

Information Note

Resilient and Sustainable Systems for Health (RSSH)

Allocation Period 2023-2025

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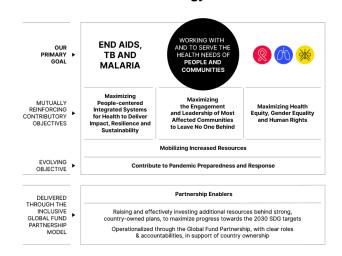
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1. Introduction

This information note offers guidance for applicants preparing a funding request to the Global Fund. It provides an overview of the types of investments in resilient and sustainable systems for health (RSSH) eligible for support and highlights specific evidence-based interventions and activities applicants can consider. It also outlines investment approaches and provides some examples of good practice for investments in RSSH.

To guide its investments, the Global Fund has developed an ambitious new Strategy Fighting Pandemics and Building a Healthier and More Equitable World 2023 – 2028 to get back on track against HIV, tuberculosis (TB) and malaria and contribute to the target of achieving universal health coverage (UHC). Applicants are encouraged to put greater focus on equity, sustainability, program quality and innovation, take determined action to maximize community engagement and leadership, tackle human rights and gender-related barriers, and leverage the fight against the three diseases to build more inclusive integrated, peoplecentered systems for health that can prevent, identify and respond to pandemics.

The Strategy's primary goal is to end AIDS, TB and malaria. This is underpinned by four mutually reinforcing contributory objectives and an evolving objective on contributing to pandemic preparedness and response. The first – and perhaps most relevant for this document – is Maximizing People-centered Integrated Systems for Health. The Global Fund will support RSSH investments that are essential to ending AIDS, TB and malaria as epidemics and which enable the delivery of individual and population health services in an efficient, effective, equitable and sustainable way. This RSSH Information Note describes the recommended investment approach and outlines priority RSSH investment areas.



2023-2028 Global Fund Strategy Framework Overview

2. Rising Above Disease-Specific Silos

The Global Fund's new Strategy 2023 – 2028 outlines a shift in its investment approach. It calls for action to rise above disease-specific silos toward building resilient and sustainable systems for health (RSSH) in a way that places people and communities, not diseases, at the center of the health system to achieve universal health coverage (UHC).

While the primary goal remains strengthening the health system to implement HIV, TB and malaria programs, the new Strategy also recognizes the importance of primary health care (PHC) to deliver integrated, people-centered services. Health systems built on the foundation of PHC are essential to achieve UHC,¹ and PHC plays a key role in the theory of change for better health outcomes, including for the three diseases and increased health security.² The swiftest and surest way to defeat today's infectious diseases as well as prevent, prepare for and response to future pandemics is by investing in health systems that support the delivery of integrated, people-centered health services.

An integrated, people-centered approach is needed for:

- Equity in access: For everyone, everywhere to access affordable quality health services they need, when and where they need them and free from stigma and discrimination.
- Quality of care: Safe, effective and timely care that responds to people's comprehensive needs.
- Responsiveness and participation: Care is coordinated around people's needs, respects their preferences, and allows for people's participation in the design and delivery of services.
- Efficiency: Ensuring that resources are strategically allocated and utilized to optimize service delivery including avoiding duplication and fragmentation of system level investment, achieving more health for money.
- **Resilience:** Strengthening the capacity of health actors, institutions and populations to prepare for, and effectively respond to public health crises while maintaining its essential functions.

Adapted from WHO's <u>Reforming Health Service Delivery for UHC, 2017</u> and <u>Position Paper on Building Health Systems Resilience for Universal Health Coverage and Health Security During the COVID-19 Pandemic and Beyond.</u>

¹ World Health Organization & United Nations Children's Fund (UNICEF). (2020). <u>Operational framework for primary health care: transforming vision into action</u>. World Health Organization

² Building health systems resilience for universal health coverage and health security during the COVID-19 pandemic and beyond: WHO position paper. Geneva: World Health Organization; 2021

The COVID-19 pandemic, setbacks in progress on HIV, TB and malaria and other health challenges have exposed gaps in most health systems and limited stewardship to ensure a comprehensive and sustainable approach. In this context, resilient and sustainable systems for health should be capable of performing essential public health functions (EPHFs).³ Global Fund's investments in RSSH should be leveraged to support high-quality health services oriented to the population's evolving needs and support the EPHFs necessary to achieve UHC.⁴ The key areas for RSSH investments are outlined in the Modular Framework Handbook and described in detail below in Section 4.

3. Investment Approach

3.1 Understand

Achieving the ambitious vision outlined in the new Strategy will require a different approach than previous funding cycles. RSSH investments must coherently support integrated health system functions that are aligned with the national health strategic plan and support national health priorities, inclusive of prevention and curative services.

A country dialogue process that rises above disease-specific silos and uses data to guide the discussion will enable Country Coordinating Mechanisms (CCMs) to better understand, identify and prioritize health system interventions, as well as the health financing landscape that supports those priorities. This is essential to develop a coherent RSSH investment plan, complementing other development partners' support.

Applicants should broaden participation in the country dialogue beyond the three national disease control programs. Key stakeholders may include other national and subnational actors in the Ministry of Health (e.g., permanent secretary, laboratory directorates, emergency/pandemic focal points, human resource for health department, department of health promotion, RMNCAH department, PHC department, health information department, etc.), other Ministries, development partners, humanitarian actors (e.g., health and logistic clusters in emergency contexts), professional accreditation bodies (e.g., nursing council), private sector, local government and, importantly, the diverse actors representing community voices. In addition, it is essential to include heads of planning from the Ministry of Health and officials within the Treasury or Ministry of Finance, including those who will review the health budget and define the budget ceilings and support more sustainable investment approaches.

⁴ UHC Compendium: Health interventions for universal health coverage

³ Essential public health functions, health systems and health security: developing conceptual clarity and a WHO roadmap for action. Geneva: World Health Organization; 2018. License: CC BY-NC-SA 3.0 IGO.

Applicants should have a data-driven discussion on the priorities and gaps (see Section 3.2 below for guiding questions) to get a better understanding of the health system landscape and investment options. Based on this, they should formulate their funding request, including completing the RSSH prioritization and gap analysis annex in the funding request form.

A single integrated funding request across HIV, TB, malaria and RSSH is encouraged for those applicants requesting funding for the three diseases. If an applicant decides to submit separate funding requests, careful consideration should be given to RSSH. Applicants can present their RSSH funding requests within a disease-specific request or as a standalone RSSH request. As splitting RSSH investments across different funding requests can create difficulties in the comprehensive planning of RSSH investments and in the assessment, coordination, implementation and performance monitoring of the health system, the Global Fund strongly recommends that applicants include their entire RSSH request together and with the first submitted funding request to allow for a full assessment of the health system investments as a whole. The supporting evidence provided in the funding request should demonstrate:

- A clear understanding of what the problems are.
- A clear linkage with the key strategic and health policy direction of the country.
- How the proposed RSSH investments are related to each other as part of the overall health system (i.e., improving PHC coverage will require investments in health workforce, supplies, data, etc.).
- How the RSSH investments will support HIV, TB and malaria programs using a differentiated approach based on the development continuum; and
- What is covered through domestic and other funding sources and the remaining gaps in funding.

Applicants should consult the Applicant Handbook for additional details.

3.2 Design

While the scale and scope of RSSH investments will greatly vary according to country context, applicants are encouraged to decide what elements of RSSH to include in their funding request to catalyze improvements in health system performance⁵ and address structural barriers to rising above silos and improving health outcomes, including for HIV, TB and malaria.

It will be important to shift from interventions that support the health system to ones that strengthen the health system. Support activities improve outcomes primarily by increasing inputs (e.g., salaries, vehicles, hardware, meetings, one-off trainings, etc.). Strengthening the health system is accomplished by more comprehensive changes to

⁵ Exemplars in Global Health. Making Better Decisions in Global Health: Understand Positive Outliers to Inform Policy and Practice.

performance drivers such as policies and regulations, organizational structures and integration across the health system. These motivate changes in behavior and allow more effective use of resources to improve multiple health services. While both supporting and strengthening the health system are necessary and important, the Global Fund strongly encourages increased focus on health system strengthening in the new funding cycle. Where support interventions are included, applicants should provide strong justification why this cannot be funded through domestic resources and include a clear, timebound exit plan from Global Fund support for those interventions.

In the context of challenging operating environment (COEs),⁷ the Global Fund suggests applicants consider an appropriate mix of humanitarian and systems strengthening approaches that focus on building resilience when addressing responses to crises and/or emergencies. This will enable a continuum from emergency response to sustainability. Applicants should review The Challenging Operating Environments Policy for additional information on the overall engagement approach in COEs.

Below are guiding questions to support applicants in the design process, including the development of standalone RSSH grants, and the identification of specific RSSH interventions within HIV, TB and/or malaria grants. In the latter approach, the guiding questions can foster a holistic understanding of key RSSH priorities and the rationale for specific RSSH intervention under each grant. It may be helpful to start with an analysis of the comprehensive system strengthening requirements, identifying what would be supported by the Global Fund and what would not, and why.⁸

 ⁶ Chee G, Pielemeier N, Lion A, Connor C. Why differentiating between health system support and health system strengthening is needed.
 Int J Health Plann Manage. 2013 Jan-Mar;28(1):85-94. doi: 10.1002/hpm.2122. Epub 2012 Jul 9. PMID: 22777839; PMCID: PMC3617455.
 ⁷ COEs are defined by Global Fund as countries or unstable parts of countries or regions characterized by weak governance, poor access to health services, limited capacity and fragility due to man-made or natural crises.

⁸ This analysis does not need to be a standalone exercise, as health systems mapping needs often take time and achieving a broad level of ownership is challenging. The Global Fund or other development partners may already have undertaken similar analysis, particularly in the context of national health strategic planning, developing health investment cases or through technical working groups, where these exist.

Guiding questions to be considered during the design process:

- What are the RSSH priorities and gaps stemming from the national health sector strategy, national strategic plans for the three diseases and other sub-sectoral strategies?
- What are the RSSH priorities for community-based and community-led service delivery and support systems?
- What are the key RSSH risks to HIV, TB and malaria program delivery, including their quality and sustainability? How will the identified RSSH priorities address them?
- What are the missed opportunities for integration, including at service delivery level, that may deliver gains in equity, efficiency and impact for HIV, TB and malaria programs? What are the potential barriers to and risks of integration?
- What interventions for the identified RSSH priorities are covered by other sources and what gaps need to be covered by Global Fund funding?
- Are the investments in the RSSH priorities more focused on health systems support (i.e., mostly short- term funding of inputs) or on health systems strengthening (i.e., activities that last beyond the funding cycle)?
- What are the lessons learned from TRP recommendations and/or implementation challenges from the previous RSSH investments?
- How well have the results of previous RSSH investments been monitored and evaluated? What positive results have been achieved and how can these be consolidated?

The Global Fund expects all funding requests exhibit good value for money, as demonstrated through the five dimensions of economy, effectiveness, efficiency, equity, and sustainability. Applicants are encouraged to review the <u>Value for Money Technical Brief</u> to understand how to demonstrate good value for money. In order to guide the design, costing, prioritization and budgeting of RSSH investments, applicants should conduct an <u>efficiency analysis</u> (i.e., how cross-cutting RSSH investments can bring efficiency to investments across diseases and specific disease outcomes). Applicants should also consider the dimensions of <u>equity</u> (i.e., how RSSH investments can reach otherwise underserved, excluded or marginalized groups, or ensure timely diagnosis, treatment initiation and care

retention) and quality (i.e., how RSSH investments can improve key program or service delivery quality priorities).

As applicants design their funding request, they should be aware that the Global Fund has articulated a series of 'program essentials' for HIV, TB and malaria which specify the characteristics of evidence-based interventions supported by the Global Fund. Investments in the health system should enable these interventions. In addition, for RSSH, the Global Fund has also identified 'critical approaches' for investing in human resources for health, health products management systems and national laboratory systems. They set out specifications for RSSH interventions supported by the Global Fund. The aim is to drive uptake and adoption of evidence-based recommendations and best practice for health system strengthening. Adherence to these critical approaches will help design, plan, develop and ensure that RSSH interventions delivered by Global Fund-supported programs are set up to achieve the maximum impact. Applicants are, therefore, encouraged to engage in inclusive and open dialogue to reflect on previous RSSH investments against the new approaches.

Where appropriate, the Global Fund also encourages applicants to address missed opportunities for delivering more efficient and effective programs, specifically preventive and curative care at the service delivery level. The COVID-19 pandemic has stressed the importance of integration, and the Global Fund's commitment to delivering integrated, people-centered health services is an opportunity to catalyze the integration of HIV, TB and malaria with additional services like mental health, non-communicable diseases (NCDs) and neglected tropical diseases (NTD).9 It is also an opportunity to leverage and strengthen existing PHC service delivery platforms¹⁰ particularly antenatal/postnatal care (ANC/PNC), sexual and reproductive health (SRH) and community health worker (CHW) programs, for the delivery of a package of essential services, inclusive of HIV, TB and malaria. The Global Fund recommends thoughtful consideration of where and how people access services (or do not) and bottlenecks to patient retention to care to identify key entry points for service delivery integration within the national context and what investments in the health system are needed to support these services, including strengthening bidirectional communityfacility referrals systems and networks of care. Applicants can review Annex 1 for an overview of the health system requirements for improving quality of care and Annex 2 for a detailed intervention approach on referrals.

Finally, applicants are recommended to consider the Protection from Sexual Exploitation, Abuse and Harassment (PSEAH), as well as child protection in the planning and design of program interventions. Program related risks of sexual exploitation, abuse and harassment to beneficiaries and people involved in the service provision, as relevant, should be identified in the proposed interventions, which should also include necessary mitigation measures to

⁹ For more information, refer to Global Fund support for coinfections and co-morbidities.

¹⁰ World Health Organization. (2018). Technical series on primary care: Integrating health services. World Health Organization

ensure that services are provided to, and accessed by, beneficiaries in a safe way. It is also recommended to include PSEAH in community awareness activities like outreach strategies, communication campaigns, trainings or other activities which target grant beneficiaries. More details are available in the PSEAH Guidance Note.

3.3 Deliver and monitor

RSSH investments should be embedded in country owned processes and plans and supported by inclusive implementation arrangements. Ensuring that the MoH and other implementing partners, including both state and non-state actors, can deliver the prioritized RSSH interventions is critical. Implementation arrangements should reflect technical capacity to deliver for maximum impact and be aligned with national health sector structures, at central and decentralized levels (i.e., national laboratory directorates should play a key role implementing laboratory system strengthening interventions). This is essential for the achievement of grant targets and absorption of the RSSH budget within the agreed timelines.

The success of RSSH investments will be measured by their impact on health outcomes for HIV, TB, malaria and by how much these interventions promote integrated, people-centered services. A set of coverage and outcome indicators are provided in the Modular Framework Handbook. The Global Fund requires applicants to include RSSH indicators as part of the grant performance framework reflective of the priority investments areas. In addition to these indicators, the performance framework includes work plan tracking measures (WPTM) that are qualitative milestones and/or input or process measures used to quantify progress over the grant implementation period for modules and interventions that cannot be adequately measured with coverage or outcome indicators. WPTM are an additional way to measure progress in institutionalizing service integration.

Independent of Global Fund monitoring requirements and aligned with the principles of country ownership, applicants are also encouraged to have indicators for their own health planning that evaluate integrated, people-centered health services, including the new Primary Health Care Measurement Framework and Indicators: monitoring health systems through a primary care lens. Applicants should review Section 4.4 below on 'Monitoring and Evaluation Systems' for additional information.

3.4 Sustain

The Global Fund's approach to sustainability focuses on the ability of the health system to both maintain and scale up service coverage to a level that will provide for continuing control of a public health problem of national and potentially global concern and support efforts to successfully manage and eliminate the three diseases beyond financing by the Global Fund or other external partners.

As part of the Global Fund Strategy and the implementation of the <u>Sustainability, Transition and Co-Financing (STC) Policy</u>, the Global Fund strongly encourages all applicants to incorporate sustainability considerations in national planning, funding request development, grant design, and grant implementation, regardless of where a country is on the development continuum or proximity to transition from Global Fund financing. While financial sustainability is a critical priority, these considerations may cut across many thematic areas, including epidemiological, programmatic, systems-related, governance, human rights, community systems, and political contexts. They will depend heavily on specific country or regional contexts, including the epidemiological situation, macro-fiscal context, reliance on external financing for the health sector and the structure of the overall health system.

As part of the larger agenda on sustainability, special attention must also be paid to the impact that health emergencies, humanitarian crises, environmental damage, climate change and other crises are having on human health and its disproportionate impact on the most vulnerable and disadvantaged communities.

More information on the Global Fund's approach to sustainability can be found in the <u>Sustainability, Transition and Co-Financing Guidance Note</u> and the <u>Global Fund's Value for Money Technical Brief</u>, as well as the Global Fund's <u>Statement on Climate Change and Environmental Sustainability</u>.

4. RSSH Interventions Eligible for Global Fund Support

The <u>Global Fund Modular Framework – RSSH Module</u> provides a summary of the RSSH interventions eligible for Global Fund support. Importantly, the modular framework itself should not be used to design RSSH interventions; rather, it can be used to organize the programmatic information for the grant. The modules and interventions selected should be based on the gaps and priorities identified during the inclusive country dialogue.

4.1 Health sector planning, leadership and governance

Effective planning, leadership and governance of the national health sector are key for improving health system performance, scaling up integrated service delivery and achieving UHC. Health sector planning enables efficient design and implementation of national health and disease control programs. Leadership and governance contribute to the successful development and implementation of health legislation, strategies, policies and regulations, and their oversight, coordination and accountability. Multiple stakeholders representing the public and private sector are engaged in health sector planning and governance. Therefore,

an inclusive and participatory approach to health sector planning, leadership and governance is essential including engagement at the different sub-national levels.

Applicants can invest in strengthening health sector planning, leadership and governance, including in the following areas:

- Strengthening national health sector strategy, policy and regulations: The Global Fund will invest in planning, developing, implementing, and reviewing national strategic, policy and regulatory frameworks with linkages to the three diseases and to broader health outcomes, especially at the primary care level. This will include support for generation and usage of robust evidence and data for decision-making. Support will be also provided for strengthening the capacity of planning, leadership and governance structures at the national and sub-national levels.
- Integration and cross-programmatic efficiency and equity: Applicants can use Global Fund investments for technical support to diagnose health sector governancerelated and cross-programmatic inefficiencies and strengthen institutional capacity for a more integrated approach. Governance interventions that promote equity may include, for example, intersectoral planning for health and health equity to address the social determinants and involving marginalized groups in decisions around resource allocation and in the design of policies to improve health and reduce inequities.
- Governance, planning, policies and regulations for health product management: Health products remain critical tools for achieving health program impact. Harnessing lessons learned from the 2020-2022 grant cycle and COVID-19, the Global Fund seeks to enhance and strengthen sourcing, procurement, quality assurance and supply chain matters from planning and forecasting to procurement, supply, delivery and distribution, including governance of Central Medical Stores and regulatory systems from product registration to post-market surveillance. For further information, see Section 4.6 Health Product Management.
- Policies and regulations supporting private sector engagement: The private sector plays a critical role in service delivery. However, many countries still lack national policy and regulatory frameworks to effectively engage the private sector, as well as fair enforcement mechanisms and clear sanctions for non-compliance with regulatory frameworks. The Global Fund supports activities focused on engaging private sector entities and leveraging their resources in service provision and other health system functions through the application of market approaches and innovations. Support is also available for improving equity, for example, through assessing care-seeking behaviours in the private sector and strategic planning on expansion of integrated health services in the private sector.

4.2 Health financing and financial management systems

A. Health financing

Strengthening health financing systems to support increased resource mobilization, pooling and purchasing and their effective use for UHC¹¹ is fundamental to achieving progress against HIV, TB and malaria. There is an increasing need for more comprehensive and innovative approaches to domestic financing that focus both on raising additional resources for health and enhancing the value for money (VfM) of existing resources, particularly in the context of the COVID-19 pandemic.

The Global Fund Strategy emphasizes strengthening country health financing systems, including a particular focus on:

- increasing domestic resource mobilization and the efficiency of domestic investments, including through leveraging loans by multilateral development banks (MDBs) to crowd in resources towards RSSH and the three diseases;
- strengthening public financial management systems;
- enhancing the generation, development and use (including capacity building) of health financing data and improving resource and expenditure tracking to inform effective health section planning;
- reducing financial barriers to access;
- enhancing sustainable government public financing of services provided by communities and civil society;
- supporting the integration of national disease responses into pooled financing mechanisms; and
- strengthening VfM of investments in individual technologies and delivery modalities.

As part of its co-financing approach, the Global Fund encourages countries to make ambitious, strategic domestic financing commitments to RSSH, particularly in low and lower middle-income contexts. The Global Fund's co-financing requirements allow for low-income countries to focus 100% of additional co-financing commitments on strengthening health systems. Co-financing commitments focused on RSSH remain critical pieces of the Global Fund's co-financing approach in middle-income countries, particularly where they help address bottlenecks to long-term sustainability and/or eventual transition from Global Fund financing.

Applicants are encouraged to consider leveraging Global Fund grants, where appropriate, to strengthen underlying health financing systems as a complement to additional domestic investments. While these investments will depend heavily on country context and the

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¹¹ Kutzin, J. (2013). "Health financing for universal coverage and health system performance: concepts and implications for policy." Bulletin of the World Health Organization 91(8): 602-611.

focus/structure of Global Fund grants, the following potential areas of investment include, but is not limited to:

- **Health financing strategies and planning:** Activities that contribute to assessment, design, development, and implementation of national financing strategies 12 and reforms/policies are eligible for support. Examples of specific investments include: sustainability planning; tracking of cashflows including through programme budgeting, fiscal space analysis; strategies for enhancing domestic revenue mobilization; and collection, design of national health insurance and benefit packages including through using Health Technology Assessment processes, strategic purchasing, and pooling and through supporting country owned institutions to sustainably drive the above functions. The new Strategy encourages applicants to consider health financing strategies for UHC, specifically including the integration of financing of priority HIV, TB and malaria services within UHC financing mechanisms that should also protect against financial hardship for individuals and households. Applicants can consider specific health financing mechanisms aimed at removing various barriers faced by vulnerable groups and ensuring their entitlement to basic benefit packages. These mechanisms can be an opportunity to strengthen coordination with other ministries, agencies and programs, including those in charge of digital identity, welfare programs or poverty alleviation. Stronger investments in planning can better link the gradual expansion of health service coverage to increased financial need and help situate external financing within realistic prioritization discussions based on available funding envelopes. The Global Fund encourages strong domestic buy-in and increasing health budget for health financing reforms that address the entire health system and leverage external technical and financial support, if required.
- Advocacy and monitoring of domestic resource mobilization: Community, district, provincial, national and/or regional-level advocacy activities for domestic resource mobilization, participation in budgeting and planning processes, resource prioritization and monitoring of resource use by community-based and -led organizations are eligible for support. This could include domestic financing advocacy activities to sustain/scale up access to services by key and vulnerable populations and capacity building to develop and implement advocacy campaigns for domestic resource mobilization for the three diseases and UHC, as well as benchmarking and accountability working through platforms such as the African Union, for example.
- Innovative finance mechanisms: Applicants should explore how innovative finance mechanisms, including Debt2Health, blending loans and grant resources, and outcome-based financing modalities, can complement existing financing functions

¹² Kutzin, J., S. Witter, M. Jowett and D. Bayarsaikhan (2017). Developing a national health financing strategy: a reference guide. Health Financing Working Paper No 3. Geneva, World Health Organization.

and how such mechanisms and be leveraged to strengthen impact and enhance efficiency. These mechanisms can be an opportunity to strengthen alignment with other partners, including MDBs, to drive more domestic resources toward health systems and PHC service delivery, including the recurrent costs of health worker education and wages, and should complement (where appropriate) Global Fund grant domestic investments.

- Health financing data and analytics: Activities that strengthen systems for generation of timely and accessible cost, budget expenditure and other financial data at intervention, program and system levels and activities that facilitate data use to improve the budgeting, planning, execution and monitoring of health and disease resources are eligible for support. Applicants are encouraged to focus on interoperability of systems used across the health information system and other data needs for monitoring and decision-making. Such investments should drive country ownership of the monitoring and reporting of financing of health systems and related outcomes achieved, as well as more granular data to enable more efficient and equitable provider payment mechanisms paid for by government own resources.
- Public financial management and routine financial management: Applicants may request support for strengthening and alignment with country financial management systems for budgeting, accounting, reporting, and assurance provision, as well as activities that enable robust resource tracking including: better visibility on absorption, improved data availability to support analysis to identify efficiency and sustainability improvement opportunities, better fiduciary control, and timely and quality reporting for program performance of Global Fund grants. See Section B on Financial Management Systems below for additional information.
- Public financing of services provided by communities and civil society: Where relevant, applicants should consider strengthening domestic financing arrangements to enhance coverage of services, including activities to strengthen, further develop, or establish mechanisms for public financing. This also includes contracting of services provided by civil society, community-led and community-based organizations. This may include analysis of the legal and policy context for public financing of community and civil society organizations; costing of services and implementation arrangements; tendering and selection processes; addressing legal, administrative, political, and resourcing bottlenecks; developing technical capacity of government entities for issuing tenders, conducting transparent selection, monitoring, supervision and evaluating projects; and strengthening institutional capacity of community-led, community-based and civil society organizations to engage with government and contracting processes.

B. Financial management systems

Strong financial systems help deliver improved financial management outcomes (i.e., timely and accurate financial reporting), improve absorption of grant funds, mitigate fiduciary risks, and deliver programmatic outcomes and health impact. The Global Fund has categorized interventions into two strategic priority areas: public financial management systems and routine financial management systems.

- Public Financial Management (PFM) Systems: Investments in activities to ensure continued use of country PFM systems or the introduction of Global Fund grants to using including strengthening such systems, where found to be inadequate, should be prioritized under the PFM systems intervention domain. The use of country public financial management systems for Global Fund grant financial management is impactful in meeting aid-effectiveness and sustainability principles. This is in addition to the catalytic nature of PFM systems in enabling domestic resource mobilization and its tracking. Collaboration and coordination with governments, development partners and other stakeholders is critical, and thus emphasized, for ensuring robust uptake and capacity building of relevant components of PFM systems. A list of illustrative activities is provided in the RSSH Modular Framework.
- Routine Financial Management Systems: Routine financial management systems refer to any financial management systems that are not derived from government or public sector financial systems, but which are used to manage the Global Fund's investments in countries. This covers investments in activities that either set up or optimize existing financial management systems that are not part of the public financial management system architecture in a country. It should be noted that this does not necessarily refer to the establishment or optimization of Global Fund-specific financial management systems and arrangements. It also refers to any integration or donor harmonization efforts for the purposes of using a shared service or common financial management system for managing development partner funding. An illustrative list of grant specific activities is provided in the RSSH Modular Framework.

4.3 Community systems and responses

Community systems are a vital part of the design, delivery and monitoring of integrated, people-centered health services and play a critical role in enhancing disease prevention and treatment across the life course, including for HIV, TB and malaria. They enable addressing shared risk factors and often allow the interventions to start at an early age and contribute to healthier populations and decrease diseases incidence in the targeted and general populations.

Community systems are the processes, structures and mechanisms that communities use to coordinate and deliver responses to their health-related and broader social needs. They are essential to strengthening health systems and ensuring that services are designed and delivered to be people-centered, accessible, equitable, cost effective and accountable. Importantly, community systems and the responses they support are based in and led by communities themselves. While aligned with health facilities, reach goes further and encompass social and structural barriers to health access and are powerful means for reaching marginalized and vulnerable people where they are with services tailored to their specific needs.

Key definitions for community systems and response

- Community-led responses are actions and strategies that seek to improve the health and human rights of their constituencies, that are specifically informed and implemented by and for communities themselves and the organizations, groups and networks that represent them. Note: Not all health responses that take place in communities are community-led.
- Community-based responses are health responses delivered in settings or locations outside of formal health facilities. They can be provided by a range of stakeholders, including community groups and networks, non-governmental organizations, civil society organizations, government and private sector.
- Community-based organizations are those organizations that have arisen within a community in response to needs or challenges and are locally organized by community members.
- Community-led organizations, groups and networks, irrespective of their legal status (whether formally or informally organized), are entities for which the majority of governance, leadership, staff, spokespeople, membership and volunteers, reflect and represent the experiences, perspectives, and voices of their constituencies and who have transparent mechanisms of accountability to their constituencies.

Adapted from <u>Progress Report of the Multistakeholder Task Team on Community-led</u> AIDS Responses.

The Global Fund encourages a systematic and targeted approach to supporting the development and integration of community systems for health, recognizing the vital role they play in improving health outcomes and reinforcing the quality of services and system resilience and sustainability. The new Strategy also includes an objective to maximize the engagement and leadership of most affected communities to leave no one behind. Applicants should adequately connect community and public infrastructure through a systems approach to avoid fragmentation and strengthen coordination and sustainability.

Community health systems should be recognized by governments with roles and responsibilities articulated, financing pathways and targets defined and agreements for public-community referrals in place. This may include reinforcing community cadres of all types, harmonizing retention/renumeration and ensuring community data is captured in health information systems, for example.

Applicants are encouraged to identify community systems and community-related health responses and interventions that can help address gaps and issues relevant to the country context. This includes determining gaps in service delivery and modalities to prioritize investment in community-based and community-led platforms for service delivery and responses that are critical in addressing inequity in access to health services amongst key and vulnerable populations. Applicants should assess barriers, needs, capacities and opportunities (including identifying champions or allies) of community systems and responses among partners, as a basis for designing capacity development and institutional strengthening interventions. They should also prioritize interventions that contribute towards holding health systems accountable. This includes both strengthening existing and encouraging community organizations to establish new community-led monitoring (CLM) mechanisms to monitor access, acceptability, affordability, and quality of health services with adequate platforms and representation where the feedback from CLM mechanisms is used to inform advocacy and quality improvement of programs.

Applicants should strongly consider what health system requirements are needed to deliver effective community health services. Section 4.5 below on Human Resources for Health and Quality of Care includes details on the community health workforce and the necessary health system requirements.

Finally, a new Decision-Making Guide for Strengthening Community Systems and Responses in Global Fund Grants is available for applicants (link forthcoming). It can be used to support the conceptualisation and design of effective community systems and responses. It uses key questions, decision triggers and problem statements that, along with available epidemiological, health system and other strategic information, helps to inform, prioritize and design the elements that will ensure effective, strong, resilient and sustainable community systems that contribute to improved health outcomes.

Applicants are encouraged to consider investments in the following priority areas:

 Institutional capacity strengthening and leadership development: The Global Fund supports the establishment, strengthening and sustainability of community-led and community-based organizations, particularly those led by key populations, women, youth and people living with or affected by the three diseases. Capacity building of these organizations should aim to contribute to effective and quality community-led and community-based service delivery at scale while improving the sustainability of community organizing. It is recommended that Global Fund grants assess the maturity and development needs of community-led and community-based structures and their roles in the health response to ensure that capacity building and leadership development support is tailored and informed by the context of operationalization. Support for legal registration of community-led and community-based organizations are included in this intervention underpinned by strengthening institutional and organizational capacity including governance, financial management, sustainability planning, internal policies, leadership development, organizing and social dialogue, program management, monitoring, evaluation and learning and reporting.

- Community-led monitoring (CLM): CLM is an accountability mechanism that uses an independently structured and planned process designed and led by equipped, trained and paid members of community-led organizations of affected communities, to systematically and routinely collect and analyze quantitative and qualitative data from health service delivery sites (i.e., facility-based and beyond) and affected communities either for a specific disease component (i.e., HIV, HIV/TB, TB, malaria) or broader primary health care. The CLM mechanism and processes should form a core part of a country's community systems and responses package of interventions. They are designed to provide valuable information from service user experiences on issues impacting the availability, accessibility, acceptability and quality of health services and human rights. This information is complementary to national health management information systems. It should feed into quality improvement plans and provide evidence-based solutions and suggestions for targeted action to improve the quality of programming and reduce social and structural barriers that negatively affect health outcomes, inform strategic and operational planning (i.e., national and community health strategic plans).
- Community-led research and advocacy: The Global Fund prioritizes community-led and participatory research that provides a better understanding of the barriers and gaps that inhibit effective, people-centered health services from the perspective of communities themselves. Global Fund supported research outcomes and evidence should be used to inform advocacy, with interventions that strengthen the capacities and mechanisms of community-led organisations to deliver targeted, effective advocacy campaigns. For example, a sex worker-led organization can be supported to conduct participatory research on the experiences of sex workers in accessing HIV and TB prevention services. The findings of the research can then be used to improve access and quality of services, as well as informing advocacy to change policing practices and law reform, building on improvements to services, including the integration of services, by ensuring that barriers to those services are addressed.

• Social mobilization, building community linkages and coordination: Activities to mobilize communities, particularly of marginalized, under-served and key and vulnerable populations, in responses to the three diseases and beyond, barriers to accessing health and other social services, social determinants of health and progress towards UHC are included in this priority area. Interventions that bring communities together for a common purpose, building capacities, mechanisms and platforms for communication, collaboration, linkages, referrals, and joint action between communities themselves, but also with components in the formal health system, are strongly encouraged. Community mobilization includes interventions to map and assess the needs of community-led organizations, groups and networks who have the potential to take up a stronger role and be more meaningfully engaged in the health response. Global Fund support in this priority area should focus on developing or strengthening effective, collaborative and representative relationships to facilitate community responses and their links with the formal health system.

4.4 Monitoring and evaluation systems

National health sector and disease programs require the right data, of the right quality, at the right level of disaggregation, at the right time to track and improve program and patient outcomes. Coordinated data collection systems and data sources that provide quality data and allow for data analysis and use at all levels of health systems are needed for ongoing program monitoring, for assessing the impact of disease control efforts and for providing early warning and detection of potential epidemics or pandemics. The Global Fund uses data from existing national health management information systems (HMIS) and supports the strengthening of these systems rather than creating parallel systems. Applicants should do a thorough assessment of their monitoring and evaluation (M&E) systems, identify data and system strengthening needs, and request funding to fill critical gaps.

Key messages for strengthening M&E systems are outlined below. In addition, applicants should refer to **Annex 4** which contains detailed guidance on the Essential M&E Investments and links to additional tools and resources.

Note that "HMIS" is used here to refer to all data systems for program surveillance and health services data, including "aggregate" HMIS, individual level and point of care data systems. Data systems for lab, logistics, human resources, and finance are each covered in the respective sections in this information note. Interoperability between these systems and cross-cutting administrative data are included here.

Investments in M&E systems and HMIS should enable:

 National HMIS strategies and M&E plans that emphasize strengthening the national data systems and data analysis and use. These should be developed based on an interdisciplinary approach between national community health, disease programs, M&E and HMIS teams.

- Integrated and/or interoperable systems that support the priority data needs of the three diseases, RSSH and pandemic preparedness and can be scaled-up nationally. Integrated and/or interoperable systems include community data and data arising from community-led monitoring mechanisms, as well as private health sector data.
- Investments that reflect an **enterprise architecture approach** which considers the linkages and shared functionality with other health information systems, such as lab, logistics, human resources, and finance information systems.
- Enhanced quality of all data sources, as well as data analysis and use activities
 including analytical capacity building at local, subnational and national levels
 and partnership with local and regional technical and academic institutions. The
 use of innovative digital approaches, as well as analytical outputs and data from
 community-led monitoring systems, is strongly encouraged.
- Platforms, approaches and adaptations of monitoring tools to collect qualitative and quantitative data to generate, analyze and use disaggregated data. An important example is the funding of a **gender analysis** to identify gender-related barriers to services with findings informing specific interventions.

M&E systems strengthening interventions eligible for Global Fund support include the following:

A. Data governance, leadership and management: The Global Fund strongly encourages applicants to allocate investments to develop and strengthen data governance structures, regulation and policies, strategies and work plans, and standards which institutionalize the foundations and governance of integrated data systems at all levels of the health system. This includes advocating for improving monitoring of health inequities and inequalities.

As best practice, countries should maintain an updated strategy for the routine data system (i.e., a costed national HMIS or RHIS Strategy). The strategy should encompass public and private facility and community health data, including for prevention, key populations and adolescent girls and young women services. Community-led monitoring (CLM) should also be included in the national strategy. Requested investments should be clearly based on this national strategy and should explain the funding roadmap across partners.

B. Data generation, availability and quality: Applicants are encouraged to continue investing in the national and sub-national data sources, systems and associated capacity listed below. Across all data sources, more attention should be given to the integration of private health sector and community data, including CLM data. Data generation investments

should strengthen the ability to monitor and analyze disaggregated data. Support for indicator surveillance of notifiable infectious diseases is also encouraged. As appropriate to the country digital health readiness and disease context, applications should include digitalization, geo-enabling, integration, and interoperability across data sources, both routine and non-routine. This includes emphasis on data agility, for example, using web-based systems that can provide more timely data and increase data accessibility while maintaining data security, privacy and confidentiality. Digital data architecture and systems which facilitate data use across data sources are encouraged; also see Data use section.

- Routine reporting: See Annex 4 for details on M&E Essential Investments in routine reporting with links to resources to plan and budget these. Overall, the Global Fund prioritizes four actions for routine data systems:
 - Focus on institutionalizing the foundations and governance of integrated and resilient routine data systems: See data governance sub-section above.
 - Use a Maturity Model as a framework for prioritizing foundations and tailoring investments to country-specific contexts: This includes better understanding and strengthening of the data and digital foundations (i.e., governance, infrastructure, interoperability readiness and workforce), as well as how well digital data systems are fit for purpose to address national disease program priorities. The Global Fund will support frequent high-level review of country maturity/readiness levels and in-depth assessments to guide country roadmaps and investments.
 - Advance levels of digitalization as a critical enabler to strengthening the routine HMIS: Applicants are encouraged to invest in digital data systems which are appropriately aligned to the digital health maturity level, strategy, and disease context in the countries. Requests for digital data systems need to:
 - Demonstrate how the proposed investments align to both the National HMIS Strategy and the National Digital Health Strategy and architecture,
 - Explain the national digital data governance policy and digital data security, privacy and confidentiality legislation in place.
 - Ensure the foundations of digital data systems, including governance, workforce, standards, infrastructure, and maintenance of these, are adequately planned for and budgeted across stakeholders.
 - demonstrate coordinated planning across disease programs, HMIS unit, and other directorates in the MoH (e.g., human resources, lab, and procurement and supply chain), and other sectors or ministries (e.g., ministries of information or telecommunications).
 - Prioritize HMIS investments to meet RSSH, HIV, TB and malaria data needs:
 The following areas of an integrated/interoperable national routine data system are prioritized, when applicable to the country context:
 - Community health services data reporting and quality assurance, integrated in the national HMIS.

- Private sector health services data reporting and quality assurance, integrated in the national HMIS.
- HIV data with increased prevention data availability and use, in "aggregate" and individual-level systems, more granular data on testing by group and testing modalities and HIV case surveillance of sentinel events digitized, with cascade analysis automated.
- TB data supported by deployment, scale-up, and maintenance of real-time digital case-based surveillance systems that are interoperable and able to monitor individual TB cases throughout the care continuum, based on country context and digital readiness.
- Malaria service delivery data completeness from all levels and sites (public, private and community- including campaign style interventions), including improvements in standard recording and reporting practices of how clinical encounters are approached, for example starting from acute febrile illness.
- Functional case-based information system enabling full case and foci investigation and response in malaria elimination settings.
- Integration and/or interoperability between HMIS (aggregate and individual level) and other data systems, particularly logistics, lab information systems and financial management (e.g., linked to national insurance schemes) to facilitate improved analysis for patient care and program planning.
- Disease-relevant disaggregation to inform and improve equitable health care programming and outcomes, and
- Geo-enabling health information to map and target interventions based on access to and availability of health services using georeferenced health facility data, national georeferenced master CHW lists hosted in a registry and other geo-spatial data layers. Note, activities supporting national georeferenced master CHW lists should be budgeted under the module "RSSH: Human resources for health and quality of care."
- Surveys: The Global Fund supports both population-based and facility-based surveys and assessments. These surveys could be supported jointly with other international partners. Of note, given not all data required to monitor the implementation of the Global Fund grants are regularly collected in the routine national health information systems, specific data collection efforts are recommended. For example, the HIV Prevention Outcome Monitoring Tool will be applied regularly (ideally every six months), as part of grant implementation monitoring, to track prevention outcomes and the use of prevention options by various population groups. Likewise, national and/or subnational surveys employing simple and cost-effective approaches will be supported to generate national and/or district-level estimates of intervention coverage and disease burden. Activities that involve generation of laboratory-based data should be included for funding under RSSH-Lab Surveillance module. The Global Fund also encourages countries to consider

including surveys that track health system performance such as using harmonized health facility assessments (HFAs), including quality of care surveys to identify health system bottlenecks. In the selected countries where targeted HFAs need to be implemented, these can be funded through the M&E budget. The protocol, policy and guidelines for implementing these HFAs will be made available accordingly. Countries can decide to collect additional information according to their needs, as long they have the implementation capacity. Note that such targeted health facility assessments do not substitute routine data collection but rather complement it, with focus on outcomes such as integration, quality and people-centeredness.

- Operational research: Operational research studies that enable program managers and implementers to introduce, understand, compare and/or optimize service delivery approaches, support integration, client perceptions, attitudes and practices, individual and community preferences to improve access to and quality of services are strongly encouraged. These studies should be planned in advance to help identify and test practical solutions to problems in the management of HIV, TB and malaria programs, including the management of co-infections and AMR, and improve decision-making. Partnerships between public and academic institutions to improve operational research capacity are encouraged. Research that involves a strong component of laboratory-based clinical testing can be linked to the Global Laboratory Leadership Program (under RSSH-Lab governance module).
- Surveillance: Applicants are encouraged to invest in disease specific surveillance (e.g., HIV, TB, malaria). Additionally, investments should aim at strengthening early warning surveillance systems to detect, analyse and respond to emerging events and outbreaks. This includes systematically strengthening communities and health facilities to detect and report events to the notifiable disease reporting system. For long-term sustainability, applicants are encouraged to invest in public health institutions to strengthen overall surveillance activities to facilitate a timely and coordinated public health response. Applicants are strongly encouraged to invest in training of surveillance actors in event triage, verification and risk assessment, as well as in tools for continuous and systematic collection, analysis, interpretation and use of disease-specific or behavioral data for public health response. Applicants are strongly encouraged to set aside easy access funds for travel to investigate and respond to events and outbreaks. Innovations in genomic surveillance using next generation sequencing for human, animal, or environmental samples, and systems to establish routine collection of population immunity data (seroepidemiological surveillance) and surveillance systems to help respond to the growing burden of AMR should be included under RSSH/PP-Lab Surveillance Module. Surveillance systems should be monitored consistently and evaluated and exercised periodically.

- Administrative data sources: This includes cross-cutting administrative data sources systems, standards and digital registries and data standards. A critical component of this is the maintenance of a geo-referenced health facility list and digital registry (including community and private sector sites, lab, pharmacies etc.). Other prioritized investments may include implementation of unique national/health sector ID and patient registries; health care terminology and other cross-cutting data standards and registries; and system and processes for digital and/or hardware assets management and monitoring. Note that human resources and finance data systems are included in the respective sections in this information note.
- Civil registration and vital statistics: Applicants are encouraged to include funding to strengthen civil registration and vital statistics (CRVS) systems. Focus should be on strengthening mortality and causes of death reporting in health facilities and to the extent possible, from community registers. These efforts should be linked with continuous support for analysis and use of mortality data to inform policy decisions and program implementation. Applicants should refer to the Information Note on Global Fund Investments in Mortality Data Systems, Analysis and Use for details.
- Data quality: The Global Fund supports the activities to strengthen country data systems and capacity to produce reliable health service data, monitor data quality, and to maintain complete, timely and accurate data in the national system to support decision making. The Global Fund supports institutionalization of routine data quality checks and audits, as well as periodic, harmonized data quality reviews at health facility and community levels, in coordination with partners and country stakeholders. Improvement plans should be developed to address the underlying causes of poor data quality including for community-led monitoring mechanisms, to ensure buy-in and support from decision makers. Applicants should commit to improving program and data quality and efficiency from program design to implementation, focusing on quality assurance in each step of the results chain, through support and enhancement of existing country platforms and mechanisms for monitoring program and data quality.

C. Data analysis and use

• Analysis, evaluations, reviews, and data use: Applicants should plan for routine national and sub-national data analysis as well as periodic program reviews, thematic reviews, epidemiological analysis and evaluations and for community-led monitoring mechanisms. In-country data analyses and program reviews should be ideally aligned with broader health sector performance reviews, led by national disease programs and jointly implemented with partners, with an enhanced focus on building analytical capacity, strengthening governance and leadership and institutionalize data-driven decision-making at all levels. Emphasis should be put into efficient feedback mechanisms to widely communicate the analytical outputs with relevant in-

country and other stakeholders. Applicants should plan to conduct program reviews or evaluations at least every three years, at mid-term and at the end of the national strategic plans. It is recommended that at least annual program performance reviews are conducted at the national level and at least semi-annual performance reviews at sub-national levels. Countries where the Global Fund investments are focused towards specific programmatic areas or population groups should plan for targeted evaluations or enhanced portfolio review of these key programmatic components. These analytical outputs should be used at all levels for continuous learning and improvement.

D. Monitoring of health inequalities and inequities: Applicants should ensure monitoring and use of disease-specific disaggregated data to inform and improve equitable and human rights-based programming and outcomes. Activities that strengthen availability, analysis, and use of granular data to identify and address inequalities and inequities at all levels are encouraged. This should include broader gender responsive monitoring, human rights assessments, capacity building for programs to analyze and translate inequality related data to programmatic action. Equity lens should be a key consideration while developing or improving existing data systems, planning, and implementing regular data/program reviews and evaluations to inform better targeting and use of resources for the populations most in need. Reviews should include analysis of quantitative and qualitative data to identify existing health inequities including gender and human rights related barriers to HIV, TB, and malaria services for key and vulnerable populations, or those experiencing marginalization based on place of residence, race/ethnicity, occupation, gender or sex, religion, education, socioeconomic status or social capital.

4.5 Human resources for health and quality of care

Human resources for health (HRH) and "health and care workforce" refer to all occupations engaged in promotive, preventive, treatment, rehabilitative, and palliative care in the public and private sector.¹³ This includes health providers (e.g., doctors, nurses, lab technicians, pharmacists, social workers), community health workers (CHWs), management and support staff (e.g., health managers, public health workers, epidemiologists, health data analysts, health financing managers), working in the private or public sector. CHWs are recognised as an occupational group by the International Labour Organization (ILO) and WHO.^{14, 15} There are many types of CHWs, who have various roles (e.g., from prevention and

¹³ Dussault G, Kawar R, Castro Lopes S, Campbell J. Building the primary health care workforce of the 21st century - Background paper to the Global Conference on Primary Health Care: From Alma-Ata Towards Universal Health Coverage and the Sustainable Development Goals. Geneva: World Health Organization; 2018.

¹⁴ World Health Organization. Guideline on health policy and system support to optimize community health worker programmes. Geneva: World Health Organization; 2018

¹⁵ International Labour Organization. International Standard Classification of Occupations. ISCO-08, vol. 1. 2012. Geneva: International Labour Organization

promotion to clinical roles to peer-support).¹⁶ Importantly, in the context of this information note, HRH does not include staff whose primary role is managing Global Fund grants (i.e., this is categorized under the Program Management).

The links between the availability and accessibility of HRH and subsequent service coverage and health outcomes are well established. A well-deployed, competent, motivated, and supported health workforce underpins delivery of integrated, people-centered services. 17,18 However, HRH challenges are common: shortages or insufficient jobs for qualified health and care workers, inequitable distribution, high turnover, inadequate skills, poor working conditions, inadequate remuneration, inadequate protection, low morale and gender inequities. Regulating HRH performance and quality of care provided in the private sector is also a challenge in several contexts. These challenges are a critical bottleneck to scaling up high quality services for the three diseases and other PHC priorities. The COVID-19 pandemic exacerbated these challenges, placing greater demands on their workloads and competences to balance surge capacity and essential service provision, exacerbating gender inequality within the health workforce¹⁹ whilst the fiscal space for investment in sustainable workforce has been reduced. 20,21 To optimize the impact of Global Fund investments, health workers (including CHWs) must provide high-quality care, including both technical quality (i.e., adherence to clinical guidelines) and patient experience (e.g., responsive and respectful care). However, provider performance and quality of care, are often inadequate. Poor patients' experiences of care and inequitable treatment of vulnerable groups compound the quality challenges.

The Global Fund has a responsibility to play a catalytic role in strengthening HRH development in a sustainable and evidence-based manner to improve quality of care, working with relevant ministries, technical partners and other donors, as formalized in the WHO Global Strategy on HRH, the Working for Health 2022-2030 Action Plan and the Global Health and Care Workers Compact. The Global Fund's HRH investments should help:

- Optimize the health workforce to ensure equitable access to and scale up integrated, people-centered health services.
- Improve HRH performance and quality of care via evidence-based innovative interventions, and
- Strengthen PHC and community level integrated service delivery.

¹⁶ Olaniran A, Smith H, Unkels R, Bar-Zeev S, van den Broek N. Who is a community health worker? - a systematic review of definitions. Glob Health Action. 2017;10(1):1272223.

¹⁷ Haldane, V., De Foo, C., Abdalla, S.M. et al. Health systems resilience in managing the COVID-19 pandemic: lessons from 28 countries. Nat Med 27, 964–980 (2021).

¹⁸ Bourgeault, I.L., Maier, C.B., Dieleman, M. et al. The COVID-19 pandemic presents an opportunity to develop more sustainable health workforces. Hum Resour Health 18, 83 (2020).

¹⁹ World Health Organization. Health workforce policy and management in the context of COVID-19 pandemic response. Interim guidance. 3 December 2020. Geneva: World Health Organization

²⁰ Shaw A., Flott K., Fontana G., Durkin M., and Darzi A. No patient safety without health worker safety. Lancet 2020 September 16, 396:10262, p-1541-1543

²¹Women in Global Health. Executive summary. Subsidizing global health: Women's unpaid work in health systems. 2022.

HRH investments should be informed by the country context, periodic assessments (e.g., through a health labor market analysis), the evidence base and country dialogue including government HRH stakeholders, and other development partners supporting HRH to ensure complementarity. Compared to the previous funding cycle, applicants are encouraged to support three key shifts reflecting the new critical approaches to investing in HRH. They are summarized in the box below.

Critical approaches for investing in HRH:

- A package of more effective interventions to improve HRH performance (see also Annex 1)
- Quality of care data to inform HRH performance improvement interventions
- More and better supervision and quality improvement, including for CHWs. This
 includes integrated technical content as feasible and relevant, use of quality-ofcare data, and use of problem-solving techniques.
- Better training that is skills- and competency focused, complemented by supervision and/or QI, delivered on-site and with integrated technical content where feasible and relevant. It should use innovative and more efficient approaches, for example blended learning.
- Institutionalization, for example strengthening quality of pre-service training and continuous professional development programs, with a focus on integrating disease-specific content, strengthening leadership and management, and supervision of supervisors.
- 2. Catalytic support for integrated HRH strategic planning supporting country workforce development (including CHWs)
- HRH strategic planning, sustainable financing and relevant HRH analyses
- Scale up production of HRH with a focus on strengthening multi-disciplinary PHC teams, based on HRH analysis
- Optimization of HRH distribution, for example workload-based assessments of service needs to inform deployment, or geospatial analysis of CHWs distribution to inform scale up.
- Strengthening data systems for HRH, including CHWs, to enable more evidence-based planning and deployment.
- 3. Enhance system readiness to scale CHWs aligned with WHO guidance
- Integrated community health programs, recognizing CHWs as a critical pillar of primary health care teams.
- Investments to fill policy and systems gaps and enhance readiness to scale up CHW approaches, in alignment with WHO guidance.
- Includes provision of non-malaria medicines (antibiotics, zinc, ORS) for children under 5 in certain contexts (Annex 3).

The following provides an overview of HRH interventions that are eligible for Global Fund support:

Education and production of new health workers, including CHWs: Increasing the HRH supply may be essential, and activities to scale up and improve quality of pre-service education and training of multidisciplinary HRH are potentially relevant in many countries. They should usually be prioritized over short-term in-service training, as they are more sustainable. Pre-service education and training should primarily focus on occupations engaged in PHC services, including supporting (e.g., labs) and public health functions, because they can deliver integrated services related to the three diseases and their comorbidities, as well as enhance pandemic preparedness. and because their remuneration and retention packages can over-time be embedded in national health budgets.²² However, an understanding of the nature of the HRH shortages is necessary to contextualise this intervention informed by health labour market analyses. If there is a labor shortage (i.e., more funded positions than existing HRH), the Global Fund can support pre-service education. If the shortage derives from HRH under-employment, investment in pre-service education may not be a leading priority. Often, both types of shortage coexist, which underscores the need for HRH analysis to ensure HRH investments are relevant and effective and to identify gaps in pre-service education and training, including its quality, where the Global Fund can play a catalytic role. Importantly as an intervention, pre-service education takes time to produce new HRH and will not address immediate shortages, so investments in HRH planning to optimize distribution of the existing workforce may need to be considered as well.

Pre-service education interventions should: promote integrated workforce development, ensure quality and equity, be skills- and competence-based (not theoretical) and lead to a certification, accreditation or license. Strengthening public and private training institutions should be prioritized to improve the quality of preservice training, as should gender and equity principles in pre-service training investments. For example, targeted admission of students from under-served groups (e.g., ethnic minorities, women and students from rural areas) and including clinical practicums at the community and primary level can contribute to improved rural retention and building a more diverse and inclusive workforce, including gender equality. Investments for CHWs should follow wHO normative guidance on competency-based pre-service training and certification, supporting an integrated service delivery package, according to an agreed and recognised scope of work.

Funding requests should articulate how pre-service education investments are catalytic or complement national HRH production investments and outline strategies to ensure sustainability of these investments (e.g., ensuring graduates are recruited

²² World Health Organization. Primary Health Care Operational Framework. 2020

and deployed in paid jobs). This can be done by promoting alignment of pre-service education investments with HRH strategic planning, including priorities for quality health systems (see points on Governance for quality, and HRH planning, management and governance below).

• Recruitment, remuneration and deployment of new and existing HRH, including CHWs: Where immediate fiscal space is constrained and/or economic demand for health and care workers is insufficient, Global Fund resources may be allocated for recruitment, training, deployment, and remuneration of new HRH, including CHWs, in alignment with national policies and mechanisms, and promoting integrated programming across diseases and between diseases and PHC platforms, particularly RMNCAH. Interventions may include: salaries and eligible allowances for HRH, development or contribution to performance-based incentive schemes, and development or contribution to retention schemes.

Funding requests must comply with national labor and other laws, supporting decent work and fair pay, including gender equality and minimum wages at a level below which nobody should fall, in alignment with ILO and WHO normative guidance and the WHO Global Strategy on HRH. Funding requests must also be aligned with current Global Fund budgeting guidelines and consider: (i) alignment with national human resource strategy, procedures and salary scales, (ii) robust justification of the rationale for full or partial salary contributions, with particular emphasis on integration, financial sustainability and transitioning and (iii) coordination with other development partners.

Recruitment, remuneration and deployment interventions often intend to improve HRH availability in underserved areas. Applicants are encouraged to consider investing in HRH workforce planning to identify and pursue options for optimal allocation and distribution of the available workforce at community and facility level, including the appropriate skills and cadre mix distribution at different levels of the system and through the mix of private and public service provision, for example using tools such as WHO Workload Indicator of Staffing Needs. For example, in Ghana, HRH analysis found that the budgetary deficit of meeting the minimum staffing requirement could be reduced by 30% just by redistributing existing staff. ²³ In contexts where the fiscal space may not allow HRH scale-up, including of CHWs, to meet essential health service needs, support to HRH remuneration, including CHWs, may be justified. Wherever feasible, these investments should support HRH, including CHWs, who provide integrated services, for example more than one disease, or one disease and pandemic preparedness or PHC. These investments should be designed taking a long-term (e.g., ten year) perspective and focus from the

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²³ Asamani JA, Ismaila H, Plange A, et al. The cost of health workforce gaps and inequitable distribution in the Ghana Health Service: an analysis towards evidence-based health workforce planning and management. Hum Resour Health. 2021;19(1):43. Published 2021 Mar 31. doi:10.1186/s12960-021-00590-3

start on promoting the sustainability and transition of such recurrent costs. For example, they should be complemented by support and capacity strengthening for the development and costing of HRH strategic plans (including CHWs), aligned with broader national sector and/or PHC plans, and health financing strategies to allow gradual transition to domestic financing when possible. Integration of CHWs in HRH strategic plans, as well as alignment of community health and HRH strategies is a core priority (see point on HRH planning, management and governance).

Often, remuneration is intended to improve retention and mitigate burnout. Applicants should analyze context-specific root causes of poor retention and consider complementary interventions to remuneration support which are shown to improve retention, such as investments that improve working conditions, enhance professional development, provide mentorship and supportive supervision, and other non-financial incentives.²⁴ Interventions to support HRH remuneration should be complemented by other HRH interventions (e.g., support HRH data systems to remove "ghost" workers from payrolls and ensure HRH are paid on-time, in-full, every time; analysis to inform workforce planning or to identify bottlenecks to equitable deployment) and RSSH interventions beyond HRH (e.g., health financing and financial management systems to ensure funds flow and transparent management of HRH funds). When allocating resources to remuneration support, applicants must consider appropriate M&E to track HRH supported and ensure that the aims of remuneration interventions, such as improved retention, are met during grant implementation. Given the complexity of HRH remuneration and deployment interventions, funding requests should demonstrate significant country dialogue with HRH actors within governments, professional councils, other donors, and relevant agencies.

• Interventions to improve health workers' performance, including CHWs: Traditionally, the Global Fund has supported in-service training as a core performance improvement intervention. However, in-service training, as a standalone intervention, typically leads to only modest improvements in performance, and its effect wanes over time. 25 Delivering integrated, people-centered health services requires attention to integrated competence development of the PHC workforce, including supportive and public health functions, beyond disease-specific training. 26,27 New interventions to improve health worker performance, including CHWs, are needed. The Global Fund strongly encourages applicants to consider a combination of interventions to improve HRH performance and adherence to clinical standards i.e., complement in-service training with other evidence-based interventions

²⁴ World Health Organization. Guideline on health workforce development, attraction, recruitment and retention in rural and remote areas. 2021 Geneva: World Health Organization

²⁵ Rowe AK, Rowe SY, Peters DH, et al. The effectiveness of training strategies to improve healthcare provider practices in low-income and middle-income countries. BMJ Global Health 2021;6:e003229.

²⁶ World Health Organization. Primary Health Care Operational Framework. Geneva: WHO 2020

²⁷ World Health Organization. Global Competency and Outcome Framework for Universal Health Coverage, Geneva: WHO 2022

described below. These should be articulated in a locally defined intervention package to improve the quality of care, driven by key local quality priorities. ²⁸ Interventions include:

- o **In-service training:** Opportunities for integration of training content and delivery between more than one disease, and between diseases and PHC platforms should be prioritized, where feasible, in line with program quality and/or efficiency priorities. If requested, single disease in-service training should be included in the relevant disease modules. Combining in-service training with integrated supportive supervision, or with group-problem solving usually yields better effects, therefore applicants are encouraged to consider complementary interventions in addition to in-service training, such as integrated supportive supervision and group problem solving. In-service training, whether integrated or disease specific, should also prioritise skills- and competency-based (i.e., not just theoretical) approaches that align with continuous professional development programmes, in line with health workforce education and competency priorities for UHC. For CHWs, WHO normative guidance on in-service training should be followed, with emphasis on covering all functions of the expected role, based on the agreed scope of work. Training should minimize disruptions to service delivery by offering it where health workers typically work, as this tends to increase training effectiveness. The development of blended learning options for continuous professional development, harnessing public-private partnerships for use of digital solutions to professional development are also encouraged as they can enhance the efficiency of training allocations, provided they are supported with the appropriate local partnerships with training institutions and professional bodies and are integrated with relevant CPD programmes and post-training support and follow up. Wherever possible, in-service training investments should contribute to strengthening continuous professional development programmes and improve their quality.
- Integrated supportive supervision: Although supervision is routinely conducted in countries where Global Fund operates, implementation of quality supervision is often challenging, resulting in limited impact and value for money. Support to strengthening coverage and quality of integrated supportive supervision is encouraged, ensuring adequate capacity building at the relevant systems level. Supervision tends to be more effective when supervisors receive supervision, and when supervision includes group problem-solving activities and audit of performance data and feedback.²⁹ In addition to support to conduct supervision, priority activities should include: developing integrated guidance, plans or tools for supportive supervision, including digital checklists; capacity building to embed

²⁸ ,World Health Organization. Quality health services: a planning guide. 2020. Geneva: World Health Organization

²⁹ Rowe, S.Y., Ross-Degnan, D., Peters, D.H. et al. The effectiveness of supervision strategies to improve health care provider practices in low- and middle-income countries: secondary analysis of a systematic review. Hum Resour Health 20, 1 (2022).

group problem-solving and audit of performance data and feedback in supervision; and capacity development for supportive supervision capacity, particularly supervision of supervisors. For CHWs, WHO normative guidance on supportive supervision should be followed, with greater emphasis on institutionalisation of supportive supervision systems to extend to CHWs and take into account expressed community needs. Supervisors of CHWs must have adequate time for high quality and frequent (i.e., at least monthly) integrated supportive supervision, or there should be dedicated HRH to ensure this is the case³⁰.

- Innovative interventions to improve quality: Innovative quality improvement (QI) interventions include group problem-solving activities where facility-level teams monitor their own performance using routine data, conduct root-cause analysis to identify obstacles to providing high quality care, and test solutions to overcome the obstacles (e.g., testing changes in processes of care with Plan-Do-Study-Act cycles). In "collaborative improvement," a network of facilities work together to improve performance on the same topic. Collaborative improvement has been implemented at scale and with good results on maternal health outcomes in Ghana, ³¹ as well as other countries where the Global Fund operates. ^{32,33,34} Note, **Annex 1** provides a complete list of interventions across RSSH modules that can be packaged together to improve provider performance and quality of care.
- Governance and capacity building for quality of care: QI work at facility level should align with and support the development of quality priorities and frameworks and institutional mechanisms for quality assurance and improvement at national and subnational level. The Global Fund will support activities focused on supporting the development and implementation of national quality of care policies and strategies, including capacity building of governance structures for quality improvement at macro, meso, and micro level,³⁵ the strengthening of regulatory quality functions, including to better regulate quality of care provided in the public sector, as well as the development and revision of standards, clinical guidelines, treatment protocols, and referral pathways for integrated care, including community-facility referrals. Leadership and management interventions to build capacity of national and

³⁰ Whideen, C., Kayentao, K., Liu J. et al. Improving community health worker performance by using a personalized feedback dashboard for supervision: a randomized controlled trial. Journal of Global Health 8, 2 (2018)

³¹ Singh K, et al. Can a quality improvement project impact maternal and child health outcomes at scale in northern Ghana? Health Research Policy and System. 2016; 14(1):45.

³² Hynes M, et al. Using a quality improvement approach to improve maternal and neonatal care in North Kivu, Democratic Republic of Congo. Reproductive Health Matters. 2017;25(51):140–150.

³³ Broughton E, et al. Cost-effectiveness of a quality improvement collaborative for obstetric and newborn care in Niger. International Journal of Health Care Quality Assurance. 2013; 26(3):250–61.

³⁴ Oyeledun B, et al. The Effect of a Continuous Quality Improvement Intervention on Retention-In-Care at 6 Months Postpartum in a PMTCT Program in Northern Nigeria: Results of a Cluster Randomized Controlled Study. J Acquir Immune Defic Syndr. 2017; 75 Suppl 2:S156–S64.

³⁵ World Health Organization. Quality health services: a planning guide. 2020. Geneva: World Health Organization

subnational health management teams and supervisors of health workers can strengthen the convergence between health service delivery, emergency preparedness, and community representation. ³⁶ Interventions include building capacity on QI among disease program staff to apply QI approaches including using data and evidence for decision making, developing skills in leadership, team management, negotiation, coordination and multi-sectoral collaboration, budgeting and planning.

HRH planning, management and governance, including for CHWs: Effective HRH planning, governance, financing and management, including for CHWs, is essential for the appropriate use and impact of HRH investments, so investments in HRH analyses, HRH data systems and/or HRH planning and management should complement other HRH interventions, particularly those in remuneration and deployment, based on an analysis of the HRH landscape and other development partners' contributions to HRH systems strengthening. A variety of analyses can be used for planning purposes, depending on context and issues at hand - the fundamental goal being ensuring the right health workers are available at the right levels of national and subnational systems to provide adequate prevention and care. These analyses include Health Labour Market Analyses, Workforce Indicator Staffing Needs to inform optimal workforce distribution based on population needs, and or gender and equity analyses, to identify and make recommendations on specific bottlenecks (e.g., to equitable workforce distribution) or barriers faced by HRH (e.g., safeguarding risks to CHWs). Support for the development and strengthening, including digitalization, of comprehensive HRH information systems should be considered and prioritised where data is still not widely available, including to integrate data on the private sector workforce. Under the WHO Global Strategy on HRH, there is a call for harmonization of HRH data in terms of definitions, analysis, and dissemination, and for the implementation of minimum data sets for HRH37 and of national health workforce accounts. 38 Priorities for HRH data system strengthening may vary depending on maturity of HRH information systems. HRH data systems should incorporate data on CHWs. Ensuring development of national georeferenced CHW master lists hosted in a registry integrated with or linked to broader HRH registries, information systems, payroll systems and HMIS is a core priority. Applicants should make use of Global Fund investments to support the necessary HRH data and analyses, such as health labour market analyses or workload indicators of staffing needs analyses, with emphasis on their use for policy and strategy development.

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³⁶ Abrampah NM, et al. Quality improvement and emerging priorities in global health. Int J Qual Health. 2018;30(1):5–9.

³⁷ World Health Organization. Human resources for health information system: minimum data set for health workforce registry. 2015 Geneva: World Health Organization

³⁸ World Health Organization. National health workforce accounts: a handbook. 2017. Geneva: World Health Organization

Support to HRH policy and strategic planning will depend on context, need and relevance to national priorities. Support to development or updating of HRH strategic plans should ensure that: these are based on relevant data and analysis; align with the NSP; are costed and align with the health financing strategy or STC plans; include CHWs and align with community health policies and strategies and are supported by annual operational plans. Other relevant HRH governance interventions may include: reorganization or definition of scope of practice for PHC workers, particularly CHWs, informed by analysis of optimal skills mix for integrated service delivery and the evidence base; workforce deployment (or optimization) plans to support new or integrated service delivery models, or an essential package of PHC interventions including for the three diseases; and capacity building for improved HRH planning, recruitment and deployment at national and sub-national levels. 39,40 Supporting coordination of planning processes and harmonisation efforts is critical, both in relation to specific CHW/community health and HRH support, as well as promoting the interlinkages between CHWs and HRH planning processes. Also a priority is the development of policies and interventions to improve resilience, protect and safeguard HRH, including mental health and occupational health and safety and decent work and fair remuneration. Considering the health workforce is often predominantly female, particular emphasis should be placed on PSEAH, both in relation to the health workforce and in relation to policies and standards for respectful care for vulnerable groups. The principle of decent work, with safeguards and protection for all health and care workers may also be benchmarked against WHO's Global health and care worker compact.

Finally, CHWs are a unique cadre of HRH. They play an important role in the delivery of integrated, people-centered health services as part of multidisciplinary PHC teams, improving access to and acceptability of services, as well as reducing health inequities, including for key and vulnerable populations. CHWs also play an important role in pandemic preparedness, including prevention, early detection, risk communication and community engagement, and other public health functions.⁴¹ They are included in the interventions mentioned above, and the features mentioned above that describe essential requirements of HRH interventions also apply to CHWs. Importantly, support for all types of CHWs should align with WHO normative guidance on CHWs.⁴² Support for CHWs must align with national law (e.g., labour law) and should align with national policies and strategies and, where

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³⁹ Mbate F., Nguni, Njoroge B., et al. Optimizing data use for effective decision-making in managing Kenya's workforce. 2021.

⁴⁰ Asamani, J.A., Amertil, N.P., Ismaila, H. et al. The imperative of evidence-based health workforce planning and implementation: lessons from nurses and midwives unemployment crisis in Ghana. Hum Resour Health 18, 16 (2020).

⁴¹ Bellard, M., et al. Community Health Workers in Pandemic: Evidence and Investment Implications. Global Health: Science and Practice Apr 2022, 10 (2) e2100648; **DOI**: 10.9745/GHSP-D-21-00648; https://africacdc.org/wp-content/uploads/2022/03/Concept-note-Role-of-CHWs-in-Pandemic-Preparedness-and-Response-Webinar.pdf

⁴² WHO guideline on health policy and system support to optimize community health worker programmes. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO; World Health Organization. (2020). Health policy and system support to optimize community health worker programmes for HIV, TB and malaria services: an evidence guide. World Health Organization. https://apps.who.int/iris/handle/10665/340078. License: CC BY-NC-SA 3.0 IGO; World Health Organization. (2021). Optimizing community health worker programmes for HIV services: a guide for health policy and system support. World Health Organization. https://apps.who.int/iris/handle/10665/350197. License: CC BY-NC-SA 3.0 IGO

necessary, support changes to national policy and strategy to align with WHO normative guidance and national law. Applicants are encouraged to support three key shifts in investing in CHWs in the next funding cycle: i) moving from fragmented to well-designed community health investments in alignment with WHO normative guidance, including integration of CHWs within the broader health system, national law, policy, and strategies; ii) moving from small-scale to scaled-up community health investments well-coordinated with domestic and partner investments; and iii) moving from short-term to medium- and long-term support, spanning funding cycles, and development of sustainable financing pathways.

Applicants should use the <u>CHW Programmatic Gap Table</u> to facilitate planning of CHWs investments for funding requests and should refer to Global Fund <u>Guidelines for Grant Budgeting</u> regarding remuneration (i.e., salaries, allowances and benefits). Strengthening community health systems also requires emphasis on improving bidirectional referrals between community and facility care. A detailed intervention approach on referrals is outlined in **Annex 2.** Finally, consideration should also be given to investments in health policy and systems support to optimize CHWs. This is summarized in **Table 1** below.

Table 1: Investments in health policy and systems support to optimize CHWs

Investments in health policy and systems support to optimize CHWs	Module and intervention
HRH: Governance, leadership capacity, coordination, policy & planning for CHWs (including as part of broader HRH), HRH analysis, development & maintenance of CHWML hosted in a registry, mobile/digital CHW payroll systems.	Module: RSSH/PP: Human Resources for Health (HRH) and Quality of Care Intervention: RSSH/PP:HRH planning, management and governance including for community health workers (CHWs)
HRH: Selection, competency-based pre-service training & certification & maintenance of certification for CHWs, competency-based in-service training for CHW supervisors, and other district, regional, or national/program staff with roles requiring training to support CHWs, strengthening institutions/systems that provide training for CHWs	Module: RSSH/PP: Human Resources for Health (HRH) and Quality of Care Interventions: RSSH/PP: Community health workers: selection, pre-service training and certification & RSSH/PP: Community health workers: In-service training
HRH: Remuneration (e.g., salary, allowances see the Global Fund Budgeting Guidance) costs for CHWs and CHW supervisors based on contracting agreement (written	Module: RSSH/PP: Human Resources for Health (HRH) and Quality of Care

agreement specifying role & responsibilities, working conditions, remuneration, workers' rights)	Intervention: RSSH/PP: Community health workers: contracting, remuneration and retention
HRH: Supportive supervision, including salaries for CHW supervisors and costs for implementation of supportive supervision of CHWs, as well as for supportive supervision of CHW supervisors	Module: RSSH/PP: Human Resources for Health (HRH) and Quality of Care Intervention: RSSH/PP: Community health workers: Integrated supportive supervision
Community engagement: Support to community engagement in CHW planning, selection, CLM, problem-solving	Module: RSSH: Community Systems Strengthening Intervention: Community engagement, linkages and coordination For CLM use Module: RSSH: Community Systems Strengthening Intervention: Community-led monitoring
Equipment: Transportation (e.g., bicycle or motorcycle inc. maintenance and fuel or transportation allowance), backpack, uniform, rain gear and boots, flashlight, thermometer, shakir tape, respiratory timers for respiratory illness	Module: RSSH/PP: Human Resources for Health (HRH) and Quality of Care Intervention: RSSH/PP: Community health workers: selection, pre-service training and certification Note: Use the cost input 9.3: Other non-health equipment
Commodities: RDTs for malaria diagnosis, ACTs for malaria treatment and rectal artesunate for pre-referral treatment of severe malaria	Module: Case management (malaria) Intervention: Integrated community case management (iCCM)
Commodities: Firstline antibiotics for pneumonia treatment and ORS and zinc for diarrhea treatment for children under 5 years of age as per national protocol for iCCM; see Annex 3 for eligibility criteria	Module: Case management (malaria) Intervention:

	Integrated community case management (iCCM)
Commodities: Condoms, lubricant, PrEP, PEP, POC EID, RDTs, and others for HIV services relevant to the CHW role	Relevant modules for HIV
Referral and counter-referral system: Allowances for transportation and meals for patients, caregivers and CHW	If for multiple diseases Module: RSSH: Health Sector Planning and Governance for Integrated Peoplecentered Services Intervention: Integration/coordination across disease programs and at the service delivery level If for single disease, use the relevant disease module and intervention
Supply chain system: Last mile distribution to health facility or CHW (can be done as part of CHW supervision),	Module: RSSH: Health Products Management Systems Interventions: Select the relevant intervention(s)
Health management information system, surveillance and M&E: Registers, paper-based job aides, routine reporting forms, mobile digital health tools (e.g., phones/tablets, sim cards, communications allowance) for CHWs and CHW supervisors	Module: RSSH: Monitoring and Evaluation Systems Interventions: Select the relevant intervention(s)
Health finance: Development of and support for sustainable financing pathways for CHWs	Module: RSSH: Health Financing Systems Intervention: Health financing strategies and planning
Above applicable if HIV, TB, or malaria services are in the	package of services CHWs deliver

4.6 Health products management systems

The Global Fund's 2023-2028 Strategy emphasizes the importance of achieving equitable access to quality-assured existing and new health products needed in the fight against HIV, TB and malaria. This includes promoting ethical and transparent procurement practices that

(preferably all relevant to population needs are integrated in the package of services)

comply with public procurement standards and the Global Fund's Value for Money Framework. It also champions environmentally sustainable sourcing and supply, promoting responsible, ethical and sustainable procurement and practices that include ecological, economical and safe waste management.

Health product management (HPM) systems should provide 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. Applicants should aim to strengthen country capacity to achieve accelerated (i.e., reduced time for new product introduction) and more equitable access to products and tools reflecting public health best practice (including phasing out older regimens) and include necessary support for the country's transition and preparedness planning for new health products.

Where HPM systems are weak and inadequately resourced, there may be bottlenecks in supply and distribution that impair the overall health system's ability to respond to surges and shifts in demand. This can lead to expiries, wastage, and detrimental impacts on the environment related to improper disposal/decontamination. When end-to-end supply chains for health products are not optimized, procurement and supply chain costs take on an outsized share of the available HPM budget and detract from other vital health spend on disease programs. Well designed and operated end-to-end supply chains not only improve product availability enabling achievement of program priorities, but also unlock capital currently tied up with inventory for the countries to reinvest in health. Disease program strategies can be directly enabled by transforming and adapting supply chains to support the multi-channel needs of customers, allowing for collection of products where they can be most easily accessed, for example in the community or in non-traditional outlets beyond the health facility.

Supply chains are also a major source of health sector carbon emissions and are particularly vulnerable to the impact of climate change. Many actions to minimize carbon emissions and strengthen resilience to climate change will also reduce waste and improve efficiency of the supply chain now and for the future. For example, improving the efficiency of transport operations to reduce kilometers driven can reduce costs and will also reduce emissions, and improving the energy-efficiency of warehouses or using renewable energy sources where applicable also has potential to reduce cost and emissions simultaneously.

Countries often require financial and technical support to develop or strengthen their capacities to perform the various functions of HPM systems. Investments in HPM should be adapted to each country's context, including country preparedness and readiness to introduce new health products and innovative health service solutions. Cross-cutting interventions include those that integrate procurement of medical and laboratory equipment and commodities across all disease programs, and support coordinated governance structures, business models, information systems, demand forecasts, warehousing and

distribution, regulatory capacity and waste management. Additional information can be found in the <u>Guide to Global Fund Policies on Procurement and Supply Management of Health Products (June 2021), Health Products Management Annex to the STC Guidance Note and the In-Country Supply Chains Technical Brief.</u>

Building on collective lessons learned to date, the Global Fund will require enhanced reporting by Principal Recipients on the procurement and supply of health products procured with Global Fund resources, regardless of procurement channel. Compliant reporting will include timely and quality information on new metrics for Procurement and Supply Chain Management performance rating. More information on HPM reporting requirements is available in the Modular Framework Handbook.

Based on current challenges and shifts for innovation, applicants should reflect on a set of critical approaches recommended for HPM investments as they design their funding requests.

Critical approaches for investing in key areas of national HPM systems

- 1. **Planning and Procurement:** Timely quantification, forecasting and VfM procurement planning and execution are critical steps in ensuring equitable and timely access to health products in countries. Quantification and forecasting exercises should be planned regularly (i.e., bi/annually) in a structured way to include important product categories of HTM health products. Once financing is confirmed, procurement planning and execution should be effective considering all VfM procurement channels e.g., (non/pooled, national/international) considering key criteria of quality, price and lead time to ensure timely delivery to countries
- 2. Storage and Distribution: Findings from national strategies and recent HPM system design and operational assessments should inform investments to enable the most effective use of existing capacity, determine if additional capacity is needed and, if so, how much and where in the system and possible financing. An objective and systematic assessment should determine what activities should be outsourced or insourced, and if sufficient processes and people are in place to manage all aspects of the HPM systems, including for required governance/coordination, monitoring and supportive supervision.
- Regulatory and Quality Assurance: Countries should strengthen the national regulatory systems to benefit the three disease programs and beyond with an integrated approach to cover Essential Medicines Lists/Diagnostics Lists development and updates, timely registration to facilitate new health products introduction, quality testing and post-market surveillance, effective pharmacovigilance and other QA system strengthening activities for pharmaceutical and laboratory products.
- 4. Health Product Information Systems: Management information system (e.g., LMIS, WMS, LIS) design, governance, management and use should be prioritized to ensure data is used regularly for evidence-based decision-making and to improve HPM system performance. End-to-end visibility of the supply chain should be addressed through the use of master data across systems and interoperability of critical systems to exchange data. A Supply Chain Digitalization Roadmap should be used in conjunction with standardized approaches to health product information systems. Inventory management practices should be data-informed to ensure national minimum/maximum stock levels of core health products are maintained at all times.
- 5. **Waste Management:** Countries should conduct comprehensive national assessments of waste management systems to inform the design of waste management systems interventions to minimize carbon footprint of segregation/removal/ decontamination/recycling/ and disposal systems using innovative technologies.

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The following areas are eligible for Global Fund support as part of national efforts to strengthen the HPM system:

Strengthen policy, strategy and governance: Applicants are encouraged to create a holistic and costed national strategic plan for health products management systems including in-country supply chains, endorsed by relevant national authorities and concerned stakeholders. Requests should articulate activities to improve the performance and efficiency of end-to-end supply chain systems to ensure uninterrupted availability of health products and minimize waste from the national essential medicines list. Strengthening national policies to more effectively manage the dispensing and use of antibiotics as per WHO's "Access, Watch, Reserve" (AWaRe) classification of antibiotics is encouraged as they help preserve the efficacy of antibiotics for the future, and help treat common co-infections in people with HIV, TB, malaria and beyond. Investments in financial reviews of Central Medical Stores (CMS) can provide valuable insight into current performance and future sustainability of a key component of the health product management system. CMS are a key component of the health product management system. Investments in financial reviews, business plans, key performance indicators and financial dashboards of CMS can provide valuable insight into their current performance and future financial sustainability. Investments in organizational audits, legal statuses and new governance arrangements can also contribute to their institutional sustainability.

Lastly, applicants are encouraged to support mechanisms to strengthen the incountry HPM coordination umbrella with government agencies, bi/multi-lateral donors and technical partners. This will ensure a robust mechanism for national coordination is formed/used and available to provide the necessary governance structure to guide national assessment and subsequently implement the costed strategies, with integration and efficiency as the core focus. The governance mechanism should also cover efficient management of an integrated supportive supervision and monitoring system that contributes to continuous performance monitoring and improvement.

To accelerate equitable access to health products reflecting public health best practice, applicants are encouraged to request support for key actions that can be taken to reduce the time to introduce products and remove products no longer considered safe or best practice. This can include policy, regulatory and programmatic enablers. See HIV, TB and malaria information notes as well as additional guidance to support the accelerated introduction of new health products at scale, which will be disseminated when available.

• Improvement of planning, storage and distribution capacity, design, and operations: Some countries have identified issues with insufficient capacity or inappropriate storage and distribution conditions and arrangements. These

bottlenecks cascade through the supply chain and often result in lower on-shelf availability of key health products at health facility and/or CHW levels or otherwise reduce the effectiveness or efficiency of the supply chain systems. Global Fund will support infrastructure improvements in storage and distribution capacity, if prioritized by the country application, including additional or enhanced warehousing and vehicles for transportation of health products to the "last mile", including health facilities and CHWs. However, before submitting funding requests for infrastructure, the Global Fund strongly encourages and will support the evaluation of: (i) the design of the supply chain (e.g., inventory norms, distribution frequency, smart product segmentation, route and fleet optimization, network design, product flows and layers in the supply chain, waste minimization, carbon emissions, integration of parallel supply chains, and other opportunities for efficiencies) and (ii) operations improvements (e.g., warehouse management, inventory management, fleet tracking and management, and more).

Outsourcing logistics services including storage and distribution could potentially increase performance and serve other needs, especially if done systematically and with the support of a comprehensive outsourcing framework. The Global Fund has developed a Logistics Outsourcing Framework. Applicants can refer to the In-Country Supply Chains Technical Brief for further guidance on supply chain design and operations, and outsourcing including contract and performance management.

Targeted investments to improve supply chain design and operations, or support for augmenting public systems with outsourcing of logistics services, often provide better value for money, improving efficiency, effectiveness and overall performance of the supply chain. As such, investments in infrastructure should be supported not only by a country-specific needs assessment, but also an evaluation of whether improvements in design or operations, or the potential to outsource, could achieve the same goals more efficiently as additional infrastructure investments. Investments in infrastructure will be mainly targeted to low-income countries, with medium and high-income countries requested to submit strong justification for the lack of domestic or other donor resources to support the need.

• Strengthening health product information system implementation and use: Increased wastage due to inefficient planning and procurement, poor end-to-end visibility, siloed and non-interoperable systems are some of the many issues faced by supply chains in lower middle-income countries. Data-driven decision-making at all levels of the supply chain can avoid such issues. The availability of high-quality data is dependent on information systems that support all the processes of the supply chain at all levels.

The Global Fund grants can be used to support the implementation of supply chain information systems to permit fulfilment of reporting requirements, such as physical stock counts and consumption reports, in a more efficient and effective manner. The Global Fund also supports investments which are standards-based, high-value investments that promote good supply chain practices, deliver high return on investment (ROI) and support a safe and efficient supply chain, including minimizing waste (e.g., electronic logistics management information systems, warehouse management systems, reporting and analytics, master data/national product catalogs, procurement/order/requisition management, track and trace, mobile solutions, innovations, and others). These solutions are critical in providing end-toend visibility through interoperability (EDI) and producing high quality data that can be used for data-driven decision-making at all levels, ensuring benefit to the end user in terms of availability, quality and lower costs. It is critical to highlight that the applicant should consider all other government and donor investments in this area and actively looking for areas of complementarities and efficiencies in investments, from design to operations.

• Strengthen countries' planning and procurement capacity for health products: The delivery of integrated, people-centered health services relies on efficient and timely procurements through multiple procurement channels, based on value for money considerations, from pooled procurement mechanisms (e.g., Global Fund's PPM, Global Drug Facility) to national procurement for establishing sustainable procurement systems. As timely and efficient procurements are central to ensuring that quality conforming and assured health products are available in-country when needed for patients, the countries should prioritize strengthening their national procurement systems and capacities. It is critical to highlight the need to adhere to Global Fund's Quality Assurance Framework of processes, standards and requirements that apply to products as well as practices; and there is also a need for strict adherence during the procurement process.

Effective and efficient procurement practices and systems for health products at the country level are essential for cost-effective acquisition of health products of assured quality, in the right quantities, from reliable suppliers in a timely manner and at the lowest total cost. The Global Fund supports a range of activities to strengthen incountry capacity for effective and efficient procurement which are detailed in the RSSH Modular Framework. Support can also be provided for strengthening national and/or PR procurement systems, including development or revision of policies and procedures; training of qualified staff who can plan and execute regular, efficient and green procurement processes, and others. Where necessary, applicants should highlight areas for active implementation support or technical assistance which can accelerate strengthening of robust procurement systems built on national and international best practices. They are encouraged to embed procurement systems

strengthening activities in their funding requests, under the RSSH investments as part of their sustainability and transition. In certain cases, applicants are allowed to reinvest portion of savings under the existing grants towards procurement and supply chain management strengthening activities.

Strengthen national regulatory and quality assurance systems: A weak regulatory system can have a direct impact on diagnostic and treatment outcomes. Many low- and middle-income countries have limited enforcement capacity of their regulatory mandate to assess, approve and proactively monitor the quality of health products. The underreporting of adverse drug reactions and adverse events, and very few regulatory decisions on medicines safety, highlights the need for improved and intensified approaches to strengthen post-marketing surveillance. In addition, the rise in substandard and falsified health products, including antimicrobial medicines, in all markets is hampering efforts to ensure the quality, safety and efficacy of health products. Exposure to substandard and counterfeited health products endangers health, promotes antimicrobial resistance and undermines confidence in health professionals and health systems. The practice of over-the-counter acquisition of antimicrobial medicines may lead to misuse of these medicines and further accelerate the emergence and spread of AMR.

Activities in this strategic area should support countries to deliver and implement regulation that protects the public while enabling timely access to and innovation of quality products and should focus on regulatory system strengthening and include market surveillance of quality, safety and efficacy. Illustrative examples of specific activities eligible for investment are provided in the RSSH Modular Framework. Additional guidance is provided in the <u>Technical Brief on Strategic Support for Effective Regulatory Systems</u>.

To further reinforce quality assurance system, a specific quality assurance plan can be developed within the masterplan/framework established for implementing national medicine/health product policy. This plan should outline all the different components under the quality assurance policy, specify approaches and activities, main actors involved (e.g., government agencies, laboratories, Principal Recipients, and others), responsibilities of key actors, estimated budget and proposed implementation timeframe. The quality assurance plan should also be used to allow coordination of both domestic and donor financing support, including from the Global Fund and assists in the timely implementation and monitoring. Proactive regional and in-country cooperation will be critical in supporting development and implementation of such quality assurance plan.

 Avoidance, reduction and management of health care waste: The climate emergency is a health emergency. Climate change threatens the foundations of good health, with direct and immediate consequences for patients, the public and programs. Globally the <u>healthcare sector is responsible for almost 5% of global greenhouse gas emissions</u>. The generation of ever-increasing waste, pollution and climate change are now a real threat to human and environmental health. In particular, the COVID-19 pandemic has led to large increases in health care waste, straining under-resourced health care facilities and exacerbating environmental impacts.

As the global health care system expands, growing amounts of waste are generated by health systems. These are not being treated properly, causing pollution, unnecessary carbon emission and waste of resources. Antimicrobial residues and resistant pathogens present in the untreated waste generated in health care facilities lead to their spread in the environment and exacerbate antimicrobial resistance. The problem is compounded by a widespread lack of efficient medical recycling system in many countries. The lack of safe segregation and treatment of potentially infectious and toxic healthcare waste is also a substantial safety issue.

Minimizing the volume of health care waste produced through routine and surge-capacity health interventions begins with environmentally responsible "green" procurement and having well-managed supply chains that do not lead to overstocking and expiries and which also minimizes packaging waste and carbon emissions associated with manufacture and distribution. As evidenced during the COVID-19 pandemic, management of commodity stocks poses enormous strain on storage and warehouse capacities, and many countries are not equipped to handle both substantial fluctuations in commodity demand, and variable volume of waste streams engendered by pandemic and emergency responses. WHO and UNICEF estimate that around 1% of the total national spend on health services is needed to ensure basic waste management (WHO and UNICEF 2020).⁴³

Applicants are recommended to evaluate national infrastructure for waste disposal, segregation, recycling, removal and treatment (e.g., landfills, waste treatment facilities, specialized disposal sites); to estimate waste volumes using newly developed Waste Tracking Tools; and to push for innovative partnerships to foster recycling, reverse logistics, and circular economies. Hunds may be allocated to develop and strengthen comprehensive, sustainable, and "climate-smart" procurement (i.e., low carbon and climate resilient) and to assess and evaluate current national capacities for systematic waste management systems. Appropriate interventions include support for operating facility costs (e.g., human resources, transport fees, etc.), strategic investments in infrastructure, baseline assessment of carbon emissions and climate vulnerability, and outsourcing of waste handling to private sector actors. Importantly, the Stockholm Convention, which most countries

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⁴³ WHO and UNICEF (2020) Global progress report on WASH in health care facilities: Fundamentals first.

⁴⁴ Innovation in manufacturing personal protective equipment: toward sustainability and circularity, IFC, UKAID, 2121.

have ratified, highlights that incineration is a major cause of air pollution, and viable alternatives to incineration exist for the majority of waste in all contexts. Further guidance is provided in the <u>Sustainable Healthcare Waste Management Technical Brief</u>.

4.7 Laboratory systems strengthening

Reliable and timely results from investigations using *in vitro* diagnostic (IVDs) either in the laboratory or at point of care are crucial elements in decision-making within almost all aspects of health services and disease prevention and control programs. Investments in systems to deliver diagnostics services underpin the ability to decentralize patient-centered service delivery, and play a central role in pandemic response efforts, informing public health security measures, and enabling countries to meet International Health Regulations (IHR).

Integration of diagnostics services refers to consolidation and coordination of existing resources (e.g., facilities, multi-disease testing analysers/equipment and personnel) and supportive processes (e.g., specimen referral, test reporting, inventory management, quality management, post-market surveillance) for multiple disease programs of public health importance, as per the Maputo declaration.⁴⁵ The clinical testing and laboratory sector provides some of the best examples of economies of scale and efficiency gains related to integration. 46, 47, 48, 49 For example, among people living with HIV (PLHIV), integrated laboratory systems should ideally provide comprehensive services for diagnosis of coinfections, including TB, Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Papilloma Virus (HPV), cervical cancer, and non-communicable diseases (NCD), such as mental health conditions and risk factors for cardiovascular diseases. Such integrated approaches are essential to scaling up quality-assured clinical laboratory services essential to diagnose infections, perform drug susceptibility testing, support patient management of comorbidities, and contribute to broader programs of syndromic surveillance. Costs per case notification are typically directly related to specimen throughput, choices of which IVDs to deploy within the tiered laboratory system, and optimal geographic placement of equipment analyzers. Importantly, in many countries the delivery of clinical testing services is already heavily privatized, and thus private sector laboratories are key partners in sustainable approaches to building national capacity. Finally, non-facility-based testing drives much of the current HIV and malaria programmatic successes; hence, it is key that investments to strengthen service delivery promote a balance of facility-based and community-based testing (e.g., mobile and outreach services, workplace and other venues where testing can be offered).

⁴⁵ WHO. The Maputo Declaration on Strengthening of Laboratory Systems. 2008

⁴⁶ Williams J, Umaru F, Edgil D, Kuritsky J. Progress in harmonizing tiered HIV laboratory systems: challenges and opportunities in 8 African countries. Glob Health Sci Pract. 2016;4(3):467-480

⁴⁷ Molecular diagnostics integration global meeting report. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO ⁴⁸ Yadav H, Shah D, Sayed S, Horton S, Schroeder LF. Availability of essential diagnostics in ten low-income and middle-income countries: results from national health facility surveys. Lancet Glob Health. 2021 Nov;9(11):e1553-e1560.

⁴⁹ https://aslm.org/wp-content/uploads/2019/11/Integrated-Testing-for-TB-and-HIV-Zimbabwe_Eng_digital.pdf?x20776

Siloed disease programming has resulted in the absence of strong governance structures to oversee the entirety of clinical testing service delivery, including both laboratory-based and community-based testing. Establishment of strong national laboratory leadership is critical to provide coordination and drive better integration. The Global Fund supports investments to ensure that the entities within the MoH responsible for the entirety of clinical testing (i.e., National Laboratory Directorates) are empowered to mobilize the financial resources and to oversee and implement the activities outlined in National Laboratory Strategic Plans (NLSPs) or National Action Plans for Health security (NAPHS). These critical planning documents, as well as available laboratory assessment outputs, should inform the investment plan for laboratory systems strengthening. For countries that have not developed/updated/approved Laboratory policies, NLSPs or NAPHS, technical assistant to prepare these is available.

The Global Fund has elaborated critical approaches to investing in laboratory strengthening, as summarized below.

Critical approaches for investing in laboratory systems strengthening:

- 1. Funding requests should be based on updated National Laboratory Strategic Plans and adopt a transparent and reliable tracking system to monitor implementation progress, including metrics on timeliness, coverage, and access of diagnostic testing services.
- 2. Successful participation in External Quality Assurance Schemes (i.e., Proficiency testing (PT) panels, inter lab comparisons, site supervision and mentoring, virtual/online PT panels etc) for all diagnostics.
- 3. Establishing all-inclusive pricing modalities that include service and maintenance and training for laboratory equipment and point of care instruments.
- 4. Implementation of ISO 15189 standards towards attainment of accreditation in all clinical public and private laboratories.
- 5. Routinely conduct integrated diagnostic network optimization/assessment exercises to increase efficiency and effectiveness of laboratory networks and systems and inform investments in diagnostics and lab systems.
- 6. Planning and implementation of integrated specimen referral networks for priority disease surveillance (zoonoses and food safety) and outbreak response. Outsourcing of transport services to the private sector is encouraged.

The Global Fund supports laboratory system strengthening in the following areas:

• Governance and leadership: The key to activating political leadership for integrated interventions across national disease programs is establishing a strong multidisciplinary coordination mechanism to provide oversight of laboratory system interventions (e.g., Health Professions Authority, Laboratory Councils, Laboratory Technical Working Group and subgroups). Applicants can request support to establish and maintain National Laboratory Directorates, including provision of programmatic operating budgets to convene coordinating bodies, inter-ministerial secretariats, Health Professions Authority, Laboratory Councils and other related consortia and authorities to provide oversight for the development of key policy, regulatory and planning documents. These laboratory bodies should have well defined Terms of Reference specifying committee membership, decision-making authority to align donors and technical assistance providers, and relationships to Laboratory Directorates, PRs/SRs, and the CCM.

Funding requests may include technical assistance to guide development of legislation relating to biomedical laboratories and clinical testing at or near to point of care and within communities; regulatory frameworks for IVDs; guidance development to promote adoption of self-care and self-testing screening/diagnostic technologies; programmatic initiatives to establish and/or reform quality management systems; specimen referral networks; adoption of digital solutions for information and data management; development of national centers to coordinate One AMR surveillance activities; and to conduct systematic assessments and reviews of network functionality. Funding requests may include regular in-depth assessments of national tiered laboratory network capacity and gaps. Countries are very strongly encouraged to invest in development of National Essential Diagnostic Lists (EDL) and Laboratory Minimum Standards to support and streamline decision-making regarding standardized IVD selection per health facility level, and procurement and inventory management.

• Human resources for laboratory systems: In many countries the human resources crisis within the laboratory system is acute, with inadequate staff numbers at each tier of the network, and no clear guidelines regarding roles/responsibilities, required competencies, induction training, or task distribution among laboratory professionals, technicians, assistants and support personnel. Medical Laboratory Councils can be established under Health Professions authority to specify and regulate the national cadres. Any additional laboratory certification of short duration training such as task shifted staff can also be maintained by such entity. Activities that may be supported by the Global Fund include those aimed at: improving distribution and retention of a skilled laboratory workforce (e.g., as part of Patient Pathway Analysis); and enhancing the competencies of staff through targeted activities. This can include

certification programs in biomedical engineering, bioinformatics, genomics, biosafety/biosecurity, etc. The Global Fund provides support for in-service career development programs such as the Global Laboratory Leadership Program.

In order to increase access to quality assured IVDs, countries must be able to effectively manage, maintain and continuously upgrade the basic infrastructure of testing facilities within the public sector. Infrastructure investments may include upgrading and refurbishing facilities to comply with international recommendations and required biosafety levels (e.g., upgrading a BSL-2 laboratory to ensure unidirectional flow for molecular testing), improvements to back-up power, internet connectivity, and information communication technology (ICT), however, expert guidance should be sought when upgrading laboratories to BSL-3.

Many countries lack robust and rigorous systems to maintain current registries of analysers/equipment at public facilities; these systems are particularly complicated where equipment has been procured with support of funding agencies through a variety of implementing partners, and there may be little or no harmonisation of contracting for warranties and service/maintenance. Countries are encouraged to invest in equipment management systems and connectivity solutions to improve and automate monitoring of key performance metrics. Challenges to provide sustainable preventive maintenance and servicing of laboratory equipment should be addressed through combined investments in human resources, policy and planning, operating directorates, well-crafted budgets to laboratory and contracts with distributors/suppliers.

System investments are needed to ensure calibration and preventive maintenance of key instruments. It is recommended that focal points for this task are hired such as a Biomedical technician and or Laboratory based supply chain officer/ Inventory control officer. These personnel should ensure that all equipment such as hematology and biochemistry analyzers, microscopes, biosafety cabinets, autoclaves, incubators, freezers, automated and semi-automated nucleic acid extractors, PCR platforms, and next generation sequencers are maintained. Maintaining functional equipment, optimizing utilization rates and coordinating removal of equipment at end-of-life represent important challenges, not least of which is the need for supply-chain workforce to oversee these responsibilities. Interventions under this module may include development of equipment policies, electronic registers, implementing traceability through leveraging unique device identification systems, and automated generation of reports on instrument functionality and key performance indicators (KPIs).

IVDs that don't require analysers/instruments such as rapid diagnostic tests (RDTs) will have other requirements. Selection of IVDs for malaria requires knowledge of the predominant plasmodium species to select the most appropriate type of RDT. Many countries lack capacities to verify HIV testing algorithms that follow WHO prescribed testing strategies. Small scale verification studies can be supported to guide product selection based on products that share the least number of common false reactive results to minimize risk of misdiagnosis.

Given the critical importance of laboratory supply chains, interventions designed to strengthen in-country capacity to manage analysers/equipment, commodities (i.e., durables and consumables), and reagents should be considered within funding requests. The Global Fund encourages innovative contracting mechanisms designed to improve maintenance and servicing; a shift towards all-inclusive pricing and reagent rental programs should be explored whenever possible. National Laboratory Directorates are encouraged to develop staffing expertise on contracts management, and to liaise with departments of finance and planning to pursue integrated procurement procedures that maximize cost efficiencies and competitive pricing for laboratory commodities and reagents, through consolidation of testing volumes and various pooled procurement mechanisms (PPM). Activities designed to facilitate improved forecasting and quantification of testing demand, to introduce novel types of IVDs, and conduct clinical utility studies or health technology assessments are encouraged.

Laboratory information systems (LIS): With advances in information communication technology, significant opportunities exist to harness the power of digital connectivity solutions to capture and manage clinical testing data, streamline workflows, and greatly facilitate the throughput of high-volume testing. Connectivity solutions and 'middleware' for analysers can facilitate all steps of recording and tracking output, enable sending automated test reports to patients, and generate performance metrics on instrument utilization rates and functionality (e.g., downtime of non-functional analysers, number of successful and failed runs/results). Investments in LIS are likely to be highly impactful for reducing turnaround time (TAT) for service delivery and increasing efficiency of case notifications. Investments in laboratory data management, information systems, and supply chain should provide evidence of interoperability of proposed solutions with the larger architecture of HMIS. It is essential that LIS solutions are interoperable with the electronic medical records (EMRs) and other components of national health management information systems (i.e., HMIS and LMIS). The use of analysers with inbuilt connectivity capabilities will facilitate data dashboards to improve program performance through real-time monitoring of key testing data (e.g., testing rates per capita, test positivity rates, viral load suppression, TB case notification etc), and are thus considered key elements to pandemic preparedness. Data from LIS can be analysed for trends in poor product performance that may need to be reported to the respective manufacturers for the purposes of post-market surveillance.

Most centralized testing facilities that use automated or semi-automated analysers have likely adopted some form of LIS. However, many lower-level laboratories still rely on paper-based reporting systems. The proliferation of multiple different software solutions to address different aspects of LIS functionalities can create challenges for scaling-up interventions. Please see <u>Global Good e-Tools</u> which reviews the details of existing laboratory-related global goods to informed country selection. In addition, the significant increase in community-based testing and introduction of self-testing poses new challenges for data capture. Global Fund resources can support development of policies and plans to guide investments in central data repositories (servers), interventions to improve management of laboratory-based and community-based testing results, development of data standards and norms, and acquisition of LIS solutions on national scale.

- Quality management systems for all levels of tiered testing networks: Quality assurance (QA) is critically important to the management of clinical testing services and underpins public trust in the reliability of test results. Quality management systems (QMS) is one of the laboratory quality essentials and a core indicator for several programs. Implementation of QMS is a key requirement for Global Fund grants. As a result, a number of tools have been developed to guide countries in implementation of laboratory quality management systems: the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA), the WHO Laboratory Quality Stepwise Implementation Tool (LQSI tool), the Laboratory Quality Management System - Stepwise Improvement Process (LQMS-SIP), and the Laboratory Quality System Handbook. It is recommended that applicants incorporate interventions for comprehensive quality systems in their funding request for the 2024-2026 allocation period, in line with national laboratory strategic plans, to enhance clinical testing quality systems. These can also be adapted for testing conducted at or near POC (outside of traditional laboratory) settings. Applicants are encouraged to pursue accreditation for national reference laboratories and facilities responsible for high volume testing based on international standards (ISO 15189), and expand the enrolment of peripheral (provincial, district) laboratories and other testing sites in SLIPTA interventions, and their participation external quality assurance (EQA) schemes. Furthermore, National Reference laboratories are encouraged to pursue ISO 17043 to support coordination of National External Quality Assurance schemes.
- Specimen transport systems and diagnostic network optimization: Effective
 management of laboratory services at the national scale is intimately linked to the
 ability to refer patients and/or their clinical specimens between facilities for
 supplemental testing. Specimen transport systems (STS) must be maintained for

both routine testing needs as well as for outbreak detection/response and are considered an essential component of pandemic preparedness. Functional specimen referral networks require many elements, including: clear roles/responsibilities for all actors involved; clarity on which tests/methods are performed at different locations to be informed by the EDL; established standard operating procedures (SOPs) for specimen collection and labelling, packaging, cold chain, test ordering, specimen and shipment tracking, and test report (results) return; defined transport routes, schedules and safety consideration; a cadre of trained and certified staff; and sufficient operating budgets to cover vehicles, motorbikes, fuel and salaries. Innovations to enable timely, safe and efficient transport of samples should be considered where current 'mainstream' approaches are underperforming. It is critically important that such innovations are combined with operational research and thorough evaluation to ensure that their cost-effectiveness is understood, and the country and other countries can learn from the innovation. Importantly, countries should consider using the private sector to support national integrated specimen transport systems. For countries with multiple parallel STS for HIV, TB, or emerging infections, the Global Fund strongly encourages Laboratory Directorates to develop a transition plan that aims to integrate transport services across disease programs and create a sustainable and cost-effective transport service.

Plans to expand diagnostic services via investments in infrastructure and equipment must be supported with quantitative data on capacity/ utilization of the current network, and ideally should be supported with output from geospatial analyses. Trade-offs for investment decisions in centralized vs decentralized systems should be supported by cost-benefit and value for money analyses. The design of a diagnostic and sample referral network is key to ensuring cost-efficient and equitable access to services. Diagnostic network optimization (DNO) is a geospatial network analytics approach to analyze current structures and recommend alternative configurations based on analysis of testing demand and testing capacity, disease burden, existing or planned facilities, road networks, and application of real-life constraints. Insights from DNO can contribute to evidence-based integrated national strategic plans, funding requests, resource allocation, as well as procurement and operational planning. While the core implementation framework can be universally applied, the process of conducting a DNO is driven by factors unique to each setting, such as the overall purpose, objectives, scope, and timing of the analysis. The Global Fund strongly encourages applicants to include DNO within funding requests, enable enhanced planning, facilitate the transition towards integrated systems, develop an ongoing and dynamic approach to maximize testing capacity, improve access to services and facilitate the adoption of new multi-disease testing platforms as they become available.

Laboratory-based surveillance: genomics, next generation sequencing, environmental surveillance, integrated human and animal disease surveillance for zoonoses, One AMR surveillance, innovation and implementation Research. Under the new Strategy, a much broader array of laboratory-based surveillance activities are eligible for funding through both RSSH and pandemic preparedness resources. During the COVID-19 pandemic, the Global Fund began support to countries to establish genomics surveillance capacities at national and regional reference laboratories for detection of SARS-CoV-2 variants of concern. Applicants are encouraged to further strengthen core facilities in cutting-edge sequence analytics to support disease surveillance and outbreak detection as part of pandemic preparedness, and to support accelerated monitoring, prevention and responding to antimicrobial resistance (AMR) of HIV, TB, malaria, and additional priority pathogens. Effective next generation sequencing (NGS) interventions require substantial investment in staff training, specialized equipment, reagents, QMS and bioinformatic infrastructure. Additionally, countries need to ensure that generated data is of good quality and is used to inform national policy. Countries are encouraged to rapidly deposit genomic data in public databases.

The COVID-19 pandemic has also has greatly expanded interest in environmental surveillance (ES), pathogen detection from wastewater, as a powerful tool for early-warning detection of changes in transmission intensity and cost-effective measures for population-level monitoring. ES complements conventional case-based disease surveillance by providing empirical quantitative data on pathogen prevalence that is independent of healthcare-seeking behavior and expands testing access. Applicants are encouraged to build and expand upon existing networks for environmental-based polio surveillance, and/or to develop pilot ES interventions to validate methodologies, develop guidance, implementation plans, data management systems, and programmatic adaptations for analysis and reporting. Funding support may include ES applications to monitor SARS-CoV-2 prevalence and variant detection, or broader applications within the context of pandemic preparedness (i.e., detection of emerging pathogens, AMR surveillance, etc.).

A new, innovative area in public health surveillance is sero-epidemiology. This provides the opportunity for population-level estimation of disease burden at the spatial-temporal level that may overcome limitations of microbial-detection based surveillance. Existing serosurveillance already in place for one disease (e.g., population-representative sampling for HIV seroprevalence) may be leveraged and expanded to multi-disease surveillance estimates (e.g., using multiplex serologic assays or multi-disease serology analyzers).

Applicants are encouraged to embed implementation research on NGS applications and/or innovative population-based surveillance strategies (i.e., ES, serosurveillance,

One AMR, One Health, etc.) within their funding requests to facilitate shared learning on both technical laboratory-related aspects, as well as operational challenges. Implementation research may be linked to planned roll-out of the Global Laboratory Leadership Program, or as part of other educational investments to foster stronger alliances with national academies.

4.8 Medical oxygen and respiratory care systems

Oxygen and respiratory care systems are an essential aspect of resilient and sustainable systems for health, and the COVID-19 pandemic demonstrated inadequate capacity of most countries for emergency preparedness and response, in particular, for respiratory pathogen-based pandemics.

Investments in oxygen and respiratory care prevent deaths from common conditions that affect the most vulnerable newborns, children, and pregnant women, including severe forms of HIV, TB and malaria. WHO has included oxygen in its Model Lists of Essential Medicines. For decision-makers looking for practical ways to improve health outcomes, strengthening medical oxygen and respiratory care systems should be a key consideration for national and subnational policies, health sector strategies, programs, and budgets. The optimal investment strategy takes a system-wide approach that considers not only how oxygen delivery and respiratory can be integrated into programs, but also efforts focused on strengthening service delivery, procurement, monitoring and evaluation, HRH, and supply chain management and sustainability.

Global strategies, guidelines, and protocols provide direction on how oxygen delivery can be incorporated into existing health programs, including HIV, TB, malaria and related programs such as MNCH. This requires investments based on robust analysis of system gaps and weaknesses, funding needs, and using reliable evidence-based interventions to address these needs. WHO and implementing partners such as CHAI and PATH have carried out structured oxygen needs assessments across multiple countries. The ACT-A emergency task force on oxygen, technical and donor partners have also come together to define approaches to rapidly respond to existing demands for these life-saving interventions, including financial and country operational aspects. All elements of country funding requests must be supported by systematic data. The box below provides an overview of investment considerations. **Annex 5** provides additional guidance and key considerations for applicants to understand and identify local oxygen needs, gaps and priorities.

Effective medical oxygen and respiratory care systems should include the following:

- 4. Integration of oxygen delivery across national, subnational policies, plans, and guidelines including: essential medicines lists, priority medical devices lists, health policies, health strategies, implementation plans, and budgets.
- 5. Clinical recommendations for the management of hypoxemia with oxygen therapy, including: standard treatment guidelines, service delivery and quality of care standards, provider training materials, health care worker policies and health care worker accreditation requirements.
- 6. Selection, installation, and maintenance of oxygen technologies and supplies with clear regulations for the registration and importation of medical devices, medical device technical specifications and standards, and guidelines on medical equipment management and maintenance.
- 7. Monitoring and evaluation integrated into routine tools for surveillance such as Health Management Information System (HMIS), including clinical surveillance, Demographic and Health Survey (DHS), Service Availability Mapping (SAM) and Service Provision Assessment (SPA), for example.

The following provides an overview of medical oxygen and respiratory care interventions that are eligible for Global Fund support:

- Bulk oxygen supply: pressure swing adsorption (PSA) plants and liquid oxygen storage equipment and supply; infrastructure investments to ensure site readiness to install, run and maintain bulk oxygen equipment, commissioning and functioning (e.g., housing, concrete slabs, electric power generators, solar power); oxygen concentrators; and warranty, service and maintenance, as appropriate, to ensure continuity and sustainability of oxygen generation and supply according to WHO standards and guidance.
- Oxygen distribution and storage: activities ensuring availability of and access to quality, safe and cost-effective distribution and supply of medical oxygen cylinders, cannister, and external distribution systems to hospital sites where there are identified gaps in supply and demand; piped O2 distribution systems within health facilities; and vaporizers (for liquid O2).

- Oxygen delivery and respiratory care: activities ensuring availability of and access
 to quality, safe and cost-effective pharmaceuticals, medical devices, oxygen and
 other health technologies considered essential for the treatment management of
 respiratory disease in health facilities according to level of care and context, including
 disposable, single-use, oxygen-delivering interfaces (e.g., nasal cannula, venturi
 mask and mask with reservoir bag), infusion pumps and IV sets, invasive and noninvasive ventilators, intensive care beds, physiological parameters monitors, pulse
 oximeters and imaging equipment (e.g., ultrasound, chest X ray (including digital) and
 CT scans. These investments should include warranty, service and maintenance and
 spare parts according to WHO standards and guidance to ensure continuous
 functioning and long-term sustainability of equipment.
- Oxygen support systems: national assessment of medical oxygen demand and gaps and use to develop national strategic and/or operational plans, including use of high-quality technical assistance, assurance and multisectoral partnerships including the private sector for the development, funding and operationalization of national plans for oxygen scale up; dissemination of regularly updated information and evidence, train, and refresh the health workforce in management of respiratory disease, using protocols based on international standards and WHO guidance on supply, distribution, and delivery of medical oxygen; evaluation of implementation and effectiveness of case management procedures and protocols (including for pregnant women, children, elderly patients, and immunocompromised patients), and adjustment of guidance and/or activities to address implementation gaps as necessary; monitoring of performance indicators at patient level to assess whether processes of respiratory care are improved; and enhancing capacity of informal caregivers in community to provide social support and outreach on aspects of respiratory care.

4.9 Additional cross-cutting considerations: private sector engagement and digital health

Two important cross-cutting areas should be also considered in the design and delivery of Global Fund RSSH investments: private sector engagement and digital health.

A. Private sector engagement (PSE)

Private sector engagement (PSE) is the meaningful inclusion of private sector⁵⁰ to harness potentials for better health outcomes. PSE requires that governments focus on governance of the whole health system –both private and public– to ensure quality of care and financial

⁵⁰ The private sector is defined by the WHO (2020): the individuals and organizations that are neither owned nor directly controlled by governments and are involved in the health services. It can be classified into subcategories as for-profit and not-for-profit, formal and informal, domestic and international.

protection for patients, irrespective of where they seek care. In most countries the health sector is managed through a mixed system and requires both the public and private sector to work closely with each other. The private sector in health is engaged in a broad range of activities across the health system. The governments can harness the potentials of the private sector by identifying shared interests and respective capabilities, as well as support more evidence-based decision making that reflects the actual care seeking behavior patterns of the population.

However, many countries are facing challenges in effective engagement with private sector. To engage more systematically, applicants may consider the pathways for engagement as control knobs and select the appropriate domains of engagement to ensure the specific needs they are going to address. Applicants can select all or a mix of the following four pathways to engage systematically:

- Including private sector in policy and dialogue, such as policy formulation, change or implementation, and strategic and technical decision-making through coordination forums like the CCM.
- Exchanging information through the inclusion private health sector information flows, establishing transparent mechanisms and including them in national surveillance systems.
- Regulating the private sector through certification, licensing, accreditation, monitoring/ oversight and allowing establishment of networks, franchising and social marketing, and
- Financing the private sector through contracting, outsourcing, establishing public-private partnerships, strategic purchasing and market shaping, for example.

These pathways should be considered across all areas of RSSH investments. For further details about the private sector engagement, applicants can review the Private Sector Engagement Technical Brief.

B. Digital health

The potential of digital technologies to strengthen health systems and improve patient health is recognized in the <u>2018 WHO Resolution on Digital Health</u> and <u>Global Strategy on Digital Health 2020 – 2025</u>. Digital technologies can be used to improve countries' health information systems, using its data to improve care and programs, and can also support program implementation directly.⁵¹ Applicants should consider the following when investing in digital health:

 Data aggregation and visualization: Health programs are implemented through multiple channels including government driven initiatives, development partners, civil

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⁵¹ WHO guideline: recommendations on digital interventions for health system strengthening. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO.

society, and private sector. While each program improves specific areas of a country's health system, it becomes essential to track the cumulative impact created to assess needs and guide future actions. Applicants are therefore encouraged to come up with aggregation and visualization tools that can complement the central reporting structure or "Control Tower". Strong consideration should also be given to industry interoperability standards such as https://linearch.nih.gov/hl/. These standards help ensure that data consumers such as the MoH and the clinician can see required data from various platforms (e.g., EHR, LMIS, LIMS) and provide, for example, a 'one-stop' dashboard for monitoring and evaluation purposes or lab test results in a point of care solution.

- Innovative digital health advancements: The Global Fund embraces and seeks to support innovative solutions across its investments. These innovations may include mobile phone applications for instance patient-tracking apps introduced to monitor COVID-19 cases, solutions using artificial intelligence (AI) and machine learning (ML) technologies for activities like diagnosis, prescriptions and vaccine tracking systems. Harnessing the potential of the private sector in this area can be a feasible approach.
- Digital health leadership and governance: The leadership and governance landscape of a country plays an important role in guiding policies and providing congenial ecosystem to enable delivery of healthcare services. The Global Fund has identified key areas that remain the cornerstone of a strong health system, namely:
 - National digital health strategy and policy: a document highlighting strategy, policies, framework, and guidelines associated with the development and use of digital technologies to improve healthcare outcomes followed by deployment of resources to implement the same.
 - Digital health governing bodies and mechanisms: presence of a digital health department in the MoH, along with well-defined governance mechanisms for digital health that is fully functional, government-led, consults with other ministries, and monitors implementation of digital health based on a work plan.
 - Digital health financing and performance management: allocation of certain budgetary funds towards digital health including for purposes of monitoring and evaluation to assess the impact of investment on digital health implementations.
 - Development of digital health capability: inclusion of a digital health curriculum in pre-service education and lifelong learning modalities for health and care professionals⁵², and inculcation of best practices prevalent across various geographies and institutions.

⁵² Digital education for building health workforce capacity. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.

- Digital health standards, terminology and architectural framework: existence of digital health or health information standards for data exchange, transmission, messaging, security, privacy, and hardware.
- Digital health capabilities at points of care: As health data sees a shift from being paper-based to electronic, various digital health applications are better suited to enhance patient experience and service delivery at the point of care. Some examples include:
 - Case surveillance/electronic health records (EHR): electronically stored longitudinal health information of patients in a digital format can be shared across different healthcare settings, ideally directly with the clinician, and to both public and private providers. These records can be used for seamless service delivery across the entire hierarchy of health infrastructure, if they are interoperable according to the enforced national policy and compliant to applicable international standards.
 - Workflow management systems: capability to have visibility and streamline the flow of patients, caregivers, staff, equipment and supplies in health facilities to introduce faster processing times, shorter wait times, quicker diagnosis, and capacity management.
 - Financial management systems: capability to manage assets, income and expenses for health facilities and ensure flow of information to regional/national level for better decision making at the administrative level and forecasting budgetary demands.
 - Logistics management information system (LMIS): ensures that the right commodities are available in the right place at the right time. The LMIS maintains records electronically, to aggregate, analyze, validate and display data on health products inventories, warehousing, distribution, and more. LMIS is an important component of the supply chain used to manage medical and laboratory supplies including drugs, diagnostics, health and non-health commodities, and equipment.
 - Communication and community engagement: capability to exchange timely health-related information, advice and opinions between the authorities, service providers and the target population in a smaller catchment area for dissemination of genuine medical information and guidance.
 - Laboratory diagnostic services: test ordering and scheduling of diagnostic procedures, manage sample repositories and workflow processes, results reporting to surveillance systems, and results return to patients. These are key functions of electronic Laboratory Information Systems (LIS). Ideally LIS should be interoperable with EMR.
 - Digital payment: ability to allow digital monetary transactions, linked to point of care information systems to avoid large cash transactions.

- Community health applications: use of technology/digital tools by CHWs in primary care outreach activities to manage patients, contact cases, drugs, rapid diagnostic tests (including self-tests), and generate a timely report related to care encounters. Community health applications also include the use of technology/digital tools by CHW supervisors for supportive supervision and performance management of CHWs.
- o **Digitized knowledge content:** capability to maintain and access digitized guidelines, reports and healthcare-related knowledge content.
- Telemedicine: capability to provide clinical services to patients without an inperson visit using information and communication technologies such as internet, laptop, video camera etc.

When implemented at health facilities, these can improve patient experience and at the same time provide better health outcomes by leveraging the insights that can be drawn through the interplay of data captured by different applications. For instance, a patient's historical diagnostics lab reports if integrated with the electronic health record, can provide a clinician better view of changes in patient's health over time.

- Digital health capabilities at national, regional and district levels: In addition to implementation at points of care as detailed above, aggregated data which is captured by various health information systems at national, regional and district levels can provide holistic view of the digital health maturity in the country. These capabilities are:
 - Case surveillance/electronic health records: A national policy to ensure health information of patients is stored electronically in a digital format which is interoperable and compliant to applicable international standards.
 - Health management information system (HMIS): capability to record, store, retrieve and process health data, from public and private facilities, to support planning, management, and decision-making by relevant healthcare authorities
 - Financial management: aggregation of financial information related to assets, income and expenses from health facilities and up to the national/regional level.
 - Logistics management information system (LMIS): aggregation of logistics information related to medical supplies from health facilities and up to the national/regional level.
 - National laboratory information systems (LIS): coordination of LIS applications used across the tiered lab network, both in the public and private sector, ensuring that all data flows are aggregated and archived in a central laboratory data repository, with interoperable linkages to HMIS, LMIS, and other facility-based resource management systems.

- Human resource information system: capability to collect, process, manage and disseminate data related to human resources and training for health; aligned with WHO standards for National Health Workforce Accounts (NHWA).
- Event-based and routine surveillance: capability of organized collection, monitoring, assessment and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice.
- Digital payments: adoption of digital payments in the country and welldefined national strategy, policies and guidelines for uptake of digital payments.
- Communication and public engagement: capability to exchange real-time health-related information, advice and opinions between the authorities and a larger population at regional/national level.
- Digital health infrastructure: Various countries where the Global Fund operates face basic infrastructure related challenges. Applicants are encouraged to consider these infrastructural gaps that may act as a barrier to implementation of digital health solutions proposed. These may include:
 - Local access to IT equipment and facilities: capability of health workers to access health information systems in a timely fashion using fixed and mobile computing devices.
 - Communication infrastructure: presence of internet connectivity at health facilities and within the community in urban, regional and rural settings, including cellular and the last mile delivery to the facility.
 - Data interoperability, integrity and traceability: capabilities include the ability to seamlessly exchange data between relevant systems typically by the use of applicable standards (e.g., FHIR) or the use of a national Health Information Exchange. Ensuring processes are in place to validate the accuracy, completeness, consistency and provenance of data.
 - Registries: collection of information related to patients, healthcare terminologies, health workers, facilities, healthcare related products and health records with the ability to store and access the information when required; development of data standards.

- Digital health accelerators: Accelerators can act as catalysts in the growth of digital health. The Global Fund has identified three areas that can be leveraged as tools to advance overall global health impact. These are:
 - Data governance, including cyber security and data privacy to ensure confidentiality, integrity and safe accessibility of health-related information.
 - Partnerships and collaborations with the private sector for digital innovation and with donors for coordinated country strategies.
 - Precision health innovation for a collaborative platform bringing together advanced and predictive analytics to inform strategic planning.

5. Good Practice Examples

5.1 Strengthening CHW programming in the context of health system reform in Mali

In Mali, the Ministry of Health and Social Development underwent a health system reform aiming to attain UHC through PHC. The Global Fund, in close coordination with other development partners, has taken a comprehensive approach to its investments by supporting the MSDS-led process to:

- Optimize the scale-up and targeted deployment of additional CHW through geospatial modelling which informed updates to national strategic plans for expanding PHC services at community level as part of the health system reform.
- Develop the policy foundation for future domestic financing of CHW and a long-term sustainable financing pathway, following a historic decree by the Government of Mali, officially recognizing CHW as health workers and the first level of the Malian health system, and
- Support a shift away from a piecemeal financing approach toward comprehensive support for strengthening the systems components needed for effective CHW performance.

This included, among other things, support to: leadership; governance and coordination; community participation in CHW selection; competency-based pre- and in-service training and certification; fair and on-time remuneration for CHW; dedicated supportive supervision including training, salary support, transportation, a digital supervision application and implementation an innovative 360-degree approach to supportive supervision and CHW performance management; HMIS and M&E strengthening; the geospatial modelling noted above, and the development of the first national CHW master list, as well as early steps toward a national georeferenced CHW master list hosted in a registry, supply chain strengthening, and rehabilitation and strengthening of primary health facilities.

More work still needs to be done and there are challenges ahead but the example of Mali underscores that even in challenging operating environments, progress can be made toward strong, resilient and sustainable CHW platforms in the context of broader PHC and efforts toward attaining UHC and that the Global Fund RSSH investments can play an important contributory role.

5.2 Joint financing for PHC strengthening in Lao PDR: HANSA Project

The Health and Nutrition Services Access (HANSA) project aims to support the reform of the Laos health system by strengthening primary care on the path to the UHC. The 36M\$ joint investment is a tripartite arrangement between the Government of Lao DPR, the Global Fund, and the World Bank. As part of the project, the Global Fund contributed 10M\$ in parallel financing to the Ministry of Health (MoH) in full alignment with both the targets established under the World Bank program and national priorities. The project is implemented by the MoH in cooperation with partners through a broad set of implementation arrangements, including payment for results and Disbursement Linked Indicators (DLIs). The funding is attached to "Quality of Health Care at Health Center Level" with a results-based payment component. The joint project also incorporates twelve DLIs at provincial and central levels with specific DLIs for HIV and TB and supports the integration of the three diseases into PHC. Further, the project has broader RSSH components such as HMIS and PFM which provides direct benefits to the specific disease programs.

5.3 Mobilizing specimen referral networks to improve TB and HIV services in Indonesia

In Indonesia, challenges with low TB case detection rates, low accessibility of HIV VL testing services and low utilization of GeneXpert machines and other molecular diagnostic platforms have been addressed by interventions to strengthen specimen referral networks. Starting in 2018, the country has systematically invested in: engaging with private sector dedicated courier services; training for healthcare workers on specimen packaging and SOPs; procuring and distributing the necessary packing consumables; adopting a purpose-built information system for test ordering and specimen tracking ('SITRUST'); and coordinated adoption of a communication platform. The country has established a series of web dashboards that help monitor user notifications, tracking of shipments, feedback on specimen quality, and enables aggregate data reporting to a central laboratory data repository. Together these interventions have realized very significant gains in the numbers of specimens referred to TB and HIV testing sites, and the increases in the throughput and utilization rates of instruments have yielded impressive cost efficiencies.

5.4 Leveraging the public financial management system in Zimbabwe

In Zimbabwe, investments were made on leveraging the existing public financial management information system (IFMIS) to meet both government and the Global Fund's

budgeting, accounting and financial reporting needs. Working with the Ministry of Finance, a grant management module was configured in the IFMIS platform to enable accounting and report automation as part of rendering accountability on Global Fund transactions. This also supported greater government visibility on resources in the health sector, supporting resource tracking of government and Global Fund funding and expenditures at sub-national or district level.

A 2021 review of countries piloted in the current strategy cycle revealed that countries using PFM systems had three times more improvement in their financial management performance than their non-PFM counterparts. These improvements were assessed along timeliness and quality of financial reports delivered, budget absorption and financial risk issues.

5.5 Community-led monitoring in Ukraine

Ensuring health services are being delivered in a manner that respects and protects human rights is an essential element of advancing program quality and effectiveness, especially for key populations. In 2018, with the support of the Global Fund, and in partnership with Frontline AIDS, the Alliance for Public Health (APH) in Ukraine began implementing REAct: Rights-Evidence-Action. REAct is a tool that assists community-based and led organizations in monitoring human rights violations experienced by individuals seeking HIV and TB services. REAct monitors the type of violations perpetrated (e.g., refusal to provide services, stigma and discrimination, physical violence, emotional violence, financial or physical damage and breach of confidentiality); the populations subjected to violations (i.e., people who inject drugs, people living with HIV and men who have sex with men); and who the perpetrators of the violations are (i.e., state healthcare workers and police). A 'hotline' for reporting violations was established which registered 775 cases of 760 clients from key and vulnerable populations though partnerships with 28 organizations across seven regions over a 12-month period. Primary legal aid was provided in 691 cases; secondary legal support in 57 cases; and psychosocial support provided in 268 cases. In addition, to direct responses to violations, data collected informed the development of appropriate national response strategies and contributed to prevention of violations at the community and systemic levels. The program strengthened meaningful dialogue between key populations and authorities based on the evidence collected and has provided evidence on what adjustments need to be made to the national HIV/TB program. Furthermore, the data forms a basis for an assessment of national drug policy as well as other laws and policies as they impact on the accessibility of HIV/TB services for key populations in the country.

5.6 Waste management during Ebola and COVID-19 in Liberia

Proper healthcare waste management has always been a challenge for Liberia, but major efforts to improve safe disposal of infectious waste were made in the wake of the 2013-2014 Ebola crisis. As part of government support for improved preparedness for health

emergencies, there have been sustained efforts to invest in training of healthcare workers on "Safe Quality Services" including waste management, WASH, relevant national health policies and quality improvement within healthcare facilities. The country has also invested in locally produced De Montfort incinerators for more than 600 primary and secondary healthcare facilities. National guidelines for the safe management of healthcare waste, SOPs and job aids have been developed and operationalized, and waste management infrastructure is now part of the remit of the Ministry of Health's infrastructure unit and is standardized across the health system and laboratory sector. These investments helped Liberia to be better prepared at the onset of the COVID-19 pandemic, in particular, to promote waste segregation at health facility level via a three-bin system and proper handling of infectious waste by specialized staff (i.e., waste managers and incineration technicians). One of the main ongoing challenges has been the inability to quantify the waste generated from routine services and during health emergencies, and a continued reliance on external donor funding to support operational costs for regular maintenance of waste infrastructure. More innovations in recycling, reverse logistics, and creative approaches to engage private sector entities in circular economies will be needed to achieve resilient and sustainable longterm solutions to waste management challenges.

5.7 Integrating mental health into HIV/TB and COVID-19 interventions in Zimbabwe

The Global Fund supports the integration of mental health with care for other co-morbidities, including infectious diseases such as HIV and TB. Integrating care can yield reciprocal benefits:⁵³ mental health care improves adherence to HIV/TB treatments, and integration with HIV/TB treatment programs could provide needed staff to support people living with mental health conditions, all the while expanding access to mental health care as a more holistic service for people living with HIV/TB. The 2020-2022 funding request from Zimbabwe included mental health in the HIV/TB and COVID-19 interventions. Specific activities included:

- provisions for training and supervision of health professionals on mental health;
- supporting community health workers to screen people who may be experiencing metal health problems; and
- strengthening peer psychosocial support for young people.

Acknowledging that a lack of psychosocial support is a barrier to ARV initiation, the funding request also included mental health services and psychosocial counselling as part of the minimum comprehensive HIV prevention package for men having sex with men.

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⁵³ Bending the Curve: The Impact of Integrating Mental Health Services on HIV and TB outcomes

5.8 Engaging the private sector in DRC

With funding from the Global Fund, a pilot was implemented in Kinshasa, DRC from 2015-2017 to improve access to quality artemisinin-based combination therapy (ACTs) in pharmacies and private health facilities through contracting, capacity building and supply of inputs. In addition to subsidizing commodities by contracting with importers, the pilot also leveraged communication and marketing, which included promoting a "green leaf" status to indicate pharmacies that had undergone capacity building and could provide quality ACTs.

Following this pilot, investments from the 2020-2022 allocation period have been used to mobilize private sector partners in a public-private partnership to improve access to quality ACTs and rapid diagnostic tests (RDTs) in private sector facilities. Support has also included assistance with registration, certification and capacity building. Additionally, the engagement strategy uses a mix of private and public actors as supervisors to render the supervision process peer-led and ensure good ownership. The program has been implemented as part of routine malaria control activities in the cities of Kisangani, Goma, Kikwit, Bunia, Matadi and Kindu, in addition to Kinshasa, covering 50 health districts/zones and nearly 16 million inhabitants. It has resulted in a significant reduction in the costs of ACTs and the introduction of RDTs in private retail pharmacies.

5.9 Improving quality of care in West and Central Africa

With Global Fund support, an innovative package of evidence-based approaches to improve quality of services for HIV, TB and malaria has been introduced for the following five countries in West and Central Africa: Chad, Democratic Republic of Congo, Mali, Niger, and Nigeria. Activities include:

- HRH planning.
- Quality improvement (QI) through integrated supportive supervision (ISS), and
- Strengthening leadership and management at national, regional, and district levels.

Delivery started with one province per country as demonstration sites and was rolled out to other provinces once context-specific adaptations are made to the interventions. The HRH planning component focuses on HRH analytics (e.g., Health Labour Market Analysis) on supply, retention, distribution, and motivation, as well as facilitating HR policy dialogue and planning in country.

In Mali, the Global Fund is supporting the Bougouni district in developing a workload assessment tool to help regional and district health levels to improve the distribution of health workers between rural and urban areas. The QI component includes collaborative improvement, training, a web-based supervision checklist, and supervision of supervisors. The goal is to support health systems on problem-solving with data, teamwork, motivating health workers, and strengthening their capacity.

In Nigeria, the Global Fund is supporting Jigawa state to roll out an integrated supportive supervision approach and train facility staff. This includes training supervisors to use a digital checklist and how to better support healthcare staff. Facility staff are being trained on QI methods to improve malaria screening and testing, as well as improved uptake of PMTCT. A network of 30 facilities in Jigawa are participating in a peer-to-peer learning collaborative, enabling them to share their experiences.

The leadership and management component focuses on mentoring a group of MoH staff at each level of the health system to further develop skills in leadership, management, budgeting, planning, advocacy, and creating culture of quality. This activity also aims at improving engagement with community structures to increase timely use of health services. In Tahoua, Niger, 12 MoH staff, compromised of four participants from the national, regional, and district levels, take part in a six-month training to equip them with improved skills for budgeting and implementation of quality improvement programs at facility and community levels. These different components come together with the objective to improve health provider performance in delivering high quality, people-centered services at facility and community levels.

5.10 Ghana's supply chain transformation journey

Ghana has undertaken a multi-year supply chain transformation journey touching every aspect of the health product management systems. All investments and activities have been guided by strategically developed and widely aligned, Supply Chain Master Plan covering a 5-year period. Areas of emphasis the include: last mile distribution, warehouse optimization, framework contracting, logistics management information system, and governance. In addition to the Ministry of Health's leadership to coordinate the Supply Chain Master Plan, Ghana points to several other critical success factors including highly skilled and competent staff, deep engagement with the strong in-country private sector and partnerships and collaboration among partners with a defined implementation approach that has resulted in a consistent availability of quality health products at all levels in the supply chain.

6. Annexes

6.1 Investing in the health system to improve quality of care (Annex 1)

Improving quality of care requires coherent interventions across the entire health system. The table below provides a complete list of interventions across the RSSH modular framework that applicants can package together to improve provider performance and quality of care. Not all will be relevant in every context, but applicants are encouraged to consider how investments across health systems pillars can contribute, together, to improving quality of care.

Design issue	Corresponding areas in the RSSH modular framework						
Design issue	Module	Intervention	Activity				
Data and analysis		Surveys	Health facility surveys that measure quality of care indicators				
to inform quality priorities and improvement approaches	Health Management Information Systems	Operational research	Analysis so that program managers and implementers can understand and/or compare service delivery approaches, support integration, and assess client perceptions to improve access and quality of services				
		In-service training of health workers	Skills and competence based, on-site in-service training with integrated technical content. This should also include clinicians who recognize and report diseases/events				
Improving health workers performance	Human Resources for Health & quality of care	Integrated supportive supervision	Support to health facility supervision delivery, including development of supervision guidance, tools, and supervision of supervisors				
		Quality improvement and capacity building for quality of care	Group problem-solving activities (facility-level teams monitor their performance, conduct root-cause analysis to identify obstacles to providing high-quality care, and test solutions to overcome the				

			obstacles with Plan-Do- Study-Act cycles)
Improve HRH deployment		HRH planning, management and governance, including for CHWs	HRH planning to improve deployment of health workers, including CHWs, and achieve an optimal skills mix, based on service delivery needs and quality priorities.
Strengthening policies, strategies, protocols and leadership for quality of care		Quality improvement and capacity building for quality of care	 Development of protocols, guidelines and standards for integrated care building leadership and management skills, related to quality improvement, of national, provincial, and district health management teams developing national quality of care policies, guidelines, regulatory functions, and governance structures for quality improvement at the macro, meso, and micro levels Capacity building to institutionalise QI approaches Policy development and implementation on HRH safeguarding and respectful patient-centered care.
Workforce development to achieve the right number of health workers with the right skills		Education and production of new health workers	Pre-service training of health workers, where there are insufficient numbers, including capacity building of training institution and quality assurance.
		Community-led monitoring	to provide information from service user experiences on issues impacting the availability, acceptability and quality of care
Improving patient- centered care	t- Community Systems and Responses Community-li research and advocacy		to better understand the barriers and gaps that inhibit effective, people-centered health services from the community perspective, with research findings used to improve access and quality of services)

	Capacity building and leadership development	to establish, strengthen, and sustain community-based organizations, to improve community-led and community-based service delivery at scale)
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Additional investment considerations for improving provider performance in the private sector include: i) including private sector in policy and dialogue; b) exchanging information (e.g., through the inclusion of the private health sector in national surveillance systems), c) regulating the private sector (e.g., through certification, licensing, accreditation, monitoring/oversight, and allowing the establishment of networks, franchising, and social marketing), and d) financing the private sector (e.g., through contracting, outsourcing, public-private partnerships, strategic purchasing, and market shaping).

6.2 Investing in the health system to strengthen referral systems (Annex 2)

Referral systems involve the transition of patients and laboratory specimens between health care settings (e.g., transporting a seriously ill patient from a health post to a hospital). Referral systems are especially important for populations in rural areas with limited access to specialized services. However, in low-resource settings, referrals are often inadequate because of systemic inefficiencies.

Successful, timely, equitable referral systems require a plan for the system, financing, guidelines and protocols on which patients need referral and on laboratory specimen referral, providers who can correctly identify patients needing referral and who can provide critical information to the patient's destination, transportation means, communication and coordination, and information systems. Global Fund encourages countries to invest in referral systems, as needed.

The following table provides a list of investments in referral systems are the RSSH modular framework. Importantly, for referral systems to have maximal impact, the quality of services must be high at the referral destination, with capacity for higher level referrals (e.g., to specialty care).

Design issue	Corresponding areas in the RSSH modular framework					
Design issue	Module Intervention		Activity			
Identify relevant opportunities and priorities for referral strengthening	HMIS	Analysis, evaluation, reviews and data use	Thematic reviews of operational issues, including referral systems			
Design referral pathways in support of integrated care	Health sector planning and governance for	Integration/coordination across disease	Develop models and plans for service delivery integration			

	integrated people- centered services	programs and at the service delivery level	Develop referral pathways for facility – facility and community – facility-service integration
Operationalize bidirectional community-facility referral services	Community systems strengthening	Community engagement, linkages and coordination	Establish or strengthen formal agreement between community-led service providers and health facilities (including for bi- directional referrals)
Development of clinical guidelines and protocols, including referrals protocols	Human Resources for Health & quality of care	Quality improvement and capacity building for quality of care	Development, adaptation and revision and revision of standards, clinical guidelines, and treatment protocols for integrated care, including referral protocols
Ensuring optimal staffing and skills mix at different levels of the referral pathway	Human Resources for Health & quality of care	HRH planning, management and governance, including for CHWs	Analysis to identify optimal skills mix based on workload and patients' needs along the referral pathway Planning and implementation of plans for HRH deployment and distribution driven by patients' needs and work Policy reform to support task-sharing
			to enable delivery of optimal skills mix, accompanied by capacity building
Capacity building of health workers, including CHWs,	Human Resources for Health & quality of care	Integrated supportive supervision	Integrated supportive supervision, combined with inservice training (of

on implementation of referral protocols		In-service training Quality improvement and capacity building for quality of care	HRH excluding CHWs and/or of CHWs) – related to referral protocol implementation
			Quality improvement (across the referral network)
Integrated lab services	Laboratory systems	Genomics and next generation sequencing	Establishing genomic surveillance strategic plans, including integration of genomic surveillance sample collection into the existing sample referral systems

6.3 Requirements for countries eligible for Global Fund support for nonmalaria medications for iCCM (Annex 3)

While the Global Fund has traditionally considered the funding of life-saving treatment for childhood illnesses at community level beyond HIV, TB and malaria a critical co-financing investment leveraging domestic and partner resources, the Global Fund will now support non-malaria medications for iCCM where CHWs provide malaria case management, where iCCM is part of the package of services CHWs are allowed to provide, and where the criteria below are met.

The support can include funding for the following components:

- Antibiotics for pneumonia (restricted to first line treatment for pneumonia in children under 5 years of age as per national protocol for iCCM)
- Oral rehydration salts (ORS) and zinc for diarrhea for children under 5 years of age as per national protocol for iCCM

All countries applying for this support are required to include the following components (whether funded by the Global Fund or another partner) and provide details in the funding request.

- 1. Investments only for non-malaria medications for children under 5 years of age (not for older children nor adults).
- 2. Investments for the aforementioned commodities only for the community platform.
- 3. Investment by the Global Fund (or other funding sources) in the appropriate diagnostic equipment (e.g., rapid diagnostic tests, respiratory timers) and training at community level to ensure timely quality diagnosis of malaria, pneumonia and diarrhea per national iCCM protocols.

- 4. Investment by the Global Fund (or other funding sources) in antimicrobial resistance (AMR) monitoring and stewardship as outlined in **Annex 4.** Similar to therapeutic efficacy monitoring for antimalarials, the expectation is drug selection will be guided by routine efficacy monitoring within the health system.
- 5. Investments by the Global Fund (or other funding sources) covering the systems components needed for quality CHW service delivery, including adherence to the iCCM protocol, rational drug use and referral and counter referral systems (refer to the CHW Gap Table and the required systems components in the table *Investments in health policy and systems support to optimize CHWs* in the above Section 4.5 'Human Resources for Health and Quality of Care.'

6.4 Essential M&E investments (Annex 4)

The table below serves as a checklist for essential investments in M&E. Budgets are indicative only, as these investments will vary and depend upon countries' M&E systems maturity level and other context.

Checklist and indicative amounts for essential M&E investments within Global Fund Grants, US\$

	For antial House	M&E Module	Ind	Indicative budgets		Damada and Dagana						
	Essential Item	Intervention	High Impact	Core	Focused	Remarks and Resources						
	M&E, Routine Health Information Systems (RHIS), and digital data systems national strategies and governance mechanisms					WHO Toolkit for Routine Health Information Systems Data WHO Digital Implementation Investment Guide WHO ITU National eHealth strategy toolkit WHO SCORE Technical package						
HMIS - all 3	HMIS readiness or maturity assessment and costed workplan, including digital	Routine reporting		Douting	Pouting	Doubling	Doubling	Doubles	~2% of	~2% of	 Planning and budgeting guidance and to for sustainable DHIS2 systems RHIS Rapid Assessment Tool HIS Stages of Continuous Improvement PAHO IS4H Toolkit: Maturity model PRISM 	 RHIS Rapid Assessment Tool HIS Stages of Continuous Improvement PAHO IS4H Toolkit: Maturity model
diseases, community, and private	National inventory of digital systems & assets routinely updated			grant budget	grant budget	varies	WHO Digital Health Atlas Map and Match					
sector	Data governance, security, privacy, and confidentiality legislation and policies, including for digital data systems					User Guide: Health Data Governance Principles OECD recommendation on health data governance UNAIDS Privacy, Confidentiality, and Security Assessment Tool ISO 27799:2016 Security considerations when implementing DHIS2						

		M&E Module	Ind	Indicative budgets		
	Essential Item	Intervention	High Impact	Core	Focused	Remarks and Resources
	HMIS workforce and capacity building including: 1. Core HMIS staff, including digital and GIS 2. Disease program staff with official coordination role with HMIS core staff 3. User training, including for digital data systems 4. Regular (e.g., semi-annually) Technical Assistance for digital HMIS Digital data system infrastructure including: 1. Devices and other hardware 2. Connectivity and power 3. Hosting and server maintenance					Planning and budgeting guidance and tools for sustainable DHIS2 systems RHIS Curriculum Measure Evaluation WHO ITU Digital Health Platform: Building a Digital Information Infrastructure for Health
	Digital data system standards and interoperability: 1. National digital data system architecture or Health Information Exchange blueprint 2. Adoption of national data standards					Health Information Systems Interoperability Maturity Toolkit Open Health Information Exchange (OpenHIE)
CRVS	Mortality reporting (Hospital & community) & analysis	Routine reporting	~500K- 1M	~250- 500K		Amount depends on the stage of CRVS implementation, country size CRVS Knowledge Gateway Global Fund investments in mortality data systems, analysis and use Info Note
Data Quality	National Data Quality Review & Data Quality Improvement plan	Data Quality	~500K	~250- 350K		Mandatory once per grant cycle in High Impact and Core countries. Implementation of improvement plan will require additional budgeting. • WHO Data Quality Review and Improvement plans
Data Analysis	Capacity building in data analysis and use - epi profiling, sub-national analysis (by gender, age, population groups), data use for program management, improvement and resource allocation	Analysis, evaluations,	~1M	~600k		To strengthen district, regional and national analytical skills and production of periodic analytical outputs. Local capacity development (workshops, on-site support) on data use.
and Use	Periodic performance reviews – systematic data analysis linked to quarterly/six monthly reviews including for community data.	and reviews	~700k	~350k	~25-50k	Ongoing. In-country partners & Global Fund joint forums to review success and challenges, and draw actions

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		M&E Module	Ind	Indicative budgets		
	Essential Item	Intervention	High Impact	Core	Focused	Remarks and Resources
						WHO Toolkit for Routine Health Information Systems Data Analysis and Use
Program Reviews & Evaluations	Program review (or country evaluation) - including epi & impact analysis: integrated or disease specific	Analysis, evaluations, and reviews	~750K	~600K	Depends on budget size	Mandatory once per grant cycle. Must be budgeted in each disease grant (~200-250K per disease component) Guide to conducting programme reviews for the health sector response to HIV Framework for conducting reviews of tuberculosis programmes Malaria program review manual Practical manual for malaria programme review and malaria strategic plan midterm review
	Evaluation – Multi-country grants	Analysis, evaluations, and reviews	~150- 250K	~150- 250K	~150-250K	Depends on the scope & coverage of grants
	Case-based surveillance and patient monitoring	Routine	~1M	~500K		Budget may be higher in larger portfolios. Should be integrated with HMIS. • WHO HIV Surveillance • DHIS2 Tracker Implementation Guide • Digital Square Global Goods Guidebook
	Key Populations - sentinel surveillance	reporting	~10K	~10K	~10K	10K estimate is per group per site
	Key populations - service coverage monitoring		~200K	~200K	~200K	Once every 3-5 years
HIV	Prevention outcome monitoring for AGYW and Key Populations		~50- 100K	~50- 100K	~30-50K	Amount may vary depending on prevailing context
	HIV service cascade analysis		~100K	~100K		Annually, incorporated into the annual HIV program review
	HIV prevention, efficiency and effectiveness analysis	reviews	~100k	~100K		Annually, incorporated into the annual HIV program review
	ART Cohort analysis		~30-50K	~30K		Annually, incorporated into the annual HIV program review
	Key populations - IBBS, Key pop size estimation, programmatic mapping	Surveys	~400K	~300- 350K	~100-200K	Once every 3-5 years

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		M&E Module	Ind	Indicative budgets		
	Essential Item	Intervention	High Impact	Core	Focused	Remarks and Resources
	National Joint HIV Data Quality Audit		~150k			Once every 3 years, budget amount is assuming additional funding available from other sources.
	Drug resistance surveillance	see Remarks	~250K			Should be budgeted under treatment, care module. Once a cycle
	Incidence Pattern Model	see Remarks	100K	100K	50K	Coincide with data availability, ideally once a cycle
	Digital real-time case-based surveillance system strengthening	Routine reporting	~ >1.5M	~1.0 – 1.5M		These are very high-level estimates and would vary based on the country digital readiness and case surveillance context. Budget may be higher in larger portfolios. Should be integrated with HMIS. • WHO TB digital cased-based surveillance • Stop TB Digital TB Surveillance System Assessment Report • DHIS2 Tracker Implementation Guide • Digital Square Global Goods Guidebook
	TB Care cascade analysis	A sa a la sa la	~50 - 100K	~50K	~50K	Frequency: Annual (at the minimum)
ТВ	Patient Pathway Analysis	Analysis, evaluations, reviews and transparency	~50 - 100K	~50K		Frequency: Every 2-3 years. The cost may vary depending on the availability of technical expertise for this analysis in-country. Conduct prior to TB NSP development or mid-term review
	TB treatment cohort analyses		~30-50K	~30K		
	Patient Catastrophic cost survey		~100- 250K	100 – 170 K	~100k	Frequency: should be conducted every 5 years irrespective of the type of portfolio classification
	National TB prevalence survey	Surveys	~2.0 - 6M	~2.0 – 3.5M		Prioritized for countries that have: (a) Never conducted a survey with estimated TB incidence of ≥ 150 per 100,000 population and U5 mortality rate >10 per 1,000 (b) Conducted a prevalence survey previously (7 – 10 years ago) and have an estimated TB incidence of ≥ 250 per 100,000 population Frequency: every 7-10 years (in the above countries). Cost may vary if it is a repeat survey

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	Essential Item		M&E Module Intervention	Indicative budgets			
				High Impact	Core	Focused	Remarks and Resources
	Drug Resistance Survey						or first survey and depending on the number of clusters
				~200 - 500K	~200 - 400K	~200K	Frequency: every 5 years. It should be prioritized in countries where the routine DST coverage for rifampicin among cases of bacteriological confirmed pulmonary TB through continuous surveillance is less than 80% and the testing coverage for isoniazid and other SLDs (among patients with Rif. and INH resistance) is suboptimal
	Inventory studies	Prospective		~200 - 500K	~200 - 350K		Not mandatory. Consider implementing in countries where a large proportion of diagnosed TB cases are thought to not be reported to the NTP from other health sectors (public or private). Frequency: every 3-5 years
		Retrospective		~50K	~25 – 50K		
Malaria	Surveillance system assessment & strengthening		Surveillance	~250K	~200K	~200K	Patient level surveillance recommended in elimination phase, which may require a higher budget. Should be integrated in the HMIS. • DHIS2 Tracker Implementation Guide • Digital Square Global Goods Guidebook • WHO Global Malaria Programme surveillance assessment and digital surveillance tools
	Malaria Data Repository		Analysis, evaluations, reviews and transparency	~300K	~200K		To enable triangulation of data from all sources through a single platform
	Malaria specific analysis: access, coverage and epi trends; stratification			~500K	~250K	~100K	Should include plan for quarterly, bi-annual and annual analysis at national and sub-national levels
	Malaria indicator survey (as needed)		Surveys	~1M	~1M		In high-burden countries, every 3-5 years
	Insecticide resistance monitoring		See Remarks	~200K	~150K		Should be budged under vector control module, every year
	Therapeutic efficacy surveillance (TES)			~150K	~120K		Should be budged under case management module, every 2 years
	HRP2 deletion studies		See Remarks	~200K	~150K		Should be budged under case management module, every 2-3 years

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6.5 Detailed medical oxygen operational guidance (Annex 5)

Demand for medical oxygen supplies and services is high in LMICs based on current epidemiological trends. Given the complexities, this annex provides additional guidance and key considerations in characterizing local oxygen needs, gaps, and priorities of national response and oxygen and respiratory scale up plans. This information is intended to aid in the development of maximally effective and impactful funding requests.

CCMs and national pandemic preparedness response managers will want to ensure their response plans accurately assess current needs and forecast future oxygen and respiratory care equipment needs, identify best-fit solutions, and leverage available incountry expertise. Most countries will want to pursue a combination of: 1) optimizing existing oxygen supply at facilities; 2) identifying non-functional equipment for potential recommissioning; and 3) securing additional required oxygen supplies and related services. Where countries have existing (or are developing) oxygen policies or broader respiratory care capacity strengthening strategies, plans should describe how prior emergency response investments for COVID-19 will align with the broader, longer-term approaches that are necessary to strengthen and build resilient and sustainable systems for health.

Applicants should consider the following activities, if not already completed, to meet these objectives:

• Conduct a rapid respiratory care stakeholder mapping exercise

- Scope/purpose: Identify in-country partners with expertise in oxygen and/or respiratory care for critical planning inputs; collect existing assessments, analyses, and quantifications of oxygen and respiratory care capacity and equipment (including oxygen delivery equipment and patient screening/monitoring devices); determine the scope, scale, and distribution of existing COVID-19 response respiratory care investments.
- Available tools/resources: Every Breath Counts partner mapping matrix; in-country coalitions or TWGs.

• Conduct rapid capacity assessments of designated, planned, and/or potential treatment centers

- Scope/purpose: Quickly determine the current availability of respiratory care equipment and oxygen supplies at priority health facilities, identify non-functional equipment for potential repairs, and identify facilities with capacity to absorb bulk oxygen supply options (e.g., facilities with piping, cylinder manifolds, etc.).
- Available tools: WHO Biomedical Medical Equipment assessment tool & phone survey guidance

Rapid oxygen and respiratory care equipment gap assessment for designated, planned, and/or potential treatment centers

 Scope/purpose: Forecast patient need for oxygen and respiratory care equipment at priority health facilities, determine the presence and size of

- oxygen and respiratory care equipment gaps at priority facilities and overall.
- Available tools/resources: <u>WHO Essential Supplies Forecasting Tool</u>; <u>WFSA Oxygen Supply & Demand Calculator</u>; <u>Unicef Oxygen System Planning Tool</u>

Develop high-level supply landscape (public + private) overview

- Scope/purpose: Compile a rapid listing of in-country oxygen, equipment, and maintenance suppliers; Identify local sources (manufacturers and/or distributors) of suitable respiratory care equipment and oxygen supplies; Reveal constraints in local supply chains impacting product availability and suitability; Identify constraints in local service markets impacting maintenance and operation of key equipment; Identify suitable short- and long-term oxygen supply solutions and operating models.
- Available tools/resources: PATH/CHAI supplier questionnaires;
 PATH/CHAI Sub-Saharan Africa distributor listing; Every Breath Counts partner mapping matrix

Develop robust procurement requests

- Scope/purpose: Determine best-fit oxygen supply options for priority facilities based on gap assessment and in-country supply landscape; Produce costed estimates of equipment and consumable needs by facility and overall; Develop allocation plans based on current equipment distribution; Identify post-response equipment re-allocation priorities, as appropriate, and opportunities in line with broader national strategies for oxygen or respiratory care capacity strengthening.
- Available tools/resources: <u>WHO Essential Supplies Forecasting Tool</u>;
 <u>WFSA Oxygen Supply & Demand Calculator</u>; <u>Unicef Oxygen System Planning Tool</u>

Develop targeted training plans

- Scope/purpose: Identify training and skills development necessary for health workers to operate respiratory care equipment and manage COVID-19 cases; Identify training and skills development necessary for biomedical engineering staff and technicians to maintain respiratory equipment. Couple this training with clinical use training for clinicians that will be using equipment to care for patients.
- Available tools/resources: WHO Health Workforce Estimator

Assess post-COVID-19 financing needs (e.g., equipment maintenance and operation) and identify potential financing mechanisms

- Scope/purpose: Identify ongoing service and maintenance requirements for equipment; Forecast recurrent costs associated with ongoing equipment operation and maintenance; Identify domestic financing channels with the potential to cover recurrent costs. This should include HR costing as well as warranties and service agreements.
- Available tools/resources: Also see <u>PATH's COVID-19 oxygen resource</u> <u>library</u> and <u>COVID-19 Training Catalogue</u> for training resources.