

Technical Evaluation Reference Group: Evaluation of Accelerating the Equitable Deployment of and Access to Innovations

TERG Position Paper, Management
Response and Final Report

November 2022

TERG Position Paper

Evaluation on Accelerating the Equitable Deployment of and Access to Innovations

Executive Summary

Context

A “greater focus on accelerating the equitable deployment of and access to innovations” is one of the ten examples of changes to accelerate the pace of implementation in the Global Fund’s Strategy for 2023-2028. Prior to the “Evaluation of Accelerating the Equitable Deployment of and Access to Innovation” (Evaluation), no comprehensive Global Fund evaluation had been undertaken to assess the design, implementation, challenges and opportunities for deployment of, and access to innovations. The Strategy Committee (SC) of the Board emphasized the need to understand these issues, including how the Global Fund’s investments complement the work of other global health actors. The Evaluation was commissioned by the Technical Evaluation Reference Group (TERG), as part of its 2022 SC-approved workplan. The overarching aim was to identify and support learning and evidence-based decision making on innovations to inform implementation of the 2023-2028 Strategy, as well as to establish a baseline against which the Global Fund can monitor and report on progress towards meeting its intended objectives regarding access to innovations.

Key Messages from the Evaluation

The Evaluation contained 22 key findings and eight high-level conclusions. The Evaluation showed that the overall funding model is not optimized to support innovation scale-up. In particular, it has not optimally employed several “strategic levers” to shape country demand. In addition, there is a lack of a clear approach to supporting innovations, especially with regard to how equity in innovation access should be supported. Moreover, the Global Fund’s comparative advantage with respect to country perspectives and insights on demand in countries is also not sufficiently used to support market shaping. It is worth noting that a number of strategic initiatives and matching fund approaches are showing positive results regarding demand shaping, including on non-product innovations, as well as partner coordination and transitions. In spite of this, there is need for further clarity on how the Global Fund will work with partners to support innovations as well as address some key gaps in partner work to support equitable scale-up by the Global Fund. Finally, there is scope for the

provision of more technical assistance to countries and the expansion of appropriate partnerships to support the rollout of innovations on service/ program delivery and health systems management tools and processes.

The Evaluation report provides the following seven recommendations:

1. Develop a systematic approach to supporting innovations, alongside necessary organizational aspects;
2. Pro-actively capture and analyze information on the introduction and scale-up progress of innovations;
3. Conduct ongoing strategic scanning to identify availability and need for innovations, and inform Global Fund support/ signaling;
4. Optimize use of Global Fund “strategic levers” to support innovations including: (i) market-shaping; (ii) funding guidance, review and support; (iii) catalytic investments; and (iv) funding modalities;
5. Strengthen the engagement and role of countries and communities within the identification and implementation of innovations;
6. Ensure more systematic partner coordination in support of innovations; and
7. Strengthen consideration of equitable deployment within the support for innovations.

The TERG endorses the key findings, conclusions and recommendations of the Evaluation, with some additional considerations.

Input Received

The scope of work and the Evaluation questions were developed after extensive consultations with the Global Fund Secretariat and the SC. The Evaluation was conducted with substantial contributions from relevant Global Fund Secretariat stakeholders and further inputs from the SC, as well as relevant external partners and stakeholders.

Report

Background

The **Global Fund's Strategy for 2023-2028** highlights ten key aspects of the Global Fund's work that will need to change to accelerate the pace of implementation to achieve the global health goals of SDG 2030. One of these aspects is – “greater focus on accelerating the equitable deployment of and access to innovations”, articulating the importance of “working with partners to take an end-to-end view to rapidly address bottlenecks to deployment to those most in need”.¹ **Previous Global Fund/TERG evaluations and reviews**² have recommended exploring how the Global Fund can better support scalable innovations; particularly products, approaches, interventions and tools. However, to date there has been no comprehensive Global Fund evaluation to assess the range of relevant innovations in the Global Fund context, and the challenges and opportunities to accelerate equitable deployment of and access to innovations.

The Strategy Committee (SC) of the Board has emphasized the need to understand how Global Fund investments currently support equitable deployment of and access to innovations, and how these issues complement the work of other global health actors. The Evaluation was commissioned by the Technical Evaluation Reference Group (TERG), as part of its 2022 workplan. The overarching aim was to identify and support learning and evidence-based decision making on innovations to inform implementation of the 2023-2028 Strategy, as well as establish a baseline against which the Global Fund can monitor and report on progress towards meeting its intended objectives regarding access to innovations. The objectives of the Evaluation were:

- To assess the **design, implementation** and **results** including challenges of equitable deployment of and access to innovations that have been supported by the Global Fund and other global health actors since 2017;
- To assess the **contribution** of some of the innovations to the achievement of selected outcomes and results; and
- To draw **lessons** learned by identifying **facilitating** and **hindering** factors to access and deployment of innovations and to develop **actionable recommendations** to guide investments and implementation, and baseline indicators during the 2023-2028 Strategy period.

The Evaluation was carried out by Cambridge Economic Policy Associates (CEPA) between May and August 2022. The terms of reference and the strategic evaluation questions were developed by the TERG in consultation with the Global Fund Secretariat and the SC. While

¹ [Fighting Pandemics and Building a Healthier and More Equitable World: Global Fund Strategy \(2023-2028\)](#)

² TERG thematic review on Private Sector Engagement 2021, HIV Primary Prevention 2021, Strategic Review 2020 and Market Shaping Strategy (MSS) Mid-term Review 2019

the Global Fund has a long history of supporting innovations since its inception, e.g., antiretroviral treatment (ART), artemisinin-based combination therapy (ACT), long-lasting insecticidal nets (LLINs), etc., the Evaluation focused on innovations relevant for the current 2017-2022 Strategy period and the next Strategy period 2023-2028 only. Following an initial work on innovation typology, the Evaluation encompasses health product as well as non-product innovations, with greater emphasis on the former.

Methods, Approach and Key Limitations

The Evaluation was framed around a bespoke **innovation typology** for the Global Fund, described in the Evaluation report. The Evaluation design comprises a total of **seven innovation case studies**: 1) PReP, 2) HIV self-testing, 3) GeneXpert/ Molbio Truenat, 4) DR-TB short oral regimens with bedaquiline (BDQ), dual active ingredient and 5) piperonyl butoxide nets, 6) facility-level financing and 7) mobile financial payments. The Evaluation design is complemented and cross-validated by country case studies/ interviews, global-level stakeholder interviews, Global Fund and partner document reviews and data analysis. These methods supported the assessment of 10 key evaluation questions, which were organized in line with the objectives of the Evaluation and focused on design, implementation and results of Global Fund-supported innovations. Within these three aspects, the Evaluation questions were grouped by topic to support a coherent presentation of findings. The topics included: (i) Global Fund role and systems for innovation; (ii) Barriers and enablers for innovations; (iii) Global Fund working with partners; (iv) Learnings from COVID-19; (v) Measurement of Global Fund work on innovations; and (vi) Contribution of key innovations to achieving Global Fund outcomes and results. Findings of the Evaluation report are organized by these topics. The Evaluation report culminates in lessons and recommendations for the Global Fund.

The main limitation of the Evaluation was the tight timeframes for analysis, which has been managed as effectively as feasible through close engagement between the evaluation team and the TERG Secretariat. Similarly, all country interviews had to be conducted remotely. Finally, current Global Fund databases (PQR, funding and performance data) did not enable a systematic quantitative analysis of the extent to which the Global Fund has supported innovations across countries, including with regards to equity in access to innovation, limiting the evaluators' ability to conduct planned landscape analysis. This was an important finding and is detailed in Section 3 of the Evaluation report.

Key Messages from the Evaluation

Key findings of the Evaluation were organized into seven sub-sections: (i) Global Fund role and systems for innovation; (ii) Barriers and enablers for health product innovations; (iii) Barriers and enablers for non-product innovations; (iv) Global Fund working with partners; (v) Learnings from COVID-19; (vi) Measurement of Global Fund work on innovations; and (vii)

Contribution of innovations to Global Fund results. A summary of the key findings can be found in Annex 5 of this paper.

The Evaluation report contains eight key conclusions, which are summarized here:

- There is a **lack of a clear approach to supporting innovations**, and specifically with regards to how **equity in innovations access** will be supported.
- The Global Fund is **not organized effectively** to support innovations, with multiple teams within the Secretariat managing different aspects of innovations (technical, procurement, country engagement) and with limited coordination, accountability and differing incentives.
- Several aspects of the Global Fund's **funding model** do not naturally support innovations and there has been **sub-optimal use of available "strategic levers"** within the funding model.
- While the Global Fund's funding model is fundamentally demand-driven, there is a **core need to guide and better inform the country demand for innovations** for optimal outcomes.
- The Global Fund's comparative advantage with respect to country perspectives and insights on demand is not being adequately used to support **market shaping**, including through timely and accurate **demand forecasts**.
- There is need for further clarity on how the Global Fund will **work with partners** to support innovations, as well as some key gaps in partner work to support scale-up by the Global Fund.
- The **Catalytic Funding** initiatives have shown positive results with regards to demand shaping, as well as partner coordination and transitions. Several Strategic Initiatives and Matching Funding approaches have been successfully deployed to support the initiation and early scale-up of different innovations.
- Innovations on **service/ program delivery** and **health systems management tools and processes** (i.e., non-product innovations) face additional challenges. The diversity of these non-product innovations makes managing and supporting roll-out by the Global Fund more complex.

Recommendations

The evaluation team made seven recommendations to accelerate the equitable deployment of and access to innovations. The main thrust and key actions are summarized in the bullet points underneath each recommendation, with suggested key implementers, timelines and capacity requirements noted. This Recommendations section is followed by a section on discussion and TERG's position.

Recommendation 1: Develop a systematic approach to supporting innovations, alongside necessary organizational aspects

- **Develop a systematic approach for the Global Fund’s support to facilitating access and equitable deployment of innovations.** This should provide a clear institutional definition and clear typology of innovation and of equitable deployment, a sense of the priority and the direction the Global Fund will take regarding support for facilitating innovations. The Global Fund should formalise the decision-making process for what innovations will be supported, including the deployment of Value for Money (VfM) criteria and equitable deployment. It should also describe how it will support its country-driven model by optimising the use of its available “strategic levers” (further detailed in Recommendation 4) and set out the actions and next steps as well as expected roles and responsibilities of the Secretariat vis-a-vis key partners.
- **Create appropriate organisational arrangements within the Global Fund to facilitate the innovation approach.** In order to effectively implement an organisation-wide approach to innovations and noting the challenges identified in the Evaluation report with regards to roles and responsibilities within the Global Fund Secretariat, it is important to clearly assign roles and responsibilities for the delivery of the innovations approach across various teams in the Secretariat. Some organisations have created “innovation teams or hubs”; while the evaluation team does not recommend this per se, the Global Fund should create the needed leadership and roles that are able to effectively coordinate the facilitation of innovation acceleration and equity. The development of these organisational elements should also take account of the partnership model to identify where partners might be better placed to achieve results. Given the importance of innovations in the 2023-2028 Strategy, the Global Fund may consider Board-level accountability (e.g., through a Board Committee).

Implementation responsibility: *Global Fund Secretariat*

Timeline: *in time for the start of the Global Fund Strategy 2023-2028*

Capacity requirements: *medium to high input required for the development of the approach, but expected through use of existing Global Fund Secretariat resources*

Recommendation 2: Pro-actively capture and analyze information on the introduction and scale-up progress of innovations

- **Create a systematic approach – and related responsibility, capacity, accountability – to capture and analyse data on innovations.** This would be a pre-requisite to effectively measure progress, identify bottlenecks and assign remedial actions.
- **Create sub-indicators to the draft KPI S10 for priority products that track introduction and scale-up by country against ambitious targets in close**

coordination with partners. The development of the draft KPI S10 on new product introductions has been a step in the right direction. However, its usefulness will be determined by the extent to which more detailed indicators are developed that meaningfully track progress.

- **Update the PQR database to allow for identification and tracking of key product innovations.** The current PQR database is outdated and does not allow for a systematic analysis of innovation. An update should include the separate categories for innovative products/ product categories (and the ability to add these at a later stage); to disentangle use cases of drugs (e.g., PrEP vs ART) and to add a simple innovation flag corresponding to any priority innovations identified through partner collaboration. These would serve as “quick wins” for the Global Fund, i.e., considerable additional benefit at minimum cost and effort.
- **Include country performance/ results indicators on innovations, including on their equitable deployment, where feasible.** The Global Fund should consider where the introduction and scale-up of innovation can be more directly included in country performance and results indicators.

Implementation responsibility: *Global Fund Secretariat in close coordination with partners (including Unitaaid, STOP TB Partnership and WHO)*

Timeline: *within the 2023-2025 Funding Cycle*

Capacity requirements: *medium – requiring some additional capacity across relevant teams*

Recommendation 3: Conduct ongoing strategic scanning to identify availability and need for innovations, and inform Global Fund support/ signaling

- **Improve the innovation knowledge base at the Global Fund Secretariat on innovation (both product and non-product) availability and needs through regular and strategic scanning.**
 - For innovation availability this should include a mapping of the innovation landscape to identify and track the evolving maturity of existing innovations as well as the corresponding evidence on emerging innovations.
 - On the innovation needs side, this should include regular analysis of the existing portfolio of tools to fight the three diseases to identify impeding issues (e.g., resistance etc.) and gaps that potential innovations could mitigate.
 - Importantly, the identification of innovation availability and need should also be done in discussion and coordination with recipient countries and upstream partners such as Unitaaid.
- **Make greater use of the established knowledge by clearly signalling needs and priorities to countries and partners, and by informing Global Fund internal processes.** This early signalling would address partner wishes to have a

stronger understanding of the type of innovations that the Global Fund is planning to support.

Implementation responsibility: *Global Fund Secretariat in close coordination with partners and recipient countries*

Timeline: *in time for the start of the Global Fund Strategy 2023-2028, and ongoing updates*

Capacity requirements: *low for product innovations, medium for high impact non-product innovations with some capacity implications for relevant Global Fund Secretariat teams*

Recommendation 4: Optimize use of Global Fund “strategic levers” to support innovations including: (i) market-shaping; (ii) funding guidance, review and support; (iii) catalytic investments; and (iv) funding modalities

- **Strengthen Global Fund market shaping activities for product innovations** – this should ensure the timely implementation of the Next Generation Market Shaping initiative. A key aspect for improvement is with regard to stronger partner coordination and alignment on innovations through the development of roadmaps (and the recent development of a Taskforce between Unitaaid and Global Fund is a step in the right direction). Another aspect is the improvement of demand forecasting as well as the use of these forecasts to improve supply negotiations
- **Improve funding guidance and review/ feedback to support demand creation for innovations** – this should include stronger guidance on the use of innovations (e.g., through information notes, technical guidance, Funding Request templates, etc.) as well as consistent and supportive messaging through Country Teams on the use of innovations as applicable to different country contexts. Additionally, stronger and more clearly communicated Technical Review Panel (TRP) criteria could be used to support innovation demand and the use of Portfolio Optimization could be leveraged more.
- **Strategic use of Catalytic Funding** – Catalytic Funding should continue to be used strategically to support innovations, while recognizing the limited resource envelope.
- **Review the expansion and adaptation of other funding modalities to facilitate innovations.** The Global Fund Secretariat should commission a review of its business processes and skillset to align with requirements to facilitate innovation through new funding modalities as well as related reporting requirements. In particular, this would include strengthening the processes and skills required to foster funding modalities which focus on output, outcomes and results, rather than on inputs.

Implementation responsibility: Global Fund Secretariat closely coordinated with partners and recipient countries

Timeline: within the 2023-2025 Allocation Cycle

Capacity requirements: high

Recommendation 5: Strengthen the engagement and role of countries and communities within the identification and implementation of innovations

- **Support access to Global Fund funding from additional non-traditional recipients of funding.** This could include supporting the CCM processes in country by encouraging the engagement of smaller/ non-traditional Global Fund recipients that are active in the innovation space e.g., community-based organizations, private sector organizations.
- **Encourage dialogue with countries on innovation pipelines.** The Global Fund should put in place processes that allow for countries to feed into the global level discourse with partners on innovation priorities and scale-up needs. For product innovations this could include country representatives to be included in partnership meetings on the upcoming innovation pipelines.
- **Providing access to the latest information and technical expertise.** This could include ensuring countries have access to the latest information on innovations at the global level, including availability of new products, market developments, evolution of WHO guidelines, etc. This could also include providing funding support to ensure the needed technical expertise is available in country for innovation introduction and scale-up.
- **Support cross country learning on innovations.** While acknowledging the different country contexts and the need to adapt non-product innovations, the Global Fund should ensure that lessons learned, and best practices are recorded and shared between countries (and also across Global Fund Country Teams and other Secretariat teams, and with partners).

Implementation responsibility: Global Fund Secretariat and recipient countries

Timeline: ongoing within the 2023-2025 Allocation Cycle

Capacity requirements: medium

Recommendation 6: Ensure more systematic partner coordination in support of innovations

- **Ensure a systematic, institution-wide and documented approach to the Global Fund's ways of working with partners on innovations.** This would go beyond the high-level MOUs that are in place with some partners such as Unitaid,

and include documentation and agreed processes regarding coordinating the work on innovations.

- **Work proactively on transition of partner work (e.g., Unitaid, STOP TB Partnership, PDPs, BMGF etc.).** This should include early engagement and visibility of the Global Fund in the upstream work of partners with early consideration on how innovations can be integrated into the Global Fund's funding applications.
- **Develop stronger collaboration with partners to generate and disseminate cost-effectiveness data and evidence.** The findings have shown that demonstration of cost-effectiveness is a key enabler for stronger demand and uptake of innovation. The Global Fund should work with partners to ensure that relevant evidence is generated and disseminated (see box in Recommendation 6 of the Evaluation report for some suggestions on priorities for data collection).
- **Collaborate and support partners in pre-scale-up work including global prioritization and WHO normative guidance and national guidelines.** Following on from Recommendation 2, this should include the Global Fund signaling to partners on country demand for innovations and the potential for funding support from the Global Fund.
- **Seek out appropriate partnerships for non-product innovations** – this can include encouraging existing upstream partners (e.g., Unitaid, STOP TB Partnership) to become more active in the non-product innovations space (especially on the service delivery approaches for product innovations), and to identify new partners on wider health system aspects. This should also include working towards an integrated approach (i.e., not vertical disease based) in coordination with partners such as Gavi or the World Bank.

Implementation responsibility: Global Fund Secretariat and key partners

Timeline: within the 2023-2025 Allocation Cycle

Capacity requirements: medium to high

Recommendation 7: Strengthen consideration of equitable deployment within the support for innovations

- **Develop a clear approach on how equitable deployment of innovations will be considered going forward** – including a definition of equitable deployment, and the way it will be considered within identification and implementation of innovation. This should also include the types of inequities which will be a focus with regard to innovation (e.g., sub-populations not receiving new tools; geographic inequities between and within countries etc.).
- **Collect data and information on equitable deployment of innovation** – where feasible, the Global Fund should explore how quantitative data could be collected with regard to innovations (e.g., coverage of tools by different population groups, coverage

within a country with regard to regional gaps etc.), and how this information would be used to improve implementation. This work can be combined with the efforts under the Global Fund Strategy to reduce health inequities across the three diseases.

Implementation responsibility: *Global Fund Secretariat*

Timeline: *within the 2023-2025 Allocation Cycle*

Capacity requirements: *medium*

Discussion and TERG Position

The TERG endorses the key findings, conclusions and recommendations of the Evaluation. The TERG is of the view that while the organization of the recommendations, setting out implementation responsibilities, timelines and capacity requirements is useful for operationalization, findings, conclusions and recommendations could be further prioritized.

The TERG wishes to highlight the following:

- A. As stated in Recommendation 2, it is important to proactively capture and analyze information on the introduction and progress of innovation scale-up. The TERG noted that the consultants were unable to offer substantial revision to the current draft KPI for innovation (S10 in the most recent list of draft KPIs). The draft KPI requires further improvement as it is limited in its ability to capture several important aspects of innovation. These include a **lack of measurement of associated equity and how innovative advances are differentially valued**. The Global Fund needs to consider whether innovation is best measured through some form of **regular qualitative assessment** that considers the **importance of specific innovations**, the **extent and speed with which scale-up has been achieved**, **how equitable deployment has been**, and the **effect of Global Fund actions and/or funded activities** compared to what would likely have happened in the absence of such actions or activities.
- B. Equitable access to innovation cannot be assessed until the Global Fund clearly **defines equity** for its purposes, and **develops protocols on how equity may therefore be measured**. This is therefore a prerequisite for Recommendation 7.
- C. Similarly, Recommendation 4 on optimizing use of strategic levers cannot be fully addressed until the Global Fund has carried out a **full review of the extent to which its funding modalities can/should be varied, potentially implying changes in business processes and alignment of skillset**. Once a decision related to funding modalities has been taken, with likely major implications for the Value for Money of Global Fund investments, it will be possible to **assess how best to support the necessary innovations in the funding of outputs and potentially outcomes on the part of implementers**. This does not suggest movement away from funding based on

current approved country allocation methodology and catalytic investments; it refers only to a potential additional set of evaluation metrics.

- D. The TERG wishes to include in Recommendation 6 a significant focus on the need for **selection and prioritization of innovations** (from among the wide universe of potential safe and efficacious innovations). This must be referenced to an assessment of the likely Value for Money of the innovations (including the incremental cost-effectiveness ratio approach described in the box in Recommendation 6 of the report). This process requires strong collaboration between countries, partners and the Global Fund Secretariat, with particular emphasis on the role of Global Fund Country Teams working closely with countries and their in-country partners.

Annexes

The following items can be found in Annex:

- Annex 1: Relevant Past Board Decisions
- Annex 2: Relevant Past Documents & Reference Materials
- Annex 3: Abbreviations
- Annex 4: Summary of Evaluation Key Findings

Annex 1 – Relevant Past Board Decisions

Relevant past Decision Point	Summary and Impact
GF/B46/DP04: Global Disease Split for the 2023-2025 Allocation Methodology (November 2021)³	The Board recognized the need to further increase funding for tuberculosis and maximize the quality and impact of tuberculosis programs in line with the ambition of the Global Fund Strategy Narrative, requests the Secretariat, partners and committees, as relevant, to propose and implement specific options to address these needs, including continuing to pursue innovative finance opportunities to increase funding to tuberculosis in high burden countries.
GF/B46/DP03: Approval of the Strategy Narrative for the 2023-2028 Global Fund Strategy (November 2021)⁴	The Board approved the Strategy Narrative for the 2023-2028 Global Fund Strategy in Annex 1 to GF/B46/03_rev1 and requests that the Secretariat develop, for presentation to the Strategy Committee in March 2022 and subsequently the Board in May 2022, an approach for Strategy implementation with a focus on delivering the key changes outlined in the Strategy using all existing levers and identifying where new solutions will be required.

Annex 2 – Relevant Past Documents & Reference Materials

- [TERG Thematic Evaluation on Strategic Initiatives](#), December 2021.
- [TERG Thematic Review on the Role of the Private Sector in Program Delivery](#), May 2021.
- [TERG Thematic Review of HIV Primary Prevention](#), May 2021.
- [TERG Market Shaping Strategy Mid-Term Review](#), December 2019.
- [Market Shaping Strategy](#), 34th Board Meeting, Annex 1 to GF/B34/17 – Revision 1, November 2015.

³ [GF/B46/DP04](#)

⁴ [GF/B46/DP03](#)

Annex 3 – Abbreviations

ART	Antiretroviral treatment
CCM	Country Coordinating Mechanism
DR-TB	Drug-resistant tuberculosis
KPI	Key Performance Indicator
PQR	Price And Quality Reporting
PrEP	Pre-exposure prophylaxis
TERG	Technical Evaluation Reference Group (Global Fund)
UNAIDS	Joint United Nations Programme on HIV/AIDS
VfM	Value for Money
WHO	World Health Organization

Annex 4 – Summary of Evaluation Key Findings

Global Fund role and systems for innovations

1. The Global Fund has a strong comparative advantage vis-a-vis other global health organisations in supporting innovation scale-up and has a long history of supporting a range of innovations in antiretroviral treatment (ART), long-lasting insecticidal nets (LLINs), artemisinin-based combination therapies (ACTs), amongst others. Notwithstanding the fact that its funding is fundamentally country owned and country driven, while it has done well to deploy a range of Catalytic Funding initiatives to support the introduction and early uptake of innovations, the overall funding model of country allocations is not yet optimised to support innovation scale-up. In particular, it has not optimally employed several “strategic levers” within its funding model to shape country demand, nor maximised on its market shaping role. There is also scope for the Global Fund to better engage with partners in the pre-scale-up stages of innovations.
2. The Global Fund does not have readily available and useable data to systematically assess its support for innovations. The Price and Quality Reporting (PQR) database on product procurements through Global Fund grants does not provide procurement data for specific innovative products. The Global Fund funding and performance data offers limited exacting information on the extent to which innovations have been supported. Further, there is no database on non-product innovations and no systematic capture of the range of these innovations.
3. In general, there has been greater focus on and visibility of health product innovations by the Global Fund as compared to non-product innovations. There has been more effort in scaling up innovations in line with Global Fund’s priorities and areas of expertise (e.g., in terms of priorities, innovations in HIV prevention have received less attention until now; in terms of expertise, there has been more attention on innovative financing approaches as compared to other non-product innovations). While the Global Fund has not “missed” any innovations per se, several innovations reviewed under the

Evaluation have seen an average of around a 10-year lag from initial product approvals by FDA and 6-7 years from initiation of WHO guidance.

4. There has been a lack of effective prioritisation of innovations by the Global Fund and there is no overall strategy or approach to supporting innovations, and specifically with regards to equitable access to innovations. There is no pro-active intelligence on the upcoming tools, nor an agreed list of innovations that will be supported by the Global Fund. There is no clear allocation of roles and responsibilities or accountability for innovation work within the Global Fund Secretariat, with multiple teams partaking in work relevant to innovations. While its model is country driven, there is no systematic decision-making process or agreement on criteria (e.g., VfM) within the Global Fund to support the scale-up of innovations, with the experience to-date largely being opportunistic and ad hoc.
5. The Global Fund has not optimally used its available “strategic levers” within the funding model for core funding allocations. Key amongst these are: the Country Coordinating Mechanism (CCM) ecosystem (i.e., organisations that participate and engage with the CCM) that may not always include organisations at the forefront of innovations in countries; lack of emphasis on innovations in the country guidance; lack of incentives in grant application and implementation, as well as funding modalities; limited use of the Technical Review Panel (TRP) review; and varying degrees of support from Global Fund Country Teams on innovations across countries.

Barriers and enablers for health product innovations, emphasising Global Fund’s role and performance

Value chain and effectiveness	6. The process to scale-up a health product innovation is highly complex and lengthy, with multiple factors driving its success or failure. Across the case studies for the Evaluation, coordinated partner action, that simultaneously addresses multiple barriers is a key factor driving success. An integrated approach where new product introduction is supported with associated innovations in service delivery approaches, and helps tackle demand side and health systems issues has been most useful.
Global prioritisation/ perceived value of innovation	7. Global stakeholders would like the Global Fund to more proactively signal its prioritisation of health product innovations. This would involve the Global Fund engaging more proactively upstream in a way that complements (and not duplicates) the mandates of upstream partners (e.g., WHO, Bill & Melinda Gates Foundation (BMGF), Unitaid, STOP TB Partnership, Product Development Partnerships (PDPs), etc.).
Normative guidance	8. The sequential order of WHO policy guidance and product pre-qualification prior to Global Fund financing extends the timeline for deployment of innovations. The Global Fund has been most effective in shortening the ‘global policy to country introduction gap’ by working in parallel to WHO policy development to ‘line up’ the levers at its disposal.
Market/ supply characteristics and price, affordability	9. The market shaping role of the Global Fund is not proactive or deliberate with regards to innovations and the Market Shaping Strategy for innovations has not been fully implemented. To date, the Global Fund’s market shaping role has been mainly through the Pooled Procurement Mechanism (PPM) and Quality Assurance

and cost effectiveness	tools, without any further tools (e.g., volume commitments) to shape markets for innovations. Stakeholders have indicated that this is an area of missed opportunity for the Global Fund.
	10. The Global Fund's comparative advantage with respect to country perspectives and insights on demand is not being adequately used to support market shaping, including through timely and accurate demand forecasts developed in coordination with partners. This is regarded as particularly important in the early stages of market growth, where lack of information on country demand has impeded the work of other partners.
	11. The importance of cost-effectiveness analysis to support innovation roll-out cannot be overemphasised, and there is a need for the Global Fund to work more with partners to ensure this evidence is developed and disseminated to countries.
Country demand and readiness, and implementation	12. Strategic levers in the Global Fund's funding model have been used on an ad-hoc basis for demand creation of innovations. There are few incentives within CCM processes, funding request guidance and reviews or Global Fund financing and performance measures to introduce innovations (and to propose a high level of ambition), contributing to inertia in funding allocations for deployment of innovations. As such, the Global Fund could do more to foster the enabling environment for innovations in countries.
	13. Catalytic Investments are overall well regarded to encourage country introduction and uptake as well as address implementation challenges, noting these are significantly smaller than core funding allocations, and are not a "silver bullet" for scaling innovations.

Barriers and enablers for non-product innovations

14. There have been a wide range of non-product innovations supported through Global Fund funding, however their extremely diverse nature – in concept, application and stakeholder understanding of these innovations – renders it challenging to scope out the universe of these innovations. This also enhances the challenge for the Global Fund in managing and supporting their varied roll outs.
15. The Global Funds lacks the capacity and systems to facilitate the roll-out of non-product innovations.
16. The variability of non-product innovations creates a challenge in balancing standardisation of approaches with the need for adaptation to specific contexts, and complicates planning for scale up. Countries could benefit from more engaged technical assistance in adapting roll-out to their specific circumstances, which would require support from technical partners.

Global Fund working with partners

17. The Global Fund is working with the right partners at the global level for innovations, and needs to adapt its approaches to engaging with: (i) smaller and more diverse country partners; and (ii) private sector (global and country).
18. Looking specifically at partner work in support of innovation scale-up by the Global Fund, there are key gaps in terms of the transition of Unitaids' early country introduction work to a wider range of

Global Fund eligible countries, as well as in terms of the capacity of WHO to provide technical support across a wide range of countries. Across partners, there is a key gap in generating and disseminating cost effectiveness evidence to support country demand and uptake – an essential pre-requisite to scale-up.

19. The Global Fund does not have a systematic, institution-wide and documented approach on working with global partners on innovation, and specifically in terms of managing the transition from Unitaaid project funding.

Measurement of Global Fund work on innovations and contribution to achieving results

20. The current Global Fund Modular Framework enables only a limited analysis of innovations, with no quantitative indicators that capture a country's intention or early uptake, as well as equitable deployment of innovations.

21. The development of the KPI S10 for new product introduction is a step in the right direction, but its usefulness will be determined to a large extent by its specific methodology (e.g., coverage vs. outcome, consideration of equity) and alignment with partners.

22. There is a lot of good published evidence on the impact of key innovations, although Global Fund performance monitoring does not explicitly track this issue, and specifically with regards to equity in access to innovations. The pathway to results from new product innovations is highly complex, and differs by innovation and country context, highlighting the complexity in their deployment and the need for continued and engaged work between countries, Global Fund and partners.

Secretariat Management Response

TERG Evaluation on Accelerating Equitable Deployment of and Access to Innovations

November 2022

Introduction

The Technical Evaluation Reference Group (TERG) is an independent evaluation advisory group, accountable to the Global Fund Board through its Strategy Committee for ensuring independent evaluation of the Global Fund business model, investments, and impact. The Global Fund values transparency and publishes TERG reports according to the TERG Documents Procedure approved by the Strategy Committee.

The 2023-2028 Global Fund Strategy outlines the ambition to accelerate impact in ending the three diseases, building resilient health systems centered on the people they serve and including a greater focus on accelerating equitable deployment of and access to innovations. The Global Fund, working with partners, seeks to take an end-to-end view to rapidly address bottlenecks of deployment to those in need. In preparation for the 2023-2025 allocation cycle and 2023-2028 Global Fund Strategy implementation, the TERG commissioned a thematic evaluation of the Global Fund's approach on Accelerating Equitable Deployment of and Access to Innovations to date, as requested by the Strategy Committee.

The Secretariat welcomes and appreciates the report and its findings and broadly agrees with the findings and high-level conclusions from the report and the TERG position. The Secretariat considers the scope, methods, and overall evaluation framework used were well-suited to assessing degree of innovation/introduction of health commodities but less pertinent to non-product innovation. Recommendations are particularly relevant for health product innovations and management and reflect support changes that had already been incorporated in the design of the NextGen Market Shaping approach and other strategy and operational shifts recommended by technical units to support the 2023-2028 Strategy.

Areas of agreement

Develop a systematic approach to supporting innovations, alongside necessary organizational aspects (Recommendation 1)

The Secretariat agrees with the recommendation for health products but is less convinced that this is fit-for-purpose or applicable for non-health products, non-commodity service delivery, and financing innovations. With respect to health products (and innovations), the Secretariat has initiated a substantial amount of work in this area which is reflected in the new Strategy, the NextGen Market Shaping approach, and continued efforts toward streamlining new health product introductions via a documented end-to-end process with clearly defined roles and responsibilities.

The Secretariat does agree that there could be benefit in having an intentional set of cross-cutting practices and processes to structure, organize and encourage innovation, but is not sure that a formalized 'decision-making process' for what innovations will be supported, including the deployment of Value for Money (VfM) criteria and 'equitable deployment', is the best way to encourage innovation as it cannot be prescribed.

The Secretariat has internal working groups looking at how to best support the accelerated introduction of health product innovations at scale. The Secretariat also participates in disease-specific situation rooms and other technical fora that flag and signal both product and non-product innovations (as highlighted by examples in the TERG evaluation report). Through the Partnership Taskforce co-convened with Unitaïd, the roles, responsibilities, and contributions will be clarified for the Secretariat and other key partners across up-, mid-and downstream areas for introducing health product innovations at scale. Through partnership engagement, the Global Fund and Unitaïd have mapped the health product pipeline and used a prioritization approach to inform specific market shaping interventions, including through innovative financing mechanisms. NextGen Market Shaping also complements cross-cutting disease and RSSH interventions such as in-country capacity-building and systems strengthening related to health products, including improved approaches for demand planning.

The Secretariat agrees that it could be useful to have a working typology and use-case 'pathways' to innovations overall and not just new health products.

Conduct ongoing strategic scanning to identify availability and need for innovations, and inform Global Fund support/signaling (Recommendation 3)

The Secretariat fully agrees with this recommendation with respect to health products and action has already been taken to implement it. Disease-specific information notes for the 2023-2025 Allocation Period include a clear signaling of priority products and their role in improving program and clinical outcomes of interest and critical for impact to the Global Fund for the next grant implementation periods. We agree that the identification of innovation availability and need should be discussed and coordinated with recipient countries as part of the funding request development process; again, this has been signaled in Information Notes for applicants.

We agree that upstream scanning and horizon mapping of innovations in the pipeline must be done together with partners and in coordination with recipient countries. Catalytic Investments proposed for the 2023-2025 Allocation Period include complementary approaches to address market access challenges for accelerating access to innovations through two complementary components for agreed prioritized innovations: NextGen Market Shaping investments for supplier-facing engagement alongside disease-specific Catalytic Investments to support country-facing engagement for country readiness and demand. Resource mobilization is still underway to secure funding for these complementary components.

For non-product innovations, what is most critical is to ensure that Global Fund processes allow for innovation that correspond to need and challenges relevant in the specific context. Program essentials are a powerful new tool to communicate areas where adoption or generation of innovation can be applied to achieve outcomes.

The Secretariat agrees that greater clarity regarding needs and priorities to countries and partners is possible and that this does occur for health products and for some non-health product innovations such as differentiation of service delivery platforms, laboratory, surveillance and digital approaches.

Optimize use of Global Fund “strategic levers” to support innovations including: (i) market-shaping; (ii) funding guidance, review and support; (iii) catalytic investments; and (iv) funding modalities (Recommendation 4)

We agree that all levers to support and foster innovation must be deployed, and this has been a focus of the strategy delivery work. With respect to partner coordination, as noted by the evaluators and referenced earlier in this response, a Taskforce between Unitaid and the Global Fund has been set up to clarify each organization’s roles and responsibilities in product-specific market shaping efforts. Existing global partnership technical groups are already used to stay abreast of technical updates across HTM. Service delivery innovations and other efforts to overcome human rights barriers, foster innovation in TB case finding activities are supported already in this cycle and have been proposed for next cycle catalytic investments. The Secretariat continues to work to ensure technical and grant support to improve demand generation and forecasting at country level, recognizing the interdependencies on country stakeholders and technical partners. Through the Global Fund’s Pooled Procurement Mechanism/wambo.org, countries can access quality-assured health products through a diverse set of global pooled mechanisms (e.g., UNOPS, UNFPA, UNICEF), when using both Global Fund financing and non-Global Fund financing, including domestic financing. The Global Fund also provides access to long-term framework agreements with suppliers and knowledge sharing for countries for both grant and non-grant funded procurement (e.g., Kenya Medical Supplies Authority/KEMSA, Ethiopian Pharmaceuticals Supply Platform/EPSP). Strategic purchasing of services in addition to evidence-informed procurement of commodities, including ability to contract with different providers, public and private, pool resources effectively through integrating HTM services into health benefits packages, quality assuring delivery and identifying efficiencies including through better visibility of inputs and outputs, and effective budget execution are all elements of health financing systems strengthening and critical levers of the Health Financing Department.

Regarding non-health product innovations, the Health Financing Department is looking at development finance opportunities and performance-based funding modalities which could help foster innovations in specific countries.

The NextGen Market Shaping approach, funding request guidance, and Catalytic Investments (for NextGen Market Shaping, HIV (such as PrEP), TB and Malaria for the next implementation period have been developed and proposed based on lessons learned to accelerate equitable access to quality assured health product introductions at scale and stimulate innovation in prevention, case finding and case management (for HTM). Resource mobilization continues to ensure that complementary interventions can be implemented to accelerate access to health product introductions at scale.

[Funding request guidance](#) regarding the importance of priority products has been incorporated in disease-specific Information Notes for the next cycle, and they also highlight the importance of including and considering the introduction of new products or the development and deployment of service delivery innovations, and country examples are provided. Program essentials (new) spell out minimum expectations for programs where we invest to support. The [RSSH Information Note](#) outlines considerations on achieving equitable access to quality-assured existing and new health products.

Regarding use of Portfolio Optimization, the Secretariat has used this mechanism to support the roll out of the shorter MDRTB regimen, and this remains an avenue for supporting the introduction of innovations, and or accelerating new product adoption (e.g., COVID-19 self-testing) but will be assessed against the Strategy Committee-approved framework. The Secretariat notes that the Strategy Committee approved the revised Technical Review Panel criteria for the 2023-2025 Allocation Period in March 2022.

Strengthen the engagement and role of countries and communities within the identification and implementation of innovations (Recommendation 5)

The Secretariat agrees that country voices (including community voices) are critical for shaping the health product innovation pipeline and for determining whether and when innovations are appropriate for replication and scale, and for generating demand for the uptake of innovative products. However, access to latest information and technical expertise is not just the role of the Secretariat but also partners. For example, the World Health Organization is primarily responsible for diffusing updated or new guidelines. Countries can already include funding for technical assistance aimed at supporting the introduction and scale of innovations.

Regarding sharing of lessons learned and best practices, the Secretariat agrees that these should be shared at all levels (e.g., Secretariat, countries and partners) and will action this as and when these are available. Situation rooms, disease-specific (HTM), RSSH (e.g., lab and CHW) and HF/PEPAR/GF collaborative and in house regional/thematic peer learning channels are active and used to disseminate and share innovation practice developed and employed in country. Technical Advice and Partnership Teams (TAP) at the Secretariat regularly share updates, e.g., the TB Team shares a quarterly update which includes highlighting new models of care/products and impact and scale-up activities.

The Secretariat acknowledges that there are non-traditional recipients that are active in innovation that can and may be well placed in a specific country context to play a more direct role in implementation which may include receiving funding. CCMs are already encouraged to ensure broad engagement in the funding request development and country dialogue processes. Country-specific context as well as the context of the Global Fund's investment in each portfolio will need to be considered.

Ensure more systematic partner coordination in support of innovations (Recommendation 6)

The Secretariat broadly endorses this recommendation and agrees more can be done to improve partner coordination and that prioritization and focus on specific innovations with specific partners already occurs but can be further elaborated. NextGen Market Shaping has been designed accordingly, including through the Partnership Taskforce co-convened with Unitaid, mapping of priority pipeline products and co-developed implementation road maps with partners, including WHO, UNAIDS, FIND, civil society organizations, regional partners, and the private sector.

The Secretariat already takes a proactive approach to the transition of partner work, and funding request guidance (including the use of program essentials) for the 2023-2025 Allocation Period has highlighted the importance of considering the introduction and scale-up of innovations as part of the development of funding requests.

We agree that the dissemination of cost-effectiveness data and evidence is important to generate country-level demand, but this needs to be a concerted effort among relevant partners who need to

work together to collect and share data. Further, country-level demand can be generated and informed through meaningful engagement with affected communities.

The Secretariat already engages extensively with a range of Private Sector, technical and community partnerships to bring both private sector insights and experience and share innovations to country challenges, e.g., digital and HIVST support, Last Mile, BDB, CHW, laboratory, public health etc.

The Global Fund also engages in other partnerships that steward 'pre-scale work', for example the Conference for Antiretroviral Drug Optimization (CADO), Paediatric Antiretroviral Drug Optimization (PADO), and GAP-f (the Global Accelerator for Pediatric Formulations), and will continue to do so as appropriate and selectively recognizing the human resource implications.

Strengthen consideration of equitable deployment within the support for innovations (Recommendation 7)

The Secretariat supports all countries that qualify and are eligible through allocations; however, the level of financial support and Secretariat support is determined by the allocation and eligibility criteria (mostly driven by epidemiology and income status respectively). In countries with less GF investment, partner and domestic support is most critical in determining the pace of adoption of new products and innovation. Program Essentials communicate global priority areas for innovations and product adoption but require a regional- or country-specific lens to account for context-specific opportunities or challenges that hinder equitable deployment and access. The Global Fund has been piloting an approach whereby eligible buyers can access health products available on the wambo.org procurement transaction platform with non-Global Fund financing. Building on the findings from an assessment by the TERG, the Global Fund Board has decided to continue to provide access through this procurement mechanism beyond the pilot. This can be a powerful tool to enable smaller countries or regional organizations to access better pricing and access conditions and enhance equity of access when using domestic funding. Many health product innovations are only to be deployed in targeted subsets of a populations or settings and may include a phased approach to permit lessons learned prior to fuller scale roll-out. Together with Unitaid, the Global Fund will develop joint implementation road maps with partners, where the planned approach is transparent and will include considerations of equity.

The Secretariat is working with partners to: i) improve capacity and capability of Secretariat staff and in-country key stakeholders on equity; ii) integrate equity-related considerations into key guidance and grant requirements; iii) develop a KPI Framework to measure progress towards equity, as well as introduce specific tools, such as the Gender Equality Marker, to incentivize/track progress towards gender equality focus across program design, implementation and evaluation. However, it could be counterproductive for the Secretariat to develop and define its own criteria and protocols for measuring equity specific to innovation, as equity is an approach that should be applied to all aspects of Global Fund operations and not only for a particular program and/or intervention.

Observations on other recommendations

The Secretariat appreciates that the findings were derived rapidly to best inform the approaches and tools needed for the next cycle of grants. While there is broad endorsement, the Secretariat considers that some of the recommendations are not relevant or conducive to managing and generating country driven innovation. Areas where the Secretariat's opinion differed with that of the TERG on sub elements of a TERG recommendation have been addressed above.

With regards to the TERG position Point C related to Recommendation 4, the Secretariat notes a full review of funding modalities does not seem appropriate at this juncture. The Board approved a six-year strategy, and in May 2022 approved the allocation methodology and catalytic investments which sets out the funding modalities (country allocations and catalytic investments) for the 2023-2025 Allocation Period.

Pro-actively capture and analyze information on the introduction and scale-up progress of innovations (Recommendation 2)

While the Secretariat acknowledges the intent behind this recommendation, we are in partial agreement. The findings, conclusions, and recommendations are relevant to health product innovations, but less applicable to non-product innovation which will also be very important to achieve the progress set out in the new Strategy.

Through its renewed and close partnership with Unitaid, the Secretariat is working with partners to maintain a shared and prioritized view of the pipeline for health products of interest. For prioritized products, progress against agreed milestones will be tracked for upstream, midstream and downstream activities for scale-up, which will complement Key Performance Indicator (S10) but we do not recommend creating sub-indicators. There is also a planned upgrade of the Price and Quality Reporting (PQR) Tool, which will facilitate reporting on health product related metrics. However, for non-health product innovations tracking implementation presents challenges given the range of innovations to be encouraged (e.g., new uses of existing products, models of care, digital tools and financing) and the varying timelines within a grant's implementation period. Potential solutions will be explored.















With respect to the recommendation to include “country performance / results indicators on innovations”, the Secretariat considers that it would be better to undertake a portfolio-level analysis for specific products/innovations to identify countries which are well positioned to scale-up innovations.

Conclusions

The Secretariat notes that innovation is not an end in of itself. Innovation generates novel solutions, ideas, and ways of doing business, to improve a process, a product or a system, ultimately to improve efficiency, effectiveness or equity. Innovation is therefore not the end goal to be measured. Most critical is to ensure that the Global Fund fosters innovation, rapid diffusion, learning and replication within and across the partnership, notably at the country level. The Secretariat is eager to ensure at all levels that Global Fund financial and non-financial support, business operations and culture fosters innovation as much as possible.

The Secretariat thanks the TERG for our partnership to strengthen the impact of the Global Fund. We agree innovation is complex across our mission, needs to be enterprise-wide and could benefit from an intentional set of cross-cutting practices and processes to structure, organize, and encourage it. As described above, much work has already advanced toward this end and will continue as we move forward to deliver on our mission.

Summary of Recommendations

TERG Recommendations	Timeframe	Level of Agreement	Level of Control
1. Develop a systematic approach to supporting innovations, alongside necessary organizational aspects	In time for the start of the Global Fund Strategy 2023-2028		
2. Pro-actively capture and analyze information on the introduction and scale-up progress of innovations	Within the 2023-2025 Funding Cycle		
3. Conduct ongoing strategic scanning to identify availability and need for innovations, and inform Global Fund support/signaling	In time for the start of the Global Fund Strategy 2023-2028, and ongoing updates		
4. Optimize use of Global Fund “strategic levers” to support innovations including (i) market shaping; (ii) funding guidance, review and support; (iii) catalytic investments; and (iv) funding modalities	Within the 2023-2025 Allocation Cycle		
5. Strengthen the engagement and role of countries and communities within the identification and implementation of innovations	Ongoing within the 2023-2025 Allocation Cycle		
6. Ensure more systematic partner coordination in support of innovations	Within the 2023-2025 Allocation Cycle		
7. Strengthen consideration of equitable deployment within the support for innovations	Within the 2023-2025 Allocation Cycle		

TERG evaluation: Accelerating the equitable deployment and access to innovations

The Global Fund to Fight AIDS, Tuberculosis and Malaria

30 August 2022

FINAL REPORT

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ACRONYMS

Acronym	Full description
ABC	Activity-based contracting
ART	Antiretroviral treatment
ARV	Antiretroviral
BCC	Behaviour Change Campaign
BDQ	Bedaquiline
BMGF	Bill & Melinda Gates Foundation
CAB-LA	Long-acting injectable cabotegravir
CBO	Community Based Organisation
CSO	Civil Society Organisation
CCM	Country Coordinating Mechanism
CHAI	Clinton Health Access Initiative
CHWs	Community Health Workers
COE	Challenging Operating Environment
CT	Country Team (Global Fund)
C19RM	COVID-19 Response Mechanism
DFF	Direct Facility Financing
DHIS2	District Health Information System 2
DSD	Differentiated service delivery
DTG	Dolutegravir
Dual AI ITN	Dual Active Ingredient Insecticide Treated Net
EID	Early Infant Diagnostics
e-LMIS	electronic Logistics Management Information System
ERPD	Expert Review Panel for Diagnostics
FCDO	Foreign, Commonwealth and Development Office (UK)
FIND	Foundation for Innovative New Diagnostics
FLF	Facility Level Financing
FPM	Fund Portfolio Manager (Global Fund)
GAC	Grant Approvals Committee (Global Fund)
GMD	Grant Management Division
HIVST	HIV Self-Testing
ICT	Information Communication Technology
IRS	Indoor Residual Spray
ITN	Insecticide-Treated Net
IVCC	Innovative Vector Control Consortium
KIIs	Key Informant Interviews
KPI	Key Performance Indicator
LMIC	Low- and middle-income country

Acronym	Full description
M&E	Monitoring & Evaluation
MMV	Medicines for Malaria Venture
MSS	Market Shaping Strategy
NNP	New Nets Project
NTI	Net Transition Initiative
OECD DAC	Organisation for Economic Co-operation and Development Assistance Committee
PAAR	Prioritised Above Allocation Request
PBF	Performance Based Funding
PBO	Piperonyl butoxide
PDPs	Product Development Partnerships
PEPFAR	US President's Emergency Plan for AIDS Relief
PfR	Payment for results
POC	Point-Of-Care
PQR	Price And Quality Reporting
PPM	Pooled Procurement Mechanism
PR	Principal Recipient (Global Fund)
PrEP	Pre-exposure prophylaxis
PSM	Procurement And Supply Management
RBF	Results-based financing
RBM	Roll Back Malaria Partnership
RDT	Rapid Diagnostic Test
RSSH	Resilient And Sustainable Systems for Health
SI	Strategic Initiative
SMC	Seasonal Malaria Chemoprevention
SR	Sub-Recipient (Global Fund)
SSC	Sourcing & Supply Chain
STAR	HIV Self-Testing AfRica initiative
TAP	Technical Advice & Partnerships (Global Fund)
TERG	Technical Evaluation Reference Group (Global Fund)
TRP	Technical Review Panel (Global Fund)
TOC	Technical Oversight Committee
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	The United States Agency for International Development
WHO	World Health Organization
WHO PQ	WHO prequalification

EXECUTIVE SUMMARY

Cambridge Economic Policy Associates (CEPA) was appointed by the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) Technical Evaluation Reference Group (TERG) to conduct an evaluation of the Global Fund's work on accelerating the equitable deployment and access to innovations. The objectives of the evaluation were to assess: (i) the **design, implementation and results** of innovations supported by the Global Fund and other global health actors since 2017; (ii) the **contribution** of these innovations to the achievement of results; and (iii) **lessons learnt and actionable recommendations** to guide 2023-28 investments and implementation.

This was a formative evaluation, that was both retrospective (i.e. looking at the Global Fund innovation landscape in the current Strategy 2017-22 in terms of what has worked and what has not worked, and why) and prospective (i.e. forward looking on what could work and why). It is recognised that the Global Fund has a long history of supporting innovations since its inception, but this assignment focused on innovations relevant for the current Strategy period 2017-22 and the next Strategy period 2023-28 only (i.e. both historic and early stage innovations were not reviewed). Also, this evaluation report focused to a large extent on health product innovations, although non-product innovations were also discussed and reviewed.

Key findings by evaluation topic are presented below, followed by recommendations. The new Strategy 2023-28 emphasises the importance of innovations to achieving the planned results and we note that several workstreams are ongoing to operationalise this Strategy objective.

Key findings

Global Fund role and systems for innovations

1. The Global Fund has a strong comparative advantage vis-a-vis other global health organisations in supporting innovation scale-up and has a long history of supporting a range of innovations in antiretroviral treatment (ART), long-lasting insecticidal nets (LLINs), artemisinin-based combination therapies (ACTs), amongst others. Notwithstanding the fact that its funding is fundamentally country owned and country driven, while it has done well to deploy a range of Catalytic Funding initiatives to support the introduction and early uptake of innovations, the overall funding model of country allocations is not yet optimised to support innovation scale-up. In particular, it has not optimally employed several "strategic levers" within its funding model to shape country demand, nor maximised on its market shaping role. There is also scope for the Global Fund to better engage with partners in the pre-scale-up stages of innovations.
2. The Global Fund does not have readily available and useable data to systematically assess its support for innovations. The Price and Quality Reporting (PQR) database on product procurements through Global Fund grants does not provide procurement data for specific innovative products. The Global Fund funding and performance data offers limited exacting information on the extent to which innovations have been supported. Further, there is no database on non-product innovations and no systematic capture of the range of these innovations.
3. In general, there has been greater focus on and visibility of health product innovations by the Global Fund as compared to non-product innovations. There has been more effort in scaling up innovations in line with Global Fund's priorities and areas of expertise (e.g. in terms of priorities, innovations in HIV prevention have received less attention until now; in terms of expertise, there has been more attention on innovative financing approaches as compared to other non-product innovations). While the Global Fund has not "missed" any innovations per se, several innovations reviewed under this evaluation have seen an average of around a 10 year lag from initial product approvals by FDA and 6-7 years from initiation of WHO guidance.
4. There has been a lack of effective prioritisation of innovations by the Global Fund and there is no overall strategy or approach to supporting innovations, and specifically with regards to equitable access to innovations. There is no pro-active intelligence on the upcoming tools, nor an agreed list of innovations that will be supported by the Global Fund. There is no clear allocation of roles and responsibilities or accountability for innovation work within the Global Fund Secretariat, with multiple teams partaking in work relevant to innovations. While its model is country driven, there is no systematic decision-making process or agreement on criteria (e.g. VfM) within the Global Fund to support the scale-up of innovations, with the experience to date largely being opportunistic and ad hoc.

Key findings

5. The Global Fund has not optimally used its available “strategic levers” within the funding model for core funding allocations. Key amongst these are: the Country Coordinating Mechanism (CCM) ecosystem (i.e. organisations that participate and engage with the CCM) that may not always include organisations at the forefront of innovations in countries; lack of emphasis on innovations in the country guidance; lack of incentives in grant application and implementation as well as funding modalities; limited use of the Technical Review Panel (TRP) review; and varying degrees of support from Global Fund Country Teams (CTs) on innovations across countries.

Barriers and enablers for health product innovations, emphasising Global Fund’s role and performance

Value chain and effectiveness	6. The process to scale-up a health product innovation is highly complex and lengthy, with multiple factors driving its success or failure. Across the case studies for this evaluation, coordinated partner action, that simultaneously addresses multiple barriers is a key factor driving success. An integrated approach where new product introduction is supported with associated innovations in service delivery approaches and helps tackle demand side and health systems issues has been most useful.
Global prioritisation/ perceived value of innovation	7. Global stakeholders would like the Global Fund to more proactively signal its prioritisation of health product innovations. This would involve the Global Fund engaging more proactively upstream in a way that complements (and not duplicates) the mandates of upstream partners (e.g. WHO, Bill & Melinda Gates Foundation (BMGF), Unitaid, STOP TB Partnership, Product Development Partnerships (PDPs), etc.).
Normative guidance	8. The sequential order of WHO policy guidance and product pre-qualification prior to Global Fund financing extends the timeline for deployment of innovations. The Global Fund has been most effective in shortening the ‘global policy to country introduction gap’ by working in parallel to WHO policy development to ‘line up’ the levers at its disposal.
Market/ supply characteristics and price, affordability and cost effectiveness	9. The market shaping role of the Global Fund is not proactive or deliberate with regards to innovations and the Market Shaping Strategy (MSS) for innovations has not been fully implemented. To date, the Global Fund’s market shaping role has been mainly through the Pooled Procurement Mechanism (PPM) and Quality Assurance tools without any further tools (e.g. volume commitments) to shape markets for innovations. Stakeholders have indicated that this is an area of missed opportunity for the Global Fund.
	10. The Global Fund’s comparative advantage with respect to country perspectives and insights on demand is not being adequately used to support market shaping, including through timely and accurate demand forecasts developed in coordination with partners. This is regarded as particularly important in the early stages of market growth, where lack of information on country demand has impeded the work of other partners.
	11. The importance of cost-effectiveness analysis to support innovation roll-out cannot be overemphasised, and there is a need for the Global Fund to work more with partners to ensure this evidence is developed and disseminated to countries.
Country demand and readiness, and implementation	12. Strategic levers in the Global Fund’s funding model have been used on an ad-hoc basis for demand creation of innovations. There are few incentives within CCM processes, funding request guidance and reviews or Global Fund financing and performance measures to introduce innovations (and to propose a high level of ambition), contributing to inertia in funding allocations for deployment of innovations. As such, the Global Fund could do more to foster the enabling environment for innovations in countries.
	13. Catalytic Investments are overall well regarded to encourage country introduction and uptake as well as address implementation challenges, noting these are significantly smaller than core funding allocations and are not a “silver bullet” for scaling innovations.

Barriers and enablers for non-product innovations

14. There have been a wide range of non-product innovations supported through Global Fund funding, however their extremely diverse nature – in concept, application and stakeholder understanding of these innovations – renders it challenging to scope out the universe of these innovations. This also enhances the challenge for the Global Fund in managing and supporting their varied roll outs.

Key findings

15. The Global Funds lacks the capacity and systems to facilitate the roll-out of non-product innovations.
16. The variability of non-product innovations creates a challenge in balancing standardisation of approaches with the need for adaptation to specific contexts and complicates planning for scale up. Countries could benefit from more engaged technical assistance in adapting roll-out to their specific circumstances, which would require support from technical partners.

Global Fund working with partners

17. The Global Fund is working with the right partners at the global level for innovations, and needs to adapt its approaches to engaging with (i) smaller and more diverse country partners; and (ii) private sector (global and country).
18. Looking specifically at partner work in support of innovation scale-up by the Global Fund, there are key gaps in terms of the transition of Unitaids early country introduction work to a wider range of Global Fund eligible countries as well as in terms of the capacity of WHO to provide technical support across a wide range of countries. Across partners, there is a key gap in generating and disseminating cost effectiveness evidence to support country demand and uptake – an essential pre-requisite to scale-up.
19. The Global Fund does not have a systematic, institution-wide and documented approach on working with global partners on innovation, and specifically in terms of managing the transition from Unitaids project funding.

Measurement of Global Fund work on innovations and contribution to achieving results

20. The current Global Fund Modular Framework enables only a limited analysis of innovations, with no quantitative indicators that capture a country's intention or early uptake as well as equitable deployment of innovations.
21. The development of the KPI S10 for new product introduction is a step in the right direction, but its usefulness will be determined to a large extent by its specific methodology (e.g. coverage vs. outcome, consideration of equity) and alignment with partners.
22. There is a lot of good published evidence on the impact of key innovations, although Global Fund performance monitoring does not explicitly track this issue, and specifically with regards to equity in access to innovations. The pathway to results from new product innovations is highly complex, and differs by innovation and country context, highlighting the complexity in their deployment and the need for continued and engaged working between countries, Global Fund and partners.

Recommendations

Recommendation 1: Develop a systematic approach to supporting innovations, alongside necessary organisational aspects

Recommendation 2: Pro-actively capture and analyse information on the introduction and scale-up progress of innovations

Recommendation 3: Conduct ongoing strategic scanning to identify availability and need for innovations, and inform Global Fund support/ signalling

Recommendation 4: Optimise use of Global Fund “strategic levers” to support innovations including (i) market-shaping (ii) funding guidance, review and support (iii) catalytic investments (iv) funding modalities

Recommendation 5: Strengthen the engagement and role of countries and communities within the identification and implementation of innovations.

Recommendation 6: Ensure more systematic partner coordination in support of innovations

Recommendation 7: Strengthen consideration of equitable deployment within the support for innovations

1. INTRODUCTION

Cambridge Economic Policy Associates (CEPA) was appointed by the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) Technical Evaluation Reference Group (TERG) to conduct an evaluation of the Global Fund's work on accelerating the equitable deployment and access to innovations. This is CEPA's Final Report for the assignment that presents the evaluation findings, conclusions and recommendations, building on a draft version that was reviewed by the TERG, Technical Oversight Committee (TOC)¹ constituted for this review and Global Fund Secretariat members as well as a workshop to co-create recommendations that was organised with the Global Fund Secretariat and TERG.²

The introduction section provides the evaluation objectives and scope (Section 1.1), evaluation framework and methodology (Section 1.2) and the structure of the rest of the report (Section 1.3).

1.1. EVALUATION OBJECTIVES AND SCOPE

As highlighted in the Terms of Reference (TOR) for this assignment, slow and inequitable introduction and scaling-up of new, game-changing innovations has had an impact on the fight against the three diseases and strengthening health systems. In recognition of this, the new Global Fund Strategy 2023-28 highlights ten examples of the organisation's work that will change in order to accelerate the pace of implementation to achieve the global health goals of SDG 2030, including "greater focus on accelerating the equitable deployment of and access to innovations".³ This emphasis is all the more important in light of the proximity of 2030 and the plateauing/reversal of progress against the three diseases due to the COVID-19 pandemic.

Recognising this priority, the TORs present the following main objectives for this evaluation:

- To assess the **design, implementation** and **results** including challenges of equitable deployment and access to innovations that have been supported by the Global Fund and other global health actors since 2017.
- To assess the **contribution** of some of the innovations to the achievement of selected outcomes and results.
- To draw **lessons** learned by identifying **facilitating** and **hindering** factors to access and deployment of innovations and to develop **actionable recommendations** to guide 2023-28 investments and implementation, and baseline indicators.

This is a **formative evaluation**, that is both **retrospective** (i.e. looking at the Global Fund innovation landscape in the current Strategy 2017-22 in terms of what has worked and what has not worked, and why) and **prospective** (i.e. forward looking on what could work and why).

The focus is on innovations implemented in countries, rather than innovations in the Global Fund model, whilst noting that the latter is nevertheless a key factor impacting deployment of innovations in countries. Innovations relevant for the current Strategy period 2017-22 are the focus, and it is recognised that the Global Fund has a long history in supporting a range of innovations since its inception which are not reviewed here. Innovations are considered within the approximate timeframe of the next Global Fund Strategy 2023-28, and as such, an analysis of very early stage innovations is not relevant for this exercise. Finally, the report focuses to a large extent on health product innovations, although non-product innovations (see Section 2 on innovation typology) are also discussed and reviewed.

¹ The TOC comprises focal points from the TERG and the Global Fund Secretariat.

² The co-creation workshop had over 45 participants from the Global Fund Secretariat and TERG.

³ The Global Fund, Fighting Pandemics and Building a Healthier and More Equitable World: Global Fund Strategy (2023-2028).

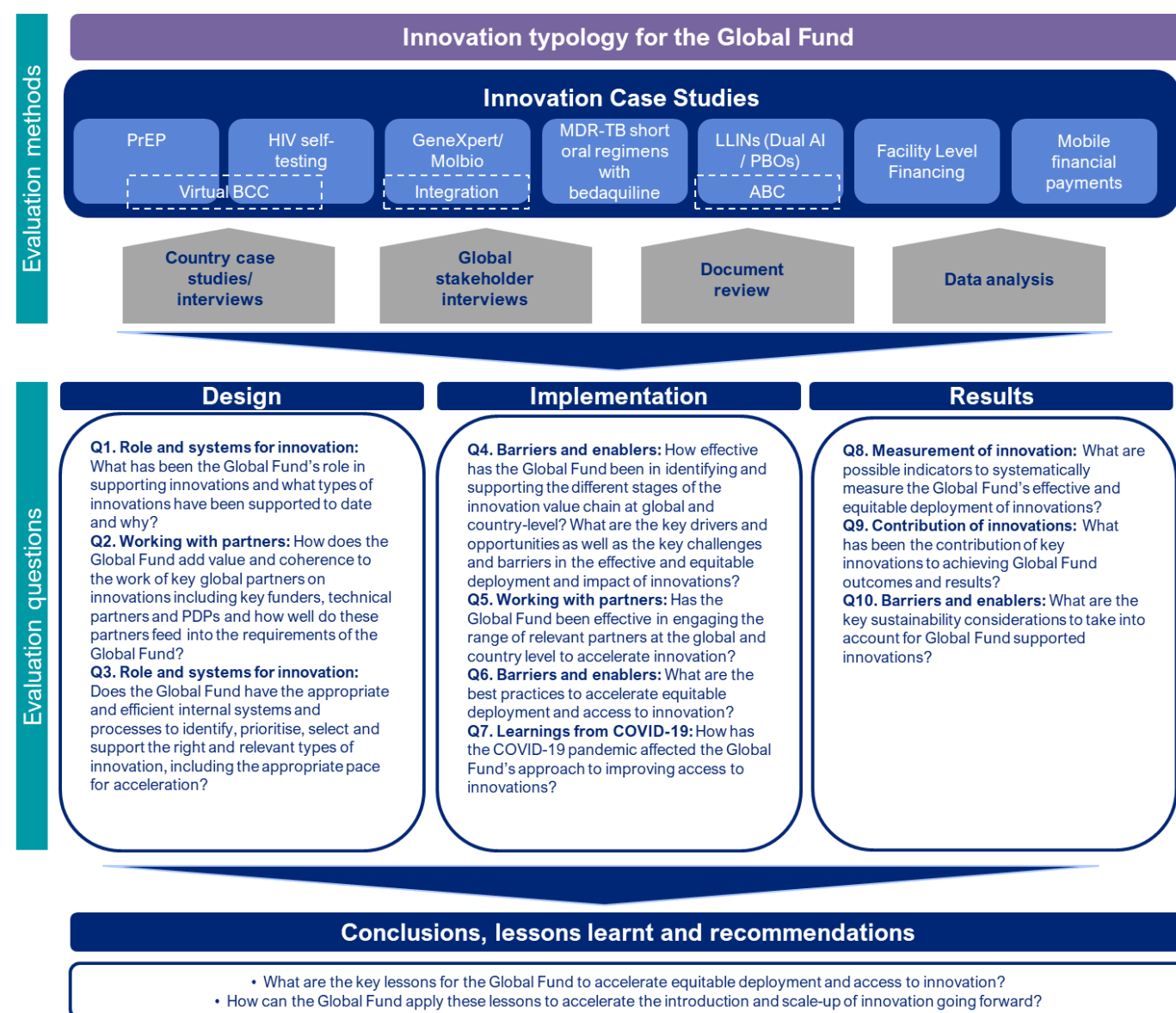
1.2. EVALUATION FRAMEWORK AND METHODOLOGY

Evaluation framework

This evaluation framework is presented in Figure 1.1. over page.

The analysis is framed around a bespoke innovation typology for the Global Fund that is described in Section 2. The evaluation design comprises a series of innovation case studies, complemented and cross-validated by country case studies/ interviews, global-level stakeholder interviews, Global Fund and partner document review and data analysis. These methods have supported the assessment of the key evaluation questions (Q1-10 in the figure below) which have been organised in line with the objectives of the review on design, implementation and results of Global Fund-supported innovations. Within this, evaluation questions have been grouped by topic to support a coherent presentation of findings. The topics include: (i) Global Fund role and systems for innovation (Q1, 3); (ii) Barriers and enablers for innovations (Q4, 6, 10); (iii) Global Fund working with partners (Q2, 5); (iv) Learnings from COVID-19 (Q7); (v) Measurement of Global Fund work on innovations (Q8); and (vi) Contribution of key innovations to achieving Global Fund outcomes and results (Q9). Findings in Section 3 are presented by these topics. The assessment culminates in lessons and recommendations for the Global Fund.

Figure 1.1: Evaluation framework



Evaluation methods

A description of the evaluation methods is as follows:

- **Innovation deep-dives/ case studies.** The innovation case studies form the backbone of this evaluation. A total of seven innovation deep-dives have been selected for this evaluation, covering the spectrum of diseases, innovations included in the typology presented in Section 2 as well as in terms of stage/ level of scale-up of the innovations (including early, moderate and late stage scale-up as of today). The case studies include: *PrEP; HIV self-testing (HIVST); GeneXpert (including the recent Molbio Truenat); MDR-TB switch to short regimens with Bedaquiline (BDQ); New nets – dual AI nets and PBO products; Facility Level Financing (FLF); and mobile financial payments*. In addition, light touch reviews of three service/ programme delivery innovations have been conducted alongside product innovations, namely: *virtual behaviour change campaigns for HIV PrEP and self-testing; integration of diagnostic services through GeneXpert; and activity-based contracting for ITN mass campaigns for malaria*. Appendix E presents the selection process for the case studies, Appendix A and C include the references consulted and stakeholders interviewed for these case studies and Appendix H presents the innovation case studies.
- **Country case studies/ interviews.** In support of the innovation case studies, country case studies and interviews were conducted to understand the experience in country of different innovations (both existing and potentially to be introduced), as well as the wider enabling environment and other country specific enablers and barriers to the introduction of any innovation in the country. These were not in-depth country case studies; rather, a focused set of interviews to bring country perspectives to the evaluation. As such, findings from the country interviews have been incorporated directly into the report, and stand-alone country case studies have not been developed. The selection criteria are detailed in Appendix E and the selected countries include: *Burkina Faso, Georgia, Ghana and Indonesia*. A fifth country, Zimbabwe, was selected but the case study could not progress due to the burden imposed on the country through multiple ongoing evaluations. Instead, perspective for the East and Southern African region was covered through interviews with the Secretariat Regional Head and select FPMs in the region. Appendix C lists the stakeholders consulted for each country. A total of 30 interviews were conducted with 56 individuals across the four countries.
- **Stakeholder consultations.** Semi structured key informant interviews (KIs) were an important methodological tool for the evaluation. In the inception phase for the assignment, stakeholder interviews were conducted to support the development of the innovation typology and a list of interviewees is presented in Appendix B. In the core phase, stakeholder organisations and representatives within them were selected based on the seven innovation case studies, and interviews were conducted in two parts comprising case study specific questions and then some general questions on the overall Global Fund role and approach for innovations. A few additional generic interviews were conducted (i.e. not case study specific). Appendix C contains the consultee list for the core phase which includes individuals from: *Global Fund Secretariat; technical partners (e.g. Unitaids, WHO, PEPFAR, UNAIDS, STOP TB, CHAI); foundations (BMGF); private sector (product manufacturers, service providers); PDPs (MMV, IVCC, FIND, TB Alliance); and CSO/CBO organisations at the global and regional level*. A total of 62 interviews were conducted with 91 individuals for this evaluation.⁴ The interview guide is provided in Appendix D.
- **Document review.** The document review included key Global Fund documents (including strategy documents, funding model documents, past and ongoing TERG reviews); partner documentation from Unitaids, WHO, UNAIDS, STOP TB Partnership, RBM, relevant PDPs working on HIV, TB and malaria, BMGF; and wider literature / peer-reviewed journals on innovation. Appendix A provides an initial bibliography and Appendix F presents the literature review on innovation.

⁴ A select number of Global Fund Secretariat staff members were interviewed twice during both the inception and core phases.

- **Quantitative data analysis.** This includes review and analysis of existing Global Fund datasets including: (i) the PQR data on health product procurement; (ii) funding allocations; and (iii) performance data – with a focus on selected innovation deep-dives and country case studies. It also includes review of select data from other organisations including PEFPAR, USAID, Unitaid, WHO, Gavi among others.

Limitations

The main **limitation** of the evaluation has been the tight timeframes for analysis (eight week period for the core phase), which has been managed as effectively as feasible through close engagement between the evaluation team and the TERG Secretariat. Another limitation is that all country interviews have been conducted remotely, due to changes in countries selected and the evaluation team members. However, as can be observed from the country consultee lists, there has been good coverage across countries. Finally, current Global Fund databases (PQR, funding and performance data) do not enable a systematic quantitative analysis of the extent to which the Global Fund has supported innovations across countries, limiting our ability to conduct planned landscape analysis. This is also an important finding in its own regard and is detailed in Section 3.

Assessing strength of evidence for findings

In line with good evaluation practice, the **strength of evidence** supporting the findings has been considered in terms of both quality and quantity (i.e. triangulation). Table 1.1 presents the robustness rating framework. All robustness rankings are *relative* robustness rankings, based on careful consideration and are ultimately judgement-based.

Table 1.1: Robustness rating for main findings

Rating	Assessment of the findings by strength of evidence
Strong (1)	<ul style="list-style-type: none"> • The finding is supported by multiple innovation/ country case studies and majority of consultations; and • The finding is supported by documentation and/ or data which is categorised as being of good quality by the evaluators.
Moderate (2)	<ul style="list-style-type: none"> • The finding is supported by majority of consultations and some innovation / country case studies; and/ or • The finding is supported by majority of the documentation and/ or data with a mix of good and poor quality.
Limited (3)	<ul style="list-style-type: none"> • The finding is supported by some consultations and one innovation/ country case study (or contradictory multiple case studies) as well as a few sources being used for comparison (i.e. documentation); or • The finding is supported by some documentation and/ or data which is categorised as being of poor quality.
Poor (4) (not included in report)	<ul style="list-style-type: none"> • The finding is supported by a few consultations or contradictory consultations; or • The finding is supported by ad hoc evidence across the case studies; or • The finding is supported by documentation and/ or data of poor quality.

1.3. STRUCTURE OF THE REPORT

The rest of the report is structured as follows:

- Section 2 presents the innovation typology used for this evaluation and proposed for the Global Fund;
- Section 3 presents the key findings of this evaluation, organised in seven sub-sections: (i) Global Fund role and systems for innovation; (ii) Barriers and enablers for health product innovations; (iii) Barriers and enablers for non-product innovations; (iv) Global Fund working with partners; (v) Learnings from COVID-19; (vi) Measurement of Global Fund work on innovations; and (vii) Contribution of innovations to Global Fund results;
- Section 4 presents the evaluation conclusions and lessons learnt; and

- Section 5 presents recommendations from this evaluation.

The report is supported by the following appendices: Appendix A presents the bibliography; Appendix B presents the list of inception phase consultations; Appendix C presents the list of core phase consultations; Appendix D presents the interview guide used in the core phase; Appendix E presents the selection process for the innovation deep-dives and country case studies; Appendix F presents a literature review of documents used to develop the innovation typology, including publicly available Global Fund Secretariat documents (Appendix F.1), partner documents (Appendix F.2) and academic literature (Appendix F.3); Appendix G presents the contribution of innovations to achieving Global Fund outcomes and results; and Appendix H presents the innovation case studies.

2. INNOVATION TYPOLOGY

The first step of the assignment was to develop a definition and typology for innovation at the Global Fund.⁵ The primary objective of the definition and typology is to serve as an assessment framework for this evaluation, but also as a framework for the Global Fund and its partners to support their thinking and work around innovation.

2.1. GUIDING PRINCIPLES

These include:

- **Relevance and applicability to the Global Fund** – noting there are various approaches to innovation in public health and development, this approach seeks to be relevant to the Global Fund in terms of its role as a funder for HIV/AIDS, TB and malaria (HTM) as well as Resilient and sustainable systems for health (RSSH).
- **Intuitive and simple** – as the typology is intended to aid understanding and planning around innovations.
- **Broad/ comprehensive** – noting the wide-ranging views on innovation (both within the Global Fund as well as the wider literature) as well as the dynamic nature of innovation (i.e. what is innovative today may not be considered innovative tomorrow or what is innovative in one country may not be innovative in another), the intention has been not to develop a prescriptive and limiting typology, but rather a more flexible and adaptable typology that can be applied in different disease and country settings.

2.2. DEFINITION

References to innovation in previous Global Fund strategies have been limited, and mainly in the context of innovative financing and innovative partnerships with the range of stakeholders, alongside some more recent references to innovation in the context of challenging operating environment (COE) countries.⁶ The wider literature acknowledges that the term innovation has been used very loosely over time without an exacting definition.⁷ Some of the commonly referred to aspects in partner definitions of innovation include: “new or improved...that differs significantly from the...previous” (Oslo OECD manual), “a creative solution” and “a novel business” (USAID Center for Innovation and Impact), “using existing commodities in new ways and developing new products and approaches” (Unitaid) and “any solution that has potential to address an important development problem more effectively than existing approaches” (Global Innovation Fund). For the purposes of this exercise, the following definition of innovation and equity in innovations is proposed:

Innovation in the context of Global Fund-supported disease programmes refers to a product or approach that is considered sufficiently new or improved and contributes (or has the potential to contribute) to better health outcomes, including improvements in equity, as compared to the pre-existing situation in the country for HTM or the health system.

Equity in innovations means that all relevant countries as well as regions and population groups within countries have timely access to the innovation.

⁵ A review of the following was conducted: (i) Key Global Fund documents – particularly, successive Global Fund strategies, country guidance documents, etc. Appendix F.1 provides a summary review of how innovation has been reflected in key Global Fund documents; (ii) Select partner documents – a landscape review of how key Global Fund partner organisations consider innovation. Appendix F.2 provides a summary of key approaches employed by partner organisations; and (iii) Academic literature – a non-exhaustive review of the academic literature on innovation. Appendix F.3 provides a summary of the key academic references consulted. In addition, focused consultations were conducted with Global Fund Secretariat members and TERG focal points for this review in the inception phase. Appendix B provides a list of individuals consulted. These were supplemented by interviews in the core phase that tested the applicability of the typology with a range of stakeholders.

⁶ Global Fund strategy 2006, 2012-16, 2017-22.

⁷ Crossan and Apaydin, 2010, A Multi-Dimensional Framework of Organisational Innovation: A systematic review of the literature.

It is important to note that any proposal or change should not be treated synonymously with innovation – i.e. an innovation is something that is sufficiently new or improved with a proven/ potential for better results. As such, examples such as south-south learning or creation of regional hubs to support multiple country learning are not considered as innovations.

The definition is further explained through the innovation typology presented below.

2.3. TYPOLOGY

The most compelling frameworks in the literature and partner documents categorise innovation by type (e.g. the OECD-Oslo manual considers innovation in terms of “product, process, marketing and organisational”, and the USAID Centre for Innovation and Impact classifies innovation by “offering, delivery, finance and process”⁸). We propose to employ a similar approach for the Global Fund. In particular, noting the three diseases and RSSH focus of the Global Fund, all innovations may be classified in the following categories:

- **Health products and devices** – i.e. preventive, diagnostic and treatment commodities for HIV/AIDS, TB and malaria, including devices such as enabling platforms and tools. These may be entirely new (e.g. HIV self-tests) or improved or adapted products (e.g. successive development of the GeneXpert diagnostic platform over time, ARV-based HIV prevention products such as the dapivirine vaginal ring or long acting injectable cabotegravir) or represent product substitutions (e.g. switching away from HRP2-based rapid diagnostic test [RDTs] for malaria⁹).
- **Service/ programme delivery approaches** – i.e. the range of different approaches to deliver programmes or services for health with regards to HIV/AIDS, TB and malaria.¹⁰ These may be directly linked to a health product/commodity (e.g. community-led approaches to deliver HIV self-testing [HIVST]) or new approaches to reach / create demand / deliver interventions (e.g. community-based approaches using ICT for HIV prevention, new approaches aimed at behaviour change and client safety/security); or they may pertain to overall health sector-wide delivery approaches (e.g. private sector engagement in selling health commodities such as condoms/ACTs, integrated delivery of health services such as HIV-TB diagnostics or with social protection and general insurance schemes, decentralisation of services).
- **Health systems management tools and processes** – i.e. tools and processes with regards to key aspects of the health systems infrastructure (i.e. physical infrastructure, systems, people) such as with regards to health information systems (data, surveillance, programme monitoring and evaluation), financing, laboratory systems, supply chains, health workforce, policy, etc. including for pandemic preparedness. Digitalisation would represent an important innovation across these health systems pillars, but other examples include additional trackers for District Health Information System 2 (DHIS2), country-level financing instruments such as blended finance (finance), innovations in quality of programme supervisions (health workforce), innovations in surveillance systems (pandemic preparedness), etc.

Several of the consultations indicated the health products focus of the Global Fund and expected that the most relevant innovations would be in this area alone. While noting this, others emphasised the importance of the other two categories as well, and hence these are included in the typology as critical and comprehensive components of innovation at the Global Fund.

Table 2.1 over page presents the above-described innovation typology with examples.

⁸ OECD, 2005, Oslo Manual: Guidelines for collecting and interpreting innovation data, 3rd Edition; USAID, 2019, Innovation Realized: Explaining the path to Health Impact, A guide to amplify Global Health innovation at USAID.

⁹ Due to high rates of false-negative RDT results caused by *Plasmodium falciparum* parasites lacking *hrp2/hrp3* genes.

¹⁰ This applies regardless of type of service/programme for health and provider (i.e. government, private, CSO/ CBO).

Table 2.1: Innovation typology¹¹

Typology	Health products and devices	Service / programme delivery approaches	Health systems management tools and processes
Scope	Preventive, diagnostic and treatment commodities for HIV, TB and malaria	Approaches to deliver health services for HIV, TB and malaria or sector wide delivery approaches which cross-cut diseases	Management tools and processes for health information systems (data, surveillance), finance, laboratory systems, supply chains, health workforce, policy, etc. including for pandemic preparedness
(Non exhaustive) examples	<ul style="list-style-type: none"> • HIV – PrEP (oral, vaginal ring, injectable), HIV self-testing, point-of-care testing for viral load/ early infant diagnostics, switch to Dolutegravir (DTG) • TB – POC platforms and tests (e.g. Cepheid GeneXpert, Molbio Truenat, Alere Urinary LAM), digital X-ray/ AI image detection • bedaquiline treatment, preventive TB (3HP) • Malaria – Seasonal malaria chemoprevention, new nets (dual active ingredient or Piperonyl butoxide), indoor residual spray (new AI), artesunate-based treatments (injectable, intra-rectal), malaria vaccine 	<ul style="list-style-type: none"> • Community-led delivery and monitoring for HIVST, PrEP • Approaches to information sharing or demand generation for prevention services (e.g. virtual-based awareness raising, social media based tools) • Access to services through tele-health • Private sector participation/ contracting • Integrated service delivery • Decentralised service delivery • Results-based contracting 	<ul style="list-style-type: none"> • DHIS2 platform including Aggregate, Tracker, Mobile and extensible apps • Digital data systems • e-financial management • electronic Logistics Management Information System (e-LMIS) • e-laboratory systems • Programme quality improvements • HR-related systems improvements • Integrated guidelines/ programme implementation policies

Further, as is evident in the descriptions of the three categories for innovation and the several examples cited, what is deemed an innovation may vary significantly according to the following aspects – highlighting the “spectrum” of innovations that are relevant for the Global Fund context:

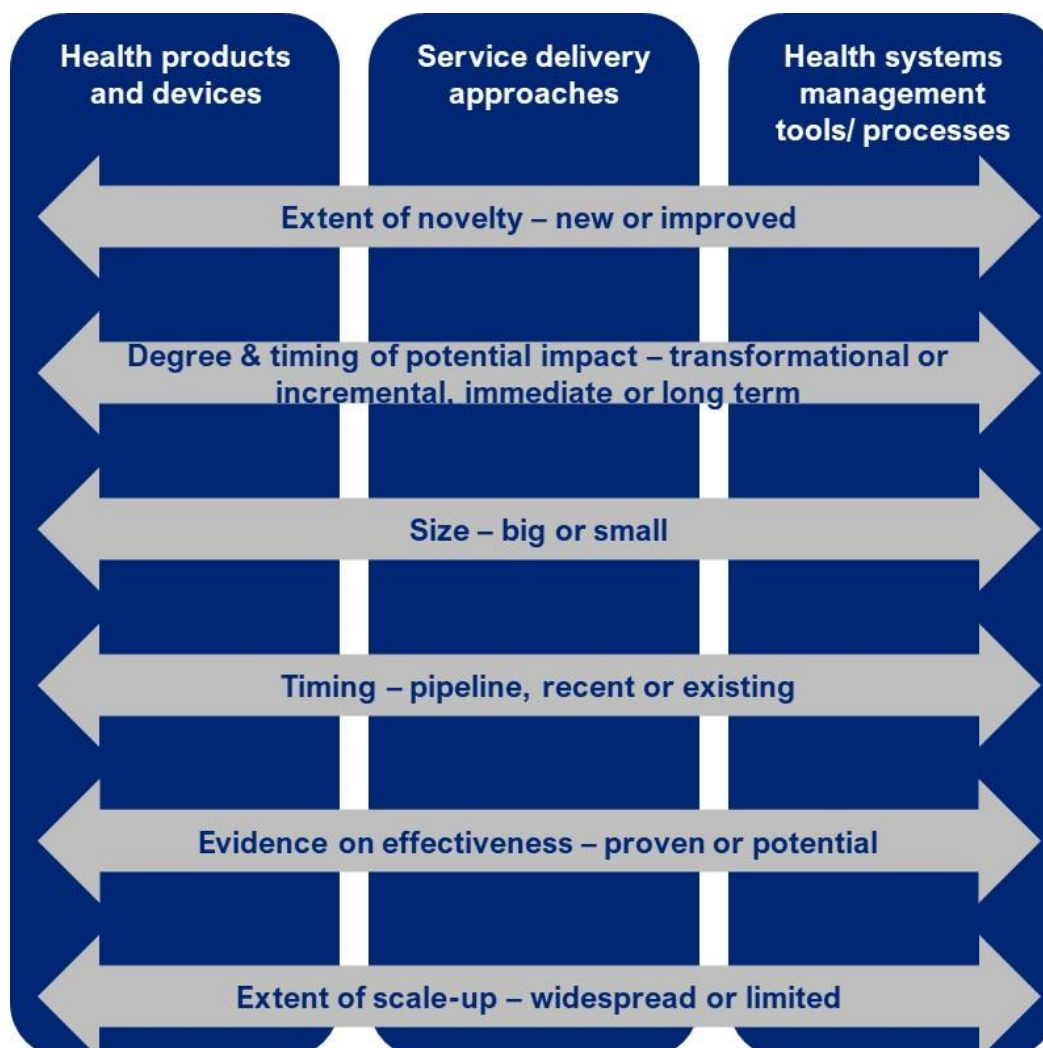
- **Extent of novelty – new or improved** – as noted previously, an innovation can be entirely novel or represent a change/ adaptation from the existing commodity/ approach (i.e. adaptation of a commodity overtime, change in use or indication of the existing product).
- **Degree and timing of potential impact – transformational/ incremental and immediate/ long-term** – an innovation may have significant/ transformative impact (whether for the country as a whole or a particular population group/ geographic area) or have impact of a lesser degree (incremental). Further, an innovation can have immediate and directly observable impact or longer-term indirectly observed impact. All types of innovation can be deemed as needed in public health.
- **Size – big or small** – innovations may be of different sizes, e.g. DHIS2 with its multiple trackers is a fairly extensive innovation in comparison to a specific mobile tool used by community health workers (CHWs), with the difference not necessarily indicating their relative significance.

¹¹ There can be some overlap between these categories, especially between service/programme delivery approaches and health systems management tools and processes. For example, mobile phone payments for non-registered small-scale private sector shops (e.g. local grocery shops) to facilitate distribution of commodities such as condoms might be classified as both a service delivery approach and health systems management tool. Another example is introduction of bio-sensors or trackers that facilitate self administration and enable monitoring. Mechanisms such as payment for results may also cut across both categories.

- **Timing – pipeline, recent or existing** – it is difficult to define a “cut-off date” for when something stops being an innovation, noting the dynamic nature of innovations and the varying rate of their application to different countries. There are two aspects of relevance here: (i) the typology considers live and immediate pipeline innovations only, in that “blue-sky” innovations with an estimated availability beyond the next Global Fund Strategy period (2023-28) are not being considered; (ii) something may be viewed as innovative for certain countries but not others (e.g. GeneXpert footprint in east and southern Africa indicates that this diagnostic may not be considered as innovative in the region any longer, but this may still be the case for west and central Africa).
- **Evidence on effectiveness – proven or potential** – reflecting the fact that certain service delivery or health systems related innovations supported by the Global Fund may not be proven upfront (as compared to commodity related innovations), but there may be an ‘expectation’ based on available (informal/ formal) evidence/ insight that the innovation may lead to an improvement.
- **Extent of scale-up – widespread or limited** – this recognises the range of innovations that might be relevant for the Global Fund, wherein some merit country-wide scale-up but others are smaller scale in nature and aimed at specific geographies and/ or populations groups.

Bringing these together, Figure 2.1 presents the innovation typology against the spectrum of possible innovations.

Figure 2.1: Innovation typology and spectrum of innovations



3. KEY FINDINGS

Section 3 presents key findings across the evaluation questions. As indicated in Section 1.2, the presentation of findings is organised around key topics rather than by evaluation question to facilitate strategic use and readability of the findings. In particular:

- Section 3.1 presents key findings on the Global Fund's role and systems for innovations covering the evaluation objective of design and evaluation questions 1 and 3.
- Section 3.2 brings together the key findings across the health product case studies to consider barriers and enablers to effective scale-up, covering the evaluation objective on review of implementation and specifically evaluation questions 4, 5 and 6. As part of this, sustainability considerations as per evaluation question 10 are also included as one of the factors impacting scale-up.
- Section 3.3 provides key findings from the non-product innovation case studies, covering the same evaluation questions as for Section 3.2.
- Section 3.4 considers what works well and less well with regards to Global Fund working with partners in the innovation value chain, and critically considers both design and implementation aspects of partner working, covering both evaluation question 2 and 5.
- Section 3.5 presents select learnings from Global Fund's approach to supporting innovations for COVID-19, and as relevant for its wider innovation work (evaluation question 7).
- Section 3.6 assess the measurement of Global Fund's work on innovation to date and forthcoming as part of the new Strategy (evaluation question 8).
- Section 3.7 presents the evidence on contribution of innovations to Global Fund results (evaluation question 9).

3.1. GLOBAL FUND ROLE AND SYSTEMS FOR INNOVATIONS

This section covers the following evaluation questions:

- *Q1. What has been the Global Fund's role in supporting innovations and what types of innovations have been supported to date and why?*
- *Q3. Does the Global Fund have the appropriate and efficient internal systems and processes to identify, prioritise, select and support the right and relevant types of innovation, including the appropriate pace for acceleration?*

The following aspects are considered below: Global Fund's role in supporting innovations (Section 3.1.1); evidence on the type of innovations supported to date (Section 3.1.2); and a review of the Global Fund systems and processes for supporting innovations (Section 3.1.3).

Key findings	Robustness rating
1. The Global Fund has a strong comparative advantage vis-a-vis other global health organisations in supporting innovation scale-up and has a long history of supporting a range of innovations in ART, LLINs, ACTs, amongst others. Notwithstanding the fact that its funding is fundamentally country owned and country driven, while it has done well to deploy a range of Catalytic Funding initiatives to support the introduction and early uptake of innovations, the overall funding model of country allocations is not yet optimised to support innovation scale-up. In particular, it has not optimally employed several "strategic levers" within its funding model to shape country demand, nor maximised on its market shaping role. There is also scope for the Global Fund to better engage with partners in the pre-scale-up stages of innovations.	Strong

Key findings	Robustness rating
2. The Global Fund does not have readily available and useable data to systematically assess its support for innovations. The Price and Quality Reporting (PQR) database on product procurements through Global Fund grants does not provide procurement data for specific innovative products. The Global Fund funding and performance data offers limited exacting information on the extent to which innovations have been supported. Further, there is no database on non-product innovations and no systematic capture of the range of these innovations.	Strong
3. In general, there has been greater focus on and visibility of health product innovations by the Global Fund as compared to non-product innovations. There has been more effort in scaling up innovations in line with Global Fund's priorities and areas of expertise (e.g. in terms of priorities, innovations in HIV prevention have received less attention until now; in terms of expertise, there has been more attention on innovative financing approaches as compared to other non-product innovations). While the Global Fund has not "missed" any innovations per se, several innovations reviewed under this evaluation have seen an average of around a 10 year lag from initial product approvals by FDA and 6-7 years from initiation of WHO guidance.	Moderate
4. There has been a lack of effective prioritisation of innovations by the Global Fund and there is no overall strategy or approach to supporting innovations, and specifically with regards to equitable access to innovations. There is no pro-active intelligence on the upcoming tools, nor an agreed list of innovations that will be supported by the Global Fund. There is no clear allocation of roles and responsibilities or accountability for innovation work within the Global Fund Secretariat, with multiple teams partaking in work relevant to innovations. While its model is country driven, there is no systematic decision-making process or agreement on criteria (e.g. VfM) within the Global Fund to support the scale-up of innovations, with the experience to date largely being opportunistic and ad hoc.	Strong
5. The Global Fund has not optimally used its available "strategic levers" within the funding model for core funding allocations. Key amongst these are: the Country Coordinating Mechanism (CCM) ecosystem (i.e. organisations that participate and engage with the CCM) that may not always include organisations at the forefront of innovations in countries; lack of emphasis on innovations in the country guidance; lack of incentives in grant application and implementation as well as funding modalities; limited use of the Technical Review Panel (TRP) review; and varying degrees of support from Country Teams (CTs) on innovations across countries.	Moderate

3.1.1. Global Fund's role in supporting innovations

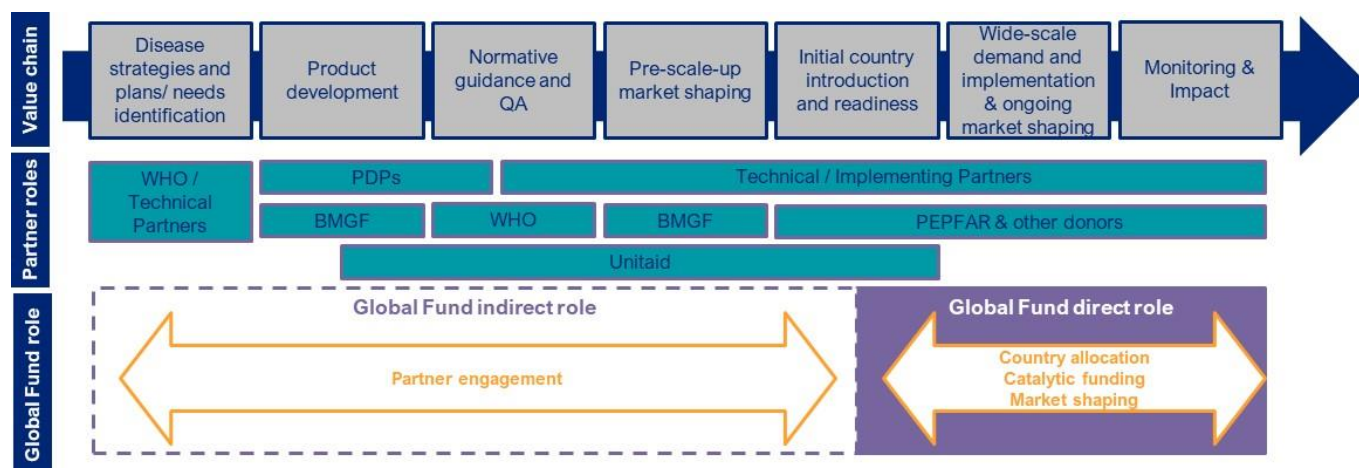
The Global Fund's role in supporting innovations is intimately linked to its particular characteristics as an organisation: By virtue of its large funding capability, direct interface with a large number of countries, country demand-driven and partnership-based model, the Global Fund has important comparative advantages vis-à-vis other global health organisations to support the scale-up of innovations in HTM and health systems. At the same time, because its model is based on financing rather than technical expertise, with a focus on scaling up proven/ recommended innovations rather than developing policy or technical guidance, or bringing innovations to market, the Global Fund is reliant on its partners to perform these and other critical functions for supporting innovation.

Figure 3.1 presents a simplified value chain for health product innovations and maps the role of the Global Fund in relation to other organisations in the global aid architecture for HIV/AIDS, malaria and TB.¹² As presented in the figure, the Global Fund's **direct role** is in the downstream aspects of the value chain – starting from supporting initial country

¹² For non-product innovations, the Global Fund's role and the value chain / ecosystem are substantially different; this is considered in Section 3.3.

introductions and uptake through its Catalytic Funding streams¹³, and then multi-country scale-up (and ongoing market shaping) through the country allocations provided through its core funding model. On the other hand, the Global Fund's role in the upstream aspects of the health product innovation value chain is **indirect**, where it seeks to work with partners to support the development of disease strategies, normative guidance and pre-scale-up market shaping (although there have been instances where the Global Fund has engaged more extensively in pre-scale up market shaping such as for new ITNs).

Figure 3.1: Global Fund role in supporting health product innovations



The Global Fund has a long history of supporting the scale-up of a number of tools for ATM, including with regards to ARVs, LLINs and ACTs since its inception. As discussed in more detail in the subsequent sections of the report, and substantiated through the range of case studies, our review of the role of the Global Fund in the current Strategy period 2017-22 indicates the following:

- With regards to its direct role, the Global Fund has done well to deploy a range of Catalytic Funding initiatives to support the introduction and early scale-up of a range of innovations. For example, the HIVST matching fund for the current allocation cycle has catalysed expansion of HIVST in 5 high burden countries in sub-Saharan Africa. The New Nets Project co-funded jointly between Unitaid and through Global Fund Strategic Initiative funding (as well as the subsequent Net Transition Initiative) have also been pivotal in addressing barriers to the introduction and early scale-up of dual AI nets such as the lack of cost-effectiveness and efficacy data and high product prices. Section 3.2 provides more details.
- However, its overall funding model of country allocations is not yet optimised to support widespread innovation scale-up. This includes inadequate utilisation of a number of “strategic levers” at its disposal (e.g. country guidance/ Information Notes, Technical Review Panel (TRP) review of funding requests, country dialogue/ engagement through the Country Teams, etc.). These are discussed further below in Section 3.1.3 on the Global Fund systems and processes and Section 3.2 on barriers and enablers to health product innovations. Key amongst this is that the Global Fund has not done enough to shape demand for innovations amongst countries.

¹³ This includes Matching Funds to incentivise programming of country allocations for priority areas, Strategic Initiatives to support the success of country allocations on areas that cannot be funded through disease-specific components of grants and Multicountry grants to address cross-border multicountry priorities. Matching Funds had a budget of US\$341.5m over 2020-22 and covered areas of HIV prevention, HIV-TB prevention, amongst others and Strategic Initiatives had a similar budget at US\$343m with 19 workstreams. Multicountry grants were supported with US\$ 230m including among others an initiative to address malaria drug resistance in the Mekong Sub-region. (Source: www.theglobalfund.org/en/applying-for-funding/sources-of-funding/)

- The Global Fund’s market shaping role for innovations – both pre and during scale-up – is currently quite narrow and not maximising its potential.¹⁴ With its considerable buying power and unique position within the partner landscape in terms of having a direct link with countries, stakeholders have indicated the need for the Global Fund to employ a more proactive role to market shaping for innovations. This is discussed further in Section 3.2 (and specifically 3.2.4) below.
- Finally, global partners are also demanding a more systematic and engaged role from the Global Fund in the upstream stages of the innovation value chain, within its overall mandate and scope of work, to better support their work and set the stage for the Global Fund to support country scale-up. Specific areas for further partner engagement by the Global Fund are discussed in Section 3.2, and an overall review of Global Fund working with partners is provided in Section 3.4.

3.1.2. Types of innovations supported

In attempting to analyse the types of innovations that the Global Fund has supported, we found that the Global Fund does not currently have readily available and useable data to answer this question systematically in a quantitative way. In particular:

- The Price and Quality Reporting (PQR) database provides data on all product procurement transactions made through Global Fund grants but does not allow one to systematically disentangle procurement data for innovative products. For example, it is not possible to disentangle PBO and Dual AI nets from within all ITNs or distinguish the use cases of products (e.g. ARVs are not distinguished by use for treatment or prevention).¹⁵
- The Global Fund funding and performance data (further discussed in Appendix G) also offers limited insights on the extent to which innovations have been supported. The data is structured according to the Global Fund Modular Framework, where innovations are not specifically disentangled (e.g. rapid molecular testing for TB is considered as a whole rather than GeneXpert specifically).
- There is no database on non-product innovations (i.e. service/programme delivery approaches and health systems management tools and processes) which are substantial in number, including several adaptations of each innovation across countries.¹⁶

As result, it has not been possible to conduct a comprehensive, data-based landscape assessment of innovations supported by the Global Fund. Instead, a qualitative review has been conducted based on document reviews and stakeholder consultations.

Table 3.1 presents a summary of the health product and devices supported by the Global Fund within the current Strategy period and in the pipeline. These are categorised on a 4-point scale – *P = in the Pipeline; E=Early scale-up; M=Moderate scale-up; L=Late stage scale-up, with many countries having scaled-up the innovation*. This table is not exhaustive but provides an overview of the main innovations. It also does not include non-product innovations, service/ programme delivery approaches and health systems management tools and processes as these are too wide-ranging and diverse. Key points are as follows:

- **Global Fund’s support has focused more on, or is more visible for, health product innovations** rather than non-product innovations (on service/ programme delivery approaches and health systems management tools and processes), where its approach has been ad hoc and piecemeal. As such, and for the data limitation reasons above, it has not been possible to include a landscape of non-product innovations in the table below.

¹⁴ For example, the Market Shaping strategy 2016-22 states that “when analysis indicates that fundamental innovation in treatment modalities or product categories are needed and funding from public or philanthropic sources are unlikely to meet this need, the Global Fund may engage with originators to explore the volumes required to support continued participation in a market”.

¹⁵ For some product areas, it is possible to disentangle between different innovative products for all purchases conducted through Wambo. However, Wambo only captures a subset of all products procured through Global Fund grants.

¹⁶ In addition, there are wide-ranging Secretariat views on the characterisation of some of these innovations, rendering a summary assessment of key innovations supported or not supported by the Global Fund challenging.

But this does not suggest that the Global Fund has not done a lot of work in the area, not only through its overall people-centred approach, but also specific mechanisms such as the Service Delivery Innovations Strategic Initiative.¹⁷ The point however remains that the work in the non-product innovations space has been disjointed and piece-meal.

- **There has been more effort in scaling up innovations in line with the Global Fund's priorities and areas of expertise** – e.g. given the lesser degree of emphasis on HIV prevention in the Global Fund Strategy to date, scaling up of innovations in PrEP has had limited attention; conversely, with the Global Fund' core expertise in financing, several innovations are being piloted on innovative financing approaches at the country level (although not reflected in the table below). That said, the extent to which different innovations (product and non-product) have been supported, and which ones have received limited or no support and why, is very innovation-specific. For health product innovations in particular, there can be a range of reasons including high price, insufficient supply, need for updating of country guidelines, need for registration of product in country, etc. as discussed in Section 3.2. In general, the Global Fund supports health products that have been recommended by WHO and where the product has been pre-qualified by the WHO or where diagnostics have been reviewed by the ERPD (Expert Review Panel for Diagnostics).

Table 3.1: Landscape of health product innovations relevant for the 2017-22 Global Fund Strategy period and in the pipeline (illustrative, not exhaustive)

	Prevention	Diagnosis	Treatment
HIV	<ul style="list-style-type: none"> • PrEP (oral) • PrEP (vaginal ring, injectable) 	<ul style="list-style-type: none"> • HIV Self-testing • HIV Point-of-Care (POC) diagnostics 	<ul style="list-style-type: none"> • Transition to TLD (from Efavirenz to Dolutegravir) • Paediatric formulation • Long-acting injectables
TB	<ul style="list-style-type: none"> • TB preventive therapy (3HP) 	<ul style="list-style-type: none"> • GeneXpert • Molbio Truenat • Digital X-ray/ AI image detection • Improved TB LAM testing/ rapid molecular testing 	<ul style="list-style-type: none"> • MDR-TB oral regimens containing Bedaquiline • MDR-TB 2nd line regimen containing Delamanid • Paediatric formulation
Malaria	<ul style="list-style-type: none"> • New ITNs (Dual AI) • New ITNs (PBOs) • SMC • Next Generation IRS • IPTp • Malaria vaccine (RTS,S) 	<ul style="list-style-type: none"> • New tools not relying on use of HRP2 	<ul style="list-style-type: none"> • Injectable and intrarectal Artesunate (switch from quinine)
Cross-cutting & Pandemic Preparedness	<ul style="list-style-type: none"> • Multipurpose prevention technology (STIs, HIV and RMNCH) 	<ul style="list-style-type: none"> • COVID-19 Self-testing • RDT-multi-disease options (STIs, HIV and Hepatitis) 	<ul style="list-style-type: none"> • Oxygen (PSA plants)

Legend: Pipeline; Early scale-up; Moderate scale-up; Late scale-up

¹⁷ The Strategic Initiative for Service Delivery Innovations has been funded with a total of US\$ 47 million under 2020-22 Funding Cycle and contained five components: (i) National Lab System Improvements (US\$ 10 million); (ii) Human Resources for Health (US\$ 10 million); (iii) Strategic Private Sector Approaches (US\$ 10 million); (iv) South-South Learning including AGYW (US\$ 15 million) and (v) Community Led Monitoring (US\$ 3 million).

On the commodity side, stakeholders did not identify any key health product innovations that have missed the Global Fund radar. However, partner perceptions varied more widely on the extent to which the Global Fund had successfully supported certain innovations, usually driven by their own level of interest in the particular product. One area that has been mentioned is the lack of stronger support by the Global Fund for TB diagnostic tools beyond GeneXpert (including for example X-Ray or TBLAM), though it was acknowledged that this has also been a failure of the wider community to support the development of stronger alternative tools (a gap which more recently has received renewed support including from Unitaid, STOP TB, USAID and FIND).

However, as is evident from Table 3.2 below which provides an indication of the timelines and pace of innovation deployment by the Global Fund for the five health product innovations reviewed under this evaluation, as of today (2022), several health product innovations have not been scaled up, having initial product approvals by FDA around 10 years ago and initiation of WHO guidance around 6-7 years ago.

Table 3.2: Timeline and pace of innovation deployment by the Global Fund

Innovation	Benchmark	Scale-up status
PrEP (oral)	<ul style="list-style-type: none"> • 2012- FDA approves first drug for use as oral HIV PrEP • 2015- WHO issues broad recommendation supporting use of PrEP among populations groups with substantial risk of HIV • 2019- PrEP included as a prioritised intervention in guidance to countries for 2020-22 Funding Cycle 	<ul style="list-style-type: none"> • PrEP is not yet at scale, 6 countries accounted for over 80% of PrEP users in 2020 and 1 million people were reached (falling short of UNAIDS target of 3 million) • Global Fund reaching a very small percentage of people with PrEP services, around 20,000 in 2019.
PrEP (vaginal ring, injectable)	<ul style="list-style-type: none"> • 2021- WHO prequalification (PQ) and recommendation of vaginal ring • 2021- FDA approval of CAB-LA • 2022- WHO conditional recommendation of CAB-LA 	<ul style="list-style-type: none"> • Not yet introduced or included in Global Fund procurement catalogue. Included in Information Note for upcoming allocation cycle.
HIVST	<ul style="list-style-type: none"> • 2012- first HIVST product (oral-fluid test, OraQuick) approved by FDA • 2016- WHO recommends HIVST • 2017- First HIVST product (OraQuick) receives WHO PQ 	<ul style="list-style-type: none"> • HIVST volumes and Global Fund procurement have grown substantially since 2017, to 14 million in 2021 • Not yet at scale in most countries, with volumes less than expected but growing
GeneXpert	<ul style="list-style-type: none"> • 2010- WHO formally endorses use of Xpert 	<ul style="list-style-type: none"> • Global Fund main funder for GeneXpert with procurement beginning in 2013 and peaking at 700 machines purchased in 2017 • Uptake considered successful although still only 33% of people newly diagnosed with TB are using a WHO-recommended rapid molecular test
Molbio Truenat	<ul style="list-style-type: none"> • 2020- WHO formally endorses Molbio Truenat 	<ul style="list-style-type: none"> • Not scaled up outside of India
MDR-TB oral regimens containing BDQ	<ul style="list-style-type: none"> • 2012- FDA approval of BDQ • 2013- WHO issues interim policy guidance recommending BDQ • 2019- WHO consolidated guidelines includes recommendation against injectables and recommends all-oral DR-TB treatment 	<ul style="list-style-type: none"> • Higher uptake began post 2019 with stronger WHO guidelines • Additional resources provided through grants and TB Portfolio Optimization (US\$55 million) in 2019 to support complete transition to BDQ • Scaled-up, has replaced old treatment regimens in all countries

Innovation		Benchmark	Scale-up status
New (Dual AI)	ITNs	<ul style="list-style-type: none"> • 2018/2019- Two Dual AI Nets receive WHO PQ 	<ul style="list-style-type: none"> • Product not at scale, lacking WHO recommendation • Global Fund has supported procurement of 65-70 million Dual AI Nets through Allocation Cycles 2017-19 and 2020-22 through Strategic Initiatives to support evidence generation, WHO recommendation, and transition to normalized procurement
New (PBOs)	ITNs	<ul style="list-style-type: none"> • 2009- First new type of ITN receives WHO conditional recommendation 	<ul style="list-style-type: none"> • Procurement of PBO nets begins in 2018, by 2021 made up around half of Global Fund procurement

3.1.3. Global Fund systems and processes

The Global Fund has some intrinsic comparative advantages in supporting scale-up of innovations, and it has made good progress on select innovations to date as described above. Notwithstanding this, it suffers from a lack of clear systems and processes to drive innovations within the organisation, as well as challenges relating to its funding model and how it (under-)uses its available “strategic levers” to support innovations. The new Strategy 2023-28 has increased focus on innovation and we understand that the work on NextGen Market Shaping and the New Product Introduction working group seeks to address some of the issues identified below. Specifically:

There has been a lack of effective prioritisation and focusing on innovations by the Global Fund.

This is evidenced by the limited visibility of innovations in the 2017-22 Global Fund Strategy¹⁸ and previous strategies. Country guidance and Information Notes have only occasional mentions of innovation embedded within lengthy text and no clear requirements for countries to include these innovations (or explain why they opt not to). Global Fund policies are largely not specific on innovations, but key policies such as the procurement policy also do not make reference to innovations. The Market Shaping Strategy (2016-22) has an objective on accelerating adoption of new products, but there has been limited to no progress on planned activities.¹⁹

There is no overall strategy or approach to supporting innovations, including with regards to equity in innovations.

- The Global Fund does not have a strategy nor an agreed, systematic approach on how to support innovations.²⁰ In particular, it has no proactive intelligence on the upcoming tools in the arsenal to fight the three diseases (and the lifespan of the current tools), nor an agreed list of innovations that will be supported by the Global Fund (though we understand that there is a plan to develop such a list for the new Strategy 2023-28).
- There has been limited focus on equity in innovations. While covered inherently due to focus on marginalised/ vulnerable groups there is no definition, data/ information, separate lens for assessment, etc.

¹⁸ The Strategy 2017-22 included an operational objective on supporting innovations within its Strategic Objective 4 on mobilising additional resources (and not within the programmatic objectives), and only made reference to innovation in the context of COEs, increased resources/ innovative financing and partnering with Unitaaid.

¹⁹ Objective 4 of the MSS is “Accelerate adoption of new and/ or cost-effective products” and includes in scope “partner on product scale-up roadmaps, target ERP, expand revolving fund (from US\$2m to US\$10m), optimize product selection including HTA”. The TERG MSS review assessed that many of these tools were not taken forward, as also confirmed in this evaluation.

²⁰ The Market Shaping Strategy (MSS) 2016-22 is the only Global Fund document that described innovations in that it includes a definition for innovation upfront. The approach is very much product focused and does not consider non-product innovations.

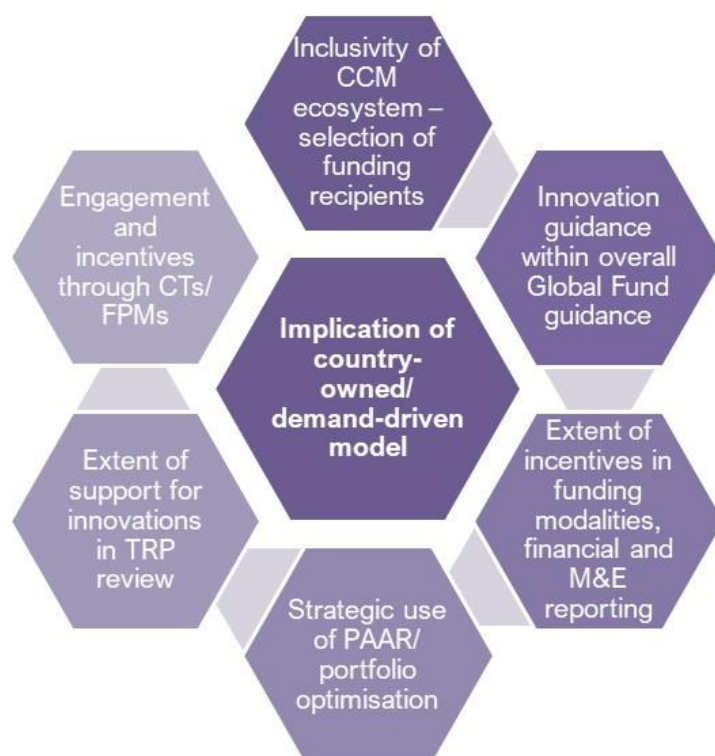
- Notwithstanding the country driven model of the Global Fund, there is no decision-making process or agreement on key criteria (e.g. VfM) within the Global Fund Secretariat to support the scale-up of specific innovations, with the experience to date largely being opportunistic and ad hoc.
- There is no clear institution-wide leadership, allocation of roles and responsibilities or accountability for innovation work within the Secretariat, with multiple teams partaking, among other priorities, in work relevant to innovations. In particular, SSC, TAP and GMD (including through the Health Product Managers (HPMs)) are all involved in health product innovations, each with different levels of focus, information and incentives on innovation. This challenge was also flagged in the TERG MSS review which noted a “lack of cross-team institution wide technical perspectives or accountabilities, and fragmented/ reactive engagement with partners leads to missed opportunities to influence/ coordinate with partners and to drive innovation, NPI/ product selection”.
- There are no systems within the Global Fund on innovations – process flows, data/ information availability and sharing, etc. For example, the limitations of the PQR and funding and performance data for innovations has been discussed previously.
- Finally, there are no plans or roadmaps, nor an explicit division of labour, agreed with partners on scale-up timeline and actions (some of this was planned for in the current MSS but never actioned, and we understand is being planned under the new Next Generation Market Shaping initiative).

The Global Fund has not optimally used its available “strategic levers” within the funding model for core allocations.

Figure 3.2 sets out a schematic of the key elements in the funding model that can serve as strategic levers to support innovations. At the core of the Global Fund funding model is the country-owned/ demand-driven nature which has implications for the accelerated and equitable scale-up of innovations. While the experience varies by country, at times, countries do not demand innovations due to limited awareness or apprehension to move away from the status quo. Also, the allocation-based model creates a fixed-budget constraint for countries who are therefore not incentivised to demand innovations that usually come with a higher price than existing commodities.

The other aspects are explained in more detail following the figure.

Figure 3.2: Strategic levers for innovations in the funding model



- **The CCM structure and processes**, while they have evolved over time to be more functional and inclusive in terms of country dialogue, have tended to create an ecosystem (i.e. organisations that participate and engage with the CCM) that may not always include organisations at the forefront of innovations in countries (e.g. small non-governmental organisations focused on TB diagnosis innovations in countries, private sector or community-based organisations may not be fully represented). Further, at times or for select countries, the CCM processes are seen to perpetuate “inertia” to adopt new products and continue with the status quo. For example, for PrEP, reported barriers included the composition of CCMs as lacking influential voices on PrEP²¹, comfort with the ‘status quo’ of existing funding flows to PRs/SRs, and desire to continue with approaches that are performing well per Global Fund metrics. Other case studies (e.g. on HIVST) also pointed to hesitancy to focus on implementing something new while simultaneously driving the performance of Global Fund core allocations. This implies that the Global Fund model may not be effectively bringing in the most relevant organisations as funding recipients and implementers for certain innovations, and there is limited innovation with regards to “who gets paid”.
- **Country guidance/ Information Notes** are significantly under-used to draw attention to key innovations and encourage their uptake. For example, the disease specific guidance (HIV/ TB/malaria information notes for 2019) reference innovation in the HIV and TB information notes only, and only with regards to finding missing cases and community engagement. In the RSSH guidance innovation is presented in terms of approaches that are “low cost”, “without much TA/management required” and “encourage domestic financing / innovative financing with private sector” i.e. very much focusing on efficiencies rather than effectiveness and impact. Further, technical briefs on in-country supply chains and CSS have no mention on innovation. We understand however that an effort is under way to revise the Global Fund guidance for the 2023-2025 Funding Cycle to better reflect innovations.
- The Global Fund model is **structured mainly around input-based financing with limited use of output or outcome-based financing**, which is particularly important in the context of financing innovations. As the term suggests, input-based financing implies a focus on inputs and does not create the needed incentives to focus on results. The Global Fund included pay for outputs in late 2019 (via the introduction of payment for results to the financing guidelines under Chapter 3.9 for the Guideline for Grant Budgeting), but to date, there has been no systematic, top-down, properly resourced corporate priority to re-align the Global Fund regulatory environment, processes, tools, and resources to operationalise these provisions (see Section 3.3.2 for further detail). Further, the range of **country application forms and grant implementation requirements** are largely non-specific on innovations and do not create any incentives for countries to actively consider innovations. In particular, the country funding request forms do not emphasise innovations²², and the M&E and financial reporting requirements do not require countries to consider uptake or specifically report against innovations. For example, which regards to Global Fund’s approach to financial management and reporting, grant recipients have to pay back money (via a recoveries process) if they violate the grant agreement and/or Chapter 5 of the Guidelines for Grant Budgeting (which lists all the ways supporting expenditure documents can be non-compliant), but not if they under-deliver on financed programmatic activities or generate late, inaccurate, inadequately granular and unreliable data or fail to generate desired outcomes or impact. As another consequence, implementers who may be highly capable in delivering on key strategic priorities, like on prevention with KVPs, or front line facilities who can deliver integrated-people centred health services, or the private sector, are kept out of the implementer pool, because these

²¹ Regarding CCMs and meaningful engagement of communities, the Global Fund TERG Community Engagement and Community led Responses Evaluation similarly reported that “some communities participate in the funding request writing process, but nearly all lose visibility into the process during finalization”, and that the requirement of the C19RM second round for funding requests to include community priorities resulted in communities feeling more heard by the Global Fund.

²² In the current funding cycle, the funding request instructions could potentially solicit a response on innovations, but this is not strictly required. For example, the funding request asks applicants to demonstrate that this funding request considers the experience of the current and former grant(s), to describe what worked well and can be replicated or enhanced, what programmatic approaches did not deliver anticipated results, and how obstacles or limitations will be addressed to increase the outcomes and impact of the response.

organisations do not have sufficient capacity to produce “complete and compliant supporting documentation” as per the Global Fund requirements and as assessed by the Local Fund Agent (LFA) and audit teams.²³ Section 3.6 provides more details on the limitations of the programmatic reporting approach of the Global Fund in terms of facilitating innovations.

- Another lever relates to the **Prioritised Above Allocation Request (PAAR) and portfolio optimisation** process, where countries are encouraged to submit additional requests for funding over and above their allocation and efficiencies in the budget are allocated to priorities. This tool has occasionally been used by the Global Fund to direct country investments to innovations, as for example, has been the case in the scale-up of oral MDR-TB regimens with BDQ²⁴ – but there is room to make more frequent use of it.
- The **TRP review** of country funding requests is another important strategic lever that can guide the effective deployment of innovations. We understand that the TRP is provided with a list of criteria to assess applications where use of priority and effective innovations is encouraged (although we don’t see this as emphatically mentioned in the country guidance in terms of advising what the TRP would be looking at). It is not fully clear though to what extent the TRP review has been effective enough in encouraging innovations, with limited evidence available on where these reviews have driven innovation uptake. For example, a review of the recent TRP review database suggests that the TRP considers innovation within the wider lens of the country’s programme, but there has not been an explicit review of the uptake and value of innovations (e.g. specific questions from the TRP enquiring why a certain country has not taken up an innovation).²⁵ This is coupled with the impact of differing expertise and views amongst the TRP in assessing innovations in country funding requests.
- Finally, the **role and engagement of the Global Fund Secretariat Country Teams, and in particular the Fund Portfolio Managers (FPMs)**, is critical in guiding and incentivising countries on the adoption and scale-up of innovations. The current approach seems ad hoc, with stakeholders reporting varying experiences across countries, i.e. some FPMs being more supportive of innovations than others. It was indicated that FPMs are driven by “getting funding out of the door” and business-as-usual approaches, and hence may not always encourage innovations which can be more tricky to implement.
- Other levers include a clear direction by the Global Fund with regards to health product transitions. For example, in the case of BDQ, Global Fund permission and technical assistance for the destruction of replaced drugs was helpful for rapid transitions. While a less frequently applied Global Fund lever, this helped to address concerns around the wastage of TB drugs in switching to BDQ regimens and was largely considered as well executed, with good coordination between partners (e.g. geographic split between USAID and Global Fund in terms of funding) and close support from the GDF. Additional funding to destroy stock was also seen as helpful for a rapid transition (though some stakeholders saw successful transition planning / technical assistance as first priority emphasising that the appearance of destroying existing drugs was not favourable for countries despite approval of donors to do so).

²³ This is in line with the findings from the recent Global Fund TERG Community Engagement and Community led Responses Evaluation which identified that the Global Fund’s systems and business model can have unintended consequences by creating barriers for some community organisations to becoming funding recipients.

²⁴ The change to all-oral regimens for DR-TB came with a considerable increase in drug costs as well as associated costs (e.g. transition planning, training etc.) which are not included as part of the grant allocation (which were made based on existing regimens with injectables). As a result, in order for countries to switch rapidly while maintaining their DR-TB treatment targets, the Global Fund provided additional funding through the portfolio optimisation process. This was also possible due to clear visibility and partner engagement on the upcoming guideline changes as well as a waiver from the TRP allowing for reprogramming across all grants (rather than requiring approval for each country individually).

²⁵ Global Fund (2020-2022), TRP Recommendations database.

3.2. BARRIERS AND ENABLERS FOR HEALTH PRODUCT INNOVATIONS

This section brings together key findings across the five health product innovation case studies - (i) PrEP; (ii) HIVST; (iii) GeneXpert/ Molbio Truenat; (iv) BDQ containing regimens for DR-TB; and (v) dual AI and PBO nets, triangulated with country reviews in Burkina Faso, Georgia, Ghana and Indonesia and global consultations to consider barriers and enablers to effective, equitable scale-up. The assessment covers the following evaluation questions for health-product innovations:

- Q4. How effective has the Global Fund been in identifying and supporting the different stages of the innovation value chain at global and country-level? What are the key drivers and opportunities as well as the key challenges and barriers in the effective and equitable deployment and impact of innovations?
- Q5. Has the Global Fund been effective in engaging the range of relevant partners at the global and country level to accelerate innovation?
- Q6. What are the best practices to accelerate equitable deployment and access to innovation?

Key findings	Robustness rating
1. The process to scale-up a health product innovation is highly complex and lengthy, with multiple factors driving its success or failure. Across the case studies for this evaluation, coordinated partner action that simultaneously addresses multiple barriers is a key factor driving success. An integrated approach where new product introduction is supported with associated innovations in service delivery approaches, and helps tackle demand side and health systems issues has been most useful.	Strong
2. Global stakeholders would like the Global Fund to more proactively signal its prioritisation of health product innovations. This would involve the Global Fund engaging more proactively upstream in a way that complements (and not duplicates) the mandates of upstream partners (e.g. WHO, BMGF, Unitaids, STOP TB Partnership, PDPs, etc.).	Strong
3. The sequential order of WHO policy guidance and product pre-qualification prior to Global Fund financing extends the timeline for deployment of innovations. The Global Fund has been most effective in shortening the 'global policy to country introduction gap' by working in parallel to WHO policy development to 'line up' the levers at its disposal.	Strong
4. The market shaping role of the Global Fund is not proactive or deliberate with regards to innovations and the Market Shaping Strategy for innovations has not been fully implemented. To date, the Global Fund's market shaping role has been mainly through the PPM and QA tools without any further tools (e.g. volume commitments) to shape markets for innovations. Stakeholders have indicated that this is an area of missed opportunity for the Global Fund.	Strong
5. The Global Fund's comparative advantage with respect to country perspectives and insights on demand is not being adequately used to support market shaping, including through timely and accurate demand forecasts developed in coordination with partners. This is regarded as particularly important in the early stages of market growth, where lack of information on country demand has impeded the work of other partners.	Moderate
6. The importance of cost-effectiveness analysis to support innovation roll-out cannot be overemphasised, and there is a need for the Global Fund to work more with partners to ensure this evidence is developed and disseminated to countries.	Moderate
7. Strategic levers in the Global Fund's funding model have been used on an ad-hoc basis for demand creation of innovations. There are few incentives within CCM processes, funding request guidance and reviews or Global Fund financing and performance measures to introduce innovations (and to propose a high level of ambition), contributing to inertia in core allocations for deployment of innovations.	Strong

Key findings	Robustness rating
As such, the Global Fund could do more to foster the enabling environment for innovations in countries.	
8. Catalytic Investments are overall well regarded to encourage country introduction and uptake as well as address implementation challenges, noting these are significantly smaller than core funding allocations and are not a “silver bullet” for scaling innovations.	Moderate

Figure 3.3 presents the range of factors that affect the scale-up of health product innovations. Against each of these factors, key barriers and enablers identified in the case studies have been set out, which for some innovations are the flip side of the other. The relative importance of different barriers and enablers is innovation specific – as detailed in the innovation case studies. Mapped at the bottom of the figure is the Global Fund role (reflecting both the current role and potential greater role) in supporting the different factors, with the darker colour shading representing the Global Fund’s greater comparative advantage and engagement. This occurs in the latter stages of scale-up, as described in Section 3.1.1, particularly in implementation, but also in supporting country demand and readiness.

Figure 3.3: Key factors, barriers, enablers and Global Fund role for scale-up of health product innovations

Factors	Global prioritisation/ perceived value	Normative guidance	Market/ supply characteristics	Price, affordability and cost effectiveness	Country demand and readiness	Implementation
Barriers	<ul style="list-style-type: none"> Extent of novelty/ paradigm shift Differing views amongst partners on value of innovation 	<ul style="list-style-type: none"> Lengthy period/ delays in issuance of normative guidance Ambiguity/limited scope in guidance Lack of funding and use cases to develop evidence 	<ul style="list-style-type: none"> Monopoly supplier Challenges for additional suppliers to enter market/pre-qualify, including burdensome WHO PQ process Product capacity challenges 	<ul style="list-style-type: none"> High sticker price Low (perceived) cost effectiveness 	<ul style="list-style-type: none"> Delayed policy updates and/or operationalisation Delayed product registration Ltd. community demand Inertia to switch to unknown products 	<ul style="list-style-type: none"> Delays in implementation Health systems challenges Weak disease prog., linkage to care and integration Sustainability issues
Enablers	<ul style="list-style-type: none"> Extent to which the innovation represents an improvement over previous options Partner agreement and support 	<ul style="list-style-type: none"> Pro-active and supportive role by WHO Use of WHO rapid communication Partner funding for operational research to support guidelines development 	<ul style="list-style-type: none"> Competitive market with diversity in supply Partner work to bring in additional suppliers Partner work on demand forecasts 	<ul style="list-style-type: none"> Price reductions secured by partners Dissemination/ advocacy of cost effectiveness research 	<ul style="list-style-type: none"> Pro-active and supportive role by WHO and partners to facilitate country demand and readiness Advocacy/ demand creation for innovations 	<ul style="list-style-type: none"> Coordinated TA by partners Complementary services funding to integrate innovation in systems
Global Fund role	<ul style="list-style-type: none"> Pro-active early engagement with partners Signaling of country interest and/ or Global Fund priority 	<ul style="list-style-type: none"> Engagement in guidelines dev. in tandem with prep. for scale-up Country financing for evidence development 	<ul style="list-style-type: none"> Engagement with partners on market shaping work Pro-active market shaping Demand forecasts and country perspectives ERP-D invitations 	<ul style="list-style-type: none"> Cost effectiveness analysis 	<ul style="list-style-type: none"> Catalytic Funding Country allocations and “strategic levers” (CCM structure and processes, guidance notes, M&E and financial reporting formats, PAAR, TRP review, FPM engagement) Market shaping tools and activities 	

The following sections review each of the factors in detail, including key barriers, enablers, relevant examples from the case studies (labelled in *italics*), and the Global Fund role (including its experience with different innovations as well as gaps and issues with its role identified through this review).

3.2.1. Global prioritisation/ perceived value of the innovation

Barrier/Enabler: Extent of novelty, improvement and paradigm shift brought by the innovation

Innovations that bring a significant paradigm change tend to encounter more resistance. More effort is required to convince and support countries which remain hesitant despite the positive experience of early-adopter countries.

- **HIVST:** HIVST was one of the first big leaps in self-care for HIV and represented a new method for learning one's HIV status beyond conventional provider-mediated models. Initial concerns on feasibility, safety, and risk of harm amongst individuals receiving a positive test result without adequate support had to first be examined through robust evaluations in high burden LMIC settings. Early adopter countries (Malawi, Zambia and Zimbabwe, followed by South Africa, Lesotho, Eswatini) were fundamental for establishing the evidence base, which was financed through the Unitaid STAR project and the Global Fund for operations research (and from PEPFAR in Zambia). Still, demand remained below expectations even after the 2016 WHO guidelines supporting HIVST. Low demand in countries with high HIV burden was the impetus for the Global Fund/ CIFF HIVST matching fund in five priority African countries. Despite nearly 100 countries now including HIVST in national policy, implementation remains slow in some countries, where challenges include fully convincing government stakeholders of the value of HIVST to their epidemic context or, political hesitancy, as in Indonesia, owing to the traditional and conservative society and a desire to 'keep the control' within health facilities rather than communities.

Innovations which represent a substantial improvement and can *replace* an existing product often experience stronger support vs. products which are *additional choices* to the product mix.

- **BDQ - substitution:** BDQ was a crucial advancement in the treatment of MDR-TB. As a shorter regimen it offered the potential to increase the proportion of patients successfully completing treatment, whilst also mitigating the harmful side effects from longer TB regimens. Even when BDQ was not yet WHO recommended, its superiority over previous treatments led to strong partner action and country demand: a donation programme was initiated between USAID, the Global Drug Facility (GDF) and Johnson & Johnson to allow countries to access BDQ for free, gain experience with the implementation of BDQ regimens, and create necessary evidence for an update of the WHO guidelines.
- **HIVST– additional method to include in the mix of HIV testing services:** In contrast to BDQ which was a substitution, HIVST expands the existing basket of HIV testing methods and is now an essential part of a strategic mix of HIV testing services countries should develop. Stakeholders view products that are 'additional choices' face greater barriers simply because of the added complexity entailed.

Barrier: Differing views on the value of an innovation

Weak stakeholder alignment to prioritise an innovation negatively impacts deployment.

- **PrEP:** PrEP (oral vaginal ring, injectable) is recommended by WHO for people at substantial risk of HIV, yet PrEP uptake has been inadequate and global HIV prevention targets (3 million on PrEP by 2020) were missed. Stakeholder consultations underscored the complexity of barriers to deployment of PrEP across the categories of the innovation value chain, including disparate views amongst national and global stakeholders involved in HIV responses of the extent to which PrEP should be prioritised within the basket of HIV prevention services. This is compounded by the absence of a comprehensive roadmap for overcoming demand and delivery challenges.

Insights on the Global Fund role in the global prioritisation/ perceived value of the innovation

- **Stakeholders would like the Global Fund to engage more proactively early in the innovation value chain.** Case studies depicted a varying level of proactivity in engaging with partners early in the value chain of an innovation depending on the innovation, Secretariat functional team, and country. Global stakeholders are supportive of a more proactive role for the Global Fund that would complement the mandates of the partners working more upstream (e.g. WHO, BMGF, Unitaid).
- **The Global Fund is not clearly communicating its priorities when it comes to product innovations it will support.** Stakeholders widely regard that, as a major financing mechanism with large purchasing power, prioritisation 'signals' from the Global Fund carry significant weight in national and global prioritisation of innovations, and by extension in determining partners' support efforts. Partners are thus requesting the Global Fund be clearer on its prioritisation of health product innovations to help better planning and forward looking actions. In addition, partners highlighted the valuable role the Global Fund can play upfront by sharing insights on potential demand and in facilitating country/CCM exposure to innovations.

3.2.2. Normative guidance

WHO normative guidance is prime in the deployment and scale-up of an innovation with Global Fund support. Case studies depicted examples where issues related to normative guidance turned into barriers to uptake of innovations, as well as examples of how the Global Fund and partners have responded to the need for robust evidence from LMICs.

Barrier: Delays in issuance of normative guidance and ambiguity in guidance

WHO guidance can take a long time to be issued due to the time taken to conduct robust studies as well as be ambiguous in terms of the extent to which a new product/ change is recommended, which can hinder rapid scale-up of an innovation. WHO follows a robust process when updating guidance, which is important to ensure the quality and safety of new products.²⁶ However, time taken to generate evidence can be lengthy, which leads to lengthy timelines in issuance of WHO guidance. Also, in the absence of evidence that is viewed as strong enough by WHO, conditional recommendations can be issued, which can cause stakeholder ambiguity in the deployment and scale-up of new products. In circumstances where the evidence base has limitations, enabling but ambiguous WHO policy, such as recommendations suggesting countries ‘consider’ use of an innovation, can still hinder uptake. These factors contribute to delays in the roll out of a promising product. Further, there is also a compounding effect in that without WHO recommendations for an innovation, there is likely to be limited uptake, leading to higher prices and no evidence, which impedes WHO’s ability to issue a recommendation.

Stakeholders recognise that there have been some improvements in the time lag to issuance of guidance over time, but overall, this continues to be an important constraint to the scale-up process. There is a need for greater coordination amongst stakeholders (WHO, donors, countries, implementers, researchers) around priority-setting and research work to support expediting of WHO guidelines.

Evidence from the case studies is as follows:

- *BDQ*: An example of this barrier is in the early stages of scale-up of BDQ. WHO made a conditional policy recommendation for its use in 2013, a key reason being initial safety concerns regarding its use in LMICs. Strong WHO guidance only came in 2019 following investment to generate evidence in LMICs. In the intervening years, WHO issued rapid communications on the use of BDQ to signal ‘direction of travel’ on policy guidance, though impact was limited as countries continued to wait for the official policy update before changing national guidance.
- *PBO nets*: Ambiguous interim WHO guidance has also been a challenge. WHO 2017 guidance stated that countries should “consider the deployment of pyrethroid-PBO nets” where particular conditions for insecticide resistance were met, including confirmation of resistance conferred (at least in part) by a monooxygenase-based resistance mechanism, and that deployment of PBO nets must only be considered where coverage with effective vector control will not be reduced. The contents of the guidance were challenging for both global partners and countries, particularly the need for data on involvement of monooxygenases - often not available at county or sub-national level. This lack of clarity discouraged orders from many countries, despite advisory efforts from partners to clarify guidance, as countries remained concerned that their practice may in some way deviate from the guidelines. PBO nets being new also meant there was a lack of operational experience to inform how to best allocate and distribute the new product. Even when the Global Fund was able to procure it (through portfolio optimisation), confusing guidance, coupled with lack of operational insight, remained a key barrier to scale-up.
- *Dual AI nets*: WHO recommendations for dual AI nets are pending the completion of RCTs funded by the New Nets Project (NNP) and partners. At present there are two pre-qualified nets, IG2 and Royal Guard, and no generic products. Production capacity of dual AI nets has been flagged as a risk to responding to demand

²⁶ In most circumstances strong recommendations are issued in the presence of high quality of evidence and conditional recommendations are issued when the quality of evidence is low or very low.

increases following WHO recommendations (which are projected for 2023 issuance). The generic dual AI net market is therefore at a 'stand still' and the position of the Global Fund on generic dual AI nets is unclear.

- *HIVST*: The first HIVST product (OraQuick HIV Self-Test Kit) was developed for the US market and gained FDA approval in 2012. However, following attention from global health partners, WHO guidance was first issued in 2016 only, due to the need to develop a product tailored to LMIC markets (price, packaging etc.) and establish evidence on HIVST use in LMIC settings. Also, more supportive WHO guidance came later in 2019 only following which there has been a greater push for scale-up by partners.

Enabler: Funding for evidence development for WHO guidelines

Investment from partners at the early stage of an innovation fast-tracks the evidence generation needed to inform WHO policy decisions. WHO requires strong evidence to make recommendations on the use of a new health product/technology. There is a key role for donors and technical partners to engage in the early stage of an innovation to help develop evidence and a foundation of experience necessary for WHO recommendations and updates to WHO guidelines. Specific examples of this enabler include:

- *ITNs*: The New Nets Project (NNP) was a multi-partner project to increase the evidence base for Dual AI nets and facilitate their scale-up if a WHO policy recommendation was made. The Global Fund and Unitaids provided a combined US\$ 66 million in financing, which was primarily allocated to a co-payment process (to ensure that pilot countries were not burdened with the additional cost of these products whilst evidence was being built).²⁷ This financing was a key enabler for an RCT on Dual AI nets, laying the basis for the generation of epidemiological and operational evidence required for the policy recommendation and subsequent scale up guidance. The NNP has illustrated that partners can take forward key innovations likely to offer improved public health value, even prior to a full WHO recommendation, thereby enabling a parallel vs a sequential process to generating further evidence and enabling full WHO approval.
- *HIVST*: The Unitaids-financed HIV Self-Testing Africa (STAR) initiative Phases 1 and 2, which was significantly steered by the WHO, generated evidence in LMICs, which significantly contributed to the WHO 2016 and 2019 guidelines. While Unitaids was the driving force behind investment in HIVST evidence, Global Fund grants in the STAR Phase 1 countries made some operations research funding available, and countries involved in STAR Phase 2 obtained HIVST funding through portfolio optimisation.
- *PrEP*: To a lesser extent, PrEP introduction was supported by the Global Fund, with South Africa being one of the few examples where Global Fund financing was seen as an enabler in the early days of oral PrEP. In South Africa, the Global Fund is working with Unitaids to provide the dapivirine ring for an implementation study to gain insights on client preferences.
- *BDQ*: The WHO conditional recommendation in 2013 on BDQ and the initial high price limited the immediate scale up of BDQ. The USAID, GDF and Johnson & Johnson donation program and financing of country evidence generation was critical for a 2019 update of the WHO guidelines on BDQ with a "strong recommendation". New evidence to identify less toxic and more effective ways to treat MDR-TB patients is currently financed by Unitaids (the EndTB project). Results from two clinical trials on BDQ and delamanid use are expected in 2023-2024 and would inform future changes in recommendations.

Insights on the Global Fund role in normative guidance

- **Proactive engagement in WHO guideline development is most valuable where the Global Fund is simultaneously priming for its scale-up support role:** Stakeholders have emphasised the importance of Global Fund close engagement with the guideline development process (in an observer capacity). This has

²⁷ Other NNP partners focused on other pillars of the project: BMGF funded the volume guarantee, IVCC led and executed the co-payment mechanisms, manufacturers were focused on planning for supply capacity, forecasting and actual supply, and various research institutes and other partners, including governments, were involved in the generation of epidemiological and operational evidence.

worked well for BDQ, where the Global Fund participated as an observer in WHO GDG meetings and simultaneously sensitized countries on forthcoming BDQ policy change, with guidance on using portfolio optimisation to introduce BDQ. Being an observer to the WHO guideline processes allows the Global Fund technical teams to work in tandem to line up the levers at its disposal (e.g. portfolio optimisation, information notes) rather than reacting *after* WHO guidelines.²⁸

- **By virtue of its significant country financing, the Global Fund has an important role in development of evidence in LMICs:** While the Global Fund is rarely in the driver's seat in innovation research, its country financing is an important enabler. Second, in the face of significant threats to HTM, as in the case of pyrethroid resistance, the Global Fund has demonstrated how it can contribute to evidence generation. Certain stakeholders believed Global Fund's investment in operational research was particularly valuable for innovations with WHO conditional recommendations. When a recommendation is conditional there is more debate within countries on guidance and less uptake from patients, compared to a strong recommendation.

3.2.3. Market/supply characteristics

Barrier: Monopoly market and limited supplier markets

Monopoly or limited supplier markets act as a barrier in the scale-up of an innovation due to high prices, potential supply security concerns and limited choice for countries. A monopoly market is often quite common in the innovation space in cases in which manufacturers use extensive patents to protect their product.

- *BDQ*: a key factor contributing to the high prices of BDQ is Johnson & Johnson being the monopoly supplier, with intellectual property protections through secondary patents expected to last until 2027 in 64 LMICs.

There are also risks that monopoly (or near-monopoly) markets can themselves hinder new innovations given the advantages the monopoly supplier holds with regard to economies of scale, existing product registration and consumer relationships.

- *GeneXpert*: GeneXpert has been a monopoly market until the recent WHO PQ of Molbio as there were no comparable products in existence. Stakeholders stated that partners' focus on and support for GeneXpert has also helped to foster a monopoly market for near point-of-care TB diagnostics and a lack of diversification with regard to other tools. Despite new tools becoming available in the same market segment (e.g. Molbio Truenat) or the broader TB diagnostic space (e.g. digital X-ray), it has been challenging for them to gain traction in the market.
- *HIVST*: The OraQuick oral fluid test has ~80% of the market due to first-to-WHO PQ advantage and a price reduction financed through a volume guarantee by the Bill and Melinda Gates Foundation (BMGF). Country preference for the OraQuick product (versus blood-based tests (BBTs)) is regarded in the near-term as limiting consumer choice as some populations prefer blood-based tests to oral fluid tests. It is too early to tell what the effect of newer, competitively priced BBTs will be on the HIVST market composition.

Enabler: Partner work to bring in other suppliers/ products

Partners have played an important role to help diversify small, near-monopolistic markets. This has been particularly a role for upstream-focused partners including BMGF, various PDPs and to some extent Unitaid. Their support may take different forms including financial and technical support during the R&D process as well as support to clinical studies and applications for regulatory approval. Interventions to lower the sticker price of innovations to challenge monopolies or near-monopolies are discussed further down.

- *GeneXpert*: In recent years, partners have renewed efforts to introduce TB diagnostic tools other than GeneXpert. These efforts include the Unitaid/FIND grant on the TB Diagnostic such as a third generation TB LAM test or the USAID and GDF "introducing New Tools Project (iNTP)".

²⁸ Most recently, the HIV Information Note for the upcoming allocation cycle (published 29 July 2022) includes long acting cabotegravir for PrEP as a Global Fund supported intervention, recently recommended by WHO (28 July 2022).

Barrier: Product capacity challenges

Production capacity challenges remain a barrier for innovation scale-up with some manufacturers not investing in increasing their manufacturing capacity due to the lack of robust demand forecasts, amongst other factors. Product capacity challenges can result from issues within the supply chain or a lack of accurate demand forecasts to give producers time to adjust manufacturing processes or invest to create more capacity to meet increasing demand.

- *Dual AI and PBO nets:* Issues around supply chain were evident in the ITNs case study and production and surge capacity remains a challenge for both AI and PBO nets. For Dual AI nets, production capacity has been affected by the COVID-19 pandemic and the insecticide is in short supply, which impacts the surge potential even if demand increases. PBO nets face a similar challenge in terms of limitation of supply of insecticide components, as most insecticides used for agricultural practice. Overall, insecticide supply issues point to the need for continued growth and diversity in net products.

Barrier: Perceived burdensome WHO PQ process

Manufacturers may not be incentivised to submit new products to WHO PQ due to the complexity of the process, time taken and uncertain demand. The WHO PQ process ensures that medicines supplied by procurement agencies meet acceptable standards of quality, safety and efficacy.²⁹ Quality assurance is very important when introducing new health products into the market and the Global Fund's Quality Assurance Policy states that pharmaceutical products can be funded using Global Fund resources *if* they are prequalified by the WHO PQ Programme (or approved by an SRA (with SRAs defined per product group) or approved by ERP/D while the WHO PQ process advance). However, the process to achieve WHO PQ can be viewed as burdensome and expensive, especially for generic manufacturers who often requiring TA from technical partners to facilitate PQ submission. The sequence of steps from WHO PQ to the innovation being included in Global Fund procurement and then in country funding requests can delay the benefit of an innovation.

- *HIVST:* The use of the WHO-hosted Expert Review Panel for Diagnostics (ERPD) on the pathway to WHO-PQ is regarded as an enabler to country access to innovative products but is not used for all products. In 2019 the Global Fund and Unitaaid issued an invitation to HIVST manufacturers to submit a product dossier for ERPD review to determine acceptability for procurement through the Global Fund. This is viewed as having accelerating country experience with different HIVST products and manufacturer experience in these markets.

Insights on the Global Fund's role in market/supply characteristics are presented jointly with those on price, affordability and cost effectiveness at the end of Section 3.2.4 below.

3.2.4. Price, affordability and cost effectiveness

Barrier: High commodity prices

High commodity prices for innovations, particularly compared to existing products, are considered a key factor in low or slow-growing country demand in the context of fixed funding envelopes. High prices can also impede sustainable transition to domestic funding of innovations. Within the Global Fund's funding model, countries' decisions to include an innovative product within the funding requests are made in the context of a fixed country funding envelope and domestic budget constraints. As a result, products considered not affordable (e.g. considerably more expensive than existing products) are often not supported by countries, with high prices consistently mentioned as a leading barrier for uptake. To a degree, there is also an unrealistic expectation that innovations come into the market at the same cost as existing products.

²⁹ Poor quality medicines constitute approximately 10% of all medicines in LMICs. World Health Organization. *A study on the public health and socioeconomic impact of substandard and falsified medical products*. Geneva, Switzerland, 2017

- *HIVST*: The original unit price for the OraQuick product designed for LMIC markets was US\$ 3, compared to ~US\$ 0.7 for conventional HIV tests. At >3 times the price of existing HIV tests, donors and countries viewed this as a barrier to scale. It is noted that this is a rapidly changing environment with the recent announcement of US\$1 HIV self-test.

Innovations can be trapped in a vicious cycle that perpetuates high prices and limited demand. Innovations often enter the market with a small market share which means that manufacturers cannot exploit economies of scale. In turn, innovative products often have high prices, so demand continues to stay low and manufacturers do not have any incentives to invest in more production capacity and to lower cost.

- *BDQ, GeneXpert*: The high price for innovations is exacerbated in cases in which companies enjoy monopoly positions for innovations through the use of patents (see discussion in previous section). This is particularly the case when innovation substantially improves on existing products (e.g. BDQ) or creates a new market segment (e.g. GeneXpert). This challenge remains even where market shaping interventions have supported initial uptake of innovations. Longer-term monopoly situations, and corresponding higher prices, have been a key challenge with regard to achieving full scale-up and a sustainable transition to domestic financing in MICs. For example, the high price of BDQ remains a barrier for large scale uptake in particular when countries have to cover all or a substantial proportion of the drug costs from domestic resources (e.g. in Indonesia). Similarly, the high price of GeneXpert and new nets have also been flagged as concerns for further scale-up.
- *PBO and Dual AI nets*: The challenges of low demand are particularly pronounced for innovations which have higher costs compared to existing products in the short-term and offer considerable health benefits that only arise in the longer term – for example innovative products aimed at addressing drug and insecticide resistance.
- *BDQ, PBO nets, GeneXpert*: These innovations are examples where the high price/ lower demand dynamic has been perpetuated by WHO recommendations that are conditional (BDQ after its first conditional WHO recommendation in 2013) or of limited scope e.g. only recommending use for high-risk / high-burden groups (PBO nets).

Enabler: Price reductions secured through market shaping interventions

Market shaping interventions are considered as critical to address the price barrier especially early-on within the innovative product life-cycle; and also critical to boosting the demand for innovative products and break the high prices/ low demand vicious cycle described above.³⁰ These interventions have taken various forms and were predominately supported by more upstream partners. Most innovations in the country case studies benefited from one or multiple of such interventions, underlining their importance in addressing in particular the initial price barrier that innovations face. Examples from the innovation case studies include interventions directly agreed with suppliers as well as co-payments/ subsidies for countries to increase demand, such as:

- **Donation**: A donation programme for BDQ supported by USAID and GDF between 2015-19.
- **Volume Guarantee**: The volume guarantee by the Bill and Melinda Gates Foundation for HIVST was instrumental in lowering the unit price of the LMIC market oral fluid test product (OraQuick) from US\$3 to US\$2, bringing it closer to conventional HIV tests (~US\$ 0.7). In July 2022, MedAccess and CHAI announced a volume guarantee to make the Wondfo HIVST (a BBT) available for US\$1, making it the lowest price HIVST on the market.
- **Catalytic investment**: Unitaid made a one-time catalytic investment in Mylan/Atomo in 2021 to lower the price of its HIVST product to be competitive with the OraQuick oral fluid test³¹.

³⁰ It is also recognized that efforts at reducing prices come with the risk of supplier exit if the terms become unattractive for them.

- Buy-down: A buy-down agreement for GeneXpert between USAID, the U.S Department of State's Office of the Global AIDS Coordinator (OGAC), Unitaid/WHO and BMGF ensured an immediate price reduction to US\$ 9.98 per cartridge.
- Co-payments/ subsidies: Dual AI nets are supported by Unitaid and Global Fund through the use of Strategic Initiative funding. Prices for Dual AI nets have come down to be comparable to PBO prices, though they are still higher than 'standard nets'. Owing to the effectiveness and solid delivery of the NNP activities, the end of project (NNP) pricing targets for Dual AI nets were met one year ahead of plan - \$2.75 for IG2 and \$2.96 for RG. However, they are not yet at levels affordable for deployment in target low- and middle-income countries without external financing.
- Pooled procurement/ price reduction agreements with the manufacturer: e.g. BDQ price reduction in 2020 negotiated predominately by GDF and USAID from US\$400 to a pro-rated price of US\$272 per bottle.³¹

Additionally, the innovation case studies suggested that early market shaping interventions needed to be combined with efforts to create a healthy competitive market for the long-term. Markets with long-term monopoly were flagged as having price barrier issues for full scale-up and transition to domestic financing. In this regard, interventions aimed at bringing in more suppliers were considered key (see enabler in Section 3.2.3 above). Stakeholders emphasised that generic manufacturers offered the biggest opportunity to achieve long-term affordable prices (e.g. with regard to the BDQ or ITNs market). A key example for such success has been the generic manufacturing in the ARV market (including dolutegravir) where affordability was achieved largely through voluntary licences provided by companies to the Medicines Patent Pool.

Barrier/ enabler: Cost-effectiveness evidence/ concerns and dissemination

Evidence on an innovation's comparative cost-effectiveness can be insufficient, or poorly communicated to decision-makers. There has been a push towards assessing cost-effectiveness of innovations which takes account of higher costs but puts this into perspective of the improved outcomes or health system savings. A key barrier has been that many innovations either lacked evidence to demonstrate their cost-effectiveness, including in the context of the specific country, or that communication/ dissemination of cost effectiveness to decision-makers was ineffective.

- *PBO nets*: There has been emerging evidence that the PBO synergist may be working well in some settings but less so in others (within and across countries). However, a lack of cost-effectiveness insight to guide prioritisation of products, as well as a lack of understanding around the operational and cost realities of multi-product campaigns, has hindered useful application of this emerging evidence across countries and negatively impacted overall demand for PBO nets.³²
- *HIVST*: Initial HIVST cost-effectiveness data at the time of the WHO 2016 guidance was regarded as too academic and insufficiently oriented to the type of evidence preferred by country policy makers and funders. The case studies indicated that the production of relevant cost-effectiveness data can be challenging in particular where country contexts are very different (e.g. for HIVST there are range of service models and of HIV prevalence and epidemic contexts that need to be considered).
- *PrEP*: The example of PrEP highlights the importance of effective messaging on cost-effectiveness, as the initial communication to policymakers did not break the myths that PrEP was a long-term intervention (similar to ART), perpetuating assumptions of high cost.

The generation and dissemination of cost-effectiveness evidence on an innovation has the potential to convince countries to introduce and scale-up the innovation. The mindset of global partners has changed on this point with bigger efforts being made to provide stronger cost-effectiveness data from the outset. For example, Unitaid has

³¹ Based on the price reduction and 20% of free goods based on the negotiated agreement: <https://stoptb.org/assets/documents/gdf/drugsupply/2020.07.06%20FAQs%20for%20bedaquiline%20price%20announcement.pdf>

³² The NNP is generating substantive data on this piece.

increasingly emphasised the need to generate and disseminate cost-effectiveness data as seen in the Dual AI nets project and HIVST (as well as in other projects such as POC EID testing). Importantly, the cost-effectiveness data should not be understood only as an advocacy tool for scale-up but also as an important element to decide whether it is worthwhile to scale-up innovations in the first place, and how and when to prioritise them in the context of other choices.

Insights on the Global Fund role in market shaping and affordability of innovations

- The market shaping role of the Global Fund is not proactive or deliberate with regards to innovations.** As noted in Section 3.1.3, there is no overall strategy or approach for innovations in the Global Fund, which reflects an agreed list of innovations that the Global Fund will support, within the context of a consideration of the range of current and pipeline tools to support HTM. While upstream partners such as BMGF, Unitaaid and others such as USAID are in a better position for early market interventions, stakeholders see the Global Fund as having a key role to play to achieve an affordable price in the medium to long-term by drawing on its increased purchasing power. The market shaping role of the Global Fund is viewed as being passive and focusing on the procurement function through the pooled procurement mechanism. Discussions with the Global Fund Secretariat indicate that its market shaping role has been mainly through the PPM and QA tools without any further specific tools (e.g. volume commitments) to shape markets for innovations. For example, it was seen as a missed opportunity that the Global Fund has not been involved more heavily in price negotiations with manufacturers (e.g. in the case of GeneXpert). Several initiatives on innovations planned under the MSS such as a revolving fund to support innovations were never implemented. The recent TERG MSS review recommended the move to more pro-active market shaping, and the TERG position paper on this review also recommended that the Global Fund adopt a more extensive approach such as the healthy markets framework adopted by Gavi. Stakeholders consulted for this review welcomed more recent changes on the Global Fund's engagement (with reportedly some positive examples in ARTs and 3HP as well as recent engagement with GeneXpert).
- The Global Fund's comparative advantage with respect to country perspectives and insights on demand is not being adequately used to support market shaping, including through timely and accurate demand forecasts.** Consultations underscored the importance of the Global Fund in strengthening demand forecasts for new innovations (and existing products). While there are challenges on this due to the demand-driven model, stakeholders emphasised that stronger demand forecasts (or even commitments), including increased visibility of multi-year demand and commitments, could play an important role in price negotiations with manufacturers as well as mitigate production capacity challenges. There is also an opportunity for the Global Fund to have a greater role in providing technical assistance in country demand forecasting, which was highlighted by stakeholders as an important enabler for countries to transition to new products. The issue of Global Fund's unclear position on support for generic dual AI nets is also seen as a barrier to being able to adequately respond to demand following the anticipated WHO guidance in 2023.
- The use of the ERP-D mechanism by the Global Fund has been viewed as highly beneficial to the deployment of innovations.** The ERP/ERPD mechanism hosted by WHO was highly regarded by stakeholders as a means of building early country experience with innovative products that are on the "longer route" to WHO PQ. Stakeholders also regarded that the emphasis on local manufacturing observed during the COVID-19 pandemic signals a need/ opportunity for the Global Fund and others to consider how to respond to this trend.
- The importance of cost-effectiveness analysis to support innovation roll-out cannot be overemphasized, and there is a need for the Global Fund to work more with partners to ensure this evidence is developed and disseminated to countries.** One of the core tools of the Market Shaping Strategy 2016-22 is cost effectiveness analysis however the role of the Global Fund in this regard has been limited. This is a key enabler for scale-up and stakeholders have highlighted the need for a more engaged and pro-active role by the Global Fund in this regard. The TERG position paper on the MSS review also recommends "piloting cost-effectiveness analysis for selected health products and interventions" by the Global Fund. The challenge of generating good cost effectiveness analysis tailored to specific country and local contexts is recognised.

3.2.5. Country demand and readiness

Barrier: Delay in policy updates and operationalisation of national guidelines

The need to update national guidelines or policies based on WHO recommendations, and their operationalisation, can considerably delay the introduction of innovations. These steps are a key pre-requisite to effectively scale up innovations and have strong country buy-in to support the innovation. While national guidelines can be updated to include innovations in the absence of a strong WHO recommendation, this remains relatively rare in practice. The translation of normative guidance to national policy can take considerable time and is affected by a range of factors. These include the country context, especially the strength of existing structures (e.g. national disease committees, etc.) and the collaboration of in-country partners to come together to discuss and agree on guideline changes. Another factor is the speed with which countries are informed of WHO guideline changes and eventually agree, based on presented evidence, that a change in national guidelines would be beneficial. Even when countries have updated their national guidelines, further delays can occur during operationalisation of the guidelines – e.g. with regard to the development of operational plans for implementation, training materials, or service models. This was the case for HIVST, with only ~50 countries implementing it of the nearly 100 countries with a national HIVST policy.

The innovation and country case studies unearthed a number of additional factors that influence the pace of national guideline updates and operationalisation, and thus CCM decisions to include innovations in their funding request (and ensure sufficient ambition in this regard, for e.g. scale vs. pilot). Examples included:

- **Political economy barriers:** On a macro level and within a restricted budget landscape, stakeholders noted that innovations were often deprioritised versus other needs (e.g. ART taking precedence over PrEP).
- **Political hesitancy, stigma and human rights barriers:** Innovations considered to be targeted predominately at marginalised and stigmatised groups can face higher hurdles to be supported (e.g. PrEP and, to some degree, HIVST as observed in Indonesia).
- **Capacity constraints with regards to unknown products:** In many cases countries were also seen as wanting to scale up existing interventions which are well known/ understood by national and regional staff even if newer alternatives offer more cost-effective approaches. For example, stakeholders described the difficulties for other TB diagnostic products to enter country markets due to high demand for GeneXpert even where these would complement existing products (e.g. use of (digital) X-ray machines).
- **Procurement and supply chain management (PSM) barriers:** Capacity challenges at national and sub-national level in PSM systems have inhibited the pace of innovation introduction. For HIVST, introducing a new product into HIV testing supply systems has a number of implications concerning quantifications and logistics to appropriately distribute HIV test products sub-nationally.
- **Role of the private sector:** In general, the role of the private sector for introduction and deployment of innovations remains under-utilised. In Indonesia, PrEP is currently only available through some larger private providers in the bigger cities and through some online platforms. Partnership with the private sector for scale up is recognized as important, and the Global Fund was strongly supportive of the idea of 'social contracting' to formalise private and community involvement in PrEP provision. In HIVST, few stakeholders are working with the private sector, with mostly smaller projects by CIFF and Unitaid.
- **Questions about local implementation:** While countries may be aware of and understand WHO's recommendation for a new innovation, there often remain concerns about its specific application to country circumstances and potential implementation challenges.

Barrier: Delay in product registration

Product registration in country is an additional hurdle which can further delay innovation introduction and scale-up and has become a growing concern in recent years. The extent of this barrier can vary considerably by country – with some accepting WHO PQ or Global Fund ERP to use the products in the country (e.g. GeneXpert in many LMICs). Product registration takes time, especially since it is often only started after issuance of WHO recommendations for the product or after updating of national guidelines (e.g. in Ghana). While these sequential

approaches make sense with regard to robustness, they also increase the risk for considerable hold-up especially when there is little visibility of upcoming changes. Besides the risk of delay, product registration is also burdensome and costly for manufacturers especially where countries have very specific processes (e.g. languages, required documentation etc.) – a concern that is currently not alleviated through a coordinated approach across countries (e.g. through Africa CDC). This can act as impediment, in particular for smaller manufacturers, to enter a market and could lead to more concentrated or monopoly markets. Additionally, this is a key concern with regard to equitable access to innovation as manufacturers may concentrate only on countries with high population/ high burden.

- *GeneXpert*: A challenge has been that countries have increasingly moved towards requiring national product registration even when a product has received WHO PQ (for example, countries increasingly require registration of GeneXpert including older equipment which previously was exempt).
- *HIVST*: The role of partners such as Unitaaid in facilitating product registration in country has been an important accelerator, such as for HIVST, and highly complementary to the Global Fund.

Barrier: Limited community demand

Limited community demand or understanding of innovative products means that there is less demand and pressure on decision-makers to scale up.

- *PrEP*: One of several barriers to deployment of PrEP at scale has been the negative community perceptions of daily oral PrEP, influenced by the initial positioning of PrEP as a service for MSM (in the first WHO guidelines) and negative community perceptions or stigma regarding sexuality among young people and high-risk groups (e.g. female sex workers and other KPs). The daily oral PrEP regimen is also stigmatized amongst AGYW given similarities to HIV treatment. Failure amongst HIV stakeholders to successfully address these community barriers has contributed to suppressed demand for PrEP. In Georgia, stakeholders identified high levels of homophobia, stigma and discrimination as the main barrier to accessing and taking up PrEP, with one stakeholder noting insufficient funding for community awareness generation. In Indonesia, community engagement and empowerment are seen as critical for the demand creation. For various KPs, their community hubs are safe environments from which engagement is initiated but this remains limited. Slow growth in community demand, owing primarily to stigmatisation, is seen as the key barrier to scale-up in Indonesia (as one consultee describes it – ‘*If the government sees the people want it, they will find the money.*’).
- *HIVST*: In Ghana, initial community receptiveness to HIVST was weak, as initial priority populations in country introduction were MSM and sex workers, who face high levels of stigma. In 2020, the establishment of a national committee on HIVST with all major partners (implementers / Ghana health service / Ghana health commission / WHO / USAID / UNAIDS and CSOs) was considered to work very well and to bring alignment and momentum behind HIVST. A multi-stakeholder committee was also established for PrEP and is similarly viewed as important for building momentum in Ghana.
- *TB*: Stakeholders also commented that, as a whole, community demand for TB products lagged behind the very strong, activism-driven demand for HIV treatment.

Enablers: Strong partner coordination and technical assistance

Strong partner coordination (at global and country level) and provision of technical assistance can greatly help overcome barriers relating to national guidelines, product registration and country stakeholder inertia to switch to new products. This was a common theme across innovation case studies and country case studies, with successfully scaled-up innovations having benefited in one form or another from strong partner coordination and technical assistance. This has worked particularly well in circumstances in which stakeholders had sufficient visibility on each other’s actions, coordinated well and also used existing structures (including regional and national bodies). For example for BDQ, the work closely leveraged existing TB structures including the (regional) Green Light Committees and TB Situation Room. In other innovation areas, strong partnership was also highlighted as key. For ITNs, this was achieved by setting up a separate initiative in the form of the New Nets Project and the Nets Transition

Initiative (including unprecedented involvement of the Global Fund at such an early stage) and in other cases Unitaïd often played a coordinating role across partners (e.g. through STAR initiative for HIVST). Key examples include:

- *Technical assistance from in-country technical partners (particularly WHO) to help countries understand the benefits of innovation and update their national guidelines:* For example, after 2016 WHO spent considerable time convincing countries on the use of HIVST, its cost-effectiveness and quality. While HIVST was initially considered a “radical change”, WHO’s normative guidance and its close working with Ministries of Health brought significant credibility to the use of HIVST and is regarded as crucial in increasing country demand. Unitaïd’s financing to WHO through an ‘enabler grant’ for HIVST is also viewed as helping to accelerate global advancement of HIVST.
- *Specific funding and technical advice to support countries with product registration, operationalisation of guidelines and preparation of Global Fund funding requests:* For example, the Unitaïd-funded technical support (STAR 3 project) focused on pragmatic steps for scaling HIVST, including preparation of the 2020-2022 cycle of funding requests for HIVST, updating HIV testing policies and operational guidelines, and product registration. The Global Fund is now providing US\$ 47 million for HIVST in these five countries (Cameroon, Mozambique, Nigeria, Tanzania, Uganda) in the current allocation period. To support francophone west African countries to introduce HIVST, Unitaïd financed the ATLAS project in Cote d’Ivoire, Mali and Senegal (2018-2022). Implemented by Solthis, the ATLAS project worked closely with governments and national HIV partners to establish national level tools for HIVST, register products, and test service models. The ATLAS project had a significant research component to build the evidence base in concentrated epidemics in West Africa, and supported countries to prepare for HIVST expansion through Global Fund financing under the 2020-2022 Funding Cycle.
- *Global and country level active planning and parallel approaches:* For example, for BDQ, collaboration between the Global Fund, GDF/ STOP TB and WHO was seen as important in the process of understanding upcoming WHO policy changes and to communicate these with other partners and with countries. At the global level, there was close interaction with the Global Fund TB advisors (who sit on WHO GDG meeting³³) but also interaction with the FPMs in key countries. This early and proactive planning regarding response to WHO changes in rapid communication or guidelines and working in parallel (e.g. to already prepare for the changes) rather than sequentially was seen as important. The work around the dual AI nets goes a step further with varied evidence generated which has informed inclusion into funding requests, and some operational guidance, which has taken place in parallel (rather than sequentially) to the development of WHO guidelines - and so when the policy recommendation for Dual AI nets comes as expected, a lot of the work to test, engage and explore operational roll-out at country level will have already been done.
- *Sharing of evidence (including on implementation and operationalisation) from other countries or support of pilot projects:* The case studies have showed that many countries strongly prefer to have pilot schemes in their own country to gain understanding and data on the intervention’s impact and implementation challenges. While there are benefits to this approach it can delay scale-up further when there is already sufficient evidence from other countries. Stakeholders emphasised the importance of ongoing discussion with countries by technical partners, and also the Global Fund to help them understand the evidence (including on implementation), and critically consider the need for further piloting. This applies in particular where WHO has issued strong guidance. An example where this was done well is the change to DR-TB oral-regimes with BDQ. In comparison, stakeholders regarded PrEP as suffering from over-use of pilots, which slowed scale up.

³³ The Global Fund participated in WHO Guideline Development Group (GDG) meeting as an observer which led to the rapid communication in 2018, which advised against the use of injectables and recommended the longer all-oral DR-TB treatment regimen.

Enabler: Advocacy/ demand creation for innovations

Proactive advocacy and demand creation interventions aimed at decision-makers or directly at affected communities have been successful in increasing uptake, especially where they addressed specific concerns. For example, programmes to explain PrEP and HIVST to communities helped overcome the initial lukewarm response from some communities to these innovations (e.g. in Ghana). Unitaid projects have also increasingly supported demand generation at the country level (e.g. STAR projects for HIVST).

Insights on the Global Fund's role in country demand and readiness are presented jointly with those on implementation at the end of Section 3.2.6 below.

3.2.6. Implementation

Barrier: Delays in implementation

Even when there is country demand and support for scale-up, practical and process-related factors can delay the implementation of innovations. These factors can relate to country specific aspects or to Global Fund processes. Examples from the innovation case studies include:

- *Global Fund cycle*: The 3-year funding cycle of the Global Fund can delay the transition to new products when WHO guidelines (and subsequently national guidance) are updated throughout the grant cycle, although reprogramming options exist. This holds in particular when the agreed grant targets should be maintained but the innovative product is more expensive than the product it would replace. As a result, additional funding is needed to successfully transition to the new recommended products. This was initially the case for BDQ, later successfully addressed through the Portfolio Optimisation process (discussed below).
- *Country concerns regarding wastage of existing stock*: Countries may be hesitant to move to large scale use of innovative products when that would mean wasting existing stocks of current products – which governments consider both a cost and a public appearance challenge. This was flagged as an initial challenge for the switch towards the oral regimen containing BDQ and the replacement of injectables.
- *Country specific challenges*: Examples include issues around receiving products on time from manufacturers for timely scale-up (e.g. HIVST for Ghana) and challenges around identifying and contracting implementers. In Burkina Faso, the deteriorating security situation has limited implementation of malaria and TB programmes, as well as of PrEP and HIVST pilots to urban areas.

Barrier: Health systems challenges including infrastructure, HR constraints and data issues

A weak health system with infrastructure and human resources constraints was considered a key challenge for implementation. Weak systems issues also include a lack of strong data on the outputs, outcomes and impact of innovations. For example:

- *GeneXpert*: Scale-up was said to be restricted as issues remain with regard to placement in some areas including infrastructure challenges and staff challenges. In Burkina Faso, power fluctuations are a recurrent issue which wastes cartridges; the country is now exploring the use of solar panels to mitigate this issue. Data connectivity remains a gap in many countries, needed to centrally track utilisation and to detect issues with the equipment.
- *PrEP*: In Indonesia, system readiness for PrEP was viewed as a barrier to scale up, with a need to focus on operations, logistics and distribution, health workers guidance and counselling capacities, targeting and follow up of recipients, monitoring, reporting, amongst others.

Barrier: Weak disease programmes, effective linkage to care and integration into existing services

Effective disease programmes with good linkage to care and integration into existing health services are needed to gain the most impact from innovations. Stakeholders emphasised the need for the introduction of innovations to not be considered in isolation or as “silver bullets”. For example:

- *PrEP*: In many countries (e.g. across Sub Saharan Africa) slow PrEP uptake is linked to wider challenges relating to weak HIV prevention programmes.
- *GeneXpert*: Linkage to care of GeneXpert machines (including lack of communication/referral pathways between health centres and laboratory sites) was considered an important reason that greater impact of GeneXpert on overall TB mortality has not been observed.

Enablers: Partner coordination and strategically designed technical assistance

Strong partner coordination and strategically designed technical assistance were considered crucial in addressing major implementation barriers. In particular, these aspects are critical to ensure that pilot programmes are integrated successfully into existing health services delivery (with this step often including a handover between partners, such as from Unitaids or STOP TB project financing to Global Fund support). Similarly, technical assistance was considered particularly effective when strategically designed, aligned with product scale-up, and actively targeted at known bottlenecks in implementation. The HIVST collaboration between Unitaids and the Global Fund is a good example of effective coordination. Subsequently, the Global Fund HIV testing DSD SI for 10 priority countries is a good example of targeted country support for quality implementation within core funding allocations.

Enabler: Complementary services funding to integrate innovation in systems

Successful and equitable deployment and scale-up of innovations requires sufficient resources for activities outside of procurement of product – e.g. for technical assistance on product transition planning, operational guidelines development, staff trainings as well as for wider health system strengthening. The country case studies showcase a number of complementary activities:

- *GeneXpert*: Between 2011 and 2015 USAID played an active role in the introduction of the GeneXpert (MTB/RIF) technology in Georgia. While the first machine was procured with Global Fund support in 2011, USAID shared the costs of cartridges and played a lead role in provision of TA. The Global Fund has since supported the rapid scale-up of GeneXpert technology in Georgia, which benefits from USAID’s early programmatic support.
- *Tuberculosis treatment adherence*: Georgia has deployed a mobile application, Adhere TB, which allowed treatment of MDR-TB to shift from daily facility-based directly-observed treatment (DOT) to home-based video-supported treatment (VST). Adhere TB was developed by the National Centre for Disease Control with support from the Global Fund in 2017 and has improved outcomes for treatment of MDR-TB and reduced loss to follow up. Additionally, VST has been shown to be a more cost-effective approach than DOT from a health system and patient perspective.
- *PrEP*: In Indonesia, the use of an online data platform to monitor PrEP pilots is reportedly helping to reassure hesitant government and clinical stakeholders on progress and supports monitoring and coordination. It is also hoped that access to real time information may support demand creation efforts, such as social media promotion and community engagement.
- *HIVST vending machine*: Introductions of novel HIV products in Georgia have also been supported through innovations in implementation, addressing access-side barriers. Following a trial testing the feasibility of providing sterile syringes for PWIDs through vending machines, Global Fund resources were used to scale up the initiative. HIVST kits were included in ten vending machines across Tbilisi, with the goal of increasing self-testing among MSM. Results of this initiative have not been reported.

- *HIVST virtual platforms:* Though not yet launched, Ghana is developing a virtual outreach platform to address gaps in reaching KPs with HIVST, with support through the HIV DSD SI.

Barrier: Sustainability issues

There have been a range of sustainability issues regarding continued scale-up and use of innovations, notably transition from pilots, maintenance of diagnostic equipment, as well as the pricing and affordability discussed above (Sections 3.2.3, 3.2.4).

Transitions from donor-supported initiatives: Country stakeholders emphasised the challenge to move from pilot programmes supported extensively by technical partners and donors, to integration of innovative products into routine services. The issue of transition also applies to market interventions where donors are effectively subsidising higher priced innovations in the near-term. This transition step was regarded as crucial, requiring sufficient prior planning (ideally to be included at the outset in programmes).

- *HIVST:* Early, joint planning amongst the Global Fund, CIFF, Unitaids and WHO supported a direct pathway from the Unitaids financed STAR 3 initiative to Global Fund financing through the HIVST Matching Funding in five sub-Saharan Africa countries. The early planning and technical support through Unitaids for transition to Global Fund financing is viewed as a good example of investment in capacity building of government systems to integrate an innovation. A small number of these countries continue to receive technical support through the Global Fund's HIV Differentiated Service Delivery (DSD) SI, as an indication of the need for continued systems strengthening.³⁴
- *Dual AI nets:* The New Nets Project (NNP) includes a co-payment by the Global Fund to ensure that countries involved in pilots are not burdened with the additional cost of these products whilst evidence is being built.³⁵ Stakeholders view this as a near-term solution, with need for a longer-term and more sustainable market strategy for Dual AI nets.
- *Potential role of private sector in GeneXpert:* In countries with significant use of the private sector in health care, their role and regulation in relation to overall TB diagnosis needs to be addressed. For example, consultees for the Indonesia case study suggested that the Global Fund have more focus on the private sector and consider various engagement options i.e. rental agreement for GeneXpert for the private sector (which may also encourage private sector to invest in GeneXpert). It is also suggested that lessons be taken from COVID-19, given how quickly PCR testing was expanded in the private sector over the last two years with data sharing between both public and private sectors via a decentralised reporting mechanism.

Maintenance of Equipment:

- *GeneXpert:* Being a point-of-care tool, the effective scale-up of GeneXpert is susceptible to infrastructure and staffing challenges in frontline locations. For example, the issue of maintenance is particularly acute due to a number of reasons including: i) the equipment was initially not ready for the conditions in LMICs; ii) there were few Cepheid service providers (or sub-contractors) in-country to conduct equipment service or maintenance; and iii) provisions for service / maintenance were not included within country contracts. While the first two have now been mostly addressed, there remain challenges around the third. The problem is particularly pronounced as GeneXpert contracts are led by countries and, reportedly, maintenance is often taken out in the last steps of the funding request stage. Stakeholders indicated that the Global Fund has not been proactive in addressing the issue of maintenance contracting, considering this largely to be a country choice. Other partners (e.g. CHAI, Unitaids, PEPFAR) have moved further in this space and have pushed for all-inclusive pricing agreements or moving to a lease-only model. While there are mixed views on whether

³⁴ Differentiated Service Delivery (DSD) SI for HIV

³⁵ For the co-payment, the Global Fund grants were used to pay the base price (equivalent to the cost of a 'standard net'), and the NNP used to pay the difference. A volume guarantee supported by BMGF for the IG2 Dual AI nets reduces the co-payment value financed by the NNP.

this could be implemented by the Global Fund, stakeholders identified that not advancing a set of minimum criteria around maintenance by the Global Fund hampered effective implementation.

Insights on the Global Fund role in country demand, readiness, and implementation

- **Strategic levers in the Global Fund core allocation funding model have significant potential to foster demand for innovations, yet have been used on an ad-hoc basis.** The range of Global Fund strategic levers as discussed in Section 3.1.3 are regarded as under-used (with some stakeholders expressing the view that the country-driven model has impeded a more directive approach). Yet their potential is significant in terms of driving country demand and ambition, as in the case of Ghana where stakeholders said they were more likely to include innovations in funding requests if they got the sense (usually through engagement with the country team/FPM) that this would be a priority for the Global Fund.³⁶
- **Catalytic Investments are overall well regarded to encourage country introduction and uptake as well as address implementation challenges, but represent a small proportion of overall Global Fund resources.** Matching Funds are particularly regarded as an effective mechanism to spur country demand within a predefined set of strategically important countries (e.g. high-burden countries). Several examples have been provided above (e.g. the HIVST matching fund, HIV DSD SI to address gaps in HIV testing and treatment, SI funding for the NNP and NTI³⁷, etc.)
- **There is scope to expand the use of market shaping tools and activities to support innovation scale-up.** The need for more pro-active market shaping by the Global Fund has been discussed above. Further, the utility of the various tools and activities supporting the market shaping has been emphasised. A positive example is the Global Fund list of eligible products which has a strong influence on country demand, and for example, impacted the switch to BDQ as injectables were removed from the Global Fund procurement list (in accordance with WHO guidelines). Some stakeholders emphasised that older/ inferior products could be removed even prior to WHO guidelines or at least to require additional justification for using these products (e.g. a soft minimum standard rule). Other aspects such as limited use of the PQR data to support assessment of innovations has been highlighted previously.
- **Leveraging of RSSH funding and other mechanisms to support new product introduction.** While this review has not considered Global Fund RSSH funding in detail, the importance of ensuring integrated disease and wider health systems support alongside new product introduction has been emphasised across all of our case studies (and highlighted as an important barrier above). The important role of the Global Fund in funding service/ programme delivery alongside its funding of health products was emphasised. The COVID-19 mechanism provided additional opportunity for countries to support demand shaping and address policy and regulatory challenges. For example, the COVID-19 Response Mechanism (C19RM) promoted HIVST as an alternative to maintain services (although the HIVST commodities themselves were not funded through C19RM).

3.3. BARRIERS AND ENABLERS FOR NON-PRODUCT INNOVATIONS

This section considers non-product innovations (i.e. innovations in service/ programme delivery approaches and health systems management tools and processes). The analysis is based on five case studies: three of service/ programme delivery approaches conducted alongside the health product innovations – (i) virtual behaviour change campaigns for HIV PrEP and self-testing; (ii) integration of diagnostic services through GeneXpert; and (iii) activity-based contracting for ITN mass campaigns for malaria; and two case studies that are not health product specific namely, mobile financial payments and facility level financing (FLF). The assessment covers evaluation questions 4, 5 and 6 for non-product innovations (*Q4. How effective has the Global Fund been in identifying and supporting the different stages of the innovation value chain at global and country-level? What are the key drivers and opportunities*

³⁶ As a step towards more systematic and directive encouragement of countries to include specific innovations in funding requests, the Information Notes prepared for the 2023-2025 allocation period now include a new “Programme Essentials” requirement, which outlines a core set of interventions regarded as critical to maximise the impact of investments.

³⁷ SI funding for the NNP and NTI has not yet resolved how the Global Fund can offer a more streamlined process to supporting new products, including incentivising manufacturers and building demand, and whether a ‘market distortion’ should always be required as in the case for Dual AI and PBO nets.

as well as the key challenges and barriers in the effective and equitable deployment and impact of innovations? Q5. Has the Global Fund been effective in engaging the range of relevant partners at the global and country level to accelerate innovation? Q6. What are the best practices to accelerate equitable deployment and access to innovation?)

Key findings	Robustness rating
1. There have been a wide range of non-product innovations supported through Global Fund funding, however their extremely diverse nature – in concept, application and stakeholder understanding of these innovations – renders it challenging to scope out the universe of these innovations. This also enhances the challenge for the Global Fund in managing and supporting their varied roll outs.	Strong
2. The Global Funds lacks the capacity and systems to facilitate the roll-out of non-product innovations.	Strong
3. The variability of non-product innovations creates a challenge in balancing standardisation of approaches with the need for adaptation to specific contexts and complicates planning for scale up. Countries could benefit from more engaged technical assistance in adapting roll-out to their specific circumstances, which would require support from technical partners.	Moderate

3.3.1. Characterising non-product innovations and Global Fund's approach

There are two key aspects here:

- **Non-product innovations are extremely diverse – in their concept, application and in stakeholder understanding of these innovations.** Innovations can differ in their scope, scale-up needs/ potential, extent of novelty and risk, Global Fund Secretariat team(s) driving or supporting the innovation, approvals process within the Global Fund, the required levels of resource, amongst others. The same innovation may also be implemented with adaptations across countries (e.g. mobile payments). Service/ programme delivery innovations, such as those we explored through our case studies, are often viewed more as efforts to support continual improvements, ongoing adaptations or expanded delivery and may not be considered as innovations by some stakeholders. This is in comparison to the health systems management tools and processes reviewed under this evaluation, which have usually been initiated to address “pain points”. There may also be a diversity in perspectives across stakeholders around what constitutes an innovation as relating to service/programme delivery efforts – for example, one consultee compared a ‘Secretariat’ perspective here with a ‘community, rights and gender (CRG)’ perspective.
- **Similar to health product innovations, there is no centralised system or approach within the Global Fund on non-product innovations** – but their diversity makes for more challenging management of roll-out by the Global Fund. Innovations in this space are harder to define or ‘group’ in terms of their innovation relevance or orientation, which can further complicate strategising and related management and support in this space. All five non-product case studies under this evaluation are either in approvals processes (DFF), pilot stage (mobile financial payments, ABC for nets, virtual BCC) or have been implemented in an ad hoc fashion or distinct way across Global Fund countries (TB diagnostics integration), with no apparent prioritised or systematic approach to roll-out and further scale-up.

For the reasons set out above, assessing the Global Fund's approach to non-product innovation is complex. It has not been possible to explore the full universe of non-product innovations within this evaluation, and due to their diversity, it has neither been possible, nor valuable, to develop an overarching value chain with homogenous key enablers and barriers that would apply across all non-product innovations. However, there are some common themes which have emerged which we continue to outline below.

3.3.2. Global Fund role, systems and capacity

A number of issues with regards to the Global Fund role and capacity to support health product innovations also apply for non-product innovations – e.g. the implications of a country/ demand-driven model, limited reference in

technical guidance and Information Notes, and dependence on the interest and engagement of the FPMs/ CTs. Beyond these, there are a number of additional aspects:

- **The role for the Global Fund in supporting non-product innovations is less clear compared with product innovations, which are usually more closely linked to WHO approvals and normative guidance.** The lack of Global Fund (and wider) guidance available for non-product innovations can limit the initiation of innovative ideas, as well as support to CTs from other departments within the Global Fund Secretariat. Also, there is a general perception that once a health product has been introduced, the Global Fund “hands over” to the country to take forward to boost ownership and sustainability, but often there is more demand for a greater role post product introduction which can involve innovations on service/ programme delivery approaches. For example, it was suggested by some consultees that the Global Fund could potentially further optimise its role in supporting product innovation through initiating a wide range of follow-on service/ programme delivery or health system innovations. In Indonesia, for example, it was suggested there would be scope for the Global Fund to support innovative community demand generation approaches following the introduction of PrEP.
- **There are varied approaches to innovation origination, which can at times, also serve as barriers to piloting implementation or facilitating wider scale-up.** Non-product innovations can originate from both countries as well as the Global Fund Secretariat. For example, the concept of virtual interventions for HIV services seems to have originated from existing country programmes. Examples shared by consultees included the use of mobile/ digital communication for youth mobilisation (led by Y+ Global) and digital initiatives supporting HIV services for KPs (financed initially by the PEPFAR LINKAGES project implemented by FHI360). Whilst useful in being country or implementing partner-led, there is limited potential for scale-up in other relevant contexts unless there is a greater push and knowledge sharing by the Global Fund.³⁸ ABC was seen as being desired by some countries and enabled by a small team within the Global Fund Secretariat who were keen to emphasise outcomes (relative to inputs) more than is routinely done by the Global Fund. The mobile financial payments innovation originated exclusively from the Global Fund Secretariat with the motive to improve financial management and accountability for physical cash payments in grants. The DFF innovation was pursued by the CT as a needed intervention to manage funds flow within a dysfunctional country health system, amongst other factors. Countries are usually not mandated to adopt these non-product innovative approaches, rather, they may choose to pursue an innovation if it appears valuable to do so within a specific country/ context. In the absence of any requirements for inclusion in Global Fund financing, countries can experience pushback during implementation (e.g. as seen in mobile payments due to lack of acceptance/ familiarity with a new tool)³⁹, inhibiting the deployment in-country and perhaps more broadly. Given the small scale and voluntary nature of these innovations, and lack of centralised system as discussed above, it is also likely that many CTs are unaware of the possible scope of non-product innovations, which could reflect various missed opportunities, as well as deter the generation of further ideas in this space. Overall it is recognized that non-product innovations would largely originate from countries given they relate to service and programme delivery approaches and tools.
- **The Global Fund Secretariat/ CTs as well as existing systems may lack the capacity to pursue these innovations.** There are several examples here:
 - First, we understand that CTs are often subject to resource constraints. These teams lack the time and resources to seek out or pursue innovative ideas, which also limits their awareness of them. Were they to be aware of innovations, at times, CTs may still choose not to pursue them due to limited incentives. For example, CT performance is measured against programme indicators, which may limit their incentive to dedicate scarce resources to learn about, design and scale-up

³⁸ In the case of integrating virtual platforms, the size of the country allocation is also regarded as influencing the level of country ambition (as found for product innovations), as well as the degree of ‘innovativeness’ of PRs, maturity of the country HIV programme for KPs, and overall digital literacy.

³⁹ For more details, please refer to Section 7.3 in Appendix H.

innovations, or progress them through relevant approval processes. While CTs often have programmatic skillsets, they may be less confident as regards the legal, financial and risk elements of innovative ideas (despite the support available in these areas from other Global Fund Secretariat members), which may make them less willing and able to pursue and navigate approvals for non-product innovations.⁴⁰

- The Global Fund's performance-based funding model is challenging to apply to programmes using digital platforms for behaviour change or service provision as it is more difficult to track outcomes in terms of service uptake or behavioural impact, whilst also importantly protecting anonymity. A key lesson specifically for the Global Fund's deployment of virtual interventions has been the fundamental need for approaches that do no harm and protect the privacy of populations using these platforms.
- Innovations that work broadly within existing structures face less challenges. For example, mobile payments perform the same function as existing payment methods (e.g. cash) but with the benefit of increased transparency, risk management and effectiveness. Further, there is no additional cost as the transaction costs associated with current payment methods are simply reallocated to mobile payments. This has made it more straightforward for CTs to operationalise these pilots. By contrast, FLF, and DFF in particular represent a more significant departure from the typical Global Fund approach. The Payment for Results (PfR) pilot had to pass through a lengthy Secretariat review process before Executive Grant Management Committee (EGMC) approval. Further, the challenges related to this process may limit the willingness of staff to pursue other innovative ideas.
- **A relatively greater focus on risk management than programmatic outcomes and a complex review approval process act as impediments to innovations (especially financing innovations).** Several of the case studies pointed to a shortcoming in the Global Fund's approach in that it focused to a large extent on risk management rather than programmatic outcomes. For example, the mobile financial payments innovation originated from the finance teams within the Global Fund Secretariat largely in an endeavor to improve financial management and accountability. However, external stakeholders have indicated that the Global Fund has narrowly used this innovation to channel funding rather than exploring the programmatic potential of this innovation in terms of supporting inclusivity and improving access. Similarly, for the DFF innovation, noting the input rather than output/ outcome-based financing approach of the Global Fund, stakeholders indicate that the review/ approvals process is highly focused on risk management and can act as impediment to the implementation of financial innovations (see box below). For ABC contracting, consultees indicated that the approach requires effective collaboration between teams focused both on programmatic data and finance/ risks assessment which is not yet routinised; and that the finance risk driver still dominates. Stakeholders opined that the overall culture of the Global Fund is risk averse that has implications for the appetite, capacity and mechanisms to support various non-product innovations (more details can be found in Appendix H, sections 6.3 and 7.3).

DFF/FLF case study demonstrated that the current review and approval processes for (financial) innovation can act as strong impediment requiring substantial additional resources and capacity to navigate the multiple layers of approval and review processes to receive sign-off. As a result of the lengthy design and review process, the DFF pilot has not started implementation and the timeline is likely to be truncated to 15 months or lower (from an initial 2-year project).

⁴⁰ For example, as part of our FLF case study we examined a Direct Facility Financing (DFF) pilot that is currently progressing through internal approvals processes. Stakeholders indicated that this pilot would not have progressed to this stage in the absence of a key individual with experience that allowed them to effectively engage with finance and legal reviewers. The Service Delivery Innovations Strategic Initiative (SDI-SI) has channelled funding to technical assistance to support the design of the DFF pilot, addressing both resource and technical capacity constraints of the CT. This experience suggests that certain innovations may only progress if sufficient support is available outside of existing CT resources.

3.3.3. Challenges in implementation and scale up

- **Need for adaptation to context.** Given the variability of non-product innovations – both across different innovations as well as application settings within the same innovation - there is a challenge in balancing standardisation with context adaption required for effective scale up. Some service delivery innovations, such as virtual behaviour change / service delivery, may require a more ‘bottom up’ approach, rather than ‘top down’ approach which is generally more the case with product introduction. There is also more thinking to be done to define what constitutes ‘quality’ in terms of a breadth of innovation approaches and ensuring that measurement approaches are both reliable and somehow applicable across contexts. One consultee suggested a ‘benchmark approach’ could be developed, which could serve as a non-product innovation value chain. As conveyed by one consultee: *“We may be funding things that are different and they could be great but are we measuring the right things? Or they may not necessarily be better and there may not be the data here to inform this.”*. There is also a challenge in the evidence base required prior, and / or to be generated alongside service delivery/programmatic innovations, useful for considering the settings in which the innovation could be usefully introduced, as well as to generate information on the innovation’s effect and impact. This is also linked to the lack of guidance available to support pilots and effective scale up efforts.
- **Multiple practical challenges in implementation.** All of our case studies have exhibited multiple challenges in implementation (similar to that flagged for health product innovations) highlighting the complexity in their deployment and risks in the pathway to results/ impact. For example, for mobile financial payments, there have been challenges with infrastructure/ network functionality, data collection, effectiveness of the service provider, etc.⁴¹ Challenges were also seen in service delivery innovation approaches which looked to boost integration across diseases, specifically HIV and TB. This includes issues to be addressed at both the Global Fund Secretariat and in-country for this service delivery innovation to be better supported. For example, whilst there have been improvements, there are a low number of combined funding requests which drive integration efforts, reflective of a lack of mechanisms for working effectively across diseases within the Global Fund Secretariat. At the country level, implementation and scale up can be hampered by ineffective coordination mechanisms and engagement between disease programmes within the Ministry of Health and other communication platforms. Integration with other data systems has also been identified as a challenge to successful scale-up for DHIS2 in a few countries by a recent TERG evaluation on data-driven-decision-making.⁴²
- **Countries could benefit from more engaged technical assistance which would require Global Fund working in coordination with partners.** Whilst the partnership landscape for non-product innovations is varied - given the innovations themselves are varied - experience through the case studies highlights the important advantages to the Global Fund from partnering with other organisations in this space. Given TA is not a core area for the Global Fund, there is merit in encouraging these partnerships to facilitate effective innovation deployment. For example, the Global Fund was recently exploring an MoU alongside the Gates Foundation and Gavi on mobile financial payments. Whilst this MoU is still in progress to fruition, it has already enabled the organisations to highlight the importance of mobile payments to their respective management, as well as adopt a more coordinated approach to influence country governments. Through the collaboration with FHI360 for virtual HIV services (facilitated by BMGF financing), FHI360 is providing technical support to countries to plan and deploy virtual services to support KP. Experience is still relatively early but has generated a number of lessons for future Global Fund work in this area. The importance of virtual platforms is underscored by the positive experiences during COVID-19 of switching many services digital/online, their

⁴¹ In Burkina Faso, where mobile payments have been implemented, despite Orange (the original provider) having negotiated its rate centrally with the Global Fund, it raised its rates after implementation had begun. The CT switched to two other providers, though one recently ceased operations in Burkina Faso. This issue, underpinned by little to no telecoms competition in Burkina Faso, has been a barrier to implementing mobile payments.

⁴² The TERG evaluation found that even in some cases in which DHIS2 is mainstreamed, siloed systems continue to exist, making data use difficult because different data sources are not properly integrated with one another.

widespread use by young people, and the continued stigmatization of key and vulnerable populations and need for innovative models of support.

Further, non-product innovations often include an implementation focus, which brings to question what role the Global Fund can/ should play in country. Many consultees called for further technical engagement of the Global Fund at the country level for these innovations, as well as the strengthening of in-country partnerships. Positive examples were praised, such as the HIV/ TB shift towards supporting network optimisation in a number of countries, done in collaboration with BMGF. The Global Fund previously worked with the World Bank on FLF approaches in the DRC. This has provided valuable insight and lessons to support an improved design of the current DFF pilot that is progressing through approvals.

3.4. GLOBAL FUND WORKING WITH PARTNERS

This section considers what works well and less well with regards to Global Fund working with partners on innovations, and assesses both design and implementation aspects of partner working, covering the following evaluation questions:

- Q2. How does the Global Fund add value and coherence to the work of key global partners on innovations including key funders, technical partners and PDPs and how well do these partners feed into the requirements of the Global Fund?
- Q5. Has the Global Fund been effective in engaging the range of relevant partners at the global and country level to accelerate innovation?

Several aspects of partner working in different aspects of the innovation value chain are discussed in Sections 3.2 and 3.3, and this section aims to bring these together at a strategic and collated level.

Key findings	Robustness rating
1. The Global Fund is working with the right partners at the global level for innovations, and needs to adapt its approaches to engaging with (i) smaller and more diverse country partners; and (ii) private sector (global and country).	Moderate
2. Looking specifically at partner work in support of innovation scale-up by the Global Fund, there are key gaps in terms of the transition of Unitaids' early country introduction work to a wider range of Global Fund eligible countries as well as in terms of the capacity of WHO to provide technical support across a wide range of countries. Across partners, there is a key gap in generating and disseminating cost effectiveness evidence to support country demand and uptake – an essential pre-requisite to scale-up.	Strong
3. The Global Fund does not have a systematic, institution-wide and documented approach on working with global partners on innovation, and specifically in terms of managing the transition from Unitaids project funding.	Strong

Key findings on how the Global Fund collaborates with partners are organised into 3 key themes: (i) the extent the Global Fund is working with the 'right' partners; (ii) key gaps in partner work to support scale-up by the Global Fund; and (iii) issues identified in the current Global Fund approach for partnerships relevant to innovations.

The Global Fund is working with the right partners at the global level for innovations, and needs to adapt its approaches to engaging with (i) smaller and more diverse country partners; and (ii) private sector.

Overall, at the global level, the Global Fund is engaging with the most relevant and active partners in the innovation value chain (key partners in the global architecture are depicted in Figure 3.1, and Global Fund is engaged with all of them through a range of formal and informal mechanisms).

At country level however a gap was identified in terms of effective engagement of smaller locally-based organisations that are involved in innovations with the CCM ecosystem (e.g. local NGOs/ CBOs delivering innovative TB diagnosis approaches). A further gap was with regards to CCM engagement with civil society and community based organisations supporting different innovations such as PrEP and HIVST (an issue that is well-recognised by the Global

Fund and transcends work on innovations). It was noted that the Global Fund would need to adapt its CCM processes to better ensure participation and engagement of these local bodies so as to solicit their knowledge and perspectives in innovation scale-up.

Secondly, there is demand from the private sector manufacturers to be considered as a partner alongside others in the innovation value chain given the importance of the private sector to achieving HTM goals. The diversity of private sector partners implicated in Global Fund responses, and of the innovations themselves (e.g. GeneXpert vs. HIVST vs. BDQ) suggests a need for tailored approaches to engaging with the private sector on innovations to address specific barriers along the innovation value chain (e.g. market/supply, price, demand), in coordination with other partners. To date, Global Fund engagement with the private sector has been mostly at arms length, with some examples of more recent closer working (e.g. with TAP and OSS in HIVST) that are well regarded. Discussions with private sector manufacturers suggest their keenness to be considered as an equal/ valuable partner in supporting scale-up objectives. Additionally, the engagement of the Global Fund with domestic private sector actors in recipient countries could be strengthened with regard to their role in accelerating innovations in service delivery and health systems support.⁴³

There are gaps between partner work on country introductions and Global Fund scale-up.

As described in Section 3.1, the Global Fund's comparative advantage in the innovation value chain is firmly in the space of country introduction and implementation at scale, thus this is where partnerships are of the highest priority to achieving Global Fund goals. Key Global Fund partners for country introduction and scale have notably been Unitaaid and WHO, with case studies also highlighting the important role of other technical partners and donors. The centrality of the role of both Unitaaid and WHO in country introduction of innovations has a number of implications for the Global Fund:

- Given Unitaaid's focus on establishing country experience with innovations, and frequently financing the evidence-base for innovations in LMICs, it often partners in 'early adopter' countries. These have both a strong epidemiological basis for the innovation (e.g. high disease burden, existence of resistance to standard therapies/ products) and importantly country willingness to be a first mover where the evidence-base for an innovation may not yet be fully established. The effect of this pragmatic approach is that a gulf arises in the translation of LMIC evidence/WHO guidelines into national policy between the early adopter countries having Unitaaid projects, and 'non project' countries. For HIVST, the need for the matching funding, and complementary Unitaaid funding (STAR 3 initiative) was explicitly to address slow progress in high burden countries where Unitaaid had not yet invested. There is thus a need for the Global Fund and partners to collectively consider how gaps in non-project countries might best be addressed. Discussions with the Global Fund Secretariat highlight the challenge of different country focus by these organisations in the past and the need to better align on early adopter/ pilot countries. We understand that the new Strategy work on NextGen Market Shaping will more pro-actively consider coordinated work between the two organisations, also with the establishment of the jointly co-led task force in this area.
- The important role of WHO global, regional and country offices in supporting country introduction was underscored in a number of case studies, including HIVST, Ghana (HIVST, PrEP) and Burkina Faso (HIVST, PrEP, TB). In Ghana, where stakeholders regarded the authority of WHO as being highly influential, technical assistance provided by WHO for HIVST and PrEP (for implementation and demand generation) was an enabler to introduction. WHO resources however are limited and thus WHO bandwidth to deeply engage in all countries that need technical assistance and are hesitant to introduce an innovation is not realistic.

Further, as important scale-up donors, coordination between the Global Fund and PEPFAR/ USAID is critical. We understand that this generally works well at the global level, and both donors aim to complement each others' areas of funding, but can at times break down at the country level. For example, there have been several instances of

⁴³ This is in line with recent findings from the TERG Evaluation on The Role of the Private Sector in Program Delivery (May 2021) which called for strengthening the engagement with the private sector in service delivery through the development of a strategy, expansion of the knowledge based and strengthening of PSE-related partnerships.

countries viewing GeneXpert machines financed by the Global Fund and USAID as distinct products with their own respective vertical supply chains and use, also impacting progress towards diagnostics integration in the country.

Another key gap, also highlighted previously but particularly relevant for partner work being transitioned to the Global Fund, is with regards to cost effectiveness analysis which is central for driving country decisions/demand but not enough partners doing this well. Case studies pointed to a lack of ‘user-facing’ (including for e.g. government, civil society, external donor) oriented cost-effectiveness data at the early stage of LMIC evidence generation (e.g. HIVST, PBO nets). The lack of cost effectiveness evidence slows demand and particularly where innovations have a higher unit price, reinforce unhelpful assumptions on the lack of affordability.

The Global Fund does not have a systematic, institution-wide and documented approach on working with global partners on innovation, and specifically in terms of managing the transition from Unitaaid.

As described in Section 3.1.3, the Global Fund does not have a clear strategy or approach to supporting innovations, and this also relates to its working with partners.⁴⁴ As noted, there are no plans or roadmaps agreed with partners on scale-up timeline and actions. This includes areas in the innovation value chain where the Global Fund has a more indirect role (as described in Section 3.1), in terms of the need for greater clarity on how the Global Fund will engage in these upstream steps to complement/ supplement the work of partners. While there are individual MoUs and agreements with different partners, it was indicated by some partners that often these are not viewed as effective and dependent on individual initiative and relationships.

The importance for partners to engage early with the Global Fund, including with FPMs, was underscored in a number of case studies and consultations.

Finally, while the Global Fund has partnered with Unitaaid extensively, stakeholders noted the lack of clarity on managing the hand-off from Unitaaid supported grants. This challenge is well explained in the TERG MSS review which states that “the Global Fund lacks clear criteria or decision points for whether and how to scale interventions and associated products. It is not currently clear what results from a pilot project would result in a decision whether or not to scale”. We understand that several efforts have been made over the years, including through discussions at the Global Fund Board level, to improve clarity and operations in this regard, however our case studies and stakeholder interviews continue to flag this is an issue that needs more attention and coordinated partner working.

3.5. LEARNINGS FROM COVID-19 ON INNOVATIONS

This section seeks to address evaluation question 7 on key learnings from COVID-19 (Q7. *How has the COVID-19 pandemic affected the Global Fund’s approach to improving access to innovations?*). We highlight that in the tight timeframe for this evaluation, this assessment was limited in that we were able to only consult a few documents publicly available on the Global Fund website as well as interview select representatives from the Global Fund Secretariat.⁴⁵

Key findings	Robustness rating
1. The learning offered through the C19RM experience is the need to carefully consider pace of deployment of innovations to ensure that they are well planned with needed implementation support. Also integrated/ cross-disease perspectives in funding design and implementation are important.	Strong
2. The speed and agility in the response to COVID-19 is not easily replicable in other contexts without an equivalent sense of urgency. Some organisations, such as	Moderate

⁴⁴ Coupled with this is also the fact that the partner ecosystem itself is also fragmented by disease area and at times by product when for example different PDPs are handling different products, and as a result, there is a lack of coordinated working. An example of fragmented partner working is the split responsibility for HIV and TB procurement between the Global Fund and GDF and implications on procurement of products such as GeneXpert which are used for both TB and HIV (and other disease) diagnosis.

⁴⁵ The Global Fund OIG, 2022, Audit of the COVID-19 Response Mechanism 2021; Pharos Global Health Advisors, 2022, Evaluation of Global Fund COVID-19 Response Mechanism (C19RM) 1.0.

Key findings	Robustness rating
Unitaid, are however exploring ways in which they can mainstream their agile practices during COVID-19 for their core business, and this may be relevant for the Global Fund.	

The following are key learnings:

- **Unprecedented mobilisation of resources and partner action.** The response of the Global Fund (and other ACT-A partners) to the COVID-19 pandemic has been unprecedented given the global scale and severity of the pandemic. For example, the Global Fund Board approved the creation of the COVID-19 Response Mechanism (C19RM) within a couple of months of the WHO declaring the global pandemic, with a substantial total amount of funding being approved for this mechanism (US\$4.3bn as of April 2022).⁴⁶ However the global interest and funding availability is already on decline with the decline of the pandemic. As such, it is clear that the speed and agility with which the Global Fund (and the global aid architecture as a whole) responded to COVID-19 is not easily replicable in other contexts without an equivalent sense of urgency. Some organisations, such as Unitaid, are however exploring ways in which they can mainstream their agile practices during COVID-19 for their core business, and this may be relevant for the Global Fund as well.
- **Accelerated response comes at a cost. As an emergency response mechanism, speed was of the essence for C19RM.** The Global Fund succeeded in fast tracking funding approvals and disbursing funds; the OIG's audits of the C19RM found that it converted funding to approved grants at the fastest rate relative to peer mechanisms in 2020, and that within the first three months of 2021, C19RM had approved more grants than in 2020 as a whole.⁴⁷ According to Pharos' evaluation, it took less than 10 days to issue Notification Letters after Funding Requests were received.⁴⁸ The pace of fund deployment, however, meant that there was not sufficient time nor bandwidth to consider the wider health system issues and prepare for effective follow through. For example:
 - The Global Fund used an allocation model for C19RM that was driven by HTM disease burden. This was not necessarily reflective of country needs in the context of a COVID-19 pandemic.
 - A monitoring system was not put in place in advance of fund disbursement, nor was a theory of change developed for C19RM. This, according to a recent review, "slowed downstream implementation, hampered the ability of the Global Fund to take early corrective actions, and reduced the level of accountability and understanding of impact."⁴⁹
 - The C19RM review also indicated the finding that approvals felt 'rushed' and guidance on use of funds was lacking, as was consideration regarding the absorption capacity of countries. By June 2021, only 57% of 2020 flexibilities and additional funds had been absorbed.

As such, the learning offered through the C19RM experience is the need to carefully consider pace of deployment of innovations to ensure that they are well planned with needed implementation support.

- **Value of integrated/ cross-disease review and partner support.** The grant approval process was adjusted under C19RM in order to fast-track requests, most notably by the introduction of an external, technical review ("GAC-CTAG review") that is not linked to any one of the three diseases. GAC-CTAG was introduced in 2021 and consists of the Grant Approvals Committee (GAC) and the COVID-19 Technical Advisory Group (CTAG), including WHO, Gavi, Stop TB Partnership and UNICEF. This review stage provides an opportunity for assessment of (i) technical robustness (ii) alignment across partner funding; and (iii) alignment with WHO technical guidance and national preparedness plans. This review stage allowed the Global Fund to consider

⁴⁶ <https://www.theglobalfund.org/en/our-covid-19-response/>

⁴⁷ The Global Fund OIG, 2022, Audit of the COVID-19 Response Mechanism 2021

⁴⁸ Pharos Global Health Advisors, 2022, Evaluation of Global Fund COVID-19 Response Mechanism (C19RM) 1.0.

⁴⁹ Pharos Global Health Advisors, 2022, Evaluation of Global Fund COVID-19 Response Mechanism (C19RM) 1.0. p.7.

the wider health system with partners when assessing grant applications, representing an innovative approach that could continue to provide value under business-as-usual circumstances.

3.6. MEASUREMENT OF GLOBAL FUND WORK ON INNOVATIONS

This section provides key findings and available evidence for evaluation question 8 (Q8- *What are possible indicators to systematically measure the Global Fund's effective and equitable deployment of innovations?*). It provides a review of the Global Fund's current approach to measuring innovation as well as the planned changes for the next Strategic Period (noting these are currently work in progress).

Key findings	Robustness rating
1. The current Global Fund Modular Framework enables only a limited analysis of innovations, with no quantitative indicators that capture a country's intention or early uptake as well as equitable deployment of innovations.	Strong
2. The development of the KPI S10 for new product introduction is a step in the right direction, but its usefulness will be determined to a large extent by its specific methodology (e.g. coverage vs. outcome, consideration of equity) and alignment with partners.	Moderate

Key findings are as follows:

The existing Global Fund Modular Framework for country M&E reporting offers limited insights into the specific support for innovation or the contribution of innovation to the Global Fund's targets, including with regards to equity in innovation. The Modular Framework is the key M&E tool for the Global Fund setting out key coverage, outcome and impact indicators and is also used to record and analyse allocation and absorption data. The Modular Framework enables only a limited analysis of innovations. Specifically:

- Only interventions which have been mainstreamed through WHO recommendation and scaled-up are included. For example, the Modular Framework includes data on PrEP and HIVST separated by target populations and also has a separate category for rapid molecular testing for TB (see Appendix G for more detail). The majority of innovations are included within wider programme/ service delivery categories and cannot be directly disentangled.
- There are no quantitative indicators that capture a country's intention or early uptake of innovations although this information can be captured through qualitative reporting such as community-led monitoring. The other option is if the adoption of an innovation is specifically included in a country's funding request/ approved funding, then progress may be picked up through the work plan tracking measures.
- With regards to outcome and impact indicators, including with regards to impact on equity, these are at the general level for HTM and aligned with partner/ global strategies and plans and it is not possible to disentangle the contribution of specific innovations. Most of these indicators are modelled indicators.

We understand that the M&E plan for the new Strategy 2023-28 aims to better consider measurement of innovations through the Modular Framework. One aspect highlighted as key during our consultations was to consider disaggregated reporting to better reflect equity of innovations.

The Global Fund is planning to develop a separate KPI S10 with regard to new product introduction in alignment with the increased emphasis on innovation in the new Strategy. Our assessment is that the development of the KPI S10 for new product introduction is a step in the right direction, but its usefulness will be determined to a large extent by its specific methodology and alignment with partners. Strategy 2023-28 KPIs are currently in development, including specifically KPI S10 on "Introduction of new products (from an agreed set of new products)". The draft KPI S10 would be calculated as the ratio of number of products on the agreed list that have become eligible and available for country procurement and the number of products agreed to be introduced, based on country's needs.

- Challenges highlighted with regards to the process for this indicator include: (i) work still needs to be conducted with partners to identify the agreed list of new products to be introduced/ scaled-up through Global Fund funding over the next Strategy period; (ii) the list of new products to be introduced is likely to change annually which limits trend analysis.
- Overall shortcomings of this indicator are also recognised. First, it only measures products supported and does not provide information on volumes or equitable access. Second, it is a process indicator and not an outcome indicator. We understand that the Global Fund Secretariat is aiming to define and collect data to measure volumes needed and delivered in the first 3 years of the Strategy and thus may refine the indicator to this effect.

Partner feedback suggested that an aggregated indicator for innovations is not very helpful given the very different nature and contexts of different innovations. Our assessment is that the aggregated level as presented in the current draft KPI S10 may be too high-level to allow an assessment of performance with regard to accelerated and equitable deployment. Important to know would be how many countries (that could benefit from a new product based on country needs) have actually introduced and scaled-up the product and at what speed. Further disaggregation by population sub-group (where relevant and needed) would also be useful for support an assessment of equitable access. This could be addressed through the development of sub-indicators specifically tailored to priority products which track the introduction and scale-up by countries over time (which we understand is the future intention of the Global Fund). This should be closely aligned with partners and entail (i) identification of a few priority products; (ii) number of countries that could benefit from scale-up based on disease burden; (iii) targets of how many countries (or % of countries) are expected to have introduced the innovation through Global Fund support by year. This could initially be based on a binary tracker on whether the product is supported through the Global Fund grant (but could also be considered to be based on volume sales vs demand at a future point in time). Such a product-by-product approach could also be linked to other efforts (e.g. roadmaps for product introduction) and should be closely aligned with partners (to the degree that the same measure could be used as performance metric for partners). It would also allow a better understanding of, in which countries products are not used and, thus, offer first data points to inquire what the delay has been caused by.

The box below presents some innovation indicators employed by partner organisations and any learnings for the Global Fund.

Lessons from measurement of innovations from partner organisations

Innovation measurement from partners includes the following:

- Unitaid included a KPI on catalysing innovation in its 2017 to 2021 strategy, which measures the total number of Unitaid-supported products for which product development activities have been successfully completed. While the KPIs that are closely connected to Unitaid grant performance are not most relevant to the Global Fund, it might be worthwhile to consider developing common/ coordinated set of goals regarding the introduction of new innovations (e.g. the progress by Unitaid on an innovation and how that feeds into the scale-up by the Global Fund).
- Gavi measures ‘*the number of vaccines and other related products with improved characteristics procured compared to the baseline year*’ as part of its innovation market shaping goal indicator for 2016 to 2020. This has similarities to the proposed Global Fund KPI including the focus on procurement. A key difference is that Gavi did not use a predetermined list of innovations to be procured meaning that it was assessed during the time period what constituted a product with “improved characteristics”.
- CEPI uses KPI and quantitative targets per outcome/ output in their strategic period for 2022 to 2026. For example, CEPI has a KPI relating to the *number of manufacturing innovations advanced*, with a target of 5. However, CEPI’s role in the innovation value-chain is very different to the Global Fund and these upstream indicators would not be directly suited for the Global Fund.

3.7. CONTRIBUTION OF INNOVATIONS TO ACHIEVING GLOBAL FUND OUTCOMES AND RESULTS

This section provides key findings and available evidence for evaluation question 9 (*Q9. What has been the contribution of key innovations to achieving Global Fund outcomes and results?*). It is based on Global Fund reported data and the current evidence on the impact and effectiveness of innovations reviewed.

Key findings	Robustness rating
1. There is a lot of good published evidence on the impact of key innovations, although Global Fund performance monitoring does not explicitly track this issue, and specifically with regards to equity in access to innovations. The pathway to results from new product innovations is highly complex, and differs by innovation and country context, highlighting the complexity in their deployment and the need for continued and engaged work between countries, Global Fund and partners.	Strong

3.7.1. Impact of innovation: Global Fund Investment Case

Rapid and equitable deployment of innovations is critical to the 7th Replenishment case and meeting Global Fund disease targets for 2023-2026.

The investment case for the Global Fund 7th replenishment proposes that with US\$18 billion, the Global Fund would contribute together with partners to saving 20 million lives between 2024 and 2026, reducing mortality rate by 64% across the 3 diseases by 2026 relative to 2020 levels. Global Fund projections assume a scale-up of new interventions and innovations across the three diseases as a contributory factor (including scale-up of PrEP and HIV self-testing, rapid molecular tests for TB diagnosis, universal access to short, safe and effective TB treatment regimens, and efficient distribution of nets). See Appendix G for more detail.

Recent work included in Unitaids' investment case estimated that without innovations in HIV, TB and malaria supported by both organisations it would take 3 more years to achieve the Global Fund's projected reduction in deaths.

3.7.2. Impact of innovation: published evidence

All product innovations reviewed in the case studies have strong evidence for effectiveness and WHO policy guidance, with the exception of a conditional WHO policy on PBO nets (to be "considered" under specific conditions), and no WHO policy for AI nets yet. The safety and effectiveness of oral PrEP for example has been demonstrated through multiple randomized controlled trials and studies since its approval. Oral PrEP reduces the risk of HIV acquisition by over 90% when taken daily, leading to a strong recommendation by WHO in 2015 based on high-quality evidence. For non-product innovations (FLF and mobile payments) evidence of impact is much more limited. Use of virtual interventions is supported by a WHO policy brief and there is substantial evidence of effectiveness from high-income contexts, although more evidence on implementation in LMICs is needed particularly from sub-Saharan Africa. The evidence base for clinical and public health impact for each of the innovations is elaborated in Appendix G.

3.7.3. Impact based on Global Fund performance data

It is difficult to disentangle the contribution of innovation work to results from Global Fund performance reporting. As described in Section 3.6, the existing Global Fund Modular Framework for country M&E reporting offers limited insights into the contribution of innovation to the Global Fund's targets. Where an indicator does exist that allows for isolation of the impact of specific innovations, data reported by countries is too limited to draw conclusions. Additionally, innovation-specific indicators are coverage-focused and not on public health impact. Table 3.3 presents the indicators that capture innovation from the Global Fund's 2022 Modular Framework. The final column describes data published from 2020 on the Global Fund results database.

Global Fund performance metrics do not allow programs to measure the extent of equitable impact of innovations. While coverage of particular interventions for key and vulnerable populations may be captured at the level of Strategic KPI or within the Modular Framework (e.g. PrEP, see table 3.3 below), outside these particular

interventions, current performance measures do not have an equity-lens when it comes to measuring the impact of innovations.

Table 3.3. Global Fund innovation indicators and performance data

Innovation	Indicator	Indicator description	2020 Data
PrEP	Percentage of eligible population who initiated oral antiretroviral PrEP during the reporting period	Coverage indicator, Disaggregated by sub-population	Numerator only, data available for 8 countries (differs by population) Vietnam: 18,373 (population not specified) Thailand: 35 (population not specified), 11,409 (MSM) South Africa: 1,612 (SW), 752 (MSM), 8,090 (AGYW) Zimbabwe: 9,680 (SW) Cambodia: 278 (population not specified) Georgia: 216 (population not specified) Senegal: 52 (SW), 31 (MSM) Lesotho: 14 (SW), 2 (MSM), 5 (AGYW)
HIVST	Number of individual HIV self-test kits distributed	Coverage indicator	No data available
GeneXpert/ Molbio Truenat	Percentage of new and relapse TB patients tested using WHO recommended rapid tests at time of diagnosis	Coverage indicator, disaggregated by type of provider (public, private)	Numerator only, data available for 10 countries Philippines: 161,809 Thailand: 29,206 Pakistan: 24,311 Zimbabwe: 14,078 Tajikistan: 1,731 Moldova: 1,569 Georgia: 1,394 Armenia: 326 Albania: 138 Cabo Verde: 86
BDQ	Number of cases with RR-TB and/or MDR/TB that began second-line treatment	Coverage indicator, disaggregated by age, gender, and TB regimen (new TB drugs, short regimens)	Numerator only, data available across 87 countries but not disaggregated by regimen Top ten- India: 44,670 South Africa: 6,051 Ukraine: 5,321 Kazakhstan: 5,220 Philippines: 5,056 Indonesia: 4,652 Viet Nam: 3,294 Myanmar: 2,357 Pakistan: 2,298 Peru: 1,587
	Percentage of cases with RR and/or MDR-TB successfully treated	Coverage indicator, disaggregated by age. Gender, treatment regimen (shorter 6-9	No data available

Innovation	Indicator	Indicator description	2020 Data
		months, longer individualised) type of provider (public, private)	
Facility Level Financing	Percentage of healthcare facilities having performance-based contracts with public entities	Coverage, disaggregated by type of provider (public, private) and level of care (primary, secondary)	No data available

Indicators tracking coverage of insecticide-treated nets are not included above as they do not differentiate between pyrethroid treated nets, PBOs, or dual AI nets. Additionally, use of mobile financial payments or virtual delivery platforms are not tracked through the Global Fund Modular Framework. Although an indicator measuring coverage of facility level financing does exist, it is specific to performance-based contracts which does not apply to all facility-level financing approaches including DFF. An indicator measuring the percent of facilities with output based contracts might better capture innovations within 'Payment for Results' under the Guidelines for Grant Budgeting.

For more detailed information on indicators and data, see Appendix G.

3.7.4. Key factors influencing results from deployment of innovations

The extent to which the deployment of innovations contribute to Global Fund results is mediated by numerous implementation factors, which differ by innovation and country context. The following key issues by innovation were identified through case studies and consultations as particularly important for the extent innovations contribute to Global Fund results. These are not comprehensive but aim to provide a high-level indication of the key issues in the pathway to results. For example:

- GeneXpert – While in clinical settings, rapid molecular tests performed very strongly, the impact on mortality has been lower than expected primarily due to challenges with linkage to care. Infrastructure challenges, such as electricity surges drive up costs and impact implementation, as highlighted by consultees from Burkina Faso.
- HIV PrEP – has been shown to be highly effective at reducing risk of HIV, however issues in adherence to PrEP as well as the constellation of factors which increase HIV risk amongst the most vulnerable groups, affect results. This is one area where virtual platforms are being used to increase the effectiveness of HIV programmes.
- HIVST – Service models for HIVST determine which populations will benefit and thus the extent HIVST is equitably deployed. For example, facility-based models employed in many countries (e.g. to increase efficiency in HIV testing services) will be less successful in reaching marginalised populations who do not access conventional services. Findings from an HIVST pilot in Indonesia under Funding Cycle 2017-2019 showed that of 1,149 MSM eligible for testing only 27% were willing to be referred to a health facility, whereas 38% of those who refused facility testing accepted community screening. Challenges have been highlighted with regards to the pathway from HIVST to confirmatory diagnostic testing and then linkage to treatment as well as preventive services.
- BDQ containing regimens are shorter and less toxic than injectable treatment courses for drug-resistant TB, leading to improved outcomes for patients with DR-TB. As a replacement to previous TB therapy, all countries have now included BDQ regimens and results are thus more mediated by the strength of TB services overall (e.g. case finding, linkage to care, adherence support). For example in Georgia, improved patient outcomes

for DR-TB patients were attributed to the transition to BDQ regimens supported by strong virtual TB delivery services.

These issues highlight the complexity in deployment of innovations, and the need for continued and engaged working from countries, the Global Fund and partners to support the successful use of innovations to lead to ultimate impact. Delays in equitable deployment and scale of innovations ultimately means more people suffer from new infections and have delayed or less effective treatment, resulting in fewer lives saved. The limited deployment of PrEP and view this has contributed to new HIV infections is regarded as a stark example of the consequences of this delay.

4. CONCLUSIONS AND LESSONS LEARNT

The importance of introducing and scaling-up health innovations cannot be overemphasised, with the Global Fund investment case for its 7th Replenishment predicating its impact on the back of scale-up of new innovations across diseases. The Global Fund model affords important comparative advantages vis-a-vis other global health actors in supporting the scale-up of innovations in countries, notably through its large funding capability and country-facing model. However, while there has been some good historic success in scale-up, such as for ARVs and bed nets, several health product innovations are seeing a lag to scale-up of around a decade from FDA approval of products for high-income countries or 6-7 years from the first indications in WHO guidelines.

Noting the complexity of the innovation value chain, and the core scale-up role of the Global Fund in relation to what partners are doing, this review finds a number of challenges with its approach, positioning and action for innovations. These present opportunities for the Global Fund as it looks to become more intentional to support innovations in the next Strategy period, and thereby support achievement of its overall goals and objectives.

Key conclusions are as follows:

- **There is a lack of a clear approach to supporting innovations, and specifically with regards to how equity in innovations access will be supported.** The Global Fund has not had a considered overall approach to supporting innovations, in terms of clearly defining the Global Fund role with regards to innovations and equity in access to innovations, an agreed list of innovations to support within the context of the existing and upcoming tools for HTM, and an agreed way of working with the different partners active in this space. Global stakeholders would like the Global Fund to more proactively signal its prioritization of health product innovations, by virtue of the influence of its financing on global and country priorities.
- **The Global Fund is not organised effectively to support innovations,** with multiple teams within the Secretariat managing different aspects of innovations (technical, procurement, country engagement) and with limited coordination, accountability and differing incentives. The Global Fund does not have an agreed decision-making process to support the scale-up of innovations, with the experience to date being largely opportunistic and ad hoc. It also does not have the needed supporting systems and data, with for example, existing databases of the PQR and performance monitoring not being useable or having the appropriate functionality to support innovation planning or assessment.
- **Several aspects of its funding model do not naturally support innovations and there has been sub-optimal use of available “strategic levers” within the funding model.** The Global Fund funding model is geared to deliver substantial amount of routine funding to countries in support of HTM goals, but not specifically to encourage the uptake of innovations. At the heart of this is the dynamic created by the demand-driven/country-owned model of the Global Fund which creates tensions between the extent of prescriptiveness by the Global Fund and the most relevant, timely and (globally) aware demand by countries. The fixed allocation to countries means that: countries may not be adequately incentivised to demand innovations that usually come with a higher price than existing commodities; the (fairly established) CCM ecosystem in countries may not always include organisations at the forefront of innovations in countries as funding recipients and implementers; the country guidance notes are significantly under-used to draw attention to key innovations and encourage their uptake; the TRP review is not emphatically driving innovation uptake; the funding modalities are mainly structured around input-based rather than output or outcome based financing which is important for introduction of innovations; the performance framework and financial reporting deters from implementing something new while simultaneously driving the performance; and managing fiduciary risk of Global Fund core allocations and the Country Teams/ FPMs are not always incentivised to support innovations focusing more on business-as-usual processes. Certain strategic levers however have good experience of being used such as the portfolio optimisation process (for BDQ transition).
- **The implication of the above conclusions is that the Global Fund does not adequately shape country demand for innovations.** While the Global Fund is fundamentally a demand-driven model, stakeholder feedback indicates that there is a core need to guide and better inform this demand for optimal outcomes.

Core to this is also the engagement of the Secretariat Country Teams and specifically FPMs with countries, and the need to adequately incentivise them to provide the needed support on innovations for countries.

- **The market shaping role for innovations has not been sufficiently pro-active or deliberate.** The Global Fund's market shaping role for innovations – both pre and during scale-up – is currently quite narrow and not maximising its potential. With its considerable buying power and unique position within the partner landscape in terms of having a direct link with countries, stakeholders have indicated the need for the Global Fund to employ a more proactive role to market shaping for innovations. The plans for innovations under the current Market Shaping Strategy 2016-22 were never really implemented for the most part, and in general, the approach taken by the Global Fund is viewed to be procurement focused rather than an effort to shape markets, in coordination with partners. This has been viewed as missed opportunities for the Global Fund to intervene. The Global Fund comparative advantage with respect to country perspectives and insights on demand is not being adequately used to support market shaping, including through timely and accurate demand forecasts. More positive experience has been with regards to the ERP/ERPD mechanism, which where used, has been an important lever to accelerate deployment of innovations.
- **There is need for further clarity on how Global Fund will work with partners to support innovations as well as some key gaps in partner work to support scale-up by the Global Fund.** There are no plans or roadmaps, agreed with partners on scale-up timeline and actions. For example, the Global Fund has been most effective in shortening the “global policy to country introduction gap” by working in parallel to WHO policy development to ‘line up’ the strategic levers at its disposal (e.g. for BDQ, ITNs) – and there is a case to better plan partner working timelines in this manner. This includes areas in the innovation value chain where the Global Fund has a more indirect role where there is need for greater clarity on how the Global Fund will engage in these upstream steps to complement/ supplement the work of partners. On its direct scale-up role as well, there is insufficient clarity between partners e.g. Unitaaid and the Global Fund on managing hand-off of innovations between the two organisations. Importantly, across partners, there is a key gap in generating adequate cost effectiveness evidence to support country demand and uptake. Stakeholders have noted that partner working is driven more by individual relationships than an institutionalised approach to working. Stakeholders have also emphasised the need for early engagement between Global Fund and partners on innovations – with the Global Fund clearly signalling its priorities and country demand and partners involving the Global Fund on their plans to ensure effective transition of funding.
- **Related to the above points, an area of good work with regards to demand shaping as well as partner coordination and transitions is Catalytic Funding,** where several Strategic Initiatives and Matching Funding approaches have been successfully deployed to support the initiation and early scale-up of different innovations (HIVST, LLINs, non-product innovations). However Catalytic Funding is not the core of the Global Fund resources and represents a small pot of the total resources, as well as limited agreed scopes or mandates and consequently attention by the countries and Secretariat Country Teams. Also, at times, there has been lack of clarity on follow-on steps with regards to innovation work supported through Strategic Initiatives that may not yet be ready for full scale scale-up (ITNs).
- **Innovations on service/ programme delivery and health systems management tools and processes (i.e. non-product innovations) face additional challenges** by virtue of not being prioritised or prioritised in an ad hoc manner or not being viewed as the comparative advantage of the Global Fund as they are concerned with in-country implementation. Their diversity – in concept, application and stakeholder understanding of these innovations – makes for more complex managing and supporting roll-out by the Global Fund. There is scope for the provision of more technical assistance to countries as well as the expansion of appropriate partnerships to help fill this gap.

We understand that there is significant work underway as part of the new Strategy 2023-28 and for the 2023-2025 Funding Cycle to better align the Global Fund model and working to successively support innovations. Key aspects that have been highlighted to us include greater emphasis on innovations in Global Fund country guidance including through the use of “Programme Essentials”, development of the concept and work plan for “NextGen Market

Shaping” which includes a priority/ strategic intervention on shaping innovation and accelerating new product introduction at scale, as well as efforts to better measure the Global Fund’s work in the area through systematic monitoring of support for innovations (although current plans for measurement are recognised as inadequate). It is intended that the findings of this evaluation are considered closely against these recent efforts by the Global Fund, to develop relevant and actionable recommendations for its work on supporting innovation scale-up going forward. External stakeholders have emphasised the need for the Global Fund to clearly exhibit accountability in this regard, and therefore planned actions/recommendations should be closely supported by an accountability framework that provides the needed assurance to Global Fund stakeholders.

5. RECOMMENDATIONS

The final section of the report presents recommendations based on the evaluation findings, conclusions and lessons learnt. Draft recommendations were discussed with the Global Fund Secretariat and TERG at a workshop, and the recommendations below seek to reflect the feedback received.

A total of seven recommendations are proposed as follows:

- **Recommendation 1:** *Develop a systematic approach to supporting innovations, alongside necessary organisational aspects*
- **Recommendation 2:** *Pro-actively capture and analyse information on the introduction and scale-up progress of innovations*
- **Recommendation 3:** *Conduct ongoing strategic scanning to identify availability and need for innovations, and inform Global Fund support/ signalling*
- **Recommendation 4:** *Optimise use of Global Fund “strategic levers” to support innovations including (i) market-shaping (ii) funding guidance, review and support (iii) catalytic investments (iv) funding modalities*
- **Recommendation 5:** *Strengthen the engagement and role of countries and communities within the identification and implementation of innovations*
- **Recommendation 6:** *Ensure more systematic partner coordination in support of innovations*
- **Recommendation 7:** *Strengthen consideration of equitable deployment within the support for innovations*

For each recommendation, we provide details on the main thrust of the recommendation and key actions, alongside signposting of implementation responsibility as well as suggested timelines and capacity requirements.

Recommendation 1: Develop a systematic approach to supporting innovations, alongside necessary organisational aspects	
Implementation responsibility	Global Fund Secretariat
Timelines & capacity requirements	<p>Timeline: in time for the start of the Global Fund Strategy 2023-28</p> <p>Capacity requirements: medium to high input required for the development of the approach, but expected through use of existing Global Fund Secretariat resources</p>

Recognising the priority accorded to innovation in the new Global Fund Strategy 2023-28 and the commencement of considerable work to develop a more focused and systematic approach to delivery against this priority (e.g. the Next Generation Market Shaping framework, the New Product Introduction (NPI) Taskforce, etc.), we recommend the following:

- **Develop a systematic approach for the Global Fund’s support to facilitating access and equitable deployment of innovations.** This should provide a clear institutional sense of the priority and direction the Global Fund will take regarding support for facilitating innovations. It should also describe how it will support its country-driven model by optimising the use of its available “strategic levers” (further detailed in Recommendation 4). As part of the development of the approach, the Global Fund should consider:
 - a clear and robust definition and typology of innovation and equitable deployment (building on the suggestion of this evaluation);

- an understanding of the Global Fund’s role and risk-appetite towards product and non-product innovation – as part of this issue the Global Fund could consider the development of a theory of change on funding of innovations (as recently done by Gavi);⁵⁰
 - formalising the decision-making process to support innovations through the Global Fund – including development of criteria around VfM and equitable deployment – to better incentivise and shape country demand for innovations;
 - provide an overview of the pathways by which the Global Fund will influence innovation and the way in which “strategic levers” will be optimised to accelerate access and innovation; and
 - set out actions and next steps as well as the expected roles and responsibilities of the Global Fund Secretariat vis-a-vis key partners.
- **Create appropriate organisational arrangements within the Global Fund to facilitate the innovation approach.**
 - In order to effectively implement an organisation-wide approach to innovations and noting the challenges identified in this review with regards to roles and responsibilities within the Global Fund Secretariat, it would be important to clearly assign roles and responsibilities for the delivery of the innovations approach across various teams in the Secretariat. Some organisations have created “innovation teams or hubs”; while we do not recommend this per se, the Global Fund should create the needed leadership and roles that are able to effectively coordinate the facilitation of innovation acceleration and equity. The development of these organisational elements should also take account of the partnership model to identify where partners might be better placed to achieve results.
 - This would need to be supported by relevant communication channels and accountability frameworks. Given the importance of innovations in the 2023-2028 Strategy, the Global Fund may consider Board-level accountability (e.g. through a Board Committee).
 - Refinements to existing business processes should be made, as feasible, to facilitate implementations e.g. review of exception processes for non-product innovations.

Recommendation 2: Pro-actively capture and analyse information on the introduction and scale-up progress of innovations

Implementation responsibility	Global Fund Secretariat in close coordination with partners (Unitaid, STOP TB Partnership and WHO) – e.g. focus of the Global Fund Secretariat could be on scale-up progress and non-product innovations and focus of partners could be on introduction, policy updates and product registration information.
Timelines & capacity requirements	<p>Timeline: within 2023-2025 Funding Cycle</p> <p>Capacity requirements: medium – requiring some additional capacity across relevant teams (e.g. Supply Operations; Strategic Information)</p>

The absence of robust and accurate data and information has been a barrier for an effective response to accelerate the access and equitable deployment of innovations. As such, we recommend that the Global Fund, in close collaboration with partners, should:

- **Create a systematic approach – and related responsibility, capacity, accountability – to capture and analyse data on innovations.** This would be a pre-requisite to effectively measure progress, identify bottlenecks and assign remedial actions. Information and data should be collected and analysed for both

⁵⁰ Gavi Board meeting June 2022: Annex C: Proposed Innovation Approach for Gavi 5.0

priority product and non-product innovations. To ensure that the data is effectively used to inform Global Fund and partner activities, this approach should be embedded within the wider efforts to coordinate across partners and the Global Fund, to accelerate equitable access to innovation.

- **Create sub-indicators to the draft KPI S10 for priority products that track introduction and scale-up by country against ambitious targets in close coordination with partners.** The development of the draft KPI S10 on new product introductions has been a step in the right direction. However, its usefulness will be determined by the extent to which more detailed indicators are developed that meaningfully track progress. This should include the development of sub-indicators for priority innovations that track progress by country over time. Setting specific and ambitious targets per sub-indicator and on the aggregate KPI will be key to ensure that the draft KPI S10 does not become a “tick-box exercise” which considers an innovation introduced as soon as it can be procured through Global Fund processes (irrespective of the number of countries and/or volumes procured by countries). The KPI development process could be leveraged to define common goals and targets with partners on the expectation of accelerating innovations. It would also be critical for the Global Fund to explore the incorporation of an equity dimension within the draft KPI S10.
- **Update the PQR database to allow for identification and tracking of key product innovations.** The current PQR database is outdated and does not allow for a systematic analysis of innovation. An update should include the separate categories for innovative products/ product categories (and the ability to add these at a later stage); to disentangle use cases of drugs (e.g. PrEP vs ART) and to add a simple innovation flag corresponding to any priority innovations identified through partner collaboration. These would serve as “quick wins” for the Global Fund i.e. considerable additional benefit at minimum cost and effort.
- **Include country performance/ results indicators on innovations, including on their equitable deployment, where feasible.** The Global Fund should consider where the introduction and scale-up of innovation can be more directly included in country performance and results indicators. This could focus on specific priority innovations as a starting point to reduce the reporting burden. The Global Fund should also introduce indicators regarding the equitable deployment of innovation to understand whether there are any key gaps within the role-out of innovations (e.g. across population groups etc.).

Recommendation 3: Conduct ongoing strategic scanning to identify availability and need for innovations, and inform Global Fund support/ signalling

Implementation responsibility	The Global Fund Secretariat in close coordination with partners and recipient countries (partners such as Unitaaid could take the lead on mapping the upcoming innovation landscape)
Timelines & capacity requirements	<p>Timeline: in time for the start of Strategy 2023-28, and ongoing updates</p> <p>Capacity requirements: low for product innovations (assuming leveraging on existing partner work) – medium for high impact non-product innovations with some capacity implications for relevant Global Fund Secretariat teams</p>

The evaluation findings indicate that there is no systematic and proactive way for the Global Fund to identify and track innovations and to signal and communicate priorities to partners and countries. As such, we recommend:

- **To improve the innovation knowledge base at the Global Fund Secretariat on innovation availability and needs through regular and strategic scanning.**
 - For innovation availability this should include a mapping of the innovation landscape to identify and track the evolving maturity of existing innovations as well as the corresponding evidence on emerging innovations.

- On the innovation needs side, this should include regular analysis of the existing portfolio of tools to fight HTM to identify impeding issues (e.g. resistance etc.) and gaps that potential innovations could mitigate.
 - The work on identifying innovation availability should be conducted in collaboration with upstream partners such as Unitaaid to avoid duplication and ease capacity burden.
 - The availability and needs analysis should encompass both product and non-product innovations. For non-product innovations in particular, more in-depth analysis of these innovations is needed, with the current evaluation not doing justice to the spectrum of innovations in this area.
 - Importantly, the identification of innovation availability and need should also be done in discussion and coordination with recipient countries.
- **To make greater use of the established knowledge by clearly signalling needs and priorities to countries and partners, and by informing Global Fund internal processes.** This early signalling would address partner wishes to have a stronger understanding of the type of innovations that the Global Fund is planning to support. Additionally, communicating the needs will also assist more upstream partners such as Unitaaid, PDPs and Stop TB to ensure that the projects they are supporting fit within the Global Fund needs. With regard to internal processes, the strategic scanning is the starting point for the Global Fund to adjust and prepare their own activities to support innovations (this should be integrated in the systematic approach to innovations set out in Recommendation 1).

Recommendation 4: Optimise use of Global Fund “strategic levers” to support innovations including: (i) market-shaping; (ii) funding guidance, review and support; (iii) catalytic investments; and (iv) funding modalities

Implementation responsibility	The Global Fund Secretariat closely coordinated with partners and recipient countries
Timelines & capacity requirements	Timeline: within the 2023-2025 Allocation Cycle Capacity requirements: high

The evaluation found that the Global Fund Secretariat can further optimise the use of its “strategic levers” to support and accelerate product and non-product innovations. The optimisation of the available strategic levers should be considered carefully within the context of the Global Fund mandate, model and resource envelope – especially ensuring that the Global Fund maintains the right balance between its country-ownership principle and being prescriptive/ directional. Key strategic levers which could be further optimised include:

- **Strengthening of Global Fund market shaping activities for product innovations** – this should ensure the timely implementation of the Next Generation Market Shaping initiative. A key aspect for improvement is with regard to stronger partner coordination and alignment on innovations through the development of roadmaps (and the recent development of a Taskforce between Unitaaid and Global Fund is a step in the right direction). Another aspect is the improvement of demand forecasting as well as the use of these forecasts to improve supply negotiations (with the recent establishment of a demand forecasting initiative being a useful step). These market shaping activities should also aim to engage early with manufacturers and explore increased use of volume commitments (or similar tools) to support innovations.
- **Improving funding guidance and review/ feedback to support demand creation for innovations** – this should include stronger guidance on the use of innovations (e.g. through information notes, technical guidance, Funding Request templates, etc.) as well as consistent and supportive messaging through Country Teams on the use of innovations as applicable to different country contexts. Additionally, stronger and more clearly communicated TRP criteria could be used to support innovation demand and the use of Portfolio Optimisation could be leveraged more (both with regard to increasing overall support for innovations as well as to allow for integration of priority innovations during grant cycles).

- **Strategic use of Catalytic Funding** – Catalytic Funding should continue to be used strategically to support innovations, while recognising of the limited resource envelope. Key aspects to support through Catalytic Funding include Strategic Initiatives for market shaping activities and product introductions (e.g. similar to the New Nets Project); Strategic Initiatives that combine product introductions with technical assistance to address barriers to scale-up (including those relating to health systems and service delivery), and Matching Funds which aim for demand creation of innovations at the country level.
- **Reviewing the expansion and adaptation of other funding modalities to facilitate innovations.** The Global Fund Secretariat should commission a review of its business processes and skillset to align with requirements to facilitate innovation through new funding modalities as well as related reporting requirements. In particular, this would include strengthening the processes and skills required to foster funding modalities which focus on output, outcomes and results rather than on inputs.

Recommendation 5: Strengthen the engagement and role of countries and communities within the identification and implementation of innovations.

Implementation responsibility	The Global Fund Secretariat and recipient countries
Timelines & capacity requirements	Timeline: ongoing within the 2023-2025 Allocation Cycle Capacity requirements: medium

The role and engagement of countries and communities is central for the successful scale-up of innovation, including both product and non-product innovations. As such, we recommend that the Global Fund work closely with country stakeholders to enhance the enabling environment for innovations, as feasible within its purview of work. Some specific actions could include:

- **Support access to Global Fund funding from additional non-traditional recipients of funding.** This could include supporting the CCM processes in country by encouraging the engagement of smaller/ non-traditional Global Fund recipients that are active in the innovation space e.g. community based organisations, private sector organisations.
- **Encourage dialogue with countries on innovation pipelines.** The Global Fund should put in place processes that allow for countries to feed into the global level discourse with partners on innovation priorities and scale-up needs. For product innovations this could include country representatives to be included in partnership meetings on the upcoming innovation pipelines.
- **Providing access to the latest information and technical expertise.** This could include ensuring countries have access to the latest information on innovations at the global level, including availability of new products, market developments, evolution of WHO guidelines, etc. This could also include providing funding support to ensure the needed technical expertise is available in country for innovation introduction and scale-up (e.g. technical expertise to interpret and/or model cost-effectiveness and effectiveness data in the context of the country, timely processes to update and change national guidelines, support for product registration etc.).
- **Support cross country learning on innovations.** While acknowledging the different country contexts and the need to adapt non-product innovations, the Global Fund should ensure that lessons learned, and best practices are recorded and shared between countries (and also across different Global Fund Country Teams and other Secretariat teams, and with partners).

Recommendation 6: Ensure more systematic partner coordination in support of innovations

Implementation responsibility	The Global Fund Secretariat and key partners
Timelines & capacity requirements	Timeline: within the 2023-2025 Allocation Cycle Capacity requirements: medium to high (requiring both Global Fund and partner resources)

The evaluation found that effective partner coordination has been the single common feature across product and non-product innovations which have been relatively successfully scaled-up. In order to improve partner coordination further, we recommend:

- **Ensure a systematic, institution-wide and documented approach to the Global Fund's ways of working with partners on innovations.** This would go beyond the high-level MOUs which are in place with some partners such as Unitaid and include documentation and agreed processes regarding coordinating the work on innovations.
- **Work proactively on transition of partner work (e.g. Unitaid, STOP TB Partnership, PDPs, BMGF etc.).** This should include early engagement and visibility of the Global Fund in the upstream work of partners with early consideration on how innovations can be integrated into the Global Fund's funding applications. Importantly, transition should not only pertain to pilot countries supported by upstream partners but also include early approaches and thinking of how an innovation is integrated into other Global Fund countries.
- **Develop stronger collaboration with partners to generate and disseminate cost-effectiveness data and evidence.** The findings have shown that demonstration of cost-effectiveness is a key enabler for stronger demand and uptake of innovation. The Global Fund should work with partners to ensure that relevant evidence is generated and disseminate (see box below for some suggestions on priorities for data collection).

Cost-effectiveness evidence: The evidence should be produced by comparing the innovation against the current standard of care (or other viable alternatives) rather than comparing against no other intervention at all. Ideally, evidence would include the production of incremental cost-effectiveness ratios (ICERs) which are calculated by dividing the difference in total costs between the two interventions by the difference in the chosen health outcome or effect (e.g. # of diagnosis / treatments, infections averted, lives saved, DALYs, QALYs etc.). Costs should include all fixed and variable costs including commodities, health staff, equipment and infrastructure etc. Importantly, the evidence should be informed by robust study designs that cover different contexts and settings. This can be supplemented by modelling to provide estimates on the type of country contexts and conditions in which an innovation is expected to be cost-effective.

- **Collaborate and support partners in pre-scale-up work including global prioritisation and WHO normative guidance and national guidelines.** Following on from Recommendation 2, this should include the Global Fund signalling to partners on country demand for innovations and the potential for funding support from the Global Fund. In terms of supporting the normative guidance development process, the Global Fund should consider where it can pro-actively prepare for guideline changes or even work in parallel to expected changes – e.g. this could range from aligning internal Global Fund processes (such as preparation to include as part of portfolio optimisation / country communication etc.) where strong guidance is expected, to supporting operational research for development of WHO guidelines where weak or conditional recommendations exist or could even include supporting more upstream projects before WHO guidelines are issued (as done by New Nets Project).
- **Seek out appropriate partnerships for non-product innovations** – this can include encouraging existing upstream partners (e.g. Unitaid, STOP TB Partnership) to become more active in the non-product innovations space (especially on the service delivery approaches for product innovations) and to identify new partners on wider health system aspects. This should also include working towards an integrated approach (i.e. not vertical disease based) in coordination with partners such as Gavi or the World Bank.

Recommendation 7: Strengthen consideration of equitable deployment within the support for innovations

Implementation responsibility	The Global Fund Secretariat
Timelines & capacity requirements	Timeline: within the 2023-2025 Allocation Cycle Capacity requirements: medium

There is currently no systematic consideration with regard to the equitable deployment of innovations, including a lack of data and analysis. While the previous recommendations encompass suggestions with regards to improving focus and approach to equity in innovations, we view it valuable as calling out this out distinctly to reflect its priority. In particular, we recommend that the Global Fund:

- **Develop a clear approach on how equitable deployment of innovations will be considered going forward** – including a definition of equitable deployment and the way it will be considered within identification and implementation of innovation. This should also include the types of inequities which will be a focus with regard to innovation (e.g. sub-populations not receiving new tools; geographic inequities between and within countries etc.).
- **Collect data and information on equitable deployment of innovation** – where feasible, the Global Fund should explore how quantitative data could be collected with regard to innovations (e.g. coverage of tools by different population groups, coverage within a country with regard to regional gaps etc.) and how this information would be used to improve implementation. This work can be combined with the efforts under the Global Fund Strategy to reduce health inequities across the three diseases.

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Country case studies

Review of the following documents for the four case studies:

- Allocation letters
- Country dialogue documents
- Funding application documents
- Grant making documents
- Portfolio optimization documents
- TRP forms
- Grant Approvals Committee documents

Appendix B LIST OF INCEPTION PHASE CONSULTATIONS

This appendix presents the stakeholders consulted during the inception phase of the review.

Table B.1: Stakeholders interviewed during the inception phase

Organisation	Position
TERG	TERG member (TERG)
TERG	TERG member (TERG)
Global Fund Secretariat	Senior Advisor, Process and Performance Optimization (Strategy and Policy Hub)
Global Fund Secretariat	Senior Technical Coordinator, Community Rights and Gender Investment Support and Key Populations (Community, Rights and Gender)
Global Fund Secretariat	Head, Private Sector Engagement (Private Sector Engagement)
Global Fund Secretariat	Senior Manager, Strategic Sourcing (Sourcing and Supply Chain)
TERG Secretariat	Senior Advisor
TERG Secretariat	Lead, Evaluation
Global Fund Secretariat	Head of HIV/AIDS (Technical Advice and Partnerships Department)
Global Fund Secretariat	Senior Advisor, Process and Performance Optimization (Strategy and Policy Hub)
Global Fund Secretariat	Senior Disease Advisor, TB (Technical Advice and Partnerships Department)
Global Fund Secretariat	Senior Disease Advisor, Malaria (Technical Advice and Partnerships Department)
Global Fund Secretariat	Senior Technical Coordinator, Community Rights and Gender Investment Support and Key Populations (Community, Rights and Gender)
Global Fund Secretariat	Senior Technical Coordinator, AGYW, CRG (Community, Rights and Gender)
Global Fund Secretariat	Head, Private Sector Engagement (Private Sector Engagement)
Global Fund Secretariat	Senior Manager, Strategic Sourcing (Sourcing and Supply Chain)
Global Fund Secretariat	Senior Specialist Public Health Monitoring & Evaluation, Central Africa Team (Grant Management Division)
Global Fund Secretariat	Senior Specialist, Anti-Corruption and Impact, Ethics Office (Service delivery innovation)
Global Fund Secretariat	Senior Manager, Country Financial Management Strengthening & Innovation, FIA (CFO)
Global Fund Secretariat	Specialist, Financial Management, Financial Insights and Analytics (CFO)
Global Fund Secretariat	Manager, Strategic Partnerships and Blended Finance (Health Finance)
Global Fund Secretariat	Senior Specialist Monitoring & Evaluation, Monitoring Evaluation & Country Analysis Team (IT / Digitalisation, including DHIS2)
Global Fund Secretariat	Country Technology Services Manager, IT Department, Country Technology Services (IT / Digitalisation, including DHIS2)
Global Fund Secretariat	Senior Advisor, COVID-19 Response, TAP, C19RM- Strategy, Investment & Impact Division (COVID-19)
TERG	TERG member (TERG)
TERG	TERG member (TERG)

Appendix C LIST OF CORE PHASE CONSULTATIONS

Appendix C presents lists of stakeholders interviewed, during the core phase, split across the following categories: (i) innovation case studies; (ii) other global consultations; and (iii) country case studies.

C.1. INNOVATION CASE STUDIES

Table C.1 provides a list of stakeholders interviewed for the innovation case studies.

Table C.1: Stakeholders interviewed in core phase for seven innovation case studies

Organisation	Position
PrEP	
Global Fund Secretariat	Advisor, Product Introduction - HIV Prevention (Country facing), TAP, Opex Co-funding
	Senior Disease Advisor, HIV
	Senior HIV Prevention Advisor, HIV team
	Pharmaceutical sourcing manager, OSS
	Category lead for ARV medicines
WHO	Team lead for testing, prevention and populations, Global HIV, hepatitis and STI programmes
CHAI	Director, HIV prevention
Unitaid	HIV Programme Manager
	Technical Officer Strategy Team
HIVST	
Global Fund Secretariat	HIV Advisor, TAP
	Senior Technical Coordinator, Adolescent Girls and Young Women, CRG Team
	Senior Technical Coordinator, CRG Team
	Manager, Global Sourcing, Health Technologies, Strategic Sourcing
WHO	Team lead for testing, prevention and populations, Global HIV, hepatitis and STI programmes
PSI STAR	Associate Director, HIV and Tuberculosis and Project Director of STAR
OraSure	Vice President, International Sales
Unitaid	HIV Programme Manager
	Technical Officer, Strategy Team
GeneXpert	
Global Fund Secretariat	TB Advisor
	Senior TB Advisor
	Laboratory Systems and Health Security
	Medical Laboratory Specialist, Technical Advice and Partnerships Department
Unitaid	Programme Manager
	Technical Officer, Strategy Team
GDF	Chief
Stop TB	Deputy Director

Organisation	Position
	Team Leader, Innovations and Grants
WHO	Team Lead
FIND	Senior Scientist, TB Program
USAID	Technical Branch Chief, Senior Laboratory Advisor
	Senior TB Technical Advisor
African Society for Laboratory Medicine	Director of Science and New Initiative
	Senior Directory Advisor
CHAI	Director
Cepheid	Global Access Director, Systems and Connectivity
Global Fund Secretariat	Senior Disease Advisor Tuberculosis, Technical Advice and Partnerships Department
	Senior Disease Advisor, TB
Unitaid	Programme Manager
	Technical Manager, Strategy Department
GDF	Chief
Stop TB	Deputy Director
	Team Leader, Innovations and Grants
USAID	Medical Officer
New LLINs	
Global Fund Secretariat	Senior Specialist, Malaria Vector Control - Catalytic Funding, TAP
	Senior Specialist, Private Sector Engagement, TAP • Technical Advice and Partnerships Department
	Senior Specialist, Anti-Corruption and Impact, Ethics Office
Unitaid	Technical Manager, Malaria
ALMA	Chief Technical Advisor for ALMA and Co-Chair of RBM Country/Regional Support Partner Committee (CRSPC)
IVCC	Director, Access and New Paradigms in Vector Control
	Director, Access and Market Shaping
	Health Science Specialist
BMGF	Senior Programme Officer, Health investor
BASF	Director Global Public Health
Facility Level Financing	
Global Fund Secretariat	Manager, Strategic Partnerships and Blended Finance (Health Finance)
	Senior Specialist, Anti Corruption and Impact, Ethics Office
	Advisor, Strategic Partnerships, Health Finance
Global Fund OIG	Head of Professional Services
Country Teams	Disease Fund Manager, Grant Management Team
Gavi	Director, Health Financing Team
World Bank	Lead Economist, Development Research Group

Organisation	Position
Global Fund Secretariat	Senior Manager, Country Financial Management Strengthening & Innovation, Financial Insights and Analytics
	Senior Specialist, Financial Management, Programme Finance, Financial Insights and Analytics
	Private Sector Engagement Team
	Specialist, Financial Management, Financial Insights and Analytics
Gavi	Public Financial Management
Better than Cash Alliance	Deputy Managing Director
BMGF	Senior Programme Officer
ABSA Bank	Global Relationship Director, Global Development Organisations
Country Teams	Grant Finance Manager, Grant Financial Management, Grant Finance Team
	Specialist, Health and Blended Finance, Health Finance Department, Health Finance Department
	Senior Fund Portfolio Manager, South East Asia Team
	Specialist, High Impact and Core Countries, Programme Finance, Grant Finance Team
	Associate Specialist, High Impact & Core Countries, Grant Finance Team

C.2. GLOBAL CONSULTATIONS

Table C.2 presents a list of global consultations conducted in the core phase of the evaluation.

Table C.2: Global consultations in core phase

Organisation	Position
Global Fund Secretariat	Head of Supply Operations
	Senior Manager, Strategic Sourcing (Sourcing and Supply Chain)
	Supply Operations Liaison
	Manager, Global Sourcing Health Technologies
	PDQ data system administrator
	Head, Access to Funding Department
	Manager, Communication and Information Management, Access to Funding
	Head, Grant Financial Management
	Head, Strategy and Policy Hub
	Senior Policy Advisor, Strategy and Policy Hub
	Senior Advisor, COVID-19 Response, TAP, C19RM- Strategy, Investment & Impact Division (COVID-19)
	Manager, Service Delivery Innovation
	Senior Specialist, Impact and Evaluation
	KPI Specialist
	Senior Manager (health product demand)
Unitaid	Director, Results

Organisation	Position
	Director, Strategy
	Team Lead Programme Management
	Advisor – Executive Office
MMV	Executive Vice President, Access & Product Management
TRP	Focal Point for SISF (Strategic Investment and Sustainable Financing)
	Focal Point for SISF (Strategic Investment and Sustainable Financing)
	Former TRP Leadership

C.3. COUNTRY CASE STUDIES

Table C.3 provides a list of stakeholders interviewed for the country case studies.

Table C.3: Stakeholders interviewed in core phase for four country case studies

Organisation	Position
Burkina Faso	
Burkina Faso Country Team (Global Fund)	Senior Portfolio Fund Manager
	M&E Public Health Specialist
	Programme officer / financial management channel
	TB Consultant
National TB Control Programme	PNT Coordinator, TB Program
Programme d'Appui au Développement Sanitaire (PADS)	Coordinator
Ministry of Health	Director of Health Information Systems (DSIS)
SPCNLS (PR HIV)	Global Fund UG Coordinator
IPC (PR for community component HIV/TB)	Director
Ghana	
Global Fund Secretariat	FPM
	M&E Specialist
	HPM
National Malaria Control Programme	Acting Programme Manager
	Head of SM&E
National Tuberculosis Control Programme (NTP)	NTP Director
	Deputy Programme Manager
	Head of M&E
National AIDS Control Programme	Head
WAPCAS	Programme Director
	Project Manager
	Programme Manager
	M&E Manager

Organisation	Position
CCM	Vice Chair
	Executive Secretary
WHO Country Office	Communicable Disease Advisor
Indonesia	
Global Fund Secretariat	Senior Programme Officer
	PHM&E
	FPM
CCM	Executive Secretary
	Past Vice Chair
	Chair of CCM
	Vice Chair of CCM, Chair of National Network of people living with HIV
In-country HIV stakeholders	Planning, Monitoring and Evaluation Manager, Spiritia
	Spiritia
	UNITAID STAR 3 programme consultant
	UNAIDS Country Director Indonesia, Vice Chair CCM Indonesia, TWG HIV Member
	Deputy NAP manager
	NAP PMU head
In-country TB stakeholders	National Programme Director, PR Konsorsium Komunitas PB-STPI
	NTP PMU head
	USAID, CCM TB TWG vice chair
	WHO Country Office, TB division
Nossal Institute	Associate Professor, Nossal Institute for Global Health, University of Melbourne (expert on HIV in Indonesia)
Georgia	
CCM Secretariat	Executive Secretary
	Vice-Chair, CSO Representative
NCDC	Deputy Director
	GF TB Programme Manager
	GF TB Programme
	NCDCPH GF HIV Programme Manager
National Centre of Tuberculosis and Lung Diseases	Head of Surveillance and Strategic Planning Department, Coordinator of the Global Fund TB Programme (GEO-T-NCDC)
Ministry of IDPs from the Occupied territories Labor, Health and Social Affairs of Georgia	First Deputy Minister
CSO's	Advocacy Coordinator, CSO Representative
WHO	Programme Coordinator, WHO Country Office
USAID	Human Rights and Resilience Team Leader, Office of Democracy, Rights and Governance

Appendix D INTERVIEW GUIDE

This appendix includes the interview guide for stakeholder consultations. Section D.1 presents the guide for the Global Fund secretariat, Section D.2 presents the guide for partners, and Section D.3 presents the guide for country stakeholders. These guides are provided for reference, and have been further tailored to specific interviews.

D.1. GLOBAL FUND SECRETARIAT

The interview will have two parts: Part 1 on the innovation case study in question and Part 2 on the overall approach of the Global Fund in supporting innovations

Part 1: Case study on [x]

Global Fund role and funding and partner landscape

1. To what extent has the Global Fund supported the deployment of the innovation in countries? What role has the Global Fund played in supporting the innovation (particularly around supply aspects) and through which approaches/ mechanisms (e.g. targeted market shaping, procurement, etc.)? Who have been the other key partners involved and in what role/ capacity?

Assessment of enablers and barriers

2. In your view, has the scale-up of the innovation by the Global Fund been successful or less successful? What countries / regions are examples where the innovation has been successful / less successful?
3. What have been the key barriers and enablers for scaling-up the innovation by the Global Fund (also specific to countries / regions if applicable)?
 - a. What aspects work less well and serve as key challenges and barriers to the role of the Global Fund in effectively and equitably deploying innovations across countries? Which aspects work well and act as key enablers?
 - i. *Aspects by key steps in the innovation value chain and market demand and supply*
 - ii. *Aspects related to Global Fund processes (e.g., funding requests, CCM, guidelines)*
 - iii. *Aspects related to country factors (e.g., awareness of innovations, guidelines, product registration, assessment of cost-effectiveness, affordability, sustainability)*
 - iv. *Aspects related to partner roles and responsibilities (WHO, other technical partners, CSOs)*
 - b. Has the Global Fund engaged with the right partners in supporting the roll out of this innovation and has it effectively engaged with all key partners?
 - c. What could the Global Fund do to overcome barriers / strengthen enablers for the innovation (or could have done previously)? Are there key gaps where the Global Fund should be operating but currently is not?

Contribution of the innovation to results

4. What has been the contribution of the innovation to achieving Global Fund outcomes and results? Are there specific examples / evidence on the contribution of the innovation (e.g., *changes in disease outcomes / grant performance; trial data / published studies*)?

Recommendations

5. What are best practises or lessons learned from this innovation on how the Global Fund generally addresses accelerated and equitable deployment of innovations?
6. What recommendations do you have for the Global Fund to accelerate equitable deployment and access to innovation?

Part 2: Overall questions on Global Fund role on supporting innovations

1. In general, what types of innovations have been well supported by the Global Fund (and conversely, which have not), and why?

2. How does the Global Fund add value to the work of other partners in the innovation value chain and how well do partners feed into the requirements of the Global Fund?
3. Does the Global Fund have the appropriate and efficient internal systems and processes to identify, prioritise, select and support the right and relevant types of innovation, including the appropriate pace for acceleration? What aspects of the Global Fund model, systems and processes are enablers or barriers in this regard?

D.2. PARTNERS

The interview will have two parts: Part 1 on the innovation case study in question and Part 2 on the overall approach of the Global Fund in supporting innovations.

Part 1: Case study on [x]

1. In your view, has the scale-up of the innovation by the Global Fund been successful or less successful? What countries / regions are examples where the innovation has been successful / less successful?
2. What has been your organisation's role in supporting the innovation and what extent of symbiosis has there been between your organisation and the Global Fund in supporting the innovation?
3. What have been the key barriers and enablers for scaling-up the innovation by the Global Fund (also specific to countries / regions if applicable)?
 - a. What aspects work less well and serve as key challenges and barriers to the role of the Global Fund in effectively and equitably deploying innovations across countries? Which aspects work well and act as key enablers?
 - i. *Aspects by key steps in the innovation value chain (see annex) and market demand and supply*
 - ii. *Aspects related to Global Fund processes (e.g., funding requests, CCM, guidelines)*
 - iii. *Aspects related to country factors (e.g., awareness of innovations, guidelines, product registration, assessment of cost-effectiveness, affordability, sustainability)*
 - iv. *Aspects related to partner roles and responsibilities (WHO, other technical partners, countries, CSOs)*
 - b. Has the Global Fund engaged with the right partners in supporting the roll out of this innovation and has it effectively engaged with all key partners?
 - c. What could the Global Fund do to overcome barriers / strengthen enablers for the innovation (or could have done previously)? Are there key gaps where the Global Fund should be operating but currently is not (e.g., gaps in market creation / country demand creation)?
4. What are best practises or lessons learned from this innovation on how the Global Fund generally addresses accelerated and equitable deployment of innovations? What recommendations do you have for the Global Fund to accelerate equitable deployment and access to innovation?

Part 2: Overall questions on Global Fund role on supporting innovations

1. In general, what types of innovations have been well supported by the Global Fund (and conversely, which have not), and why do you think so?
2. How does the Global Fund add value to the work of other partners in the innovation value chain and how well do partners feed into the requirements of the Global Fund?
3. Does the Global Fund have the appropriate and efficient internal systems and processes to identify, prioritise, select and support the right and relevant types of innovation, including the appropriate pace for acceleration? What aspects of the Global Fund model, systems and processes are enablers or barriers in this regard?

D.3. COUNTRY CASE STUDIES

The following questionnaire was developed for use within the Burkina Faso country case study, and was tailored to each of the country case studies.

The interview will have two parts: Part 1 on the experience within country Global Fund Burkina Faso with respect to the innovations in 1a and Part 2 on the overall approach of the Global Fund in supporting innovations in Burkina Faso.

Part 1: Specific questions per selected innovation

Global Fund role and funding and partner landscape

1. To what extent has the Global Fund supported the scale-up of the specific innovation in Burkina Faso? (e.g., thinking through the different stages of the innovation value chain (see annex)? Who have been the other key partners involved and in what role/ capacity?

Assessment of enablers and barriers

2. In your view, has the scale-up of the innovation by the Global Fund been successful or less successful?
3. What have been the key barriers and enablers for scaling-up the innovation by the Global Fund? This could include:
 - a. *Aspects by key steps in the innovation value chain and market demand and supply*
 - b. *Aspects related to Global Fund processes (e.g., funding requests, CCM, guidelines)*
 - c. *Aspects related to country factors (e.g., awareness of innovations, guidelines, product registration, assessment of cost-effectiveness, affordability, sustainability)*
 - d. *Aspects related to partner roles and responsibilities (WHO, other technical partners, countries, CSOs)*

Contribution of the innovation to results

4. What has been the contribution of the innovation to achieving Global Fund outcomes and results? Are there specific examples / evidence on the contribution of the innovation (e.g., *changes in disease outcomes / grant performance; trial data / published studies*)?

Lessons learned

5. What are best practises or lessons learned from this innovation on how the Global Fund generally addresses accelerated and equitable deployment of innovations?

Data and consultations (for Global Fund Secretariat)

6. What other stakeholders should we interview as part of this innovation deep-dive [if not covered already]?
7. Do you have any additional data and documentation that could support the analysis of this innovation in Burkina Faso?

Part 2: Overall questions on Global Fund role on supporting innovations

1. In general, what types of innovations have been well supported by the Global Fund in Burkina Faso (and conversely, which have not), and why?
2. Are there any cross-cutting barriers or enablers with regard to innovation in Burkina Faso which have not been covered through the discussion on the specific innovations?
3. What recommendations do you have for the Global Fund to accelerate equitable deployment and access to innovation?
4. Does the Global Fund have the appropriate and efficient internal systems and processes to identify, prioritise, select and support the right and relevant types of innovation, including the appropriate pace for acceleration?

Appendix E CASE STUDY SELECTION

Section E.1 below presents the analysis supporting selection of the innovation deep-dives, followed by Section E.2 which presents the shortlist of countries.

E.1. INNOVATION CASE STUDY SELECTION

Table E.1 presents a mapping of the key innovations for the three diseases and cross-cutting RSSH against the innovation typology developed in Section 2 of this report. The identification of innovations is based on a high-level review of key Global Fund and partner documents outlining the most relevant innovations (e.g. Unitaids disease narratives) and inception phase consultations with the Global Fund Secretariat. The focus has been on innovations which are relevant for the 2017-22 and 2023-28 Global Fund Strategy period (i.e. innovations in the pipeline not expected to be scaled-up within the next Strategic period have not been included). The mapping is more comprehensive for product innovations as compared to non-product innovations given the range of innovations in this latter area.

Based on this mapping, we purposively selected 7 innovations (as represented in bold highlighted font in the table below) based on innovations deemed a priority by the Global Fund and where interesting insights can be obtained including from a mix of both successful and less successful country experiences, as indicated from our inception phase consultations with the Global Fund Secretariat. Further, certain innovation case studies will be “bundled” in that they will consider both product and non-product related innovations for the same overall intervention/ programme and this is also highlighted in the table below through dashed boxes (see also footnotes).

The selection aims to represent a mix across:

- Categories within the innovation typology (i.e. health products and devices, service delivery approaches, and health systems management tools and processes), albeit with a larger focus on the first category given the Global Fund mandate.
- Three diseases of HIV/AIDS, TB and malaria as well as cross-cutting/ RSSH
- Prevention, diagnosis and treatment continuum
- Stage/ level of scale-up of the innovations – early, middle, late (marked as E/M/L in the table)

The final selection of 7 (+3) innovations has been made based on feedback received from the TERG and Global Fund Secretariat.

Table E.1: Mapping of key innovations against the innovation typology (selected core innovation bolded; innovations covered within another deep-dive in blue boxes)

	Health products and devices			Service/programme delivery approaches	Health systems management tools and processes
	Prevention	Diagnosis	Treatment		
HIV	<ul style="list-style-type: none"> • PrEP (oral, vaginal ring, injectable) (E) 	<ul style="list-style-type: none"> • HIV Self-testing (M) • HIV Point-of-Care (POC) VL/ EID 	<ul style="list-style-type: none"> • Transition to TLD (from Efavirenz to Dolutegravir) • Paediatric formulation • Long-acting injectables 	<ul style="list-style-type: none"> • Virtual behaviour change for HIV prevention/ HIVST (E)⁵¹ • Private sector engagement (ART treatment) 	
TB	<ul style="list-style-type: none"> • TB preventive therapy (3HP) 	<ul style="list-style-type: none"> • GeneXpert / Molbio Truenat (L) • TB LAM testing/ rapid molecular testing • Digital X-ray/ AI image detection 	<ul style="list-style-type: none"> • MDR-TB short regimens containing Bedaquiline (M) • MDR-TB 2nd line regimen containing Delamanid • Paediatric formulation 	<ul style="list-style-type: none"> • TB bi-directional screening/ integration (E/M)⁵² • Optimized integration of TB services for children 	
Malaria	<ul style="list-style-type: none"> • New LLINs (Dual AI / PBOs) (E/M) • SMC • Next Generation IRS • IPTp • Malaria vaccine (RTS,S) 	<ul style="list-style-type: none"> • New tools not relying on use of HRP2 	<ul style="list-style-type: none"> • Injectable and intrarectal Artesunate (switch from quinine) • Treatment for vivax (Tafenoquine) (E) 	<ul style="list-style-type: none"> • Private sector engagement (Activity-based contracting for LLINs) (E/M)⁵³ • CHW redeployment based on georeferencing / stratification of disease burden 	
Cross-cutting & Pandemic Preparedness	<ul style="list-style-type: none"> • Multipurpose prevention technology (STIs, HIV and RMNCH) 	<ul style="list-style-type: none"> • COVID-19 Self-testing 	<ul style="list-style-type: none"> • Oxygen (PSA plants) 	<ul style="list-style-type: none"> • Results-based financing / Direct Facility Financing (E) • Community-led monitoring and service delivery • Private Sector Engagement (e.g., activity based contracting) • Integrated lab systems strengthening 	<ul style="list-style-type: none"> • Financial management / mobile payments (M) • DHIS2 (e.g., Aggregate, Tracker, Mobile and extensible apps) • HRH planning and quality improvement • Mobile tools for CHWs • Blended finance / debt-relief

⁵¹ To be included alongside the PrEP product case study

⁵² To be included alongside the GeneXpert/ Molbio TB diagnostics case study

⁵³ To be included alongside the malaria LLINs case study

E.2. COUNTRY CASE SELECTION

We have selected 5 countries for case studies: Burkina Faso, Georgia, Ghana, Indonesia and Zimbabwe. However the Zimbabwe case study could not progress due to burden imposed on the country through multiple ongoing evaluations. Instead, perspective for the East and Southern African region has been covered through a focus group discussion with the Secretariat Regional Head and select FPMs in the region.

The countries were selected based on:

- Countries that can offer insights into more than one innovation
- Countries that offer a mix of successful and less successful experiences with introduction and scale-up of innovations
- Countries that are a priority for the Global Fund in terms of the fight against the three diseases and therefore scale-up of innovations – this has meant a focus on high impact countries in Sub Saharan Africa.
- Countries that can offer a balanced regional mix

Appendix F LITERATURE REVIEW ON INNOVATION

Appendix F presents a literature review on innovation of the following sets of documents: (i) publicly available Global Fund Secretariat documents, (ii) partner documents, and (iii) academic literature.

F.1. GLOBAL FUND DOCUMENTS

Table F.1 presents a summary of how innovation is reflected in publicly available Global Fund Secretariat documents. This involved a review of documents, found on the Global Fund's website, searching for references of innovation or innovative products / interventions / processes.

Table F.1: Review of publicly available documents from the Global Fund Secretariat

Source			Description
Strategy documents:			
Global Fund Strategy (2023-2028)			<p>Identified innovation as one of the 10 differences in the new strategy, with a '<i>greater focus on accelerating the equitable deployment of and access to innovations working with partners to take an end-to-end view to rapidly address bottlenecks to deployment to those most in need</i>'. Important aspects of the new strategy include:</p> <ul style="list-style-type: none"> • NextGen marketing shaping – continued efforts to facilitate market transparency and competition by working with private sector partners to uphold the market shaping objectives of availability, accessibility, affordability, acceptability, quality, sustainability and a focus on innovations in order to facilitate healthier global markets for health products. • Private sector partners – to 1) seed innovations, through targeted investments and guarantees and collaborate on the introduction and equitable scale-up of health innovations, 2) provide financing and support for innovative models of service provision; and 3) spearhead innovative partnerships and provide co-financing to advance equity, gender equality and human rights objectives in countries. <p>Innovation is a focus in the fight against all three diseases:</p> <ul style="list-style-type: none"> • HIV – Global Fund is looking to support market priming and accelerated access to affordable new HIV prevention options, such as new PrEP formulations and technologies that provide dual protection against both HIV and pregnancy. • TB – innovative opportunities include: the possibility to shorten regimens for drug-susceptible TB and TB preventative treatment; shorter and fully oral regimes for DR-TB; and more sensitive and affordable diagnostic tests. • Malaria – the strategy highlights working with industry to accelerate the introduction of effective product innovations to address barriers hampering the rapid scale up of new products to fight the impact of insecticide resistance and residual transmission. This could include supporting efforts to catalyse early adoption of new tools, leveraging market shaping influence and working with industry to accelerate the introduction of effective product innovations.
Global Fund Strategy (2017-2020)			<p>Less content on innovation than most recent strategy document. Innovation is one of the 'Operational Objectives' which will contribute to maximising their impact against the three diseases - 'improve effectiveness in challenging operating environments through innovation'. Also, references innovation in the context of increased resources, innovative financing and through partnering with Unitaaid.</p>

Source			Description
Global Fund Strategy (2012-2016)			Less content on innovation than more recent strategies. States that innovative funding mechanisms must be more explored, such as Debt2Health.
Global Fund Strategy (2006)			Mentions innovative financing mechanisms and developing 'innovative' partnerships with government, private and non-government organisations.
Policy documents:			
Operational Policy Manual (2022)			Innovation is highlighted as one of the principles that guides the management of COEs portfolios with the aim to maximise access to essential services and/or coverage. It states that new approaches will be encouraged throughout the grant cycle in order to maximise results in COEs.
Quality Assurance for Diagnostic Products (2010, amended 2017)			Limited mention of innovation.
Procurement Policy (2008)			Limited mention of innovation.
Country guidance documents:			
Applicant Handbook 2020-2022 (2021)			States what is different for the new funding cycle, one example is encouraging applicants to promote and test bold innovations and evaluate them rigorously. Whether the country has identified opportunities for innovation and evaluation will be addressed during country dialogue.
Modular Framework Handbook (2019)			<p>Limited reference to innovation.</p> <ul style="list-style-type: none"> Some aspects in RSSH such as innovations on e-learning; integrated supervision of services and laboratory systems The current structure of the modular framework does not allow to disentangle impact / funding to interventions which could be considered new / innovative
Building RSSH Information Note (2019)			<p>This guidance states that RSSH investments should:</p> <ul style="list-style-type: none"> Innovate and evaluate, to maximise learning. Emphasis placed on innovations that are practical, low-cost, can be reproduced at scale and can be implemented without significant technical assistance or management support. Encourage increased domestic resources. The Global Fund can support efforts by countries to explore innovative financing mechanisms with private sector partners
HIV Information Note (2019)			The Global Fund have identified a set of prioritised interventions to help achieve HIV targets. This includes encouraging applicants to request funding for rapid scale-up of new and innovative medicines and technologies, as well as new testing approaches such as HIVST. The guidance also emphasises the importance of planning for long-term sustainability of innovations from the start.
Malaria Information Note (2019)			Less content on innovation than core notes for HIV and TB. Briefly states how the Global Fund encourages innovative ideas on data collection.
Tuberculosis Information Note (2019)			<p>This note provides guidance to applications preparing a Global Fund request for TB funding. The note encourages investment in innovative intervention.</p> <p>Examples of high impact TB interventions involving innovation:</p>

Source	Description
	<ul style="list-style-type: none"> Finding the 'missing' millions – millions of those with TB are missed as they are undiagnosed. Innovative approaches are needed to find these people, such as the Global Fund's TB Catalytic Investment which focuses on 13 selected countries that account for 75% of missing people with DS-TB and 55% of DR-TB globally. As part of this process, a website for sharing experiences has been developed to guide efforts for finding missing people with TB. This includes newsletters, case studies and e-learning modules. Community engagement – innovative approaches that engage communities and civil society organisations in the implementation of national TB intervention strategies, could be tailored to country specific contexts and used to strengthen community responses. For example, the successful TB REACH funded projects and the ENGAGE-TB Approach.
Technical Brief: In-Country Supply Chains (2019)	Limited mention of innovation.
Guidance Note for Developing a RSSH Funding Request (2020)	<p>This guidance includes several questions for consideration in proposing RSSH investments, including the following regarding innovation:</p> <ul style="list-style-type: none"> What kind of innovations related to RSSH have been introduced recently in the country? Have any evaluations been carried out? What kind of innovations related to RSSH are being requested? Have they planned evaluations of the innovations? Are the innovations likely to be sustainable?
Technical Brief: Community Systems Strengthening (2019)	Limited mention of innovation.
Technical Brief: Laboratory Systems Strengthening (2019)	Limited mention of innovation.
Supply and procurement documents:	
Supply Chain Roadmap (2021)	<p>This documents provides an enhanced supply chain vision for the Global Fund partnership, which will be driven by five strategic objectives and focus on four key thematic areas. One of these was around fostering innovation, to support the improvement of in-country supply chains through public-private partnerships, innovation incubation, development or knowledge hubs. Activities to support country objectives could include:</p> <ul style="list-style-type: none"> Providing visibility on innovative solutions to provide opportunities to address supply chain issues Sharing successful innovation stories to make the risk for new supply chain management solutions more appealing Support the development and scaling of innovative solutions for data management and end-to-end supply chain visibility Foster partnerships with educational institutions and supply chain professional organisations to create innovation incubators
Progress report documents:	
Results Report (2021)	Recognises the opportunities for innovation during COVID for all three diseases, for example patient-centred diagnostic approaches, such as co-testing for HIV, TB and COVID-19. Some of these innovations can continue post COVID.

Source	Description
	<ul style="list-style-type: none"> The report also highlights the importance of innovative partnerships to fight HIV, TB and Malaria. An example of a private sector engagement is the partnership between Global Fund and Zenysis Technologies, a U.S. based big data integration and software startup. Both teamed up with the ministries of health of Rwanda and Zambia to develop an innovative platform that aims to harness the power of quality data to strengthen health programs. In 2021, two major Debt2Health agreements signed (innovative financing mechanism).

F.2. PARTNER LITERATURE

Table F.2 presents a summary review of partner literature, which involved scanning partner websites for relevant documents/webpages referencing innovation in particular with regard to their approach to defining or categorising innovation.

Table F.2: Review of key literature from partners and other multilateral organisations

Organisation / key sources	Description
Unitaid: <i>Resources:</i> Strategy 2017-2021	<u>Definition:</u> In the Unitaid context, innovation means: <ul style="list-style-type: none"> To use existing commodities in new ways to increase their impact Foster continued development of new products and approaches to address unmet needs in prevention, diagnosis, and treatment of HIV/AIDS, tuberculosis and malaria (e.g., long-acting formulations, multi-platform diagnostics). <u>Other observations:</u> The first strategic objective is to promote innovation. This is achieved by funding interventions that foster access to innovative health products and ensuring innovators understand and address the requirements of those most in need, thereby making it possible for innovative ideas to become a reality. 2022 - New Strategy draft materials: <ul style="list-style-type: none"> Vision/mission statements include innovation Forward looking: e.g. innovative supply chain aligned to climate goals Innovative supply models and approaches (including local manufacturing); innovative products, delivery systems, AI and technology
OECD: <i>Resources:</i> Oslo Manual: Guidelines for Collecting, Reporting and Using Data on Innovation, 3 rd Edition (2005)	<u>Definition:</u> An innovation is a new or improved product or process (or combination thereof) that differs significantly from the unit's previous products or processes and that has been made available to potential users (product) or brought into the unit (process). <u>Typology / Characteristics:</u> The OECD distinguish four types of innovation: <ul style="list-style-type: none"> Product innovation: introduction of a good or service that is new or significantly improved with respect to its characteristics or intended uses. This includes significant improvements in technical specifications, components and materials, incorporated software, user friendliness or other functional characteristics.

Organisation / key sources	Description
	<ul style="list-style-type: none"> • Process innovation: implementation of a new or significantly improved production or delivery method. This includes significant changes in techniques, equipment and/or software. E.g. efficiencies and quality improvements: improved logistics or product tracking systems, GPS, software • Marketing innovation: the implementation of a new marketing method involving significant changes in product design or packaging, product placement, product promotion or pricing. Aimed at better addressing customer needs, opening up new markets, or newly positioning a firm's product on the market, with the objective of increasing the firm's sales (e.g. packaging, sales channels, product placement, advertising/promotion, branding. Note marketing innovations include product design innovations that are part of a new marketing concept) • Organisational innovation: implementation of a new organisational method in the firm's business practices, workplace organisation or external relations. E.g. Knowledge sharing, training and staff retention, quality-management systems
<p>USAID:</p> <p><i>Resources:</i></p> <p>Center for Innovation and Impact (CII) - available online.</p> <p>Global Health Innovation Index: A tool for identifying the most promising Global Health Innovations (2020)</p> <p>Innovation Realized: Expanding the path to Health Impact: A guide to amplify global health innovation at USAID (2019)</p>	<p><u>Definition:</u></p> <p>An innovation can be “a creative solution to any global development problem.” Innovations are broadly defined and include new or improved services, processes, and applications of business or delivery models—in addition to products and technologies.</p> <ul style="list-style-type: none"> • Innovation is considered as either: a) Inventing the new (new models e.g. delivery, business that reach previously unreached communities) b) Improving the known (enhancements that reach existing and expanded communities). <p><u>Typology / Characteristics:</u></p> <p>Doblin developed 10 types of innovation (available online) which USAID has adapted to Global Health:</p> <p>Offering:</p> <ol style="list-style-type: none"> 1. Product performance – how you design your core offerings (form and function) 2. Product system – how you link and/or provide a platform for multiple products 3. Service – how you provide value to customers and consumers beyond and around your products <p>Delivery:</p> <ol style="list-style-type: none"> 4. Channel – how you get your offerings to market 5. Brand – how you communicate your offerings 6. Customer engagement – how your end users feel when they interact with your company and its offerings <p>Finance:</p> <ol style="list-style-type: none"> 7. Business model – how products or services are bought and sold 8. Network – how you join forces with others for mutual benefit <p>Process:</p> <ol style="list-style-type: none"> 9. Enabling process – how you support the organisation's core workers and processes 10. Core process – how you create and add value <p><u>Global Health Innovation Index:</u></p> <p>The index is an analytical tool to assess global health innovations and identify those with the greatest potential for global health impact. The index examines products, practices, and services (not drugs or vaccines due to unique regulatory requirements and pathways to scale).</p> <p>The index has two main goals:</p>

Organisation / key sources	Description
	<ul style="list-style-type: none"> • Provide a versatile tool to evaluate a diverse range of health innovations at every stage of development to assess which ones are the most promising and should be considered for further support — for example, funding, technical assistance, and connections with partners; • Highlight some of the most promising near-term innovations to support greater adoption and incorporation in ongoing health programming. <p><u>Other observations:</u></p> <p>USAID believe that around 70-90% of global health innovation efforts focus on improving existing products, services and practices, termed incremental or adjacent innovations. Only about 10% of innovation efforts focus on inventing something entirely new, termed transformative innovations. Transformative innovations carry a greater risk and need to be developed and tested first, and then scaled up.</p> <p>USAID identify five common innovation opportunities in the context of global health:</p> <ul style="list-style-type: none"> • Develop new or improved solutions; • Scale existing solutions; • Cultivate new or different partners/engagement models; • Access more or better funding; and • Incorporate more flexible working structures.
<p>Gavi:</p> <p><i>Resources:</i></p> <p>Annual Progress Report (2020)</p> <p>Maintaining, Restoring & Strengthening Immunisation: Gavi Innovation Catalogue (2020)</p>	<p><u>Definition:</u></p> <p>No set working definition of innovation.</p> <p><u>Typology / Characteristics:</u></p> <p>One of Gavi's goals is to shape markets for vaccines and other immunisation products. One indicator for the market shaping goal is innovation. This is described as <i>'the number of vaccines and other related products with improved characteristics procured compared to the baseline year'</i>.</p> <p><u>Other observations:</u></p> <p>To support Gavi-eligible countries to put in place better immunisation services, the Alliance has put together an initial, non-exhaustive, tool and provider agnostic list of 21 innovations that countries could consider depending on their specific needs and context. These address COVID-19 related needs such as preparing frontline health workers for the "new normal" of immunisation and ensuring agile cold chain and logistics post pandemic. This document has an overview of all 21 innovations.</p> <p>The list includes innovations that have been tested before in developing country settings, have reached a certain level of maturity, and would have a reasonable timeline to be implemented in the light of the pandemic. The catalogue is therefore a first step towards a potential innovation marketplace that Gavi envisions as part of the 5.0 strategy. It will be updated on a regular basis.</p>
<p>FIND:</p> <p><i>Resources:</i></p> <p>Testing for Healthy and Safe Lives: Find Strategy (2021)</p>	<p><u>Definition:</u></p> <p>No set working definition of innovation.</p> <p><u>Characterisations:</u></p> <p>FIND split innovation in their strategy between technology (supply) and access (demand).</p> <p><i>Technology innovation</i> - partner with users and buyers to co-create fit-for-purpose tools with policy in place and a path to procurement.</p> <p><u>Objectives:</u></p>

Organisation / key sources	Description
	<ul style="list-style-type: none"> • Develop transformational diagnostic tools - partner with countries, communities and patients to understand diagnostic gaps, working collaboratively to fill them through proactive technology scouting and open calls to co-create new tests and digital solutions with users and buyers. • Generate evidence - design and conduct operational and evidence-generation studies (including phase I–IV clinical trials) through a streamlined clinical trial programme. • Build out local production - work with diagnostics developers and local manufacturers on innovative business approaches such as technology transfers to produce diagnostics closer to the people who need them. This strengthens local innovation ecosystems while diversifying and securing supply chains. • Develop marketplace and market interventions - provide a digital marketplace to bring transparency to the market and share verified information and evidence on new tests, aggregate demand and leverage existing procurement channels. <p><i>Access innovation</i> - partner with countries to embed testing as an integral part of sustainable, resilient health systems.</p> <p>Objectives:</p> <ul style="list-style-type: none"> • Design new delivery models (including self-testing and digital) – e.g. focus is on driving the uptake of self-testing, delivery of testing services through community channels, and other models that can enable diagnosis beyond formal health services and closer to patients • Support countries to embed testing and surveillance into broader national health strategies – e.g. provide catalytic support to countries to develop policy and incorporate testing and surveillance into funded national health strategies. This includes joint assessment of needs, customizing global implementation guidance to account for local contexts, and provision of initial test volumes to catalyse use. • Strengthen diagnostic capacity – e.g. work with local and regional partners to build in-country diagnostic capacity that will enable uptake of existing and new tools. • Support advocacy and mutually agreed accountability frameworks – e.g. work with partners on targeted advocacy efforts from global and ministerial to community levels, to raise the profile of testing and increase diagnostic literacy.
Global Innovation Fund <i>Resources:</i> Available online .	<u>Definition:</u> The Global Innovation Fund defines ‘innovation’ broadly to include new business models, policy practices, technologies, behavioural insights, or ways of delivering products and services that benefit the poor in developing countries — any solution that has potential to address an important development problem more effectively than existing approaches.
International Development Innovation Alliance (IDIA) <i>Resources:</i> Available online .	<u>Definition:</u> IDIA define innovation, from a development perspective, as a new solution with the transformative ability to accelerate impact. Innovation can be fuelled by science and technology, can entail improved ways of working with new and diverse partners, or can involve new social and business models or policy, creative financing mechanisms, or path-breaking improvements in delivering essential services and products. Innovation has been and will be pivotal for reaching sustained, scalable solutions to the world’s complex problems.
Global Innovation Index (2021) <i>Resources:</i> Available online .	The GII 2021 captures the innovation ecosystem performance of 132 economies and tracks the most recent global innovation trends. The GII relies on two sub-indices – the Innovation Input Sub-Index and the Innovation Output Sub-Index. Three measures are calculated: <ul style="list-style-type: none"> • Innovation Input Sub-Index – five input pillars capture elements of the economy that enable and facilitate innovative activities • Innovation Output Sub-Index – innovation outputs are the result of innovative activities within the economy. Even though the Output Sub-Index includes only two pillars, it carries the same weight as the Input Sub-Index in calculating the overall GII scores.

Organisation / key sources	Description
	<ul style="list-style-type: none"> The overall GII score is the average of the Input and Output Sub-Indices, on which the GII economy rankings are then produced
Stop TB Partnership <i>Resources:</i> Improving Tuberculosis Case Detection: A compendium of TB REACH case studies, lessons learned and a monitoring and evaluation framework (2021)	<u>Definition:</u> No set working definition of innovation. <u>Typology / Characteristics:</u> No set classification of innovation. <u>Other observations:</u> TB Reach funds promising, but untested methods for reaching and treating vulnerable populations. TB REACH does the following: <ul style="list-style-type: none"> Offers one-year grants to TB programmes and partners for technically sound, innovative and cost-effective TB case detection interventions Focuses on poor, vulnerable and marginalised groups and populations with limited or zero access to TB care services Encourages local innovation and bold solutions that may not be funded elsewhere Requires detailed reporting on technical and financial progress and case notification data Ensures external monitoring and evaluation of all projects Delivers rapid results for improved TB care Provides fast-track funding Xpert MTB/RIF is one of the innovative approaches of TB Reach to detect and treat TB cases by using a new diagnostic technology.
TB Alliance: <i>Resources:</i> Keeping the Promise: Product development partnerships' role in the new age of health research and product development (2021) Charting the Course: 2021 Annual Report (2021)	<u>Definition:</u> No set working definition of innovation. <u>Typology / Characteristics:</u> No set classification of innovation. <u>Other observations:</u> Since 2010 the coalition of PDPs have developed and introduced 66 new health technologies. This success has been driven by a needs-based approach, developing products appropriate for the settings in which they are most needed, which are often low-resource environments. A key initiative is LIFT-TB (Leveraging Innovation for Faster Treatment of Tuberculosis). This programme seeks to broaden the adoption of new treatments in seven countries most affected by drug-resistant forms of TB across Southeast and Central Asia, and Central Europe. The result of these efforts to speed implementation, operational research (OR) has commenced in 12 countries.
IVCC: <i>Resources:</i> Strategy (2020) New Nets Project (NNP) - available online .	<u>Definition:</u> No set working definition of innovation. <u>Typology / Characteristics:</u> No set classification of innovation. <u>Other observations:</u>

Organisation / key sources	Description
NgenIRS – available online .	<p>IVCC's mission is to build partnerships that create innovative solutions to prevent the transmission of insect-borne disease. IVCC look to capitalise on knowledge and innovation to address malaria and other vector borne diseases outside sub-Saharan Africa.</p> <p><i>Examples of innovation projects:</i></p> <ul style="list-style-type: none"> • NNP – These new nets don't yet have a World Health Organisation (WHO) policy recommendation confirming that countries with pyrethroid resistance should consider them over standard nets. NNP will build the epidemiological evidence needed to allow WHO to consider making this new policy recommendation. • NgenIRS - IVCC are making the most effective, long lasting insecticides available to malaria programmes and implementation partners to support insecticide resistance management strategies.

F.3. ACADEMIC LITERATURE

Table F.3 provides a review of the academic literature. This exercise involved a quick google search for academic literature defining innovation or setting out a framework/typology of innovation.

Table F.3: Review of key academic literature

Source	Description
A Multi-Dimensional Framework of Organisational Innovation: A systematic review of the literature (Crossan and Apaydin, 2010)	<p><u>Overview:</u></p> <p>This paper provides a systematic review of the academic literature on innovation over the past 27 years, synthesised into a multi-dimensional framework of organisational innovation – consisting of three sequential components: innovation leadership, innovation as a process and innovation as an outcome.</p> <p>A challenge for this review was the loose application of the term 'innovation', which is often employed as a substitute for creativity, knowledge or change.</p> <p><u>Definition of innovation:</u></p> <p>Authors' definition – <i>innovation is production or adoption, assimilation, and exploitation of a value-added novelty in economic and social spheres; renewal and enlargement of products, services and markets; development of new methods of production; and establishment of new management systems. It is both a process and an outcome.</i></p> <ul style="list-style-type: none"> • This includes both internally conceived and externally adopted innovation ('production or adoption') • Highlights innovation as more than a creative process, by including application ('exploitation') • Emphasises intended benefits ('value-added') • It leaves open the possibility that innovation may refer to relative, as opposed to the absolute, novelty of an innovation (an innovation may be common practice in other organisations but would still be considered as such if it is new to the unit under research) • Draws attention to the two roles of innovation (a process and an outcome) <p><u>Framework:</u></p> <p>Ten dimensions of innovation surfaced from the literature, which could be organised into two categories:</p>

Source	Description
	<ul style="list-style-type: none"> • Those pertaining to innovation as a process. This answers the ‘how’ question • Those relating to innovation as an outcome. This answers the question ‘what
Introducing Responsible Innovation in Health: a policy orientated framework (Silva, Lehoux, Miller and Denis, 2018)	<p><u>Overview:</u></p> <p>The aim of paper is to introduce an integrative responsible innovation in health (RIH) framework that is meant to inform the work of public actors who influence the supply of health innovations.</p> <p><u>Method:</u></p> <p>Using a preliminary set of criteria, such as innovativeness, health relevance and subsidiarity, Silva et al., created an inventory of health innovations that could potentially qualify as responsible by performing a structured social media based horizon scan. This exercise generated around 100 empirical examples. The inventory of potential examples of RIH enabled the team to gradually consolidate the framework.</p> <p>Examples of an innovation in the inventory is the distribution of menstrual cups, free of charge, to young women in developing countries through strategic partnerships with local organisations and a ‘buy one, give one’ model.</p> <p><u>RIH Framework:</u></p> <p>Definition of the framework - RIH consists of a collaborative endeavour wherein stakeholders are committed to clarify and meet a set of ethical, economic, social and environmental principles, values and requirements when they design, finance, produce, distribute, use and discard sociotechnical solutions to address the needs and challenges of health systems in a sustainable way.</p> <p>There are five value domains of the framework: population health, health system, economic, organisational and environmental. These comprise of a total of nine dimensions, such as health relevance, inclusiveness and responsiveness.</p>
The coordinates of scaling: Facilitating inclusive innovation (Rodriguez, MacLachlan and Brus, 2020)	<p><u>Method:</u></p> <p>The review scoped 20 scaling frameworks that addressed socially inclusive innovations targeting vulnerable populations. This search was narrowed to the following criteria:</p> <ul style="list-style-type: none"> • Scaling up in development contexts • For innovations of development actors, e.g. public sector and NGOs, with the intent to improve the living conditions, such as health and education <p><u>Definitions of scaling:</u></p> <ul style="list-style-type: none"> • ExpandNet – considers scaling as ‘expanding, replicating, adapting and sustaining successful policies, programs or projects in geographic space and over time to reach a greater number of rural poor (ExpandNet, 2010, p.17) • USAID – definition focuses on the growth of the intervention from improvements that serve a small group to ‘a significantly larger population, such as an entire region or country’ (USAID, 2008, p.8) <p>The following four directions of scaling were distinguished:</p> <ul style="list-style-type: none"> • Up (changes in laws, policies, institutions or norms) • Down (resource allocation to support implementation) • In (ensuring organisations have the capacity to deliver the type and number of good practices required) • Out (geographically replicating or broadening the range or scope of good practice)

Source	Description
Innovative approaches for improving maternal and newborn health – A landscape analysis (Lunze et al., 2015)	<p><u>Method:</u> Systematic literature review based on the maternal and newborn health (MNH) continuum of care framework and the WHO health system building blocks.</p> <p><u>Results:</u></p> <ul style="list-style-type: none"> • Most innovations in MNH are iterations of existing interventions, modified for contexts in which they had not been applied previously • Innovative approaches include: health technologies; interventions based on community ownership and participation, and; novel models of financing and policy making. <p><u>Conclusions:</u></p> <ul style="list-style-type: none"> • Countries with the most progress in MNH reached out to the poorest and most remote populations, improving equity in MNH service coverage. <p>In order for any innovative intervention to be scaled up in low-resource settings, evaluation studies need to consider cost, feasibility and acceptability.</p>

Appendix G CONTRIBUTION OF KEY INNOVATIONS TO GLOBAL FUND RESULTS AND IMPACT

Appendix G provides an overview of the contribution of key innovations to achieving Global Fund outcomes and results. Section G.1 examines how innovation contributes to the Global Fund's projected impact from 2023-2026. Section G.2 presents key indicators related to innovations included in the Global Fund's monitoring framework and a description of results reported publicly on the Global Fund website. Section G.3 provides an overview of the current evidence on impact and effectiveness of : (i) HIV PrEP; (ii) HIV self testing; (iii) GeneXpert/ Molbio Truenat; (iv) MDR-TB switch to short regimens with BDQ; (v) LLINs – dual AI nets and PBO products; (vi) direct facility financing; (vii) mobile financial payments and (viii) virtual service delivery.

G.1. IMPACT OF INNOVATION: GLOBAL FUND INVESTMENT CASE

Rapid and equitable deployment of innovations is critical to the 7th replenishment case and meeting Global Fund disease targets for 2023-2026.

The Global Fund recorded declines in key programmatic results across three disease areas for the first time in its history during 2020. The Global Fund's 7th replenishment case presents a stark choice between increased funding for the three diseases, or abandoning SDG3 targets to end these pandemics as public health risks by 2030. To support and complement intensified focus on reducing incidence and death across the three diseases, the Global Fund envisages significant changes in key aspects including increased focus on ensuring rapid access to lifesaving innovations. The Global Fund's Replenishment case calls for intensified collaboration with upstream partners like Unitaids, close coordination with WHO and regional entities on regulatory approvals and guidance development, and expanded partnerships to support roll out of innovations at scale.

The Replenishment case proposes that with financing of US\$18 billion, the Global Fund would contribute, together with partners, to saving 20 million lives between 2023 and 2026, reducing mortality by 64% across the 3 diseases by 2026 relative to 2020 levels. It is not possible from Global Fund projections to attribute outcomes or results to specific innovations, however projections assume a contribution from scaling new interventions and innovations across the 3 diseases, including:

- HIV- modelling assumes improvements in the proportion of patients being tested and virally suppressed due to new approaches including community-based testing, adherence support groups, diagnostics including self-tests, and drugs including PrEP.
- TB- modelling assumes universal reliance on X-rays for screening and rapid molecular tests (e.g. GeneXpert) for diagnosis, as well as universal access to the latest short, safe and effective treatment regimens, and routine drug susceptibility testing.
- Malaria- modelling assumes the roll out of RTS,S vaccine, scale-up of private sector provided malaria treatment, and efficient distribution of long-lasting insecticidal nets in every country matching the most successful recorded distribution to date.
- Finally, an emphasis on equitable deployment of innovations will contribute to Global Fund's objectives of building resilient, sustainable and people-centred health systems, maximizing community engagement and ownership, and maximizing health equity, gender equality and human rights.

Recent work included in Unitaids's investment case estimated that without innovations in HIV, TB and malaria supported by both organisations it would take 3 more years to achieve the Global Fund's projected reduction in deaths.

G.2. PERFORMANCE DATA FROM GLOBAL FUND

It is difficult to disentangle from Global Fund performance reporting the contribution of innovation work to results. The existing Global Fund Modular Framework for country M&E reporting offers limited insights into the

contribution of innovation to the Global Fund's targets. Where an indicator does exist that allows for isolation of the impact of specific innovations, data reported by countries is too limited to draw conclusions. Additionally, innovation-specific indicators are coverage-focused and not on public health impact. Table G.1 presents indicators and 2020 published data from the Global Fund's 2022 Modular Framework capturing the impact of innovations, and data published from 2020 on the Global Fund results database.

Indicators that do not make a distinction between a conventional and innovative interventions are not included in Table G.1. For example, the number of men who have sex with men that have received an HIV test is not listed below although HIV Self-Testing may count towards this indicator, because it is not possible to determine whether a conventional test or a self-test was used.

Table G.1. Global Fund innovation indicators and performance data

Innovation	Indicator	Indicator description	2020 Data	Notes
PrEP	Percentage of eligible men who have sex with men who initiated oral antiretroviral PrEP during the reporting period	Coverage	Results: 12,194 (numerator only) Thailand: 11,409 South Africa: 752 Senegal: 31 Lesotho: 2	New PrEP formulations not included in this indicator
	Percentage of eligible transgender people who initiated oral antiretroviral PrEP during the reporting period	Coverage	No data	See above
	Percentage of eligible sex workers who initiated oral antiretroviral PrEP during the reporting period	Coverage	Results: 11,358 (numerator only) Zimbabwe: 9,680 South Africa: 1,612 Senegal: 52 Lesotho: 14	See above
	Percentage of eligible adolescent girls and young women who initiated oral antiretroviral PrEP during the reporting period	Coverage	Results: 8,095 (numerator only) South Africa: 8,090 Lesotho: 5	See above Population limited to AGYW in high prevalence settings
	People using pre-exposure prophylaxis	Coverage	Results: 18,905 (numerator only) Viet Nam: 18,378 Cambodia: 278 Georgia: 216 Thailand: 35	
HIVST	Number of individual HIV self-test kits distributed	Coverage	No data available	

Innovation		Indicator	Indicator description	2020 Data	Notes
GeneXpert/ Truenat	Molbio	Percentage of new and relapse TB patients tested using WHO recommended rapid tests at time of diagnosis	Coverage indicator	Results: 234,648 (numerator only) Philippines: 161,809 Thailand: 29,206 Pakistan: 24,311 Zimbabwe: 14,078 Tajikistan: 1,731 Moldova: 1,569 Georgia: 1,394 Armenia: 326 Albania: 138 Cabo Verde: 86	
BDQ		Number of cases with RR-TB and/or MDR/TB that began second-line treatment	Coverage indicator, disaggregated by age, gender, and TB regimen (new TB drugs, short regimens)	Results: 18.905 Data available across 87 countries Top ten: India: 44,670 South Africa: 6,051 Ukraine: 5,321 Kazakhstan: 5,220 Philippines: 5,056 Indonesia: 4,652 Viet Nam: 3,294 Myanmar: 2,357 Pakistan: 2,298 Peru: 1,587	2020 data not disaggregated by regimen, unable to determine relative use of oral BDQ regimens
		Percentage of cases with RR TB and/or MDR-TB successfully treated	Coverage indicator, disaggregated by age. Gender, treatment regimen (shorter 6-9 months, longer individualised) type of provider (public, private)	No data available	
Dual products	AI/ PBO	Existing indicators track distribution of all LLINs without differentiating between pyrethroid treated nets, PBOs, or dual AI nets			
Facility Financing	Level	Percentage of healthcare facilities having performance-based	Coverage, disaggregated by type of provider (public, private) and	No data available	This indicator is specific to performance-based contracts which applies to some FLF

Innovation	Indicator	Indicator description	2020 Data	Notes
	contracts with public entities	level of care (primary, secondary)		approaches but not all (does not apply to direct facility financing)
Mobile financial payments	No indicator			
Virtual services	No indicator			

Indicators tracking coverage of insecticide-treated nets are not included above as they do not differentiate between pyrethroid treated nets, PBOs, or dual AI nets. Additionally, use of mobile financial payments or virtual delivery platforms are not tracked through the Global Fund Modular Framework. Although an indicator measuring coverage of facility level financing does exist, it is specific to performance-based contracts which does not apply to all facility-level financing approaches including DFF. An indicator measuring the percent of facilities with output based contracts might better capture innovations within 'Payment for Results' under the Grant Management Guidelines.

G.3. EVIDENCE OF EFFECTIVENESS AND POTENTIAL IMPACT

All product innovations reviewed in the case studies have strong evidence for effectiveness and WHO policy guidance, with the exception of a conditional WHO policy on PBO nets (to be “considered” under specific conditions), and no WHO policy for AI nets yet. The safety and effectiveness of oral PrEP for example has been demonstrated through multiple randomized controlled trials and studies since its approval, leading to a strong recommendation by WHO in 2015 based on high-quality evidence. For non-product innovations (FLF and mobile payments) evidence of impact is much more limited. Use of virtual interventions is supported by a WHO policy brief, and there is substantial evidence of effectiveness in high-income contexts although more evidence on implementation in LMICs is needed.

Section G.3 summarises evidence around the clinical and public health impact of (i) HIV PrEP; (ii) HIV self testing; (iii) GeneXpert/ Molbio Truenat; (iv) MDR-TB switch to short regimens with BDQ; (v) LLINs – dual AI nets and PBO products; (vi) facility level financing; and (vii) mobile financial payments. Evidence was gathered through stakeholder consultations and document review.

HIV PrEP

PrEP has been shown to be highly effective at reducing risk of HIV, however issues with adherence to PrEP as well as the constellation of factors which increase HIV risk amongst the most vulnerable groups, affect results

In adherent individuals, daily oral PrEP is nearly 100% effective at preventing HIV infection.⁵⁴ Other documented benefits of PrEP include feeling safer during sex, decreased anxiety and improved mental health, decreased HIV stigma, and increased intimacy. PrEP has been shown to empower users by providing them with greater control over their HIV risk, rather than relying on partners to use condoms, take antiretroviral therapy, or accurately disclose their serostatus.⁵⁵

Other PrEP formulations have also been shown to reduce HIV risk effectively, with varying advantages and disadvantages. With regards to the potential impact of the dapivirine ring, two clinical studies with women 18-45 years of found the ring was associated with a 27-35% lower risk of HIV-1 acquisition than women with a placebo ring. Although the protection observed in this trial among high-risk women is significantly lower than risk reduction from oral PrEP for men who have sex with men and heterosexual HIV-1-discordant couples, the ring was developed to be discreet, self-initiated and monthly to increase adherence which was found to be poor among African women

⁵⁴ CDC, (2022) PrEP Effectiveness, CDC.

⁵⁵ Bavinton and Grulic, (2021), “HIV pre-exposure prophylaxis: scaling up for impact now and in the future”. *The Lancet*.

using daily oral PrEP.⁵⁶ A modelling exercise conducted by Avenir Health, FSG, FHI 360, and AVAC estimated that if use of the ring was scaled up in 13 countries in Eastern and Southern Africa from 2018 among medium and high-risk women with 52% ring effectiveness (75% efficacy and 69% adherence), the ring could avert 39,000 new HIV infections by 2030. This is in addition to 68,000 infections averted by oral PrEP, and assuming that all 13 countries achieve 90-90-90 targets.⁵⁷

A meta-analysis of two efficacy studies found a 79% reduction in risk of HIV acquisition among study participants receiving CAB-LA compared to oral PrEP, likely largely due to differences in adherence. While CAB LA has been shown to be highly effective however, there are still important safety and implementation issues including how CAB LA will be delivered in practice within HIV prevention programmes and health systems which may affect scale-up and impact.⁵⁸

HIVST

HIVST has the potential to ensure more equitable access to HIV testing services by reaching key populations and people who have previously not tested for HIV. Evidence generated from HIVST pilots, including STAR3 which was co-funded and supported by the Global Fund, have found that HIVST is safe, effective and acceptable among hard-to-reach populations. The WHO strongly recommended HIVST as a safe and accurate method of HIV testing in 2016, on the basis of moderate-strength evidence.

HIVST volumes have grown significantly from 1 million tests in 2017 to nearly 14 million in 2021. The WHO HIVST demand forecast (produced every 2 years) projects total LMIC demand to reach 27.7 million tests by 2025, which would be a near doubling of the volume procured in 2021. However, uptake has been slow due to the need for evidence in low- and middle income markets with concerns remaining around the safety of blood-based tests. Additionally, the higher unit cost of HIVST in the context of flat-lining global HIV funding necessitated evidence on cost-effectiveness which has been insufficient. While many countries have included HIVST in national HIV testing policies these have not been operationalised. Self-testing's position as an additive rather than a substitution product may also slow down implementation, limiting population impact of the innovation.

GeneXpert/ Molbio Truenat

While in clinical settings rapid molecular tests performed very strongly, the impact on mortality has been lower than hoped for primarily due to challenges with linkage to care.

A WHO-recommended rapid molecular test was used as an initial diagnostic test for 33% of people newly diagnosed with TB in 2020. Results from a systematic review analysing the implementation of GeneXpert for TB testing in LMICs, showed that seven out of 11 studies outlined some sort of public health impact achieved.⁵⁹ Out of the five studies who identified a measurable impact related directly to TB testing using Xpert, three found an increase in identified cases of TB, one for DR-TB and one MDR-TB.

The review identified two main barriers to the identification of active TB cases through rapid molecular testing: the underutilisation of Xpert and the inadequate identification of eligible patients. These barriers were frequently due to a lack of communication/referral pathways between health centers and laboratories and inadequate training to support staff knowledge of testing. The review suggests success relies on an integrated and coordinated approach when implementing Xpert models into a health setting.

⁵⁶ Annalene Nel et al. (2016), 'Safety and efficacy of a dapivirine vaginal ring for HIV prevention in women', N Engl J Med 2016; 375:2133-2143.

⁵⁷ Avenir Health, FHI360 and AVAC (2019), 'Modelling the potential impact of the Dapivirine ring for HIV prevention', PrEPWatch.

⁵⁸ WHO (2022), Long-Acting Injectable Cabotegravir for HIV Prevention.

⁵⁹ Brown et al. (2021), Implementation of GeneXpert for TB Testing in Low- and Middle-Income Countries: A Systematic Review

Stakeholder interviews through the innovation case study highlighted that although GeneXpert increases confirmed cases it doesn't necessarily translate to successful treatment and lower mortality, corroborated by medical literature.⁶⁰

Short regimens with BDQ to treat MDR-TB

BDQ containing regimens are shorter and less toxic than injectable treatment courses for drug-resistant TB, leading to improved outcomes. Outside of trials however, uptake has been limited due to high prices and early safety concerns.

In 2018, treatment success rates for patients with drug-susceptible TB were 85%, whereas the treatment success rate for those with MDR-TB was 57%.⁶¹ In 2019, an estimated 500,000 people developed DR-TB and 182,000 died globally.⁶²

The endTB Observational Study Team commissioned Franke et al. to investigate the effectiveness of BDQ and delamanid in treatment of MDR-TB. 1,109 patients with RR-TB or MDR-TB were treated with BDQ and/or delamanid containing regimens according to WHO guidance. 73% of patients initiated a multidrug treatment containing BDQ. Of the whole cohort, 85% experienced culture conversion within 6 months comparable to rates for treatment of DS-TB.

A stakeholder from the National Centre for Disease Control in Georgia reported that *“shorter regimens have contributed to good treatment outcomes... there are less adverse drug reactions... not having to inject every day has improved compliance to treatment and to complete treatment.”* Loss to follow up for MDR-TB patients reduced from 35% in 2014 to 19% in 2019, and treatment success improved from 43% in 2013 to 67% in 2018 which has been attributed to the switch to oral shorter regimens by stakeholders aided by virtual service delivery.

LLINs: dual AI nets and PBO products

In response to the rapid spread of pyrethroid-resistant vectors, PBO treated nets have been shown to have an impact on epidemiological outcomes and dual AI treated nets have demonstrated efficacy in entomological studies. However, further evidence of epidemiological impact is needed for scale-up and WHO recommendation.

Insecticide-treated nets (ITNs) and, more recently, long-lasting insecticidal nets (LLINs) are the most widely used preventive measure for controlling malaria. Pyrethroids are currently the only type of insecticide used routinely on ITNs (or LLINs) and the rapid spread of pyrethroid-resistant vectors seriously threatens to reverse the gains achieved so far.⁶³ Several studies have demonstrated that ITNs treated with pyrethroids are becoming less effective at killing mosquitoes in areas of high resistance compared to areas of susceptibility⁶⁴, although epidemiological evidence remains inconclusive. The first nets to contain a mixture of active ingredients with evidence for impact on epidemiological outcomes were nets that combined a pyrethroid insecticide with the synergist piperonyl butoxide (PBO) which restores susceptibility to pyrethroid by neutralising mixed-function oxidase function responsible for resistance in vectors.⁶⁵ New classes of ITNs combining two insecticides with differing modes of action could have the potential to improve vector control and delay the evolution of resistance and preserve the lifespan of both active ingredients (AI). The two most advanced products are the pyrethroid-pyriproxyfen LLIN (Olyset® Duo and Royal

⁶⁰ Umubyeyi et al. (2016), The role of technical assistance in expanding access to Xpert MTB/RIF: experience in sub-Saharan Africa.

⁶¹ WHO (2020), Global Tuberculosis Report.

⁶² Global Fund (2020), Why drug-resistant tuberculosis poses a major risk to global health security, available [online](#).

⁶³ Ranson H, N'guessan R, Lines J, Moiroux N, Nkuni Z, Corbel V. Pyrethroid resistance in African anopheline mosquitoes: what are the implications for malaria control? Trends Parasitol. 2011;27:91–8

⁶⁴ Asidi A, N'Guessan R, Akogbeto M, Curtis C, Rowland M. Loss of household protection from use of insecticide-treated nets against pyrethroid-resistant mosquitoes, Benin. Emerg Infect Dis. 2012;18:1101–6

⁶⁵ Protopopoff N, Mosha JF, Lukole E, Charlwood JD, Wright A, Mwalimu CD, et al. Effectiveness of a long-lasting piperonyl butoxide-treated insecticidal net and indoor residual spray interventions, separately and together, against malaria transmitted by pyrethroid-resistant mosquitoes: a cluster, randomised controlled, two-by-two factorial design trial. Lancet Lond Engl. 2018;391:1577–88

Guard®) and a pyrethroid-chlorfenapyr LLIN (Interceptor® G2).⁶⁶ While both types of ITNs had – by 2017/8 – demonstrated improved efficacy in entomological studies, there was so far limited epidemiological, cost and operational evidence to enable further scale up and related, a WHO recommendation.

Facility level financing

Despite plentiful interest in performance-based funding (PBF) approaches among development organisations, direct facility financing (DFF) interventions and assessments remain somewhat limited to date both within and beyond the Global Fund. Most stakeholders held the view that DFF can have a positive impact, but emphasised that this was specific to certain contexts and outcomes.

The Global Fund has amassed comparisons from global health literature on performance based financing and DFF in Benin, Cameroon, DRC, Nigeria and Zambia implemented between 2015-2018. It brought together this data to understand the impact of each approach on (i) health service utilisation and delivery; (ii) quality of care; (iii) health outcomes; and (iv) facility autonomy. In the vast majority of cases the results were inconclusive or not assessed, though DFF was found to be preferable for points (i) and (iii) above in DRC.⁶⁷

World Bank analysis have suggested the impacts of PBF and DFF are variable across different outcomes, and tend not to be statistically significant. A point frequently highlight is that DFF comes at a much lower cost than PBF due to lower resource requirements for verification. However, the two approaches are often considered to have relatively similar impacts.

Mobile payments

Mobile money deployment remains at a relatively early stage within the Global Fund and among key partners, and results from deployment are limited. From stakeholders, we understand that the Global Fund is monitoring pilots to a degree but saw no evidence of a coordinated evaluation that would capture insights from experience across piloted countries or pre-defined measures against which the impact of the pilots would be assessed.

The Gates Foundation have brought together results of their digital payments for campaign health workers across 19 countries. Noting further research is required, their evidence suggests that workers place high value on timely payments which can be enabled by mobile money. Further, that this could positively impact attendance.⁶⁸

Virtual services for HIV delivery

Virtual interventions have the potential to expand access to HIV services, create efficiencies in health systems, and improve HIV outcomes. However implementation research in LMICs has been limited and concerns persist around potential harms related to equity in digital access and data privacy.

Virtual interventions- interventions which use virtual channels to create demand for services, reach, and engage clients in services- have become increasingly more common in the last decade. Virtual interventions enable healthcare to be decentralized and patient-centred, allowing for differentiated case management and for clients to access services virtually or anonymously outside of facilities if preferred. Virtual interventions may also improve efficiencies within health systems and facilities.⁶⁹

A systematic review of interactive virtual interventions have shown a positive effect on HIV knowledge and prevention behaviours compared with minimal interventions (leaflets, waiting lists), and no evidence of difference between interactive digital interventions and face-to-face interventions.⁷⁰ Systematic reviews have shown that eHealth

⁶⁶ N'Guessan R, Odjo A, Ngufor C, Malone D, Rowland M. A Chlorfenapyr mixture net interceptor® G2 shows high efficacy and wash durability against resistant mosquitoes in West Africa. PLoS One. 2016;11:e0165925.

⁶⁷ Witter, Bertone & Diabonu, 2021, Review of Global Fund experience with facility-level financing: summary for Brown Bag lunch.

⁶⁸ The Gates Foundation, 2022, Digital Payments for Health Workers

⁶⁹ WHO and UNAIDS, 2022, Policy Brief: Virtual interventions in response to HIV, sexually transmitted infections and viral hepatitis, 2022.

⁷⁰ Bailey et al, 2021, Interactive digital interventions for prevention of sexually transmitted HIV. AIDS. 35(4):643–653.

interventions increase HIV testing among MSM⁷¹, and that mHealth interventions also increase HIV testing among MSM and other higher-risk populations.⁷² Although the majority of included studies in the above systematic reviews were done in the United States, a review of mHealth interventions in Asia also found an improvement in antiretroviral therapy adherence among PLHIV.⁷³ SelfCare, a virtual intervention for the distribution of HIV self-testing in the Philippines, successfully reached 5,279 clients with kits, 1,804 of whom reported results and 8.09% of whom tested positive for HIV.⁷⁴

Generally however, research on implementation of virtual services is still lacking in LMICs and stakeholders interviewed pointed to concerns around equity in digital access (particularly in sub-Saharan Africa), data privacy and capacity. In 2022, FHI360 funded by USAID/ PEPFAR conducted a landscape analysis of 16 countries in Sub-Saharan Africa to identify countries with the highest potential for using virtual channels to support demand and service delivery (specially related to the dapivirine PrEP ring). The analysis found that overall mobile connectivity reaches 28% of the population in Africa with significant coverage gaps and between rural and urban areas and gender posing a risk to population impact. However the analysis also found that eHealth and mHealth activities are rapidly expanding across Africa, largely based on country gross national income, with South Africa and Botswana classified as high potential countries.⁷⁵

⁷¹ Long et al., 2019, A systematic review of eHealth interventions addressing HIV/STI prevention among men who have sex with men. *AIDS Behav.*23(9):2253–2272.

⁷² Horvath KJ et al., 2020, A systematic review of technology-assisted HIV testing interventions. *Curr HIV/AIDS Rep.*17:269–280.

⁷³ Adil M, et al. 2020, Effect of mobile health interventions on adherence of anti-retroviral therapy in HIV infected Asian patients: a systematic review and meta-analysis. *Int J Infect Dis.*101(Suppl. 1):205.

⁷⁴ WHO and UNAIDS, 2022, Policy Brief: Virtual interventions.

⁷⁵ FHI360, 2022. Digital Health Landscape Report: PROMISE 2021 Digital Health Landscape Report for Introduction of New HIV Prevention Products in Africa. [resource-going-online-digital-health-landscaping-report.pdf \(fhi360.org\)](https://fhi360.org/resource-going-online-digital-health-landscaping-report.pdf).

Appendix H INNOVATION CASE STUDIES

1. HIV PRE-EXPOSURE PROPHYLAXIS (PREP)

Context/ background: PrEP is the use of antiretroviral medication by HIV-negative people to reduce the risk of HIV infection. WHO first recommended oral PrEP in 2012 for select populations based on available evidence, and in 2015 expanded this guidance, recommending PrEP be offered to all groups at substantial risk of HIV infection. Uptake has been slow however. By 2020 around 1 million people had initiated PrEP in LMICs falling significantly short of the UNAIDS goal of 3 million people by 2020, and scale-up remains concentrated within a small number of countries.

Global Fund role and funding to date: Under NFM3 (2021-2023), \$17.9m in funding requests for PrEP were approved. This is an increase from the NFM2 allocation (2018-2020) financing of \$11m in PrEP, with a reach of 20,000 people. Given rising HIV infections in some contexts and the high burden of HIV, the limited deployment of PrEP is regarded as a missed opportunity.

Successes and enablers

- There is a robust product pipeline for HIV PrEP including novel long-acting products. WHO has responded with guidelines to adapt to these products
- The Global Fund has taken measures to address slow PrEP uptake including improvement of data visibility and staffing changes

Challenges and barriers

- Low country demand for PrEP, driven by stigma and negative community perceptions of PrEP, mis-messaging with regard to PrEP costing and use, and weak HIV prevention systems
- Slow adoption and operationalization of evolving guidance from WHO into national guidelines
- Poor end-user engagement across the value chain of introduction activities
- Lack of advance planning and weakly coordinated oral PrEP introduction, overuse of pilot studies
- Deficit in ambition on PrEP among national, civil society and global stakeholders including the Global Fund
- Global Fund factors- internal dialogue on prioritization of prevention interventions conflicted, stronger position and guidance needed to promote uptake, lack of visibility on PrEP demand from funding requests, weak CCM incentive to move away from standard approaches and set ambitious PrEP targets.

Lessons learnt

- The experience of PrEP may be the strongest example of the Global Fund CCM and country driven model being weakly incentivized to introduce innovative approaches
- The Global Fund has an important role to play in signalling a strong and clear position to increase country demand and deployment of PrEP, with significant scope to coordinate more effectively with partners on PrEP scale up and introduction of the dapivirine ring and CAB-LA
- Low uptake in PrEP is contextualised within broadly weak HIV prevention systems which will also need to be strengthened to accelerate PrEP uptake

1.1. BACKGROUND

Rationale for PrEP

An estimated 28 million new HIV infections in LMICs will need to be averted between 2015 and 2030 in order to meet global targets and end the AIDS epidemic by 2030. Scaling up of HIV pre-exposure prophylaxis (PrEP) is critical to meeting that goal.⁷⁶

Why Pre-Exposure Prophylaxis (PrEP): PrEP is the use of antiretroviral medication by HIV-negative people to reduce the likelihood of HIV acquisition. Daily oral PrEP is nearly 100% effective and the WHO recommends PrEP be offered to all population groups at substantial risk of HIV infection and individuals who may request it.^{77,78} Other documented benefits of PrEP include feeling safer during sex, decreased anxiety and improved mental health, decreased HIV stigma, and increased intimacy. PrEP has been shown to empower users by providing them with greater control over their health, rather than relying on partners to use condoms, take antiretroviral therapy, or accurately disclose their serostatus.⁷⁹ Agency to reduce one's likelihood of HIV acquisition offered by PrEP is profoundly important for adolescent girls and young women (AGYW) and key population groups.

The number of people taking PrEP fell significantly short of the UNAIDS goal of 3 million people by 2020⁸⁰

- Globally the number of people taking PrEP has risen 49% between 2019 and 2020. In absolute numbers uptake remains low however and by early 2021, around 1 million people in LMICs had initiated or reinstituted oral PrEP.
- Scale up is concentrated in a small number of countries, with 6 countries accounting for over 80% of PrEP users in 2020.⁸¹ The rate of PrEP uptake in African countries is still too slow to expect a substantial population impact on the HIV epidemic. Many countries in the Asia Pacific region have introduced PrEP, with the largest programs existing in Thailand and Vietnam, though coverage of rural areas is still very limited across the region.⁸²

Global and national PrEP policy

Table 1.1: Key milestones for PrEP recommendations⁸³

Year	FDA approval and WHO recommendations
2012	FDA approved the first drug for use as HIV PrEP. (oral emtricitabine/tenofovir disoproxil fumarate, brand name Truvada). ⁸⁴
2012	WHO conditionally recommended offering oral PrEP as a possible additional intervention for uninfected partners in serodiscordant couples, and men and transgender women who have sex with men when additional HIV prevention choices are needed. WHO recommended that

⁷⁶ UNAIDS (2014), Fast-track: ending the AIDS epidemic by 2030.

⁷⁷ CDC (2022), PrEP Effectiveness, <https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.html#:~:text=How%20effective%20is%20PrEP%3F,99%25%20when%20taken%20as%20prescribed>. Accessed 3 August 2022.

⁷⁸ WHO (2022), <https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/prevention/pre-exposure-prophylaxis>. Accessed 3 August, 2022.

⁷⁹ Bavinton and Grulich, (2021), "HIV pre-exposure prophylaxis: scaling up for impact now and in the future". *The Lancet*.

⁸⁰ UNAIDS, (2020), HIV Prevention 2020 Road Map.

⁸¹ Segal, Kate (2021), "Evolution of Oral PrEP Access: Tracking trends in global oral PrEP use over time", HIV R4P Conference.

⁸² Bavinton and Grulich, (2021), "HIV pre-exposure prophylaxis: scaling up for impact now and in the future". *The Lancet*.

⁸³ WHO, Global HIV Programme, Pre-exposure prophylaxis (PrEP) <https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/prevention/pre-exposure-prophylaxis>. Accessed 3 August, 2022.

⁸⁴ PrEPWatch (2022), About Oral PrEP, <https://www.prepwatch.org/about-prep/oral-prep/>. Accessed 3 August 2022.

Year	FDA approval and WHO recommendations
	countries introducing oral PrEP should undertake demonstration projects to ascertain the most appropriate groups and best delivery approaches.
2014	WHO recommended offering oral PrEP to men who have sex with men. WHO recommended that all people at substantial risk of HIV infection be offered oral PrEP containing tenofovir disoproxil fumarate (TDF). WHO guidelines suggest that PrEP should be an additional prevention choice in a package of services.
2015	WHO recommended that all people at substantial risk of HIV infection be offered oral PrEP containing tenofovir disoproxil fumarate (TDF). WHO guidelines suggest that PrEP should be an additional prevention choice in a package of services. ^{85,86}
2017	WHO developed a tool to provide additional guidance to countries and support implementation of PrEP among a range of populations in different settings. ⁸⁷
2019	WHO released a technical brief updating WHO recommendations on oral PrEP to include an option of event-driven dosing for men who have sex with men. ⁸⁸
2021	WHO recommended the dapivirine ring be offered as an additional prevention choice for women at substantial risk of HIV as part of combination prevention approaches.
2021	WHO released consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring which included guidelines on oral PrEP, event-driven dosing and the dapivirine ring. ⁸⁹ FDA approved CAB-LA for use in at-risk adults and adolescents.
2022	WHO conditionally recommended CAB-LA as an additional prevention choice for people at substantial risk of HIV infection
2022	WHO recommendation on simplified oral PrEP regimen

Figure 1.1 demonstrates that there has been a significant increase in the number of countries with guidelines supporting PrEP following WHO guidelines in 2015, however scale-up of PrEP is limited to a small number of countries. In 2020, 130 countries reported having national guidelines incorporating oral PrEP according to WHO recommendations and 23 countries reported planned adoption in the next two years.⁹⁰ The number of people receiving PrEP varies significantly, with fewer people on PrEP in many high-incidence countries in sub-Saharan Africa and Asia.

Figure 1.1: Countries with guidelines supporting PrEP and number of oral PrEP users by country (2020)

⁸⁵ The prevention package of services includes HIV testing, counselling, male and female condoms, lubricants, ARV treatment for partners with HIV infection, VMMC, and harm reduction for people who use drugs.

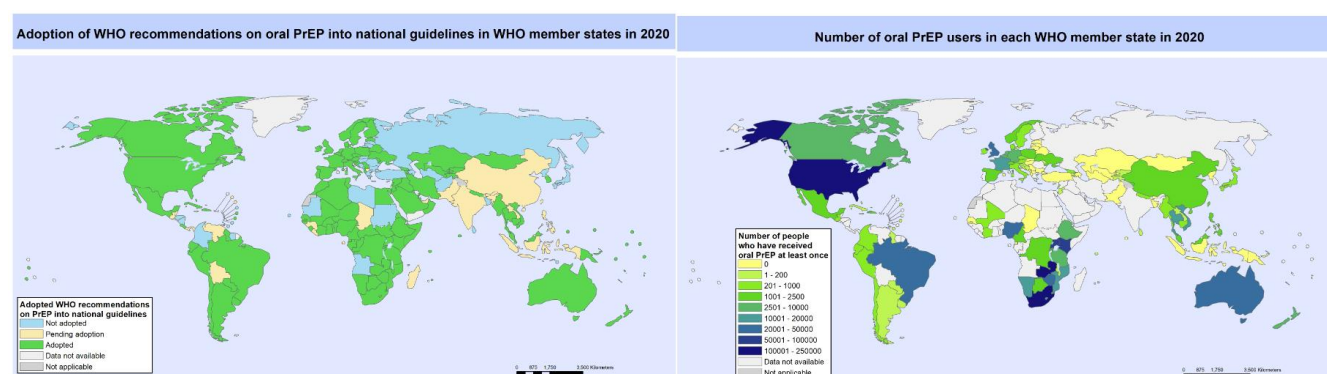
⁸⁶ WHO, (2015), Policy Brief: WHO Expands Recommendation on Oral PrEP.

⁸⁷ WHO, (2017), PrEP Implementation Tool.

⁸⁸ WHO, (2019), Technical Brief, What's the 2+1+1? Event-driven oral Pre-Exposure Prophylaxis to prevent HIV for men who have sex with men: Update to WHO'S recommendation on oral PrEP.

⁸⁹ WHO (2021), Consolidated Guidelines on HIV prevention, testing, treatment, service delivery and monitoring: Recommendations for a public health approach.

⁹⁰ WHO, (2022), Global State of PrEP, <https://www.who.int/groups/global-prep-network/global-state-of-prep>. Accessed 3 August 2022.



PrEP products and market

There is a robust product pipeline for HIV prevention including novel long-acting products to expand user choice with more acceptable options and reduce barriers associated with oral PrEP use. Table 1.2 summarises key information about PrEP options currently on the market.

Table 1.2: PrEP products in the LMIC market

Product	Regimen	Developer	Eligibility (WHO or GHTF countries)	Efficacy	LMIC Price (USD)	Key Issues
Oral PrEP-Truvada (300 mg TDF/ 200 mg FTC)	Daily or event-driven ⁹¹	Gilead	2012- FDA approval 2014/2015- WHO recommendation	99%	GF pooled procurement reference pricing- \$4.25 per month ⁹²	Low adherence common due to issues around access and stigma, resistance risk
Oral PrEP-generics	Daily or event-driven	Multiple manufacturers	2010-2020- 11 products have WHO PQ	99%	To be confirmed	See above.
Oral PrEP-Descovy (25 mg TAF/200 mg FTC)	Daily or event-driven	Gilead	2019- FDA approval	99% (DISCOVER PrEP trial showed non-inferior efficacy to daily TDF/FTC)	To be confirmed (see price above)	See above. Also limited evidence among cisgender women*
Oral PrEP-generics	Daily or event-driven	Multiple manufacturers	2010-2020- 11 products have WHO PQ	99%		See above.
Dapvirine vaginal ring- (25 mg Dapivirine)	Monthly	International Partnership for Microbicides Janssen Pharmaceutical Companies	2021- WHO PQ and WHO recommendation for women where oral PrEP is not available (2021)	~ 30% ⁹³	\$13 per ring/ month ⁹⁴	Lower effectiveness (unclear if PEPFAR will fund)

⁹¹ Event-driven dosing, recommended for cisgender men who have sex with men, consists of a double dose of oral PrEP 2-24 hours before sex, followed by a third dose 23 hours after the first two doses, and a fourth dose 48 hours after the first two doses.

⁹² Global Fund (2022) Pooled Procurement Mechanism Reference Pricing: ARVs, https://www.theglobalfund.org/media/5813/ppm_arvreferencepricing_table_en.pdf.

⁹³ WHO (2021), WHO recommends dapivirine vaginal ring, [available online](#).

⁹⁴ CHAI (2021), HIV Market Report.

Product	Regimen	Developer	Eligibility (WHO or GHTF countries)	Efficacy	LMIC Price (USD)	Key Issues
Injectable Long-acting Cabotegravir (CAB-LA)- Apretude (600 mg cabotegravir)	Every 8 weeks	ViiV Healthcare	2021- FDA approval 2022 WHO conditional recommendation	79% reduction in risk of HIV acquisition among study participants receiving CAB-LA when compared to oral TDF/FTC ⁹⁵⁹⁶		Conditionality of WHO recommendation based on lack of implementation data within certain populations

*trials are underway to test Descovy among cisgender women

A number of PrEP products are at the clinical or preclinical stage. Trials have begun to investigate once-monthly oral PrEP formulations and six-month subcutaneous injectable forms of PrEP. CHAI in addition to a coalition of partners⁹⁷ is supporting the development and introduction of a dual prevention pill, which is a co-formulated tablet combining TDF/FTC and hormonal contraception.⁹⁸ A landscape report on multipurpose prevention technologies published by Unitaaid and ClIFF in 2021 identified nine products aimed at prevention of HIV and pregnancy at the preclinical stage and one product in Phase 1 clinical trials.⁹⁹

1.2. GLOBAL FUND SUPPORT FOR PREP

2018-2021 (including NFM2 and NFM3 cycles)

For NFM2 (2018-2020) the Global Fund financed \$11m in PrEP. This was approximately 1.5% of the Global Fund's HIV primary prevention spending. Two percent (2%) of the funding for AGYW interventions went to PrEP, and 9% of the funding for KP interventions (SWs and MSM, TG programs not funded for PrEP). The absorption rate for PrEP services was low at 50% and trailed behind other prevention pillars (AGYW, condoms, KPs, VMMC).

PrEP was rolled out at a relatively small scale across Global Fund programmes. In terms of coverage, more than 20,000 people were recorded as receiving access to PrEP services in 2019 across five countries.

- Three countries in particular were responsible for the majority of figures in 2019, namely Thailand (~12,400), Zimbabwe (~5,500) and Viet Nam (~7,500).¹⁰⁰
- These figures show that the rollout of PrEP within Global Fund-supported programmes was relatively low, especially when compared to PEPFAR where data for the fourth quarter of 2019 suggested that more than 106,500 people were accessing PrEP through their programmes.¹⁰¹
- Overall, PrEP rollout among Global Fund programmes is viewed by stakeholders as limited, and where it has been implemented this has largely been on a pilot basis.¹⁰² Positive examples of Global Fund support for

⁹⁵ Differences are likely due to effective use of oral PrEP rather than differences in efficacy.

⁹⁶ WHO (2022), Guidelines on long-acting injectable cabotegravir for HIV prevention, [available online](#).

⁹⁷ Partners include AVAC, Mann Global Health, Viartis and the Population Council with funding from the Children's Investment Fund Foundation, the Bill & Melinda Gates Foundation, USAID, and WCG Cares.

⁹⁸ CHAI (2021), HIV Market Report.

⁹⁹ Unitaaid and ClIFF (2021), Technology Landscape and Potential for Low- and Middle-Income countries: Multipurpose Prevention Technologies.

¹⁰⁰ Global Fund Data Explorer (2019), <https://data.theglobalfund.org/results>. Accessed 03/08/2022.

¹⁰¹ CEPA (2021), Technical Evaluation Reference Group: Thematic Review on HIV Primary Prevention.

¹⁰² CEPA (2021), Technical Evaluation Reference Group: Thematic Review on HIV Primary Prevention.

PrEP included early investment in South Africa, regarded as suitably flexible when few countries had PrEP experience.

The 2019 Information Note included PrEP as a prioritised intervention in guidance to countries for NFM3 funding cycle.¹⁰³ The Information Note advised that scale-up of PrEP should be “effectively targeted for people at increased risk in all epidemic settings especially MSM, trans women and sex workers, and AGYW in some settings in East and Southern Africa”. Country requests were encouraged to refer to normative guidance to determine the HIV incidence threshold for which providing PrEP is cost-effective, and to consult 2017 WHO guidance (Implementation Tool for PrEP of HIV infection) when preparing funding requests.^{104,105,106}

1.3. ASSESSMENT OF BARRIERS AND ENABLERS

This section provides an overview of key enablers and barriers to the Global Fund’s deployment of PrEP. Given the very low funding of PrEP by the Global Fund, this section focuses primarily on understanding the barriers to the Global Fund’s equitable deployment of PrEP both external and internal to the Global Fund. Stakeholders have pointed to an evolution in the Global Fund’s approach to accelerating scale-up of PrEP in the last year. These changes, still under development, are presented as enablers.

Barriers

- **Stakeholders cited numerous factors which converge to dampen country demand for PrEP, notably:**
 - Negative community perceptions of PrEP, resulting from initial positioning of PrEP as a service for MSM, as well as beliefs attached to sexuality among AGYW/youth and to the behaviours of high-risk groups (e.g. female sex workers and other KP).¹⁰⁷ Amongst certain groups, particularly vulnerable AGYW, stigma is also attached to the daily oral PrEP regimen given similarities to HIV treatment. For countries with significant KP epidemics, political barriers are also a factor, despite a number of country stakeholders recognising the demand for it.¹⁰⁸
 - Misperception that PrEP is a long-term intervention, and therefore high cost. Stakeholders view that initial messaging to policymakers on PrEP and PrEP cost-effectiveness was poorly communicated. Given the need to keep people on treatment and the context of a restricted budget landscape, use of ARVs for prevention is deprioritized. WHO revised guidance on a simplified oral PrEP regimen (released July 2022) is regarded as an opportunity to revitalize communication with policy makers on PrEP costs and benefits.
 - Weak HIV prevention systems in countries. As a whole HIV prevention programs suffer from under-funding and consequently lack robust consumer insights, provider training and market data. In Indonesia, system readiness for PrEP was viewed as a barrier to scale up, with a need to focus on operations, logistics and distribution, health workers guidance and counselling capacities, targeting and follow up of recipients, monitoring, reporting, amongst others. As demonstrated in Figure 1.1 above, the number of countries that have incorporated oral PrEP within national guidelines per

¹⁰³ Global Fund (2019), HIV Information Note.

¹⁰⁴ WHO (2017), Implementation tool for PrEP of HIV Infection, <https://apps.who.int/iris/bitstream/handle/10665/258515/WHO-HIV-2017.29-eng.pdf?sequence=1&isAllowed=y>

¹⁰⁵ Global Fund (2020), Technical Brief: HIV Programming for AGYW in High-HIV Burden Settings.

¹⁰⁶ Global Fund (2019), Technical Brief: HIV and key populations.

¹⁰⁷ For instance, belief that PrEP promotes promiscuous sexual activity, belief that PrEP will increase STI incidence or prevalence rates.

¹⁰⁸ EHG (2022), Unitaid PrEP end-of-grant evaluations.

WHO's recommendation has grown but operationalisation lags behind because of system-wide challenges.

- **Lack of advance planning and weakly coordinated oral PrEP introduction.** LMIC introduction of oral PrEP was delayed after WHO recommendation due to: i) limited research to identify and understand potential users, ii) lack of coordination for demonstration projects; iii) few tools for country-level decision makers; iv) failure to invest in strategic demand creation (relevant also to the above barrier of weak HIV prevention systems).¹⁰⁹
- **Stakeholders regard PrEP as having suffered from overuse of pilots, hampering scale.** Many countries prefer to implement pilot programmes to generate data on its impact and implementation challenges in the local context. However, while there are benefits to this approach this can delay scale-up further when there is already sufficient evidence from other countries, and strong guidance from WHO. Stakeholders felt that in the case of PrEP, demonstration projects were uncoordinated, duplicated efforts, and did not answer key implementation questions from donors and governments.
- **Weak stakeholder alignment to prioritize PrEP with deficit of global ambition.** Weak support for PrEP in most high burden countries is underpinned by the absence of a comprehensive roadmap for overcoming demand and delivery challenges, and insufficient prioritization amongst national and global stakeholders. Consultations underscored the complexity of barriers to deployment of PrEP across the categories of the innovation value chain, including disparate views amongst stakeholders involved in HIV responses of the extent to which PrEP should be prioritized within the basket of HIV prevention services.
- **Poor investment in raising awareness about PrEP.** There is a lack of knowledge and confidence among key populations about PrEP. Limited community demand or understanding of innovative products means that there is less demand and pressure on decision-makers to scale-up. In comparison, access to ARTs was accelerated through powerful rights-based advocacy. Failure amongst HIV stakeholders to successfully address these community barriers have contributed to suppressed demand for PrEP. In Georgia, stakeholders identified high levels of homophobia, stigma and discrimination as the main barrier with respect to accessing and taking up PrEP. In Indonesia, community engagement and empowerment are both seen as critical for the creation of demand. Slow growth in community demand, owing primarily to stigmatisation, is seen as the key barrier to scale up in Indonesia (as one consultee describes it – *‘If the government see the people want it, they will find the money.’*)
- **Global Fund factors.** Internal dialogue within the Global Fund has been conflicted on prevention priorities and country teams have different levels of understanding of PrEP (owing to diversity in their technical backgrounds). Stronger communication of HIV prevention priorities and a clear vision of PrEP's place in funding requests is needed, particularly given the context of underfunding for HIV prevention and insufficient awareness, technical support and guidance at country level which underpin low demand. Additionally, there is a lack of visibility on metrics related to PrEP throughout various levels of the Global Fund: procurement data do not show the proportion of ARVs being used for PrEP, making it challenging to track deployment of PrEP. Monitoring of PrEP is complex, including that discontinuation is not a failure of PrEP for example. To an extent, Global Fund reliance on country M&E processes makes it difficult to implement program monitoring that may be more useful.
- **CCM related factors.** Against the challenging backdrop described above, the CCM is regarded as lacking inducement needed to set ambitious goals for PrEP within funding requests. Specific barriers within the CCM raised in consultations included the composition of CCMs as lacking influential voices on PrEP, comfort with the 'status quo' of funding flows to PRs/SRs, and desire to continue with approaches that are performing well per Global Fund metrics. There is also a view that PEPFAR's significantly higher country funding for PrEP

¹⁰⁹ AVAC and CHAI (2020), HIV Prevention Market Manager Summary.

complements Global Fund financing, reducing the impetus for Global Fund grants to fund PrEP. These barriers are linked, to a degree, to an overall risk aversion within funding proposals and prioritisation of constrained resources to HIV treatment.

Enablers

- **There has been demonstrable recognition in the last year that the Global Fund has not taken a strong enough position to support the rapid and equitable deployment of PrEP, and changes are under development to address this.** Consultees noted that the Global Fund has engaged with stakeholders regarding how to avoid the same delays in deployment of CAB-LA as experienced in the implementation of oral PrEP. Recent enablers in regards to deployment of PrEP include:
 - KPIs have been developed to closely monitor PrEP, with data disaggregated by population group. Changes to Global Fund information systems are planned to disaggregate PrEP from ART beneficiaries in grants.
 - A new position has been created within the Global Fund Secretariat through Bill & Melinda Gates Foundation support, focused on introducing HIV prevention products.
 - In order to speed up the introduction and scale-up of new PrEP products such as CAB-LA and the dapivirine ring, planning is in place to ensure that more of the innovation introduction steps occur concurrently. For example, the Global Fund has supported implementation research on client preferences in South Africa with Unitaid. Prior to CAB-LA receiving WHO recommendation the Global Fund was working in Mozambique to accelerate donations of CAB-LA for the purpose of operational research.
 - The new HIV information note for NFM4 contains language articulating that PrEP is a ‘programme essential’, defined as key evidence-based interventions and approaches all applicants are expected to address. In funding allocation requests for the 2023-2025 period, applications must outline how they will advance implementation of PrEP. This specifically includes all modalities of PrEP recommended by WHO, such as the dapivirine ring and CAB-LA.¹¹⁰

Figure 1.2: Barriers and Enablers to the Global Fund equitable deployment of PrEP

Factors	Global prioritisation/ perceived value	Normative guidance	Market/ supply characteristics	Price, affordability and cost effectiveness	Country demand and readiness	Implementation
Barriers	<ul style="list-style-type: none"> • Perceived issues of stigma and risk • Deficit of global ambition on PrEP, including by GF 	<ul style="list-style-type: none"> • Initial 2012 WHO guidance prioritizing PrEP for MSM linked to community stigma and political hesitancy on oral PrEP 	<ul style="list-style-type: none"> • IPM withdrawal of dapivirine ring from US FDA review based on US HIV epi landscape [has WHO PQ] • PEPFAR-procured products need FDA approval 	<ul style="list-style-type: none"> • Misperception that oral PrEP is a <u>long term</u> intervention and with high cost • Higher price of <u>dapivirine ring</u> and CAB-LA 	<ul style="list-style-type: none"> • Some countries with policy updates but limited <u>operationalisation</u> • Weak national HIV prevention systems • Limited demand creation 	<ul style="list-style-type: none"> • Weakly coordinated oral PrEP introduction- ‘<u>pilotitis</u>’ • Limited voice for PrEP amongst CCM or incentive to move away from standard approaches
Enablers	<ul style="list-style-type: none"> • In the last year, changes underway in the Global Fund to strengthen position on PrEP and accelerate scale-up 	<ul style="list-style-type: none"> • 2015 WHO recommendation for all groups at substantial risk of HIV • 2021 WHO guidance on vaginal ring, PQ • 2022 WHO guidance on CAB-LA and revisions for oral PrEP 	<ul style="list-style-type: none"> • Robust product pipeline including novel long-acting products and MPTs to expand user choice and reduce barriers associated with oral PrEP use 	<ul style="list-style-type: none"> • CAB-LA voluntary licensing agreement for 90 LMICs for generic manufacturing • GF and technical partners convening Coalition to Accelerate Access to Long-Acting PrEP 	<ul style="list-style-type: none"> • Stronger guidance under NFM3 for roll-out of PrEP • Countries have requested funding for new PrEP options 	<ul style="list-style-type: none"> • Pro-active advocacy and demand creation interventions successfully increasing uptake

¹¹⁰ Global Fund (2022), HIV Information Note.

1.4. LESSONS LEARNT FROM PrEP FOR THE GLOBAL FUND'S APPROACH TO INNOVATIONS

Given rising HIV infections in some contexts and the high burden of HIV, the Global Fund's limited deployment of PrEP is regarded as a missed opportunity for reducing the number of new HIV infections. In July 2022, WHO released guidelines recommending the use of injectable CAB-LA as a new method of PrEP with high effectiveness, and for differentiated and simplified oral PrEP implementation. While countries are sensitized (to a degree) on PrEP services, CAB-LA will still require changes to service models given the different regimen and route of administration. The recent or near-term changes underway within the Global Fund noted as potential enablers in the previous section are certainly timely with the view to the Global Fund responding to the newest PrEP guidance and addressing continuing barriers with PrEP deployment. Lessons learned from the PrEP case study include the following:

- **The experience of PrEP may be the strongest example of the Global Fund CCM and country driven model being weakly incentivized to introduce innovative approaches due to the additional effect of stigma and low community demand.** The Global Fund therefore has an important role to play in signalling a clear position to increase country demand and deployment of PrEP. Guidance in the 2022 HIV information note is a step towards such clearer positioning. Still, in the context of insufficient HIV resources and emphasis within national HIV programmes on treatment, there is likely still a need to engage CCMs in setting more ambitious PrEP goals and engaging on cost-effectiveness of PrEP and the importance of method choice. In this regard, a stronger civil society effort to increase demand and accountability for PrEP and bring a level of urgency to HIV prevention as achieved for access to treatment is crucial.
- **Low uptake of PrEP is contextualised within broadly weak HIV prevention systems where the Global Fund could assume a greater leadership role.** Stakeholders felt that a comparative advantage of the Global Fund was in its position as a funder for health systems strengthening where it could play a greater role in strengthening the systems around PrEP and integration of services, careful not to take a 'product-focused' approach.
- **Increased Global Fund support for PrEP should be strongly coordinated with partners and have a vision for scale (vs. the pilot trap).** The Global Fund and stakeholders should take heed of the learnings from the failure to deploy oral PrEP. There is a need for investment to understand client preferences, implementation and operationalisation challenges of PrEP, share learnings across countries and contexts, and establish a coordinated roadmap for taking PrEP (all products) to scale across different countries.

2. HIV SELF-TESTING (HIVST)

Context/ background: HIVST can be self-administered without the supervision of a trained provider and was recommended by WHO as a safe and accurate method of HIV testing in 2016. The convenience and privacy afforded by HIVST makes it an important innovation for reaching groups less likely to know their status including men, adolescents, and key populations who are often unable or reluctant to access conventional HIV testing services for reasons of stigma, discrimination and lack of access.

Global Fund role and funding to date: Global Fund financing for HIVST increased from US\$ 17m (NFM2) to US\$ 71.8m (NFM3). For NFM3 the Global Fund and CIFF established a matching fund to stimulate country demand for HIVST in 5 priority countries (Cameroon, Mozambique, Nigeria, Tanzania, Uganda). The Global Fund has been an engaged partner on WHO guideline development and in HIVST market shaping, which has been led by BMGF and Unitaids. Global Fund demand/procurement data are made available to global stakeholders and manufacturers through a mix of individual country requests and global-level procurement data.

Successes and enablers

- Global Fund - CIFF HIVST matching fund, with country technical support through Unitaids's STAR 3 project
- Global Fund ERPD invitation to manufacturers
- WHO's highly supportive and active role with global and country HIV stakeholders
- Unitaids and BMGF as early investors to address key market and country challenges

Challenges and barriers

Initial barriers prior to WHO guidelines

- Product first developed for HIC markets
- HIVST was a paradigm change for HIV services, requiring strong evidence in LMICs
- Higher cost of HIVST, with initially insufficient evidence for policymakers and donors
- Low country demand for HIVST with the exception of early adopter countries

Remaining barriers

- Policy change has been slower outside of donor-focused countries in sub-Saharan Africa (with some exceptions)
- Gap between policy and implementation in many regions, apart from East and Southern Africa and early adopter countries

Lessons learnt

- The Global Fund has an important role to play to stimulate scale-up through use of its catalytic funding (e.g. matching funds, SI) and supply side levers (e.g. issuing manufacturer applications for ERPD approval)
- Strategic partnerships for country support, timed with Global Fund funding cycles can significantly complement and amplify the Global Fund's investment (which is inherently limited by its mandate)
- Strategically designed Global Fund financing of quality TA can play a vital role in facilitating the introduction and quality implementation of the innovation

2.1. BACKGROUND

Rationale for HIV Self-Testing

Knowledge of HIV status is critical for curbing the HIV epidemic and putting people on treatment: In 2015 UNAIDS estimated that of 36.9 million people living with HIV (PLHIV), **46%**, did not know their status, putting them at risk of premature death and onward HIV transmission. By 2020, **16%** of PLHIV were still not aware of their status. Groups less likely to know their status include men, adolescents, and key populations¹¹¹ who are less likely to attend places where HIV testing services are offered, or are often unable or reluctant to access conventional HIV testing services for reasons of stigma, discrimination and lack of access.¹¹²

Why HIV Self Testing (HIVST): HIVST use either an oral swab or blood from a fingerpick to provide a result in under 20 minutes. HIVST can be self-administered without the supervision of a trained provider and was recommended by WHO as a safe and accurate method of HIV testing in 2016. HIVST offers a number of major benefits including:

- Privacy and convenience, making it an effective way to reach people who may not test otherwise;
- In some settings, HIVST is used to bring efficiencies to existing HIV testing services through screening out those who self-test negative;
- Self-testing can contribute to HIV prevention goals by linking those who test negative to prevention services (e.g. voluntary medical male circumcision (VMMC) and pre-exposure prophylaxis (PrEP));
- WHO now recommends HIVST for PrEP monitoring, thus enabling differentiated service delivery approaches for PrEP to reduce clinic visits.¹¹³ HIVST was first recommended by WHO to support continuity of HIV services during the COVID-19 pandemic for people taking post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP), including for maintenance of PrEP.¹¹⁴



When first recommended by WHO in 2016, HIVST was considered a paradigm change in HIV testing services as it removed the need for a trained provider. For this reason, it is one of the first big leaps in self-care for HIV. Prior to the 2016 WHO guidelines and in the initial years following, HIVST has faced a number of initial concerns regarding feasibility, safety (particularly for blood based tests) and risk of social harm. An important operational challenge has been the absence of implementation experience, specifically how to integrate HIVST within the mix of HIV Testing Services.

Global and national HIVST policy

UNAIDS and WHO have had a policy position since the early 2000s stating that HIVST should be considered, though this was not widely implemented.¹¹⁵ Formative research and pilot projects in high burden LMICs began in earnest from approximately 2011 in a small number of countries (including Kenya, Malawi, South Africa) using a range of prototypes and existing rapid diagnostic tests (RDTs) adapted for self-testing. In 2013 the first international symposium on self-testing for HIV was convened by WHO and partners and the consensus statement from the meeting encouraged countries to “actively explore HIV self-testing as a complementary strategy to increase knowledge of HIV status and uptake of prevention, care and treatment”. Momentum led in 2015 to Unitaids financing

¹¹¹ UNAIDS includes the following groups within key populations: female sex workers, men who have sex with men, transgendered people, people who inject drugs.

¹¹² Unitaids (2018), Impact Story: HIV Self-Testing, <https://unitaid.org/assets/Impact-story-HIV-Self-Testing.pdf>

¹¹³ WHO (2022) Differentiated and simplified pre-exposure prophylaxis for HIV prevention: update to WHO implementation guidance

¹¹⁴ WHO (2020), Maintaining essential health services: operational guidance for the COVID-19 context.

¹¹⁵ WHO (2013), Report on the first international symposium on self-testing for HIV.

the STAR investment to generate evidence on the feasibility and acceptability of HIVST in a number of high burden countries.

In 2016, WHO recommended HIVST as a safe, accurate and effective way to reach people who may not test otherwise, including people from key populations, men and young people (*strong recommendation, moderate quality of evidence*).¹ This was informed by findings of the STAR initiative and other studies. The WHO guidance on HIVST was strategically paired with the HIV Testing Services (HTS) Partner Notification guidelines.¹¹⁶

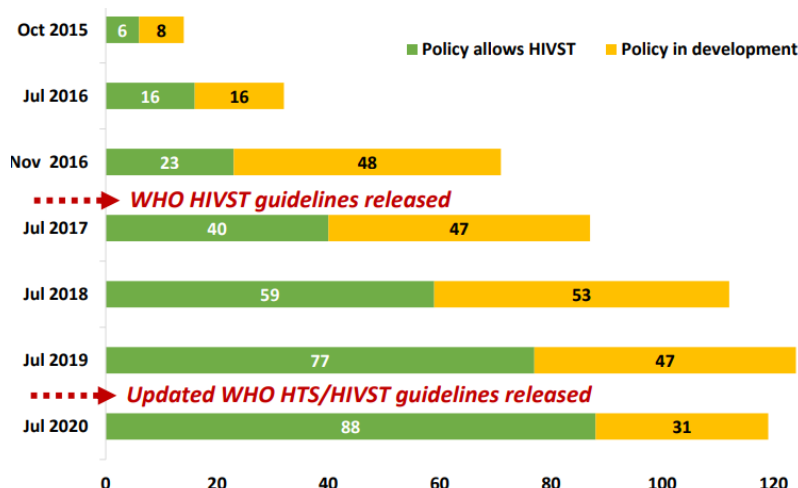
In 2019, WHO revised global HTS guidelines recommending HIVST should be offered as an approach within differentiated HIV testing services (*strong recommendation, moderate-quality evidence*) and provided evidence of a range of effective service delivery and distribution models.

WHO guidelines for routine use of HIVST for maintenance of PrEP were issued in July 2022 (expanding on the COVID-19 emergency recommendations).¹¹⁷

The number of countries including HIVST within national HIV Testing Services (HTS) has significantly grown

In late 2015, six countries had a supportive policy for HIVST and a further 8 countries had a policy in development. This rose to 88 countries in 2020 with an HIVST policy (Figure 2.1). As of July 2022, nearly 100 countries have a permissive policy.

Figure 2.1: Number of countries with HIVST policy 2015-2020 and release of WHO guidelines¹¹⁸



HIVST products and market

The HIVST product landscape has expanded from a single oral fluid HIVST in 2012 to six products in 2022 with WHO PQ/ERP. The first HIVST product (OraQuick oral-fluid test, manufactured by OraSure) was approved by the FDA in July 2012 as a home-use test for HIV. It was named one of Time Magazine's best inventions of the year, marketed as the first "DIY test for HIV" with a cost of US\$ 40-42 in the US-market.¹¹⁹ An OraQuick product for LMIC markets was then developed and received WHO PQ in 2017. There are now six HIVST products with WHO PQ or ERP as of June 2022 (Table 2.1). Five of these are blood based tests (BBT) and one is oral-fluid based. More HIVST products are at various stages in the development pipeline.

¹¹⁶ Wong V et al. (2019), Journal of the International AIDS Society 2019, 22(S1)

¹¹⁷ WHO (2016), Guidelines on HIV self-testing and partner notification- supplement to consolidated guidelines on HIV test services. Per WHO guidelines, individuals with a reactive HIVST result must receive a confirmatory test from a trained provider.

¹¹⁸ WHO, Unitaids (2020) Market and Technology Landscape 2020 HIV rapid diagnostic tests for self-testing

¹¹⁹ <https://techland.time.com/2012/11/01/best-inventions-of-the-year-2012/slide/oraquick-home-hiv-test/>. Accessed 28/06/2022

Table 2.1: Approved (WHO PQ or ERPD) HIVST products for LMICs¹²⁰

HIVST Product	Type	Manufacturer	LMIC Price (USD) ¹²¹	Year WHO PQ/ERPD
One Step HIV 1&2 Whole Blood Serum Plasma Test*	Blood	Wondfo Biotech Co., Ltd. Ghangzhou, China	Public sector \$1	2022
CheckNOW	Blood	Abbott Rapid Diagnostics	To be confirmed	2022
Mylan	Blood	Atomo Diagnostics Pty Ltd, Leichhardt, Australia	\$1.99 (public sector in 135 eligible countries)	2019
INSTI	Blood	BioLytical Laboratories, Richmond, Canada	Public sector \$3-6 Retail \$6-14	2018
EXACTO TEST HIVST	Blood	Biosynex SA, Strasbourg, France	Volume dependent	2019
SURE CHECK	Blood	Chembio Diagnostic Systems, Medford, USA	\$2.99 (public sector)	2019
OraQuick	Oral	OraSure Technologies Inc, Bethlehem, USA (Manufactured in Thailand)	\$2.00 (all public sector purchasers of WHO PQ product)	2017

HIVST volumes have grown significantly from 1 million tests in 2017 to nearly 14 million in 2021. The WHO HIVST demand forecast (produced every 2 years) projects total LMIC demand to reach 27.7 million tests by 2025, which would be a near doubling of the volume procured in 2021. The Global Fund and PEPFAR are now the largest purchasers of HIVST.

HIVST volumes are led by the OraQuick oral-fluid test (~84% market share). In 2017 the Bill and Melinda Gates Foundation (BMGF) supported a volume guarantee to lower the price of the OraQuick LMIC product from US\$ 3/unit to US \$2/unit. The US \$2 price has since become a de facto benchmark for other HIVST products to be competitive. This ‘first mover’ advantage has contributed to OraQuick having ~84% of the global market share of HIVST in 2021.¹²² In 2020, to diversify the manufacturer and product landscape, Unitaid made a catalytic investment in Mylan/Atomo to lower the price of its BBT product to be competitive with the oral-fluid test. Abbott, the largest manufacturer of conventional HIV tests, has since received WHO PQ for its HIVST BBT (2022) with prices for LMICs to be confirmed. Most recently in July 2022, the Clinton Health Access Initiative and MedAccess announced a volume guarantee agreement with Wondfo. Through this partnership, Wondfo has agreed to launch their self-test at \$1 for public sector purchasers in LMICs making this the lowest ever priced WHO prequalified HIV self-test. At 50% of the price of OraSure, this agreement is likely to have a significant impact on the HIVST market with MedAccess projecting that the agreement will lead to an additional 8.1 million people being tested for HIV.¹²³

Funding for HIVST from other donors/ partners

Unitaid has been the largest funder of country introduction of HIVST through the STAR and ATLAS projects (2015-2022) and funding to WHO for global and regional level HIVST support. Other notable funders have been BMGF (who funded early country experience and the sole volume guarantee for HIVST) and CIFF’s investment to explore demand through the private sector market.¹²⁴ Donors have invested in countries with different epidemic typologies and

¹²⁰ The Global Fund (30 March 2022), List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy. Version 44.

¹²¹ Ex-works pricing; information sourced from 2020 WHO HIVST landscape and may not be current

¹²² As reported by the Global Fund (20 June 2022)

¹²³ MedAccess (July 2022), HIV self-test. <https://medaccess.org/guarantee-portfolio/hiv-self-test/>. (Accessed August 3, 2022).

¹²⁴ These funders do not include the financing of HIVST research owing to challenges identifying the financing sources of some research. Donors for research studies in LMICs include the Wellcome Trust through the Malawi-Liverpool Wellcome Trust Clinical Research Programme and LSHTM.

worked through a number of global technical partners (including PSI, PATH, Jhpiego, Solthis) who in turn partnered with national HIV programmes, civil society, and community based organisations.

The HIV Self-Testing AfRica (STAR) Initiative, was funded by Unitaaid to address key market challenges limiting access to HIV self-testing.¹²⁵ STAR Phase 1 (2015-2017) aimed to generate evidence on how to distribute HIVST products effectively, ethically and efficiently through investments in Malawi, Zambia and Zimbabwe. Phase 2 built on this foundation and scaled up self-testing in the Phase 1 and additional countries (South Africa, eSwatini and Lesotho). STAR was implemented by a consortium led by PSI that included the London School of Hygiene and Tropical Medicine (LSHTM), the Liverpool School of Tropical Medicine (LSTM), University College London (UCL), WHO and local research partners. A STAR Phase 3 investment was linked to Global Fund NFM3 financing (elaborated below). In addition, Unitaaid funded Solthis to support introduction of HIVST in West Africa (2018-2022).

2.2. GLOBAL FUND SUPPORT FOR HIVST

2015-2017

Prior to release of the WHO 2016 guidelines, BMGF and Unitaaid were the primary partners funding HIVST operational research (Unitaid) and market shaping (BMGF). Investments focused on establishing the evidence base which informed WHO guidelines and the OraQuick volume guarantee. The Global Fund was engaged as a key HIV stakeholder but was not funding HIVST.

2018-2021 (including NFM2 and NFM3 cycles)

Following the WHO 2016 guidelines, Global Fund country grants were eligible to include requests for HIVST.

For NFM2 (2018-2020), the Global Fund financed \$17 m in HIVST. This was regarded by stakeholders as below expectations given inclusion in WHO policy (described later under barriers).

For NFM3 (2021-23), the Global Fund financed \$71.8 m in HIVST (which included a matching fund for HIVST). The following efforts are linked to expanded Global Fund HIVST financing:

- Inclusion of HIVST within the Global Fund **HIV Information Note** (September 2019). The 2019 Information Note recommended NFM3 funding requests for the 2021-2023 allocation period include scale up of innovative testing approaches, such as HIVST (see footnote for excerpt from the HIV information note).¹²⁶
- The Global Fund and Unitaaid issued an invitation to **HIVST manufacturers** to submit a product dossier to the Expert Review Panel for Diagnostic Products (ERPD) to determine acceptability for procurement through the Global Fund (October 2019) (for either pooled or direct country procurement financed by GF). The ERPD process is regarded as a useful intermediary step for manufacturers to enter the LMIC market given the longer process of WHO PQ.
- **NFM3 HIVST matching funds investment in 5 countries (US\$ 25m), planned jointly with Unitaaid-funded country investments.** The matching fund is a Global Fund instrument to incentivize countries to prioritize particular focus areas within the Global Fund allocation (where the Global Fund will match the value of a funding request). In 2019, CIFF made a US\$ 25 m grant to the Global Fund to establish a matching fund for HIVST focused on 5 high burden sub-Saharan African countries with a large testing gap (Cameroon, Mozambique, Nigeria, Tanzania, Uganda).¹²⁷ Country allocation requests for HIVST within NFM3 plans were matched, doubling the size of HIVST NFM3 resources. The matching fund and country prioritisation was done

¹²⁵ PSI (2017), HIV Self-Testing Africa Initiative Brochure

¹²⁶ Global Fund (2019) HIV Information Note. *"Self-testing should be used as method to reach high-risk populations that do not access health services, such as young men, including male partners of antenatal care (ANC) clients, and key populations and contacts of key populations."* The Information Note linked to the WHO (2018) HIV self-testing strategic framework: a guide for planning, introducing and scaling up.

¹²⁷ Webinar (July 8 2021) Optimizing HIV Testing Services, the importance of HIV self-testing. <https://www.psi.org/2021/07/webinar-optimizing-hiv-services-through-self-testing/> (Accessed 11/07/2022).

jointly between the Global Fund, Unitaïd and ClFF (and WHO), with Unitaïd providing complementary funding to support the 5 countries to prepare for NFM3 (Self-Testing Africa (STAR) initiative).

- **Differentiated HIV Service Delivery (DSD) Strategic Initiative (SI) in 10 countries (\$15 m)** (launched November 2020, after delay due to the COVID-19 pandemic). The DSD SI supports the provision of expert technical assistance to 10 country programs to ensure DSD models, adaptations or innovations are developed and scaled up. The 10 countries include 4 of the 5 countries included in the HIVST matching fund: Cameroon, Cote d'Ivoire, Guinea, Ghana, Indonesia, Mozambique, Nigeria, Philippines, Tanzania, Zambia. The DSD SI is synergistic with the HIVST matching fund and supports technical assistance for HIVST as an innovation in HIV Testing Services (SIs are needed to support the success of country allocations but cannot be funded through country grants).

2022 (and preparation for NFM4)

The HIV Information Note for the NFM4 allocation cycle includes HIVST as a 'Program Essential' which requires all HIV grants to include HIVST within funding requests and to report on HIVST in performance reporting.

2.2.1. Analysis of Global Fund HIVST support

More than 50 countries receive HIVST financing through NFM3 with a total value of US\$ 71.8 m. The Global Fund-ClFF HIVST matching fund in 5 countries is a significant share of NFM3 HIVST resources (US\$ 47.9 m of US\$ 71.8 m). The balance of US\$ 23.9 m supports HIVST in ~45 countries.

Overall, approximately 19% of the NFM3 HIV testing budget is allocated to HIVST. Facility based testing (~51%) and community-based testing (~30%) comprise the remainder of the HIV testing budget.

The number of countries ordering HIVST through Global Fund's pooled procurement mechanism (PPM) has increased from 3 in 2019, to 30 in 2021. This does not include countries who procure HIVST directly using government procurement mechanisms (with Global Fund financing). Countries using Global Fund resources to procure HIVST include South Africa, Ethiopia, Kenya, Tanzania.

2.3. BARRIERS AND ENABLERS

Barriers to the Global Fund's deployment of HIVST

Barriers have significantly evolved over time, resulting from stakeholder efforts to address initial barriers to product entry in LMIC markets and WHO policy guidance.

Initial barriers:

- **OraQuick product development was focused on high-income markets.** Product development of OraQuick did not have a parallel track for LMICs, meaning there was limited evidence outside some feasibility and acceptability studies from high burden countries at the time of FDA approval (despite WHO and UNAIDS advising self-testing for HIV should be considered since the early 2000s). Reasons for this are twofold: i) there was no demand for HIVST in LMICs at the time/no HIVST projects, and ii) OraSure who produce the OraQuick product were focused on HIC markets. Five years elapsed between FDA approval of the first OraQuick product and having an HIVST product for LMIC markets with a volume guarantee to further increase affordability.
- **HIVST a paradigm change for HIV services, requiring strong evidence in LMICs.** HIVST was one of the first big leaps in self-care for HIV. Initial concerns on feasibility, safety (particularly for blood based tests) and social harm had to first be examined through robust evaluations in high burden LMIC settings. As described earlier, the evidence-base established for HIVST and its subsequent inclusion in WHO HIV testing guidelines

helped to shift mindsets towards acceptance of HIVST and self-care more broadly.¹²⁸ With this came operational experience integrating HIVST into HIV Testing services in a small number of early adopter countries. Despite nearly 100 countries now including HIVST to help reach the UN global -95 targets, some concerns persist, particularly on safety of BBT (and some countries have chosen not to adopt BBTs) and approaches for HIVST follow up which are not advised by WHO guidelines.¹²⁹

- **Higher cost of HIVST, with initially insufficient evidence on cost effectiveness for policymakers and donors:** In 2016, the cost of HIVST for LMICs was US\$ 3-16 compared to US\$ 0.5-11 for professional use tests. The BMGF/CIFF volume guarantee subsequently reduced the cost of the OraQuick HIVST to US\$ 2 for LMICs, though modelling analysis in Zimbabwe suggested that for HIVST to be cost-effective in a LMIC context, price should be reduced to at least \$1.50. ^{130,131} In a context of “flat-lining” of global HIV funding, the higher unit cost of HIVST necessitated evidence on cost effectiveness. This was complicated by the range of different HIVST service models countries could adopt (e.g. community distribution, index testing), and the need to take into account levels of HIV prevalence and epidemic context.¹³² While the initial studies on cost effectiveness in LMICs were of value to WHO 2016 guidance, they did not necessarily address the evidence needs of country policy makers and funders like Global Fund and PEPFAR.¹³³
- **Low country demand for HIVST with the exception of early adopter countries:** Early adopter countries were predominantly those in Southern Africa where HIVST research was conducted with Unitaid and other stakeholder support (Eswatini, Lesotho, Malawi, South Africa, Swaziland, Zambia and Zimbabwe). Beyond these countries, demand remained low, despite WHO guidance and the price reduction through the volume guarantee. While many countries beyond this region had included HIVST in national HIV testing policies, these had not been operationalised, meaning many countries had not registered an HIVST product, developed operational plans for implementation, training materials, or service models. The Global Fund-CIFF-Unitaid partnership sought to address this barrier ahead of NFM3 and is discussed under ‘Enablers’.
- **Need for evidence of HIVST service models and technical expertise for implementation:** Evidence of HIVST service models required ~1-3 years to be established from the initial Unitaid investment in 2015 (informing the WHO 2016 and 2018 guidelines). Still, these tested models have not necessarily been relevant to all epidemic contexts, prompting in 2018 Unitaid financing the ATLAS project in Mali, Senegal and Cote d'Ivoire to develop the evidence for HIVST models in West African settings. Where HIVST projects have been financed, such as in Unitaid supported countries, there has been a strengthening of technical expertise as countries developed key materials (e.g. national guidelines, training and monitoring tools etc.). This technical expertise was mostly absent prior to significant Unitaid investment, and is weaker in countries that have not received technical support.

Remaining barriers to expanded Global Fund support for HIVST:

- **Gap between policy and implementation in many regions, apart from East and Southern Africa and early adopter countries.** Only ~50 countries are implementing HIVST of the nearly 100 countries with national HIVST policy. The policy-to-implementation gap is underpinned by several factors which combine to dampen demand for HIVST. These include an understanding of HIVST cost-effectiveness within the national HIV context, as HIVST is still priced higher than conventional HIV tests (~US\$ 2 vs. \$ 0.7). In time this price differential is expected to fall further with new BBTs coming to market which may mitigate hesitancy on the basis of unit costs. Other barriers include hesitancy to focus on implementing something new while

¹²⁸ HIVST evidence base has been an accelerator for expansion of self-care in high burden countries, as well as evidence for Covid-19 rapid tests.

¹²⁹ Including Cote d'Ivoire, Mali, Mozambique, Senegal.

¹³⁰ WHO, Unitaid (2020) Market and Technology Landscape 2020 HIV rapid diagnostic tests for self-testing

¹³¹ World Health Organization. Annex 23: cost-effectiveness of different delivery approaches for HIV self-testing in Zimbabwe. Geneva: World Health Organization; 2016

¹³² CEPA (2019), Unitaid Mid-Term Evaluation of the PSI HIV Testing AfRica (STAR) Project

¹³³ CEPA (2019), Unitaid Mid-Term Evaluation of the PSI HIV Testing AfRica (STAR) Project

simultaneously driving the performance of Global Fund core allocations, and internal country factors such as degree of emphasis within national HIV responses on clinical and laboratory services.

- **Time to implement and scale. HIVST can be implemented through multiple HIV Testing models** (e.g. facility-based, community distribution, secondary distribution through KP etc.). Each country needs to assess the models that will be implemented, and to develop the appropriate supporting tools (e.g. job aids, training and communication materials). This process takes time and is aided by different technical assistance support (for e.g. from the Global Fund DSD SI, Unitaids, CHAI). The number of HIVST models implemented varies by country, which may also affect the pace of expansion.
- **Policy change has been slower outside of donor-focused countries in sub-Saharan Africa** (with some exceptions). A number of countries, particularly with less partner engagement/funding, have been reluctant to include HIVST or to expand its use with concerns including conservative diagnostic regulatory approaches and need for local evidence and linkage to treatment. Policy uptake in Latin America the Asia and the Pacific (AP) have been slower, though with some early adopters (e.g. Vietnam). The largest countries in AP region, India and Indonesia, were strategically included within Unitaids' expanded STAR project 2020-2022 to create a supportive national environment for HIVST introduction and scale. India is expected to change its policy in 2022 but first required local evidence which was supported in 14 States, and concerns remain regarding linkage to HIV treatment where HIVST is offered in settings far from health/HIV services. Indonesia has since adopted an HIVST policy but as of May 2022, an HIVST product had yet to be registered with the national regulatory authority.

Enablers to Global Fund Support for HIVST

We found three enablers disproportionately bolstered country demand for, and technical capacity to implement HIVST: one is Global Fund-driven, and two were driven by other key stakeholders. A fourth, the COVID-19 pandemic, is also discussed:

- **Global Fund - ClIFF HIVST matching fund, with country technical support through Unitaids' STAR 3 project. This was a highly influential enabler for the following reasons:**
 - Matched technical support to amplify country demand, with Global Fund commitment to increase HIVST supply in NFM3
 - The Unitaids-funded technical support (STAR 3 project) focused on pragmatic steps for scaling HIVST including: preparation of NFM3 funding requests for HIVST, updating HIV testing policies and operational guidelines, product registration, procurement and supply management (PSM) strengthening, service model testing, development of training materials and tools, demand generation. The five matching fund countries are among the top 6 countries with largest procurement volumes through the Global Fund.¹³⁴
 - Unitaids HIVST grantees are now financed through the Global Fund DSD SI (PSI - STAR program, Solthis - ATLAS program in West African countries) to provide TA to select countries for HIVST.
- **WHO's highly supportive and active role with global and country HIV stakeholders.** WHO was closely involved in country HIVST research evidence to ensure the degree of robustness required to influence WHO policy guidance. The multi-stakeholder HIVST research consortium which involved WHO, addressed a number of critical concerns on introduction of HIVST including feasibility, applicability and usability of HIVST. Unitaids' financing to WHO through an 'enabler grant' for HIVST is also viewed as helping to accelerate global advancement of HIVST (as compared for instance to innovations in STI self-testing where there is not a dedicated grant to WHO and progress in building demand and a market is slower).

Later, WHO spent considerable time convincing countries on the use of HIVST, cost-effectiveness and quality. Given HIVST was initially considered a "radical change", WHO normative guidance ability to engage

¹³⁴ Most of the increase in NFM3 HIVST funding (US\$47.9m) was from the catalytic effect of the matching fund investment.

directly with Ministries of Health brought significant credibility to the use of HIVST and is regarded as critically important for changes in country demand.

- **Unitaid and BMGF as early investors to address key market and country challenges.** Unitaid and BMGF were highly complementary to the Global Fund through financing early steps in the innovation value chain which has set the stage for scaling HIVST. A range of evidence on HIVST in different contexts has been published and disseminated and significant technical expertise developed to diffuse HIVST experience to other countries. Unitaid HIVST grantees such as PSI and Solthis are also receiving Global Fund support to provide technical assistance on HIVST, including in DSD SI countries and others such as Guinea (with support to Chad, CAR, Guinea Bissau under discussion).
- **The COVID-19 Response Mechanism (C19RM) promoted HIVST as an alternative to maintain services.** Under C19RM, HIVST resources could be requested for a range of activities supporting the policy and regulatory environment, country readiness (including community involvement), demand creation and M&E (but not HIVST commodities).

Figure 2.2: Barriers and Enablers to Global Fund equitable deployment of HIVST

Factors	Global prioritisation/ perceived value	Normative guidance	Market/ supply characteristics	Price, affordability and cost effectiveness	Country demand and readiness	Implementation
Barriers	<ul style="list-style-type: none"> Required a paradigm shift (big leap in self-care) 		<ul style="list-style-type: none"> OraQuick FDA approved in 2012, but unsuitable for LMICs until 2017 when PQ'ed Oraquick monopoly for several years, also with BBT resistance 	<ul style="list-style-type: none"> Higher price of HIVST than RDTs (US\$2 vs US\$0.7) Need for evidence/ advocacy on cost effectiveness 	<ul style="list-style-type: none"> Substantial increase in countries with supporting policies but limited outside SSA and overall low operationalization 	<ul style="list-style-type: none"> Global Fund HIV Information Note has limited reference to HIVST Lack of technical expertise for implementation/different HIVST models
Enablers	<ul style="list-style-type: none"> Clear knowledge and agreement today that HIVST key to achieving 90-90-90 	<ul style="list-style-type: none"> WHO's active role in developing guidance (2016 guidance on HIVST for KP and 2019 guidance on HIVST within HTS) Global Fund ERPD invitation to manufacturers 	<ul style="list-style-type: none"> Competitive market today with several BBT products and rich pipeline ERP-D invitation 	<ul style="list-style-type: none"> Oraquick price brought down to US\$2 through Gates/CIFF volume guarantee 	<ul style="list-style-type: none"> WHO's highly active role in supporting countries Global Fund-Unitaid-CIFF catalytic funding and Global Fund DSD SI 	<ul style="list-style-type: none"> COVID-19 as a facilitator for use of HIVST Global Fund HIV note programme essentials
	<ul style="list-style-type: none"> UNITAID STAR initiative key to driving HIVST value, developing evidence for WHO guidelines, supporting market competition, generating country demand and readiness 					

2.4. LESSONS LEARNT FROM HIVST FOR THE GLOBAL FUND'S APPROACH TO INNOVATIONS

- **The Global Fund has an important role to play to stimulate scale-up through use of its catalytic funding (e.g. matching funds, SI) and supply side levers (e.g. issuing manufacturer applications for ERPD approval).** Use of matching funds and other instruments which signal Global Fund commitment to scaling an innovation importantly provide confidence to countries that funding for scale will be available. It also signals to manufacturers multi-year donor commitment for volumes, underpinned by country forecasting to increase the predictability of orders. ERPD approval is useful intermediary in the lengthy WHO PQ process to build early country and manufacturer experience for products in LMIC markets.
- **Strategic partnerships for country support, timed with Global Fund funding cycles can significantly complement and amplify the Global Fund's investment (which is inherently limited by its mandate).** Overcoming country-level bottlenecks to introducing an innovation require different instruments and flexibilities which do not fit within the Global Fund's operating model. For innovations which require a

significant change to existing service models, partnerships focused on these operational bottlenecks, and timed prior to funding cycles, are highly complementary to the Global Fund and influence the performance of Global Fund grants.

- **Quality TA financed by the Global Fund can only happen once a pool of experts exists.** Paradigm changing innovations require a pool of expertise to be established before technical assistance at scale can be provided to countries. This 'pool' results from investments that establish the evidence base and implementation science, prior to significant Global Fund investment.

3. GENEXPERT/ MOLBIO TRUENAT & SERVICE INTEGRATION

Context/ background GeneXpert offers the first near Point of Care (PoC) diagnostic tool in the TB space which had a high sensitivity and could be placed closer to the patient and thus addressed shortcomings of microscopy and conventional laboratories. It was recommended by WHO 2011 for MDR-TB and HIV/TB patients and in 2020 for all pulmonary TB patients. Another POC diagnostic platform, Molbio Truenat was endorsed by WHO in 2020.

Global Fund role and funding to date The Global Fund grants first allowed for the procurement of GeneXpert in 2013 which then started to increase peaking by over 700 purchased machines in 2017. In more recent years, the purchase of new machines has dropped and instead cartridge purchases have increased. GeneXpert has been heavily supported through grant allocation funding and through targeted matching funds and strategic initiatives. RSSH support and strategic initiative funding have also supported the integration of laboratory services.

Successes and enablers

- First near POC technology for TB leading to strong donor support and country demand
- Global Fund grant allocations and complementary catalytic funding has been critical for scale-up
- Extra support through COVID-19 recently provided a chance to purchase additional GeneXpert machines as well as some X-ray machines. Extra support through COVID-19 recently provided a chance to purchase additional GeneXpert machines as well as some X-ray machines
- In-country coordination between key stakeholders as well as technical assistance from partners such as WHO were considered enablers for effective implementation

Challenges and barriers

- The overall cartridge price for GeneXpert acts as a barrier in particular with regard to wider scale-up and use.
- Issues around service and maintenance have been a key barrier for effective use and implementation of GeneXpert. Issues around service and maintenance have been a key barrier for effective use and implementation of GeneXpert
- GeneXpert only is a near POC diagnostic tools and issues remain with regard to placement in some areas including infrastructure challenges, staff challenges and data challenge
- The Near Point-of-Care Diagnostic space has been a monopoly market, and combined with country inertia to switch to unknown products, making it harder for new products to enter the market

Lessons learnt

- The Global Fund can play a pivotal role in strong scale-up of innovations when there is strong country demand, and the product is early on supported through the grant allocation funding.
- Maintenance and service contracting has remained a challenge with the Global Fund not seen as being proactive in addressing this issue
- The Near Point-of-Care Diagnostic space has been a monopoly market with a lack of support to diversify the diagnostic tool kit.
- Country inertia to stick with known products which requires country demand creation / support for new innovations to “break into” Global Fund country ecosystem
- Global Fund could have been more involved in the price negotiations of GeneXpert given their large purchasing power

3.1. BACKGROUND

Rationale for near point-of-care (POC) diagnostic tools

Globally, one third of individuals with TB and two thirds of those with DR-TB are not detected, presenting a real challenge in diagnosis.¹³⁵ Over the last decades, one of the most prevalent TB diagnosis methods include sputum smear microscopy, which has several limitations.¹³⁶ These include the inability to identify DR-TB and a relatively long and complex process for laboratory staff and patients.¹³⁷ Similarly, conventional systems were often not accessible to many patients in LMICs. Thus, there was a strong need for a diagnostic tool to be able to detect DR-TB and provide a near point-of-care alternative to conventional laboratory systems.

Why GeneXpert: GeneXpert is an automated molecular test for rapid simultaneous detection of TB and rifampicin resistance (RR), a key first-line drug when treating TB, from sputum and extrapulmonary samples. Xpert MTB/RIF is the assay used in the test. GeneXpert will deliver faster results within two hours, compared to previous TB diagnostics methods which could take weeks to give results. This delay in results can lead to patients being untreated which increases the risk of TB spreading and increasing the disease burden.¹³⁸ In comparison to culture, GeneXpert has the benefit of being available at lower-level health facilities, there is no need for labs with extensively trained staff or technical equipment, which can improve access to testing.¹³⁹ In 2017, Cepheid launched the Xpert MTB/RIF Ultra.¹⁴⁰ When compared to the original Xpert, the Ultra has the following benefits: higher sensitivity in smear-negative TB cases, faster results, improved detection of mixed infections and improved accuracy of Rifampicin results.¹⁴¹ GeneXpert can also be used for multiplexing and identify different conditions with a single diagnostic test, including HIV viral load test and more recently COVID-19.

Why Molbio: Molbio Truenat is a test that uses real-time micro polymerase chain reaction technology.¹⁴² This device has the advantage of having the ability to be used closer to the patient than GeneXpert (which requires a stable power source and stable temperature conditions), as they are battery operated, do not need air-conditioned facilities and require minimal user input.¹⁴³ Similar to GeneXpert, Molbio Truenat also offers the advantage of a multiplex diagnostic platform.

Summary of WHO guidelines

Table shows a summary of WHO guidance updates in the diagnosis of TB. The main development has been the change from guidelines in 2013 which recommended Xpert to only being used as a first line test in individuals with suspected MDR-TB or HIV-associated TB, to guidelines in 2020 which recommend Xpert as the initial diagnostic test in all adults with suspected TB. In 2020, WHO has also endorsed the use of Molbio Truenat assays for initial TB diagnosis.

¹³⁵ WHO, Scaling up diagnosis of TB and drug-resistant TB, available [online](#).

¹³⁶ Kik et al. (2014), Replacing smear microscopy for the diagnosis of tuberculosis: what is the market potential?

¹³⁷ Harries and Kumar (2018), Challenges and Progress with Diagnosing Pulmonary Tuberculosis in Low- and Middle-Income Countries.

¹³⁸ Cepheid, Xpert MTB/RIF: The need, available [online](#).

¹³⁹ Cepheid, The GeneXpert System: Game-changing performance, available [online](#).

¹⁴⁰ Hoel et al. (2020), Xpert MTB/RIF ultra for rapid diagnosis of extrapulmonary tuberculosis in a high-income low-tuberculosis prevalence setting.

¹⁴¹ Cepheid, Xpert MTB/RIF Ultra, available [online](#).

¹⁴² FIND (2020), World Health Organisation endorses Truenat tests for initial diagnosis of tuberculosis and detection of rifampicin resistance, available [online](#).

¹⁴³ FIND, Point-of-care molecular TB test, available [online](#).

Table 3.1: Summary of WHO guidance updates in the diagnosis of TB

Year	WHO guidance updates
2010	WHO formally endorses the use of Xpert as a new diagnostic tool for active TB
2011	WHO publish policy recommendation which recommended that: i) Xpert should be used as an initial diagnostic test in individuals suspected of MDR-TB or HIV-associated TB; and ii) Xpert may be used as a follow on test to microscopy in settings where MDR and/or HIV is of lesser concern, especially in smear-negative specimens. ^{144,145}
2013	WHO publish a policy update for the use of Xpert. ¹⁴⁶ This included recommendations for use in paediatric and extrapulmonary TB.
2014	WHO publish a revised Xpert implementation manual to accompany the policy update. ¹⁴⁷
2020	WHO publish consolidated guidelines which recommend Xpert as an initial diagnostic test in adults with signs and symptoms of pulmonary TB. WHO also endorsed Molbio Truenat as an initial diagnostic test for adults and children with symptoms of pulmonary TB rather than smear microscopy. ¹⁴⁸

Market conditions

As shown in Table 3.2 below, Cepheid is the supplier of GeneXpert and for many years had a monopoly in the TB near POC diagnostic market which only very recently has been challenged by the entry of Molbio Truenat.

Table 3.2: WHO endorsed TB Diagnostic Products

TB Diagnostic Product	Manufacturer	First year of WHO endorsement	LMIC Price (USD) ¹⁴⁹
GeneXpert	Cepheid	2011	9.98 USD
Molbio Truenat	Molbio Diagnostics	2020	8.00 USD

Following WHO's endorsement of Xpert MTB/RIF in 2010, the test was introduced at a reduced price of 16.86 USD per cartridge. This was reduced further in 2012 through a 'buy-down agreement' between USAID, the U.S Department of State's Office of the Global AIDS Coordinator (OGAC), Unitaid/WHO and BMGF, which ensured an immediate price reduction to 9.98 USD per cartridge for the following 10 years, which was made available to the 145 countries.¹⁵⁰ In 2017, Cepheid introduced a new Xpert MTB/RIF cartridge version with superior sensitivity to the market (Xpert MTB/RIF Ultra). This is also available at the same concessional price of 9.98 USD per cartridge.

In 2020, the WHO consolidated guidelines on TB recommend Molbio Truenat in the following circumstances: i) Truenat MTB may be used as an initial diagnostic test for adults and children with symptoms of pulmonary TB, rather than smear microscopy; and ii) in adults and children with symptoms of pulmonary TB and a Truenat MTB positive result, Truenat MTB-RIF Dx may be used as an initial test for rifampicin resistance rather than phenotypic DST.¹⁵¹

¹⁴⁴ WHO (2011), Policy statement: Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Xpert MTB/RIF System.

¹⁴⁵ Albert et al. (2016), Development, roll-out and impact of Xpert MTB/RIF for tuberculosis: what lessons have we learnt and how can we do better?

¹⁴⁶ WHO (2013), Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Xpert MTB/RIF assay for the diagnosis of pulmonary and extrapulmonary TB in adults and children. Policy update.

¹⁴⁷ WHO (2014), Updated: Xpert MTB/RIF implementation manual technical and operational "how-to": practical considerations.

¹⁴⁸ WHO (2020), WHO consolidated guidelines on tuberculosis, Module 3: Diagnosis, Rapid diagnostics for tuberculosis detection.

¹⁴⁹ Ex-works pricing

¹⁵⁰ 11.1 million USD was provided to Cepheid by USAID, OGAC, Unitaid and BMGF to guarantee reduced prices.

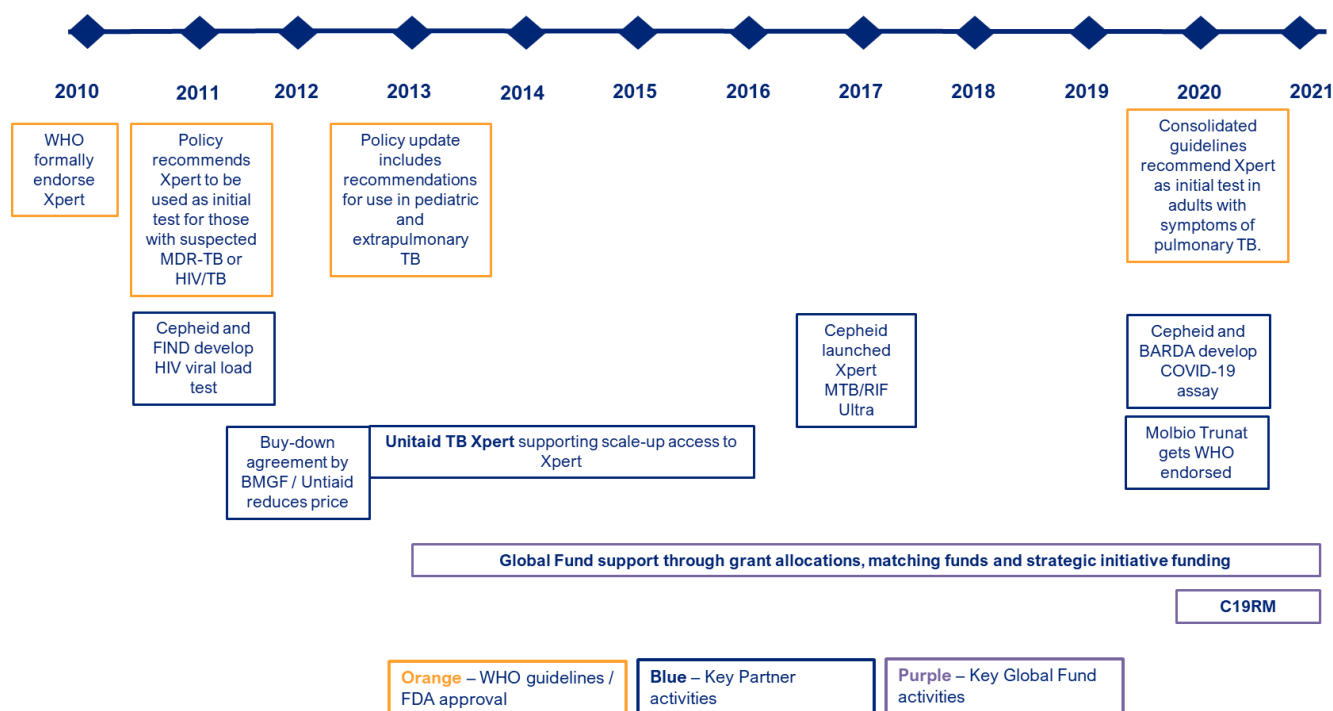
¹⁵¹ WHO (2021), WHO consolidated guidelines on tuberculosis, Module 3: Diagnosis, Rapid diagnostics for tuberculosis detection, 2021 update.

Both are conditional recommendations. The price for Molbio cartridges is currently around US\$ 8.00 as listed in the GDF catalogue.¹⁵²

Timelines and partner coordination

Figure 3.1 below provides the timeline of events in the scale-up of GeneXpert, including WHO recommendations, development of new assays and price negotiations. This also includes the additions of tests for new disease areas as well as the endorsement of Molbio Truenat by WHO. Other key events included the buy-down agreement mentioned above and the wider Unitaid TB Xpert project.

Figure 3.1: Timeline of events



The key Global Fund activities as well as actual GeneXpert machines and cartridges procured with funding from the Global Fund grants is detailed in Section 3.2. below.

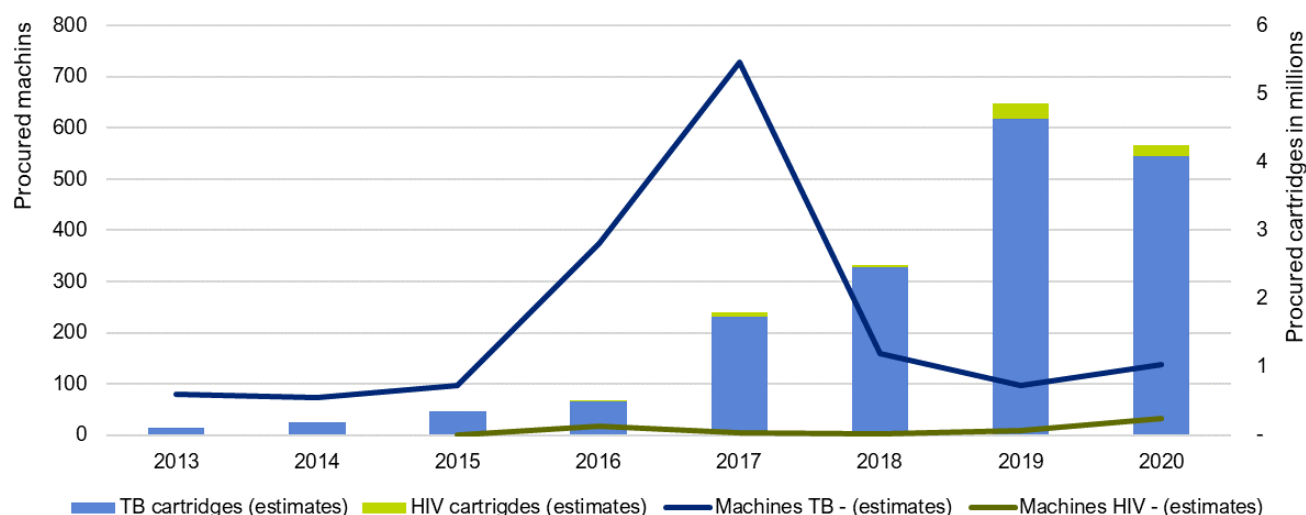
3.2. UPTAKE AND GLOBAL FUND SUPPORT

Procurement of GeneXpert machines and cartridges with Global Fund funding

Figure 3.2. below shows the uptake of GeneXpert which has been funded through Global Fund grants over time based on PQR data (majority of countries use GDF as the procurement channel). The figure shows that GeneXpert uptake has been closely aligned with the strength of the WHO recommendations over time.

¹⁵² https://www.stoptb.org/sites/default/files/gdfdiagnosticsmedicaldevootherhealthproductscatalog_0.pdf

Figure 3.2: GeneXpert machines and cartridges procured through a Global Fund grant over time based on PQR data



Source: CEPA analysis based on PQR data

While the exact data points from the analysis above should be interpreted with care given limitations in the PQR database ¹⁵³, there are a few trends that can be observed. The Global Fund grants first enabled the procurement of GeneXpert in 2013 which then started to increase peaking by over 700 purchased machines in 2017. In more recent years, the purchase of new machines has dropped and instead cartridge purchases have increased. This makes sense as the increase in the stock of machines in country requires additional purchases of cartridges in later years. The trend is also in line with the Global Fund approach to encourage to increase the utilisation of existing machines rather than continue to buy additional machines. Lastly, the data shows that the majority of procured machines and cartridges have been through the TB programmes with the share from HIV being below 10%. A caveat is also that recently more GeneXpert machines have reportedly been purchased using funding from the C19RM. The available data also does not allow to comment on the overall uptake of GeneXpert given that it has also been supported by other funders such as PEPFAR and USAID or been procured directly through domestic funding.

Overall, stakeholders did consider that the uptake of GeneXpert has been largely a success especially when considered only against the narrow WHO guidelines prior to 2020 (which focused only on MDR-TB and HIV/TB). The Global Fund was seen as playing a critical role in that being the main funder for TB GeneXpert machines. At the same time, stakeholders also acknowledged that there are severe testing gaps for rapid molecular tests (or equivalent) with only 33% of people newly diagnosed with TB in 2020 using a WHO-recommended rapid molecular test (which predominately is GeneXpert). The barriers and enablers of these trends are further discussed in Section 3.3. below.

Catalytic Funding

Besides supporting the purchase of GeneXpert through the main grant allocation, the Global Fund has also supported the increase in TB diagnostic through catalytic funding. In particular, this included the Matching Funds to find missing TB cases in both NFM2 and NMF3 which were US\$ 115 million and US\$ 149 respectively. During the 2020-2022 funding cycle, 20 countries with the largest number (and proportion) of missing people with TB were selected for the Matching Fund. The main objective of the matching funds is to find missing people with TB among both drug susceptible (DS) TB and DR-TB. The funds were encouraged to be used to scale-up successful interventions to find and treat people with TB and implement new and innovative interventions, approaches and ideas beyond business as usual. A key activity listed included the intensified TB screening and diagnosis at health facilities through X-rays and rapid molecular tests.

¹⁵³ Exact findings should be interpreted with some care given the way in which the PQR database is structured and given self-reported data from countries. Trend analysis also becomes more difficult due to different contracting modalities.

Additionally, the Global Fund provided Strategic Initiative funding to provide targeted technical assistance for Innovative Approaches to Finding Missing People with TB (US\$ 10 million in NFM2 and then US\$ 14 million in NFM3). The technical support was provided through the Stop TB Partnership (Stop TB) and the World Health Organization (WHO) and included 13 countries in NFM2 which were expanded to 20 in NFM3. Similar to the first phase, the current model includes global-level technical support backed by country-level, demand-driven technical assistance (TA) with strong country ownership to sustain gains.¹⁵⁴

Multiplexing guidance and service integration

The Global Fund are encouraging through its Information Notes the integration of services including through the use of multiplexing disease platforms for TB, HIV and COVID-19. The Information Note states that HIV/TB joint programming will optimise investments in TB and HIV programs and require high burden TB and HIV countries to submit a single funding request that presents an integrated program.¹⁵⁵ These funding requests can include scale-up of GeneXpert, Digital X-rays and LF-LAM to jointly diagnose the two diseases. Additionally, the Global Fund has supported laboratory service integration through RSSH funding and more recently has also started to support network optimisation in countries.

3.3. ASSESSMENT OF ENABLERS AND BARRIERS

This Section provides an overview of the key barriers and enablers with regard to GeneXpert (Section 3.3.1) as well as service integration across TB and other disease areas (Section 3.3.2). It closes with observations regarding the barriers and enablers currently faced by new TB technologies.

3.3.1. Barriers and enablers for GeneXpert

Figure 3.3 below provides an overview of the barriers and enablers mapped against six overarching factors which sit across the innovation value chain.

Figure 3.3: Key barriers and enablers for the introduction and scale-up of GeneXpert

Factors	Global prioritisation/ perceived value	Normative guidance	Market/ supply characteristics	Price, affordability and cost effectiveness	Country demand and readiness	Implementation
Barriers	• ...	• Time gap between WHO first recommendation (2011) and expansion to wider TB patients (2020)	• Near PoC market dominated by GeneXpert • Difficulties of new tools to enter market / GF ecosystems in-country	• High cartridge prices limit wider scale-up and use	• Trade-offs between utilisation and procurement of new machines	• Issues on service and maintenance • Lack of generated data on use • Linkage to care challenges limit the impact on mortality • Infrastructure and staff challenges
Enablers	• First near POC technology for TB leading to lot of donor support and country demand	• ...	• Recent support from partners (Unitaid, FIND, Stop TB, USAID) to diversify TB diagnostic toolkit	• 'Buy-down agreement' between USAID, Unitaid and Stop TB reduced price to USD9.98 in 2012	• Catalytic funding to supporting finding missing TB cases • Extra support during COVID-19 to purchase additional GeneXpert machines	• In-country coordination of stakeholders and TA from WHO, STOP TB and supported by the Global Fund • All-inclusive pricing models

¹⁵⁴ https://www.theglobalfund.org/media/11449/tb_2021-quarterly-tuberculosis_update_en.pdf

¹⁵⁵ The Global Fund (2019), Tuberculosis Information Note.

Barriers

- **The overall cartridge price for GeneXpert acts as a barrier in particular with regard to wider scale-up and use.** Despite the buy-down agreement bringing a substantial reduction in the price of GeneXpert in 2012, the price still remains too high for many countries to roll out GeneXpert tests in accordance with the latest WHO guidelines which recommend molecular tests to be used for all expected pulmonary TB cases (rather than just MDR-TB or HIV/TB cases). Some work by MSF (supported by Unitaid) suggested that the price needs to come further down to between US\$ 3 and \$5 rather than the current US\$ 9.98. The high price is also linked to the monopoly position that GeneXpert had for a long-time in the near POC TB diagnostic space (this is discussed further in Section 3.3.3).
- **Issues around service and maintenance have been a key barrier for effective use and implementation of GeneXpert.** This has been due to a number of reasons including (i) equipment not ready for conditions in LMICs; (ii) low Cepheid service providers (or sub-contractor) in-country to conduct service / maintenance; and (iii) no inclusion of service / maintenance during contracting. While the first two have been mostly addressed, there remain challenges around the inclusion of service and maintenance as part of the contracting modalities. Some solutions include an “all-inclusive” contracting approach advocated for by Unitaid/ CHAI and PEPFAR which does not purchase any machines but only leases them for HIV. However, the all-inclusive model has not been introduced so far or has been supported by the Global Fund at a large scale. Instead, contracting continues to be done largely by countries with some stakeholder considering all-inclusive pricing to not be sustainable once a country transitions from donor support. GDF offers instead a surcharge modality for maintenance and services, but a key risk has been that during the Global Fund funding process these surcharge costs are taken out of the proposal at the last minute.
- **GeneXpert is a near POC diagnostic tools and issues remain with regard to placement in some areas including infrastructure challenges, staff challenges and data challenges.** Infrastructure challenges include: limited internet access, paper based systems, sample transport problems, lack of refrigeration and lack of telephone communication.¹⁵⁶ And staff challenges include: lack of basic computer skills, inadequate staffing, lack of regular formal training.¹⁵⁷ More recently, a major challenges has been the lack of data connectivity of GeneXpert machines meaning that there is no/limited central data on the utilisation or even maintenance status of equipment. While this is changing, this has been highlighted as a major impediment for more effective use and rapid maintenance response.
- **Implementation challenges and effective linkage to care has limited the impact of GeneXpert with regard to reducing TB mortality** (though some stakeholders pointed out that this is an issue beyond any single innovation / product). Some stakeholders flagged that scaling up GeneXpert has not led to the expected reduction in TB mortality figures in some countries considering implementation challenges and gaps in the linkage to care as the underlying drivers of this. This is also supported in the evidence from recent results from a systematic review analysing the implementation of GeneXpert for TB testing in LMICs.¹⁵⁸ The review identified the underutilisation of Xpert and the inadequate identification of eligible patients as key reasons for the lack of stronger impact on mortality figures and stipulated that these issues were frequently due to a lack of communication/referral pathways between health centres and laboratories and inadequate training to support staff knowledge of testing.
- **Most stakeholders welcomed the focus on utilisation of existing machines though acknowledged that there is a trade-off with regard to purchasing of new equipment within a constraint funding space.** The majority of stakeholders were largely supportive of the Global Fund approach to encourage countries to

¹⁵⁶ Nalugwa (2020), Challenges with scale-up of GeneXpert MTB/RIF in Uganda: a health systems perspective.

¹⁵⁷ Rendell et al. (2017), Implementation of the Xpert MTB/RIF assay for tuberculosis in Mongolia: a qualitative exploration of barriers and enablers.

¹⁵⁸ Brown et al. (2021), Implementation of GeneXpert for TB Testing in Low- and Middle-Income Countries: A Systematic Review

increase utilisation and deployment of existing machines before purchasing new ones (at least prior to COVID-19). There were a few dissenting voices which considered that such a focus on deployment had led to a reduction in the overall machines purchased (with an argument that the lack of machines in country itself led to inefficiency such as needs for transport networks as well as restriction of access to machines). The related criticism has been that the Global Fund has not provided more funding in the TB space to allow for a more large-scale uptake.

- **Time gap between the WHO guideline changes to expand the recommendation to all pulmonary TB patients.** While stakeholders acknowledged that the lack of the WHO recommendation constituted a barrier, many also stated that they did not consider that GeneXpert would be suited to fulfil the WHO recommendation at this stage given its high price as well as limitation with regard to placement (as only near POC).

Enablers

- **The market shaping work by partners was considered important to address the price barrier though was seen as insufficient to lead to more large scale uptake.** The engagement of USAID, Unitaaid and Stop TB to reduce price to US\$ 9.98 was helpful in 2012 was ultimately considered insufficient to really increase scale-up. Stakeholders highlighted that Global Fund were not involved in the pricing negotiation in 2012 (or since) and saw it as a missed opportunity given the Global Fund purchasing power with regard GeneXpert (though acknowledged that they are reportedly more involved in the recent ongoing price negotiations).
- **First near POC technology for TB leading to strong donor support and country demand.** A key enabler has been that GeneXpert promised to fill an important gap in the TB diagnosis landscape by providing much higher sensitivity tests compared to microscopy while being able to be placed closer to patients than conventional systems.
- **Global Fund grant allocations and complementary catalytic funding.** The role of the Global Fund has been seen as critical for the scale-up of GeneXpert. As shown in Section 3.2, it has been involved since 2013 in the procurement of GeneXpert and, importantly, has done through the grant allocation part of its portfolio. Catalytic funding has also played an important role but has been targeted and complementary to the main allocation. For example, the strategic initiatives to finding of missing TB cases has been critical for providing technical assistance and allowing budget for implementation aspects (e.g., including transportation networks) and linkage to care. Matching funds were used to bring in domestic resources to an underfunded diagnostic space.
- **Extra support through COVID-19 recently provided a chance to purchase additional rapid molecular diagnostic tests (including GeneXpert machines) as well as some X-ray machines.** Most recently, there have been additional opportunities for countries to leverage the C19RM funds to expand on the number of GeneXpert machines or to improve the wider laboratory networks in country.
- **In-country coordination between key stakeholders as well as technical assistance from partners such as WHO were considered enablers for effective implementation.** In cases in which countries had strong in-country coordination between involved actors (e.g., BMGF funded stakeholder meetings in countries like South Africa) this was considered to help with speed of national guidelines and effective operationalisation of them.

3.3.2. Assessment of enablers and barriers – Service Integration

Figure 3.4 below provides an overview of the barriers and enablers of service integration across disease areas for GeneXpert mapped against six overarching factors which sit across the innovation value chain.

Figure 3.4: Key barriers and enablers for GeneXpert service integration

Factors	Global prioritisation/ perceived value	Normative guidance	Market/ supply characteristics	Price, affordability and cost effectiveness	Country demand and readiness	Implementation
Barriers	• ...	• ...	• Countries make a differentiation between USAID and GF machines	• Challenge of higher prices for HIV cartridges, resulting in less support from HIV as there are cheaper alternatives.	• Limited role of laboratory experts in funding request stage / CCM • Global Fund lack an accountability framework and performance indicators on integration	• Vertical procurement within Global Fund funding requests and between TB and HIV in-country departments challenges integration
Enablers	• ...	• ...	• ...	• ...	• Extra support available as part of Global Fund COVID-19 support (as well as bi-directional testing)	• Shift towards network optimization supports a more integrated approach to diagnostic services

Key Barriers

- **Vertical procurement within the Global Fund between TB and HIV remains a challenge for integration as well as limited role of laboratory system experts in the funding request stage and CCM.** Challenges in integration often reflect the level of coordination between the disease programmes in the ministry. However, stakeholders stated that the Global Fund processes do not necessarily help to address this point. For example, from an integration point of view, some stakeholders consider that there are still not sufficient combined funding requests with regard to HIV and TB diagnostics (even though this has been improved). Similarly, laboratory systems experts or at least diagnostic expert were considered to be underrepresented during the CCM / funding request negotiations.
- **Lack of an accountability framework / performance indicators from the Global Fund on integration.** In addition to vertical funding, stakeholders commented on the absence of an accountability framework which incentives countries to invest more into joint service integration. Currently, countries are not rewarded for using their equipment for multiple diseases.
- **Differentiation between PEPFAR and Global Fund machines further complicates service integration.** In addition to differentiation between disease programmes outlined above, in some countries it also is a challenge to coordinate across machines depending on the donor who supported the project.
- **The higher prices for HIV and other disease areas have also been a challenge in particular as these other disease areas have cheaper alternatives available.** Another challenge has been that HIV cartridges for GeneXpert have a price of just below \$15 (compared to US\$ 9.98 for TB). As result, there has been less support from other disease areas to use or expand GeneXpert use especially where there are cheaper alternatives available (as in the case for HIV).

Key Enablers

- **Shift towards network optimisation has been supporting a more integrated approach to diagnostic services.** Stakeholders have been supportive on the recent focus on supporting network optimisation in countries through partners (e.g., through support from BMGF) but also through more recent support from the Global Fund on network optimisation.

- **Extra support through COVID-19 recently provided a chance with regard to bi-directional testing but also just to provide additional funding to strengthen an integrated laboratory system.** This includes the general COVID-19 funding but also more targeted smaller initiatives such as the STELLAR programme.¹⁵⁹

3.3.3. Barriers and enablers for Molbio and other innovations

Barriers and enablers

- **The Near Point-of-Care Diagnostic space has been a monopoly market for a long time with a lack of diversification with regard to other tools making it harder for other products to enter.** The extended focus and support for GeneXpert has supported the establishment of monopoly market for a long time in the near PoC diagnostic space for TB. Stakeholders emphasised that this was an issue for the wider TB community (including Partners more involved in upstream market shaping including Unitaid and FIND) but also include the Global Fund. A lesson would be across actors to look at the full tool kit that needs to be developed and not to focus too heavily on a single product. This has changed more recently with Molbio TrueNat but also with renewed efforts from partners to introduce other tools (e.g., the Unitaid/FIND grant on the TB Diagnostic such as a third generation TB LAM test or the USAID / GDF “introducing New Tools Project (iNTP)”. Global Fund was seen as having an important role to (i) push also for a full tool kit approach and (ii) to ensure that other products getting a space even where countries prefer existing products.
- **Country inertia to stick with known products and difficulties for new innovations to “break into” Global Fund country ecosystem.** Some stakeholders emphasised that many countries focus on additional GeneXpert machines with available budget without considering other innovative approaches even where these could be cheaper (e.g., digital X-ray machines or Molbio TrueNat). To some extent, this was considered sensible due to the additional costs of training / switching to a different machine, but it was also flagged as an impediment for new innovation. This dynamic gets amplified that the Global Fund “country ecosystem” (e.g., Global Fund GMD country teams / CCM / funding request processes) were not seen to be easily accessible for actors supporting new innovation (at least there is no formal or structured process and instead relies on people in key positions- such as Global Fund FPM).

3.4. LESSONS LEARNED

- **Recent engagement of the Global Fund and partners with diagnostic manufactures, including GeneXpert and TrueNat suppliers, has been welcomed. Earlier engagement resulting in a significant period of price stability may not have been good practice, as it limited ability to regularly negotiate price reductions.** While there have been price reductions and agreement in 2012 (with the same price applied to a newer product), stakeholders considered that the Global Fund could have played a larger role in price negotiations. An important aspect to this more effectively were strong demand forecasting for the need of GeneXpert (even if just done accurately with a focus on high burden countries) and with some stakeholders suggesting a volume commitment would be ideal. Reportedly, recent engagements on future GeneXpert purchases as well as Molbio TrueNat have therefore been welcomed.
- **The Global Fund can play a pivotal role in strong scale-up of products especially where there is strong country demand, and the product is early on supported through the grant allocation funding with targeted catalytic funding.** GeneXpert is a good example of the purchasing power that the Global Fund holds through its grant allocation funding which remains the biggest and strongest route for large scale-up. A key pre-requisite for this has been strong country demand for the product.

¹⁵⁹ https://www.theglobalfund.org/media/11815/covid19_c19rm-project-stellar_briefingnote_en.pdf

- **Maintenance and service contracting has remained a challenge with the Global Fund and partners. More efforts could have been put in place to help countries to build capacity to administer adequate service and maintenance, particularly at the point of care level.** While some aspects around maintenance and servicing have improved, the contracting modalities remain patch-work with different agreements done by countries (with some not including maintenance / servicing). More inclusive procurement modality (AccessCare) has been introduced for TB programs for GeneXpert technologies, which covers the service and maintenance costs through a surcharge on the number of tests with standardized Service Level Agreement and KPIs. This approach has to be expanded to more countries.
- **The Near Point-of-Care Diagnostic space has been a monopoly market with a lack of support to diversify the diagnostic tool kit.** The GeneXpert example illustrates the risk of focusing heavily on a single product that leads to a monopoly market (with repercussion around price and contract modality negotiations). This is a lesson for the wider TB community, including more upstream partners, but also for the Global Fund which was seen as being able to do more to support new innovations entering the market (see below).
- **Country inertia to stick with known products which requires country demand creation / support for new innovations to “break into” Global Fund country ecosystem.** Global Fund was seen as too reactive to new innovations with no structured plan to support the introduction and scale-up of new innovations. Suggestions for improvements included: (i) provide access to actors supporting innovation; (ii) support technical partners to provide evidence on innovation to countries; (iii) support of operational research / piloting in grants; (iv) TRP requirements for other products / innovation and (v) more active demand creation with countries and communities for new products.

4. MDR-TB SWITCH TO ORAL REGIMENS WITH BEDAQUILINE

Context/ background: bedaquiline is an oral medication used to treat MDR-TB alongside other medicines. Since 2019 the WHO guidelines recommend all-oral bedaquiline-containing regimens to treat DR-TB as they are safer, shorter and less toxic than previous treatments with injectables.

Uptake and Global Fund role: The uptake of BDQ through Global Fund grants can be seen in two phases - pre 2019 with low uptake due to weak WHO recommendation with procurements mainly for operational research, and post 2019 with the change in WHO guidelines and decline in injectables, which is viewed as a timely adaptation to WHO guidelines. The Global Fund coordinated closely with partners and had good visibility on guideline changes, and it also provide technical support to countries in coordination with partners. The transition to oral regimens was conducted throughout the grant cycle with the help of the portfolio optimization process.

Successes and enablers:

- Substantive improvement of bedaquiline over previous treatments led to strong partner action and country demand
- Early market intervention in the form of the donation programme between J&J, GDF and USAID was critical
- Partner coordination, technical assistance to countries and the use of WHO rapid communications
- Use of portfolio optimisation funding allowed regimen change to take place during Global Fund grant cycle
- Joint WHO-GF-GDF FAQs, update of the Global Fund TB information notes, GDF removal of injectables from catalogue, and Global Fund rules to stop procuring injectables all accelerated uptake
- Update of the Global Fund TB information notes and rules to

Challenges and barriers:

- Limited WHO recommendation for the use of Bedaquiline in 2013 and the long-time period until a strong recommendation was included in the WHO guidelines in 2019
- Despite some price reduction, the high price of Bedaquiline remains a barrier for large scale uptake in particular in settings where countries have to cover the drug costs from domestic resources
- Continued monopoly for J&J is underlying factor for high prices and is seen as barrier for large and sustainable uptake. Continued monopoly for J&J is underlying factor for high prices and is seen as barrier for large and sustainable uptake

Lessons learnt:

- Proactive coordination at global and country level is important to respond quickly to WHO guidance updates
- The Global Fund has tools to switch to treatment regimens within a grant cycle but this not a standardised process and requires upfront visibility and partner coordination
- Coordinated technical assistance is key to aid countries with transition planning, such as taking stock of existing products and addressing wastage concerns
- Immediate removal of injectables from GDF Catalog and changes to procurement rules following WHO guidelines was an important factor in speeding up the transition process
- Market shaping intervention have been key to boost introduction and scale-up of bedaquiline but have relied entirely on partners

4.1. BACKGROUND

Rationale for shorter oral regimens

Drug resistance can emerge when anti-TB medicines are used inappropriately, through incorrect prescription, poor quality drugs, stockouts and when patients are unable to complete treatment. Specifically, MDR-TB is TB that does not respond to at least both isoniazid and rifampicin. Multidrug-resistant TB (MDR-TB) remains a public health crisis and a health security threat. Only about one in three people with drug resistant TB accessed treatment in 2020.¹⁶⁰

Previous treatment for MDR-TB has been longer, more expensive and more toxic than for DS-TB. Before recent innovations in MDR-TB treatment, WHO recommended regimens lasting at least 20 months, compared to just 6 months for DS-TB, and painful injectables resulted in harmful side effects, such as hearing loss, Arthralgia and gastrointestinal disorders.^{161,162}

Short oral-regimens were needed to treat MDR-TB to increase the proportion of patients successfully completing treatment. There is also a need for shorter-regimens to be safer, as toxic medicines in previous treatments have led to harmful side effects that also increase the risk of patients stopping treatment early.

DR-TB regimens with bedaquiline

Bedaquiline is an oral medication used to treat MDR-TB alongside other medicines. In 2012, bedaquiline was granted license by the US-FDA. There have been several advancements in the treatment of MDR-TB over the last decade. WHO guidelines have been updated several times to move away from injectable agents to safer all-oral bedaquiline-containing regimens. Table summarises the key changes to WHO DR-TB treatment recommendations over the years 2013-2022.¹⁶³

Table 4.1: Key changes to WHO DR-TB treatment recommendations, 2013-2022

Year	WHO guidance updates
2013	Interim policy guidance recommends bedaquiline for DR-TB treatment. ¹⁶⁴
2015	Companion DR-TB treatment handbook includes the use of bedaquiline. ¹⁶⁵
2016	Guidance recommends standardised shorter regimen (the injectable containing 'Bangladesh regimen') ¹⁶⁶
2017	Guidance recommends conditions for expanded combined and extended use of bedaquiline. ¹⁶⁷
2018	Rapid communication recommends against injectables and recommends all-oral DR-TB treatment regimen. ¹⁶⁸
2019	WHO releases consolidated guidelines on DR-TB treatment including recommendation for all-oral DR-TB treatment and against injectables. ¹⁶⁹

¹⁶⁰ WHO (2021) Global Tuberculosis Report

¹⁶¹ Falzon et al. (2011), WHO guidelines for the programmatic management of drug-resistant tuberculosis: 2011 update.

¹⁶² Zhang et al. (2017), Adverse Events Associated with Treatment of Multidrug-Resistant Tuberculosis in China: An Ambispective Cohort Study.

¹⁶³ Stop TB Partnership (2020), Step Up for TB: Tuberculosis Policies in 37 Countries.

¹⁶⁴ WHO (2013), The use of bedaquiline in treatment of multidrug-resistant tuberculosis: Interim policy guidance.

¹⁶⁵ WHO (2014), Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis.

¹⁶⁶ WHO (2016), WHO treatment guidelines for drug-resistant tuberculosis: 2016 update.

¹⁶⁷ WHO (2017), WHO best-practice statement on the off-label use of bedaquiline and delamanid for the treatment of multi-drug resistant tuberculosis.

¹⁶⁸ WHO (2018), Rapid Communication: Key changes to treatment of multidrug- and rifampicin-resistant tuberculosis (MDR/RR-TB).

¹⁶⁹ WHO (2019), WHO consolidated guidelines on drug-resistant tuberculosis treatment.

Year	WHO guidance updates
	Rapid communication recommends shorter all-oral bedaquiline-containing regimen and new BPaL regimen under operational research conditions. ¹⁷⁰
2020	Consolidated guidelines confirm previous DR-TB updates recommending shorter, all-oral bedaquiline-containing regimen and recommending BPaL under Operational Research. ¹⁷¹
2022	Rapid communication recommends BPaLM/ BPaL regimen. ¹⁷²

Market and price development

Johnson & Johnson (J&J) is the monopoly supplier of bedaquiline and holds intellectual property protections on bedaquiline until at least 2027 in 64 low- and middle-income countries (while the primary patent on bedaquiline expires in 2023 but evergreening can extend the patent protection by several years).¹⁷³ Generic versions of the drug cannot be sold until patents expire unless country governments issue compulsory licenses. As a result, it is likely the monopoly market for bedaquiline will persist for several years from now.

In 2015, USAID and Janssen Therapeutics, a pharmaceutical company of J&J, set up a drug donation partnership where Janssen to donate bedaquiline to LMICs facilitated through the Global Drug Facility. The programme distributed over 105,000 treatments between 2015-2019 reaching with 110 countries being eligible for support.¹⁷⁴

Following on from the donation programme, J&J agreed a price reduction negotiation with USAID and STOP TB Partnership/GDF and the Global Fund in July 2020. This made bedaquiline available to STOP TB Partnership's Global Drug Facility (GDF) at a reduced the price of bedaquiline from a suggested post-donation price of USD\$400 to USD\$340 per six-month treatment course.¹⁷⁵ The agreement also included an escalating percentage of free goods when certain volume thresholds are reached on an annual basis: 10% above 55,000, 20% above 125,000 and 30% above 200,000 treatment courses. As result, in 2020 the prorated price for bedaquiline has been US\$ 272 per treatment. Prior the negotiations there has been an extended advocacy campaigns led by civil societies, including MsF, to reduce the price for bedaquiline.

Timeline of key activities

Figure 4.1 below provides a timeline of the key events including both partner and Global Fund activities. Besides the WHO guidelines, the donation programme and the price reduction described above, key activities included extended partner coordination to support countries in the introduction and scale-up of oral regimens which leveraged on existing TB structures such as the (regional) Green Light Committees (GLCs), the Global Task Force and the TB Situation Room. This is further discussed in the enabler section below. Additionally, Unitaids' EndTB project focused on delivering clinical evidence on safety and efficacy of scalable, effective treatment DR-TB regimens that are less toxic, shorter, and less expensive than the existing standard of care. They conducted an observational study in 17 counties which was finalised in 2018 and helped shape national guidelines supporting the use of new TB drugs on a global level and informing the revision of the global MDR-TB treatment guidelines. The clinical trials supported for new regimens are expected between 2023-24.

The key Global Fund activities as well as actual bedaquiline procured with funding from the Global Fund grants is detailed in Section 4.2. below.

¹⁷⁰ WHO (2019), Rapid Communication: Key changes to the treatment of drug-resistant tuberculosis.

¹⁷¹ WHO (2020), Consolidated guidelines on tuberculosis, module 4: treatment – drug-resistant tuberculosis treatment.

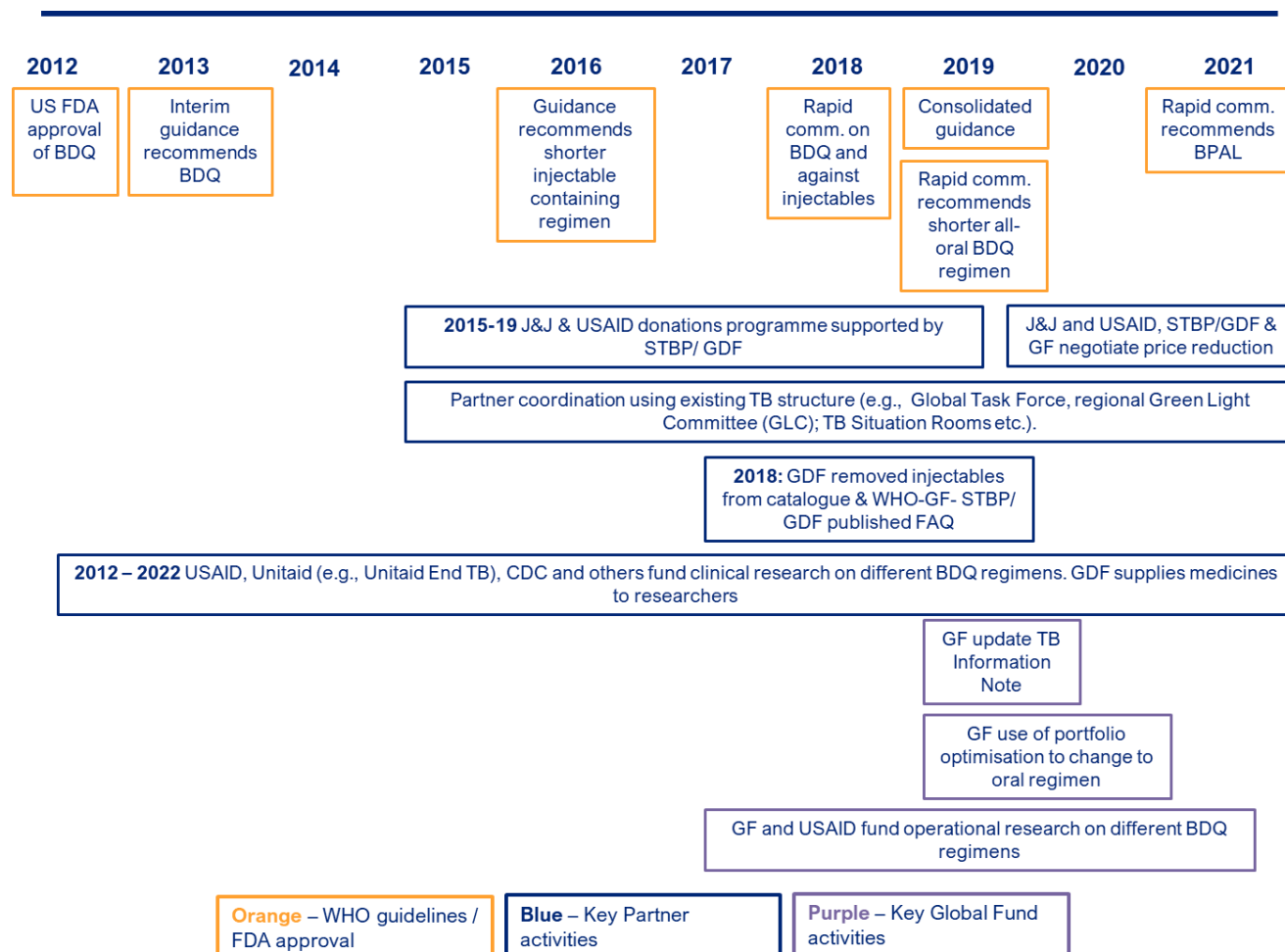
¹⁷² WHO (2022), Rapid Communication: Key changes to the treatment of drug-resistant tuberculosis.

¹⁷³ <https://www.tbonline.info/posts/2022/7/1/activists-across-world-demand-urgent-action-improv/>

¹⁷⁴ STOP TB (2021); GDF Experience with Global Access Agreement for Bedaquiline

¹⁷⁵ Johnson & Johnson (2020), Stop TB Partnership and Johnson & Johnson, with support from USAID and The Global Fund, Announce Price Reduction for SIRTURO (bedaquiline) for Treatment of Drug-Resistant Tuberculosis in Low- and Middle-Income Countries, available [online](#).

Figure 4.1: Timelines of key activities

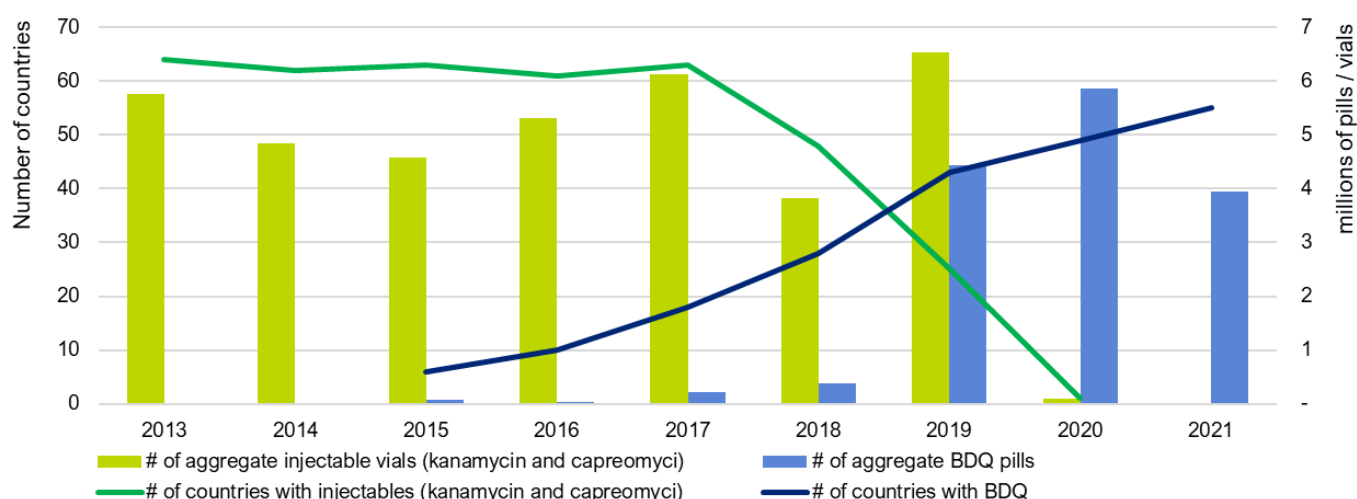


4.2. GLOBAL FUND SUPPORT

Procurement of bedaquiline with Global Fund funding

Figure 4.2. below shows the uptake of BDQ which has been funded through Global Fund grants over time based on PQR data (majority of countries use GDF as the procurement channel). The figure shows that BDQ uptake has been closely aligned with the strength of the WHO recommendations over time.

Figure 4.2: BDQ and injectables procured through a Global Fund grant over time based on PQR data



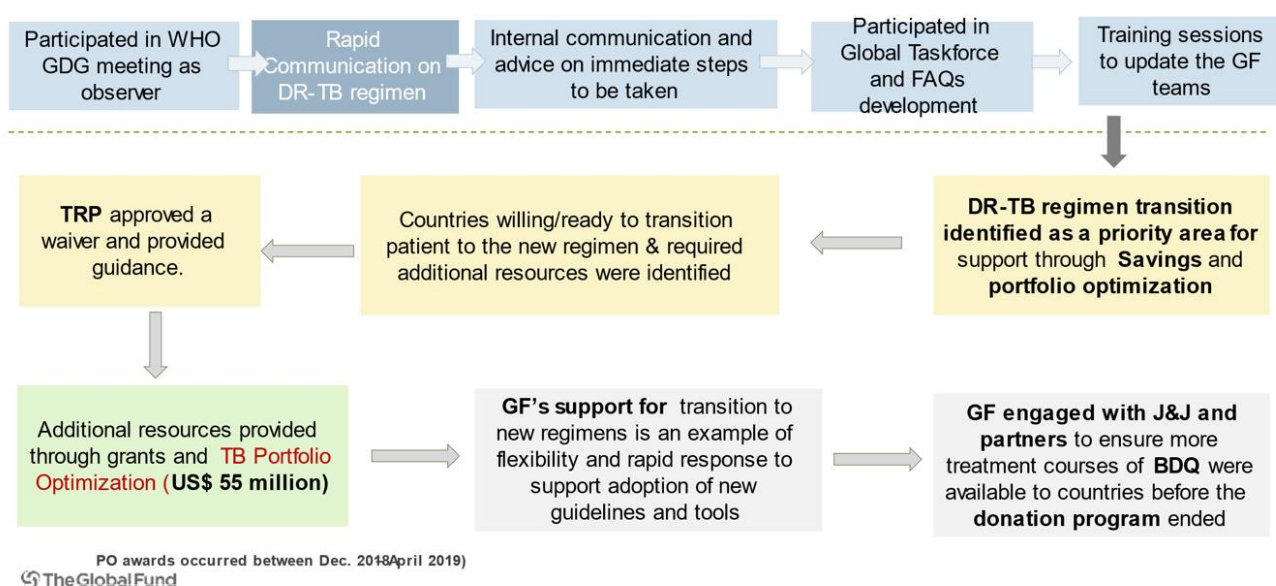
Source: CEPA analysis based on PQR database

The uptake of BDQ through Global Fund grants can be seen in two phases - pre 2019 with low uptake on account of weak WHO recommendation with procurements mainly for operational research or pilots, and post 2019 with the change in WHO guidelines and decline in injectables, which is viewed as success story particularly when comparing with other recommendations in the past such as on Fixed Dose Combinations.

Global Fund rapid response after WHO 2018 rapid recommendation

The Global Fund had strong visibility of the changes in the WHO guidelines through participating in WHO GDG meetings and wider partner coordination and used the portfolio optimisation process to ensure that the transition to an oral based regimen could occur during grant implementation (rather than waiting until the next funding cycle). The process of this approach is detailed in Figure 4.3.

Figure 4.3: Global Fund support to implement WHO recommendations



Source: Global Fund (2018)

This also included to receive a TRP waiver to ensure that all grants could be updated rather than to seek approvals on a country-by-country basis. In total, an additional US\$ 55 million were provided through the grants and the TB Portfolio Optimisation process. Additionally, the Global Fund also coordinated with partners to provide targeted financial and technical support to countries to transition to the new regimen. This was coordinated through the Global Task Force and included a geographical split between USAID and the Global Fund. At the time, eleven countries were identified for immediate prioritisation.¹⁷⁶

Following the 2019 WHO recommendation which advised the use of a shorter all-oral bedaquiline-containing regimen, the Global Fund updated the TB Information Note to include a strong recommendation to shorter term regimen with BDQ. The Information Note also encourages countries to procure bedaquiline through reliable mechanisms, such as the GDF.¹⁷⁷ Procurement rules were also adjusted to align with WHO recommendation and no longer supported the use of injectables (as can be observed in drop in injectable use in Figure 4.2 above).

Operational research

More recently, the Global Fund has also continued to support operational research for specific shorter regimens such as BPAL. This included a Strategic Initiative with the aim was to accelerate the introduction of innovation for MDR-TB

¹⁷⁶ Philippines, Uganda, Cameroon, Ethiopia, Georgia, Uzbekistan, Kyrgyzstan, Tajikistan, Belarus, Ukraine and Zambia

¹⁷⁷ Global Fund (2019), Tuberculosis Information Note.

treatment through regional operational research in Eastern and Central Europe. This included eleven countries in EECA and was closely coordination with WHO.

4.3. ASSESSMENT OF ENABLERS AND BARRIERS

This section provides an overview of the key barriers faced in the introduction and scale-up of all oral DR-TB regimens with Bedaquiline as well as the key enablers which were critical in achieving the observed scale-up. Figure 4.4 below provides an overview of the barriers and enablers mapped against six overarching factors which sit across the innovation value chain.

Figure 4.4: Key barriers and enablers for the introduction and scale-up of all-oral regimens

Factors	Global prioritisation/ perceived value	Normative guidance	Market/ supply characteristics	Price, affordability and cost effectiveness	Country demand and readiness	Implementation
Barriers	<ul style="list-style-type: none"> Initial concerns regarding safety of BDQ use in LMICS (successfully addressed) 	<ul style="list-style-type: none"> Long process to WHO issuance of clear guidance (2013-19) 	<ul style="list-style-type: none"> J&J as monopoly supplier with secondary patents until 2027 	<ul style="list-style-type: none"> High prices for BDQ (especially key for transition countries) 	<ul style="list-style-type: none"> Updates to national guidelines / product registration (successfully addressed) 	<ul style="list-style-type: none"> Concerns regarding wastage of replaced products (successfully addressed)
Enablers	<ul style="list-style-type: none"> Substantive improvement of BDQ over previous treatments has meant strong partner action and country demand 	<ul style="list-style-type: none"> More recent use of WHO rapid communication has facilitated speed Studies supported by partners (e.g., Unitaid EndTB) 		<ul style="list-style-type: none"> J&J-GDF-USAID-GF price reduction from \$400 to \$272 prorated price for six-month treatment course 	<ul style="list-style-type: none"> Strong partner coordination and provision of TA by USAID, WHO, STB/GDF, and supported by the Global Fund Concerted action by the GF & partners—guidelines on BDQ use & stop of funding injectables after 2019 WHO guidelines. Approval to destroy inferior products, alongside use of portfolio optimization. Use of operational research / pilots (supported by GF including through SIs) 	<ul style="list-style-type: none"> J&J- USAID-GDF drug donation programme provided access to BDQ to more than 100 countries Concerted action by partners, facilitated by the existence of strong organizing bodies/ groups such as the GLC, the Global Task Force and the TB Situation Room.

Key barriers

- A key barrier has been the limited WHO recommendation for the use of Bedaquiline in 2013 and the long-time period until a strong recommendation was included in the WHO guidelines in 2019.** A key reason for the limited WHO recommendation has been the initial uncertainty with regard to the safety of Bedaquiline within regimens in LMICs. Together with the high price for Bedaquiline between 2013-15, this resulted in low uptake and demand for the product in the first few years after it had FDA approval. This in turn reduced available evidence to support a stronger update of the WHO guidelines. Similarly, the limited recommendation, and corresponding very small market share, meant also that no immediate economies of scale would reduce the price. This impasse was changed through the J&J and USAID donation programme facilitated by STBP / GDF which is discussed further in the enabler section below. Another important factor for the guideline changes has been the decision of South Africa to roll out the use of Bedaquiline, including the use of short-oral regimens in 2018 prior the WHO guideline changes.
- Despite some price reduction, the high price of Bedaquiline remains a barrier for large scale uptake in particular in settings where countries have to cover the drug costs from domestic resources.** For a larger scale-up of all-oral regimens, including BPaL, the price of BDQ is still seen as key barrier. The price

reduction in 2020 negotiated by STBP/GDF, USAID and Global Fund, was seen as a step in the right direction with a prorated price of US\$ 272 per bottle.¹⁷⁸ But stakeholders emphasised that further reductions need to be achieved in the future. The price is particularly challenging for countries which are in (pre-) transition of Global Fund support and cover increasingly drug costs from domestic resources. For example, in Indonesia, the BDQ was covered by the Global Fund during the pilot phase, but following its formal introduction, this needed to be covered by domestic sources and there is need to secure large, ongoing quantities. The extent of government funds to cover a continued scale up of BDQ on an ongoing basis, as well as supportive costs, is unclear. The high prices are closely linked to the monopoly position of J&J in the market.

- **Continued monopoly for J&J is underlying factor for high prices and is seen as barrier for large-scale uptake.** A key underlying factor for the high prices is the monopoly for Johnson and Johnson on the bedaquiline market. Johnson & Johnson have intellectual property protections on bedaquiline (through the use of secondary patents including process and FDCs) until 2027 in 64 low- and middle-income countries which means that new generic version cannot be sold until these patents expire, unless compulsory or voluntary licenses are issued.¹⁷⁹ There is now one generic manufacturer for BDQ with ERP approval (Macleods) but it is not clear where their products can be used given the patent situation.
- **Further strengthening of community demand for all oral regimens could have facilitated the scale-up of bedaquiline further.** While not raised as major barrier to introduction, a few stakeholders mentioned that work directly with affected communities could have facilitated scale and speed of bedaquiline uptake further. For example, they considered that TB lacks the strong community demand for new and improved regimens which can be observed for HIV.

Key enablers

The following key enablers have been identified (most already described above within the overcoming barrier sections):

- **Substantive improvement of bedaquiline over previous treatments has meant strong partner action and country demand.** Once initial concerns regarding safety of bedaquiline right after the FDA approval have been addressed through additional evidence, there was strong country demand and partner action for bedaquiline in particular as it was seen as a strong improvement over the use of injectables which use led to many side-effects as well as adherence problems.
- **Early market intervention in the form of the donation programme between J&J, GDF and USAID has been critical in boosting introduction of BDQ and to gather necessary evidence to update WHO guidelines.** As outlined above, a key enabler to move forward in the early years after FDA approval has been the donation programme initiated between USAID and GDF and Johnson and Johnson. This allowed countries to gain access to Bedaquiline for free, gain experience with the implementation of regimens and create necessary evidence for an update of the WHO guidelines. While a few stakeholders noted the limitation of the donation programme in terms of longer-term pricing (e.g., in comparison to price reductions or voluntary licensing for example), it was overall viewed as critical to speeding up the progress towards bedaquiline introduction.
- **Partner coordination, technical assistance to countries and the use of WHO rapid communications were critical in translating WHO recommendations into country guidelines in timely manner.** Stakeholders generally felt that the response after the WHO 2018 guideline changes was fast in translating the regimen change into national policy. Key factors for this were:

¹⁷⁸ Based on the price reduction and 20% of free goods based on the negotiated agreement: <https://stoptb.org/assets/documents/gdf/drugsupply/2020.07.06%20FAQs%20for%20bedaquiline%20price%20announcement.pdf>

¹⁷⁹ TAG (2022), Activists Across the World Demand Urgent Action to Improve Access to Lifesaving Tuberculosis (TB) Medicine, Bedaquiline, available [online](#).

- **Active planning, a proactive approach and visibility through existing TB partnerships.** With GDF / STOP TB in collaboration with WHO seen as important in the process of understanding upcoming changes and to communicate these with other partners and countries. Leveraging also the existing TB organisations at global and country level (e.g., Global Task Force, GLC, TB Situation Room) was considered key. Stakeholder interviews also highlighted the importance of ongoing discussions with countries to help them understand the clinical evidence and realise there is no need for further piloting after the WHO guidelines were updated. This work through technical partners (and in conjunction with Global Fund Country Teams) was seen as important as countries otherwise often would like to a pilot testing in their own country context (and while there are benefits to this approach it can delay the scale-up in cases with sufficient evidence). Critical has also been the technical assistance led by STBP/GDF with regard to PSM work around the transitioning of regimens.
- **The use of WHO rapid communications was seen as helpful to speed-up the process and reduce the time until WHO guidelines updates have been made.** Though some stakeholders also stressed the risk of communication fatigue with many different updates on treatment regimens over the last years.
- **The change to all-oral regimens after the 2018 WHO rapid communication / 2019 guideline change was also driven by previous work on registering and introducing bedaquiline already in-countries.** This was driven in particular through the donation programme mentioned above and the work by GDF but also operational research which had been supported by Unitaid through EndTB, USAID and, to a lesser degree, the Global Fund.
- **Global Fund's response based on coordination with partners allowed to transition to new regimen within allocation cycle and to address key country concerns.** The response of the Global Fund was largely considered to have been well aligned and coordinated with partners allowing for a rapid response once WHO guidelines were updated. In particular, the following aspects were considered helpful in accelerating the scale-up of bedaquiline:
 - **The use of portfolio optimisation funding was key to ensure that the regimen change could take place during the Global Fund allocation cycle.** The change to all-oral regimens came with a considerable increase in drug costs as well as associated costs (e.g., transition planning, training etc.) which are not included as part of the grant allocation (which were made based on existing regimens). As result, in order for countries to switch rapidly while maintaining their DR-TB treatment targets, additional funding was required. This was addressed successfully through the portfolio optimisation process, including the TRP waiver to change grants without needing individual country approval. Despite seen overall favourable, a few stakeholders noted that there was no standardised process to go through portfolio optimisation requiring strong coordination with partners and upfront visibility of guidelines and coming with some additional administrative burden to countries.
 - **The update of the Global Fund TB information notes, issuing of WHO-STBP/GDF- GF FAQs, and rules to stop procuring injectables after the WHO guideline change in 2019** was considered a key to move country programmes towards bedaquiline and stopping the use of injectables altogether. Importantly, this also included an immediate update to the STBP/ GDF catalogue which included the removal of injectables meaning that countries could not use this procurement channel for injectables any longer.¹⁸⁰ With the exception on India (which pushed to continue to have injectable in 2019) countries followed this guidance and switched out of the injectables.
 - **The provision of technical assistance coordinated between partners as well as Global Fund permission for the destruction of replaced drugs helped to address concerns around the wastage of drugs.** The Burnet Institute review found that countries are worried about urgent change

¹⁸⁰ STBP/GDF (2018). August 2018 Medicines Catalogue

to nation-wide stock and wastage.¹⁸¹ Stakeholders stressed the technical assistance to countries in planning procurement and mapping of stocks and demand forecasts were critical for successful transition. As outlined above, this was largely considered to be well done with coordination between partners (e.g., geographic split between USAID and Global Fund in terms of funding) and close support from STOP TB/GDF within these processes. Additional funding to destroy stock were also seen as helpful for a rapid transition (though some stakeholders saw successful transition planning / technical assistance as first priority emphasising that the appearance of destroying existing drugs was not favourable for countries despite approval of donors to do so).

- **Use of operational research that provided evidence not only for WHO recommendations but also learnings around successful country implementation was welcomed and was also supported through Global Fund Strategic Initiative support.** This was seen as helpful to advance the discussion with national stakeholders for more rapid update of national guidelines and product registration. Work under the EndTB project funded by Unitaid includes this. The Global Fund has also allowed countries to conduct operational research with regard to TB regimens with the most recent example including support for the BPAL regimen. While this has generally been welcomed, there has been some caution not to overdo small-scale operational support across too many countries in particular in cases in which wide-scale recommendations are expected soon (e.g., USAID chose not to support operational research in BPAL instead trying to push countries to go for a complete change in regimen).

4.4. LESSONS LEARNED

The following lessons learned can be drawn from the introduction and scale-up for oral regimens:

- **Proactive partner coordination at global level and at country level has been key in responding relatively quickly to WHO guideline changes and scaling-up bedaquiline.** This was driven especially by using existing global and country TB platforms and included a range of key partners such as Global Fund, STOP TB/ GDF, USAID and WHO.
- **The Global Fund has tools to switch to treatment regimens within a grant implementation cycle but this not a standardised process and requires upfront visibility and partner coordination.** The challenge of increased commodity and transition costs (while having fixed allocation during a grant cycle) were successfully addressed by the Global Fund through the portfolio optimisation process, including the TRP waiver to change grants without needing individual country approval. A stakeholders noted that a more standardised process to go through portfolio optimisation for new regimens could be favourable to the current ad-hoc system.
- **The provision of technical assistance during the transition process by the Global Fund and partners (STBP/GDF, USAID, WHO, etc.) was considered to be key in order to aid countries with transition planning such as the STBP/GDF-led work of taking stock of existing products / costs for transition and to address wastage concerns.** The Burnet review also emphasised this point in their review and highlighted the potential for the Global Fund to provide more funds for updating, costing, quantification of drugs and materials and planning transition to the new guidelines as well as to provide tools for drug calculations for transition.
- **The update of the Global Fund TB information note and rules to stop procuring injectables after the WHO guideline change in 2019 was also considered a key enabler to speed up the process towards all-oral regimen transition.** A few stakeholders suggested that an earlier approach to changing the

¹⁸¹ Burnet Institute (2019), Rapid review on the feasibility of implementing new WHO treatment guidelines on MDR/RR-TB and LTBI.

procurement options to countries (e.g., a minimum standard) could have made this transition even quicker though the difficulties were noted to move ahead of WHO guidelines. A potential option would be “a softer requirement” around minimum rule ahead of WHO guidelines such as additional justification required from countries to purchase injectables.

- **Market shaping intervention have been key to boost introduction and scale-up of BDQ.** While efforts by partners have been key (particularly during the early phases – e.g., through the donation programme), high prices remain a challenge. Some stakeholders suggested that there might be potential for the Global Fund to exploit its purchasing power more strongly. While others emphasised the need to have stronger support for generic manufacturing to ensure long-term affordable prices.

5. INSECTICIDE TREATED NETS

Context/ background While both pyrethroid-PBO and Dual AI ITNs ('next generation nets') had by 2017/ 2018 demonstrated improved efficacy in entomological studies, there was limited epidemiological, cost and operational evidence, to enable further scale up and related, a WHO recommendation. The scale up of PBO nets had been slow owing to this lack of evidence base, higher cost and limited supply, despite a later interim recommendation (now a 'conditional recommendation'), and so there was a perceived need to deliberately 'speed this up' in the case of Dual AI nets through a market intervention with various components.

Global Fund role and funding to date The Global Fund and its partners provided catalytic support for Dual AI nets to essentially address the barriers experienced through the PBO net experience. The New Nets Project (NNP) (NFM2+) was allocated a total of \$66m from both Unitaid and the Global Fund and the Net Transition Initiative (NTI) (NFM3+) a total of \$50m from the Global Fund. The NNP procured a total of 35m Dual AI Nets, and the NTI, almost 38m. The projects aimed to increase the evidence base for Dual AI nets, increase supply capacity, and reduce the net cost to affordable levels to facilitate scale-up if a WHO policy recommendation was achieved. Financing for PBO nets is generally prioritised in portfolio optimisation windows and procurement of PBO products was scaled up considerably from NFM1 to NFM2.

Successes and enablers

Dual AI nets

- Strategic Initiative funding through the NNP and NTI
- Strong partnership and joint commitment
- Applicable learnings from slow initial growth of PBO nets within the market
- Dual AI PQ listings considered exceptions during transition to new WHO evaluation process for vector control interventions
- Solid forecasting and production planning

PBO products

- Some evidence on efficacy and effectiveness of PBO products
- Interim WHO policy recommendation

Challenges and barriers

Dual AI nets

- Production and surge capacity remains a challenge
- Price barrier still exists with demand not fully tested
- Country registration may remain a bottleneck
- Future role of generics in the market remains unclear

PBO products

- Challenges in specificity of WHO interim policy recommendation initially slowed uptake
- Epidemiological, durability and cost-effectiveness data show variations in added benefits
- Continued high prices, supply and production capacity issues

Lessons learnt

- How a process which enables a parallel operational and epidemiological evidence generation effort alongside the WHO approval process can be applied to other products which may be associated with more risk and less certain added public health value needs to be considered
- More strategic thinking needs to guide the next phase of multiple nets use in countries in line with a sub-national tailoring approach
- Support to country readiness by the Global Fund needs further clarifying
- Using catalytic funding to continue support for certain products is only appropriate up to a certain point, but finding that right point is a challenge. How the Global Fund can offer a more streamlined process to supporting new products, including incentivising manufacturers and building demand, and whether a 'market distortion' should always be required, needs further consideration

5.1. BACKGROUND

This case study includes primary focus on both Dual AI nets and PBO products (health products and devices).

Rationale for innovation investment

Insecticide-treated nets (ITNs) and, more recently, long-lasting insecticidal nets (LLINs) are the most widely used preventive measure for controlling malaria. Pyrethroids are currently the only type of insecticide used routinely on ITNs (or LLINs) and the rapid spread of pyrethroid-resistant vectors seriously threatens to reverse the gains achieved so far.¹⁸² Several studies have demonstrated that ITNs are becoming less effective at killing mosquitoes in areas of high resistance compared to areas of susceptibility¹⁸³, although epidemiological evidence remains inconclusive. Due to concerns about the potential failure of current control tools as a result of insecticide resistance, WHO has encouraged manufacturers to develop new types of ITNs as part of the Global Plan for Insecticide Resistance Management in malaria vectors (GPRIM).¹⁸⁴ The first nets to contain a mixture of active ingredients with evidence for impact on epidemiological outcomes were nets that combined a pyrethroid insecticide with the synergist piperonyl butoxide (PBO) which restores susceptibility to pyrethroid by neutralising mixed-function oxidase function responsible for resistance in vectors.¹⁸⁵ New classes of ITNs combining two insecticides with differing modes of action could have the potential to improve vector control and delay the evolution of resistance and preserve the lifespan of both active ingredients (AI). The two most advanced products are the pyrethroid-pyriproxyfen LLIN (Olyset® Duo and Royal Guard®) and a pyrethroid-chlorfenapyr LLIN (Interceptor® G2).¹⁸⁶ While both types of ITNs had – by 2017/8 – demonstrated improved efficacy in entomological studies, there was so far limited epidemiological, cost and operational evidence to enable further scale up and related, a WHO recommendation.

The catalytic support by the Global Fund and its partners for Dual AI nets was essential to address the barriers experienced through the PBO net experience. PBO products have been seen as a ‘missed opportunity’ – PBO products had been around for a number of years but there were various barriers to their wide scale uptake/ adoption, including a lack of epidemiological data to inform WHO recommendation, high price, supply capacity, operational/ cost understanding of multi product campaigns, and a lack of local effectiveness data (these are elaborated under Barriers and Enablers below).

A market intervention was seen to be required to accelerate scale-up of Dual AI nets. A multi-partner New Nets Project (NNP) (2018-2022) was established to support the market entry of new nets combining pyrethroid and non-pyrethroid active ingredients and in particular, to target some of the barriers that prevented rapid scale-up of PBO nets. There was a recognised need to accelerate scale-up of Dual AI nets, drive up the volume and experience curves, ensure sustainability of the manufacturer’s investment in developing the product, and hence allow the products to reach sustainable and affordable prices. Market research shows that the Global Fund accounts for ~60% of the LLIN market (volume), equating to 250 million nets per year (worth \$500 million), giving it significant leverage over the LMIC market.¹⁸⁷

¹⁸² Ranson H, N'guessan R, Lines J, Moiroux N, Nkuni Z, Corbel V. Pyrethroid resistance in African anopheline mosquitoes: what are the implications for malaria control? *Trends Parasitol.* 2011;27:91–8

¹⁸³ Asidi A, N'Guessan R, Akogbeto M, Curtis C, Rowland M. Loss of household protection from use of insecticide-treated nets against pyrethroid-resistant mosquitoes, Benin. *Emerg Infect Dis.* 2012;18:1101–6

¹⁸⁴ World Health Organization. Global plan for insecticide resistance management in malaria vectors; 2012. p. 132. Return to ref 8 in article

¹⁸⁵ Protopopoff N, Mosha JF, Lukole E, Charlwood JD, Wright A, Mwalimu CD, et al. Effectiveness of a long-lasting piperonyl butoxide-treated insecticidal net and indoor residual spray interventions, separately and together, against malaria transmitted by pyrethroid-resistant mosquitoes: a cluster, randomised controlled, two-by-two factorial design trial. *Lancet Lond Engl.* 2018;391:1577–88

¹⁸⁶ N'Guessan R, Odjo A, Ngufor C, Malone D, Rowland M. A Chlorfenapyr mixture net interceptor® G2 shows high efficacy and wash durability against resistant mosquitoes in West Africa. *PLoS One.* 2016;11:e0165925.

¹⁸⁷ Global Fund (2019). Technical Evaluation Reference Group: Market Shaping Strategy Mid-Term Review Position Paper

It was recognised that Dual AI nets uptake was at the time limited by:

- A lack of efficacy data to support a WHO policy recommendation;
- A lack of cost-effectiveness data or an associated policy recommendation, preventing countries from procuring these nets at higher prices (compared to standard ITNs);
- Absence of policy recommendation and cost-effectiveness information (compared to standard ITNs) and implementation guidelines, limiting country demand as well as wide adoption;¹⁸⁸
- Higher product prices - existing best practice guidance obliged countries wishing to adopt novel ITN technologies to do so in a way that did not reduce overall coverage and with no foreseeable expansion in the overall budget envelope, this could most easily be achieved if the new products were brought close in price to the existing pyrethroid ITNs.

The hope was that, when the policy recommendation for Dual AI nets comes, *“we will be ahead of the game as a lot of the work to test, engage and explore at country level has been done, the manufacturing capacity will be there and prices have already been brought down.”* A subsequent project, the Nets Transition Initiative (NTI) (2021 – 2024) is now aiming to bridge the gap between the NNP and anticipated WHO policy recommendation, to help sustain demand and commitment for Dual AI products, continue the stabilisation of prices, and support countries in making that shift towards adoption of Dual AI nets and/or multi-product campaigns.

Policy context

The WHO’s Vector Control Advisory Group (VCAG) guidance indicates that both these types of Dual AI ITNs require epidemiological evidence to allow VCAG to evaluate whether they have public health value (or, more specifically, public health value distinct from that of pyrethroid only ITNs). That assessment is needed before a recommendation for their use can be made – through the process of WHO VCAG and the WHO Guidelines Development Group leading to a new WHO GMP recommendation – a precondition to large scale adoption by countries and major funders. Pyrethroid-PBO nets have a conditional recommendation (since 2017) and the remaining epidemiological data requirements have been addressed. Country and donors are responding to the conditional recommendation, and these products are being requested and deployed (as funding allows and where there is seen to be particular demand owing to growing insecticide resistance). There is hope that formal policy recommendation for Dual AI nets could be acquired by end of the year, but most likely Q1 of 2023.

There is an overall shift from universal coverage of in malaria control interventions to ‘sub-national tailoring (SNT) of malaria interventions, which is defined as the use of local data and contextual information to determine the appropriate intervention mixes.¹⁸⁹ This is emphasised in the recently launched Malaria Information Note and the approach itself will demand more context appropriate use of a mixture of vector control tools so as to encourage optimum effectiveness of all interventions as well as slow insecticide resistance.¹⁹⁰ ITN types effective against the local vector population are expected to be proposed and sub-nationally varied as appropriate.

Products and market

Seven ‘new nets’ (five PBO and two Dual AI) have so far acquired prequalification. Pyrethroid-only LLINs continue to be considered the current standard of care across most malaria-endemic countries. All other nets (PBO products and Dual AI nets) are considered ‘new types’. In 2009, the first new type of ITN – PermaNet® 3.0 – received an interim recommendation from the former WHO Pesticide Evaluation Scheme (WHOPES). The public health value of a pyrethroid-PBO net was first demonstrated by Olyset® Plus leading to a conditional policy recommendation that encompasses all WHO prequalified pyrethroid-PBO ITNs.¹⁹¹ To date, five pyrethroid-PBO products have been

¹⁸⁸ Unitaaid (2019). Catalytic LLINs Project Plan

¹⁸⁹ Global Fund (July 2022). Information Note – Malaria. Allocation Period 2023-2025

¹⁹⁰ Ibid

¹⁹¹ <https://www.who.int/teams/global-malaria-programme/prevention/vector-control/new-types-of-insecticide-treated-nets>

prequalified by WHO, as indicated in Table 5.1. In recent years, two Dual AI nets have also received prequalification: Interceptor® G2 (IG2) in 2018 and Royal Guard® (RG) in 2019. In the absence of a specific WHO policy recommendation, these listings were considered an exception during the transition from WHOPES to the new WHO evaluation process for vector control interventions. WHO released conditional recommendations on the deployment of pyrethroid-PBO nets in 2017, including guidance on the characteristics of settings most likely to benefit from their deployment. For Dual AI nets, no formal deployment guidance is available as this would normally accompany a WHO policy recommendation, though operational guidance has been developed through the NNP.

Table 5.1: PBO and Dual AI nets which are prequalified by WHO

Product name	Manufacturer	Product type	WHO policy recommendation
Olyset® Plus	Sumitomo Chemical Co. Ltd	PBO	Conditional recommendation
PermaNet® 3.0	Vestergaard Frandsen Holding SA	PBO	Conditional recommendation
Tsara® Boost	NRS Moon Netting	PBO	Conditional recommendation
Tsara® Plus	NRS Moon Netting	PBO	Conditional recommendation
Veeralin®	V.K.A. Polymers Pvt. Ltd	PBO	Conditional recommendation
Interceptor® G2	BASF SE	Dual AI	No specific recommendation
Royal Guard®	Disease Control Technologies, LLC	Dual AI	No specific recommendation

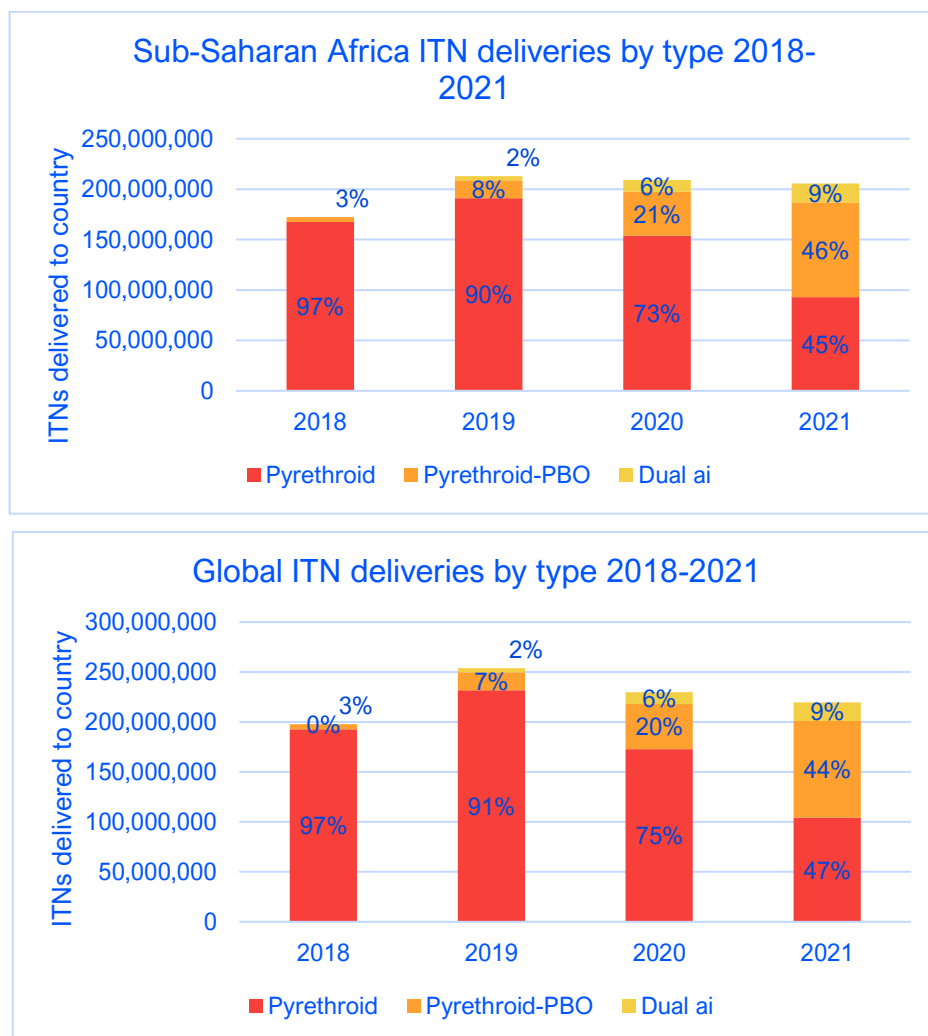
PBOs are generally seen as a ‘stop gap’, whilst other tools enter the market. In absence of a WHO policy recommendation indicating an added benefit for the additional cost, PBO nets were not procured by the Global Fund until 2017 when a conditional WHO recommendation was issued.¹⁹² Despite significant investment, PBO nets’ market share remains relatively low (but growing), considering 68 countries face pyrethroid resistance.¹⁹³ The expectation is that Dual AI nets will likely take over the market once a WHO policy recommendation is required, and supply and demand are further enabled and boosted.¹⁹⁴ The shifting market share of both PBO products and Dual AI nets is shown in Fig 5.1 and 5.2 (these relate to all ITN deliveries and not just Global Fund funded nets). Overall, the global market supports the procurement of around 200 million ITNs per year. Prices for Dual AI Nets have come down to be comparable to PBO prices, though are still higher than ‘standard nets’ (see more discussion in this in Results).

¹⁹² WHO (2017). Conditions for deployment of mosquito nets treated with a pyrethroid and piperonyl butoxide

¹⁹³ Global Fund (2019). TERG Market Shaping Strategy Midterm Review

¹⁹⁴ Unitaid (2019). Catalytic LLINs Project Plan

Figures 5.1 and 5.2: Growing market share of new net types from 2018-2021¹⁹⁵



There is some discussion around the extent to which generic Dual AI nets will enter the market. Once a policy recommendation is in place, the availability of emerging generic versions (such as new Dual AI PermaNet® by Vestergaard) would likely drive prices down, boosting affordability for countries and overall expanding the supply of Dual AI nets in the global market.

5.2. GLOBAL FUND SUPPORT

The above mentioned Strategic Initiative projects, the NNP and NTI, have been focused on expanding the supply and demand for Dual AI nets, with the NNP focused on solving core barriers to entry and the subsequent (but overlapping) NTI focused on solving core barriers to initial market growth and transition to normalised procurement. The NNP (NFM2+) was allocated a total of \$66m from both Unitaaid and the Global Fund and the NTI (NFM3+) a total of \$50m from the Global Fund. The NNP procured a total of 35m Dual AI Nets, and the NTI almost 38m. Figures 5.3 and 5.4 below outline the timeframes and scope for both projects respectively.

¹⁹⁵ Alliance for Malaria Prevention (2020). Net Mapping Data, available at <https://allianceformalariaprevention.com/working-groups/net-mapping/>.

Figure 5.3: Timeframes for the NNP and NTI

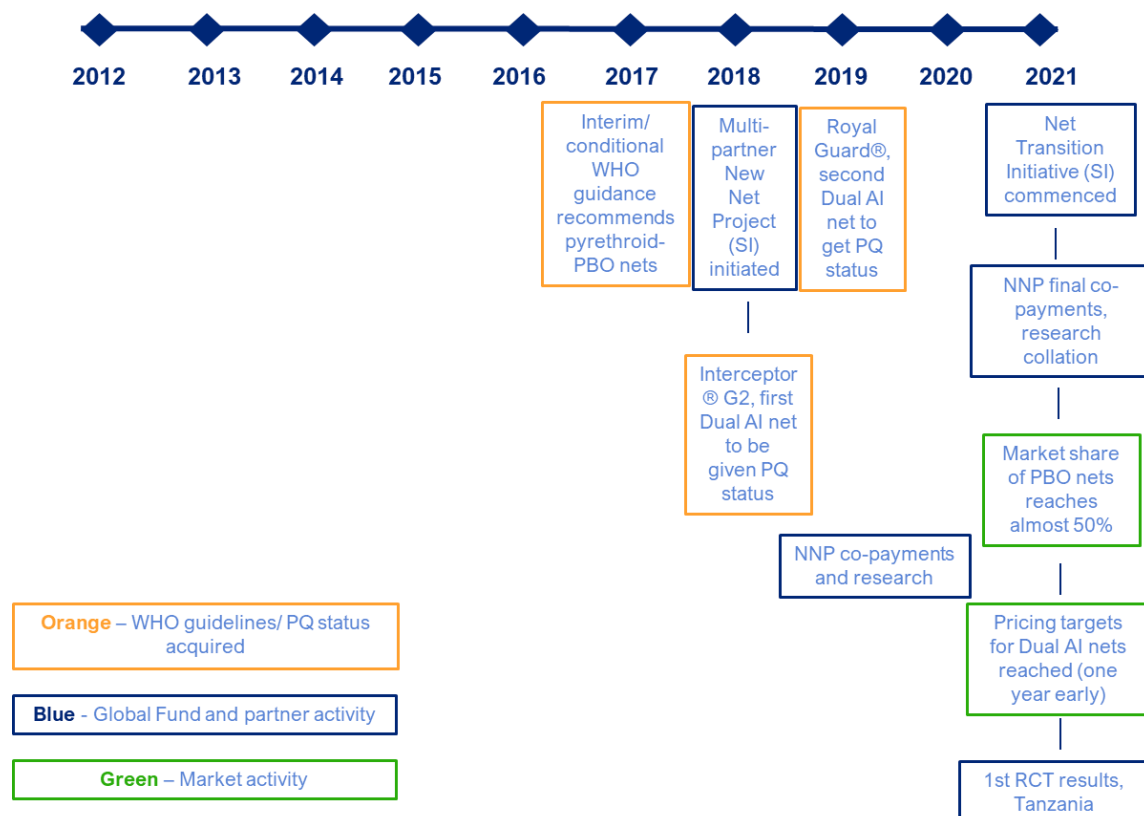


Figure 5.4: Overview of investment scope of NNP and NTI¹⁹⁶

Ensuring the most effective tools are scaled up		Strategic Initiatives	
NFM 2 (+)		NFM 3	
New Nets Project (\$66M total investment: Unitaid and Global Fund equal partnership)		Net Transition Initiative (\$50M total Global Fund investment)	
Solving core barriers to market entry Copayment support – pilot introductions, also supports price reduction and supplier capacity Evidence building – RCTs for WHO recommendation		Solving core barriers to initial market growth and transition to normalized procurement Copayment support – access prior to and immediately after WHO recommendation, accelerates prices reductions and builds supplier capacity ready for generalized scale up Evidence building – Data for decision making across all net types and IRS	
Burkina Faso, Rwanda, Mali, Nigeria, Cote d'Ivoire, Mozambique, Malawi, Liberia, Ghana, Niger, Burundi = ~35M dual a.i nets		Burkina Faso, Rwanda, Mali, Nigeria, Cote d'Ivoire, Mozambique, Malawi, Liberia, Ghana, Niger, Burundi, DRC, Cameroon, Djibouti, Benin = ~30-35M dual a.i nets	

¹⁹⁶ Global Fund (2022)

New Nets Project

The NNP aimed to increase the evidence base for Dual AI nets and reduce the net cost to affordable levels so as to facilitate scale-up if a WHO policy recommendation was achieved. Specifically, the project expected to overcome commodity access issues by:

- Implementing an RCT to provide 'gold standard' evidence with epidemiological endpoints ascertaining public health values needed to inform policy recommendations;
- Undertaking pilot implementations with cost effectiveness measures to provide evidence to support the development of operational guidance and country decision making;
- Using the co-payment process to ensure that countries involved in pilots do not burden the additional cost of these products whilst evidence is being built;
- Negotiation with manufacturers on the basis of the project and parallel activities to obtain commitment to reduce prices to an affordable and sustainable level, and ensure availability in low and middle-income countries;
- Removal of these access barriers is expected to enable more rapid widespread adoption of these tools once policy recommendations are in place.¹⁹⁷

The NNP supported both the IG2 and RG ITNs, with a more dominant focus on IG2 given emerging evidence was suggesting it may be more effective (see Results below). For the co-payment, the Global Fund grants were used to pay the base price (equivalent to the cost of a 'standard net'), and the NPP used to pay the difference.

The volume guarantee (supported by the Bell and Melinda Gates Foundation) underwrote the procurement of 35m IG2 nets over the four years of the project which reduced the price by US\$0.78 per net in the first year (US\$4.88 initially negotiated price down to US\$4.10 with volume guarantee) rising to a price reduction of US \$1.25 by the end of the project. The reduction of price in the volume guarantee was linked to steps in the overall volume of nets procured under the NNP.¹⁹⁸

Overall, in addition to the upfront \$66m investment by the Global Fund and Unitaïd, the project also leveraged substantial co-funding, including donations of Dual AI LLINs and controls from manufacturers (\$430,000), support to current trials in Tanzania Medical Research Council (\$2.8m), support to trials and the volume guarantee agreement from BMGF (\$12m), and LLIN distribution costs in pilots funded by the Global Fund (for campaign LLINs) and PMI (for continuous distribution) (estimated at a total of \$42m).¹⁹⁹

Net Transition Initiative

The aims of the NTI were to a) maintain access to Dual AI nets immediately before and after anticipated WHO policy recommendation, readying for normalisation, b) continue to leverage procurements to achieve price decreases and capacity increases, and c) continue to generate evidence for decision-making, specifically on incremental cost-effectiveness for the wider vector control toolbox. As under the NNP, for countries accessing the Dual AI nets, the cost of the nets was shared between the grant (cost of 'standard net') and the NTI (cost difference).²⁰⁰ The countries targeted were similar to those targeted under NNP but an expanded number (see Figure X above), with prioritisation given to countries/ areas with high malaria burden, pyrethroid resistance, where ITN use given access is high and where Indoor Residual Spraying (IRS) is not planned.

¹⁹⁷ Unitaïd (2019). Catalytic LLINs Project Plan

¹⁹⁸ Unitaïd (April 2020). New Nets Project: Project Amendment

¹⁹⁹ Unitaïd (2019). Catalytic LLINs Project Plan

²⁰⁰ Feasibility considerations are important here and entomological, epidemiological and operational considerations should be used to decide where different net types would go

PBO products

The Global Fund has not allocated any catalytic funding towards PBO products but it does procure PBO LLINs as well as standard LLINs as part of its usual product procurements across countries.²⁰¹ Due to ensuring financing for PBO nets was prioritised in portfolio optimisation windows, procurement of PBO products was scaled up considerably from NFM1 to NFM2.

5.3. ASSESSMENT OF BARRIERS AND ENABLERS

5.3.1. Dual AI nets

Barriers

- **Some quality issues early on which have since been resolved.** Some quality concerns were raised across countries, such as Rwanda and Malawi and owing to various reasons and incentives, though have since largely been resolved, though not all nets which have since been proven non-faulty have been reallocated.
- **Production capacity remains a challenge.** This was affected by the Covid-19 pandemic, as were all net manufacturers, though the insecticide supply itself it in short supply which affects ongoing production capacity and surge potential, even if demand increases. This emphasises the need for generic Dual AI nets to enter the market once a policy recommendation has been acquired so as to boost the overall supply potential. However, the future role of generics in the market, and the support the Global Fund may provide to them, is unclear.
- **Concerns that a price barrier still remains.** While Dual AI nets remain above the cost of the standard net, a price barrier may exist when SI funding is no longer available to reduce the unit cost. While the Global Fund, other donors and in-country vector control guidance continue to prioritise coverage, this disincentivizes the use of more expensive nets even if robust cost-effectiveness data is emerging in favour of Dual AI nets. There is also not yet clarity on what an affordability exit price would constitute.
- **Variable country registration processes may still create a bottleneck.** A WHO policy recommendation will pave the way for in-country registration, through varied processes and timeframes exist for this across countries.
- **Demand remains untested,** given the market has been supported by volume guarantees and co-payments to this point.

Enablers

- **The New Nets Project.** The Strategic Initiative funding through the NPP, and follow-on funding through the NTI, were themselves key, given the volume guarantee and co-payments which boosted supply and enabled affordable prices to countries. The NNP and NTI also enabled the opportunity to generate operational experience and evidence, alongside further epidemiological evidence required for WHO approval. The projects were designed based on important learnings from the slow growth of PBO nets within the market. That Dual AI PQ listings were considered exceptions during transition to new WHO evaluation process for vector control interventions also enabled the NNP project to be initiated.
- **Strong global level partnership and joint commitment.** All consultees claimed that the strong partnership, effective and strong communication (including transparency on challenges), as well as overall commitment to bringing improved nets faster to the market (as compared to PBO nets) were key to the effectiveness of the NNP. The partnership is described in Table 5.2. There were reports of adjusting the partnership in line with evolving/ emerging needs. For example, the Alliance for Malaria Prevention were brought in to develop some operational guidance around managing multiple product campaigns, and the steering committee was

²⁰¹ Unitaid (April 2020). New Nets Project: Project Amendment

adjusted midway to ensure more representation of organisations from malaria endemic countries. Key will be to ensure effective partnership continues under the NTI and ongoing.

- **Solid forecasting and production planning.** Building on the good communication and coordination across the partnership, including specifically with the countries and manufacturers, forecasting was reported to be strong, with solid phasing of orders as per requirements and effective management of the ebbs and flows of demand and supply chain issues which emerged. Modelling was also used to support sensitivity analyses to help predict demand under different scenarios.

Table 5.2: Partners and role under the New Nets Project

Partner	Role/scope of work
Global Fund	Strategic and technical co-design, co-funder, management of projects
Unitaid	Strategic and technical co-design, co-funder, management of projects
National Malaria Control/Elimination Programmes	Decision making on whether and how to include new types of nets in campaigns; managing and monitoring all activities in country; feeding into lessons learnt and guidance documents for other countries
Gates Foundation	Supportive financing contributions i.e. volume guarantee and topped up funding to the Tanzania Dual AI net RCT; early bridge funding to NNP partners whilst the NNP grant was still being finalised; overall partnership with MedAccess
PMI	Supported work in many countries by leveraging their in country activities such as entomological monitoring, durability monitoring or funding of nets of specific types to complement the Dual AI pilots and early deployments; technical and strategic discussions
IVCC	Consortium lead and executed the co-payment intervention for the pilots
Alliance for Malaria Prevention	Technical and operational support to NMC/EPs in campaign planning
Suppliers (BASF for Interceptor G2 and less so Disease Control Technologies for Royal Guard)	Planning around supply capacity; quality issues; actual supply
Research institutions	Universities in Rwanda, Nigeria, Burkina Faso and Mozambique which designed and led work for the RCT and pilots, in partnership with PATH international (pilots) and LSHTM (RCTs)

At this point, barriers and enablers have been very much at the global level given the orientation of the project and progression of Dual AI net roll out. Whilst some countries have deployed more Dual AI nets than others, this is not really a measure of success at this point given the WHO policy recommendation is not in place. Going forward, it will be useful to track scale up of Dual AI nets across countries and to reflect on variability there.

5.3.2. PBO nets

Some evidence on efficacy and effectiveness of PBO products and the interim policy recommendation could be seen as enablers, though more significant have been the gaps in evidence, which have slowed wide scale uptake/ adoption, though these have been more minimal in recent years.

Barriers

- **Interpretability of WHO interim policy recommendation.** The interim recommendations were difficult to interpret and required extensive liaison among partners to inform operationalisation. It was stated, for example, that countries should “consider using” PBO nets when they “have the type of insecticide resistance which would qualify” and when it “wouldn’t compromise coverage”. This lack of clarity discouraged orders from many countries, even when the Global Fund was able to procure them (really only available through portfolio optimisation). The guidance doesn’t also speak well to the cost effectiveness imperative - the higher

cost means coverage would likely be compromised, but given growing insecticide resistance, other metrics are becoming more important than just coverage – but these are not yet well articulated.

- **Lack of epidemiological, cost-effectiveness and operational evidence.** As indicated above, between 2009 (first WHOPES interim recommendation of a PBO net) and 2017, there were significant gaps in evidence which discouraged donors from purchasing PBO nets which at the time cost twice as much as a pyrethroid-only net. While epidemiological trial data became available in 2017 (which led WHO to issue a clear recommendation for deployment of PBOs), and prices at that point had also come down, evidence in some countries suggested that the synergist may not be working well. There was also a continued lack of field data on insecticide resistance/metabolic resistance allowing for targeting of PBO nets to areas where they would achieve the largest impact, as well as a lack of operational/ cost understanding of multi product campaigns.
- **High prices.** PBO nets, like other newer products, tend to be more expensive than their traditional predecessors because of higher production costs, smaller volumes, and developers' need to recoup research and development costs. There is concern that more expensive bed nets could lead to lower coverage of ITNs and/or less frequent replacement.²⁰² As above, cost-effectiveness studies have been called for and there is a growing volume of data here. However, despite the availability of guidance to inform targeting, there appears to remain insufficient data to justify higher costs in some contexts given the vector control trade-offs that need to be made, alongside insufficient data at country level on localized insecticide resistance to inform specific prioritisation of PBO products.
- **Supply and distribution capacity issues.** Despite demand for pyrethroid-PBO nets picking up, suppliers continue to face challenges scaling up production to meet demand²⁰³ owing in particular to overall supply of PBO. Particularly during COVID-19, shipping capacity to endemic areas also presented a bottleneck. As such, the number of PBO nets procured can also not be considered reflective of demand.

Enablers

WHO interim policy recommendation and conditional deployment. This enabled PBO nets to enter the market despite full policy recommendation not having been acquired. A summary of the barriers and enablers of the Global Fund's investment in PBO products and Dual AI nets is provided in Figure 5.5 below.

²⁰² Awolola S, Adeogun A, Olojede J, Oduola A, Oyewole I, Amajoh C, 2014. Impact of PermaNet® 3.0 on entomological indices in an area of pyrethroid resistant *Anopheles gambiae* in south-western Nigeria. *Parasit Vectors* 2: 236

²⁰³ Global Fund (2019). TERG Market Shaping Strategy Midterm Review

Figure 5.5: Barriers and enablers of the Global Fund's investment in PBO products and Dual AI nets

Factors	Global prioritisation/ perceived value	Normative guidance	Market/ supply characteristics	Price, affordability and cost effectiveness	Country demand and readiness	Implementation
Barriers	<ul style="list-style-type: none"> Some quality issues early on, exacerbated by Covid-19 (AI) 	<ul style="list-style-type: none"> ITN coverage still key metric confusing role for more expensive but effective nets (AI and PBO) Interpretability of WHO interim policy recommendation (PBO) 	<ul style="list-style-type: none"> Production and surge capacity remains limited even if demand increases (AI and PBO) Future role of generics in the market is unclear (AI) 	<ul style="list-style-type: none"> Net price remains higher than standard net (AI and PBO) Lack of cost-effectiveness evidence (PBO) 	<ul style="list-style-type: none"> Variable country registration processes to follow WHO policy approval (AI) Demand untested as market has been supported by volume guarantees and co-payments (AI) 	<ul style="list-style-type: none"> Lack of operational evidence (PBO)
Enablers	<ul style="list-style-type: none"> Strong global level partnership and joint commitment to bring improved nets faster to the market (AI) Applicable learnings from slow growth of PBO nets within the market (AI) 	<ul style="list-style-type: none"> Dual AI PQ listings considered exceptions during transition to new WHO evaluation process for vector control interventions (AI) WHO interim policy recommendation and conditional deployment (PBO) 	<ul style="list-style-type: none"> Solid forecasting and production planning across partners (AI) Volume guarantee provided by BMGF (AI) 	<ul style="list-style-type: none"> Co-payments of nets (from GF and Unitaied) so affordable for countries (AI) 	<ul style="list-style-type: none"> ... 	<ul style="list-style-type: none"> Operational guidance developed through the NNP (AI)

Dual AI nets = AI
PBO nets = PBO

5.4. LEARNINGS AND SUSTAINABILITY CONSIDERATIONS

The NNP in particular has proven to be very successful as compared with its aims and has illustrated that partners can take forward key innovations likely to offer improved public health value, even prior to a full WHO recommendation, thereby enabling a parallel vs a sequential process to generating further evidence and enabling full WHO approval. The extent to which this process can be applied elsewhere in relation to other products when there may be more and varied risks and potentially less certain added public health value, remains to be seen. As we look forward from here, three over-arching strategic issues emerged from the above considerations which link to both sustainability of the Dual AI and PBO nets within the market, and which should form part of strategic considerations of the Global Fund in this space.

- More strategic thinking needs to guide the next phase of multiple nets use in countries.** There are many options within the ITN space for programs to weight up i.e. less coverage with newer, better more effective tools? More coverage with less effective but cheaper tools? Prioritising nets that are more durable instead of having a better insecticide? If we have a tool which is an equivalent to existing tools but can better mitigate resistance, how can we assign value to that? Focus so far has been on assigning public health value to nets but broader strategic thinking needs to guide the next phase of ITN innovations, uptake and operationalisation, as well as measurement of impact. A lot of this needs to be led by WHO but the Global Fund also has an important role to play here, which needs to be further defined.
- Support to country readiness by the Global Fund may need further clarifying.** Some consultees were of the opinion that a continued limitation of the Global Fund's focus is that it approaches market shaping from the perspective of strategic sourcing, whilst giving less focus to the country readiness and demand 'muscles'. Further engagement with countries (at all stages in product development, pilot and scale up) could generate deeper understanding of demand scope and levers. Similarly, there was some limited criticism that the NTI

is focused at ‘price transition’, rather than ‘market transition’ with the latter potentially giving more insight, focus and guidance to the varied technical and operational realities across countries. *“If we carry on walking as we are, we will be reactive to country demand rather than thinking more strategically. It feels like it is going to be – a country wants a net, what admin is needed to support that? It is very supply orientated.”*

- **Using catalytic funding to continue support for certain products is only appropriate up to a certain point, but finding that right point is a challenge.** Related to the points made above, the discussion around when a market take over is a difficult one which has not yet been resolved in relation to the PBO or Dual AI net examples. There were many components to NNP and NTI which have seemed to promote innovation²⁰⁴, but how the Global Fund can offer a more streamlined process to supporting new products, including incentivising manufacturers and building demand, and whether a ‘market distortion’ should always be required, needs further consideration. Also, how the Global Fund supports the generics market also needs further consideration, recognising they will be key to enabling further supply in the Dual AI net market, especially if demand grows substantively from here.

5.5. CONTRIBUTION TO RESULTS

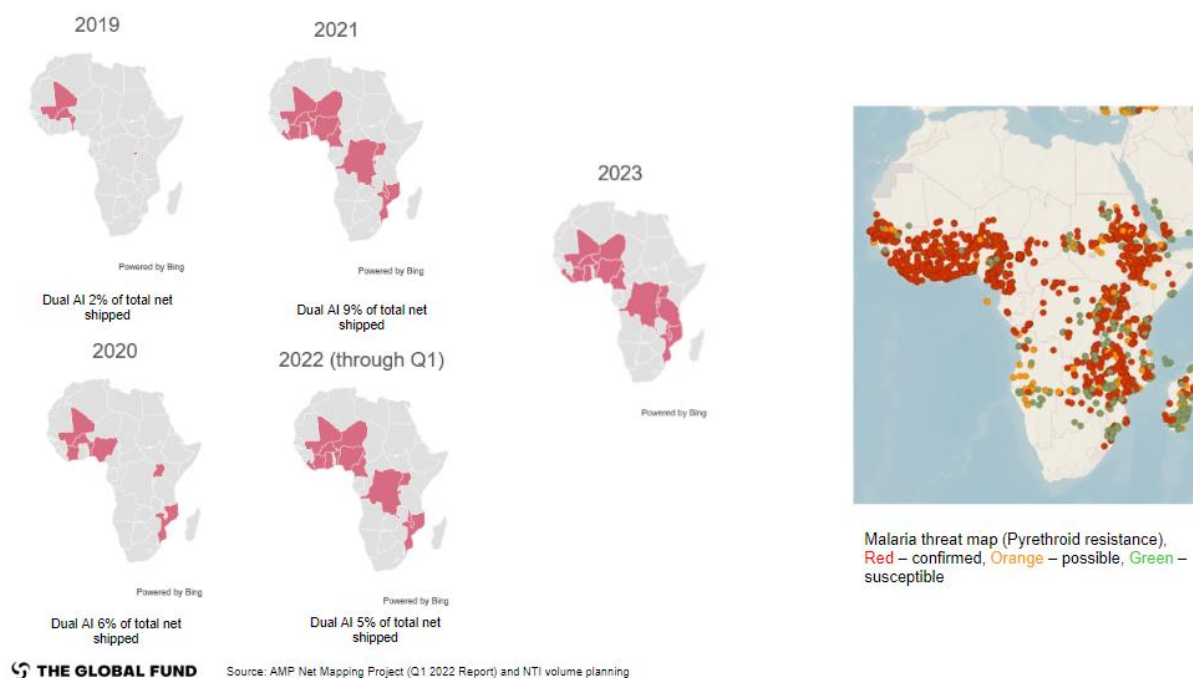
Volumes of both PBO and Dual AI nets are increasing and a shift in the market towards Dual AI nets is already underway. On completion of the NNP and NTI projects, there will likely be two ‘new net’ product classes with policy recommendations and PQ listings, and cost effectiveness data/operational guidance available to help guide deployment by countries and procurers in contexts that have been characterised as suitable for these products to demonstrate high impact. Supply will be in place with some capacity for ramp up, and some demand will be generated across countries (the extent depends on various aspects discussed and remains to be fully seen). The effect of this will likely be a steady shift in the market away from monotherapy pyrethroid nets, with PBO products more readily available and towards uptake of Dual AI LLINs and an increase in their market share.²⁰⁵ This is evidenced by Figures X above and Figure X below, which shows the low initial start in terms of growth in the PBO market share, the scale up thereafter, alongside a recent growth in the market share of Dual AI nets (not the scale of PBO nets as that also would not be appropriate ahead of WHO policy recommendation). For PBOs, these represented about 8% of nets distributed (2019), 21% (2021), 46% (2021) and 42% (2022, Q1). For Dual AI nets, this was 2% (2019), 5% (2021), 9% (2022).

“The Global Fund are trying to avoid having the 2018 and 2019 PBO type years for Dual AI nets following a WHO recommendation – we want to go straight to more like the 2020/2021 PBO type years to ensure the better tools achieve impact as widely as possible as soon as possible.”

²⁰⁴ Global Fund (2019). Technical Evaluation Reference Group: Market Shaping Strategy Mid-Term Review Position Paper

²⁰⁵ Unitaid (2019). Catalytic LLINs Project Plan

Figure 5.6: Countries with Dual AI nets in their campaigns, 2019-2023²⁰⁶



6

Prices for Dual AI Nets have come down to be comparable to PBO prices, though are still higher than ‘standard nets’. The end of project (NNP) pricing targets for Dual AI nets were met one year ahead of plan - \$2.75 for IG2 and \$2.96 for RG.²⁰⁷ However, they are not yet at levels affordable for deployment in target low and middle-income countries.

Untested demand. The extent to which the price continues to drop and how much that affects demand relates to some of the sustainability considerations discussed above. It is also worth noting that countries which have already used PBO or Dual AI nets will be likely to do so again (and strongly encouraged in that regard) and so may be encouraged to find the extra funds.

²⁰⁶ Alliance for Malaria Prevention (2022). Net Mapping Data, available at <https://allianceformalariaprevention.com/working-groups/net-mapping/>.

²⁰⁷ Unitaid (2021). New Nets Project: Annual Report

6. FACILITY LEVEL FINANCING

Context/ background. Facility Level Financing (FLF) involves the provision of funds directly to health facilities. It can take many forms, with designs often including transparency and accountability reforms, supportive supervision, TA and community engagement. Direct fund provision allows middle levels of dysfunctional health pyramids to be bypassed, reducing transactions costs and providing facilities with the resources to address constraints to improve quality of care and service coverage.

Global Fund role and funding to date. In this case study we consider the Global Fund's recent experience with Direct Facility Financing (DFF), drawing in other FLF examples throughout. The Global Fund's has previously worked with partners on similar FLF approaches (i.e. performance based financing), but the organisation's first DFF pilot is currently progressing through an approvals process. This process has been challenging, with extensive discussions and reviews focusing on legal, finance and risk. Contributing to this challenge is a perceived lack of programmatic perspective, a lack of boundaries for the scope of reviews, as well as a skill-set mismatch between programmatic staff and the fiduciary focus of the approvals process.

Successes and enablers.

- There is country-driven momentum for output-based approaches within the Global Fund, such as Activity Based Contracting.
- Development partners are interested in output-based approaches.
- Strategic Initiative funds should enable the exploration of output-based approaches.

Challenges and barriers

- There remains a lack of concrete evidence of DFF success, as it is often considered relative to PBF and pilots have been limited.
- Lack of capacity to bring forward innovative ideas in terms of resources, awareness and skills.
- Perceived organisational risk aversion driven by the fiduciary focus of the organisation.
- Approvals process considered arduous.
- No central capacity to manage innovative finance and capture learnings and best practice

Lessons learnt.

- Donor accountability may create a culture of risk aversion and processes, such as the EGMC review, that can dampen the willingness to pursue innovative ideas.
- Pain points nonetheless continue to result in innovative ideas from country teams.
- Strategic Initiative funds can support innovation; the Global Fund may wish to reflect on whether an increased level of risk-absorption could improve overall impact / results.
- Efforts should be made to ensure the retention of best practice / lessons learned.
- Working with partners can enable greater understanding of innovative approaches.

6.1. BACKGROUND AND RATIONALE FOR NEED

In a number of developing countries, particularly in Sub-Saharan Africa, health facilities do not have control of their own operating budget. Supplies such as drugs and equipment are procured at a central level and disbursed to facilities, often based on size and services provided. However, there can be delays in re-stocks and repairs, hindering the facility's ability to deliver quality of care. Further, in some cases, significant transaction costs in dysfunctional health systems mean that little, if any of the funds, reach the facility level. In an effort to overcome these issues, Facility Level Financing (FLF) involves the provision of funding directly to facilities, bypassing the middle levels of the health system.

There are a suite of approaches designed to address a failure to adequately finance primary care. In this case study we consider the Global Fund's recent experience with Direct Facility Financing (DFF), drawing in other FLF examples throughout, most notably Performance Based Financing (PBF), which DFF is often considered alongside. Both DFF and PBF involve the direct funding of health facilities. Designs can vary, but typically involve transparency and accountability reforms, supportive supervision, TA and community engagement. The funding mechanism may also be designed to offset fees paid by patients. The key difference between DFF and PBF, is that PBF includes performance incentives for individuals (e.g. frontline health workers), while DFF does not.

FLF may be considered a valuable approach in certain contexts as it can support:

- Improved impact and efficiency by circumventing dysfunctional health pyramids and associated transaction costs;
- An additional source of facility revenue to better manage resource constraints;
- Reduction in user fees which can support an increase in service coverage; and
- Improved outputs (e.g. quality of service), depending upon design.

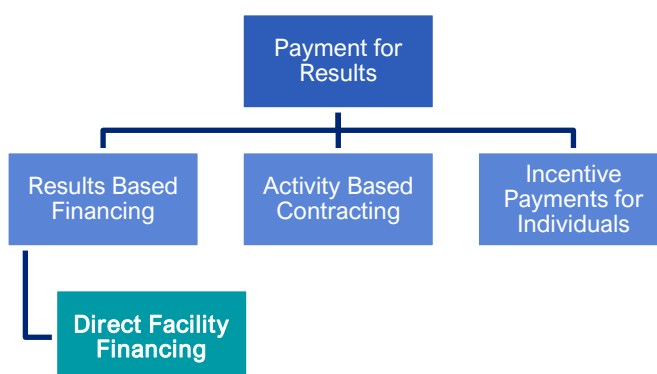
The WHO has defined DFF in particular as a public financial management approach with three guiding principles:²⁰⁸

- **Sound facility financial management.** Facilities must have the systems and capacity to carry out appropriate financial management, accounting and reporting practices.
- **Facility autonomy.** Facilities must be given sufficient autonomy to utilise their operating budget in the way they see fit; community engagement and supervision are often incorporated to provide oversight on use of funds.
- **Output-based payments.** This is not akin to performance payments for individuals. Rather, it means that disbursements to health facilities are contingent upon the facility meeting certain requirements that are considered to be within the control of the facility, such as quarterly budget submission and approval.

²⁰⁸ WHO, 2022, Direct facility financing: concept and role for UHC.

6.2. GLOBAL FUND MODEL AND APPROACH

The existing Guidelines for Grant Budgeting do not yet include DFF.²⁰⁹ However, we understand from stakeholders that the Global Fund has recently chosen where to classify DFF within the guidelines. The figure to the right shows depicts the categorisation of the Payments for Results (PfR) disbursement modalities in the 2019 Guidelines for Grant Budgeting. DFF is homed within the Results Based Financing (RBF) disbursement modality. Both Activity Based Contracts (ABC) and Incentive Payments for Individuals (IP) also fall under PfR, and are focused on suppliers/service providers and individuals, respectively.



Based on stakeholder engagement we understand that the process that led to defining DFF as a component of RBF within the Global Fund guidelines was extremely lengthy, involving extensive discussions with various teams. Some stakeholders also noted that RBF has to date been defined as being focused on national systems, which may not be well aligned with DFF which is, by definition, a facility level modality.

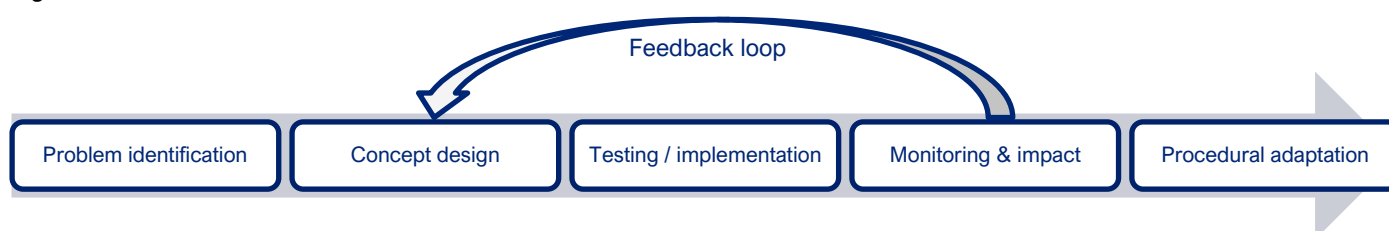
There are no guidelines for countries who may wish to explore or implement DFF, which we expect is due to the relatively recent pursuit of a DFF approach within the Global Fund.

Under the 2019 Grant Guidelines, RBF, and therefore DFF, can be used for certain interventions within a grant, enabling flexibilities in use of funds the country level. Should the RBF value exceed the lesser of USD\$3 million 20% of the grant amount, it must become a part of the Funding Request, or, if enabled during implementation, requires an internal approval process.²¹⁰ The final level of this process, referred to as EGMC, requires approvals from GMD, Finance, Risk and Legal, and is considered arduous by numerous stakeholders.

Value chain

DFF is an innovative FLF approach within the Global Fund. It differs from the Global Fund's traditional approach in which funds flow from PRs through the country's health pyramid. The value chain for this innovative approach is shown in Figure 6.1 below.

Figure 6.1: DFF value chain



6.3. GLOBAL FUND SUPPORT TO DATE

The Global Fund has worked with partners, most notably the WB, on the provision of FLF across a number of countries. This includes DRC, Cote D'Ivoire, Benin and Haiti. The designs of these programmes would best be described as PBF approaches which, as outlined above, are notably different from DFF in that they include incentive payments for individuals. In an effort to identify the relative impact of a PBF approach in countries including DRC, the WB simultaneously operationalised a DFF approach at different facilities. Aside from the programmes pursued in

²⁰⁹ Global Fund, 2019, Guidelines for Grant Budgeting.

²¹⁰ Global Fund, 2019, Guidelines for Grant Budgeting.

partnership with the WB, the Global Fund's experience with DFF has been minimal to date. However, a DFF pilot in DRC is currently progressing through an internal approvals process.

In this section we first discuss the PBF and DFF approach undertaken in DRC in partnership with the WB and others, using this as an example of the Global Fund's support in such an arrangement, which has also been pursued in a number of other countries. We subsequently discuss the proposed Global Fund DFF DRC pilot.

PFR approach in DRC (2014 – 2018)

In 2014 the WB designed and approved the Programme de Développement de Services de Santé (PDSS), launched in 2017 and operating in 140 zones in DRC. Part of PDSS involved the direct provision of financing to health facilities, with the objective of reducing user fees and improving service quality. Facilities were encouraged to ringfence a certain percentage of the funds, typically 50% or more, for incentive payments to health workers, thus representing a PBF approach. Simultaneously, the WB implemented a DFF approach (similar, though without incentive payments) in other facilities to act as a control. Etablissement à Utilité Publique (EUPs), which support in the management of funds for health services through, for example, verification, were adopted within PDSS.

The Global Fund was involved in PDSS from a very early stage, and thus was able to influence the design of the programme to better align with their mandate. USAID, GAVI, UNICEF and UNFPA were among the other partners in PDSS. The arrangement entailed the Global Fund contributing to a single donor trust fund, an approach often taken by the WB and despite the Global Fund had proposed other mechanism in country. This caused challenges for the Global Fund as they were unable to trace their money within the trust fund, and thus had to obtain board approval. According to stakeholders, there were further upsets within the Global Fund around the requirement to pay WB fees as well as more existential issues about channelling funds through the WB as opposed to disbursement via the Global Fund's own channels.

These issues meant that the establishment of the trust fund took two years, remained unsatisfactory to the Global Fund and hindered impact evaluation for the three diseases in particular. Further, because the timeline was not extended to accommodate this delay, the element of the programme that was funded by the Global Fund came to a close only two months after the establishment of the trust fund.

The WB has taken away a number of overarching design lessons for both PBF and DFF approaches based on challenges encountered in the programme. These include delays in payments to facilities, an insufficient proportion of funding spent on drugs, and issues with investment bonuses due to procurement challenges.

DFF approach in DRC (approvals in progress)

The DRC country team at the Global Fund is currently seeking approval for a DFF scheme in Maniema province for a 2022/23 implementation. DFF would enable the Global Fund to sidestep the middle layers of the health pyramid, which have been described by stakeholders as dysfunctional and instead provide direct support to the health care centres, where care is provided. The country team feels strongly that this approach can benefit primary health care delivery in the DRC as well as the fight against the three diseases. Whereas the pilot is not co-funded by other partners, it has been designed using experiences from other donors such as the World Bank.

Under the current DFF design, facility allocations would be based on catchment size and facilities would have control over 70% of the funds disbursed to them, with the remainder delivered via health commodities. A portion of the allocation will be earned by delivering against 6 performance parameters including financial reporting, health product management and hygiene. The DFF design involves verification, capacity building and community engagement as well as zone-level supervision. The team designing the pilot has been engaging with the World Bank to leverage their lessons learned, such as delivering a portion of funding via health commodities. The Service Delivery Innovations Strategic Initiative (SDI-SI) has channelled funding to technical assistance to support the design of DFF.

This pilot application is currently progressing through the relevant approvals process within the Global Fund. Under the Grant Management Guidelines, DFF, as a part of RBF, requires Secretariat's Executive Grant Management Committee (EGMC) review, involving approvals from the GMD as well as legal, finance and risk departments. We understand from stakeholders that this has been a challenging and lengthy process.

- Stakeholders told us that they believe the challenges encountered to date are at least partly due to a mismatch in skillset; the individuals seeking to implement DFF are at the programmatic / country level, and as such, are less likely to have the know-how to pre-emptively anticipate and address issues that EGMC raise. Multiple stakeholders informed us that the predominant reason that the pilot has progressed to this stage is due to the involvement of a key individual with experience that has allowed them to effectively engage with EGMC reviewers.
- Stakeholders felt that the EGMC decision making level has a strong focus on risk and potentially lacks sufficient programmatic input. This raised concerns over the ability to obtain approval for a cohesive design with an overall focus on impact / results.
- Feedback also suggested that the volume of input coupled with the lack of clear boundaries for the scope of reviews made the process more cumbersome. We understand that a policy note is being developed to improve this.

Our engagement suggested that this issue is not isolated to the DFF pilot. Rather, for (non-product) innovations, the EGMC approval process is more generally viewed as onerous, which can impede and delay implementation. More broadly, feedback we received suggested that stakeholders perceive there to be a limited degree of openness to innovative systems approaches such as DFF within the Global Fund. Stakeholders opined on the potential reasoning, agreeing that donor accountability resulted risk aversion at board level, and causing legal, risk and audit to have a key role in safeguarding assets in a way that is aligned with the organisational level of risk tolerance. This is discussed further in the barriers section below.

However, some (though not all) stakeholders noted that, that despite this, Global Fund staff were still encouraged to consider innovative approaches, despite the perceived lack of follow-through. Further, we have been told that there is an ongoing shift within the Global Fund to facilitate approaches focused on outputs and results which includes for example the development of funding request templates allowing for payment-for-results modalities for Focus countries.

6.4. CONTRIBUTION TO RESULTS

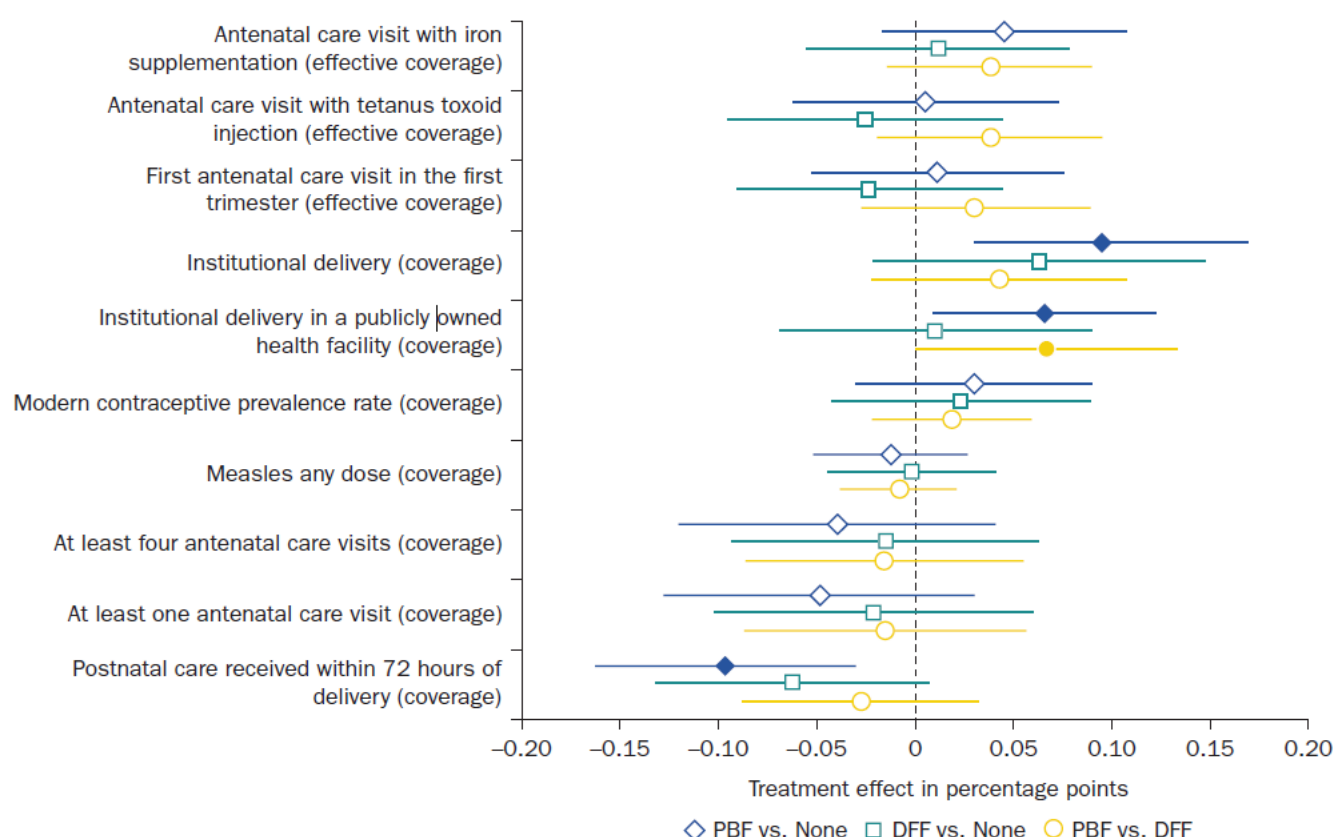
Despite plentiful interest in PBF approaches among development organisations, DFF interventions and assessments remain somewhat limited to date both within and beyond the Global Fund. Even where evaluations have taken place, DFF is often considered relative to PBF rather than on its own merits. Most stakeholders we spoke with held the view that DFF can have a positive impact, but emphasised that this was specific to certain contexts and outcomes.

The Global Fund has amassed comparisons from global health literature on PBF and DFF in Benin, Cameroon, DRC, Nigeria and Zambia implemented between 2015-2018. It brought together this data to understand the impact of each approach on (i) health service utilisation and delivery; (ii) quality of care; (iii) health outcomes; and (iv) facility autonomy. In the vast majority of cases the results were inconclusive or not assessed, though DFF was found to be preferable for points (i) and (iii) above in DRC.²¹¹

Analysis that we have seen from the WB suggests that the impacts of PBF and DFF are variable across outcomes of interest, and tend not to be statistically significant as shown in Figure 6.2 below.

²¹¹ Witter, Bertone & Diabonu, 2021, Review of Global Fund experience with facility-level financing: summary for Brown Bag lunch.

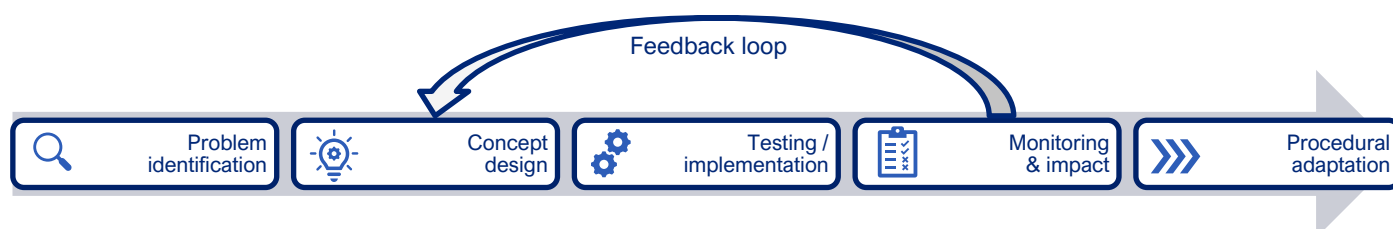
Figure 6.2: Comparison of the pooled impact of PBF and DFF in Cameroon, Nigeria, Rwanda, Zambia and Zimbabwe



Source: World Bank Group, 2022, *Improving Effective Coverage in Health: Do Financial Incentives Work?*



Note: Solid markers indicate statistically significant estimates ($p < .05$); markers that are open indicate imprecise estimates. "Whiskers" around markers represent 95% confidence intervals.

6.5. ASSESSMENT OF ENABLERS AND BARRIERS






Enablers

- Country-driven momentum towards output-based approaches within the Global Fund.** We understand from stakeholder engagement that there is an increasing number of countries that are interested in exploring RBF approaches. Thus far, this has been concentrated on ABC (see section 6.2), with feedback suggesting that 37 country teams have expressed interest. We note that country teams are aware of this option because it is explicitly defined and categorised in the existing Grant Guidelines, whereas DFF is not. This interest suggests that output-based approaches may be perceived to hold value for the countries in which the Global Fund operates.



- **An interest in exploring DFF and other output based approaches among development partners.** For many years PBF approaches were of great interest to donors given the perceived benefits of direct funding and the accountability / transparency associated with performance and output based design. Following pilots and evaluations, a growing body of evidence is suggesting that a more paired down approach such as DFF may deliver similar impacts, requiring lesser resources but also greater risk. As such, there are an increasing number of pilots, studies and publications (e.g. WHO, WB) exploring DFF. This represents an opportunity for the Global Fund to both learn from and collaborate with partners. 
- **Strategic Initiative funds should enable the exploration of output-based approaches.** The Global Fund allocates resources to Strategic Initiatives (SIs) that are deemed critical to meet the Strategic Objectives within the organisation's strategy. In line with this, and as set out above, SDI-SI is supporting the design of DFF, contributing to objective 7 of the 2023-2028 strategy: "greater focus on accelerating the equitable deployment of and access to innovations, working with partners to take an end-to-end view to rapidly address bottlenecks to deployment to those most in need."²¹² 

Barriers

- **Challenging approvals process.** The EGMC approvals process through which some RBF approaches, including DFF, must progress through involves significant time and effort from those staff proposing the innovation. Stakeholder considered that the Global Fund internal review and approval processes have been a key reason leading to a delay in implementation and, reportedly, a truncated project timeline overall. Feedback suggests that approvals processes such as these are also considered onerous and act as a barrier to staff members' willingness to try new innovations. As noted in section 6.3, the lack of clear boundaries for the scope of reviews contributes to these difficulties. 
- **Lack of capacity to bring forward innovative ideas.** This capacity barrier is threefold. 
 - First, it relates to resources. Country teams often do not have available resources to explore and pursue innovative approaches. Without additional support, there is limited incentive for country teams to attempt to innovate unless there are extreme pain points.
 - Second, it relates to awareness. Though country teams are likely to be knowledgeable on grant implementation issues in-country, they may be unfamiliar with novel approaches (e.g. being discussed and tested among development partners) available to address such issues. This may limit the ideas considered by country teams and act as a barrier to buy-in. In reference to DFF specifically, the guidelines currently in development should help to address this barrier.
 - Finally, it relates to skills. As discussed above, country-teams often do not have the skills required to pre-emptively address the concerns of EGMC reviewers (e.g. legal, finance, etc). This limits the ability, and potentially willingness, to bring forward innovative propositions. Stakeholders have suggested that teams be able to receive support on these required skills (e.g., through Strategic Initiative funding, from the TAP team etc.), as was done with DFF.
- **Perceived organisational risk aversion.** Within this evaluation a key element of the definition of innovation is something that is "considered sufficiently new or improved". This suggests a deviation from a known process, which inherently will be associated with some level of risk. As discussed in section 6.3, stakeholders told us that the Global Fund has a risk-averse corporate culture due to donor accountability. The DFF disbursement modality remains in its infancy with light touch verification processes and limited direct control over funds. Such an approach may be at odds with the 

²¹² Global Fund, 2023-2028, Fighting Pandemics and Building a Healthier and More Equitable World: Global Fund Strategy (2023-2028)

existing risk tolerance within the Global Fund. However, a sufficient degree of risk aversion will act as a barrier to any innovation.

- **No central capacity to manage innovative finance** (country requests, learnings, best practice etc.) Stakeholders told us that there is an absence of the central capacity to manage overarching activities from innovative financing approaches. This acts as a barrier; it is not possible to leverage lessons to support wider uptake (or not, in the cases where an innovation fails to deliver improvements in health outcomes) without a central entity responsible for wider assessment and support of innovative propositions. In other words, there will be no return from investing in innovation without the systems in place to monitor and learn from it on a wider scale. 
- **Lack of concrete evidence of DFF success.** As set out in section 6.4, evidence regarding the impact of DFF is not clear cut. Further, there are limited (if any) stand-alone evaluations of DFF that do not compare it against PBF. DFF is a nuanced approach with mixed results. The absence of clear positive impact can be a barrier to generating buy-in and/or obtaining approvals. Further, obtaining additional evidence would require significant resource commitment through both pilots and robust monitoring and evaluation. 

Lessons learned

The structure of the Global Fund naturally comes with a level of donor accountability that has an impact on innovation. Risk is inherent in products / approaches that differ from the norm, and yet the need for transparency and accountability limits the level of risk the organisation is willing to take and has created a culture of risk aversion. Despite this, teams have continued to spur novel approaches, such as DFF. As outlined above, this may be enabled by factors such as country needs and Strategic Initiative funds.

Those pursuing innovative approaches nonetheless face what many describe as significant challenges, to the point that innovation may be stifled due to a perceived high likelihood of failure. Evidence suggests that, in the case of DFF, there are efforts underway to address some of the barriers listed above (e.g. policy note under development for EGMC reviews).

Further lessons can be drawn from this case study, including:

- The Global Fund may wish to examine the internal business processes (e.g., review and approval) and skill requirements to ensure it is structured in a way that supports facilitation of financial innovations (including output-based financing), considering elements such as staff skillsets, programmatic input and ensuring a results-focused outcome.
- Partner expertise has and should be leveraged to support improved design.
- The Strategic Initiative funds can play an important role in supporting innovation, though they are not a silver bullet. The Global Fund may consider reflecting on whether an increased level of risk-absorption could improve overall impact / results.
- Efforts should be made to ensure the retention of best practice / lessons learned and the support of effective scale-up of innovative financial approaches that demonstrate positive impact.

7. MOBILE FINANCIAL PAYMENTS

Context/ background. Mobile money is a form of digital payments, and refers specifically to payments and receipts conducted via mobile wallet accounts and relying on a network of physical-access points. The Global Fund is exploring mobile payments to mitigate financial management issues associated with traditional physical cash-based payment methods (e.g. delays and corruption risk from cash payments) in an effort to improve programmatic delivery of Global Fund grants. Mobile money has wider benefits such as financial inclusion and equity, and can act as a gateway to the provision of other mobile based services.

Global Fund role and funding to date. The Global Fund's roll-out of mobile money has been driven by a need for improved financial management. Since 2017, 14 pilots have been pursued with end-to-end deployment in four countries – Madagascar, Mali, Burkina Faso and Afghanistan – with future expected roll-outs in DRC, Burkina Faso and Afghanistan. There have been mixed levels of deployment (\$100k to \$40m) supporting a range of activities (e.g. LLIN campaigns, payments for trainings). Acceptability and enabling architecture have presented key challenges, requiring careful design.

Successes and enablers.

- A new use for an existing technology that is proven to be successful, helping to leverage existing knowledge and generate buy-in.
- Starting with a needs-based assessment to target the innovation where it is viable and can have greatest impact.
- Coordinated approach with partners.
- Leveraging relationships and skills of the Global Fund HQ teams.

Challenges and barriers.

- The Global Fund sees mobile payments predominantly through a financial management lens, despite wider benefits.
- It is unclear whether best practice / lessons learned are being robustly assessed.
- The in-country architecture that enables mobile payments is highly variable, requiring careful and context-reflective design to maximise impact.
- Challenges with the acceptability of mobile payments from beneficiary level up to PRs.
- The Global Fund approach does not currently require payment formats, therefore limiting uptake.

Lessons learnt.

- Financial management innovations that help to deliver impact are valued by country teams and governments.
- They broadly work within existing budgets and processes and are an area of comparative strength for the Global Fund.
- Increasing accountability and transparency comes with implementation challenges.
- Supporting PR understanding and capacity is vital.
- Variable enabling architecture necessitates context-reflective design and deployment.
- The ability to leverage lessons learned will depend on continued coordinated partner working and internal, robust evaluations.

7.1. BACKGROUND AND RATIONALE FOR NEED

Digital payments, in which payments are made by electronic means, are increasingly widespread in both developed and developing markets. Mobile money falls under this payment umbrella, and refers specifically to payments and receipts conducted via mobile wallet accounts. In order to utilise mobile payments, customers require a network of physical-access points to deposit or withdraw cash from their mobile money accounts, as well an interface to initiate transfers and payments via their mobile phones.

Historically within the Global Fund there has been a reliance on cash, cheques and bank transfers for payments throughout grant implementation. Over time, however, it has become clear that such payment methods, especially physical cash, can introduce a number of issues. These include:

- Hidden costs (e.g. due to middleman, handling charges), reducing the level of impact of grant funds.
- Lengthy processing time and delays in the receipt of documentation, hindering effective grant monitoring and management.
- Lack of transparency, and relatedly, the risk of theft, corruption, fraud.²¹³
 - Such issues are more prominent in certain areas such as WCA where, between 2009 and 2018, nearly US\$100m of funding was classified as either misappropriated, unsupported or ineligible.
 - In countries where these risks are significant, the Global Fund puts in place the 'Additional Safeguard Policy' under which it can require, for example, the use of fiscal agents, a zero-cash policy and/or mandatory procurement arrangements. Such policies can create implementation bottlenecks, contributing to reduced absorption which, ultimately, can risk a reduced country allocation in future.

Mobile money offers a number of benefits that go beyond addressing the payment issues set out above. The Global Fund and many of its partner organisations operate in contexts where a significant proportion of the population are “unbanked” (do not hold a bank account). They may, however, have a mobile phone which can allow them to both receive and send mobile payments, increasing financial inclusion. Evidence suggests that households with mobile money are also more financially resilient. From an equity perspective, women have mobile phones, enabling them to hold a mobile money account and have greater control over their financial resources. Further, mobile money can act as a gateway to the provision of other services, such as mobile-based health advice.

In 2017 the Global Fund reported that mobile money is available in 61 percent of developing markets, with the highest proportion of registered accounts in Sub-Saharan Africa.²¹⁴ When implemented effectively, mobile money can result in a variety of benefits and are thus being explored and operationalised both within and beyond the Global Fund.

7.2. GLOBAL FUND MODEL AND APPROACH

The Global Fund’s roll-out of mobile money has been, by design, driven by a need for improved financial management of country allocations. The Global Fund first proceeded with a needs assessment on a country by country basis (e.g. looking at financial risk or traceability issues), aiming to improve the flow of funds. Based on this, a range of potential solutions were considered, including mobile money.²¹⁵ The Global Fund has to date undertaken assessments with

²¹³ The Global Fund OIG, 2019, Advisory Report: Grant implementation in Western and Central Africa (WCA)

²¹⁴ The Global Fund, 2017, Financial Management Handbook for Grant Implementers

²¹⁵ The Global Fund’s Financial Management function is exploring other innovative payment solutions including blockchain, though these are not the focus of this case study, and mobile money is the main innovative payment solution that has been piloted to date.

twelve countries; four of these resulted in a pilot of an innovative finance solution in 2017/2018 – Madagascar, Mali, Burkina Faso and Afghanistan.²¹⁶ Each of these countries has a proven track record of deploying mobile money.

The Global Fund developed a value proposition document on Innovative Financial Management (IFM) in 2021. Within it, they include a proposed implementation approach to be employed for IFM solutions going forward. This approach is shown in Figure 7.1 below. We understand that this is broadly aligned with the approach taken on pilot countries to date (discussed in section 7.3 below).

Figure 7.1: The Global Fund 2022 proposed approach for innovative financial management tools

Needs assessment to identify pilot country	Plan for deployment	Implementation	Monitoring & reporting
<ul style="list-style-type: none"> Conduct desk review to identify potential countries Define criteria for selecting pilots Increase awareness of IFM solutions through Brownbag, newsletters 	<ul style="list-style-type: none"> Prioritise countries Formalise roles and responsibilities within Project Teams Develop deployment plan with Project Teams 	<ul style="list-style-type: none"> Coordinate implementation with country teams, PRs, Service Providers Initiate deployment 	<ul style="list-style-type: none"> Monitor progress versus initial deployment plan Escalate challenges and key risks to relevant focal point Provide monthly / quarterly reporting

Source: Adapted from *The Global Fund, 2021, Innovative Financial Management: Overview Document*

The use of mobile money comes in at the grant-making stage, involving PRs and Secretariat country teams. It is a solution that, in most cases, is proposed for countries by the Global Fund, as opposed to limited cases being demand-driven. Funding for mobile payments is encompassed within the existing allocation, and does not require additional funding. This is possible because, as set out above, existing payment methods such as cash or cheques have associated transaction costs; the funding that would have been spent on these payment approaches within the existing allocation is redirected to utilising mobile money.

It is the PR that ultimately selects and signs the contract with the mobile money service provider. The Global Fund has aimed to support countries by developing a list of pre-qualified service providers for (i) financial management information systems; (ii) mobile device solutions; (iii) mobile money solutions; and (iv) consultancy services for capacity building.²¹⁷ This list has been developed by exploring providers in-country and engaging with country teams, as well as leveraging partnerships that the Global Fund private sector teams have with global players (e.g. with Societe General and Ecobank). The Global Fund also provides technical assistance to PRs, for example with selecting and contracting with providers. We understand that this list is not updated periodically, though at least some service providers proactively update the global fund on their service coverage and the market.

Within the Global Fund, mobile money falls solely within the Financial Management function, which “*brings together planning, budgeting, accounting, financial reporting, interbank controls, auditing, procurement...and the performance of the grant with the aim of managing approved grant resources properly to achieve greater impact.*”²¹⁸ The introduction of mobile payments is considered to support the financial management objectives of grants providing:

- reliable and value-added information for grant implementers, managers and supervisors
- assurance on efficient use of funds for key stakeholders; and
- deterrence and prevention against fraud and corruption.

²¹⁶ A Global Fund stakeholder informed us that in 2020-2022 due to Covid-19 pandemics and with shifting priorities on vital interventions, 10-12 pilots were put on hold and postponed.

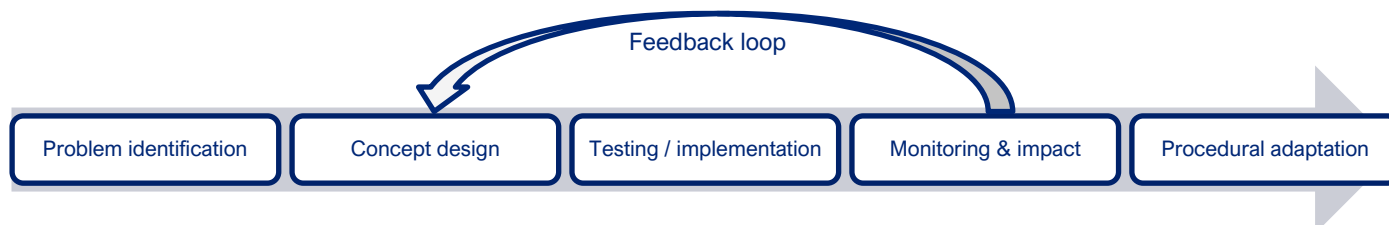
²¹⁷ [Financial Management - Funding Model - The Global Fund to Fight AIDS, Tuberculosis and Malaria](#)

²¹⁸ The Global Fund, 2017, Financial Management Handbook for Grant Implementers

Value chain

Mobile money is considered innovative in this context not because the technology is new, but rather, the application of the technology is innovative in the Global Fund context. The value chain for this innovative approach is shown in Figure 7.2 below.

Figure 7.2: Mobile money value chain



7.3. GLOBAL FUND SUPPORT TO DATE

As set out above, in 2017/2018 four countries achieved end-to-end deployment from 14 mobile money pilots. The experience of these four countries is summarised in the table below, based on documentation provided by the Global Fund. It shows that, in three of the four countries, mobile payments has been used to deploy between \$100k and £2m. Comparatively, in Burkina Faso deployment has reached \$32m.²¹⁹ In terms of use, mobile payments have supported a range of activities including LLIN campaigns and payments for trainings and for CHWs.

Table 7.1: Mobile money pilot countries implemented in 2017/2018

Country	Madagascar	Mali	Burkina Faso	Afghanistan
Partner(s)	Orange Money	Orange Money	Orange Money	mHawala UNDP
Beneficiaries	>50k	>50k	>80k	>0.8k
Mobile payments deployed	US\$2m	US\$1m	US\$32m	US\$100k
Need addressed	Absence of connected banking network, cash flow delays between districts	Zero cash policy	Zero cash policy	Lack of bank accounts and remote locations of beneficiaries
Payment detail	Used to pay communal assistants, authenticators and mobilisers for LLIN campaign.	Largest deployment used to mobilise LLIN campaign including payments to CHWs, per diems, and allowances/distribution costs to other partners	Across four grants for per diem, transportation allowance for workers for malaria, and TB campaigns	Reimbursements for trainings attended for 800+ participants

Source: Global Fund, 2021, *Innovative Financial Management: Overview Document*

Our stakeholder consultations gave us further insight into the country experience with mobile payment pilots. Though the issues for pursuing the pilot were different, they centred around financial management issues that negatively impacted implementation. For example, in Afghanistan significant delays in cash payments meant that activities were slow to progress, while in Mali security issues prevented cash payments and therefore activities from reaching remote areas. Global Fund country teams were eager to use mobile payments in an effort to mitigate these issues, and felt they drove the initiative.

²¹⁹ Global Fund, 2021, *Innovative Financial Management: Overview Document*. Figures quoted from slides 3 and 18.

Stakeholders explained that they saw that mobile payments were being utilised in other sectors (e.g. salary payments to police officers) and by other development organisations. This encouraged them to explore how mobile payments could be utilised in the health sector. One stakeholder also noted that they were inspired to pursue mobile payments from a Brown Bag presentation within the Global Fund. Though these experiences provided valuable lessons, the design of mobile payments must be adjusted to context. For example, though not reflected in the table above, stakeholders told us that in Mali they work with both Ecobank and Orange. The latter is used to pay health workers who have access to centralised banking infrastructure, while the former is used in more rural areas, and involves payment agents travelling to trainings. Innovative approaches continue to be explored to roll-out mobile money in places where enabling infrastructure is not in place, and often involves supporting activities by the service provider.

Country teams noted that, though governments were often in favour of mobile payments, they experienced resistance to its adoption at various levels. Some of this resistance was from beneficiaries, who may have been less trusting of the payment mechanism or less willing due to lack of enabling infrastructure (e.g. absence of banking network in rural areas). Resistance at higher levels was also seen; it is thought this was due to the increased transparency mobile payments brings. To overcome this in Burkina Faso, the PR made its funding support contingent on the government introducing mobile payments for CHWs. Some PRs were also resistant; country teams believe this was because adopting mobile payments created additional work which the PRs did not feel sufficiently resourced or knowledgeable of to manage. The Global Fund is working to mitigate this through TA.

Engagement with service providers has been mixed. We understand that, in some cases, service providers undertake a variety of supportive activities. This may include sending representatives at rural trainings, change management activities or capacity building. There have been challenges also. For example, when the Global Fund sought to extend its contract with Orange in Burkina Faso the fees increased from 1% to 3%. The PR chose to move to an alternative service provider, but choice was limited as the network is monopoly owned by Orange. Relatedly, we were told that engagement with service providers was more effective when done at the Global Fund HQ level, relative to PRs undertaking negotiations at the local level. However, service providers also expressed that they felt it would have been valuable to speak to country teams.

We understand from stakeholders that the Global Fund may be initiating new mobile payment initiatives in DRC, Burkina Faso and Afghanistan, but these remain in their infancy.

7.4. PARTNER ENGAGEMENT AND EXPERIENCE

At the outset of this evaluation, the Global Fund was in the process of developing an **MoU with the Gates Foundation and Gavi** for coordinated their work on mobile payments. The goal of the MoU was to “*combine knowledge, resources, efforts to promote, increase, improve digital payments for frontline health workers via creation of exemplars, public knowledge products, tools, collective action.*”²²⁰ Gavi noted that demonstrating alignment among partners would help to generate government buy-in.

During the evaluation, the Gates Foundation chose not to continue with the MoU as a format for partnership. This was not for lack of dedication or desire to engage. Rather, the leadership felt that an MoU was not an appropriate mechanism given the existing partnership structure that they have already committed to. Nonetheless, we were told that the process of agreeing the MoU brought high-level attention to mobile payments across the organisations. Parties agreed to continue working together to achieve the same goals set in the MoU but through the format of a Multi-Agency Working Group as a more comfortable set-up under existing contribution agreements.

Stakeholders from the Global Fund and partner organisations all referenced the importance of the **Better Than Cash Alliance** (BTCA), a UN-based partnership of governments, companies and international organisations focused on the transition to digital payments. This acts as a platform where members can discuss initiatives and consider how they

²²⁰ The Global Fund, 2021, Innovative Financial Management: Overview Document

can best collaborate. Activities include sharing approaches and lessons learned, as well as member state engagement and awareness raising.

Gavi's experience with mobile payments

Gavi's latest Board funding approval sets out an objective to support country governments to build and strengthen systems through Financial Management Risk and Assurance Grants (FMRAG). In line with this, Gavi is exploring the deployment of mobile money, also taking a needs-based and Secretariat-led approach. This "strategic scale up" focuses on a small number of countries every year where innovative payment approaches are more viable.

It has undertaken assessments in DRC and Liberia, which has helped to identify key barriers to the scale-up of mobile payments, including the need to manage confidentiality legislation (and hence imposing challenges in monitoring) as well as the issue of unregistered mobile phones.

Gavi also noted that they were exploring developing a pre-qualified service provider list. Whilst there are discussions as to whether Gavi could use the Global Fund's existing service provider relationships, Gavi noted that their country-by-country focus may mean that different providers are considered. Further, they expressed uncertainty around the benefit of the resource investment required to develop a service provider list.

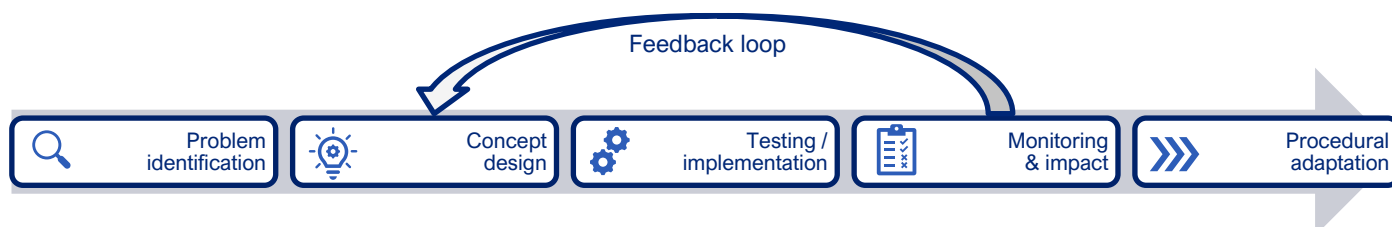
7.5. CONTRIBUTION TO RESULTS

Mobile money deployment remains at a relatively early stage within the Global Fund and among some of its key partners, such as Gavi. As such, results from deployment are limited. We understand from stakeholders that the Global Fund has monitored pilots to some degree (e.g. a report was developed on the pilot in Afghanistan). However, we saw no evidence of a coordinated evaluation that would capture insights from the experience across the piloted countries, nor did we hear of an intention to undertake one. Further, there was no evidence of any pre-defined measures against which the impact of the pilots would be assessed.

Stakeholders explained that there is a centralised online repository where knowledge regarding mobile payments is shared. However, country teams must be proactive in accessing and navigating through this documentation. They noted that some form of structured, centralised entity that helped teams put together mobile solutions based on experience to date would be valuable. One stakeholder noted that they had attempted to develop a "lessons learned" document based on the country experience, but found it challenging to advance in the absence of a centre that supports innovation.

The Gates Foundation have brought together results of their digital payments for campaign health workers. They have completed campaigns in eight countries, have ongoing implementation in seven and are pursuing campaigns in a further eleven. Noting further research is required, their evidence suggests that workers place high value on timely payments which can be enabled by mobile money. Further, this could positively impact attendance.²²¹

7.6. ASSESSMENT OF ENABLERS AND BARRIERS






Enablers






- **New use for an existing technology that is proven to be successful.** Though the application of mobile payments is novel within the Global Fund, the technology itself is not. A great deal of research has been undertaken to date as to the benefits of mobile payments, enabling

²²¹ The Gates Foundation, 2022, Digital Payments for Health Workers

contexts and best practice. The Global Fund can and has benefitted from this experience in its design and scale-up. Country familiarity with mobile money should also ease understanding and help to generate buy-in at the country and beneficiary level.

- **Starting with a needs-based assessment.** The success of mobile payments is dependent upon the enabling in-country infrastructure and, accordingly, the relevance of the design. Additionally, there are contexts in which it can have a greater impact from a financial management perspective. By taking a needs based approach, the Global Fund can seek to ensure the mobile payments solution is targeted to areas in which it is viable and can have the greatest impact. 
- **Coordinated approach with partners.** Despite challenges in agreeing a partnership format between Gates Foundation, the Global Fund and Gavi, our stakeholder engagement has shown a clear commitment among partners to progress mobile payments in a coordinated manner. Partners continue to work together to share knowledge and move as one to influence country governments. Gavi and the Global Fund appear to be at a similar phase of maturity in terms of implementing mobile payments, representing a key opportunity to learn from one another. 
- **Leveraging relationships and skills of the Global Fund HQ teams.** The private sector engagement team have been well placed to support negotiations and help to identify service providers for pre-qualification. 

Barriers

- **Seen predominantly through a financial management lens.** As discussed in section 7.1, mobile payments can offer a variety of benefits beyond financial management. However, within the Global Fund Structure, mobile payments falls solely within the Financial Management function. This may limit the ability to demonstrate the value of mobile payments to countries, as well as design the roll-out to capture the full scope of benefits. 
- **Unclear whether best practice / lessons learned are being robustly assessed.** To date there has not been a full evaluation of the roll-out of mobile money in the pilot countries, nor have we seen evidence of measures of success against which pilots would be evaluated. The impact of pre-qualifying of service providers also has not been evaluating, despite a potential intent to roll-out a similar approach elsewhere in the Global Fund. The organisation could better leverage its experience through evaluations and a structured central knowledge base. 
- **Enabling in-country architecture is highly variable.** At a base level, the uptake of mobile payments relies on infrastructure and a high penetration of registered mobile phones. Enabling architecture can also relate to rules and regulations (e.g. confidentiality management); compatible and robust data systems to ensure traceability; as well as ownership structure and market characteristics (e.g. monopoly network in Burkina Faso). Each of these alone can act as a barrier to effective implementation, and yet they are common in many of the countries in which the Global Fund operates, creating challenges for the scale-up of mobile money. 
- **Acceptability of mobile payments.** Resistance to the introduction of mobile money can be seen at multiple levels, from beneficiaries to PRs. The Global Fund has sought out innovative ways to overcome this depending upon the context, but has and will continue to experience real barriers to uptake in this area. To enable the scale-up of this innovation, the Global Fund must reflect on how it can best invest in change management activities. 
- **The Global Fund approach does not currently require payment formats;** countries chooses whether or not to pursue mobile payments. This naturally limits the ability to scale, exacerbated by acceptability issues above, but it also ensures that country teams are bought into the innovation. The Global Fund must focus resources on promoting mobile payments and managing implementation; these activities can be resource intensive and may lack a proven return on 

investment. For example, we understand the pre-qualified service provider list entailed significant effort, but its value has yet to be assessed and the experience in Burkina Faso suggests that pre-qualification does not necessarily translate to smooth implementation.

7.7. LESSONS LEARNT

Financial management innovations are valued by country teams and governments as they respond to a need and can help to increase the impact of country allocations. At a high level, the introduction of such innovations is eased by the fact that they broadly work within existing budgets and processes, and are an area of comparative strength for the Global Fund. Mobile payments in particular benefit by the fact that they build on a proven and familiar technology that is often already utilised in other sectors in country.

Increasing accountability and transparency, though appealing to country teams, nonetheless comes with its own implementation challenges around acceptability, and supporting PR understanding and capacity is vital. Further, the architecture on which mobile payments and other financial management approaches are deployed is highly variable across countries. As such, the Global Fund must design approaches that are reflective of the unique circumstances in a country / region, and able to adapt as circumstances change. Additionally, a broader view of potential benefits could help to increase the programmatic impact of this innovation.

Coordinated partner working is a step in the right direction to take forward this key innovation. However, benefitting from past experience relies on the ability to capture and evaluate that experience in a robust and structured way.



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