Recommended Updates to Risk Appetite

46th Board Meeting

GF/B46/06
8-10 November 2021, *Virtual*

Board Decision

Purpose of the paper: This paper presents amendments to certain Risk Appetite Statements, including risk appetites, target risk levels and timeframes to achieve target risk as described in the table in Annex 1 to GF/BM46/06 for approval by the Board, based upon the decisions of the Strategy Committee and Audit and Finance Committee.

Decision

Board Decision Point: GF/B46/DP05: Amended Risk Appetite Statements

1. ***The Board:***
   a. ***recalls its ultimate responsibility to the Global Fund's stakeholders for overseeing the implementation of effective risk management;***
   b. ***affirms the Strategy Committee's concurrence with the amended Risk Appetite Statements under such committee's oversight, as set forth in Annex 1 to GF/SC17/14_Rev2 and pursuant to decision point GF/SC17/DP02;***
   c. ***further affirms the Audit and Finance Committee's concurrence with the amended Risk Appetite Statements under such committee's oversight, as set forth in Annex 1 to GF/AFC17/02_Rev2 and pursuant to decision point GF/AFC17/DP02; and***
   d. ***instructs the Secretariat to provide greater reporting on emerging risk trends and the effectiveness and results of the assurance measures, including the additional assurances put in place.***

2. ***Based upon the recommendation of the Audit and Finance Committee, the Board approves the amended Risk Appetite Statements, including risk appetites, target risk levels and timeframes to achieve target risk, as set forth in Annex 1 to GF/B46/06, acknowledging that the target risk level for each risk shall become the revised risk appetite at the target due date.***

3. ***This decision point and the amended Risk Appetite Statements approved by it shall supersede decision point GF/B39/DP11 (May 2018).***

Budgetary implications (included in OPEX budget)

Executive Summary

Context

1. The COVID-19 pandemic has had a significant impact on the Global Fund's operating environment, causing widespread disruption. Risk levels are significantly higher, implementing mitigating actions will take time, and for those risks where the Global Fund has less influence, higher risk levels may need to be accepted for longer as we allow time for mitigating actions to take effect. The Global Fund's risk appetite needs to reflect this new reality whilst also facilitating future decision-making and intelligent risk taking.

Approach to developing recommendations on risk appetite

2. A five-step approach was adopted to develop recommendations on risk appetite adjustments:

    i. A top-down and bottom-up analysis of grant risk levels;
    ii. Engagement with disease Situation Rooms and partners on the global level of ambition in terms of making up lost ground in achieving programmatic targets (the best approach for a specific country will always be decided on a case-by-case basis, taking into account the country context, the likelihood of success of proposed adaptations and mitigations, and the risk trade-offs. However, as risk appetite is set at an aggregate level, it needs to be underpinned by an organizational position on the level of ambition);
    iii. Prioritization of interventions and mitigating measures on a country-by-country basis for all countries in the risk apeptite cohort;
    iv. Assessment of the impact of COVID-19 and mitigations on the time it will take to reach the target risk level for program quality (working with partners, including the HIV, TB and malaria partner communities) – including looking at baseline risk levels, current risk levels, past performance trajectory, level of ambition, likelihood, and the timeframe for prioritized adaptations to have a positive impact on programmatic results; and,
    v. Assessment of the impact of COVID-19 and mitigations on the time it will take to reach the target risk level for grant-facing risks other than Program Quality – including looking at baseline risk levels, current risk levels, the cumulative effect of the incremental risk as a consequence of program adaptations over the next 12-24 months, delays in planned systems strengthening initiatives; and timeframes for the mitigating actions to have an impact.

Summary of recommendations

3. Increases in risk appetite are being requested for four out of eleven grant-facing risks: Program Quality TB, procurement, and the two financial and fiduciary risks. This is to reflect the fact that increases in inherent risk levels mean that these risks are already outside risk appetite, and to ensure program continuity. The Secretariat expects the increase in risk appetite for three of these four risks (procurement, and the two financial and fiduciary risks) to be short-lived and revert to original levels by December 2022.

4. Extensions of timeframes for reaching target risk levels are being requested for five out of the eleven risks: Program Quality HIV, TB and malaria to reflect the time it will take to implement priority adaptations and regain lost ground, M&E to reflect the time it will take to respond to evolved M&E needs and expectations around recency and use of data, and the In-Country Supply Chain risk to reflect delays in implementing key supply chain strengthening initiatives.

5. Target timeframes are also being proposed for reaching target risk levels for Procurement and the financial and fiduciary risks. These risks have not previously had target timeframes because they were within risk appetite and at the target risk level. The timeframes reflect the fact that risk levels are expected to return to pre-COVID levels within 12 to 18 months, assuming COVID-related disruptions start to subside within a similar timeframe.

6. No changes to risk appetite statements are being proposed for three out of the eleven risks: In-Country Governance, Quality of Health Products, and Foreign Exchange.

Input Sought

7. The Board is requested to approve the Decision Point presented on page 1.

Input Received

8. The Audit and Finance Committee (AFC) and the Strategy Committee (SC) acknowledged the need to temporarily increase risk appetite for certain risks and/or extend the timeframe for reaching target risk levels. It was noted that any acceptance of increased risk needs to come with clear accountability and for a clearly defined period. The Committees highlighted the importance of striking the right balance between risk mitigation and avoiding adverse impacts on program delivery. The Committees also noted the importance of in-country missions and of country-level engagement in risk management.

Report

Context

1. The COVID-19 pandemic has had a significant impact on the Global Fund's operating environment, causing widespread disruption and driving up risk levels. Resources have been diverted towards the COVID-19 response, which has negatively impacted HTM programs. COVID-19 related restrictions on movement have seen patients avoiding health facilities. Prevention and treatment programs have been disrupted with a decline in outreach prevention programs, case notification, new patients being put on treatment, and treatment adherence. There has also been significant disruption to global and in-country supply chains, impacting the availability of critical HTM and COVID-19 health products and equipment, whilst economic upheaval and uncertainty have increased the risk of fraud and other negative behaviors.

2. As is typical in a crisis, the Global Fund has had to quickly adapt to ensure its risk management approach remains aligned to the broader context. However, new mitigation strategies deployed to adapt to these changes, such as grant flexibilities and C19RM, have impacted the risk landscape. For example, through the introduction of new interventions and health product categories, and in some cases engagement with new stakeholders and/or the need to work with untested supply chains and implementers, as well as ensuring continuity of in-country assurance activities.

3. With the emergence of COVID-19 vaccines there was initially some hope that the pandemic might start to be brought under control during the course of 2021. However, the reality is that it has continued to come in waves, exacerbated by the emergence of new variants and challenges in vaccine roll-out, particularly in lower income countries. The expectation, therefore, is that the crisis is likely to continue for the next 12 to 18 months and that the situation may get worse in some countries before it gets better.

4. As a result of the disruption caused by COVID-19, the ability of Global Fund supported programs to achieve their targets is far more challenging than in the pre COVID-19 context. Although several programs, with support from Global Fund partners, have successfully adapted, it will take time to catch up the ground that has been lost. Risk levels are significantly higher, implementing mitigating actions will take time, and for those risks where the Global Fund has less influence, higher risk levels may need to be accepted for longer as we allow time for mitigating actions to take effect. The Global Fund's risk appetite needs to reflect this new reality whilst also facilitating future decision-making and intelligent risk taking.

Key Risk Appetite concepts

Risk appetite

5. Risk appetite is the amount of risk, at a broad level, that an organization is willing to accept in pursuit of its strategic objectives. Risk appetite reflects the risk management philosophy that a Board wants the organization to adopt and, in turn, influences its risk culture, operating style and decision-making.

6. Risk appetite is set by the Board and should align with the strategic objectives that the organization wants to achieve. Risk appetite may change over time, it may decrease as risk management and internal controls mature to a point where strategic objectives can be achieved with less risk. Alternatively, it may increase in response to a crisis situation where increased risk may need to be accepted, to allow for operational continuity or to counter any setbacks in reaching objectives.

7. Since the Board set risk appetite in 2018[1] the way in which the Global Fund thinks about and operationalizes risk appetite has matured. In determining how best to respond to increases in inherent risk levels resulting from the pandemic, the Global Fund's starting point has been to look at the level of programmatic ambition and the activities that would need to be implemented to deliver on that ambition.

Target risk

8. Target risk is the Board's anticipated future appetite for risk. The target risk timeframe is the period of time that the Board confirms it is prepared to accept, until the current risk is reduced to the target risk level.

9. The target risk level can be affected by a range of factors. Mitigating actions may start to take effect, the external environment may become more or less volatile, or the organization's level of ambition may change. In response to any or all of these scenarios, the Board may need to reassess the target risk level and/or the time frame for reaching that target risk.

Selecting risks for risk appetite

10. Risk appetite should only be set in certain circumstances. The criteria that are used to determine whether risk appetite can be effectively operationalized in the Global Fund context for a given risk and whether it would serve as a useful risk management tool, include that:

    i. The risk must be important to achieving the Global Fund's mission;
    ii. Subject to measurement in a simple, transparent, and objective way; and,
    iii. Be capable of being at least partially mitigated by the Global Fund and partners.

11. If implemented, risk appetite should provide management teams with clearer direction when making trade-off and resource allocation decisions. With this clearer decision-making ability, risk appetite has the potential to have a material impact on risk outcomes.

[1] GF/B39/DP11 and GF/B39/07. In 2018, the Board approved risk appetite statements for eight grant facing risks and one external facing risk: foreign exchange. Detail can be found in Annex 1.

12. Risk appetite is not a useful or appropriate tool for all risks and the absence of a risk appetite is not a measure of the relative importance of that risk[2].

Approach to assessing risk appetite adjustments

Assessment of grant risk levels

13. In Q1 2021, a top-down analysis was used to assess the impact of COVID-19 related disruption on current grant risk levels. Operational context, the extent and impact of disruptions including on performance against programmatic targets and strategic objectives, anticipated future volatility and effectiveness of mitigating actions were all considered when assessing and revising grant risk levels (a range of tracer indicators, including outcome and coverage indicators, were used as a proxy for measuring the impact of disruption).

14. This was then followed by a bottom-up assessment involving the Risk Department, 2nd line of defense teams, and Country Teams, to review and validate the conclusions of the top-down analysis and to ensure the context of the different countries and grants was taken into account and reflected in the final adjustments to current risk levels.

Engagement on level of ambition

15. Risk levels for all grant-facing risks have increased. Importantly, for a subset of these, current risk levels are now higher than the Board-approved risk appetite. For these risks, risk appetite needs to be adjusted in order to ensure program continuity.

16. For grant-facing risks that remain within the risk appetite, there is a need to assess the Global Fund's and partners' level of ambition in terms of making up lost ground in achieving programmatic targets. The level of ambition will drive the types and extent of risk trade-off decisions that may need to be taken, and level of operational flexibility (or risk appetite) required.

17. The Global Fund effectively has three options in how it decides to respond:

    i. Maintain current targets and objectives (the level of ambition) and accept the risk that these are unlikely to be achieved (passive risk taking);
    ii. Choose to innovate, adapt, or scale-up in an effort to regain lost ground, but also accept the trade-off that there may be a negative outcome (active risk taking); and,
    iii. Extend target timeframes, and thereby give programs an extended opportunity to strive towards a revised target and reduce the risk level (scale back ambition).

18. The best approach for a specific country will always be decided on a case-by-case basis, taking into account the country context, the likelihood of success of proposed adaptations and mitigations, and the risk trade-offs. However, as risk appetite is set at an aggregate level it needs to be underpinned by an organizational position on the level of ambition. To establish the global level of ambition, disease Situation Rooms and partners were approached for input.

[2] At the July 2018 Strategy Committee meeting the SC reviewed the risk management strategies for the Human Rights and Gender Inequality risk, the Transition risk, and the Drug and Insecticide Resistance risk. The SC agreed that the Drug and Insecticide Resistance risk would be covered by risk appetite for Program Quality. The SC decided not to set risk appetite for Human Rights and Gender Inequality, and Transition recognizing that setting risk appetite would not change the Global Fund's management of these risks or produce better outcomes.

Prioritization of interventions and mitigating measures

19. Building on input from Disease Situation Rooms and partners, a review of prioritized interventions and mitigating actions was initiated on a country-by-country basis for all countries in the risk appetite cohort[3].

20. This analysis has enabled an assessment to be made of the types of risk trade-off decisions that may be needed to successfully implement the interventions and mitigations identified as priorities (i.e., by how much risk appetite may need to be increase).

21. It has also enabled triangulation of timeframes for implementation of prioritized interventions and mitigations and an assessment of when we can expect risk levels to reduce (i.e., for how long risk appetite may need to be increased or target timeframes extended).

Assessment of impact of COVID-19 and mitigations on time to reach target risk for program quality[4]

22. A detailed analysis was undertaken to determine the time needed to reach the target risk level for program quality (as per the Board approved Risk Appetite Framework of 2018), looking at a cohort of high investment, high impact portfolios. A key underlying assumption for the analysis was that COVID-19 related disruption will continue for the next 12 to 18 months and then start to abate.

23. For each country within the cohort the following factors were considered:

    i. Baseline risk (pre COVID-19);
    ii. Current levels of risk as assessed in early 2021;
    iii. Past performance trajectory;
    iv. Level of ambition (grant targets for the NFM3 grants through 2023); and,
    v. The likelihood and timeframe for prioritized program adaptations to have a positive impact on programmatic results.

Assessment of target risk level and timeframes for grant facing risks other than Program Quality

24. For risks other than program quality, a number of the drivers that have increased risk levels are expected to be temporary, i.e., upstream procurement disruption, and an increased inherent risk of fraud. The Global Fund also has more direct control of these risks and a range of mitigating actions with shorter lead times are already being implemented. Again, on the assumption that COVID related disruption will continue for the next 12 to 18 months but then start to reduce, inherent risk levels for grant-facing risks other than Program Quality are expected to go back to pre-COVID levels within a similar timeframe. In the interim, the suite of mitigating actions and grant-level assurances already being implemented or planned will ensure these risks can be managed.

25. To assess the time to reach target risk levels for risks other than program quality, the following factors were considered:

[3] A full list of countries included in the risk appetite cohort can be found in Annex 4.
[4] Program Quality covers all programmatic elements that contribute to successful program outcomes including access, service delivery, coverage, integration, efficiency and effectiveness, and spans prevention, retention and treatment.

i. Baseline risk (pre-COVID);
ii. Current levels of risk as assessed in early 2021;
iii. The cumulative effect of the incremental risk as a consequence of program adaptations at a country/portfolio level over the next 12-24 months; and other changes to the level of ambition driven by the changing context,
iv. Delays in planned systems strengthening initiatives; and
v. Timeframes for the mitigating actions to have an impact.

Analysis of individual risks

Program quality – HIV risk *(under Strategy Committee purview)*

Inherent risk level

26. The key factors driving the increase in the program quality-HIV risk include diversion of critical health resources to the COVID response, fear of COVID exposure and restrictions on movement impacting client access to services, disruptions in outreach prevention programs for key and vulnerable populations including AGYW services, and increased instances of reported human rights violations and gender abuse. Examples of tracer indicators, used as a proxy for measuring the impact of disruption on HIV programs are: people currently on ART, people newly enrolled on ART, PMTCT coverage, and key populations reached and tested.

Level of ambition

27. The HIV disease Situation Room partners reaffirmed the need to maintain the level of ambition in line with the global UNAIDS declaration (2021). They also highlighted the importance of prioritizing program adaptations, innovations in service delivery models and scale-up to maintain critical prevention and treatment programs.

Mitigating measures

28. National disease programs and Global Fund grant implementers, with technical support from partners, continue to adapt their programs to mitigate the impact of COVID disruption on HIV prevention and treatment services. To sustain the progress being made, HIV technical partners have articulated five priority interventions:

    i. Multi-month dispensing of prevention, care and treatment products (ART, PrEP, Condoms/lube, injecting supplies/naloxone/OST);
    ii. Out-of-facility dispensing of prevention, care and treatment products (pharmacy, community, outreach, virtual);
    iii. Virtual service delivery through telephone or online platforms (triage, linkage, follow-up, adherence, and other support);
    iv. Differentiated HIV testing –including self-testing (HIVST); and
    v. Out-of-facility models and KP and AGYW Prevention Programming adaptations (PPE, smaller group sizes, mobile/outreach/virtual enhancement).

29. An example of a trade-off decision associated with these mitigations is rapidly scaling up multi-month dispensing to improve retention and decongest clinics but accepting the risk of loss to follow-up and irregular or inadequate treatment.

Risk appetite recommendation

30. The recommendation is that the current level of risk appetite of High is maintained. Despite the ground that needs to be regained to reach programmatic targets for HIV and the fact that COVID related disruption is expected to continue, the current level provides sufficient flexibility for any risk trade-off decisions that need to be made to implement priority interventions. However, given the scale disruption it is also recommended that the timeframe for reaching the target risk level of Moderate is extended by 12 months from June 2023 to June 2024.

Program quality – TB risk *(under Strategy Committee purview)*

Inherent risk level

31. The key factors driving the increase in the Program Quality-TB risk include interruptions to access to TB diagnosis due to lockdowns and restrictions in travel, associated challenges of respiratory symptoms for TB and COVID, and repurposing of TB diagnostic capacity for the COVID response, leading to a negative impact on case notification rates and disruption to both TB and MDR-TB services. An example of a tracer indicator used as a proxy for measuring the impact of disruption on TB programs is TB notification for drug sensitive and drug resistant TB.

Level of ambition

32. The TB disease Situation Room partners confirmed that the level of ambition remains the same. They also emphasized that prioritized adaptations and interventions should be actively pursued in order to try and close the gap on missing TB cases.

Mitigating measures

33. To reverse the declines in TB case notifications, TB technical partners are recommending a focus on the following priority interventions:

    i. Optimize existing health and laboratory capacity, bi-directional screening and testing of symptomatic patients for TB and COVID;
    ii. Scale-up multi-month dispensing to mitigate risk of treatment interruption and improving adherence; and,
    iii. Digitalize TB services including adherence technologies to support TB treatment and patient monitoring, prevention and surveillance systems.

34. As with MMD for HIV, an example of a risk trade-off associated with scale-up is the potential for treatment interruptions and poor treatment outcomes, associated stress on supply chain systems, and the risk of product diversion. For digitalization the potential risk trade-offs include high investment costs, and longer implementation lead times.

Risk appetite recommendation

35. Taking into account the fact that the risk level for Program Quality -TB is now above risk appetite, the impact of COVID on programmatic results and the time it will take to regain ground against a backdrop of ongoing disruption, the recommendation is that the current risk appetite of High is increased to Very-High. This reflects the current risk level and provides flexibility for any risk trade-off decisions that need to be made to implement priority interventions. Given the scale of disruption it is also recommended that a timeframe of December 2023 is set for reaching a target risk level of High and that the timeframe for reaching the original target risk level of Moderate is extended by 24 months from June 2023 to June 2025.

Program quality – **Malaria risk** *(under Strategy Committee purview)*

Inherent risk level

36. As with HIV and TB, the key factors driving the increase in the Program Quality-malaria risk are restrictions on movement impacting access to health services including malaria diagnosis and treatment. Social distancing and availability of PPE for health personal and malaria campaign staff has also impacted timelines and implementation of ITN, IRS and SMC campaigns. Challenges with global sourcing and freight/supply chain capacity has led to longer lead times to delivery of essential malaria supplies (mRDTs, ACTs, ITNs and IRS). An example of a tracer indicator used as a proxy for measuring the impact of disruption on malaria programs is the number of malaria suspects having a parasitological test (microscopy or RDT)

Level of ambition

37. The Malaria Country/Regional Support Partner Committee confirmed that the level of ambition remains the same and highlighted the importance of meeting timelines for delivery of malaria campaigns and ensuring uninterrupted malaria supplies They also noted that the level of ambition was already challenging with higher costs for delivery in the COVID context and that consequently it is expected to take time to regain lost ground.

Mitigating measures

38. Several operational adaptations to campaign operations have been put in place to maintain social distancing and reduce the risk of COVID transmission. However, ensuring availability of PPE for health staff for routine service delivery and door-to-door campaign operation is the single most important mitigation action. Malaria partners have also prioritized commodity security (RDTs, ACTs, ITN, IRS, SMC) and preventing stock-outs as critical.

39. An example of a trade-off decision is implementing door to door delivery of LLINs to avoid delays to campaigns but accepting the risk of sub-optimal coverage in the absence of household enumeration and mapping, diversion of nets and funds and increased cost and budget allocation.

Risk appetite recommendation

40. The recommendation is that the current risk appetite of High is maintained. Despite the ground that needs to be regained to reach programmatic targets for malaria and the fact that targets were already challenging, the current level provides sufficient flexibility for any risk trade-off decisions that need to be made. However, given the scale disruption it is also recommended that the timeframe for reaching the target risk level of Moderate is extended by 12 months from June 2023 to June 2024.

M&E risk *(under Strategy Committee purview)*

Inherent risk level

41. The completeness, timeliness and accuracy of reporting has systematically improved over the years with focused investments and interventions. The factors driving the increase in the M&E risk level are the evolution of M&E needs both for COVID and HTM, the need to strengthen monitoring and evaluation accordingly, particularly in terms of data availability and use. Measurement has become more difficult as a result of certain adaptations, e.g. virtual prevention and multi-month dispensing. COVID has also increased expectations in terms of the frequency with which data can be made available whilst C19RM and the volatility of the operating environment mean that additional data is needed and more frequently. In addition, repurposing of M&E staff for COVID related duties is impacting risk levels in the short term.

Mitigating measures

42. Joint efforts with WHO and partners have facilitated the establishment of COVID surveillance systems, including specific reporting modules under national HMIS tools like DHIS. Sizeable investments are being directed towards improving surveillance capacity (WHO Pillar 3) and digitization of HTM programs especially for reporting, malaria control campaigns and patient monitoring and adherence systems. Establishing the infrastructure for more frequent reporting and better use of data to drive decision making on program adaptations both at the country and global levels, and within the Secretariat, are also being prioritized.

43. An example of a trade-off decision is increasing the frequency and breadth of data through digitization of systems through third party suppliers and accepting the risk of increased cost, loss of country ownership, limited use of data and dilution of country capacity building.

Risk appetite recommendation

44. The recommendation is that the current risk appetite of High is maintained. Although COVID has effectively moved the goalposts in terms of expectations around recency, use of data and surveillance systems, the current level provides sufficient flexibility for any risk trade-off decisions that need to be made. However, the fact that M&E needs and expectations have changed means that it is also recommended that the timeframe for reaching the target risk level of Moderate is extended by 18 months from June 2021 to December 2022.

Procurement risk *(under Strategy Committee purview)*

Inherent risk level

45. The key factors driving the increase in the Procurement risk level are global volatility resulting from the pandemic, delays at manufacturing sites due to human resources constraints and lack of raw material, prioritization of manufacturing chains for COVID products and lengthy international transportation processes causing disruption to freight and logistics. Higher flows of products through non-PPM channels and the introduction of more complex product categories, like oxygen supply which typically flow through local government channels and where these is more limited collective technical knowledge, also introduce additional risk and the potential for diversion of resources and product leakage.

Mitigating measures

46. Procurement challenges are being managed through a range of interventions including collaboration with ACT-A partners to ensure equitable access across countries to limited supplies (such as SARS-CoV-2 diagnostics), coordination with WHO and UNICEF to help secure new sources of products (oxygen equipment and services), and aggregated demand planning to facilitate negotiations with manufacturers. Order placement is being strengthened leveraging Wambo/PPM mechanisms as the preferred procurement channel for C19RM grants, accelerating off-line Wambo/PPM on-boarding processes, and through communications with countries on product lead-times and order placement deadlines, whilst pre-award reviews are being leveraged to provide assurance in relation to non-PPM orders.

47. An example of a trade-off decision is leveraging the use of Wambo/PPM as the preferred procurement channel and accepting the risk of perceived longer lead times and the potential dilution of in-country procurement capacity.

Risk appetite recommendation

48. Taking into account the fact that the risk level for Procurement is above risk appetite and that some mitigating actions will take time to take effect, the recommendation is that the current risk appetite of Moderate is increased to High. This reflects the current risk level and provides flexibility for any risk trade-off decisions that may need to be made to support implementation of programmatic priorities. As risk levels are expected to return to pre-COVID levels in the next 12 to 18 months it is recommended that the timeframe for reaching the pre-COVID risk appetite and target risk level of Moderate is December 2022.

In-country supply chain risk *(under Strategy Committee purview)*

Inherent risk level

49. Despite the relative resilience of in-country supply chains risk levels have increased. The key factors driving the increase in the In-Country Supply Chain risk are diversion of resources, and reduced workforce capacity combined with delays to the roll-out of planned supply chain transformation and capacity building initiatives. Mitigations being implemented to support programmatic ambitions, such as HIV and TB MMD and the upcoming injection of high volumes and/or highly technical and sensitive COVID commodities (such as PPE, Oxygen & equipment, and C19RM Dx) will also place additional pressure on already over-burdened supply chains and human resources.

Mitigating measures

50. Supply chain challenges, including those associated with interventions being implemented in response to increased programmatic risk, are being managed through a combination of activities. Assurance activities are being strengthened, including the introduction of Supply Chain and Health Services Spot Checks, to improve visibility, facilitate root cause analysis and enable more agile course correction. The private sector is being selectively engaged to deliver specific supply chain functions, such as storage and transportation, in more under-performing environments. The Global Fund is working with partners (WFP, UNDP) to set up parallel supply chain in a number of challenging operating environments. Restructured technical assistance modalities are also planned, with a particular focus on regional and remote assistance.

51. As with leveraging Wambo/PPM to mitigate the Procurement risk, the risk trade-offs associated with the creation of parallel supply chains include a potentially negative impact on country capacity building.

Risk appetite recommendation

52. The recommendation is that the current risk appetite of High is maintained as it provides sufficient flexibility for any risk trade-offs that may need to be made to support implementation of programmatic priorities. However, as key supply chain strengthening initiatives have been delayed it is also recommended that the timeframe for reaching the target risk level of Moderate is extended by 12 months from June 2023 to June 2024.

Financial and fiduciary risk (Grant-Related Fraud & Fiduciary, and Accounting & Financial Reporting by Countries) *(under Audit and Finance Committee purview)*

Inherent risk level

53. The key factors driving the increase in the two financial and fiduciary risks are macro-economic pressures, disruption and uncertainty, which may drive negative behaviors and increase the risk of fraud. Banking and treasury operations are being affected. The shift to virtual working has increased the risk of cyber fraud and fraudulent financial transactions, and at the country and grant level restrictions on movement and travel disruption are making SR monitoring, and PR reporting more challenging and could negatively impact the ability of our typical assurance providers such as LFAs and Fiduciary and Fiscal Agents to provide requisite assurance and oversight.

Mitigating measures

54. The Secretariat is working proactively with PR and grant implementers, fiduciary and fiscal agents and LFAs to strengthen grant assurances, including agreeing Business Contingency Plans and related flexibility to facilitate continuity of grant operations during acute stages of COVID related disruptions and lock downs. The scope of assurance activities has also been adapted to drive greater focus on areas with the highest investment and highest risk of diversion or fraud (procurements and in-country supply chain systems), combined with an increased emphasis on systemic assessments of fraud risk. Strengthened systems, process controls and guidance to mitigate cyber security fraud risk have also been introduced.

55. An example of a trade-off decision is mandating additional LFA led assurances and use of fiscal and fiduciary agents and accepting the risk of r slower pace of execution of programs

Risk appetite recommendation

56. Taking into account that the risk levels for the two financial and fiduciary risks are now above risk appetite, and that risks are likely to materialize the recommendation is the current risk appetite of Moderate is increased to High. This reflects the current risk level and provides flexibility for any risk trade-off decisions that may need to be made to support implementation of programmatic priorities. Although the cyber security risk is expected to persist, overall risk levels are expected to return to pre-COVID levels in the next 12 to 18 months. Therefore, it is recommended that the timeframe for reaching the pre-COVID risk appetite and target risk level of Moderate is December 2022.

In-country governance risk *(under Audit and Finance Committee purview)*

Inherent risk level

57. COVID related disruptions and travel restrictions have impacted the ability of CCMs to organize in-person meetings and provide the necessary support to, and oversight of, Global Fund grant implementation. The ability of program staff, across all levels of health service delivery, to support PR governance and provide oversight of program implementation has also been negatively impacted. However, whilst there has been an impact on in-country governance the primary impact is reflected in the increase to the inherent risk levels across other risk categories with a dependency on effective PR oversight, e.g. procurement, in-country supply chain and financial and fiduciary risks.

Mitigating measures

58. Secretariat and partner support was rapidly mobilized to ensure technological support for CCMs in facilitating and organizing virtual CCM meetings, C19RM funding request submissions and the inclusive engagement of civil society and affected communities. This technology has also been leveraged to ensure ongoing engagement between CCMs, the Secretariat and partners, throughout the NFM3 process including country dialogue and grant making. The introduction of Business Contingency Plans at an early stage in the crisis have also provided operational flexibilities to support PRs in prioritizing and managing grant document submission. The creation of the Global Fund's Health Financing Department will also help increase visibility of the impact that in-country governance challenges are having on domestic health financing.

Risk appetite recommendation

59. While challenges have been noted in certain countries, at an aggregate level the risk level remains moderate and is within risk appetite. Therefore, no change is recommended.

Quality of health products risk *(under Strategy Committee purview)*

Inherent risk level

60. Although the Quality of Health Products risk remains within risk appetite, the risk level has increased during the last 12 months. The key factors driving the increase in the risk level are the introduction of two new categories of health products (oxygen equipment and SARS-CoV-2 diagnostics), the scale up of a third category (PPE), an increase in new manufacturers joining the market or scaling up production and insufficient regulator capacity. In addition, the delivery of medical services linked to oxygen equipment (administration of medical oxygen) is highly depending on the existence of an effective supporting infrastructure (electricity, maintenance, biomedical staff, infrastructures), which in some countries is not fully present.

Mitigating measures

61. The Secretariat has introduced a range of measures to build flexibility into the quality assurance process and minimize procurement delays, without jeopardizing the safety of beneficiaries. These include review of pre-shipment inspection waiver requests to accelerate availability of health products in-country and the expansion of the terms of reference of the Health Products Risk Committee to cover consideration of health product quality related risks for Global Fund health products and associated supply, programmatic, end-user and/or institutional risks. New interim quality assurance requirements for the procurement of COVID medical devices and pharmaceutical products were also issued as well as an update of the guidance relating to procurement and supply management of PPE.

Risk appetite recommendation

62. While the risk level has increased from moderate-low to moderate it remains within risk appetite. Therefore, no change is recommended.

Operationalization of risk appetite

63. Increasing risk appetite and / or extending target risk timeframes ensures the organization has the flexibility it needs to make intelligent risk reward trade-off decisions. It enables more active risk-taking in contexts where the potential for a positive programmatic outcome outweighs the risk of a negative one. However, as already highlighted, every decision is taken on a case-by-case basis taking into account the country context, the likelihood of proposed adaptations and mitigations being successful, the risk trade-offs and the potential for the risk trade-offs to be successfully mitigated.

Decision making and accountability

64. The Portfolio Performance Committee (PPC) and the C19RM Investment Committee are the primary forums for decision-making on country level risk trade-offs. Decisions are made on a country-by-country basis through a combination of full and executive sessions. The PPC is co-chaired by the Chief Risk Officer and the Head of Grant Management Division and also includes the Chief Financial Officer, and senior level representatives from the different 2nd line of defense risk owners (Technical Advice and Partnerships, Community, Rights and Gender, Supply Operations, Finance etc). The PPC meets frequently and provides ongoing oversight of grant and country portfolio risk. It provides organizational sign-off on risk mitigation strategies including any risk trade-offs and ensures clear accountability for implementation and decision-making.

65. The Investment Committee is chaired by the Chief Risk Officer and also includes the Head of Grant Management, the Chief Financial Officer, the Head of Supply Operations and the Head of Technical Advice and Partnerships. The Investment Committee meets on a regular demand-driven basis. The primary focus of the Investment Committee over recent months has been the review and approval of C19RM funding requests. This focus is now expanding to include operational oversight of C19RM upstream processes, including internal Global Fund processes linked to awards and integration into grants, order placement through PPM and non-PPM channels, and ultimately downstream processes linked to in-country implementation and outcomes. As the Investment Committee starts looking at C19RM implementation the focus will be on identifying and un-blocking bottlenecks, including ensuring the effective implementation of mitigating actions being rolled-out through C19RM, and early identification of emerging risk drivers that have implications for the organizational risk profile and risk appetite.

Risk mitigation

66. Any risk trade-off decision by the PPC involves an assessment of the mitigating actions being put in place to reduce the likelihood and impact of additional risk resulting from a risk trade-off decision. The existence of appropriately tailored and effective mitigating actions that minimize the risk of a negative outcome is a pre-requisite for PPC acceptance of any additional risk. All policy and procedural exceptions are approved by relevant governance mechanisms like EGMC for policy exemptions and escalated as relevant to TRP or Board.

67. The PPC routinely follows up on the implementation of mitigating actions to monitor the ongoing impact of inherent risk levels and mitigating actions on the organizational risk profile relative to risk appetite.

Assurance

68. Assurance activities provide visibility of the extent to which risks are materializing. All high impact and core portfolios undertake a comprehensive risk assessment and prioritize a set of key mitigating actions. Based on the risk drivers and planned actions, LFA assurance activities are tailored. With additional investments under C19RM, new health product categories and interventions, LFA assurance activities have been further strengthened to provide increased visibility on the risks and effectiveness of various mitigating actions. The scope of audits and of fiduciary and fiscal agents, where present, is also being enhanced to respond to changes in the operating context. In response to the expansion of C19RM a suite of mandatory assurances has been introduced for the 45 portfolios that account for approximately 90% of the C19RM investment envelope. Mandatory assurance activities focus on higher risk areas through targeted programmatic and financial / PSM reviews and other spot checks. A new centralized Supply Chain and Health Services Spot Check is also being rolled out from Q4 for the same 45 countries focused on providing increased visibility and assurance in relation to health product and service availability and disruption at facility level. In addition, risk-based LFA-led assurance activities are also built into expanded LFA budgets for all portfolios.

Monitoring and oversight

69. Strengthening monitoring and oversight of HTM and C19RM grant implementation has been a priority in 2021. The C19RM monitoring and oversight workstream (M&O) is being used as an entry point for strengthened oversight of C19RM 2021 investments but it will also be used to track disruptions to HTM programs, implementation of adaptations for HTM and the impact on programmatic performance.

70. Routine PR reporting is being enhanced through the introduction of quarterly Pulse Checks and updates to Progress Updates. Pulse Checks are being rolled out from Q4 to improve visibility on programmatic performance, implementation progress and expenditure and forecasts, whilst Progress Updates are being revisited to increase visibility into progress of grant implementation across multiple functional areas and enable insights into C19RM investments. Internal processes for operational monitoring and oversight are also being strengthened, Updated guidelines for grant oversight by Country Teams are being introduced alongside enhanced internal monitoring tools, to ensure newly available data is more accessible, and a standardized quarterly cross-cutting review by the Investment Committee to identify C19RM implementation bottlenecks, outliers and opportunities for course correction.

Reporting

71. The Board and the Committees will continue to receive updates on risk levels and progress towards target risk levels through the Organizational Risk Register, which is updated and reviewed internally on a quarterly basis and included as an annex in the Risk Report and Chief Risk Officer's Annual Opinion to the Board in May and the Risk Report to the Board in November. The Board and Committees also receive a detailed monthly update on C19RM including information on awards, and increasingly on implementation as more data becomes available.

Case study on operationalization of risk appetite

Country context	Country X is a COE country managed under the Additional Safeguards Policy (ASP). The country has been under ASP since 2010 due to political and security considerations. Weak governance and program management capacity has contributed to financial misappropriation and fraud, noted through both LFA assurance activities and an OIG audit. Current grants are implemented by an iNGO as the largest recipient of grant funds and MOH as co-PR.
Recent trade-off decision	Country X requested funding through C19RM for urgent PPE to support an upcoming malaria campaign. The request was to source locally to mitigate the risk of perceived longer lead times using UN channels or Wambo/PPM. The country also requested to source oxygen using national procurement channels. The PPC reviewed the malaria campaign operational plan, planned assurance activities in the context of COVID, and ongoing security issues. Building on the PPC review the Investment Committee recommended using Wambo/ PPM for sourcing PPE to mitigate the in-country procurement and fraud risk but with clearly identified lead times to secure the timeliness of the malaria campaign.
Agreed mitigating actions	As part of procurement channel optimization, the Investment Committee recommended use of Wambo/PPM for sourcing PPE For oxygen, the Investment Committee advised the Country Team to explore with in-country partners (Unicef, WHO) mobilization of TA to support procurement of oxygen, and also to identify opportunities for sourcing through Unicef (long lead times vs immediate demand). The Investment Committee also recommended a detailed assurance plan as part of the notification letter, including pre-award procurement reviews and implementation spot checks to monitor operationalization of PSA plants.
Assurance activities	An additional US$ 195,000 was included in the assurance budget for LFA assurance activities under C19RM for 2021. Agreed assurance activities are: • Budget and HPMT/quantification reviews • Pre-award procurement review • Warehousing and inventory management spot checks • Programmatic and financial spot checks (verification of implementation) and review of internal controls for LLIN campaign As one of the 45 portfolios that account for approximately 90% of the C19RM investment envelope Country X will also be part of the Supply Chains & Health Services Spot Check cohort.
Routine monitoring	• Quarterly Pulse Checks • PUs • PUDRs • Within cohort of countries reviewed through weekly C19RM M&O progress update meetings and quarterly Investment Committee implementation reviews • Next PPC (if applicable): planned in Q4 2021

Recommendation

The AFC recommends the Decision Point presented on page 1 to the Board.

Annexes

The following items can be found in this Annex:

- Annex 1: Risk appetite statements
- Annex 2: Trade-off case studies
- Annex 3: Prioritized Program Adaptations and Risk Trade-off Analysis (Illustrative)
- Annex 4: Risk appetite country cohort
- Annex 5: Summary of previous Committee Input (October 2021)
- Annex 6: Relevant past Board Decisions
- Annex 7: Links to relevant past documents and reference materials

Annex 1 – Risk appetite statements

		2018 Board Approved			Recommended			
Risk Name[5]	Lead Committee	Risk Appetite	Target Risk	Target Due Date	Current Risk Level	Risk Appetite	Target Risk	Target Due Date
Program Quality - HIV	SC	High	Moderate	Jun-23	High	High	Moderate	Jun-24 (extend by 12 months)
Program Quality – TB	SC	High	Moderate	Jun-23	Very-High	Very-High	High	Dec-23
							Moderate	Jun-25 (extend by 24 months)
Program Quality – Malaria	SC	High	Moderate	Jun-23	High	High	Moderate	Jun-24 (extend by 12 months)
M&E	SC	High	Moderate	Jun-21	High	High	Moderate	Dec-22 (extend by 18 months)
Procurement	SC	Moderate	Moderate	N/A	High	High	Moderate	Dec-22
In-Country Supply Chain	SC	High	Moderate	Jun-23	High	High	Moderate	Jun-24 (extend by 12 months)
Grant-Related Fraud & Fiduciary	AFC	Moderate	Moderate	N/A	High	High	Moderate	Dec-22
Accounting & Financial Reporting by Countries	AFC	Moderate	Moderate	N/A	High	High	Moderate	Dec-22
In-Country Governance	AFC	Moderate	Moderate	N/A	Moderate	Moderate	Moderate	N/A
Quality of Health Products	SC	Moderate	Moderate	N/A	Moderate	Moderate	Moderate	N/A
Foreign exchange	AFC	Moderate-Low	Moderate-Low	N/A	Moderate-Low	Moderate-Low	Moderate-Low	N/A

*At the target due date, the target risk level will become the revised risk appetite.

[5] The following changes have been made to risk names since the initial Risk Appetite Framework adopted in May 2018:
- Program Quality has been replaced with Program Quality – HIV, Program Quality – TB, Program Quality – Malaria;
- Strategic Data Quality and Availability is replaced with M&E; and,
- Grant Oversight and Compliance has been replaced by In-Country Governance.

Annex 2 – Trade-off case studies

Trade-off case study #1 – Program quality HIV

Multi-Month Dispensing **(MMD) for ART**	
Context:	Country X is a low-income high HIV burden country with weak health system in Southern Africa. In recent years the country has witnessed internal security risks, natural disasters, and the health system has been grappling with insufficient domestic funding, donor dependency, significant gaps in human resources for health and a weak community health delivery model. Targeted testing strategies and linkage to care saw a rapid rise in first and second 90. People on ART increased by 1.5 times in last 2 years (with), leading to country running low on ART stocks (over 90% of grant funds invested for pharmaceutical and health product procurement). Coverage for third 90 (viral load testing) remained low at around 30%. Detailed review of the program indicated 12-month retention rates at a low of around 63%. The country was in the process of establishing a community health worker program.
Intervention:	In the context of COVID, and overwhelmed health system the HIV program was considered rapid scale up of MMD.
Potential benefits:	Opportunity to maintain patients on treatment and improve treatment outcomes, decongest clinics and limit pressure on already over-stretched health systems.
Key risks:	• Higher loss to follow-up and adverse treatment outcomes (treatment failure, drug resistance, deaths) • Quantification and forecasting – With over 90% funds tied up, limited ability to increase procurement volumes • Stock outs at central and peripheral level leading to treatment interruptions (outstretched supply chain) • Loss of health product – cross-border migrations, weak patient monitoring system, and defaults mean higher volumes of product loss and wastage
Mitigation of key risks:	• Phased approach to scaling up of MMD (first focusing on urban high volume centers). • Use of digital technology to improve patient monitoring (mobile messaging and tracking). • Partner support to enroll community volunteers for treatment adherence.
Trade-off decision:	The primary trade-off is primarily Program Quality to - Program Quality given the programmatic consequences of adverse events.

Trade-off case study #2 – Program quality TB

Bidirectional screening and testing for TB and COVID	
Context:	Country X is a high burden TB country that has noted over 20% drop in TB notifications in 2020 relative to 2019. COVID related strict lockdowns, associated stigma due to respiratory symptoms have reduced people accessing TB services. Repurposing of TB lab capacity (staff and GeneXpert machines) for COVID has also contributed to declines in number of presumptive TB cases undergoing microscopy of molecular testing. The country has a robust decentralized network of molecular testing capacity with sample referral mechanism Limited programmatic experience in conducting bidirectional screening and testing
Intervention:	In the context of COVID, commonality of respiratory symptoms (fever and cough) creates an opportunity for bi-directional screening for TB and COVID.
Potential benefits:	Increase in TB notification, early diagnosis and treatment would contribute to improved treatment outcomes.
Key risks:	• Program quality: Low yields in TB notification; outstretched health and lab systems cannot accommodate additional demand • Procurement & in-country supply chain: With over 90% funds tied up, limited ability to increase procurement volumes. Stock tensions including risk of stock outs of diagnostic tools (Gene Xpert cartridges)/reagents. Fiduciary: Repurposing of critical resources for scale-up diagnostic capacity within existing grant funds and likely yield and VFM considerations
Mitigation of key risks:	• Prioritization of portfolios for scale-up based on levels of disruptions and opportunities • Technical support to scale-up screening tools and in-country prioritization of high-volume diagnostic sites. Supporting health staff to improve quality of screening program to obtain higher diagnostic yield. • Use of digital technology to improve monitoring of diagnostic capacity and yield/outcomes • Maintaining strategies for finding missing TB cases, including private sector engagement • Partner support to link to care and enroll community volunteers for treatment adherence.
Trade-off decision:	The primary trade-off is Program Quality to procurement and fiduciary risk (opportunity cost for repurposing available resources to scale-up diagnostic access). Accepting a higher threshold for lower yield.

Trade-off case study #3 – Program quality Malaria

ITN Campaigns in the context of COVID	
Context:	Over 35 countries had undertaken ITN campaigns in 2020. Country X had planned for ITN campaign over a 4 month period towards second half of 2020 to ensure universal coverage. Nearly a third of population at risk of malaria lived in regions that had travel restrictions due to internal security risks. COVID related restrictions meant social distancing, PPE and sanitization was critical, health personnel were diverted for COVID related activities and challenges in enrolling community volunteers. While LLINs were procured through PPM/Wambo - Shipments of LLINs were delayed due to a) longer lead times for procurement and delivery (global supply side constraints) and b) delays in pre-shipment QA testing; Operational cost of campaign had increased by 10-15% due to the various adaptations (door to door campaign; PPE)
Intervention:	LLIN Campaign operations were moved to door-to-door delivery with changes in timing of household enumeration. Increased cost of LLIN campaign operations partially met through C19RM 2020 funds and adjusting quantification (buffer) In-person PR and assurance provider oversight and verification was restricted. Digitization and electronic same day reporting to PR and LFAs and desk review of reporting coverage. Health Product Review Committee approved delivery of LLINs to the country pending pre-shipment results based on previous track record of supplier (samples were collected and PR notified and results were communicated immediately upon receipt)
Potential benefits:	ITN campaign delivered on time before the transmission season and thereby averting infections and deaths. Digitization and use of technology facilitate remote review and oversight PPE protected communities and staff against COVID.
Key risks:	Risk of lower coverage • Reduced buffers translated into limited or no spare stock to account for higher demand identified during household enumeration. • Household enumeration and mapping relied on previous campaign data – and likely to not account for population increases at the community level. • Operational challenges may adversely impact distant hamlets from centre of village and more likely the most vulnerable are impacted. QA related risk

	• Plan to deliver nets awaiting pre-shipment testing to mitigate delayed campaign increased the risk of higher costs to address any adverse consequences (reverse logistics, reputational damage and loss of confidence among communities). <u>Risk of diversion and fraud</u> • Limited PR and assurance provider oversight over campaign activities, such as: trainings, delivery of nets, and payment of campaign operators.
Mitigation of key risks:	• Additional investments through C19RM supported procurement of PPE. • Cross function Secretariat HPRC committee reviewed the QA issue on a case-by-case basis looking at track record of supplier, risk of QA failure vs delayed campaign operation (as the campaign was in 2nd half of 2020 with grants coming to close in Dec 2020) and made informed choices with open transparent communication of PR and having their consent. • Digitization of campaign and redesigning for SOPs with support from malaria partners. • Decentralized oversight activities to local administrators and sought community confirmation (village elder/representative) of LLIN delivery as additional assurance. • Desk review of reported results and financial accounts by the LFA with a post-facto review when restrictions are lifted.
Trade-off decision:	Revised assurance guidelines for campaign operations developed jointly by technical teams, finance and risk streamlined CTs to obtain necessary approvals on risk trade-offs through PPC. <u>Program Quality to Program Quality</u> • Accepting risk of lower coverage due to challenges in door-to-door operations, limited buffers to account for higher operational costs to minimize spread of COVID <u>Program Quality to fiduciary</u> • Acceptance of higher operating costs (multiple smaller training sessions, higher allowances for volunteers, associated PPE costs) to deliver on campaign <u>Fraud risk</u> • Acknowledging higher risk of financial fraud and diversion of nets during campaign due to limited oversight.

Annex 3 – Prioritized Program Adaptations and Risk Trade-off Analysis (Illustrative)

HIV

Interventions	Countries	Upside (justification/rationale)	Potential unintended consequences, with risk type and level	Risk Trade-off and Impact of Key Risks	Time needed to result	Risk recommended
Multi-Month Dispensing (MMD) for ART	13 HIA2 & 1 - where we support national program & 3-4 HIAs -which drive KPI2 reporting	Multi-month dispensing reduces the frequency of patient/health care provider interactions at the health facility thereby freeing up provider time for patients 2) reducing exposure to C19RM & TB, & decongests clinics reduces travel time and cost of attending clinic for the patient by reducing frequency of ART pick-up reduces cost of care to the facility (time, staff). Already recommended prior to COVID- major shift is % of patients shifted (quickly) to	Stock-outs due to supply chain inability to manage greater ART outflows (procurement, distribution)	Supply Chain Risk - Moderate Fiduciary Risk - Low	12 months	Active Risk Taking Overall risk is considered low to moderate and the intervention is to be prioritized in countries with high C19RM disruptions, robust ART programs and good retention rates
			Stock outs lead to loss of confidence in staff and services (and poor perception so QoC) with consequences for patient retention and willingness to use services	Program quality Risk - Moderate	Stock management and finances, first 12 months	
			Wastage due to supply chain inability to manage greater change in ART procurement patterns (procurement, distribution)	Fiduciary Risk - Low	12 months	
			Resale due to larger amount of ART pills in the hands of individuals.	Fiduciary Risk - Low	12 months	

Interventions	Countries	Upside (justification/rationale)	Potential unintended consequences, with risk type and level	Risk Trade-off and Impact of Key Risks	Time needed to result	Risk recommended
		MMD. Long term pharmacy dispensing is better option, with considerable cost savings, but complexity of fiduciary & supply management.	Reduction in patient retention, and delayed recognition of loss to follow up.	Program quality Risk - Moderate	Quality of care delivered, 12-24 months	
			Adverse clinical outcomes due to reduced patient monitoring-e.g., missed diagnosis of TB	Program quality Risk - Low	Clinical outcome results, 24 months	
Multi-Month Dispensing (MMD) for Prevention	TBD -Uganda and Ethiopia high condom budget, Pakistan OST/ prevention	As above-noting low threshold services require non HCWs and trained CSO providers to be able to offer and support prevention options- (condoms, PrEP, etc.), this ensures continued availability of preventive tools to protect clients	As above for 1-3. Opportunities for resale - concern with OST as controlled medicine Sub-optimal linkage to care cascade and missed opportunity for HIV testing and management of STIs	Fiduciary Risk - Low Program quality Risk - Low to Moderate	12 months	Active Risk Taking Approach recommended with targeted prevention programs and active CSO engagement
Drug delivery out of the facility - pharmacy - Community/CSO	As above for MMD	Lowest cost model for drug dispensing is pharmacy model. As above otherwise.	Client concerns on confidentiality, stigma and discrimination	Program quality Risk - Moderate	Rate of uptake, 12-24 months	Active Risk Taking Approach recommended and build on
			Outstretched supply chain for last mile delivery	Supply Chain Risk - Moderate/High	12 months	

Interventions	Countries	Upside (justification/rationale)	Potential unintended consequences, with risk type and level	Risk Trade-off and Impact of Key Risks	Time needed to result	Risk recommended
			Inadequate oversight, monitoring and reporting	M&E Risk - Moderate	12 months	existing grant arrangements and or CSOs
			Need to supply pharmacies - and maintain patient records	Fiduciary & supply risk - moderate	12 months	
			Additional costs/HR to incentivize service providers	Fiduciary Risk - Low to Moderate	24 months	
HIV diagnosis & Testing Self-testing and community	5 countries with matching funds	HIV ST offer benefits for diagnosis of HIV and prevention. Increases access to testing, reduces delay and allows earlier diagnosis for people who do not have routine contact with health services, w/out visiting health facility (reduces TB/COVID exposure). Greater convenience, autonomy and privacy for test users. Promotes self-care and reduces delay in treatment initiation. HIV ST Requires	Client concerns on confidentiality, stigma and discrimination	Program quality risk - low		Active
			Quality control of out of facility testing	Program Quality risk - low		
			Need for confirmatory testing at health facility	Program quality Risk - low		
			Cost if being used in low risk populations. Regulatory and policy hurdles to use by non health care workers	Fiduciary & supply risk - moderate		

Interventions	Countries	Upside (justification/rationale)	Potential unintended consequences, with risk type and level	Risk Trade-off and Impact of Key Risks	Time needed to result	Risk recommended
		access to confirmatory testing. Community based testing - less people have to attend health facility, but requires training, supervision & testing QA of providers				
Digital and mhealth adaptations		Range of options from simple to complex. Simple use of telephone, WhatsApp and other local message systems - allows triage and supports patient monitoring and follow-up, and supports linkage to HIV care and advice.	Data, handsets -costs - potential for misuse and personal use Loss of privacy (patient confidentiality) Poor quality patient data	Program, fiduciary and supply Risk-low		Active
Digital and mhealth adaptations		Complex - App or web-based or virtual service provision	Platform issues Unsafe Apps Regulatory & clinical oversight Inappropriate but reversible clinical action (e.g. patient	Risk higher - depends on PR/CSO supplier & which services being provided		Active but caution

Interventions	Countries	Upside (justification/rationale)	Potential unintended consequences, with risk type and level	Risk Trade-off and Impact of Key Risks	Time needed to result	Risk recommended
			decision and diagnostic support) Inappropriate and irreversible clinical action (clinical decision tools (e.g. TB screening) Apps that are used as medical device Interoperability & ongoing system support need can be high and costly many high risk young people may not have access to confidential digital platforms			
KP programming adaptation - Smaller groups size; Outreach; PPE		Continued delivery of package of prevention services while adhering to COVID restrictions on aggregation and or need for social distancing	PPE - no risk. Loss of confidentiality and risk of stigma and discrimination remain same, requiring close neighbours might jeopardize this. Usual risk level for community outreach activities	Risk depends on CBO capacity - low in general		Active

TB

Interventions	Countries	Upside (justification/rationale)	Potential unintended consequences, with risk type and level	Risk Trade-off and Impact of Key Risks	Time needed to result	Risk recommended
Bi-directional screening and testing for TB and COVID	9 countries with significant disruption in TB/DR-TB services due to COVID (Bangladesh, India, Indonesia, Myanmar, Pakistan, Peru, Philippines, S Africa, Ukraine)	To improve TB case notification (and to restore the lost ground), there is a need to increase screening (including using digital x-rays with AI) and testing (using rapid molecular tests) for TB and AG RDT/PCR for COVID	Operational Risk - Lack of operation plan and experience as this is new to most programs. Systems related gaps on HRH and lab capacity	Program quality risk - Low to moderate	12 months	Active risk taking The approach is innovative and new - evidence on its effectiveness only from one country, but a good opportunity to increase testing. Hence recommended for additional attention and investments in prioritized portfolios while encouraging bidirection screening across all countries with disruptions
			Funding Gap - Insufficient funding or prioritization for investments or displacement of core investments (opportunity cost)	Fiduciary Risk - Moderate		
			Value for Money - Coverage and yield of screening/testing could be low and mayn't have impact at national level	Program quality - Moderate Fiduciary - Moderate	12-24 months	
			Risk of Stock Outs - Demand outstrips supply	Supply Chain Risk - Moderate	12 months	
			M&E reporting gaps to monitor progress or evaluate performance	M&E Risk - Low	12 months	

Interventions	Countries	Upside (justification/rationale)	Potential unintended consequences, with risk type and level	Risk Trade-off and Impact of Key Risks	Time needed to result	Risk recommended
Digitalizing TB services including connectivity (lab, sample transportation), digital adherence technologies (DAT - VOT, SMS, 99DOTS) to support TB treatment/prevention, surveillance (moving to real-time case-based reporting)	9 countries with significant disruption in TB/DR-TB services due to COVID (Bangladesh, India, Indonesia, Myanmar, Pakistan, Peru, Philippines, S Africa, Ukraine)	Digitalization facilitates provision of people-centred TB services, improve use of data, proved to be effective for COVID response	Risk of operational failure - IT systems constraints (connectivity and hardware) and HRH capacity gaps;	Program quality risk - low to moderate Fiduciary risk - low to moderate	12 months (18 months for digital surveillance)	Active risk taking Digitalization of TB services is the way forward and could be implemented anywhere as successfully implemented for COVID.
			Value for Money - Lack of standardization and evidence on effectiveness/cost-effectiveness of some of the apps	Fiduciary Risk - Low to Moderate		
			Confidentiality and ownership of data	Governance Risk - Low M&E risk - Low to Moderate		
			Sustainability and ownership - Long term political and financial commitment for moving to real-time case-based reporting (usually low for TB unlike COVID)	Health Financing and Sustainability Risk - Moderate to High Governance Risk - Moderate		
Multi-Month Dispensing (MMD) for TB/DR-TB	All Countries	Multi-month dispensing reduces patient interaction with the facility, thereby (1)	Reduction in patient retention –and delayed recognition of loss to follow up.	Program quality Risk - Moderate	12 - 18 months (treatment outcome of	Active risk taking The risk is low as patients with

Interventions	Countries	Upside (justification/rationale)	Potential unintended consequences, with risk type and level	Risk Trade-off and Impact of Key Risks	Time needed to result	Risk recommended
		reducing C19RM exposure, decongests clinics; (2) reduces time and cost of attending clinic for the patient by reducing frequency of TB medicine pick-up and costs to patient (transport, time); and (3) reduces cost of care to the facility (time, staff) (4) could be linked to remote support (SMS, VOT) as needed/feasible	Stock Outs - supply chain strain and consequential effect on quality of care	Program quality Risk - Moderate Supply Chain Risk - Low	patients with DR-TB would take longer if treated using longer regimens)	TB/DR-TB used to collect their medicines in monthly bases (after initial phase). As countries are moving to all-oral regimen for DR-TB, but MMD needs to be complemented by remote support and education
			Wastage due to supply chain constraints (procurement, forecasting, distribution)	Fiduciary Risk - Low		
			Resale or diversion into private sector or market	Fiduciary Risk - Low		
			Adverse clinical outcomes including increase in drug resistance - due to reduced patient monitoring, including adverse drug reactions; and potential consumption by TB symptomatics (household contacts etc)	Program quality Risk - Low		

Malaria

Interventions	Countries	Upside (justification/rationale)	Potential unintended consequences, with risk type and level	Risk Trade-off and Impact of Key Risks	Time needed to result	Risk recommended
Commodity security (RDTs, ACTs, LLINs, IRS, SMC)	All countries	Continuation of service delivery at both HF and community despite restrictions	Stock outs of RDTs and ACTs due to overlap of Covid/malaria symptoms and 'reopening' of primary care services	Supply Chain and Fiduciary Risk - Moderate	First 12 months	Active
			Wastage/expiry if oversupply at lower levels	Supply Chain and Fiduciary Risk - Moderate		
PPE for health care providers for routine service delivery (diagnosis + treatment) (HWs and CHWs)	All HBHI countries; All Sahel 5 countries; All HIAfr1&2 countries	Continuation of service delivery at both HF and community despite restrictions	Stock outs of RDTs and ACTs due to overlap of Covid/malaria symptoms and 'reopening' of primary care services	Supply Chain and Fiduciary Risk - Moderate	First 12 months	Active
		Availability of services closer to households (by CHWs)	Wastage/expiry if oversupply at lower levels	Fiduciary Risk - Low to Moderate		
		Reduce cost care delivery (free services by CHWs)	If PPEs poorly used, lead to increased infection rates amongst HWs and CHWs	Program quality Risk - Low		
Adaptations for campaigns – PPE & relevant operational	Countries with LLIN and SMC	Continued provision of vector control/	Risk of further escalating infections D2D	Program quality Risk - Low	24 months	Active

Interventions	Countries	Upside (justification/rationale)	Potential unintended consequences, with risk type and level	Risk Trade-off and Impact of Key Risks	Time needed to result	Risk recommended
changes (ex. door to door D2D) delivery	campaigns in 2022-2023	prophylaxis despite restrictions Prevent malaria upsurge/resurgence	Higher costs for malaria operations	Fiduciary Risk - Low to Moderate		
			Inadequate coverage as operational strategy not following standard best practices (while developing best practices for Covid context 2020-present – insufficient time/possibility to evaluate impact)	Program quality Risk - Low		
Deploying and refining HBHI stratification and implementation quality approach	HBHI countries, Sahel 5	Intervention stratification based on epidemiologic and other contextual factors Stratification of quality of implementation allow for targeted improvement approaches Both of which will maximize impact and value for money	Overburdening the overstretched national malaria programs and their counterparts at lower levels Diverting attention from Covid mitigation priorities Underestimating strength of 'good performers' (who would receive less attention under stratification of quality of implementation approach) and losing gains made	Program quality Risk - Low	24 months	Active

Annex 4 – Risk appetite country cohort

The Global Fund - 25 country cohort

1. Bangladesh
2. Burkina Faso
3. Cameroon
4. Congo (Democratic Republic)
5. Côte d'Ivoire
6. Ethiopia
7. Ghana
8. India
9. Indonesia
10. Kenya
11. Malawi
12. Mali
13. Mozambique
14. Myanmar
15. Nigeria
16. Pakistan
17. Rwanda
18. South Africa
19. Sudan
20. Tanzania (United Republic)
21. Uganda
22. Ukraine
23. Viet Nam
24. Zambia
25. Zimbabwe

Annex 5 – Summary of previous Committee Input (October 2021)

Secretariat Presentation

The Secretariat summarized the impact of COVID-19 disruption on risk levels, why this means that adjustments to risk appetite are needed, and the four-step approach taken to develop recommendations on adjustments. The Secretariat also highlighted that increasing risk appetite does not automatically mean more risk taking, that bringing down risk levels is a priority, and that decisions to take more risk will be made country by country leveraging tried and tested internal decision-making structures that drive accountability.

Audit and Finance Committee *(extract from the Draft Report of the AFC17 Committee Meeting)*

AFC Discussion

i. **Balancing risk and program quality:** The Committee highlighted that mitigations deployed to manage risk should not adversely impact HTM programs. The Secretariat was asked to expand on grant flexibilities available to adapt programs.
ii. **Sharing risk:** The Secretariat was asked to outline the level of involvement country partners and PPCs have in developing risk mitigation strategies and making risk trade-off decisions.
iii. **Community involement:** The Committee noted that checks could be strengthened with a validation mechanism from community and grassroot partners, to ensure mitigations are effective. The need for long term mitigations was highlighted, and the Secretariat was asked how community partners can access funding.
iv. **Risk measurement and reporting:** The Committee noted the increased pressure placed on LFAs, and asked the Secretariat if any changes are being considered for how risk is measured at a country level. The Committee requested greater transparency on the effectiveness of mitigation strategies, with increased and extended risk appetite.
v. **Use of Supreme Audit Institutions:** The Committee noted greater use of SAIs could bring better value-for-money, and asked for more information on the Secretariat's position on capacity building programs in place to increase their use.
vi. **Interconnectedness of risks:** The Committee highlighted that risks are interconnected; accepting greater risk in one area could have undesirable consequences in other areas, e.g. reputational risk.
vii. **Use of risk appetite:** The Secretariat was asked to expand on how risk appetite adjustments would influence the types of decisions made.

Secretariat Response

i. **Balancing risk and program quality:** A major consideration when establishing assurance mechanisms is the impact on program effieciency. This is a trade-off decision that is considered on a country-by-country basis. Risk appetite allows the Secretariat the flexibility needed to ensure this balance is appropriate and guide program adaptions to reach program objectives. Reprogramming grants can take more time where there is a matarial change, as this requires a Board decision.
ii. **Sharing risk:** The Secretariat noted risk-based decisions are highly influenced by the country level. CCMs help inform adaptations needed, and PPCs facilitate making trade-off decisions. Often proposals made to the PPC are cautious, and discussions lead to agreement that taking greater risk is appropriate.
iii. **Community involement:** The Secretariat noted that greater work in developing a feedback loop with community partners could be useful to ensure risk trade-offs being implemented are effective. Examples of what has worked well across countries could be identified, and prioritized for scale up across programs.
iv. **Risk measurement and reporting:** The Secretariat noted changes made to measure risk, including use of numerical questions to gain greater consistency across countries, and the recent

use of a gap-to-target analysis. New data sources are also expected to allow for more dynamic risk assessments. The Secretariat noted information on the status and progress of mitigations actions will be included in monthly reports to the Board.

v. **Use of Supreme Audit Institutions (SAI):** The maturity, capacity, and independance of SAIs are considered on a country-by-country basis. The Secretariat have been using SAIs in East and South Africa, and are tending to use them more often. Guidelines have been updated to increase their use where possible, and place greater emphasis on capacity building initiatives.
vi. **Interconnectedness of risks:** The interconnectedness of risks is important to consider. A stronger emphasis is placed on driving risk levels down for those that the Secretariat has a greater ability to mitigate. This helps to indirectly support other risks, such as reputational risk.
vii. **Use of risk appetite:** The Secretariat noted risk appetite allows for trade-off decisions that would not normaly be made, e.g. using fast-tracked procurement at a higher cost to reduce program quality risk.

Strategy Committee *(extract from the Draft Report of the SC17 Committee Meeting)*

The Secretariat noted the impact of COVID-19 disruption on risk levels, the required risk appetite adjustments, and the four-step approach taken to develop recommendations on adjustments.

SC Discussion

i. **Cross-cutting risk mitigation:** The Secretariat was asked to expand on frameworks in place to manage cross-cutting strategies for risk mitigation, e.g. digitization.
ii. **Staff capacity:** The Committee asked how the re-prioritization of staff capacity (internally and at country level) to support C19RM has impacted HTM programs, and how this risk is being mitigated.
iii. **Strengthening country systems:** The Committee highlighted that when parallel systems are being put in place to mitigate risk, the Global Fund must not lose sight of the importance of strengthening country capacity.
iv. **In-country missions and country level engagement:** The importance of in-country missions was highlighted and clarification was sought on when they are likely to be reintroduced. The importance of strong communication between Country Teams and PRs was also emphasized along with the involvement of countries in risk mitigation planning.

Secretariat Response

i. **Risk mitigation:** There are a dozen or so mitigations that have been identified as critical. How these are implemented varies by country. If the Secretariat starts to see an intervention routinely experiencing challenges then it would look to regroup and strategize, leveraging the AFC.
ii. **Staff capacity:** Approximately 120-130 additional staff have been recruited to increase capacity to meet the needs of C19RM. However, staff internally and in-country are stretched. It is important to manage the cascade of messaging on priorities.
iii. **Strengthening country systems:** Using short-term, parallel solutions can impact country capacity building. This kind of trade-off decision is carefully considered each time, with the PPC taking a lead role. Currently, there is very limited capacity at country level to strengthen systems.
iv. **Country missions:** Consideration is currently being given to restarting 'business critical' missions to countries. Not all countries would be visited, and not for general purposes. Despite the lack of in-country missions, communications and engagement with countries continues to be extensive.

Annex 6 – Relevant past Board Decisions

Relevant past Decision Point	Summary and Impact
Decision Point: GF/B39/DP11: Approval of the Risk Appetite Framework[6] **(May 2018)**	Based on the recommendations of the Strategy Committee and the Audit and Finance Committee, the Board approved the Risk Appetite Framework, including Risk Appetite, Target Risk levels and the indicative timeframes for achieving Target Risk, as described in the table in Annex 3 to GF/B39/07.
Decision Point: GF/B32/DP: Approval of the Risk Management Policy[7] **(November 2014)**	Based on the recommendation of the Finance and Operational Performance Committee, the Board approved the Risk Management Policy, as set forth in Annex 3 to GF/B32/13.

Annex 7 – Relevant past documents & reference materials

Risk Management Report and CRO's Annual Opinion GF/B45/17

Update on Risk Appetite GF/AFC16/05A

Update on Risk Appetite GF/SC16/02

[6] https://www.theglobalfund.org/board-decisions/b39-dp11/
[7] https://www.theglobalfund.org/board-decisions/b32-dp11/