances identified

5	Domestic funding and co-financing, willingness to pay verification
6	Review preparedness for reliance on country financial management systems/assurance mechanisms
7	Review design and/or effectiveness of the internal control environment
8	Financial data quality review
10	Validation of financial statements
11	Audit related activities (a,b,c,d)
16	Review of Financial Management Transition
17	Analysis of root causes of systemic/structural bottlenecks
18	Budget Variance Analysis

- Use of a procurement agent e.g. PPM etc
- Monthly budget monitoring with explanation of variances and reprogramming
- Periodic review of pre-qualified lost of supplies and market conditions survey
- Training on procurement policies and procedures
- Development of required documentation (tools, templates) for all methods of procurements
- 1 **Budget Review** 2 Review of adequacy of the funds flow 3 Value for money reviews and analysis 9 Expenditure verification and / or review of compliance 13 Review of reconciliations of imprests, SR/SSR advances and decentralized activities 18 Budget Variance Analysis

- Change external auditor
- Reinforce internal audit function (skillset, training, etc)
- 4 Review of independence and effectiveness of the audit arrangement 8 Financial data quality review 10 Validation of financial statements 11 Audit related activities (a,b,c,d)

Budget Review This is the process of review of the Grant budget for reasonableness, relevance of proposed activities or modifications to the program objectives and considerations on cost efficiencies Budget review is designed to provide assurance that the grant budget is reasonable to achieve the grant objectives and is based on the most economic and efficient use of grant resources. Frequency requirement/recomme ndations - Mandatory throughout grant lifecycle - Guidelines for Grant Budgeting https://www.theglobalfund.org/media/3261/core_budgetinginglobalfundgrants_guideline_en.pdf?u=636486806820000000 - Financial Management Handbook for Grant Implementers https://www.theglobalfund.org/media/7034/financial_grantimplementersmanagement_handbook_en.pdf?u=636487747740000000 - LFA detailed Budget Review and Recommendation Form - LFA Average duration

Review of adequacy of the funds flow

General Definition

Funds flow refers to the manner in which the disbursements of cash resources is channeled from the Global Fund to various grant implementers for the execution of program activities, in accordance with grant agreements and the agreed implementation arrangement map. This involves the need to understand how funds (including the various steps) will be transmitted from the Global Fund to a Principal Recipient and from a Principal Recipient to sub-recipients and other implementers in the implementation landscape

Assurance areas

Reviews aimed at providing assurance that that funds budgeted by the Global Fund are not used by Principal Recipient (PR) or Sub-Recipients (SRs) outside the timelines agreed in the grant budget due to:

(i) inadequate implementation arrangements;

(ii) bottlenecks in the flow of funds from the Principal Recipients to the SRs and other implementing partners including beneficiaries due to external factors; and (iii) inadequate cash flow management by the Principal Recipient.

Frequency
equirement/recomme

- Mandatory during grant-making for new PRs and strongly recommended throughout grant implementation
- Strongly recommended for continuing PRs during grant-making and throughout grant implementation

Guidance/ToR

- Guidelines for Grant Budgeting https://www.theglobalfund.org/media/3261/core_budgetinginglobalfundgrants_guideline_en.pdf?u=636486806820000000
- The Global Fund Guideline on Financial Risk Management (Specific ToRs yet to be developed)

Note: Related LFA service will be available in LFA portal upon the issue of the respective terms of reference.

Providers

- LFA

Average duration

Value for money reviews and analysis

General Definition

This is the process of reviewing grant budgets to identify:

- (i) whether a fair price is paid for program activities as compared to local market conditions and funds are not misused; and
- (ii) whether fund is allocated effectively and efficiently to reach the targets

Assurance areas

Review and analysis aimed at providing assurance that Global Fund resources are not lost because of the lack of Effectiveness and Efficiency and implementers not choosing the most economical options

requirement/recomme ndations

- Strongly recommended during grant-making and throughout grant implementation

Guidance/ToR availability and link

- Guidelines for Grant Budgeting https://www.theglobalfund.org/media/3261/core_budgetinginglobalfundgrants_guideline_en.pdf?u=636486806820000000
- Financial Management Handbook for Grant Implementers (Suggested scope of work in section on Funds Flow) https://www.theglobalfund.org/media/7034/financial_grantimplementersmanagement_handbook_en.pdf?u=636487747740000000
- The Global Fund Guideline on Financial Risk Management (Specific ToRs yet to be developed)

Note: Related LFA service will be available in LFA portal upon the issue of the respective terms of reference.

Providers - LFA
- External Auditors

Average duration

Review of independence and effectiveness of the audit arrangement and function

General Definition

This is the process where the Global Fund establishes, in consultation with the Implementer during grant-making, certain aspects of the conduct of the audit process, including the following:

(i) the entity to conduct the audit (Supreme Audit Institution, Corporate auditors, UN OAI, contractual auditors)

- (ii) the overall approach to auditor selection and approval and an assessment of its adequacy
- (iii) whether the standard GF audit terms of reference would apply.

It may also involve the review of the internal audit (IA) function of the implementer to assess its objectivity and independence, including the availability of qualified professionals to provide quality internal audit deliverables

Assurance areas

Reviews aimed at providing assurance that external and internal auditing arrangements are effective (design and operating effectiveness) to provide the Global Fund with the level of financial assurance expected in this area

Frequency equirement/recomm ndations

- Strongly recommended at grand-making and for internal audit also throughout grant lifecycle

Guidance/ToR availability and link - Guidelines for Grant Budgeting https://www.theglobalfund.org/media/3261/core_budgetinginglobalfundgrants_guideline_en.pdf?u=636486806820000000

- LFA Review of PR/SR Audit Arrangements
- Guidelines for Annual Audits of Global Fund Grant Program Financial Statements

Note: Related LFA service will be available in LFA portal upon the issue of the respective terms of reference.

Providers

- LFA

Average duration

Domestic funding and co-financing, willingness to pay verification and analysis

General Definition

The Global Fund Sustainability, Transition and Co-financing Policy https://www.theglobalfund.org/media/4221/bm35_04-sustainabilitytransitionandcofinancing_policy_en.pdf

Assurance areas The Global Fund Sustainability, Transition and Co-financing Policy

Frequency requirement/recomme ndations

The Global Fund Sustainability, Transition and Co-financing Policy

Guidance/ToR availability and link

- $\hbox{-} \ {\sf Guidance} \ {\sf on} \ {\sf LFA} \ {\sf verification} \ {\sf of} \ {\sf Counterpart} \ {\sf Financing} \ ({\sf Available} \ {\sf to} \ {\sf CTs} \ {\sf upon} \ {\sf request})$
- Regional Audit Terms of Reference (Optional Audit). Contact Country Teams for further guidance.

Providers

- LFA
- External Auditor

Average duration

Review preparedness for reliance on country financial management systems/assurance mechanisms

General Definition

This refers to the assessment performed by the Global Fund and/or partners to determine whether an implementer has adequate country financial management systems and capabilities to ensure accountability, including sound and robust financial management. The goal is to support effective transitioning from Global Fund and other donor financing by supporting the use and strengthening of country financial management systems

Assurance areas

Review outcome is aimed at providing a reasonable basis for decision-making by the Global Fund and/or partners, on whether host country financial management systems are adequate, with a long term view of building resilient and sustainable systems for Health to support the grant implementation and enhance the financial management and oversight capacity of national entities.

Frequency requirement/recomme ndations

- Strongly recommended during grant-making and throughout grant implementation $% \left(1\right) =\left(1\right) \left(1\right) \left($

Guidance/ToR availability and link

- Co-LINK Project Implementation Framework

	- LFA
Providers	- External Auditor
	- Partners
Average duration	
	Review design and/or effectiveness of the internal control environment
General Definition	This activity consists of: (i) identifying per key process, the main risks as well as the controls designed by management to prevent/ reduce the risks, (ii) assessing whether the controls, in their current design are effective or not (iii) test whether these controls are effectively implemented.
	In doing so, it is important for the reviewer to consider the role of those charged with governance in enforcing the culture of control in the entity and how the outcome of the reviews is used to improve the overall environment.
Assurance areas	Reviews aimed at providing assurance that Global Fund resources are not lost as a result of lack of (i) well designed and effective control at entity, process and transactional levels, (ii) compliance with policies, procedures and applicable law and (iii) safeguarding of Global Fund assets.
Frequency requirement/recomme ndations	- Mandatory during grant-making for new PRs and strongly recommended throughout grant implementation - Strongly recommended for continuing PRs during grant-making and throughout grant implementation
	- Guidelines for Grant Budgeting https://www.theglobalfund.org/media/3261/core_budgetinginglobalfundgrants_guideline_en.pdf?u=636486806820000000
Guidance/ToR availability and link	- Financial Management Handbook for Grant Implementers (Suggested scope of work in section on Funds Flow) https://www.theglobalfund.org/media/7034/financial_grantimplementersmanagement_handbook_en.pdf?u=636487747740000000
	- The Global Fund Guideline on Financial Risk Management (Specific ToRs yet to be developed)
	- LFA
Providers	- External Auditor
	- Partners
Average duration	

8 Financial data quality review

General Definition

This involves carrying out a review of information provided by an implementer so as to drive accuracy of cash/stock/assets reconciliation, expenditure forecast, and cash flow forecast.

This is essentially reconciling and correlating data from different Implementer reporting to confirm the quality of reported information and to facilitate decision-making

Assurance areas

Financial data quality review is to provide assurance on the completeness, accuracy, and reasonableness of cash/stock/assets reconciliation, expenditure forecast, and cash flow forecast

Frequency requirement/recomme ndations - Strongly recommended throughout grant lifecycle and at year end prior to external audit to ensure accurate and complete financial information

Guidance/ToR availability and link - Guidelines for Annual Audits of Global Fund Grant Program Financial Statements

Providers

- LFA

Average duration

Expenditure verification and / or review of compliance

General Definition

This involves carrying out verifications of amounts reported by the implementer to source documents (tracing reported expenditures to approved budget lines/activities, checking invoices and other supporting documents justifying the use of funds to reported expenditures etc.).

Compliance reviews involve assessing the implementer's adherence to local laws and regulations relating to expenditures or to specific requirements in the Grant Agreement

Assurance areas

Expenditure verification and / or review of compliance is an activity to aimed at providing assurance that the grant funds have been used in conformity with the provisions of the Grant Agreement, including the approved budget and work plan and any amendments thereto as contained in implementation letters.

This service would usually be used at the PR level. On the SR/SSR level this type of activity is usually included in the Financial Spot Checks

- Mandatory during grant reporting cycle for HI and Core portfolio (PU/DR reporting) and/or at year end during external audit process - Mandatory at year end during external audit process for Focused portfolio - Guidelines for Grant Budgeting - Financial Management Handbook for Grant Implementers Guidance/ToR availability and link - The Global Fund Guidelines on Financial Risk Management - PUDR Guidelines - External Auditor Average duration 10 Validation of financial statements This is the process where the external auditor plans and performs the audit to obtain reasonable assurance, by the auditor obtaining sufficient and appropriate audit evidence, that the financial statements are prepared in all material respects in accordance with an applicable financial reporting framework. The auditor communicates this by forming an opinion in the audit report on whether the auditor concludes that he/she has obtained reasonable assurance that the financial statements as a whole are free from material misstatements whether due to fraud or error. Assurance areas Validation of financial statements aims at providing assurance that the financial statements are accurate and complete - Mandatory at year end during external audit process - Guidelines for Annual Audits of Global Fund Grant Program Financial Statements Providers - External Auditor Average duration Audit related activities: Review of audit terms of reference This activity requires the LFA (mandatory for Focused portfolio) to review the terms of reference for the audit of an Implementer to ensure that the proposed terms of reference is in compliance with the requirements of the standard terms of reference as stipulated in the guidelines for Annual Audits of Global Fund **Grant Program Financial Statements** The review of the proposed terms of reference provides assurance that they are in compliance with the provisions of the standard terms of reference. Note: This service will not be required in the case of the regional audit initiative and the single audit approach with INGOs. - 3 months after grant start date for Year 1 of IP - Subsequently, prior to start of auditor selection process - Guidelines for Annual Audits of Global Fund Grant Program Financial Statements - LFA Review of PR/SR Audit Arrangement - LFA Average duration Audit related activities: Review of the auditor selection This activity refers to the review of the auditor selection process to ascertain whether the process was carried out in compliance with the guidelines for Annual Audits of Global Fund Grant Program Financial Statements and the Global Fund procurement regulations. This review is aimed at providing assurance that the selected auditor meets the minimum requirements stated in the guidelines for Annual Audits of Global Fund Grant Program Financial Statements, including ensuring that the Global Fund approved the selection process which was carried out following a competitive and transparent process - Prior to start of audit field work but after finalization of auditor selection

- Guidelines for Annual Audits of Global Fund Grant Program Financial Statements

- LFA Review of PR/SR Audit Arrangement

- LFA

11c

Audit related activities: External audit report review and analysis

General Definition

This activity requires the LFA (for Focused portfolio) or the Finance specialist (for HI and Core portfolio) to review that the audit report presented by the external auditor to ensure that it has been prepared in compliance with the terms of reference as stipulated in the guidelines for Annual Audits of Global Fund Grant Program Financial Statements

Assurance areas

The review and analysis of the audit report provides assurance that the audit was conducted in compliance with the terms of reference.

Frequency requirement/recommondations

- Upon submission of the final audit report by the external auditor

Guidance/ToR availability and link - Guidelines for Annual Audits of Global Fund Grant Program Financial Statements

- LFA Review of PR/SR Audit Arrangement

Providers

- LFA

Average duration

11d

Audit related activities: Follow up on audit recommendations

General Definition

This activity refers to the monitoring by the LFA (for Focused portfolio) or the Finance specialist (for HI and Core portfolio) of the rate at which an implementer is clearing/addressing recommendations from the audit report and management letter.

Assurance areas

The follow up of audit recommendations provides assurance that the Principal Recipient has taken actions within specified timelines to address the findings included in the audit report and in the Management Letter

Frequency quirement/recommondations

- Can be done by the LFA as part of their assurance work (semester with PU/DR reviews for HI and Core portfolio and annual for Focused portfolio
- For Core and HI, Finance Specialist can monitor quarterly or as part of in-country missions

Guidance/ToR availability and link

- Guidelines for Annual Audits of Global Fund Grant Program Financial Statements
- LFA Review of PR/SR Audit Arrangement
- Financial Management Handbook for Grant Implementers https://www.theglobalfund.org/media/7034/financial_grantimplementersmanagement_handbook_en.pdf?u=636487747740000000

Providers

- LFA
- External Auditor

Average duration

12

Country Coordinating Mechanism expenditure verification

General Definition

This involves carrying out verifications of amounts reported by the CCM to source documents (tracing expenditures to budgeted activities to see if the expenditure is included in the approved budget, checking invoices and other supporting documents to the amounts reported by the implementer). Usually done by the LFA or external auditors

Assurance areas

This review is aimed at providing assurance that CCM expenditures have been used in conformity with the CCM agreement

Frequency requirement/recomme ndations

CCM Funding Policy

https://tgf.share point.com/sites/inside/investing-for-impact/managing-grants/operational-guidance and the property of the p

Guidance/ToR vailability and link - CCM Funding Policy

https://tgf.share point.com/sites/inside/investing-for-impact/managing-grants/operational-guidance and the property of the p

- Regional Audit - Terms of Reference (Optional Audits). Contact Country Teams for further guidance.

Providers

- LFA
- External Auditor

Average duration

12

Review of reconciliations of imprests, SR/SSR advances and decentralized activities

General Definition

This refers to the review of the periodic reconciliations that the Principal Recipient performs on cash advances made to the SRs/SSRs for the implementing of grant activities. The PR reconciles the cash advances made, the opening bank account cash balance of the SR/SSRs, expenditures made during the period under review and the ending cash balance, including forecast for subsequent periods.

Assurance areas

This review is aimed at providing assurance that there is (i) compliance with provisions of the grant agreement between GF and the PR and with that of the subgrant agreements between the PR (SR) and the SRs (SSRs) (ii) accuracy of the financial and programmatic information provided by SRs (SSRs) and reported by the PR to the Global Fund as part of the PUDRs (iii) that Global Fund resources have been used appropriately in line with the approved work plan and budget for the intended purposes

Frequency requirement/recomm

- Strongly recommended throughout grant lifecycle

Guidance/ToR availability and link - Guidelines for Grant Budgeting https://www.theglobalfund.org/media/3261/core_budgetinginglobalfundgrants_guideline_en.pdf?u=636486806820000000

- Financial Management Handbook for Grant Implementers

https://www.theglobalfund.org/media/7034/financial_grantimplementersmanagement_handbook_en.pdf?u=636487747740000000

- The Global Fund Guidelines on Financial Risk Management

Note: Related LFA service will be available in LFA portal upon the issue of the respective terms of reference.

Providers

- LFA

- External Auditor

Average duration

Financial spot checks

General Definition

This activity refers to the enhanced financial verifications that are done at the level of high-risk implementers or high risk activities or interventions that are susceptible to misuse whether due to fraud or misappropriation. It involves verifying reported amounts to source documents.

Assurance areas

This reviews is aimed at providing assurance that funds relating to high risk activities or interventions and/or high risk implementers, are being spent appropriately.

Usually this service is requested at the SR/SSR level.

Frequency requirement/recomme ndations

- CT prioritization in LFA work plan

- Guidelines for Grant Budgeting

- LFA Manual

Guidance/ToR availability and link

- The Global Fund Guidelines on Financial Risk Management

- Terms of Reference on Financial Verification at SR/SSR level (available on the LFA website)

Providers

- LFA

- External Auditor

Average duration

Joint programmatic, financial and supply chain spot checks

General Definition

This activity should be used when either the Program Quality verifications and spot checks and /or Data Quality verifications and spot checks assurance activity(ies) are being conducted jointly with other spot checks (e.g. Finance, Supply chain , Laboratory etc.) for effective triangulation.

Assurance areas

See guidance section for program, data, financial and/or supply chain spot checks as relevant

Frequency requirement/recommo ndations

As relevant

Guidance/ToR availability and link

See guidance section for program, data, financial and/or supply chain spot checks as relevant

Providers

LFA

Average duration

See guidance section for program, data, financial and/or supply chain spot checks as relevant

15

Fraud specific review

General Definition

This activity refers to verifications that are performed following suspicions of instances of misappropriation or fraudulent use of grant funds at the level of implementers. Usually performed by the LFA and external auditor or other partners. Triggers include reports from assurance providers (LFA, external audit, partners, internal audit) or other risk mitigating mechanisms (fiscal/fiduciary agents etc.)

This review is aimed at providing assurance that (i) Global Fund assets (financial and non-financial) are not misappropriated, (ii) financial statements reported to the Global Fund are not intentionally misstated and (iii) Global Fund does not incur financial loss as a result of corruption (including conflict of interest and bribery/extortion) As needed

Guidance/ToR availability and linl

- Guidelines for Grant Budgeting

Financial Management Handbook for Grant Implementers

https://www.theglobalfund.org/media/7034/financial_grantimplementersmanagement_handbook_en.pdf?u=636487747740000000

- The Global Fund Guidelines on Financial Risk Management
- The Global Fund Financial anti-Fraud Management Guidelines (under development)

Note: Related LFA service will be available in LFA portal upon the issue of the respective terms of reference.

- LFA

- External Auditor

Average duration

Review of Financial Management Transition

This activity refers to the review for introduction of "shared services, donor harmonization that is performed at the level of a country /implementer.

This review is aimed at providing assurance that adequate financial management policies and procedures are available at the level of a country/implementer to be able to introduce the "shared services" approach to managing a grant via a Program Management Unit and also transition towards donor harmonization in relation to financial management as opposed to standalone, donor-specifics policies and procedures.

Based on country/implementer preparedness (maturity, control environment, political will, financial systems in place)

Guidance/ToR vailability and link

- Co-LINK Project Implementation Framework
- Financial Management Handbook for Grant Implementers

- LFA
- External Auditor
- Partners

Average duration

Analysis of root causes of systemic/structural bottlenecks

This activity refers to the capacity assessment that is performed at the level of a country /implementer in order to identify the root causes of systemic or structural challenges and thereafter developing an appropriate mitigation plan to address the issues. The assessment is done on all financial management systems including internal control environment, financial management information systems, human capacity, leadership, accountability etc.

This review is aimed at providing assurance that there is a clear understanding of the structural or systemic issues which are contributing to the identified risks and that any proposed mitigating actions are actually adequate, not just generic mitigating actions

As needed

Guidance/ToR availability and link

- Co-LINK Project Implementation Framework
- Financial Management Handbook for Grant Implementers

Note: Related LFA service will be available in LFA portal upon the issue of the respective terms of reference.

- LFA
- External Auditor
- Partners

Average duration

Budget Variance Analysis

Page 17

Finance

General Definition

This activity refers to the analysis that is carried out in order to tying in the numbers reported by the Implementer as expenditure and forecast information for a given period to underlying documents and identify opportunities for reprogramming and portfolio optimization

Assurance areas

This review is aimed at providing assurance of rhe reasonableness of the assumptions and explanations of variance provided by the PR, as well as the accuracy and reasonables of the forecast in order to understand the rate of absorption and take appropriate actions in a timely manner

Frequency requirement/recomme ndations

- Can be done by the LFA as part of their normal assurance work (semester with PU/DR reviews for HI and Core portfolio and annual for Focused portfolio
- For Core and HI, Finance Specialist can monitor on a semester basis during semester expenditure reporting or quarterly during submission of cash balance information

Guidance/ToR availability and link

- Guidelines for Grant Budgeting

https://www.theglobalfund.org/media/3261/core_budgetinginglobalfundgrants_guideline_en.pdf?u=636486806820000000

- Financial Management Handbook for Grant Implementers

Providers

- LFA

Average duration

Fixed (non-health) Asset Verification

General Definition

This activity refers to verifications carried at implementers to ascertain the existence, completeness of assets and reconcile the books amounts per the implementer records to the physical verifications on the ground.

This process also involves providing evidence of the fixed asset management policies and procedures of implementers to order to identify gaps or weaknesses in the process.

Assurance areas

This review is aimed at providing reasonable assurance regarding misuse, loss or theft of grant's assets that could have a material effect on the financial statements or the program

Frequency equirement/recomm ndations - Strongly recommended throughout grant lifecycle and at year end prior to external audit to ensure accurate and complete financial information relating to fixed assets.

Guidance/ToR availability and link - Guidelines for Grant Budgeting

- Guidelines for Annual Audits of Global Fund Grant Program Financial Statements
- Financial Management Handbook for Grant Implementers

Providers

- LFA

- External Auditor

Average duration

Health Product Management and Supply Chain

List of assurance activities

1 Health Products quantification and budget review	Verification of procurement transaction reporting in the PQR database	Review of the in-country SC systems security and integrity
4 PSM arrangements and capacity review	5 Supply chain spot checks	Joint programmatic, financial and supply chain spot checks
Measuring availability of tracer medicines and diagnostic products at health facilities (KPL 6b)	7 Medical lab equipment deployment mapping, including installation, calibration, maintenance, use	8 Risk-based procurement transaction reviews
9 Verification of key internal Supply Chain controls and procedures	10 Review of quality monitoring activities	11 Stock level/inventory verification
12 LMIS review (full or partial)	Laboratory related supply chain review	Supply Chain review (full or partial)
15 Supply Chain Diagnostics		

Mapping of mitigations & assurance against risks

Risks

Inappropriate selection of health product and equipment Unreliable forecasting, quantification and supply planning

- 3.3 Inefficient procurement processes and outcomes
- 3.4 Inadequate warehouse and distribution systems

Typology of mitigating actions

- Ensure use of appropriate/updated guidelines according to Standard treatment guidelines and introduction of new technologies
- Up to date treatment guidelines and diagnostic protocol according to STGs, functional drug and treatment therapeutic committees.
- to STGs, functional drug and treatment therapeutic committees
 Up to date national essential medicines lists and formularies
- Ensure effectiveness of controls and oversight
- Up to date Forecasting and Quantification process with written procedures
- Regular updated demand forecasts and supply plans for highspend items, based on changes in program interventions or scale up
- Ensure timely availability of logistic data and programmatic data for forecasting activities
- Forecasting/Quantification committees are functional (regular meetings with minutes)
- meetings with minutes)
 Stakeholders coordination mechanism for joint supply planning with TOR and centralized forecasting procedures with SOPs
- Use of PPM or a procurement service agent or third-party service provider.
- provider

 Validation of procurement manual with SOPs
- Capacity development (training/mentoring, improve SOPs/records management, recruit qualified staff, etc)
- Establish prequalified list of suppliers and/or a supplier performance monitoring tool
- Joint supply and procurement planning with partners and tracking of disbursement of funds
- CT approval of bid solicitation docs, evaluation reports and contracts for high-spend contracts (non-objection procedures for key procurement activities)
- Capacity building (staff, information systems, operations management)
- Outsource warehousing and distribution activities to a third party logistics
- Strengthen controls and security of transport/warehouse facilities, track and trace systems

 The continued less mile (delivery schedules frontes, consolidation).
- TA to optimize last mile (delivery schedules/routes, consolidation of loads, 3PL)
 Update key SOPs for inventory management, ensure compliance
- Update key SOPs for inventory management, ensure compliance with GWP/GDPs
 Improve/maintain infrastructure (store conditions, fleet,
- equipment)
- Optimize receiving, order processing, dispatch and housekeeping
 Define/maintain max-min inventory levels for all levels, regular stock status monitor
- Assets and inventory are appropriately insured against loss due to fire, theft, damage.

Assurance activities

1	Health Products quantification and budget review
2	Verification of procurement transaction reporting in the PQR database
7	Medical lab equipment deployment mapping, including installation, calibration, maintenance, use
9	Verification of key internal Supply Chain controls and procedures
13	Laboratory related supply chain review

1	Health Products quantification and budget review					
5	Supply chain spot checks					
M&E 3	Joint programmatic, financial and supply chain spot checks					
9	Verification of key internal Supply Chain controls and procedures					
11	Stock level/inventory verification					
13	Laboratory related supply chain review					
14	Supply Chain review (full or partial)					
15	Supply Chain Diagnostics					

ТЭ	Supply Chain Diagnostics
2	Verification of procurement transaction reporting in the PQR
8	Risk-based procurement transaction reviews
9	Verification of key internal Supply Chain controls and procedures
13	Laboratory related supply chain review
14	Supply Chain review (full or partial)
15	Construction Discussion

3	Review of the in-country SC systems security and integrity					
4	PSM arrangements and capacity review					
5	Supply chain spot checks					
M&E 3	Joint programmatic, financial and supply chain spot checks					
6	Measuring availability of tracer medicines and diagnostic products at health facilities (KPI 6b)					
9	Verification of key internal Supply Chain controls and procedures					
11	Stock level/inventory verification					
13	Laboratory related supply chain review					
15	Supply Chain Diagnostics					

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Limited quality monitoring and inadequate product

- Strengthen systems for collecting and reporting data throughout the SC (create supply chain dashboard, control tower)
 Update SoPs for LMIS
- Implement track and trace systems to improve visibility and traceability
- Information systems capacity building (infrastructure,
- tools/processes, people)
 Explore interoperability/linkages of SC data and programmatic data (DHIS2)

 • Integrate SC KPIs in national HMIS performance monitoring
- framework
 Establish LMIS working group
- Procure 1A to develop/support in-country quality monitoring plan,
- including QC plan

 Outsource QC sampling and testing to Lab ISO certified or WHO prequalified
- Monitor adherence to treatment guidelines/protocols by monitoring product use/consumptions against treatment guidelines,
- Programmatic data.

 Build regulatory capacity to monitor compliance with GF QA nolicies including waste disnosal through TA CR SQP development.

5	Supply chain spot checks
M&E 3	Joint programmatic, financial and supply chain spot checks
6	Measuring availability of tracer medicines and diagnostic products at health facilities (KPI 6b)
9	Verification of key internal Supply Chain controls and procedures
11	Stock level/inventory verification
12	LMIS review (full or partial)
13	Laboratory related supply chain review
15	Supply Chain Diagnostics

7	Medical lab equipment deployment mapping, including installation, calibration, maintenance, use
9	Verification of key internal Supply Chain controls and procedures
10	Review of quality monitoring activities
13	Laboratory related supply chain review

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Health Products quantification and budget review

General Definition

This is the range, quantity, value and schedule of health products based on national health products forecast that is funded by GF to support implementation of approved interventions under each grant. The content of list is reviewed periodically based on updated health product demand forecast assumptions, supply planning and program implementation.

Assurance areas

Review of the LoHP ensures that demand forecast assumptions are consistent with program objectives, scale/targets by intervention area, funding landscape, treatment/user guidelines, introduction of new solutions, stock and supply status, national/GF PSM policies. In addition, this review ensures that health product budgets are based on recognized benchmark prices (including PPM reference price for core products) and that these are correctly apportioned and entered by cost category

Frequency requirement/recomm endations

Annually or quarterly

Guidance/ToR

LFA Manual; user instructions on GF website: https://www.theglobalfund.org/media/5907/fundingmodel listofhealthproducts instructions en.pdf

Providers

LFA

Average duration

~ 2-4 days

2

Verification of procurement transaction reporting in the PQR database

General Definition

The verification ensures that reporting of procurement transactions for core HP products is complete and accurate. Procurement reporting by PRs of health products is grant agreement obligation.

Assurance areas

PQR is a publicly accessible online database that collects and displays data on procurement transactions made by Global Fund-supported programs for core health products. PQR data provides visibility of prices paid by reporting grant recipients as estimated at the time of delivery of the products in the recipient country. PQR checks the extent to which PRs achieve benchmark prices in their procurement processes. It also facilitates verification of compliance with GF QA policies for various categories of health products

Frequency requirement/recomm endations For all core health products as described on the PQR pages and user manual

It is usually done during PUDR

Guidance/ToR availability and link "LFA Guide to Price and Quality Reporting" available on the LFA website.

Providers

LFA

Average duration

~ 0.5-2 days

3

Review of the in-country SC systems security and integrity

General Definition

Builds on OIG reports on market surveillance to estimate the level of SC integrity and security as a proxy measure for risk of product leakage or verify the adequacy of implemented mitigation measures

Assurance areas

Assess security and integrity of levels of inventory management in the national SC, and review the level of residual risks to be addressed.

requirement/recomm endations As relevant

Guidance/ToR availability and link

The guideline is under development and will be available by 30 June. The related LFA service is not yet available in LFA portal.

Providers

LFA or Specialized providers

Average duration

~ 1-2 weeks

4

PSM arrangements and capacity review

General Definition

This is a mapping of the flow of funding, products and information in the procurement and supply of products financed by GF. In addition the map names key actors and responsibilities in product management. Capacity review relates to the tailored assessment of capacity of key actors to identify improvement areas to reduce risk and supply-chain vulnerabilities

Assurance areas

It provides visibility of all function areas in the health product management particularly for new implementers/actors at the start of the grant. It serves as a baseline for further and ongoing improvements in product supply management.

Frequency requirement/recomm endations

Grant making or as relevant

Guidance/ToR availability and link

LFA Manual

Simplified Capacity Assessment Tool User Guide and Simplified Capacity Assessment Tool available on the LFA website
The IRM User Manual will provide guidance for conducting capacity assessments. This is still under development and will be available by June 2018

Providers

LFA

Average duration

~ 10 davs

Supply chain spot checks

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Use standard check list of requirements to measure performance or check compliance to procedures by the PR, verify reliability of product information. Assurance areas Applies to any area of SC/HPM management. Opportunities exist for jointly planning of some spot-checks with PHM&E or Finance As relevant Refer to LFA web link for examples of spot-checks. Refer to MECA web link for additional guidelines on spot-checks Providers LFA Average duration ~ 5-10 days Joint programmatic, financial and supply chain spot checks This activity should be used when either the Program Quality verifications and spot checks and /or Data Quality verifications and spot checks assurance activity(ies) are being conducted jointly with other spot checks (e.g. Finance, Supply chain, Laboratory etc.) for effective triangulation. Assurance areas See guidance section for program, data, financial and/or supply chain spot checks as relevant As relevant See guidance section for program, data, financial and/or supply chain spot checks as relevant LFA Average duration See guidance section for program, data, financial and/or supply chain spot checks as relevant Measuring availability of tracer medicines and diagnostic products at health facilities (KPI 6b) (corporate KPI 6b) % HF with tracer medicines/diagnostic services with tracer items (through HFA or spot check or routine LMIS reporting cycle) Assess availability of core medicines by program area at HF level

Assess availability/readiness of diagnostic services at HF level Provides a one-time verification of product availability and gives indication on the supply chain performance Annually (may be more frequent) Refer to web link on board approved KPI definitions: $https://www.theglobalfund.org/media/7061/bm38_05a-2017-2022 strategick piper for mancetargets_report_en.pdf$ Providers Specialized providers/LFA (spot check)

Average duration ~ 4 weeks Medical lab equipment deployment mapping, including installation, calibration, maintenance, use Mapping of lab equipment (such as GeneXpert) location, capacity and utilization level versus testing needs, geographical test coverage and gaps and equipment standardization by level of care as per national guidelines Checks for testing coverage gaps, standardization of test platforms, installation, calibration & maintenance, as well as utilization of installed testing capacity and functionality of equipment As relevant SC Department

Providers LFA/specialized providers Average duration ~ 4 weeks Risk-based procurement transaction reviews This is a review of selected procurement transactions to determine if the implementer processes are effective and in line with the grant agreement as well as the applicable national or PR and GF procurement policies and principles The tool ensures that processes and outcomes of procurement activities financed by GF meet the requirements for competitiveness, transparency, value for money, product quality and cost-effectiveness Annually (HI or high risk for procurement) or as relevant PSM

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Guidance/ToR
availability and link

Providers

LFA

LFA Manual
"LFA website

LFA

Average duration

~ 13 days

Verification of key internal Supply Chain controls and procedures

General Definition Generally applies a tailored CAT and audit approaches to assess effectiveness of controls or procedures introduced to manage the SC and/or reduce SC risks.

Any function area at any level of the in-country supply-chain management such as inventory management, receiving procedures, stock card use, etc.

Frequency
requirement/recomm
and tions
As relevant

Guidance/ToR
As part of CAT/internal audit

Providers LFA

Average duration Depends on the scope of work

Review of quality monitoring activities

General Definition Review the implementation of quality monitoring activities for pharmaceuticals and diagnostics in accordance with the Global Fund's quality assurance policies

Verify implementation of Quality monitoring activities, including QC testing conducted by WHO PQed lab/SRA for health products at country level as requested by the GF QA Policies

Frequency

Guidance/ToR

Refer to LFA web link for QM scope of work

Annually or as relevant

Providers LFA

Average duration Depends on the scope of work but usually maximum up to 2 weeks

Stock level/inventory verification

The verification of stock levels/inventory is based on inventory stock status reports and enables analysis of the national inventory position for core products. It also informs on the analytical capacity of the implementers to take data driven actions on inventory management.

Country's national stock status reports should include the minimum information below.

- Stock on Hand (SoH)

- Average Monthly Consumption (AMC)
- Quantity on Order (& expected delivery dates)
- Months of Stock
- Expiry date

Stock level/inventory verification provides visibility of the national inventory position and the likelihood of stock-outs and/or expiry of products in the country over the next six months.

The verification should (1) guide the need for any adjustment of the supply plan and/or improvement of the demand planning and (2) inform on the capacity of the implementers to analyze consumption patterns against national treatment guidelines and other programmatic data.

Low and medium risk grants: Every 6 months or once a year.

Review of stock information as per the description above; the LFA PSM expert provides inputs through a desk review and develop recommendations on the need for any supply plan adjustment and/or improvement of the demand planning.

High risk grants: Every 6 months.

LFA website

Review of stock information as per the description above, can be combined with spot check verification of physical stock at the central level warehouse(s) (or at peripheral warehouses, as relevant) for consistency and accuracy of inventory stock status records/reports for a selection of core items, if requested by the Country Team; the LFA PSM expert provides inputs through a desk review and develop recommendations on the need for any supply plan adjustment and/or improvement of the demand planning.

Country Team; the LFA PSM expert provides inputs through a desk review and develop recommendations on the need for any supply plan adjustment and/or improvement of the demand planning.

Providers LFA

Average duration Depends on the scope of work

LMIS review (full or partial)

General Definition This activity assesses the extent to which LMIS are established and functioning to enable informed policy and operational SC decision making.

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Tailored assessment of SC data management capacity to establish adequacy of LMIS tools/technology/processes, people (skills, numbers) and systems (structure, interoperability with HMIS systems, governance, financing, strategies) As relevant ToR for LMIS Implementation Review available on the LFA website SC SharePoint Providers LFA Average duration ~ 5-15 days Laboratory related supply chain review 13 Assess the adequacy of the supply chain management systems for lab commodities to ensure continuous availability of functional equipment and consumables. In addition, review the utilization and maintenance activities of equipment. This could potentially provide assurance over the whole lab supply chain system, including product selection; forecasting, quantification, and supply planning; procurement processes and outcomes; warehousing and distribution systems; quality monitoring and product use Every 3 years ToR on "Joint M&E/PSM Lab Services and Related Supply Chain Review" on the LFA website SC Department

14 Supply Chain review (full or partial)

Providers selected by coountries/partners/LFA/SC contractors

LFA/specialized providers

~ 5 weeks

Average duration

Average duration ~ 13 weeks

Assert the adequacy and maturity of the supply chain management systems and highlight areas that require improvement

SC review is intended to obtain assurance that health product supply chain management is undertaken safely, efficiently and effectively. The review is usually tailored to target important risk areas such as SC integrity and security more than low risk areas such as SC integrity and security, LMIS (as above) distribution systems, inventory management more than low risk areas.

Frequency requirement/recomm endations

Guidance/ToR availability and link

ToR on Supply Chain Management Review available on the LFA website SC SharePoint

Average duration ~ 1-4 weeks

Systematic review of national SC capacity, maturity and identification of improvement areas. The implementation of the SC diagnostics is undertaken in collaboration with all key stakeholders and builds on recent assessments to build consensus on a plan to transform SC

Assurance areas

Country selection is a Corporate decision in consultation with CT, government and its partners.

Frequency requirement/recomm endations

Guidance/ToR availability and link

SC Department

Various (19 contractors)

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Governance, Oversight and Management

List of assurance activities

1 PR capacity assessments	2	Key implementer assessment	3	Targeted LFA review of progress on identified risks
4 LFA review of PUDR	FIN 7	Review design and/or effectiveness of the internal control environment	M&E 3	Joint programmatic, financial and supply chain spot checks

N

Risks		Typology of mitigating actions		Assurance activities
4.1	Inadequate national program governance	Strengthen implementation arrangements Clearly define roles & responsibilities from national to local levels Enhance collaboration between government and non-government stakeholders Strengthen planning, budgeting, implementation and supervision across national disease programs	2	PR capacity assessments Key implementer assessment
4.2	Ineffective program management	Enhance HR capacity, control environment, risk management Strengthen policies, processes and tools to identify and manage risks Strengthen organizational structure to manage the program Strengthen HR management such as policies, procedures, staff job descriptions to ensure sufficient and qualified human resources Dedicated program management unit Enhance information and communication systems and use of data for decision making	1 2 3 4 FIN 7	PR capacity assessments Key implementer assessment Targeted LFA review of progress on identified risks LFA review of PUDR Review design and/or effectiveness of the internal control environment
4.3	Inadequate program coordination and SR oversight	Improve engagement and coordination with other implementers, partners and stakeholders Improve processes, procedures and systems for SR selection, reporting and oversight	1 2 4 FIN 7	PR capacity assessments Key implementer assessment LFA review of PUDR Review design and/or effectiveness of the internal control environment

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PR capacity assessments

When the CCM nominates one or more PRs, it is expected, in accordance with the CCM Eligibility Requirements and relevant Global Fund policies, to assess each nominated PR against a set of minimum standards and to capture this assessment in the concept note. Building on the information provided by the CCM, the GF Secretariat undertakes a further capacity assessment of the Principal Recipient and, as relevant, other key implementers nominated (such as key SRs). The GF will decide which implementers to assess based on an initial exercise to map the implementation arrangements.

The capacity assessment serves to ensure that the proposed implementation arrangements, systems and capacities of key grant implementers are adequate for effective financial and programmatic management of the grant funds with the aim of achieving maximum impact against the three diseases. Based on the results of the capacity assessment, the Global Fund may propose capacity strengthening and mitigating measures for identified capacity gaps and risks, or changes to implementation arrangements

As required & tailored to the information requirements of the CT

Guidance/ToR ailability and link

LFA Manual

Simplified Capacity Assessment Tool User Guide and Simplified Capacity Assessment Tool available on the LFA website The IRM User Manual will provide guidance for conducting capacity assessments. This is still under development and will be available by June 2018

Providers LFA

Average duration 3-4 weeks

Key implementer assessment

The management of sub-recipients is the responsibility of the Principal Recipient. The Global Fund has no direct contractual relationship with sub-recipients. Instead, it falls under the Principal Recipients' responsibility to select sub-recipients, assess their capacity to implement aspects of the grant, conclude agreements with them and oversee their activities. It is thus critical that Principal Recipients have the ability and adequate systems to manage sub-recipients. It is for this reason that the minimum standards for Principal Recipients specify that the Principal Recipient must have "the capacity and systems for the effective management and oversight of sub-recipients".

The Principal Recipient is responsible for evaluating sub-recipients. If the Principal Recipient has, however, known capacity issues or is not deemed sufficiently independent to conduct a thorough assessment of key implementers that are critical to grant implementation and achieving impact, or the Country Team has another reason to request independent assessment of certain implementers, the Country Team may extend the scope of the capacity assessment conducted during grant making to key implementers, whether they are formally sub-recipients or not. The Country Team may alternatively decide to incorporate the key implementer/sub-recipient assessment into future LFA oversight activities. For additional circumstances that may trigger LFA assessment of key implementer/subrecipient assessments, please refer to the LFA manual.

The assessment could for example cover the key implementer's/sub-recipient's capacity, resources, systems and controls, but also reviews of the sub-recipient budget and work plan from a value for money perspective. The tools available for capacity assessments of Principal Recipients which take place before grant signing, can serve as guidance for areas to be considered for the sub-recipient assessment

As required & tailored to the information requirements of the CT

LFA Manual

Providers

PR/LFA

Average duration

Targeted LFA review of progress on identified risks

The LFA may be asked to verify the implementation or outcome of specific risk prevention or risk mitigation actions. This is generally done as part of the PU/DR review, where the LFA looks at the Principal Recipient's update on implementation of conditions or management actions. LFAs may also be asked to undertake a stand-alone verification outside the scope of the PU/DR.

As relevant

PUDR Guidelines

Providers LFA

Average duration

LFA review of PUDR

At the Global Fund request, the LFA verifies the Principal Recipient's progress report, reviews the disbursement request, provides a performance rating for the grant and makes an independent annual funding recommendation to the Global Fund. The Global Fund considers the Principal Recipient report and LFA recommendation in taking a decision on the annual funding decision and disbursement schedule. In cases where only a progress update (and not a disbursement request) is required to be submitted to the Global Fund, the Principal Recipient and LFA complete only the sections of the PU/DR form relevant to reporting on progress of implementation and grant performance and/or as agreed in advance with the Global Fund.

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The PU/DR form contains the following information: -The Principal Recipient's programmatic progress, tracking results reporting on impact/outcome indicators; -The Principal Recipient's financial information, including cash outflow, budget variance analysis, cash reconciliation, calculation of the disbursement request amount: -The Principal Recipient's update on the fulfilment of the conditions precedent, special conditions as well as management actions; -The Principal Recipient's Enhanced or Annual Financial Reporting (as applicable), to be completed once per year; -The Principal Recipient's comments/issues relating to procurement of pharmaceuticals and other health products; -An annex on sub-recipient financial information, to be completed at the discretion of the Global Fund; -LFA comments are provided in separate sections that mirror the Principal Recipient's sections. There is also a section for the LFA findings and recommendations. Varies LFA Manual/OPN on annual funding decisions and disbursements PUDR Guidelines Providers Average duration

Review design and/or effectiveness of the internal control environment

This activity consists of:

- (i) identifying per key process, the main risks as well as the controls designed by management to prevent/ reduce the risks,
- (ii) assessing whether the controls, in their current design are effective or not
- (iii) test whether these controls are effectively implemented.

In doing so, it is important for the reviewer to consider the role of those charged with governance in enforcing the culture of control in the entity and how the outcome of the reviews is used to improve the overall environment.

Reviews aimed at providing assurance that Global Fund resources are not lost as a result of lack of (i) well designed and effective control at entity, process and transactional levels, (ii) compliance with policies, procedures and applicable law and (iii) safeguarding of Global Fund assets.

- Mandatory during grant-making for new PRs and strongly recommended throughout grant implementation
- Strongly recommended for continuing PRs during grant-making and throughout grant implementation

Guidance/ToR availability and link

- Guidelines for Grant Budgeting
- - Financial Management Handbook for Grant Implementers (Suggested scope of work in section on Funds Flow)
- The Global Fund Guideline on Financial Risk Management (Specific ToRs yet to be developed)

- LFA
- External Auditor
- Partners

Average duration

Joint programmatic, financial and supply chain spot checks

This activity should be used when either the Program Quality verifications and spot checks and /or Data Quality verifications and spot checks assurance activity(ies) are being conducted jointly with other spot checks (e.g. Finance, Supply chain, Laboratory etc.) for effective triangulation.

See guidance section for program, data, financial and/or supply chain spot checks as relevant

As relevant

See guidance section for program, data, financial and/or supply chain spot checks as relevant

Providers LFA

Average duration See guidance section for program, data, financial and/or supply chain spot checks as relevant

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