



# **Guidance Note**

## Sustainability, Transition and Co-financing

**Allocation Period 2023-2025**

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<sup>1</sup> The STC Guidance Note was originally published in Dec. 2020. This updated version of the Guidance Note reflects changes made ahead of the 2023-2025 allocation cycle and in line with the 2023-2028 Strategy.

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# Background and Summary

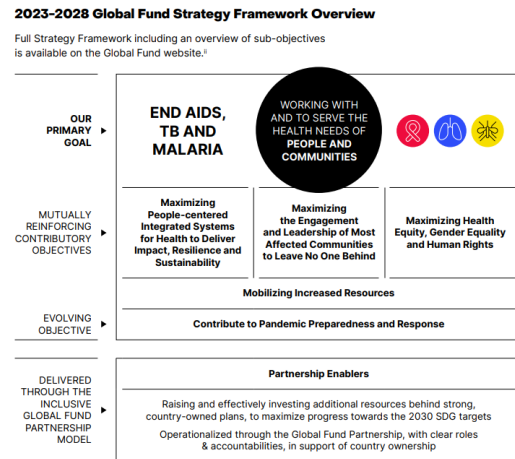
The Global Fund’s Sustainability, Transition, and Co-Financing (STC) Policy was approved in April 2016<sup>2</sup> and implemented during the 2017-2019 and 2020-2022 funding cycles. The STC Policy formalized the Global Fund’s approach to strengthening sustainability, enhancing domestic financing and co-financing, and supporting countries to better prepare for transition away from Global Fund financing.

The purpose of the STC Policy is to guide countries in better investing external financing and in catalyzing domestic resources in order to strengthen health systems and address critical sustainability and transition challenges. The goal is to enable countries to maintain and scale service coverage and thereby accelerate the end of the three diseases. The 2023-2028 Global Fund Strategy reinforces these themes, highlighting the importance of resilient and sustainable systems for health (RSSH) as well as the need to support comprehensive domestic resource mobilization and health financing.

**Figure 1. Three Elements of the STC Policy**



**Figure 2. Strategy Framework 2023-2028**



This document is intended to support countries as they work to strengthen sustainability<sup>3</sup>, improve domestic financing, and enhance preparations for transition away from Global Fund support. The guidance is relevant not only for the development of funding requests, but also as countries implement Global Fund grants and manage national [HIV](#), [TB](#), and [malaria](#) responses.<sup>4</sup> Due to the distinct challenges related to the sustainability of HIV, TB and malaria responses and a variety of specific technical areas (including [health product management](#), [health information systems](#), and [public financing of civil society and community service provision](#)), the document also includes specific, more detailed considerations on those thematic areas in the annexes.

<sup>2</sup> Approved by the Global Fund Board via GF/B35/DP08.

<sup>3</sup> Sustainability is a core dimensions of Global Fund’s Value for Money (VfM) framework, which include 5 dimensions: economy, effectiveness, efficiency, equity and sustainability.

<sup>4</sup> As set forth in Annex 1 to GF/B35/04 – Revision 1 and approved by the Board in April 2016 under decision point GF/B35/DP08.

# 1. Overview of the Global Fund Approach

## 1.1 Strengthening sustainability

In the context of substantial economic challenges faced by countries, the 2023-2028 Global Fund Strategy recognizes that tackling the HIV and TB epidemics and eliminating malaria will require comprehensive approaches to strengthening the financing of health systems. This will require a focus on both raising additional resources and on strengthening the efficient, effective, and equitable use of existing resources, as well as supporting sustainable national responses to the three diseases and building RSSH.

The Global Fund's approach to **sustainability** focuses on *the ability of a health program or country to both maintain and scale up service coverage to a level - in line with epidemiological context - that will provide for continuing control of a public health problem and will support efforts for elimination of the three diseases, even after funding from the Global Fund or other major external donors comes to an end.*<sup>5</sup> **The Global Fund's approach to sustainability recognizes its many dimensions, including financial, programmatic, epidemiological, equity, systems-related, governance, human rights, and political dimensions.**

Countries are strongly encouraged to strengthen sustainability and address sustainability challenges in their national planning, their program design, and their implementation of Global Fund grants. In doing so, countries should consider how to maximize impact while balancing both short and long-term results, taking into consideration not only current costs and financing available today, but also the future costs which domestic financing will need to cover in order to support continued improvements in service coverage.

Sustainability considerations (described in this Guidance Note in more detail) will vary according to country context but often include: strengthening national health sector planning (including for the three diseases); strengthening financing of health and the national responses to HIV, TB, and malaria; investing in resilient, sustainable systems for health and supporting integration of disease programs into broader health systems; enhancing alignment and implementation through national systems; sustaining access to quality health products; increasing efforts to address human rights and gender-related barriers to access, especially for key and vulnerable populations; and strengthening national governance. Importantly, sustainability entails priority setting and explicit consideration of trade-offs on what to finance in the context of finite resources and multiple competing demands on these resources.

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<sup>5</sup> [The Global Fund Sustainability, Transition and Co-financing Policy](#).

## 1.2 Preparing for transition from Global Fund financing

Eligibility for Global Fund funding is determined by a country's income classification<sup>6</sup> and disease burden, as defined in the Eligibility Policy.<sup>7</sup> As countries move upwards in income classification and/or experience a decline in disease burden, considerations around the sustainability of Global Fund-supported programs and the overall national disease response become increasingly pertinent.

For the Global Fund, **transition** is the process by which a country (or a country component), *moves towards fully funding and implementing its health programs independent of Global Fund support while continuing to sustain the gains and scaling up as appropriate.*<sup>8</sup> In line with this definition, the Global Fund considers a transition to have been successful where national responses and health systems are able to at least maintain (and preferably improve) equitable coverage and uptake of services even after Global Fund support has ended.

While the timeframe for transition from Global Fund financing and the total amount of financing received each allocation cycle will vary by country, all countries are strongly encouraged to design, develop and implement Global Fund funding requests, grants, co-financing commitments, and national programs with the aim of eventual and full transition to domestically funded and managed national responses in a manner that sustains and continues to improve coverage, impact, and efforts toward elimination. Since successful transitions take time and advance planning, all countries are strongly encouraged to ensure that sustainability is addressed long before full transition from Global Fund financing. As countries move along the development continuum and to higher income categories they are encouraged to put an even greater focus on preparing for transition. For upper middle-income countries (UMICs) and/or lower middle-income countries (LMICs) with low disease burdens, the Global Fund encourages a national sustainability and transition planning process which would ideally be informed by a transition readiness assessment or equivalent analysis.

The Global Fund also encourages increased attention to both [sustainability considerations](#) and various [enabling factors](#) that often affect transition outcomes (described in detail in this Guidance Note), for all countries, not only those preparing for or close to transition by Global Fund criteria.

## 1.3 Transition funding

When a country disease component becomes ineligible for Global Fund support, it may receive up to one allocation period of transition funding.<sup>9</sup> Transition funding is separate from standard grant funding. Its purpose is to support countries in their transition away from Global Fund financing by providing countries with additional time and resources to mitigate any remaining transition challenges, with Global Fund support as necessary.

The funding request for a transition funding grant should be based on a detailed transition workplan and it will be reviewed by the Technical Review Panel (TRP). Transition funding should build on efforts made in previous allocation cycles to gradually address sustainability challenges.

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<sup>6</sup> The Global Fund uses the latest three-year average of Gross National Income (GNI) per capita to determine income classifications according to the World Bank income group categories and thresholds. Data from: <http://databank.worldbank.org/data/home.aspx>

<sup>7</sup> GF/B39/02, Annex 2.

<sup>8</sup> The Global Fund [Sustainability, Transition and Co-financing policy](#).

<sup>9</sup> The amount of transition funding as well as the period for funding may vary. The Global Fund Eligibility Policy provides circumstances when transition funding may not be awarded. Specifically, countries not eligible for transition funding are those that a) move to High Income classification, b) become G-20 UMIC with less than an 'extreme' disease burden, or c) become members of the Organization for Economic Co-operation (OECD) and OECD's Development Assistance Committee.

## 1.4 Co-financing

Enhancing and increasing domestic financing is an integral aspect of strengthening sustainability and fostering successful transitions. The Global Fund co-financing requirements encourage improved domestic financing for health and the three diseases, as well as more equitable and efficient use of existing resources. Co-financing requirements in the STC Policy are differentiated by income classification and disease burden, and other contextual factors, and are described in detail in this guidance.<sup>10</sup>

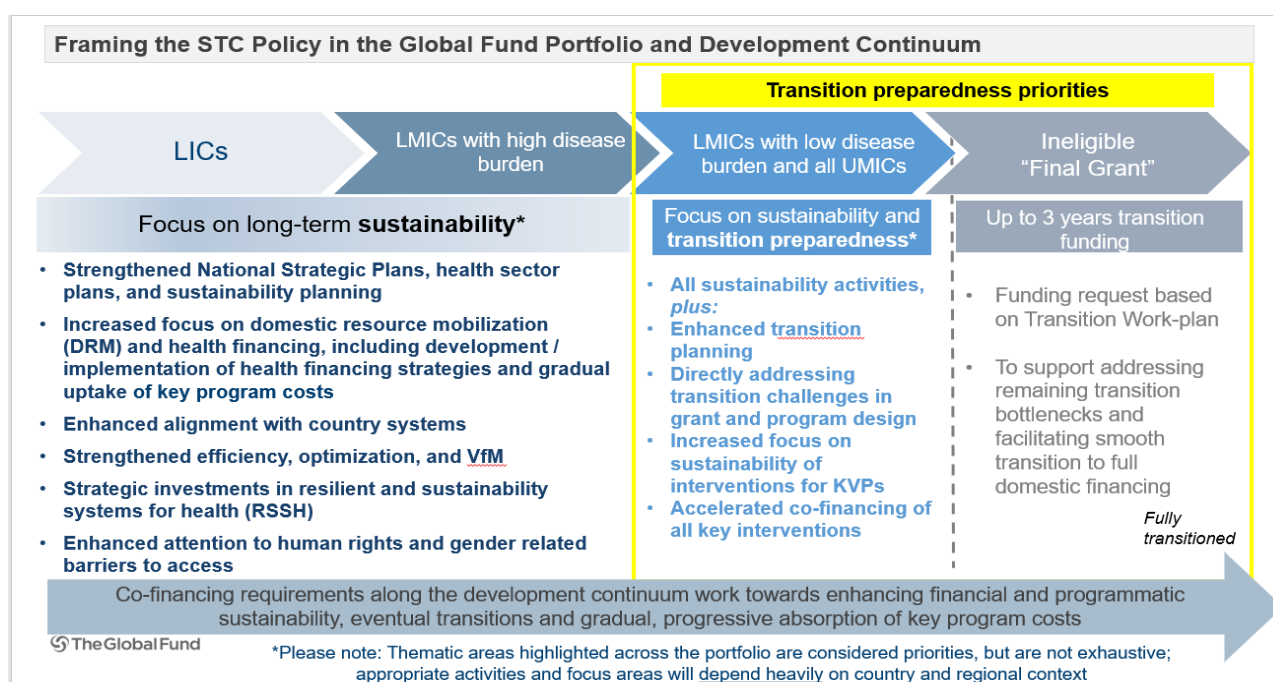
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<sup>10</sup> The Global Fund [Sustainability, Transition and Co-financing policy](#). See also the [Global Fund Operational Policy Note on Co-Financing](#). [https://www.theglobalfund.org/media/3266/core\\_operationalpolicy\\_manual\\_en.pdf](https://www.theglobalfund.org/media/3266/core_operationalpolicy_manual_en.pdf)

## 2. Application Focus Requirements

The Global Fund’s “*application focus requirements*” identify how countries should invest Global Fund financing. These requirements are key to sustainability and transition readiness because they ensure that funding requests for countries at different income levels are strategically focused on the most relevant and impactful interventions as countries progress along the development continuum.

**Figure 3: Summary of the Global Fund’s approach to sustainability, transition, and co-financing across the development continuum**



### 2.1 Key considerations for strengthening sustainability

Sustainability should be a fundamental principle of national planning, funding request development, grant design, co-financing commitments, and implementation **for all countries, regardless of their stage of development or their proximity to transition from Global Fund financing.** Sustainability includes multiple dimensions, including financial, programmatic, programmatic, systems-related, equity, governance, human rights, and political dimensions<sup>11</sup>. These dimensions will depend heavily on specific country or regional context, including epidemiological context, relative reliance on external financing for the health sector, and the structure of the overall health system.

Sustainable and effective responses to the three diseases require the engagement and commitment of multiple stakeholders across all levels of program development and implementation. As part of the Global Fund’s commitment to country ownership and participatory decision-making, efforts to strengthen sustainability should be conducted through inclusive, country-led processes that involve

<sup>11</sup> A number of frameworks set out the different dimensions of sustainability. This reference is partially adapted from Oberth, G., & Whiteside, A. (2016). *What does sustainability mean in the HIV and AIDS response?*



the meaningful engagement of all stakeholders. Communities most impacted by the three diseases – such as key and vulnerable populations - bring to these processes critical expertise about interventions and responses appropriate for and most accessible to marginalized populations. In particular, they can provide expertise on activities to reduce human rights- and gender-related barriers, monitoring and reporting on access and quality, and specific interventions required to maintain coverage and quality of services for key and vulnerable populations.

While sustainability challenges are heavily influenced by country context, there are a number of key considerations that the Global Fund recommends all countries consider.<sup>12</sup> They include:

### **2.1.1 National planning**

Strengthened national planning is critical for improving sustainability. National Strategic Plans (NSPs) and/or other health sector plans should be robust, costed and prioritized, and they should be anchored in and aligned to broader health sector and health systems planning as well as national budgets.<sup>13</sup>

While the planning process is country specific, overall national planning can help countries **define short- and long-term program goals**, including how to financially and programmatically sustain impact. It is important to consider not only what financing is available today, but also what governments will need to finance and continue financing in the future. National strategic and health sector planning should include strong intervention prioritization to maximize and sustain equitable and quality health outputs, outcomes, and impact. This can be achieved by allocating resources to the most cost-effective interventions, providing quality services and products at affordable cost in order to achieve the desired health outcomes.

Cost-impact analysis supported by the application of allocative efficiency tools can help policy makers identify the opportunities for efficiency gains and allocate resources across interventions, geographies and population groups to maximize impact. It is important that resource allocation analyses include interventions that cannot be easily quantified in a cost-effectiveness analysis (such as health systems strengthening activities or human rights interventions) and that they take into account the challenges of conducting accurate priority setting for interventions when reliable data is limited (as in the case of key and vulnerable population size estimates).

Costing of NSPs and/or other national planning is critical. Interventions and systems building efforts to achieve programmatic goals should be costed to define the full (as well as incremental) funding needed over the period of the national strategic plan, following appropriate methodology and using suitable tools.<sup>14</sup> As part of these efforts, it is essential to ensure robust unit costs are used and costing is linked to available resources in government budgets, to ensure strong linkages between programmatic goals and available resources.

In terms of financing, resources from all funders (including government) should be mapped against the funding need to provide a financial gap analysis<sup>15</sup>. This will serve as a key input to determine by how much domestic investments need to realistically increase to progressively take up programmatic costs.

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<sup>12</sup> For in-depth guidance regarding sustainability considerations and measures specific to the three diseases, please refer to the [annexes](#) in this guidance note.

<sup>13</sup> Countries are highly recommended to consult NSP guidelines issued by technical agencies (e.g., WHO, UNAIDS, etc.) to formulate and develop their NSPs.

<sup>14</sup> Countries are encouraged to consult NSP guidelines issued by technical agencies (e.g., WHO, UNAIDS, etc.) to appropriately develop and cost NSPs.

<sup>15</sup> Please refer to the Global Fund website for a recommended template for financial gap analysis ([Funding Landscape Table](#)).



The Global Fund also encourages countries to specifically identify key sustainability challenges in national strategic plans and broader health sector planning, so that those sustainability challenges are part of institutionalized national strategic planning. This should include efforts to enhance efficiencies that consider resources available across the health system, and which can be leveraged to achieve programmatic objectives.

Working with relevant partners, the Global Fund may support countries to strengthen the development of national strategic plans or broader national planning. For example, countries may seek technical assistance to apply available tools for costing and priority setting; ensure an inclusive and robust process so that affected communities are meaningfully engaged; and/or include an assessment to identify and respond to gender- and human rights-related barriers to services. The Value for Money (VfM) Technical Brief provides more information on costing and resource allocation tools that countries have previously implemented to inform the development of NSPs and Global Fund funding requests.

## 2.1.2 Financing

Strengthening health financing systems to support increased resource mobilization, pooling and purchasing and their effective use for universal health coverage (UHC) is fundamental to achieving progress against HIV, TB and malaria. There is an increasing need for more comprehensive approaches to domestic financing that focus both on raising additional domestic resources for health and enhancing the VfM of existing resources, particularly in the context of current macro-economic challenges facing countries around the world. The [Global Fund 2023-2028 strategy](#) emphasizes strengthening country health financing systems, including a particular focus on:

- increasing domestic resource mobilization and the efficiency of domestic investments;
- strengthening public financial management systems;
- enhancing the generation, development and use of health financing data and improving resource and expenditure tracking to inform effective health sector planning;
- reducing financial barriers to access;
- enhancing sustainable public financing of services provided by communities and civil society (often referred to as ‘social contracting’);
- supporting the integration of national disease responses into pooled financing mechanisms and health benefit plans; and
- strengthening the VfM of investments in individual technologies and delivery modalities, including through health technology assessments for services and products.

As part of comprehensive efforts to strengthen health financing, countries are encouraged to:

- Continue the development and implementation of health financing strategies, as part of efforts to sustain and increase financing of national responses and health systems. As a measure to progressively raise domestic public revenues to finance the health sector and the three disease programs, the Global Fund encourages countries to implement strategies for developing and advancing health financing towards universal health coverage (UHC). These strategies should provide a detailed overview of how health care will be financed, including sources of financing (external, domestic public, domestic private) and revenue type (e.g., unmarked public spending, earmarked public spending, tax subsidies, voluntary prepayment, out-of-pocket spending).<sup>16</sup> They should consider the government’s fiscal situation now and

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<sup>16</sup> WHO guidance on developing Health Financing Strategies: [http://www.who.int/health\\_financing/tools/developing-health-financing-strategy/en/](http://www.who.int/health_financing/tools/developing-health-financing-strategy/en/)

in the near future, as well as the allocation and execution of the national budget. They may also provide a framework for increasing domestic public funding for health and alleviating the health financing burden on households, such as reforms to remove user fees, establish a single payer system, cost a UHC/benefits package, or strengthen social health protection. The Global Fund will engage with countries, where appropriate, by working with partners to support the development or operationalization of strategies for health financing<sup>17</sup>.

- **Consider the use of innovative health financing solutions to crowd in additional resources, strengthen alignment of development partner financing, and improve efficiency.** Countries are encouraged to engage with development partners on the use of blended finance instruments (including both joint investments with development partners and Debt 2 Health) which bring together domestic resources, grants and resources in full alignment with country strategic goals. Such instruments are often applied to RSSH projects which strengthen health systems components underpinning the performance of health programs. Moreover, they often rely on an output-based performance framework which may promote greater efficiency and sustainability in the use of resources. Debt swaps for health represent another innovative approach to financing health, especially in countries with high levels of debt and where debt servicing limits fiscal space. Applicants intending to pursue innovative financing solutions as a part of their funding application are encouraged to seek additional guidance from their Country Team members and/or relevant focal points in the Health Finance Department of the Global Fund, and are encouraged to include in Funding Requests any planning related to Debt 2 Health and or joint investments that may be considered during the 2023-2025 allocation cycle.
- **Support the gradual, phased uptake of key programmatic costs and interventions, including those currently funded by external financing.** It is essential that countries plan how to finance and gradually uptake (or absorb) key programmatic costs and interventions as they work to strengthen sustainability. Gradual, progressive financing of these costs can help decrease dependencies on external financing for key interventions and build national capacity to implement and manage interventions that have been traditionally reliant on external financing.
- **Strengthen the generation, development and use of health financing-related data, including improving tracking of health and national response spending.** Having the right information at the right time is imperative to strengthening financing of health and the national responses, as is institutionalizing the appropriate processes for the analysis and use of health financing-related data. The Global Fund encourages countries to use national health accounts and to strengthen overall resource tracking so that data on past spending can be used regularly to inform health sector policy-making.<sup>18</sup> It is recommended that programs have processes in place to track spending by intervention/product and major sources of funding. This can then be used to inform program planning, costing and budgeting. This also assists countries to reliably report on realization of co-financing commitments in a timely fashion. Countries can request that Global Fund grant funds be used to invest in resource-tracking efforts, and the new Health Financing Systems category of the RSSH module within the Global Fund's modular framework prioritizes investments in health financing related data.

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<sup>17</sup> While all countries are encouraged to have and implement health financing strategies, the Global Fund will provide support particularly in countries where government health spending is low, disease burden is high, and the government has expressed a commitment, often by collaborating with partners and global platforms

<sup>18</sup> See <http://www.who.int/health-accounts/en/> for more information on health accounts and the standard methodology for tracking health spending recommended by WHO.

The Global Fund encourages countries 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 focus/structure of Global Fund grants, the Global Fund's [RSSH Information Note](#) outlines specific focus areas of potential Global Fund support, including health financing strategies and planning, advocacy and monitoring of domestic resources, innovative finance mechanisms, health financing data and analytics, public financial management and routine financial management, health product procurement systems, and capacities for public financing of services provided by communities and civil society.

### **2.1.3 Strengthening efficiency and value for money**

Given the substantial funding shortfalls that exist in global plans for HIV, TB, and malaria and the significant financing challenges faced by countries, strengthening sustainability is strongly linked to maximizing the impact of available resources by improving the efficient, effective, and equitable use of these resources. Countries are strongly encouraged to strengthen the efficient use of existing resources as they develop Global Fund funding requests, consider co-financing commitments, conduct national planning, and design / implement Global Fund grants. The Global Fund's [Value for Money Technical Brief](#) provides an overview of the Global Fund's approach to Value for Money, including the specific VfM dimensions of economy, efficiency, effectiveness, equity (in addition to sustainability) and other activities countries can take to strengthen the impact of available resources.

### **2.1.4 Alignment with national systems**

Global Fund-financed programs should be aligned with and implemented through country systems whenever possible, including using national health information and monitoring and evaluation (M&E) systems, national procurement and supply chain systems and public financial management systems. It should be noted that "national systems" are not exclusively government systems. They may also include community systems, or instances when government contracts with or otherwise works with non-governmental organizations (NGOs) to provide critical health services. Applicants are encouraged to include systems strengthening (including related to health financing data and resource tracking) measures in their funding requests so that national systems can be increasingly used to implement Global Fund financing. When grants are currently implemented through parallel structures, countries should articulate plans and take tangible steps to expand the use of country systems for the implementation of donor-financed programs.

### **2.1.5 Strategic investments in RSSH**

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 delivery integrated, people-centered health services. RSSH investments should support integrated health system functions and services that are aligned with national health strategic plans and support national health priorities, inclusive of prevention and curative services. Examples of integrated approaches include integration of health financing flows, channeling Global Fund resources via countries' own systems, and integration of HIV, TB and malaria services and commodities into essential medicines lists, health benefits packages and service delivery platforms.

Investments should align with and strengthen primary health care (PHC) strategies and health financing approaches that support the achievement of universal health coverage (UHC).

The scope and scale of RSSH investments will vary greatly according to country context. The Global Fund's information note on [Building Resilient and Sustainable Systems for Health through Global Fund Investments](#) and related technical briefs provide more information on Global Fund's RSSH investment approach. Applicants are also encouraged to use the new [RSSH Gaps and Priorities Annex](#) to prioritize their RSSH funding request, and to ensure that RSSH investments help achieve HIV, TB and malaria health outcomes. In addition, this Guidance Note includes annexes related to specific thematic areas linked to RSSH that are often critical to strengthening sustainability, including developing strong health management information systems and M&E systems, addressing sustainability challenges related to the procurement and management of health products, and improving the contracting and financing of services provided by communities and civil society.

### **2.1.6 Sustaining access to quality health products**

One of the key challenges as countries assume a greater role in the management and financing of national programs is maintaining access to quality, affordable health products and ensuring efficient systems are in place to deliver those health products to those who need them.

Greater ownership of health product management by countries is essential to the sustainability of national responses, and many countries already successfully procure and deliver quality assured health products with domestic financing and systems. However, several challenges exist in maintaining an uninterrupted supply and sustained access to quality health products, particularly as countries who have historically used Global Fund financing or pooled procurement mechanisms take greater responsibility in domestic health product procurement, financing, and management. These challenges may include: inadequate financing or misalignment of domestic financing with the national procurement cycles; lack of ability to select products, quantify and signal/guarantee demand and then negotiate prices with suppliers; legislative, licensing, or regulatory barriers that limit access to international or regional pooled procurement mechanisms; weaknesses or gaps in country quality standards and weak national regulatory agencies; outdated procurement or national guidelines that may create barriers for new products to enter the market or slow uptake of new products; slow, limited, or time intensive registration processes, and reliance on waivers for products purchased with external financing.

To mitigate challenges to access critical health products, the Global Fund strongly encourages countries to identify and address these barriers as they assume a greater role in financing health products. This may include strengthening the capacity of national procurement systems and national stringent regulatory authorities, considering use of international or regional pooled procurement mechanisms (like Wambo.org, UNICEF, or the Global Drug Facility for TB health products, etc.) to maintain quality and increase efficiency, leveraging globally agreed prices for newer products, using global pricing benchmark and reference prices (such as those from the Global Fund Pooled Procurement Mechanism) to inform supplier negotiations, or leveraging technical assistance to proactively address country specific barriers to effective procurement.

In addition, where parallel procurement and supply chain management (PSM) systems are being used, these should be transferred to national systems in a stepwise fashion well before a country

stops receiving Global Fund support.<sup>19</sup> This should include a focus on gradual integration of fragmented vertical/program supply chain systems into national systems.

The Global Fund includes in its [Guide to Global Fund Policies on Procurement and Supply Management of Health Products](#) detailed descriptions of standards and principles for health product procurement, covering areas such as efficiency and effectiveness, transparency and ethics, and intellectual property, including TRIPS. In addition, this guidance now includes a specific [annex on Health Product Management and Sustainability](#), which outlines a variety of challenges countries may face across health product management and considerations for addressing them.

### **2.1.7 Barriers to services**

Human rights- and gender-related barriers undermine countries' efforts to scale up quality service coverage, negatively affecting the sustainability of national responses. National planning should incorporate an assessment of the barriers to services, particularly for key and vulnerable populations, and include interventions and activities to overcome these barriers. A human rights-based and gender-responsive approach to addressing health problems means integrating human rights and equity norms and principles – nondiscrimination, transparency, participation and accountability – into the design, implementation, monitoring, and evaluation of health programs. It also means empowering vulnerable groups and key populations; putting in place necessary programs to address their particular vulnerabilities and needs; ensuring their participation in decision-making processes; and ensuring that there are mechanisms for monitoring, complaint and redress when rights are violated. [Technical briefs](#) on advancing human rights and gender equity in HIV, TB and malaria provide information on the comprehensive intervention packages and approaches to using data (including quality assessments), to ensure an equitable approach to health system planning and budgeting.

### **2.1.8 Governance**

Country Coordinating Mechanisms (CCMs) can play a key role in promoting increased sustainability and supporting transition away from Global Fund support. With their links to the external and internal environment through CCM membership, CCMs are encouraged to strengthen attention to sustainability during the country dialogue process. This should include identifying and assessing key sustainability challenges and gaps and taking a more proactive role in holding governments to account on domestic financing commitments. CCMs may also consider modifying the composition of their membership to ensure appropriate engagement of actors particularly relevant to sustainability (such as the Ministry of Finance or Planning, development banks, the private sector, and others, as outlined in the [CCM Policy](#)). CCMs can take a more proactive role in monitoring efforts to strengthen sustainability, such as monitoring the realization of co-financing commitments; the implementation of recommendations from assessments of sustainability; supporting the review and approval of innovative financing mechanisms; and efforts to crowd in additional resources, etc.

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<sup>19</sup> Procurement and supply management refers to all procurement, supply and distribution activities required to ensure the continuous and reliable availability of sufficient quantities of quality-assured, effective products to end-users, procured at the lowest possible prices in accordance with national and international laws. It includes aspects such as selection, financing, pricing/affordability, quantification, procurement, storage, distribution, rational use, and monitoring.



## 2.2 Preparing for transition from Global Fund financing

As countries move along the development continuum, it is essential that they increasingly focus on an eventual transition from Global Fund support. Disease components fully transition from Global Fund support when: a) they are no longer eligible for funding as per the Global Fund [Eligibility Policy](#), b) they voluntarily transition, or c) they have received their final allocation in discussions with the Global Fund.<sup>20</sup> However, preparations for transition may also be affected by changes in the size of Global Fund allocations, which often require countries to progressively assume key parts of the national response multiple allocation cycles prior to becoming ineligible. Modifications in investments of other partners may also affect ongoing availability of external financing for health and the three diseases, increasing the need to strengthen sustainability and plan for transition in advance.

Lessons learned suggest that successful transitions take time and require resources, and therefore early and proactive planning is a key part of transition preparedness. While all countries should incorporate sustainability considerations into their national planning, in addition the Global Fund encourages all UMI countries (regardless of disease burden) and all LMI countries with “not high” disease burden to accelerate preparations for eventual transition from Global Fund support. This means that planning for eventual transition should be a priority, and considerations for transition should be built into country dialogue, funding requests, co-financing commitments, grant design, and program design.

To support advanced planning and increase transparency on transition timelines, the Global Fund has published a list of the disease components projected to transition from Global Fund support by 2028 due to potential income classification changes.<sup>21</sup> These [transition projections](#) are estimates based on the latest available information, and are updated annually. For disease components where the timelines are particularly short, countries should work with the Global Fund to evaluate how current grants can be used to strengthen transition preparedness in the short term.

### 2.2.1 Readiness and national planning

To prepare for transition, countries should assess their readiness and strengthen national planning in order to manage their transition from Global Fund financing, including through transition readiness assessments and/or sustainability assessments. This transition planning should highlight financial, programmatic, and other potential risks related to transition from donor financing, as well as actions to address those risks. This should include (although it is not limited to) a phased plan for domestic financing or integration of Global Fund-financed activities as well as specific actions to address any identified transition challenges.

Countries have the flexibility to decide what form readiness assessments and/or transition and sustainability planning should take. Regardless of the specific approach, robust transition planning should be part of the national planning process, where possible aligned or included with the NSP and broader health sector planning, informed by fiscal realities, and well-coordinated with other donor plans and partners. Moreover, it should be developed through a rigorous, transparent and inclusive process, including the full engagement of all stakeholders. Such engagement is critical to ensuring strong analysis of transition challenges, high-level political commitment, and ongoing monitoring of the transition process.

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<sup>20</sup> [www.theglobalfund.org/documents/core/eligibility/Core\\_ProjectedTransitions2016\\_List\\_en/](http://www.theglobalfund.org/documents/core/eligibility/Core_ProjectedTransitions2016_List_en/)

<sup>21</sup> <https://www.theglobalfund.org/en/funding-model/before-applying/eligibility/>

Sustainability and transition readiness assessments will differ (often substantially) based on country context. The Global Fund has published [guidance to support countries on sustainability and transition assessments](#) and planning specific for HIV and TB national responses, and [guidance also exists to support planning related to Malaria](#). Key thematic areas to consider when undertaking sustainability and transition planning include:

- *Epidemiological and programmatic context:* Having a solid understanding of the current epidemiological and programmatic context is the starting point for developing specific options to strengthen sustainability and plan for transition, and it helps frame the challenges in reaching goals for the national responses and sustaining these achievements. This includes current and projected burdens of disease and drivers of infection; status of coverage and access to services; analysis of the future programming needs to enable the country to maintain and scale up coverage, as well as whether service delivery will be programmatically feasible for national governments to take over in the future; priority interventions and how these interventions are delivered and their effectiveness. The Global Fund disease information notes, particularly the sections focused on Investment Approach and Prioritized Interventions/Program Essentials provide critical insights into interventions critical to maintain impact and strengthen sustainability.
- *Health systems:* the capacity and quality of health systems elements that are critical for transition, including: M&E systems; human resources for health, including community health workers; laboratory systems; community systems and responses; procurement and supply chain systems; the current capacity for health systems planning, monitoring and evaluation; what reforms are happening in the health sector and their potential relevance for the sustainability of the disease program and how disease-specific functions can leverage system-level components; what systems components present roadblocks to transition.
- *Community responses, and the role of community and civil society organizations:* The role of communities and civil society organizations in the national response, including any dependencies on external financing.
- *Health financing and economic situation:* the country's macro-economic outlook and the fiscal capacity of the government to increase or improve public sector financing, with a particular focus on meeting national strategic goals and taking on costs previously supported through external resources. This also includes current and projected funding landscape for the health sector and the specific national response; major funders; financing and functionality of the public financial management system; financing impact of the reduction in donor funds; opportunities to mobilize additional domestic resources and strengthen innovative financing; any progress or bottlenecks in the implementation of health financing strategies and reforms; etc.
- *Governance and political context:* Existing governance structures, and whether those will maintain strong, inclusive multi-sectoral voices representing the TB, HIV, and malaria communities during the transition process and/or after the end of Global Fund financing, and the government's commitment to managing and financing the national response, including specific interventions (such as prevention for key and vulnerable populations). This includes not only national level authorities but also sub-national authorities, particularly in cases where health systems rely on sub-national authorities for planning and implementing key interventions.
- *Policy and legal environment:* the policy and legal issues that may impact long term sustainability and transition. This includes the human rights and gender-related barriers to access services and how these will be addressed in transition planning – for example, stigma and discrimination against people living with the diseases and key and vulnerable populations, enabling policy and legislative environment, sensitivity and capacity of the health



system to meet the needs of these communities. This includes the effects of gender and age inequities and barriers to access services, including gender-based violence, low levels of health-seeking behavior among men, availability and accessibility of youth friendly services, etc.

- *Prioritization of challenges and potential support TA needs:* The key challenges should be prioritized, along with the strategies to address them. This should include identification of any needs for technical assistance and resources available to support transition and sustainability planning.

Forming a national multi-sectoral transition or sustainability working group (or leveraging an existing body) is often a good first step to ensuring an inclusive process. It is often effective for setting up systems for accountability and coordinating efforts on transition planning. Findings from transition and sustainability assessments should inform a country's overall national planning for transition and/or a transition workplan. Some countries may be able to draw from or use ongoing exercises carried out by partners related to sustainability and transition to inform assessments, or leverage tools developed by the Global Fund to support countries to assess sustainability and transition readiness. [Annex 1](#) to this document provides a non-exhaustive overview of these tools and exercises.

A significant number of countries undertook the development of *transition and sustainability assessments* or equivalent analyses and *transition workplans* (or other equivalent planning) in the 2017-2019 and 2020-2022 funding cycles. Actively using these to inform funding requests, Global Fund grants, and ongoing implementation of national programs in the 2023-2025 funding cycle will be key to continue strengthening transition preparedness.

## 2.2.2 Enabling factors for transition

Preparing for transition depends on the specific country context, the level of reliance on donor funding, epidemiological situation, national strategies and health sector plans and structures, and many other factors. However, in addition to the sustainability considerations outlined above, there are several enabling factors and activities that are often particularly important as countries face reductions in external financing and/or prepare to fully transition from donor support. Many of these factors take significant time to be put in place and institutionalize, re-emphasizing the importance of early attention to national planning. They include (but are not limited to):

- **Continuity of services.** When programs financed by the Global Fund transition to domestic funding, lessons learned indicate that the continuation and scale-up of effective, evidence informed, rights-based and gender-responsive interventions for key and vulnerable populations are often at risk of cessation or interruption. Programming that serves marginalized and/or criminalized communities (such as people who inject drugs, men who have sex with men, transgender persons, sex workers, prisoners and migrants, hard-to-reach populations) including critical interventions to remove human rights and gender-related barriers to access, often lack adequate domestic financing or political commitment. Political prioritization is fundamental to maintaining service coverage for these critical interventions. In order to safeguard against disruptions to these critical interventions when disease components transition from Global Fund support, key and vulnerable populations should be central in all transition processes and planning, not only as recipients and implementers of services but also as advocates for well-planned, data-driven transitions that maintain and expand effective evidence informed and human rights-based interventions.

- **Community, civil society organizations, and other non-state actors.** In many national responses, non-state actors (particularly civil society and community organizations) play an essential role in the implementation of key activities. The Global Fund has encouraged the use of dual-track financing (where both government and non-government actors serve as implementers) to maximize the effectiveness and impact of programs it supports and to ensure the necessary development and inclusion of civil society in national responses. While this approach has been successful in elevating the role of these actors (such as NGOs, CSOs, and CBOs) and increasing their capacity to perform a variety of roles within the national disease response, experience suggests that there are challenges to maintaining services provided by these entities when Global Fund allocations decrease, especially those targeting key and vulnerable populations. As such, activities that enable or strengthen relationships between government and civil society organizations/community organizations to ensure strengthened capacity and sustainability in and the design of the national response and service delivery should be prioritized as countries prepare for transition. Institutionalizing these relationships takes time, thus requiring early attention and advanced planning.

A critical factor in sustaining and scaling effective responses is the capacity of governments to fund and contract community and civil society organizations with public financing. Fiscal, legal, and political factors may make it difficult to maintain or increase funding for these organizations and to continue their role in national responses. One way to mitigate this is to set up or strengthen appropriate mechanisms to use public financing to ensure continued provision of services by these entities. Even where public financing and contracting of civil society is possible within a country's legal framework, if the health sector is not actively contracting civil society and community organizations it may take time to ensure these mechanisms function properly or are properly financed. For those countries with existing platforms for contracting of non-state entities, dialogue on this issue should include identification of specific strategies for adequate levels of financing through consistent, annual budgeted mechanisms, as well as ensuring fairness and efficiency of the procurement process. To support country level dialogue on these critical activities, a specific [annex](#) dedicated to public financing of civil society service provision (often referred to as “social contracting”) is included in this guidance.

Civil society and communities also play a crucial role in encouraging accountability for adequate financing of disease responses and health systems, as well as provision of quality services – including to key and vulnerable populations. Ensuring that civil society and community organizations have sufficient capacity and financing to continue advocacy activities is essential to maintaining strong national responses, including after transition from Global Fund financing. This may include supporting civil society organizations to develop and implement strategies for resource mobilization. In cases where governments are not able to fund these types of activities, other stakeholders could support them, such as the private sector or national/international philanthropy.

- **Co-financing.** While the Global Fund encourages all countries to gradually assume program costs (as outlined above), accelerated co-financing of interventions currently financed by the Global Fund is particularly important in contexts where countries are preparing for transition. Gradually accelerating co-financing of critical interventions (or actively working to integrate those services into broader service delivery modalities) while increasing focus on efficiency-enhancing measures may help avoid service disruption and support continued progress against the three diseases.
- **Implementers.** In preparing for successful transitions, the Global Fund encourages CCMs to consider which entity is the most appropriate to guide transition preparedness and to implement transition activities and grants. CCMs should carefully consider the selection of local entities and government entities as Principal Recipients (PRs). While country context

matters, this may help ensure national ownership of the key interventions financed by external donors, while building national capacity for implementation of donor-financed activities. When it is not possible or appropriate to select either a local entity or a government entity to implement Global Fund grants, CCMs are strongly encouraged to include in their funding requests specific details as to how international NGOs or other entities will ensure that capacities are transferred to local institutions as quickly as possible. It is not recommended that a CCM waits until a transition funding grant, but rather start as early as possible to shift essential functions of the disease response to local institutions.

- **CCMs and transition.** CCMs can play a key role in supporting the transition preparedness process and overseeing the transition away from Global Fund support. As a country prepares for transition in at least one of its components, the role of the CCM should be appropriately adapted to enable a successful transition process. This could include enhancing linkages to key national actors (such as the Ministry of Finance); updating “oversight” plans to increase focus on monitoring domestic commitments related to transition (including co-financing); using CCM funding to help drive the transition planning process; supporting implementation or oversight of transition workplans; or enhancing capacity of CCM members around transition-related topics.

Countries preparing for transition in all eligible components should envisage the evolution of the role of the CCM, particularly with respect to maintaining the key principles of inclusion and participatory decision-making in the national health governance architecture. Options to consider include: 1) maintaining the CCM when it plays a strong and effective role in the national governance architecture, in which case resources may need to be mobilized to continue CCM functions of inclusive health governance after transition; or 2) merging the CCM with other national governance entities while ensuring that the core CCM principles of inclusivity and participatory decision-making are maintained/integrated.

## **2.3 Transition funding and transition work-plans**

Once a country disease component becomes ineligible for Global Fund financing, countries *may receive* up to three years of transition funding to help support full transition to domestic financing and management of the national response for that disease component.<sup>22</sup> This funding should be used exclusively for activities essential to maintaining service coverage and addressing critical challenges that may prevent continued progress against the diseases once Global Fund support comes to an end.

### **2.3.1 Transition workplan**

The funding request for transition funding components is subject to a tailored review by the TRP, and applicants applying for transition funding are required to submit a transition workplan along with their funding request. While there is no prescribed format, the transition workplan should be derived from findings in transition and sustainability assessments or an equivalent analysis, be aligned with the NSP and health sector planning and fiscal realities, be practical, measurable, costed and include a detailed outline of the steps that the country will take to transition to fully funding and managing the national response over the three-year transition funding period. The workplan should consider including the following:

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<sup>22</sup> The Secretariat, based on country context and existing portfolio considerations, will determine the appropriate period and amount of funding for priority transition needs. The Global Fund Eligibility Policy provides circumstances when transition funding may not be awarded. Specifically, countries not eligible for transition funding are those that a) move to high income, b) become G-20 UMIC with less than an ‘extreme’ disease burden, or c) become members of the Organization for Economic Co-operation (OECD) and its Development Assistance Committee.

- Epidemiological context and current country context, including service coverage, current programmatic interventions financed by the Global Fund, and an overview of the activities that require financing or integration to enable a successful transition.
- A phased financing plan towards full government financing of all activities (or full integration of those activities) by the end of the final transition grant.
- Specific analysis of priority interventions that can support addressing transition challenges and could be financed by the Global Fund transition grant.
- Where applicable, options and strategies for reprogramming existing funds and/or seeking additional funds from new sources to fill existing coverage and service delivery gaps.
- Description and budget of any activities essential for enabling a successful transition that are not financed by the Global Fund transition funding grant.

### 2.3.2 Transition funding

Requests for transition funding should focus on activities described in the transition workplan and which were prioritized during the country dialogue and funding request process. While country context will strongly influence the content of transition funding, transition funding should be used to address key sustainability and transition challenges (including those outlined in this guidance note), with a specific focus on:

- Activities that enhance the sustainability and support the transition of effective and evidence-based services for key and vulnerable populations, or address human rights, gender, or other enabling environment-related barriers to access to services.
- Activities that strengthen the overall health system in a manner that supports continued progress against the three diseases. This may include: activities that strengthen linkages between the government and non-state actors, including strengthening public financing of services provided by communities and civil society organizations; activities to secure the availability of robust programmatic and health financing data for program planning and monitoring; activities that strengthen public financial management; activities to strengthen integration of services or systems; activities to ensure adequate procurement processes and help maintain access to affordable, quality health products during and after transition; etc.
- Activities to ensure the financial sustainability of Global Fund-supported programs (e.g., integrating service provision into social health protection schemes, activities to strengthen budget advocacy for service provision to key and vulnerable populations, activities to strengthen resource mobilization for non-state actors and civil society, etc.).

Transition funding is not expected to be used to maintain the status quo of current grants or to extend the activities currently financed by the Global Fund. While different country contexts will affect the prioritization of activities and speed at which national authorities can take up interventions, the aim of transition funding is to help facilitate the process to move to full domestic financing and management of the national disease response.

Any activity expected to be continued after the end of Global Fund support (if included in transition funding requests) should be accompanied by specific, time-bound plans to phase out Global Fund financing as well as the steps taken to secure funding from alternative sources. This may include, for example, co-financing commitments that specifically require increased domestic financing of these activities at the early stages of transition funding grant implementation. These activities include:

- 1) *Service delivery.* A significant portion of service delivery activities should ideally be fully domestically funded by the time that a country receives transition funding, regardless of the type of implementing entity. Transition funding requests that include the provision of essential services should include a clear plan to shift the source of funding to domestic resources during the life of the grant, as well as specific complementary activities designed to achieve the full domestic uptake of service provision. This includes services related to key and vulnerable population, and/or any other interventions dependent on external financing. While these are often financed by the Global Fund up until the transition grant, there are significant risks regarding continuity of services if they are not integrated into domestic financing as early as possible.
- 2) *Procurement of health products.* It is expected that all (or a significant proportion) of procurement of medicines or other health products and supplies for treatment, diagnostic and prevention activities be fully funded domestically by the time a country reaches the transition grant stage. However, when funding for the procurement of health products or treatment has not yet been secured or is being used to support scale-up or transition to new regimens or updated treatments, the inclusion of health product procurement should also be subject to a clear plan to absorb them over the life of the grant. Specific, costed, time-bound commitments to take up all necessary procurement to maintain coverage in line with national strategic plans and the complementary activities necessary to achieve this goal should be included in the funding request.<sup>23</sup>
- 3) *Human resources and other recurrent operational costs.* The majority of recurrent costs for the management of disease responses of all implementing entities involved (including salaries, travel-related costs for supervision visits, office costs, fuel, maintenance and insurance of vehicles, and others) should be fully funded domestically by the time of the transition funding grant. This reflects the Global Fund's overall approach of integrating into grants sustainability considerations regarding human resources for health.<sup>24</sup> When a specific country context has prevented essential human resources or program operational costs from being absorbed, requests for these activities as part of transition funding should include time-bound and specific commitments to transfer them to national authorities during the life of the grant.

Countries should evaluate – in cooperation with the Global Fund - how best to use transition funding and they should agree on a performance framework for the transition funding grant. This framework should focus on scaling up and strengthening impact against the three diseases as well as addressing specific transition challenges. Effectively using performance frameworks to monitor the implementation of these grants – with the adequate choice of standard impact and service coverage indicators vs. workplan tracking measures – is essential.

## 2.4 Co-financing

Enhancing and increasing domestic investment in health systems - including HIV, TB, and malaria national responses - is essential to accelerating progress toward ending the three diseases as public health threats and strengthening the sustainability of national responses. As countries move along the development continuum and expand their fiscal capacity, they are expected to take on greater

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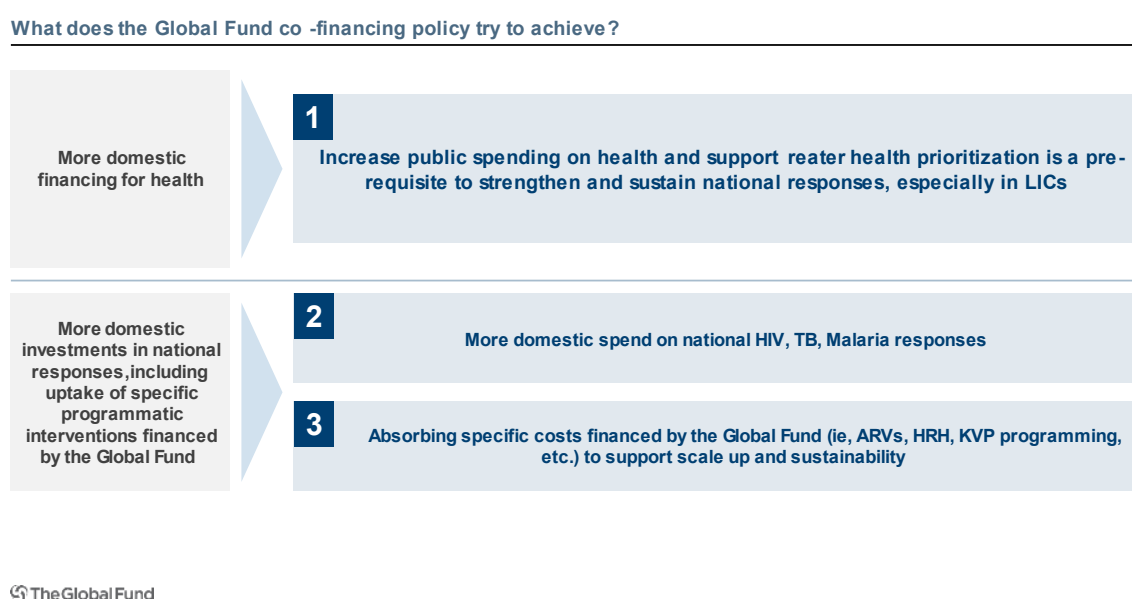
<sup>23</sup> For detailed guidance regarding sustainability considerations and measures specific to health product management, please refer to Annex 5 of this document and/or the Guide to [Global Fund Policies on Procurement and Supply Management of Health Products](#)

<sup>24</sup> [Briefing Note for Global Fund applicants on Strategic Support for Human Resources for Health](#)

ownership of the national response to the three diseases by increasingly contributing to national responses and health systems. The Global Fund’s approach to co-financing is designed to encourage and support countries to strengthen the sustainability of national responses and increase impact by encouraging countries to:

- Increase public spending on health and further prioritize the health sector;
- Enhance and increase resources available for national HIV, TB, and malaria responses (either by increasing investments in national responses and/or improving efficiencies of existing resources);
- Progressively absorb (or “uptake”) specific program costs and programmatic interventions essential to national HIV, TB, and malaria responses, including (and particularly) those financed by the Global Fund.

**Figure 4: Objectives of Co-financing**



In order to access Global Fund allocations, countries should show progressive government expenditure on health and progressive uptake of key program costs, including those supported by the Global Fund. In addition, a portion of a country’s allocation (the “**co-financing incentive**”) is available only if countries comply with the Global Fund’s co-financing requirements. Except in specific circumstances, the co-requirements to access the allocation are specified in a country’s Allocation Letter.

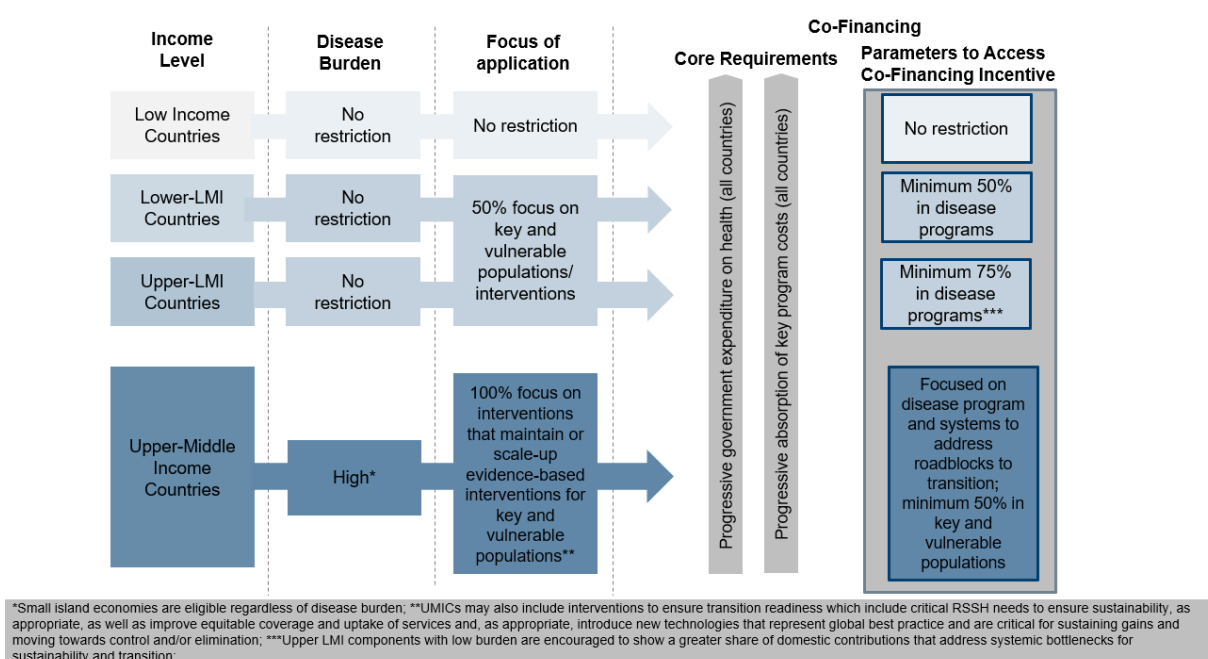
Unless otherwise noted in a country’s Allocation Letter, the scope of additional co-financing investments should be:

- For low-income countries (LICs), additional domestic investments should be at least 50% of the total amount of the allocation tied to co-financing;
- For middle-income countries (MICs), additional domestic investments should be at least 100% of the total amount of the allocation tied to co-financing.<sup>25</sup>

<sup>25</sup> [Sustainability, Transition, and Co-Financing \(STC\) Policy](#)

Unless otherwise specified in a country's Allocation Letter, requirements for additional co-financing commitments are differentiated by country context and income classification, with significant flexibility for the focus of co-financing investments in low-income contexts and more targeted requirements in higher income contexts (as described in Figure 4).

**Figure 5: Application focus and co-financing requirements across income levels**



This includes:

- **Low-income countries:** Low-income countries have the flexibility to make additional investments either in national responses and/or RSSH activities.
- **Lower-middle-income countries:** As countries move along the development continuum, co-financing commitments must be increases focused on disease responses and specific thematic areas. For Lower-LMI countries, a minimum 50% of co-financing contributions should be in line with identified priority areas within the national disease response. For Upper-LMI countries, a minimum 75% of co-financing contributions should be in line with identified priority areas within the national disease response. For Upper-LMI countries with a “Not High” disease burden, applicants are encouraged to invest a greater share of additional domestic contributions to address systemic bottlenecks for transition and sustainability.
- **Upper-middle-income countries:** To strengthen transition preparedness, 100% of the additional commitments in UMICs must focus on the national disease response and/or RSSH activities that specifically address barriers to transition. Within this amount, a minimum of 50% should be invested in specific activities targeting key and vulnerable populations as part of the national response (as relevant to the country context). Applicants for transition funding are also required to meet the co-financing commitments.



### **Illustrative co-financing incentive examples:**

**Country A** is a UMIC and has received an allocation for HIV only. It receives an allocation of US\$10 million for 2023-2025, of which 20% is a co-financing incentive. To access its full allocation, Country A must commit additional investments over the three-year implementation period that are at least US\$2 million more than what it spent over the previous three years. Of the US\$2 million, at least US\$1 million must be committed to activities for key and vulnerable populations.

**Country B** is a LIC and has received an allocation for all three diseases of US\$100 million, of which 15% is a co-financing incentive. To access its full allocation, Country B must commit additional investments over the three-year implementation period that are at least US\$7.5 million more than what was spent over the previous three years. Country B has the flexibility to invest all of the additional US\$7.5 million in either disease programs or RSSH activities.

Across all income levels, it is essential to note that the total co-financing requirements – including baseline spending plus the additional investments – is what the Global Fund considers for co-financing.

## **2.4.1 Evidence of Realization of Commitments:**

During the funding request and grant-making process for the 2023-2025 funding cycle, countries will need to show evidence of having met their previous co-financing commitments from the 2020-2022 allocation cycle (including demonstration of specific expenditure and evidence of realization of programmatic commitments). They will also need to make sufficient commitments as per the stipulations outlined above and in their allocation letter in order to access their full allocation for the 2023-2025 allocation cycle. Failure to realize previous commitments or to provide evidence of realizing commitments may result in the reduction of grant funds and/or reductions in future allocations. The realization of previous commitments will be verified throughout the funding cycle and prior to the approval of 2023-2025 Global Fund grants. Further details on the implementation of the Global Fund's approach to co-financing can be found in the Global Fund [Co-Financing Operational Policy Note](#).

## **2.4.2 Co-Financing Lessons Learned and Focus Areas for 2023-2025:**

Lessons learned from co-financing implementation indicate a number of focus areas that are particularly important for countries to consider to as they are developing co-financing commitments for 2023-2025. These include (but are not limited to):

- **Country ownership and accountability** – Ensuring co-financing commitments are backed by formal, approved financial commitments, including from relevant national ministries (i.e., Ministry of Finance). This includes the submission of clear, high quality commitment letters that identify the specific financial and programmatic commitments made as part of co-financing, and include the total co-financing commitment (and not only the additional commitments). **Commitment Letters are mandatory for all countries. They are strongly encouraged to be submitted alongside funding requests, and must be submitted prior to the approval of Global Fund grants.** A template for commitment letters is available here.
- **Risks** – Proactively identify and address any risks associated with commitments - and efforts to mitigate these risks - particularly in cases where failure to realize commitments can

negatively affect overall program design and impact (such as non-realization of commitments related to procurement of health products, non-absorption of human resources, lack of realization of commitments to specific programmatic areas such as prevention, key and vulnerable populations, etc).

- **Monitoring and tracking** – Greater attention to and up-front documentation for how commitments will be formally monitored, tracked, and reported to the Global Fund.
- **Improved data quality** – Strengthening the quality and consistency of data supporting co-financing commitments. This includes: a) increased rigor in the completion of Funding Landscape Templates (FLT), which outline the projected domestic investments in the national responses and previous expenditures, including for the overall national response and specific interventions; b) clear identification of sources of information for projected and previous domestic investments; and c) ensuring consistency in information on co-financing commitments submitted through the FLT, the commitment letter (CL), the Funding Request, and the RSSH gap analysis.
- **Linking financial with programmatic** – Stronger linkages between financial commitments and programmatic priorities, including those priority areas outlined in the new Global Fund Strategy and/or where ongoing dependencies on Global Fund financing can create challenges for the sustainability of the national response. These programmatic commitments should be costed and realistic, to ensure they are in line with a country’s fiscal space and overall spending on the national responses.
- **CCM and Principal Recipient engagement** – Greater CCM engagement in supporting the realization and monitoring of commitments. This is a core part of a CCM’s oversight function and it is the role of the PR to support the implementation of mitigating actions to address co-financing risks.
- **Visibility and transparency** – Increasing the visibility and transparency of co-financing commitments at the country level, to ensure national stakeholders are aware of commitments and can be held to account by their peers as well as by government stakeholders and civil society and community organizations.
- **Alignment with fiscal capacity** – Ensuring co-financing commitments made are in line with a country’s fiscal capacity, particularly in lower-income contexts and/or places with larger Global Fund allocations (relative to the size of the national response or investments in health). Greater attention to the quality of commitments (the “what”) is just as important as the overall quantity of commitments (the “how much”).
- **Criticality of targeted, clear RSSH investments** – RSSH is critical to sustainable national responses. Therefore, RSSH investments included as part of co-financing requirements need to be specific and accompanied with a clear rationale on how they support stronger systems and sustainable responses (for example through investments in primary health care, investments in specific RSSH priorities identified in the Global Fund strategy, etc).

The Global Fund’s *Operational Policy Note on co-financing* outlines additional information on the implementation of the Global Fund’s co-financing policy and may be used as a reference for countries as they make and fulfil co-financing commitments for the 2023-2025 cycle.

## 2.5 Application focus requirements

The Global Fund's *application focus requirements* identify how countries should invest Global Fund financing. These requirements are key to sustainability and transition readiness because they ensure that funding requests for countries at different income levels are strategically focused on the most relevant and impactful interventions as countries progress along the development continuum. The application focus requirements emphasize that all funding requests must consider evidence-based interventions that respond to the epidemiological context; position national responses to maximize impact against HIV, TB and malaria; and contribute towards building RSSH. Application focus requirements are differentiated along the development continuum and are reviewed as part of the funding request:

- **Low-Income Countries:** For low-income countries, there are no restrictions on the programmatic scope of allocation funding for HIV, TB or malaria requests and applicants are strongly encouraged to include RSSH interventions in the funding request. Applications must include (as appropriate) interventions that respond to key and vulnerable populations, human rights and gender-related barriers, inequities and vulnerabilities in access to services.
- **Lower-Middle-Income Countries:** For lower-middle-income countries, at least 50% of allocation funding should be for disease-specific interventions for key and vulnerable populations and/or highest-impact interventions within a defined epidemiological context. Requests for RSSH must be primarily focused on improving overall programmatic outcomes for key and vulnerable populations in two or more of the diseases and should be targeted to support scale-up, efficiency and alignment of interventions. Applications must include, as appropriate, interventions that respond to human rights and gender-related barriers, inequities and vulnerabilities in access to services
- **Upper-Middle-Income Countries:** For upper middle-income countries, 100% of the Global Fund allocation should focus on interventions that maintain or scale-up evidence-based interventions for key and vulnerable populations. Applications must include (as appropriate) interventions that respond to human rights and gender-related barriers and vulnerabilities in access to services. Applications may also introduce new technologies that represent global best practice and are critical for sustaining gains and moving towards control and/or elimination; and interventions that promote transition readiness, which should include critical RSSH needs for sustainability (as appropriate) and improvement of equitable coverage and uptake of services.

## Annex 1: Resources to Support Sustainability and Preparations for Transition

Note: resources referenced in this annex are *not exhaustive*.

### A. Main tools available and methods to enhance efficiency to inform resource allocation:

Type of tool	Disease program	Tool/Methods	Description	Tool/Method developer <sup>26</sup>
Allocative efficiency	HIV	<a href="#">AIM/Goals model</a>	Projects HIV burden (PLHIV; HIV infections, AIDS cases and deaths) and optimal intervention and coverage mix to maximize impact under a given resource envelope.	Avenir Health
		<a href="#">AIDS Epidemic Model (AEM)</a>	Projects current and future HIV infections and ART needs at a given period. Has an Intervention workbook component for assessing program impacts and costs and a separate Impact Analysis workbook for comparing scenarios. The model is primarily used for concentrated HIV epidemics in Asian country settings and can inform optimal intervention mix for a given resource envelope.	East-West Center
		<a href="#">Optima HIV</a>	Optima HIV can improve spending efficiency by identifying how new or existing funding can be optimally allocated across interventions to maximize impact, at national or sub-national levels. User-defined key populations and targeted interventions can be included, and health or epidemic outcomes estimated under specified or optimal spending scenarios.	Optima Consortium for Decision Science
	TB	<a href="#">Australian Tuberculosis Modelling Network (AuTnMN)</a>	Assists national TB programs to identify cost-effective TB control interventions that will maximize impact against TB.	Australian Tuberculosis Modelling Network
		<a href="#">Imperial TB Model</a>	The model links the TB care cascade to transmission with the aim of identifying which improvements in the cascade can yield the greatest effect on incidence and mortality. Provided with country-specific cost data, the model can also inform what intervention scenarios can be most cost-effective to guide strategic planning of national programs. Models are developed specifically for each country.	Imperial College London
		<a href="#">Optima TB</a>	Optima TB can identify how new or existing funding can be optimally allocated across interventions to maximize impact at national or sub-national levels. User-defined key populations and targeted interventions can be	Optima Consortium for Decision Science

<sup>26</sup> Co-developers or collaborators of some of the tools can be found on the website of the tools.

			included, and health or epidemic outcomes estimated under specified or optimal spending scenarios.	
		<a href="#">TB Impact and Modelling Estimates (TIME)</a>	Estimates TB burden among population targeted for a specific TB intervention or intervention mix and projects service volumes needed for an impactful response to TB.	TB Modelling Group, London School of Hygiene and Tropical Medicine
	Malaria	<a href="#">Elimination Scenario Planning</a>	Models and assesses technical, financial and programmatic feasibilities of achieving malaria elimination based on existing program coverage, interventions selected and resource availability.	Imperial College London
		<a href="#">Epidemiological MODELing (EMOD) malaria modelling</a>	Simulates changes in malaria transmission dynamics based on interactions with malaria control interventions.	Institute of Disease Modelling
		<a href="#">Malaria Elimination Transmission and Costing (MEMTC)</a>	Estimates the rate of decline and costs towards malaria elimination. It incorporates transmission dynamics, seasonality and intervention coverage specific for each country against <i>P. falciparum</i> and <i>P. vivax</i> malaria.	Mahidol Oxford Tropical Medicine Research Unit
		<a href="#">OpenMalaria</a>	Simulates the impact of malaria interventions against changes in malaria vector transmission dynamics.	Swiss TPH
		<a href="#">Optima Malaria</a>	Tool that can improve spending efficiency by identifying how funding can be optimally allocated across malaria interventions to maximize impact at national and sub-national levels. User-defined key populations and targeted interventions can be included, and health or epidemic outcomes estimated under specified or optimal spending scenarios.	Optima Consortium for Decision Science
		<a href="#">Spectrum Malaria</a>	Projects malaria intervention coverage and its expected impact on malaria prevalence, cases and mortality. The projections consider available resources and the relative costs and cost-effectiveness of changing strategic plans or policies. It is specific to sub-Saharan African region.	Avenir Health
	Health Systems	<a href="#">Health Intervention Prioritization Tool (HIPtool)</a>	Assists policy-makers to identify health funding priorities and target coverage across diseases at country level for a given level of available resources. The tool incorporates context-specific disease burden data and their respective effectiveness on intervention effectiveness.	University College London
		<a href="#">WHO-Choosing Interventions That Are Cost Effective (WHO-CHOICE)</a>	Designed to facilitate country level cost-effectiveness analysis of a wide range of health interventions across disease programs to inform priority setting for health development overall.	World Health Organization

		<a href="#">Cross-programmatic Efficiency Analysis</a>	A diagnostic approach to enable countries to look across health programs that are part of their health system to detect “cross-programmatic” inefficiencies. The approach uses applied health system analysis to unpack vertical programs by their functional components and places them within the context of the broader health system.	World Health Organization
		<a href="#">Financial Evaluation of Investments in Public Health Supply Chains</a>	A free-online course designed to provide framework and method for supply chain professionals to make a financial evaluation of investment options against alternative course of actions and guide their decisions about the cost-effectiveness of their investments and efficient use of scarce resources.	Jointly by the Global Fund and Empower School of Health
	Health product & technology; health programs.	<a href="#">Health Technology Assessment Toolkit</a>	Aims to systematically document the expected cost and effectiveness/benefit consequences of new health technologies such as drugs, medical equipment, diagnostic techniques and public health programs to inform the adoption of a new technology or inform priority setting including the creation of an essential medicines list and a health benefit packages for UHC.	International Decision Support Initiative (iDSI)
<b>Budget impact analysis</b>	Applicable for an intervention or intervention mix	<a href="#">Budget impact template</a>	Assessment of expected financial changes in health expenditure upon implementation of new intervention/interventions. Budget impact analysis evaluates the affordability of implementing and sustaining new intervention. Countries can adapt this template to their own settings, to obtain insights as to whether or not to adopt a new technology or intervention mix given its budget implications to ensure affordability and sustainability.	National Institute for Health and Care Excellence
<b>Extended cost-effectiveness</b>	Health systems	<a href="#">Socio-Technical Allocation of Resources (STAR)</a>	Facilitates policy dialogue among health decision-makers to identify and prioritize interventions across different health areas incorporating cost-effectiveness and other factors such as equity and feasibility.	London School of Economics
<b>Costing</b>	HIV and other diseases	<a href="#">Activity-based Costing and Management</a>	Generate patient-level cost data that will promote local efficiencies in care delivery, optimization of care over the patient’s treatment cycle, and inform policy-makers’ strategic planning, budgeting, resource allocation and program implementation for high-quality HIV care and related services.	Harvard Business School, Heller School for Social Policy and Management
	TB	<a href="#">Value TB Costing Tool</a>	Supports collection and estimation of unit costs of providing multiple TB interventions from the healthcare providers’ perspective. The estimates can then be used to inform for efficient and fair prioritization and planning for TB services.	World Health Organization

<b>Resources needs estimates/ Budgeting</b>	Health systems	<a href="#">OneHealth</a>	Supports costing and budgeting of resources needs across the health sectors, linking national strategic objectives to programmatic targets set across different disease programs. A key focus of OneHealth is on integrated health planning and strengthening of health systems.	Interagency Working Group on Costing / Avenir Health
<b>Geospatial analysis</b>	Health systems	<a href="#">AccessMod (Version 5)</a>	Leverages Geographical Information Systems (GIS) technology to visually display geographic coverage and population access to existing health facility and service networks. The tool can be used in scaling up health facility coverage by identifying new sites that maximizes geographic coverage and reducing access times and optimally deploying CHWs or health technologies to improve service access and efficiency.	WHO, UNICEF, University of Geneva, Health GeoLab
		<a href="#">ArcGIS</a>	Licensed software tool that combines geographic information system technology with demographic to aid planning of health facility networks and population access to health services.	Esri
		<a href="#">Reveal</a>	Open-source spatial intelligence tool supporting end to end campaign management including web-based planning workflows, in-field spatial guidance and real-time geolocated household monitoring of last-mile health service delivery. Outcomes include a precise understanding of coverage intervention gaps designed to inform real-time in-field responses and program strategy adjustments.	Akros
		<a href="#">OptiDx</a>	Open-access Diagnostic Network Optimization (DNO) tool aimed at maximizing limited diagnostic capacity in low resource settings whilst achieving a high overall efficiency. The tool can be used to strategically link the optimization to national health priorities across multiple disease programs.	FIND, USAID-PSM, Coupa Software
	TB	<a href="#">MATCH approach</a>	Combines GIS and surveillance data to inform health policy and planning geared towards sub-national tailoring of interventions around TB and investment decisions.	KIT Royal Institute



**B: Global Fund-supported tools to support sustainability and transition planning:**

	<p><b><u>Guidance for Sustainability and Transition Assessments and Planning for National HIV and TB Responses</u></b></p>	<p><b><u>Sustain: A Sustainability and Transition Readiness Assessment Tool for Malaria</u></b></p>	<p><b><u>Diagnostic Tool on Public Financing of CSOs for Health Service Delivery (PFC)</u></b></p>
<p><b>What is it?</b></p>	<p>Guidance to support countries in identifying financial, programmatic and governance gaps, bottlenecks and risks that need to be addressed in one or more of the components of the health system to promote a smooth transition.</p>	<p>The SUSTAIN tool is an assessment and planning tool for guiding national malaria programs through the process of preparing for a sustainable transition from donor support.</p>	<p>Tool to examine the ability of civil society organizations to register, receive funds from government, use those funds for service delivery, particularly to key populations and other HIV, TB and malaria efforts.</p>
<p>For those tools without public links, please contact the Global Fund Secretariat (via Global Fund Country Teams)</p>			

## Annex 2: HIV and Sustainability

### *HIV Specific Annex to the STC Guidance Note*

#### **Background**

The HIV epidemic poses a unique spectrum of challenges to countries that must both maintain programmatic capabilities to manage a lifelong transmittable illness and respond to the social and economic factors that foster vulnerability to new infections. Successfully addressing these challenges requires continual attention to issues of sustainability and the effective use of limited resources. Reducing new infections, evolving the chronic care model towards integration and self-care, ensuring reliable uninterrupted supply of drugs to treat HIV and related co-infections, laboratory systems and commodities to support necessary testing (HIV diagnosis, CD4, viral load, etc.), service delivery platforms to provide HIV prevention, treatment and care services including adequate and trained health care staff, and addressing vulnerabilities are all crucial components of a sustainable national HIV response. Ensuring quality HIV services will also require sufficiently robust information systems for program management and continuous adaptation to support a precision public health approach. Efficient and effective national programs lead to incidence reduction, improved well-being for people living with HIV and reduced AIDS mortality while at the same time incidence reduction enables leaner programs and reduces fiscal burden of national governments.

Through its Sustainability, Transition and Co-Financing (STC) policy,<sup>27</sup> the Global Fund encourages countries to embed sustainability considerations in national program design and proactively plan for a sustainable response independent of external support. The STC policy provides high level guidance to all countries as they work to build efficient and sustainable health systems and disease responses, regardless of when a country might anticipate the decline or end of external financing. In the context of the HIV epidemic, there are specific challenges countries may face in achieving long-term successful health outcomes. Tailored approaches to address these may help strengthen long-term sustainability of national responses and support successful transitions from Global Fund financing.

#### **Box 1. How to use this Annex**

- This annex builds on the **Global Fund’s STC Guidance Note** and provides HIV-specific sustainability and transition considerations that complement other annexes, including on Public Financing for Civil Society Organization Service Delivery (also known as “social contracting”); Health Product Management; and Health Management Information Systems and Monitoring and Evaluation.
- Considerations are organized around the following thematic areas: leadership and governance, financing, program planning, implementation and service delivery platforms, health systems and HIV, and human rights and equity. For each, the annex includes principal challenges and potential responses.
- This annex is also intended to complement the [HIV information note](#), the [information note for Resilient and Sustainable Systems for Health \(RSSH\)](#), technical briefs on [HIV, Human Rights and Gender Equality](#), and [Value for Money](#).

<sup>27</sup> The Global Fund (2016). [The Global Fund Sustainability, Transition and Co-financing Policy](#).

Country context varies widely in terms of HIV burden of disease, economic capacity, the populations affected, financing, and health systems environment, and will significantly impact the appropriate focus areas for sustainability planning. Both the size and nature of national HIV programs and responses reflect many factors, including the size of the epidemic, the populations affected, governance structures, and models of financing, including external support. Respecting these differences, the considerations presented here are not intended to serve as prescriptions applicable to each country, but rather aim to support country dialogue and planning around sustainable and effective national programs and mobilization of domestic financing to decrease funding gaps, accelerate scale up, and support countries as they prepare for transition.

## Challenges and considerations

### Leadership and governance

Sustainable and effective national HIV responses require broad, multi-sector political will and the engagement of people affected by HIV, including key and vulnerable populations, in decision-making processes related to HIV. Health sector reforms, including Universal Health Coverage (UHC), integration, and decentralization, present opportunities as well as new policy questions for HIV programs.

#### Key Challenges

- *Sustaining attention for a long-term response:* In the context of competing priorities for investment in health and across other sectors, it can be difficult to sustain political will and investment in HIV. This challenge is particularly acute where overall HIV prevalence is low but elevated in key and vulnerable populations, which external financing often helps bring attention to.
- *Limited and sub-optimal domestic investments in HIV prevention:* Domestic investments in HIV prevention have lagged behind support for HIV treatment. Traditionally, there is little attention to challenging human rights issues and discriminatory policies or laws that impede marginalized populations' access to essential HIV services. This is compounded by limited data on the financing needs and programmatic costs of prevention contributing to sub-optimal investment in effective, person-centered, and data-driven prevention programs for those who need them most.
- *Creating new governance structures for integrated programs:* Many HIV programs continue to operate in silos despite opportunities to improve efficiency and impact through integration. UHC and the movement towards integrated health systems present many opportunities for increased efficiency and sustainability, but also present new governance challenges. Health ministries need to evaluate which HIV interventions and systems should be integrated to enable long-term integrated chronic care, and which should be retained within a vertical HIV program approach. It can also be difficult for HIV programs to engage in broader health service delivery because they may not have participated in earlier integration discussions, in part due to the vertical nature of much of the external funding.
- *Maintaining and coordinating multi-sector partnerships:* The intersection of social, economic, legal, and cultural factors driving vulnerability to HIV requires a multi-sectoral response that engages ministries and stakeholders beyond the health sector, including across finance,

gender, education, justice and law enforcement, youth and affected communities. Country Coordinating Mechanisms and national AIDS commissions can help facilitate this engagement, but these functions may change as countries shift to broader health and development planning bodies.

- *Decentralization presents new governance challenges:* In contexts with decentralized planning and budgeting, sustaining political support and funding for HIV and health may require new capacities and coordination between the central and local levels. For example, in some settings, policies to pool HIV and TB funding have gained support at the central level but encountered implementation problems at local levels.
- *Addressing the legal, policy and practice frameworks that create barriers and inequities to service access.* HIV program stewardship requires coordination, funding and accountability beyond the HIV program and beyond the health sector. Governance issues related to human rights and equity are described in [Health Equity, Gender Equality and Human Rights](#), below. Other laws and policies reducing service access are described in [Program Planning, Implementation and Service Delivery Platforms](#), also below.

## Key Considerations

- *Broaden HIV leadership and ownership:* Engage multi-stakeholder groups that include a broad range of ministries, parliamentarians, policymakers at the central and local level, and community representatives to garner support for HIV programs, mitigate resistance that may exist regarding particular populations or services, and proactively leverage new opportunities that emerge. Identify opportunities for complementary planning and investments and institutionalize governance structures that can withstand political and staff turnover. In some countries, setting a high-level vision for the HIV program has facilitated this type of broad and multi-level investment in an effective health sector response for HIV.
- *Strategically integrate HIV functions into the broader health system:* Identify how and where services for HIV can be integrated within broader health services and funding channels without loss of integrity of health outcomes (e.g., integration with sexual and reproductive health (SRH), TB, routine antenatal and postnatal services and primary health care). Ensure policies/implementation strategies extend from central to district level.
- *Embed civil society in leadership and governance structures:* Civil society and affected populations should be integral in the governance of the HIV response. Countries should work early on to identify and build mechanisms for institutionalizing this engagement.
- *Raise attention to and investment in public financial management:* Investments in public sector management and finance at all levels strengthens planning, budgeting, and accountability. Countries should prioritize effective health budget utilization along with expanding the health fiscal space.
- *Advocate for and promote legislative, practice, program and policy changes to reduce barriers to services.* Address policies and practices that constrain the ability and/or flexibility of programs to implement proven intervention or to introduce innovations in service delivery. And address HIV-related stigma, discrimination, criminalization and other barriers and inequities, particularly for people living with HIV and key and vulnerable populations. These considerations are further discussed in [Program Planning, Implementation and Service Delivery Platforms](#) and [Health Equity, Gender Equality and Human Rights](#), below.

## Financing

Sustainable financing for HIV requires securing domestic financing for interventions for key and vulnerable populations and treatment scale-up, as well as strengthening efficiency to decrease long term-costs.

### Challenges

- *Ministries of Finance may not track all external funding for health:* Many countries receive significant support for HIV from various donors, but a significant percentage of external finance is not captured in domestic budgets. As a result, governments may not have a complete picture of the needs, costs, challenges, and importantly, the future implications for domestic financing of the national response.
- *Financing HIV is a long-term prospect:* People living with HIV need to remain on treatment for life. Therefore, countries should plan for long-term investments in effective and integrated chronic care models for HIV. In addition, countries must plan for significant investments in prevention; as noted above, incidence reduction enables leaner programs and reduces fiscal burden on national governments. Financing needs to be sustained, and therefore needs to be diversified. Sustaining finance may be additionally challenging in the face of competing priorities within the health sector and a limited health budget.
- *Insufficient financial and cost-effectiveness data:* HIV national strategic plans often lack solid data on unit costs for services and the full costs of supporting non-service-delivery functions and capacities required for effective national response. In addition, existing costing efforts do not always include all necessary stakeholders, and costing methodologies across donor and partner-supported programs are not uniform. For example, the laboratory sector is often not engaged despite the importance of lab infrastructure to program sustainability, and costing does not always include programs run by Civil Society Organizations (CSOs) that in some countries make up the core of prevention programs. Moreover, cost-effectiveness and cost-efficiency data may be available for some program elements, mainly treatment, and that limits allocative efficiency in the decision-making process. Allocative efficiency is realized by strategically apportioning program resources across interventions, population groups and sub-national geographies to maximize health impact.

### Considerations

- **Fully track all sources of funding:** Ministries of finance or equivalent national entities need to understand the full health systems investments from both domestic and external sources. This can facilitate dialogue between the ministries of health and finance on what is needed, how available funds are being used, and opportunities to improve the efficient and effective use of available funding. In some countries, the Ministry of Finance serves as the Global Fund PR, which has helped increase the priority of health and domestic resource mobilization. The introduction of financing tracking tools may facilitate this type of dialogue as well as support budget advocacy efforts by the HIV program and civil society partners. (See country example in Box 2.)
- **Strengthen core budget and diversify sources of funding for long-term sustainability:** To help ensure sustained financing for HIV, funding sources should be as diversified as possible. Assess the options for alternative financing sources given existing laws, regulations, and capabilities, as well as the likelihood that these mechanisms can provide long-term sources of revenue. Integration of HIV services into national health insurance programs is one

promising strategy for sustainable domestic finance. Although identifying diversified sources of financing is important, it is essential to maintain focus on strengthening core budgetary support to increase stability of financing.

- Enhance efficiency and fund utilization: Technical efficiency includes employing interventions that are technically the most appropriate and in line with the latest normative guidance; that reflect optimal use of existing capacity, such as common laboratory services or combined training across diseases; and mechanisms to address common bottlenecks in service delivery, such as stockouts or health worker constraints, for example, through task-shifting. It also includes efforts to deliver quality services through efficient modalities, for example, through scaling up patient-centered, differentiated service delivery (DSD) models along the HIV cascades. This reflects the need to critically review enablers and bottlenecks in performance, and to continuously address barriers to delivery and ultimately fund utilization. Additionally, such efforts must include government, donor, and CSO-delivered programming, such that any program eventually transitioned from donor to government funding is as affordable and efficient as possible.

### **Box 2. Engaging the Ministry of Finance**

The Ministry of Finance is a critical partner for HIV programs and health ministries to achieve financial sustainability. For example, one sub-Saharan African country initiated a dialogue between the ministries of health and finance to discuss health workforce constraints and the risks associated with HIV. The leaders prioritized integrating the donor-supported HIV workforce into the health system, and applied a [value for money](#) approach to identify efficiencies in workforce duties, training, and supervision. The ministries developed a joint plan for government co-financing of donor-supported positions, and regular progress updates are provided in Country Coordinating Mechanism meetings.

## **Program Planning, Implementation and Service Delivery Platforms**

The pathway to a sustainable HIV response depends on reducing new infections by ensuring HIV prevention options are more widely available and used, identifying people living with HIV who are not yet on treatment and ensuring effective, easily accessible, life-long treatment for people living with HIV including but not limited to children, pregnant women, and key populations. Countries must ensure that people with need for HIV prevention, treatment and care continue to receive quality person-centered services. This requires understanding where and amongst whom new infections are occurring, who is being left behind, and putting in place real-time feedback loops on quality of services – precision public health. It also requires long-term integrated chronic care, expanded, differentiated service delivery platforms (for example community service delivery and virtual interventions) to increase accessibility, and self-care models where feasible.

To link program effectiveness with efficiency, it also requires a good understanding of the cost of core interventions and program areas (see [HIV Information Note](#), Section 2 Investment Approach). This is particularly important for assessing the implications for innovations that enter the market at higher costs. For innovations with higher product costs, national programs should holistically assess the impacts of new products, going beyond straightforward commodity cost calculations and accounting for the impact on the broader health system. For innovations entering the market at relatively lower costs, budget efficiencies, whether from the commodity cost differential or health system, can likely be realized and re-directed toward other priority programmatic areas.



## Key Challenges

- *Key and vulnerable populations often do not access general health services because they face barriers to accessing them:* Services for key and vulnerable populations require tailored strategies to reduce the barriers to accessing and continuing prevention, treatment, and long-term care for successful health outcomes. Challenges to program access are also described below in [Health Equity, Gender Equality and Human Rights](#).
- *Multi-sectoral approaches are often lacking:* Planning and delivering services is often done vertically, but HIV responses require multi-sectoral approaches that reduce barriers to access and decrease vulnerability to HIV. For example, in high-incidence settings, HIV prevention services in the health sector may need to be complemented by investments to reduce vulnerabilities of adolescent girls and young women (AGYW) such as interventions to promote completion of secondary education, provide economic and livelihood opportunities, and avert early marriage or teenage pregnancy. These multi-sector approaches are often beyond the scope of limited HIV prevention resources and require resourcing from education and social welfare budgets.
- *Poor quality of care:* Poor quality of care can jeopardize long-term sustainability, for example services that do not effectively start all newly diagnosed individuals on treatment, and programs that have poor performance on treatment continuity (large lost-to-follow-up rates) may lead to an increased number of people needing more expensive second-line treatment, people returning to care with advanced HIV disease requiring more expensive interventions, and increased onward HIV transmission. Implementing quality HIV programs requires policy and operational shifts, including but not limited to adequate deployment of financial and human resources and updating necessary policies to improve service delivery (for example, task-shifting to enable nurse-led ART initiation).
- *Poorly targeted services:* Similarly, poorly targeted services will miss the individuals most in need of them, limiting epidemic impact.
- *Dependencies on external financing for health workforce for HIV:* Countries may be particularly reliant on HIV donor funding to support health workers, in particular for community-based prevention and outreach services. Well-trained community health workers, such as adherence counselors, are critical for the HIV response. Many countries do not opt to or lack a coordinated plan to retain and sustain donor-supported workers as external financing decreases and/or countries fully transition from external support.
- *Essential role of civil society and its continued dependencies on external finance:* In some countries, CSOs provide a significant share of preventive and other services, often for key and vulnerable populations, and these services may be particularly at risk if and when countries face reductions in external financing or prepare to transition from external support. This is especially true in countries without formal mechanisms or a history of publicly financing CSOs that are providing HIV services.
- *Challenges to absorb large, donor-supported HIV programs:* HIV programs designed and implemented with external funding are frequently more expansive in terms of scope of services provided and engage a greater number of health care workers than the public sector system can support alone. It may not be feasible or desirable for governments to absorb the exact same donor-supported structures. At the same time, significant changes (such as layoffs or reduced services), can create major programmatic, political, and social challenges that may negatively affect the national response.

- *Policy barriers to effective implementation:* Some countries have been slow to adopt policies that allow for implementation of proven-effective HIV interventions, such as pre-exposure prophylaxis (PrEP) and self-testing, as well as latest HIV treatment regimens (such as dolutegravir-based formulations). Other countries have adopted strong policies but encountered challenges in implementation because service delivery constraints are not well understood or reflected in ministry planning policies. Furthermore, lack of appropriate engagement of the subnational programs and partners result in sub-optimal adoption of national strategies at local level. Existing health policies may also constrain the ability and/or flexibility of programs to introduce innovations in service delivery, for instance moving towards differentiated service delivery, enabling community health workers to play a role in ARV distribution, multi-month dispensing (MMD) of products for HIV prevention and treatment, or access to HIV prevention products in pharmacies or community outlets.

## Considerations

- *Streamline program activities and costs linked to impact:* Analyze program activities for impact and link with cost data to inform program implementation and decision-making (i.e., value for money). Consider opportunities to improve targeting through differentiated service delivery. Ongoing attention to quality and outcomes benefits both effectiveness and efficiency of investments.
- *Enhance human resources planning:* Review and prioritize HIV human resources needs and strengthen human resources planning. Consider how to retain community health workers providing HIV services, which may include absorbing HIV services into community-based primary care or developing partnerships with CSOs.
- *Support civil society efforts to plan for sustainability:* National programs should consider working with CSOs to ensure their functions can continue if and when external financing decreases. This may include establishing public financing of services provided by CSOs (i.e., through “social contracting”), improving coordination and linkages of services across sectors, engaging civil society to strengthen services for key and vulnerable populations within government delivery platforms, and working with civil society to develop robust and diversified sustainability plans (See country example in Box 3). For more information, see [Annex VII on “Public Financing of Civil Society Service Provision”](#) in the STC Guidance Note.
- *Retain community engagement in the HIV response:* Consider strategies to institutionalize community engagement to help ensure that HIV-affected communities can inform the design of accessible and acceptable service delivery strategies over the long-term. Develop a plan to maintain community engagement, particularly those activities managed by non-governmental partners and funded by donor sources. For more information, see [Technical Brief: Community Systems Strengthening](#) and the forthcoming Global Fund publication [Community Engagement: Opportunities throughout the Grant life Cycle](#).
- *Evolve and expand the range of platforms for access to and delivery of people-centered HIV services.* Services should be delivered in a way that respond to individuals’ needs, providing options that leverage the strengths of public sector, community, civil society and private sector delivery systems for greater differentiation, innovation and sustainability. Examples include community-based and community-led services, integrating HIV into sexual health or chronic disease services, and expanding to online, pharmacy-based and other easy-to-access services.
- *Address policy barriers to effective implementation.* Examples include ensuring regulatory approval for new products (e.g., dual HIV and syphilis rapid diagnostic tests, new PrEP

products); ensuring lay workers and peers are able, trained and supervised to perform HIV testing, particularly among key and vulnerable populations; and ensuring that community ART initiation (per WHO guidance) is supported to make treatment available as close to point of HIV testing as possible, in particular for adolescents and key populations; ensuring task-shifting to enable nurse-led ART initiation and continuity.

- *Ensure program essentials are in place.* To help focus attention on program elements that are crucial for all national programs, the Global Fund has described HIV program essentials, which are key evidence-based interventions and approaches to ensure equity in access to high-impact services for those who need them most.

### **Box 3. Embedding civil society's leadership in the HIV response**

Many governments recognize the essential contributions of CSOs in HIV prevention and service delivery and are seeking mechanisms to support this role long-term. For example, in one southern African country the government and CSOs assessed the existing guidance on public financing for CSOs and updated it to then create a new mechanism to formalize the public-private partnership, allow the government greater financial oversight, and create more stable financing for CSOs. They prioritized keeping the guidance simple and ensuring the mechanism would be easy to manage. They also implemented a quarterly review meeting to track financing, results and ensure coordination. The Global Fund is supporting the pilot of this new mechanism through its grant, in addition to domestic financing.

## **HIV and National and Community Systems for Health**

Procurement and supply chains, diagnostic and laboratory networks, and information systems are key functions of the national health system that require special attention for HIV sustainability and transition planning. Similarly, strong and sustainable community systems are essential for providing comprehensive people-centered services, particularly to populations not well served by the formal health sector, who are often disproportionately affected by HTM.

### **Challenges**

- *Constrained availability, quality, and use of data for decision-making:* Navigating transition processes and enhancing sustainability requires programs that can effectively plan and target services, and efficiently manage procurement, human, and financial resources. Lack of adequate and accurate information on populations and geographies may lead to gaps in HIV services, ineffective planning and implementation, and inefficient use of available resources. Many country programs lack up-to-date and comprehensive data systems, the capacity to analyze data, and the programmatic flexibility to respond to emergent data. These challenges are amplified by the existence of parallel and non-harmonized data sources.
- *Lack of focus on laboratory infrastructure and capacity:* The quality and efficiency of the laboratory system is crucial for a sustainable and targeted HIV response, yet is lacking in many countries.
- *Difficulty procuring small quantities and specialized products and securing good prices for commodities:* Countries may face particular difficulties when procuring small quantities or specialized products, such as pediatric ARVs and second- and third-line regimens. Procurement may be additionally hindered by poor alignment between country procurement guidelines and evolving WHO guidance, as well as weak quantification and forecasting capacity. Furthermore, countries procuring without Global Fund support may face challenges in negotiating prices, even for those commodities procured in larger quantities.

## Considerations

- *Ensure comprehensive data systems:* Strengthen nationally standardized data tools and processes to collect quality and sufficiently detailed data on populations affected by or at risk of HIV infection. HIV information systems should specifically include data on key and vulnerable populations. Pursue opportunities to better integrate key HIV indicators into national information and surveillance systems. Countries may wish to explore alternative approaches to collecting bibehavioral data now captured by integrated bio-behavioral surveys (IBBS) at significant expense, in consultation with community members concerned about risks in confidentiality. For more information, see Annex on Health Management Information Systems and Monitoring and Evaluation included in the STC Guidance Note.
- *Update procurement policies:* Countries should work to improve responsiveness to changes in global treatment guidelines and develop policies that leverage external purchasing platforms to maximize efficiency and quality, particularly for specialized HIV treatments. Closely assess and monitor risks related to co-financing of certain HIV drugs that may have lower accessibility and supply, to avoid delays or gaps in procurement.
- *Strengthen HIV laboratory services through an integrated national laboratory system:* Countries can increase the quality, efficiency, and cost-effectiveness of the HIV response through the development of strong national laboratory systems that serve all disease areas and levels of care. (See [RSSH Information Note](#)). A national strategic plan for laboratory services should include HIV services and address HIV priorities, such as optimizing timely access to tests, adopting digital systems for results return, and determining appropriate and timely diagnostic technologies.
- *Consider adopting multi-disease diagnostic platforms:* Multi-disease testing devices can help countries achieve greater technical and financial efficiencies across disease programs. “All inclusive pricing” (AIP) contracts in which the manufacturer is responsible for the maintenance and servicing of laboratory equipment can help countries ensure adequate maintenance, and improve utilization rates and efficiencies (by reducing instrument downtime), and improve quality management processes through adoption of key performance indicators (KPIs).

### Box 4. Building an integrated laboratory system

Achieving HIV targets requires creating efficient, reliable and sustainable national laboratory systems where HIV laboratory services are integrated with other programs and sectors. Ministries of Health across all regions are increasingly recognizing the inefficiencies of siloed disease-specific laboratory networks, particularly regarding under-utilization of molecular diagnostic platforms, fragmented data reporting systems, poorly coordinated sample referral systems, and disruptions resulting from public health emergencies. To address inefficiencies, MoH governance structures across the globe have been reformed through creation of national laboratory directorates (NLDs), with a mandate to oversee and coordinate integrated laboratory services across all diseases. NLDs help provide consolidated and harmonized approaches to health product management, supply chains, maintenance and servicing of equipment, digitization of information systems, data management, contracting and many other systems components with benefits across disease programs. However, dismantling parallel disease-specific laboratory systems is challenging, and requires strong high-level leadership with a vision; it is critical to have a multi-stakeholder process with coordinated support from multiple partners to drive development of NLDs and the corresponding framework of national lab strategic plans, which have been so instrumental to realizing the gains from integrated systems.

## Health Equity, Gender Equality and Human Rights

Ensuring that all people who need services can access them is central to reducing acquisition and transmission of HIV. Human rights- and gender-related barriers, including stigma, discrimination and criminalization, increase vulnerability to HIV and limit access to services and must be addressed. However, services for key and vulnerable populations and interventions that seek to reduce barriers to access are commonly the last to be domestically financed by national programs and are often most at risk of sustainability challenges when external support is reduced.

### Challenges

- *High levels of stigma and discrimination restrict access to HIV services:* Stigma and discriminatory attitudes and actions within health care settings commonly occur, including poor quality of care and denial of services. Punitive laws and policies, such as criminalization of sex work, personal drug use or possession, or consensual same sex conduct, may make it unsafe for key and vulnerable populations to access HIV prevention, treatment, and care services. Programs focused on human rights, gender, and key and vulnerable populations remain heavily reliant on donors and civil society for financial and implementation support.
- *Social, legal, and economic inequities contribute to HIV risk:* Laws and policies relating to gender inequality (e.g., early marriage, gender-based violence and intimate partner violence, and property and custody rights) impact HIV vulnerability. Additional policies that can further place individuals and communities at increased risk for HIV include discriminatory employment practices, such as mandatory HIV testing; lack of protections for confidentiality; parental consent for HIV testing, and other gender, age, and socio-economic related practices that stigmatize or restrict access to care for key and vulnerable populations.
- *Financial barriers to access:* Key and vulnerable populations may face particular difficulties in accessing health financing schemes and may be more heavily burdened by user fees and out-of-pocket costs for services.

### Considerations

- *Use age and gender disaggregated data:* Draw on age and gender disaggregated data to identify inequities and focus attention and funding on evidence-based programs that address them. Opportunities to strengthen programming may involve inclusion of gender assessments in funding requests.
- *Pursue strategies to increase safe and equitable access to health services:* Identify, strengthen, and support community-based organizations and networks of trusted key and vulnerable populations to provide improved programming at scale. Document the cost of effective interventions for inclusion in planning and budgeting at the appropriate local or national level. Consider reviews to assess the impact of punitive policies and laws on the uptake of HIV-related services by affected populations, and the benefits of reforming or removing these policies. Support community-led monitoring and research to inform the design and evaluation of programs.

- *Reduce discriminatory attitudes and behaviors in the health workforce:* Embed programs to increase health care workers' awareness and understanding of their duty to treat all persons in a non-discriminatory manner as a part of pre-service education and workplace supervision.
- *Address fee-for-service and out-of-pocket costs as a barrier to care for vulnerable populations:* Engage in and help inform health system financing dialogues with the ministries of health and finance to reduce financial barriers for HIV services. Identify and pursue strategies to remove legal and policy barriers to inclusion of all vulnerable and marginalized populations in health financing schemes and expand equitable access to health services regardless of employment status. Monitor and quantify out-of-pocket expenditure for people living with HIV to support advocacy around financial protection.



# Annex 3: Tuberculosis and Sustainability

*TB Specific Annex to STC Guidance Note*<sup>28</sup>

## Introduction and background

The Global Fund's Sustainability, Transition and Co-financing (STC) Policy outlines the key principles of the Global Fund's approach to sustainability, transition, and domestic co-financing, and the Global Fund's STC Guidance Note provides additional details on the considerations related to strengthening sustainability, enhancing co-financing and domestic financing, and preparing for transition from external financing. While the STC Guidance Note provides overall guidance for addressing STC considerations and while many challenges are cross-cutting, in some contexts there are specific TB-related challenges that may need to be addressed in order to continue strengthening sustainability of TB programs, or cross cutting issues that are particularly relevant for TB programs.

This annex presents a number of the key challenges country TB programs may face when planning for program sustainability and are addressing reductions of external financing (including Global Fund financing), as well as suggestions to ameliorate these challenges, particularly as countries conduct program reviews, update national strategies, and develop funding requests to the Global Fund or any other donor. *It is essential to note* that both the challenges and considerations to meet them are heterogeneous, and there will be strong differences between countries and regions based on country and regional context. The challenges highlighted and considerations recommended *are not intended* to be applicable and relevant for every context; rather, they are designed to help drive increased country dialogue on key thematic areas that may hinder efforts to strengthen sustainability, and considerations that may be useful as countries and country stakeholders develop their specific responses to address those challenges.

Key areas where there may be TB-specific challenges and/or specific considerations to enhance sustainability and planning of TB programs include 1) governance and leadership of TB programs, 2) policy environment, 3) domestic financing and co-financing, 4) procurement and regulatory environment; 5) service delivery models, including attention to key and vulnerable populations, human resources for health (HRH), and health information systems. These areas are explored in more detail below.

## Governance and leadership of TB programs

Stakeholders who lead and manage TB programs that face reductions in external financing may encounter critical challenges which, if not addressed early, can affect the performance of a country's TB program.

### Key challenges may include:

- Some lower-income countries and/or high-disease-burden countries may not be planning as proactively as necessary to strengthen sustainability and/or prepare early for eventual, long-term transition from external financing, including Global Fund support.

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<sup>28</sup> This TB and sustainability annex was completed with the support, partnership, and collaboration of USAID.

- External financing may cover a significant percentage of key interventions of TB programs (e.g., drugs and diagnostics, salaries for community health workers, laboratory technicians and district coordinators, information managers, etc.) and lengthy and difficult negotiations may be required at the country level to allocate funding or introduce policy changes to support sustainability of these interventions.
- TB programs in some countries may be embedded within lesser priority programs of the Ministry of Health, and therefore may receive less political attention from leadership, making it hard to advocate for increased domestic financing and sustainability of externally financed interventions.
- With the introduction of external financing, many countries were able to expand programs, including to key and vulnerable populations, and include important new actors for TB efforts, such as civil society, private sector, and other stakeholders.

To address these challenges, country stakeholders may want to consider:

- Dialoguing early with external donors regarding the continuity of external investments, including timelines and processes for transition from external financing – ideally multiple allocation cycles prior to full transition from Global Fund financing.
- Including sustainability and transition considerations when conducting national reviews of TB programs and when updating TB NSPs, including defining how major areas currently financed by external financing will be supported with domestic financing, where efforts will be undertaken to enhance efficiency of the national responses, etc.
- Consider developing longer-term approaches to sustainability and beginning sustainability planning (including in the context of NSP development and funding request development), particularly for those lower income and middle-income contexts where sustainability planning for TB programs is still in its early stages.
- Since TB programs may receive less political attention in some contexts or compete with other health issues, seek the highest possible level of political commitment to key aspects of TB sustainability and transition planning.
- Strengthen early planning to identify and address context-specific challenges related to access to quality-assured and affordable health products (e.g., local regulation, local budgeting and financing, access to international pooled procurement mechanisms, etc.) as countries assume a greater share or increase co-financing of health product procurement and financing.
- Look for ways to institutionalize multi-stakeholder oversight functions (including those that include affected populations) at a high level within the government to maintain a strong focus on TB, particularly in places where there is less TB advocacy and coordination at the country level.
- In partnership with key local stakeholders (including local TB caucuses and parliamentarians), keep commitments to the Sustainability Development Goals and United Nations High-Level Meeting prioritized, including emphasizing the importance of materializing commitments made globally at the country level.

## Policy environment for TB programs

To improve sustainability, the TB policy environment should accommodate either new or revised policies that are essential to strengthening TB program outcomes. *Policy-related challenges may include:*

- It may be unclear to what extent TB and TB-related concerns are considered in countries undergoing health reforms, including (but not limited to) the degree to which TB is included in benefits packages and the extent to which payment mechanisms align with the needs of quality TB care.
- Certain policy changes/modifications introduced with Global Fund financing—such as contracting mechanisms for civil society and the private sector to engage with the government and carry out specific aspects of national TB programs—may not be institutionalized. These non-governmental TB providers are often key to a holistic national TB response

Considerations to address these policy-related challenges may include:

- During health reform efforts, consider, as appropriate, the inclusion of TB in the health benefit packages of care. Ensure that a well costed NSP for TB exists to assist with the inclusion of TB medicines, diagnostics, and/or other relevant interventions in benefit packages, as well as for the inclusion of social support/adherence and ancillary services/commodities costs, and community TB services in domestic budgets. Ensure that TB is included in discussions about how to strengthen PHC and reach UHC. When exploring UHC approaches, consider designing them in such a manner that they make explicit provisions to support TB public health interventions in the community, and capitalize on the concurrent expansion of UHC and the potential for national health insurance to incentivize private providers to deliver quality TB care.
- Seek to institutionalize, as early as possible, new innovations or policy changes that were introduced with external financing, such as contracting with civil society organizations CSOs/NGOs for community services, national health institutes for research, and private sector service providers, for detection and treatment to carry out the full TB program. This should include planning a transition process for such contracting, including definition of the necessary policy framework and capacity building in contracting for government stakeholders.
- Consider linking TB related vulnerable households with already existing social protection and nutrition schemes

## Domestic financing and co-financing for TB programs

Successful TB programs require significant increases in domestic financing to fill critical funding gaps, particularly as external financing is reduced. Specific financing challenges may include:

- The true cost of eliminating TB may not be known, whereas budgets for external financing are well defined. Thus there is the potential for national TB financing discussions to focus only on replacing external financing and not plan for financing for the overall program required to end TB. Focusing only on external financing could underestimate the cost of ending TB and may not be aligned with a country's TB epidemiology.

- There may be inadequate domestic financing or co-financing for CSOs/NGOs or private sector activities, even if contracts with these entities are legally possible. This may lead to little or no early co-financing of case detection in the community or TB advocacy efforts, both often carried out by CSOs.
- TB programs may not always be intimately aware about how the details of the TB services are funded through the national general or line-item budgets, and therefore challenged when it comes to advocating for additional or more effective uses of resources.
- TB programs have been less inclined to engage in the development of both medium term and annual expenditure frameworks both at the national and sub-national levels. These frameworks eventually translate into national and sub-national health budgets.
- When new WHO treatment or diagnostic guidelines are released, countries may not be able to respond quickly and support for responding to new or changing TB protocols may not be included in the country's health budget or procurement systems.

#### **Considerations for addressing these challenges may include:**

- Ensure that the full TB program costs are clearly defined so that countries have a clear picture of what is needed to ensure financial sustainability. Strengthening costing of the full TB program (and not just portions financed by external financing) can help ensure clarity on the costs required to end TB.
- Early on, on-budget co-financing of critical interventions financed by external financing may help build national ownership and institutionalization and establish the mechanics of domestic funding streams before external TB financing decreases.
- Where advocacy for TB could be helpful in achieving increased domestic financing for critical interventions, consider using external financing to strengthen domestic advocacy.
- To ensure efficient TB programming, analysis and improvement of public financial management systems for TB are critical, to encourage use of limited domestic TB budgets.
- Encourage proactive involvement of national TB programs in national and sub-national budget making processes, and support programs have access to relevant technical expertise for such process.
- Encourage and advocate for inclusion of TB in already ongoing Ministry of Health results-based financing programs

#### **Procurement and regulatory environment for procurement of TB drugs and diagnostics**

In some contexts, external financing provides significant funding for TB drugs (particularly second line) and diagnostics (such as GeneXpert instruments and cartridges). Although this support has catalyzed significant progress in reducing TB globally, as external financing reduces country procurement and regulatory systems may not be adequately prepared to absorb the acquisition of the formerly donor-funded TB drugs and diagnostics and ensure ongoing access to quality, affordable health products.

*Specific regulatory environment and/or domestic procurement challenges may include:*

- Regulations related to domestic procurement may create barriers to accessing international pooled procurement mechanisms, including requirements related to national procurement or requirements for nationally run competitive tenders. In addition, when new recommendations on TB diagnosis and treatment are released by the WHO, local regulatory rules may not be sufficiently nimble to adapt quickly.
- While individual registration ensures proper quality, safety, and efficacy reviews per product, when each new drug or diagnostic requires its own registration, the processes may be lengthy and challenging in some contexts. Local registration processes may create barriers for manufacturers to register new drugs or diagnostics, potentially reducing local availability.
- The Global Fund requires that TB drugs procured with its funds are WHO prequalified, registered by a stringent drug regulatory agency, or ERP approved. TB diagnostics procured with Global Fund financing are recommended by WHO TB program, WHO prequalified, stringently assessed by a stringent regulatory agency, or ERP approved. When procured using domestic financing, manufacturers may not be required to meet standards that reach the levels required for WHO prequalification or approval by a stringent national regulatory authority, potentially impacting the quality of TB drugs.
- Countries may not have sufficient quality assurance and oversight guidelines to assure that locally produced TB drugs are of sufficient quality to effectively ensure program outcomes.
- Countries may not have all TB drugs, particularly newer drugs and second-line anti-TB drugs (SLDs), in the local essential drug list.
- Capacity for local tender processes may be weak.
- When a domestic tender involves a low volume, international suppliers may have less incentives to bid.
- In cases where drugs or diagnostics are being purchased with external financing, value added tax (VAT) or other import or duty taxes may be exempted. Reintroduction of such taxes may raise local prices for delivery of goods.
- Domestic procurement regulations may not allow for purchasing on-credit from global pooled procurement platforms.
- In some countries, domestic procurement (and financing) of health commodities is decentralized or conducted by several entities. This creates additional challenges in moving from a typically centralized, donor-funded procurement process to a decentralized, domestically funded process, requiring consideration of how both the financing and procurement processes can be adapted and ensured in multiple locations in the country.

**Considerations to address these critical procurement and regulatory challenges may include:**

- Consider early adoption of legislative and regulatory changes to allow access to international pooled procurement platforms with domestic public funds. Consider the use of international pooled-procurement platforms, such as but not limited to the Global Drug Facility, to access quality-assured affordable TB medicines and health products, particularly where there are concerns that other procurement methods will result in sub-optimal quality or price or where volumes are low.

- Explore cluster-pooled procurement or pooling demand with other countries to increase negotiating power, where possible.
- Consider enrolling in the WHO Collaborative Registration Procedure (CRP) to facilitate national registration and reduce regulatory challenges.
- Consider reduction of regulatory barriers for registration of new drugs and diagnostics recommended for TB by the WHO and seek other local solutions which would allow for expedited registration of TB commodities which already have WHO prequalification or registration from a stringent regulatory authority.
- When the legislative and regulatory changes for accessing non-registered TB drugs and diagnostics will be lengthy, consider short-term importation waivers for unregistered products needed for TB while proactively working to accelerate national registration.
- Continue strengthening national mechanisms to procure and monitor quality-assured affordable health products, including national regulatory authorities.
- Explore regulatory and policy pathways that would allow tax exemption for certain TB commodities, even when those commodities are procured and financed domestically.
- When considering local production as a long-term solution to ensuring access to TB drugs and diagnostics, carefully consider cost/benefit analysis which includes quality and supply requirements.
- Strengthen the use of forecasting tools to improve forecasting accuracy for TB drugs and diagnostics.
- Consider strategies for enhancing transparency throughout the procurement and tendering processes, including information on pricing, bidders, and tenders.
- In countries with decentralized procurement of health commodities, explore the introduction of systems that aggregate at least some procurement functions at the national level (e.g., pooling of demand, issuing bids, and price negotiation) even if commodities financing remains a decentralized activity. Ensure such systems are open to participation by both public and private providers.
- Explore the use of service level agreements between Ministries of Health and relevant product manufacturers

### **Service-delivery models, including attention to key and vulnerable populations, human resources for health (HRH), and health information systems (HIS)**

The health system context, including the role of CSOs, available HRH, and HIS systems which support TB programs must all be considered when planning for sustainability of TB programs.

#### **Key challenges for these areas include:**

- In certain contexts, there may be TB stand-alone or hospital-based TB programs that result in inefficiencies in service delivery models, and/or other inefficient use of resources (ie, mass screening). This may make TB programs more expensive and less efficient than using WHO-



recommended models of care (e.g., community based or outpatient care since government health budget may be determined by number of beds).

- For a variety of reasons, traditional, government-led TB programs may not target or prioritize key and vulnerable populations that are often most affected by TB, such as incarcerated populations, people living with HIV, migrants and/or indigenous populations. External financing has typically expanded TB programs to address these vulnerable groups, often through contracting directly with CSOs/NGOs. When external financing decreases, these groups may lack access to critical services.
- Specialized human resources are required to manage cases of drug-resistant TB in children and adults, deliver adequate services for case detection, and scale-up of diagnostic and laboratory capacity. In some countries, training and education of new providers has not been updated to align with new global guidelines.
- Because the human resource program support costs for TB are sometimes less identifiable and often linked to broader health system human resources, domestic funding for these support systems, including supervision and related costs, training, and incentives, may be less visible and therefore more challenging to secure from domestic sources.
- Domestic financing, particularly in countries that are adopting social health insurance, may focus more on compensating curative care rather than on financing other public health functions, such as adherence support, recording and reporting, tracing loss to follow-up, contact investigation, and latent TB treatment. In the absence of specific financing and staffing for these public health functions, the overall TB response may suffer.
- TB Programs funded through external financing typically have support for the strengthening of the TB information system. These systems allow for procurement forecasting, use of sub-national data for decision-making, and efficient use of CSO TB services. While these systems provide the progress-monitoring required by both the national program as well as the grant requirements, they are frequently funded as parallel systems susceptible to reductions in external financing.

To strengthen a more comprehensive TB response, options to address these challenges may include:

- Where relevant, consider modifying the TB care model from in-patient/hospitalization to greater out-patient services and community-based services, to strengthen efficiency of service delivery and improve care of TB patients.
- Consider the use of allocative efficiency tools to help guide the design of country TB programs, to maximize investment efficiency while ensuring equitable access to TB services.
- TB leadership should consider prioritizing key populations as part of the country's TB program and institutionalizing this decision as part of their TB NSP, and also highlight these populations for more intensive effort in sustainability and transition planning.
- Encourage a key role for CSOs and the private sector to cover TB services not provided by the public sector (e.g., case detection via the CSO and diagnosis and treatment by the private sector). Leverage existing external financing to begin the process of institutionalizing contracting of CSOs and ensure that they are on-budget and flow through government

systems, to help encourage longer term domestic financing through government contracting mechanisms.

- When planning, take into account human and financial resources needed for training TB care providers on new WHO TB protocols, and look for ways to increase efficiencies (i.e., distance learning) and to finance the support factors (supervision, transport, etc.).
- Consider developing specific financing and staffing arrangements dedicated to the provision of TB public health functions. Such staff could support both public and private providers who are being compensated primarily for the curative aspects of TB care.
- Ensure integration of key TB program indicators, key procurement indicators and forecasting processes, and CSO TB program data into the national health information system.

## **Conclusion**

Early planning and strong governance / leadership, a supportive policy environment, sufficient domestic financing, a streamlined procurement and regulatory environment for procurement of TB drugs and diagnostics, and a supportive service-delivery model that includes attention to TB-specific key populations, HRH, and HIS may help strengthen the sustainability of national TB programs. Given the scope of challenges in these areas, countries should consider establishing clear timelines for introducing the necessary reforms gradually, but with specific, mutually agreed upon milestones and accountability mechanisms while external financing is still available.

# Annex 4: Malaria and Sustainability

*Malaria-specific Annex to STC Guidance Note*<sup>29</sup>

## Introduction and background

A wide variety of countries receive financial support from the Global Fund to advance their national and regional efforts to control and eliminate malaria. The Global Fund's Sustainability, Transition and Co-Financing (STC) Policy encourages countries to embed sustainability considerations in grant and national program design and proactively plan and prepare for transition from the Global Fund. As per the Global Fund's STC approach, national malaria programs are anticipated to increase domestic financing of malaria programs as they experience increases in national income, reduce malaria burden, and/or achieve national malaria elimination.

As external financing reduces, various factors – such as the epidemiology of malaria transmission and strength of the national malaria program and health system – may present challenges with respect to how malaria prevention and response activities are managed, financed, and implemented. To effectively strengthen sustainability and manage the transition from Global Fund malaria support, countries may need to conduct detailed planning and implement adjustments to ensure changes in external finance do not threaten progress to achieve and maintain malaria elimination.

This annex outlines malaria-specific sustainability and transition considerations, organized by various thematic areas: political will and governance, human resources, financing, epidemiological surveillance and information systems, program implementation and service delivery, and supply chain. For each area, this annex presents the principal challenges countries may experience, and a set of potential responses to mitigate these challenges and strengthen long-term program sustainability.

National malaria programs are diverse in their structure and capacity, and the economic, policy, and health system environments in which they operate also vary widely across country and region. In addition, the scope of Global Fund financing for malaria varies by country, from broad support across program activities to support for targeted interventions or particular high-risk geographies. As such, the challenges and responses presented in this annex are not intended to serve as prescriptions applicable to each country, but rather as indicative of the major programmatic areas national malaria programs and their partners should consider as they move to strengthen sustainability, mobilize domestic financing, and prepare for transition.

## STC challenges and responses

### Political will and governance

Countries working to enhance domestic financing for malaria, particularly those facing reductions in external malaria financing, will need to generate and maintain political will to ensure the national malaria program has adequate resources and policy attention to achieve and maintain impact. National malaria programs will also need to adapt their governance systems as they re-orient their programs towards elimination and prevention of re-establishment (POR), or seek to leverage integration, decentralization and other health sector reforms as an opportunity for accelerating

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<sup>29</sup> This Malaria sustainability annex was completed in collaboration with UCSF-Malaria Elimination Initiative.

progress with shifting financial constraints. While political will and good governance are important for all health programs that face reductions in donor financing, there are unique aspects of malaria programs that make generating and maintaining political will and developing new governance frameworks particularly essential. Key challenges and potential responses in this area include the following:

#### Challenges:

- *Generating political commitment for a low-burden disease:* Political support for malaria typically declines as malaria becomes less visible and other health issues take precedence. This is a particular risk in countries nearing malaria elimination or focused on POR, where Global Fund financing can help catalyze financial and policy support to maintain essential services for a low- or no-burden disease. Additionally, malaria programs often lack adequate engagement with other sectors (e.g., environment, labor, military, private) to mobilize broader political and implementation support.
- *Maintaining attention to marginalized and vulnerable populations:* It may be hard to sustain political will when malaria transmission is concentrated among migrants, indigenous communities, or other marginalized populations that may not be sufficiently prioritized or included in national policies.
- *Civil society support for the malaria program:* Unlike other diseases, there tends to be limited engagement of civil society in advocacy for malaria; therefore, malaria advocacy is typically led by national malaria programs. Advocacy success is often tied to the capacity of malaria program managers to provide political leadership and navigate budget decision-making processes.
- *Gap in management capacity:* Changes in malaria transmission, financing, and health sector reforms may require adjustments to the structure of malaria programs, such as re-sizing the program for efficiency. Some malaria programs lack the change management skills needed to oversee these changes. Poor coordination across national and sub-national program levels may further constrain management, particularly in the context of decentralized health systems.

#### Considerations:

- *Embed advocacy capacity across multiple levels of program governance:* Malaria program managers will need to play a more central role in malaria advocacy as countries face reductions in external financing. The national malaria program can work with partners to strengthen relationships with senior leadership within ministries of health and finance, and to broaden the stakeholders invested in malaria and elevate the priority of malaria.
- *Strengthen sub-national leadership and management:* Sub-national leadership is crucial, particularly in countries with highly localized malaria efforts and decentralized health systems. The national malaria program can facilitate early and active engagement with sub-national policymakers, such as by building the capacity of sub-national program managers to lead local malaria activities. Strengthening sub-national program management can also promote efficient and effective local programs, particularly in high-burden areas.
- *Focus attention on vulnerable populations and regions:* National malaria programs can work with country stakeholders and partners to develop strategies for ensuring the sustainability of services to high-risk populations and geographies, which may be particularly reliant on

external finance and thus vulnerable to reductions in external financing. This may also include cross-border and private sector partnerships, where relevant.

- *Consider elimination targets:* Setting a target date to achieve malaria elimination may help to engage senior political leaders within the Ministry of Health and other ministries. Incorporating strategies to achieve elimination into national strategic plans for malaria may also help to mobilize stakeholders around a shared goal. Certification (malaria free) can be a critical motivator for countries to allocate resources to intensify activities, ensure continued surveillance and prevent reintroduction and resurgence.
- *Build national malaria committees to support advocacy and technical capacity:* In transition contexts, high-level oversight bodies dedicated to malaria control and elimination may help fill some of the advocacy and technical review functions previously supported by the Country Coordinating Mechanism and other Global Fund-supported partners. National malaria elimination committees or independent technical committees could also serve this role.
- *Leverage regional initiatives:* Regional initiatives may help elevate malaria on national and regional policy agendas and mobilize domestic resources for malaria (for example, by activating a mandate for malaria elimination from senior political leaders and linking to financial partners). Country programs may need to engage early with regional partners to build technical, financial, programmatic, and political support to strengthen sustainability.

## Human resources

Global Fund grants often support a portion of a country's health workforce for malaria, including strategic, technical, and program implementation staff within health ministries and civil society organizations. Reductions in external financing therefore necessitate substantial planning to ensure essential capacities are maintained. Additionally, reductions in external financing or full transition may coincide with the move from a control to an elimination-oriented program, or from elimination to a POR program, during which time malaria programs may also undergo significant shifts in the size and structure of the malaria workforce. Key challenges and potential responses for successfully managing these overlapping changes in human resources for malaria include:

### Challenges:

- *Policy barriers to absorbing Global Fund-supported positions:* National malaria programs often face a number of policy barriers to absorbing or retaining key staff supported by the Global Fund, such as higher compensation than equivalent national salary scales for similar positions; positions not included in human resource plans (e.g., HRH plans; HRH establishment); short-term hires (e.g., for indoor residual spraying).
- *Loss of key staff positions and capacities:* Where the national government is unable to absorb or retain key Global Fund-supported positions, reductions in Global Fund finance and transition can result in a rapid loss of human resource capacity. Eliminating and POR countries may have difficulty justifying the hiring or retention of malaria-specific staff given little to no disease burden.
- *Declining malaria knowledge in eliminating and POR settings:* Clinical and public health staff may lack awareness and knowledge about malaria, particularly in eliminating and POR settings where there have not been recent cases. This can result in delayed or missed diagnoses, jeopardizing malaria program goals.

## Considerations:

- *Support HRH planning (optimization of workforce needs):* National malaria programs should assess the skills, staff, and cadres required at each level of the health system to sustain the malaria response, based on anticipated future transmission. skills mix (i.e., mix of cadres) to sustain service coverage and quality. This can include determining how functions can be integrated within the health system, and the optimal mix of skills and cadres at each level to ensure service delivery is sustained at an appropriate coverage and quality. Sustaining HRH investments may not necessarily mean continuing funding all currently supported positions supported by the GF, especially if future transmission needs are changing, or GF-supported staff have been remunerated at a significantly higher level than national position equivalent.
- *HRH strategic planning:* Malaria program engagement in the national HRH strategic planning processes can help ensure the longer-term needs of malaria programs are built in costed HRH plans that underpin government's HRH investments. This should include the community workforce involved in both preventative, promotive and curative interventions. An updated, costed human resource plan, integrating malaria workforce requirements, may help support advocacy and resource mobilization strategies.
- *Engage in early and strategic advocacy to absorb and/or retain key malaria staff:* Sustainability of human resources for malaria may require updating government human resource policies and/or mobilizing additional resources, both of which may take significant time and require the support of ministry-level decision-makers. It is important to start this process well before expected reductions in Global Fund finance and tie this into governments' own timelines for HRH strategic planning, which often have long lead times. The Global Fund's co-financing policy may be a tool to ask for uptake of specific positions deemed essential to the maintenance of the malaria program.
- *Embed malaria training in medical and nursing curricula and continuous professional development:* Ensure that facility and community-based health workers are knowledgeable about malaria case management throughout malaria elimination and POR phases.
- *Embed malaria in routine integrated supportive supervision processes:* ensure that key malaria program quality indicators are embedded in routine integrated supportive supervision process, so that deviations from strong performance at sub-national level can be rapidly picked up and quality improvement measures including refresher training rapidly tailored to competence strengthening needs.
- *Develop knowledge management processes:* Consider strategies to ensure that staff turnover, including that due to changes in external finance, does not result in the loss of essential institutional knowledge (e.g., procurement management) and relationships (e.g., connections with policymakers and political leadership).

## Financing

Reductions in external financing or full transition from Global Fund support may create funding gaps that inhibit program operations and the sustainability of national malaria programs. Countries may face a number of financial, policy, and information constraints to effective domestic resource mobilization for malaria programs. Key challenges and potential responses regarding program financing include:

## Challenges:

- *Cuts to functions that facilitate efficiency:* It is likely that even where domestic investments increase in response to reductions in external financing or full transition, total funding levels may decrease, requiring country programs to increase efficiency and/or adjust program activities.
- *Limited financial management systems:* Few malaria programs have budget management and expenditure tracking systems to support resource mobilization and improve the strategic allocation and utilization of resources, especially at sub-national levels.
- *Loss of flexibility:* External financing often provides countries with a more flexible source of funding than domestic budgets to support priorities beyond routine activities, such as strengthening the malaria information system or hiring contract staff for malaria responses in targeted regions. Even in situations where domestic financing is available to fill gaps from reductions in external financing, the lack of flexibility in government budgets may make it hard to respond to emerging priority areas.
- *Loss of external leverage for domestic investment:* External financing not only provides monetary support to program operations but also provides a valuable signal to the national government and other partners about the importance of the malaria program.

## Considerations:

- *Start early:* Mobilizing government commitments for domestic funding can take time. Consider developing detailed investment cases to quantify the value of elimination and POR and support co-financing and resource mobilization activities.
- *Focus on improving efficiency:* Strengthened sustainability will require a greater focus on improving program efficiency, including better targeting of malaria control and elimination activities to high-risk areas and populations. A priority is to define the minimum necessary investments to maintain progress and conduct detailed costing to determine program needs and opportunities for efficiency (e.g., opportunities for improved targeting based on local transmission dynamics and epidemiology).
- *Consider leveraging health sector reforms for malaria:* Broader health system policies such as contracting of non-state actors (often referred to as “social contracting” in Global Fund contexts) and universal health coverage may provide additional financial and implementation support to support essential malaria activities.

## Epidemiological surveillance and information systems

Strong surveillance and information systems are essential for malaria program sustainability. Targeting and tailoring program activities is a high priority for all national malaria programs to improve impact and efficiency and requires strong data and information systems. Key challenges and responses for surveillance and information systems include:

### Challenges:

- *Reliance on external support:* National malaria programs may rely on external funding to support surveillance and information systems, including the hardware and software of information infrastructure (such as cloud ability, security, computer systems, smart phones, and IT). Country programs may lack ownership of, or the ability to effectively use, their data.



- *Loss of technical advisory services:* National malaria programs may rely on Global Fund-supported technical experts who advise on the design and targeting of malaria control and surveillance activities. Programs may face challenges in integrating this expertise into government-funded programming or maintaining technical support with government funds.
- *Parallel and fragmented systems:* Some malaria programs manage Global Fund-supported surveillance and information systems that operate in parallel to government systems and structures. Where this occurs, programs risk losing key components of their information systems when these are not integrated into government-managed systems prior to transition.
- *Lack of data for planning:* A barrier to efficiency is that many countries lack either the data or capacity to carry out micro-stratification activities to identify the risk of malaria at a sufficiently small geographic level to effectively plan and target programming.

#### Considerations:

- *Invest in integrated national information systems and evidence-based decision making for malaria:* Countries that make large systematic investments in their malaria information systems or are able to effectively leverage and strengthen available national data platforms (e.g., DHIS2) to ensure integrated systems, are often better positioned to strengthen program management and efficiency. Programs should prioritize investments on data quality, access, and usability, and take steps to assess and plan for integration of vertical systems, as applicable<sup>30</sup>.
- *Consider partnering with national academic institutions:* Local academic partners can support the malaria program's information systems and data use through research, monitoring, surveillance, and other activities.
- *Leverage community-based surveillance systems and rapid response teams:* Where available, leveraging community-based programs may help to improve surveillance and response for malaria.

#### Program implementation and service delivery activities

Reductions in external finance and transition from Global Fund support can introduce new tensions for national malaria program managers, who must balance pressures to improve efficiency with the need to maintain sufficient program implementation and service delivery coverage to maintain progress towards malaria goals and prevent resurgence. Key challenges and responses for program implementation during transition include:

#### Challenges:

- *Determining the appropriate level of integration:* Integrating aspects of the vertical malaria program into the broad health system may help promote long-term sustainability of the program. However, there is a risk that adequate attention to malaria and necessary technical skills could be lost during integration. There is limited evidence to inform the appropriate level of integration, and to ensure the maintenance of sufficient technical expertise and quality in an integrated system.
- *Lack of evidence to inform POR program structure:* Countries nearing elimination and under POR face important questions regarding the appropriate scale of vector control and other

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<sup>30</sup> For detailed guidance on evidence-based decision making please see the [malaria information note](#)

program activities, including if these programs should be scaled back, how much, and when. To date, there is a lack of evidence to guide these decisions.

- *Ensuring technical skills and quality assurance:* Retaining the technical expertise of the malaria program, including highly skilled entomologists and laboratory technicians, is essential for quality assurance, malaria prevention, and response. Under reduced funding and/or integration, malaria programs may struggle to maintain these functions.

#### Considerations:

- *Strengthen evidence to inform program strategy and structure:* National malaria programs should consider working with technical partners to monitor and evaluate their response to policy and program changes, such as integration, decentralization, and POR. This evidence can help inform national and global decision-making on how to achieve and maintain elimination with changes in financing and governance.
- *Improve targeting of interventions:* National malaria programs should consider ways to sharpen the targeting and tailoring of program interventions at the subnational level.
- *Consider integrating entomological surveillance and vector control:* Vector control activities can typically be integrated with those of other vector borne diseases. For example, malaria requires different traps for different mosquitoes, but with training, vector surveillance staff can manage this alongside other efforts. Countries should consider sufficient planning, training, and monitoring to support integration.
- *Leverage regional platforms for learning and collaboration:* These platforms may facilitate the development and sharing of best practices for countries undergoing changes in external finance and seeking support in developing responses to support long-term sustainability.

## Supply chain

As countries assume a greater role in procurement and supply chain responsibilities, perhaps in response to reductions in external funding or transition, they may need to develop or strengthen national procurement processes and regulations. Key challenges and responses for supply chain are listed below. Please note that this guidance note also includes a separate annex on [Health Product Management](#) with many relevant considerations for malaria programs.

#### Challenges:

- *Challenging environment for procurement:* Regulations and procedural issues governing procurement of malaria commodities may present barriers to the timely procurement and distribution of quality-assured commodities. Specific challenges for malaria programs include: (1) procuring small quantities of commodities in eliminating and POR countries, including identifying suppliers who will enter contracts and provide adequate prices for small quantities of commodities; (2) burdensome administrative processes that inhibit rapid procurement in response to outbreaks and may limit effective utilization of regional or global procurement platforms; (3) insufficient quality assurance mechanisms.
- *Need for continued vector control commodities:* Vector control remains a commodity-heavy and necessary function of malaria programs, even after elimination is achieved. To prevent resurgence, malaria programs will need to ensure sufficient financing and management of vector control commodities.

## Considerations:

- *Address procurement challenges early:* Focus on streamlining and updating regulations and administrative procedures governing procurement to facilitate sustainable procurement of high-quality and affordable commodities, even before these interventions are assumed by domestic financing / procurement.
- *Leverage regional or global procurement platforms:* Platforms such as Wambo and the Pan American Health Organization's (PAHO) Strategic Fund may offer malaria programs alternative procurement mechanisms to overcome the challenges of procuring small quantities of quality-assured commodities. Other bodies, including WHO and regional economic communities, have procurement mechanisms that could potentially be leveraged to support malaria programs both before and after transition. The WHO and regional malaria platforms can also provide technical support to country programs on effective management of the procurement process.
- *Consider regional warehousing approaches:* Regional warehousing, in conjunction with regional procurement, could facilitate access to commodities during emergencies as well as commodity transfers between countries. Additional information may be required to determine the utility of this approach for malaria.
- *Strengthen logistics management information systems and sub-national distribution:* Improving national supply chain systems is critical across disease areas. For malaria, it's particularly important that program managers be able to manage and distribute drugs and other commodities in a timely manner.
- *Engage the private sector:* Where appropriate, leverage private sector partnerships to finance or support implementation of malaria program activities. For example, this could include engaging specific sectors or industries whose employees make up a high-risk group for malaria or who operate in a high-risk geography.

# Annex 5: Health Product Management (HPM) and Sustainability

*HPM-specific Annex to STC Guidance Note*

## Introduction and background

Many countries supported by the Global Fund are assuming greater ownership of health product procurement, management, and supply through domestic financing and systems. This is a positive trend that is essential to the Global Fund's ability to support scale up of investments in other critical interventions necessary to end the epidemics. The Global Fund's STC policy encourages uptake of all programs costs in national strategic plans, including health products, human resources, interventions for key and vulnerable populations service delivery, and other interventions supported by external financing. However, due to the significant investments made by the Global Fund in health products, these costs are often gradually taken up by countries (including as part of co-financing commitments), including as countries face reductions in Global Fund support, increase their financing of disease programs and/or prepare for transition from Global Fund financing.

Many countries already successfully procure, manage, and distribute quality assured health products using domestic financing and through national supply chain systems, including products for HIV, TB malaria. This said, there are real challenges in some contexts maintaining access to quality assured health products, particularly when countries previously using Global Fund financed and/or supported systems take greater responsibility for procurement and management. For sustainable, quality and effective national disease responses it is critically important to ensure that these challenges are effectively addressed and that the level of access to quality assured health products, often strengthened at the time of Global Fund support, is maintained and further improved.

This annex outlines key challenges countries may face when increasing financing and their role in the procurement and management of health products, as well as considerations to avoid or address those challenges. The annex is not intended to be exhaustive or comprehensive. Rather, it's intended to highlight potential challenges that could negatively impact the sustainability of a country's national disease response, as well as key considerations that countries are encouraged to consider during the development of Global Fund funding requests, grant-implementation, and national planning. It is also essential to note that both the challenges and considerations to meet them are heterogeneous, and there will be strong differences between countries and regions based on country and regional context. The outlined challenges and considerations may not be applicable to and relevant for every context. Instead they are designed to help drive increased dialogue on key thematic areas that may hinder efforts to strengthen sustainability, and considerations that may be useful as countries and country stakeholders develop their specific responses to address those challenges.

## Understanding the HPM building blocks

To think about challenges and key considerations in health product management, it is helpful to understand and consider the HPM building blocks. Each building block impacts the ability of a health system to regulate, procure, and manage quality assured health products to those who need them. These building blocks include:

Building Block	Description
<b>Policy, legislation, and regulation</b>	This is the national regulatory, legal, and policy environment that applies to and regulates management of health products and as such may have impact on access to health products in a given country. The objective is to improve access to affordable, quality assured products that may face market entry barriers due to regulatory constraints, protective procurement legislation, public procurement regulations, weak governance, or lack of transparency.
<b>Selection and Rational Use</b>	This encompasses the existence of modern and updated treatment and diagnostic guidelines that are aligned with the most recent WHO or internationally recognized norms and standards. Selection of products as per the applicable guidelines and existence of systems to ensure right prescription and rational use are also addressed in this topic.
<b>Procurement and Sourcing</b>	This includes products procured efficiently and supplied reliably, ensuring evaluation beyond unit price (i.e. best VfM); employing the total cost of ownership, and ensuring service and maintenance provisions where applicable (e.g. health equipment, including laboratory technologies and devices or other supportive equipment).
<b>Supply Chain</b>	Efficient and responsive in-country supply chains (from the estimation of need through to the products' use), including warehouse infrastructure, inventory management processes, distribution systems, and security at all levels of the supply chain.
<b>Organization and Management</b>	This includes ensuring that the HPM system has adequate people, policies, systems, and processes to support the delivery of products and provision of services. This should also address: human resource capacity to plan, manage, and deliver procurement and supply chain services, including waste management; and information systems to collect, analyze and report data

## Ensuring sufficient financial resources, alignment, and early planning

First and foremost, it is essential to ensure adequate financing is available for health products to meet the needs and targets of national strategic plans, and to align the timing and distribution of that financing with the procurement cycle. Ensuring sufficient financing and strong public financial management of available resources can help strengthen availability and distribution of health products, reduce the likelihood of stock-outs, and increase long-term sustainability. In addition, strengthening early, proactive, robust, country-owned planning – *including long before countries transition from the Global Fund and as they assume a greater share or increase co-financing of health products* – can help highlight and address potential challenges in advance of reductions in external financing.

## Key challenges and considerations across the HPM building blocks

In addition to core considerations of sufficient financing and early planning, based on lessons learnt from ongoing implementation of Global Fund financed programs, there are various key challenges countries may face, as well as key considerations that may be helpful for countries to consider as

they develop Global Fund funding requests, update national strategies, and/or review the efficiency and efficacy of their programs. To structure the dialogue around challenges and mitigation measures, this annex is organized into thematic areas based on the HPM building blocks. They include:

Potential Challenges	Key considerations and tools to address
<b>Policy, Legislation and Regulation</b>	
<p>As countries increase use of national funding and systems to procure health products, domestic policies and legislation need to assure access to quality assured health products. Significant challenges can arise, including with respect to:</p> <ul style="list-style-type: none"> <li>• <i>Products of Public Health Interest</i> – Key products for HIV, TB, and malaria programs are not always prioritized for funding and/or included in a national essential medicines and diagnostics lists, which may negatively impact proper procurement, registration, and tax exemption.</li> <li>• <i>Regulatory framework / quality</i> – Greater use of country systems is essential to long term sustainability. In certain contexts, however, increased reliance on country quality standards may be limited or not aligned with internationally recognized stringent quality standards could impact quality and safety of procured health products. Weaknesses and gaps in some national regulatory systems that enforce quality and safety of health products may be insufficient and weak, or implementation of those systems may be ineffective. This may impact a country’s ability to acquire quality-assured health products</li> <li>• <i>Procurement legislation</i> – <i>Outdated</i> procurement legislation and regulations, or those with protective provisions may unintentionally limit access to affordable and quality assured health products by creating barriers for products to enter a local market. Furthermore, legislation may require national procurement. This is particularly true for ‘small market’ countries with low demand or for low-volume limited use products.</li> </ul>	<p>To address these challenges, countries may consider:</p> <ul style="list-style-type: none"> <li>• Mapping and or analyzing access issues and agreeing to a country-led response. This may include reviewing outcomes and limitations of the previous procurement processes.</li> <li>• Introducing flexibility in national legislation that allows at least an option of access to international pooled procurement mechanisms. This is particularly important where, based on historical experience, there have been challenges related to sourcing of quality assured health products at affordable costs.</li> <li>• Promoting that WHO recommended optimal products are used by disease programs, including development or update and use of clinical guidelines and national essential medicines and diagnostic lists. These products are also generally easier to procure and optimal health products for patients.</li> <li>• Investing in strengthening national regulatory authorities (NRAs), specifically the capacity of NRAs to ensure that there is an adequate process for registration, use of registration waivers when applicable, market authorization of health products, donations and waste management.</li> <li>• Investing in strengthening NRA capacity to issue, implement and monitor national guidelines for quality assurance, quality control and pharmacovigilance to ensure that only quality assured health products circulate in the market and reach end users.</li> <li>• Leveraging global and regional quality assurance mechanisms and standards, including the WHO collaborative procedure for accelerated national registration. This could entail supporting national manufacturers, wholesalers and distributors in meeting the required quality standards.</li> <li>• Conducting required market research studies, for e.g., to determine what is needed as per national strategies but not available locally while available on the international market.</li> </ul>
<b>Selection and Rational Use</b>	
<p>Optimal products to ensure maximum disease impact and prevent/minimize chances of development of resistance to medicines may not be adopted or used in national guidelines, and/or the uptake or adoption of these products may be slow. In particular, challenges may include:</p> <ul style="list-style-type: none"> <li>• <i>Outdated guidelines</i> -- If treatment and diagnostic guidelines are not updated regularly and in line with WHO or other international recognized clinical</li> </ul>	<p>To address these challenges countries may consider:</p> <ul style="list-style-type: none"> <li>• Ensure WHO recommended optimal products are used by disease programs. This will also improve the ability to procure these products, even in small volumes (please refer to the procurement section).</li> <li>• Work towards the alignment of national treatment guidelines and essential medicines’ lists (EML) with WHO guidelines, optimal regimens, and EML.</li> </ul>



Potential Challenges	Key considerations and tools to address
<p>standards, this may lead to selection and use of sub-optimal products, that may lead to undesirable treatment outcomes.</p> <ul style="list-style-type: none"> <li>• <i>Outdated guidelines</i> – May also lead to unnecessary prescriptions and hence encourage the unrequired use of products.</li> <li>• <i>Financing</i> – There may be a lack of financing to introduce or expand access to new and modern diagnostic and pharmaceutical products and technologies</li> </ul>	<ul style="list-style-type: none"> <li>• Support the procurement of optimal regimens, FDCs (where applicable) and diagnostic products regardless of funding source;</li> <li>• Advocating a government committee or a working group to be tasked with regularly reviewing and updating guidelines, diagnostic algorithms and medicines lists as well as monitoring prescription practices and rational use (including compliance with treatment guidelines). In countries where guidelines are outdated, and/or the EMLs requires revision or updating, this is a key step to begin planning and quantifying what products will be needed and when they can be they will be transitioned to government budgets.</li> <li>• Consider using external financing, where available, to strengthen the capacity and capability of implementing and monitoring the rational use of health products.</li> </ul>
Procurement and Sourcing	
<ul style="list-style-type: none"> <li>• <i>Procurement Processes</i> -- Procurement processes and practices may be restrictive, over-regulated, inefficient, and/or outdated, which may lead to sub-optimal procurement outcomes (for example, higher prices or an inability to source the full range of the needed products). Specific challenges may include: 1) Barriers for manufacturers to participate in national tenders; including, but not limited to, the need for local agents, the submission of bids in local languages, the submission of bank guarantees issued by local banks, the short submission deadlines of bids, the mandatory denomination of bids in local currency, and unrealistic aftersales service obligations; 2) Procurement rules, regulations, and processes may not consider aspects specific to health products procurement and may not allow purchasers to procure products from the international market or through pooled procurement mechanisms. This is particularly problematic for 'small market' countries and for low volume and/or limited use products.</li> <li>• <i>Financing</i> – There may be a lack of alignment between fiscal and procurement cycles, preventing adequate and timely budget allocation for the procurement of health products and leading to a risk of stock-outs. In addition, funding may be centralized but procurement may be de-centralized, with discretion by sub-national authorities in how budgets are spent.</li> <li>• <i>Information</i> – There may be limited access to market knowledge and intelligence to inform the procurement strategy, including the identification of reliable quality assured sources, reference prices (to benchmark the procurement outcomes) and other relevant information.</li> </ul>	<p>To address these challenges, countries may consider:</p> <ul style="list-style-type: none"> <li>• Explore opportunities to update national legislation that enables local purchasers access to and acquisition of products from the international market and/or through pooled procurement mechanisms. This is particularly critical where products' volumes are low or there are specialized products.</li> <li>• Ensure procurement systems and processes consider quality, and reliable on-time supply during evaluation of offers, in addition to evaluation of financial offers.</li> <li>• Ensure procurement requirements and specifications are non-restrictive and responsive to market conditions.</li> <li>• Ensure procurement requirements and specifications are the outcome of national quantification and Forecasting exercises, through established committee using standard tools.</li> <li>• Regularly review previous procurement processes and practices to identify limitations and ensure future procurements are non-restrictive, responsive to market conditions and offer best value-for-money considering all available procurement modalities. Encourage the active use of available international market knowledge and intelligence to inform procurement decisions at the national level (including the benchmarking of prices, experience of other disease programs, as well as experience from neighboring countries etc.).</li> </ul>



Potential Challenges	Key considerations and tools to address
<b>In-country supply chain</b>	
<p>There may be challenges related to efficient and responsive in-country supply chains, including:</p> <ul style="list-style-type: none"> <li>• When and where parallel systems have been used (e.g., multiple warehousing set-ups and/or distribution channels), reverting to inadequate country systems may result in the disruption of supply or may have negative effect on quality of supplied products.</li> <li>• Poor shape and capacity and/or under prioritization of relevant infrastructure essential for storing, distributing, and managing health products / medicines.</li> </ul>	<p>To address these challenges, countries may consider:</p> <ul style="list-style-type: none"> <li>• Well before transition, consider opportunities for using grant funds for investing into and strengthening/optimizing of health product supply chains.</li> <li>• Where relevant and applicable, countries may consider the outsourcing of various activities to non-government entities (e.g., procurement, storage, distribution, warehouse management). If considered, this requires: strong management skills on both sides (public and private); sound performance management system and practices; and knowledge of the market conditions and availability of services on the market.</li> <li>• If parallel systems have been used in the past, strengthen country level planning for integration. Map out national systems, storage and distribution arrangements and what is required to strengthen capacity or reformulate and optimize arrangements.</li> <li>• In cases where treatment disruptions are likely, countries can plan for stop-gap measures such as PPM's Rapid Supply Mechanisms, pre-positioning of buffer stocks at select strategic health facilities.</li> <li>• Identify opportunities for RHSS activities – e.g., to strengthen LMIS, forecasting/ quantification/SCM tools, improve national warehousing and distribution capacities, develop SOPs for inventory management.</li> </ul>
<b>Organization and Management</b>	
<p>There may be organization and management challenges, including:</p> <ul style="list-style-type: none"> <li>• Overdependence on disease specific parallel systems, which may undermine long-term ability of countries to regulate, procure, and deliver quality assured health products in an efficient and cost-effective manner.</li> <li>• Insufficient human resources and or limited capability to finance required workforce and regulate, procure, and deliver health products and medicines, including more limited resources to oversee the specific delivery of HIV, TB, and malaria health products / medicines when external financing is reduced.</li> <li>• If elements of management information systems have not been embedded in country systems, these may be discontinued when external financing ends, decreasing overall availability and quality of data.</li> <li>• Routine monitoring may not be inclusive of 'availability' of health products.</li> <li>• Waste management systems are insufficiently developed (regulations, infrastructure, implementation) and under-prioritized for investments. National coordination will need strengthening as it can be regulated by more than one national authority (e.g., health and environment agencies).</li> </ul>	<p>To address these challenges, countries may consider:</p> <ul style="list-style-type: none"> <li>• Where possible, mainstream the use of national systems. If parallel systems are being used, embed system strengthening, and a clear plan of action for the integration of key organization and management processes over time, well ahead of the transition for national institutionalization.</li> <li>• Work with appropriate stakeholders to determine the importance of embedding Management Information Systems (MIS) into country systems, and plan for any investments required in both qualified human resources across the entire HPM cycle and in the information systems necessary to be fully integrated and compatible with national systems.</li> <li>• Where relevant and applicable, countries may consider out-sourcing various activities to non-government entities if they are cost-effective and offer better value-for-money.</li> <li>• Well before the transition, consider opportunities for using grant funds for investing in strengthening national waste management system.</li> </ul>

Potential Challenges	Key considerations and tools to address
<b>Additional Considerations Related to Diagnostics and Laboratory Services</b>	
<p>Additional challenges specifically related to diagnostics and lab services may include:</p> <ul style="list-style-type: none"> <li>• Delays in adopting and making available to patients new technologies and diagnostic methods.</li> <li>• In the absence of external financing, reverting to outdated, less accurate or efficient but cheaper diagnostic products and methods.</li> <li>• In the absence of external financing, reverting to less frequent monitoring treatment outcome or effectiveness.</li> <li>• Lack of routine maintenance of health equipment, which may lead to inaccurate test results, malfunction of equipment, downtime, waste of reagents.</li> <li>• Lack of maintenance of biosafety standards and requirements, including a failure to secure necessary accreditations, risk of environmental contamination.</li> <li>• Absence of or a weak and ineffective External Quality Assurance System, including an inability to assess and ascertain performance of laboratories and or loss of staff capacity and qualifications.</li> <li>• Weaknesses in samples referral and transportation network.</li> </ul>	<p>To address these challenges, countries may consider:</p> <ul style="list-style-type: none"> <li>• Work with in-country stakeholders, specifically with disease programs and lab divisions, to: 1) Integrate lab network and services; 2) Increase the utilization rates of idle equipment towards optimal utilization rates; 3) Encourage the use of multi-platforms where possible and feasible; 4) Opt for open source technologies where feasible; 5) Consider both high throughput vs Point of Care (POC) technologies; 6) Encourage equipment procurement vs. reagent rental; and 7) Ensure the availability of regular maintenance services.</li> <li>• Consider financing of relevant activities, including equipment, reagents, training, to address lab related issues.</li> <li>• Consider greater focus on how to more efficiently use existing infrastructure, such as strengthening the sample transport network rather than opening additional laboratories.</li> </ul>

# Annex 6: M&E, HMIS and Sustainability

## *M&E and HMIS Specific Annex to STC Guidance Note*

### **Introduction and background**

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. This annex outlines key high level challenges countries may face when increasing financing and their role in the HIV, TB and malaria components of the M&E system in country, as well as considerations to avoid or address those challenges.

### **Global Fund M&E system guidance and resources**

The Global Fund encourages systematic efforts and long-term sustainable investments in data systems to improve the availability and quality of data, and enhanced capacity to disaggregate, analyze and use data for strategic decision-making. There are several M&E systems strengthening investments and activities that the Global Fund recommends all countries to undertake to enhance sustainability of HIV, TB, and malaria programs as well as the overall health sector; and to prepare for eventual transition from Global Fund support:

- *Systems for tracking of health and disease program spending:* Countries should build on and institutionalize the national health accounts processes to track domestic expenditures on health so that data on past spending can be used regularly to inform health sector policy-making, program planning, costing and budgeting.
- *Using national M&E systems:* Global Fund financed programs should be implemented using country M&E processes and systems. Where grants are currently implemented using parallel structures, countries should articulate plans for integrating the implementation of donor-financed M&E activities through country systems.
- *Building national HMIS/routine reporting systems:* This should include through: a) Use of digital 'global public health goods', such as software to collect, manage, visualize and explore data; b) Implementation and regular maintenance of national aggregated and case based reporting systems (e.g. DHIS2, Open MRS based), including integration and interoperability of these systems; c) Integration of community and private sector health services data; d) Interoperability with other data systems including Logistics Management and Information Systems (LMIS), laboratory information systems, Human Resources information systems (including community health workers) and financial data systems.
- *Using resilient and sustainable national M&E systems:* Planning and funding for building and maintaining sustainable M&E systems should be aligned with the national M&E plan and national digital health plans. This includes investing in:

- Data availability across the relevant data sources: routine reporting, surveillance, population size estimates, surveys, and others.
- Frequent data analysis and use at national and sub-national levels: building analytical capacity as well as institutionalizing routine processes for reviewing and using data (e.g., periodic national program reviews and routine performance reviews at national and sub-national levels).
- Data quality improvement and assurance, improvement mechanisms that are integrated into the routine processes for data collection, analyses and use.
- *Develop a strategy for transition including an M&E plan:* with clear benchmarks and indicators to assess the effectiveness of the strategy for transition to national M&E and HMIS systems.
- *Consider challenges and mitigating actions in developing and using national M&E systems,* engaging with the Global Fund and other partners and mobilizing required support.

Further details on the Global Fund's approach to investment in data systems and M&E can be found on the GF [M&E webpage](#). Specific guidance on prioritizing M&E system investments is provided in the [M&E section \(Section 4.4, page 20\)](#) and the [List of Essential M&E Investments \(Annex 4, page 74\)](#) of the GF RSSH Information Note.

## M&E and HMIS sustainability challenges and considerations

Potential Challenges	Key considerations
<b>Policy, Legislation and Governance</b>	
<ol style="list-style-type: none"> <li>1. Lack of national health information policy and strategy</li> <li>2. Funding for data systems and activities not always aligned with country priorities.</li> <li>3. Inadequate coordination and alignment of M&amp;E investments across diseases and stakeholders</li> </ol>	<ol style="list-style-type: none"> <li>1. Provide technical assistance and/or political/advocacy support for development of national health information policy and strategy</li> <li>2. Strengthen in-country coordination through HMIS, M&amp;E and digital health Technical Working Group(s) that will coordinate the national and donor funding.</li> <li>3. Advocate for and convene stakeholders to support one M&amp;E platform and M&amp;E investments plan.</li> </ol>
<b>Financing</b>	
<ol style="list-style-type: none"> <li>1. Insufficient funding for national HMIS and M&amp;E systems and/or fragmentation of this funding across diseases and stakeholders.</li> </ol>	<ol style="list-style-type: none"> <li>1. Work through governance structures to mobilize, coordinate and use more efficiently all stakeholder support in HMIS and M&amp;E.</li> </ol>
<b>Routine reporting HMIS system</b>	
<ol style="list-style-type: none"> <li>1. Project-based data systems investments leading to duplication of data collection, with no attention to data quality and future system sustainability.</li> <li>2. Parallel and/or multiple systems that do not speak to each other. Lack of integration, or fragmentation of data sources, especially between public /private /community sectors, and inter and intra-disease.</li> </ol>	<ol style="list-style-type: none"> <li>1. Ensure funding requests submitted to the Global Fund include activities related to building national and sustainable HMIS and M&amp;E systems and frameworks, while engaging and coordinating with the private sector and communities.</li> <li>2. Guide countries in developing one single M&amp;E platform and interoperable HMIS, integrating private sector and community-data collection and use into the national HMIS.</li> <li>3. Institutionalize routine processes and SOPs for data quality review and improvement, including as part of routine program and performance reviews.</li> </ol>

Potential Challenges	Key considerations
3. Insufficient planning and funding for the routine maintenance and updates needed beyond deployment of systems.	
<b>Other Data Sources including surveys</b>	
1. Insufficient or out-of-date data needed from non-routine system data sources.	1. Ensure national M&E plans and budgets include critical population and/or facility-based surveys - based on the country context. Utilize M&E governance forums to leverage needed resources across domestic resources and partners.
<b>Program Review and Evaluations</b>	
1. Insufficient national capacity for carrying out quality national program reviews and evaluations.	1. Strengthen country ownership and coordination to lead periodic national program reviews and use of recommendations. See The Global Fund OPN on Oversee Implementation and Monitor Performance, Section E.4.3 within the <a href="#">GF OPN Manual</a> for additional guidance on program reviews and evaluations. 2. Engage and build the capacities of local or regional academic or research institutions to support program reviews.
<b>Data analysis and use</b>	
1. Lack of analysis and regular use of available data for decision making at all levels (central, regional, district and facility) for program planning, resource allocation, program improvement, and patient care. 2. No regular downstream feedback from higher to lower levels of data collection and reporting.	1. Ensure national M&E systems strengthening and building local capacity and at all levels for data analysis, interpretation, presentation (dashboards) and data use. 2. Support mechanisms and processes for routine sub-national data use, e.g., performance reviews. 3. Support dissemination of analyses and recommendations upstream and downstream at all levels.

## **Annex 7: Public Financing for CSO Service Delivery and Sustainability**

*“Social Contracting” Specific Annex to STC Guidance Note*

### **Introduction and background**

While significant progress in prevention and treatment of HIV, TB, and malaria has been made, achieving targets by 2030 will require a stronger focus on reaching those hardest to reach – ‘leaving no-one behind’. To achieve greater impact, health systems use different ways to reach a range of populations with a recommended package of services. Each country should find the most efficient way to provide services to those most affected and excluded and, in most cases, this will imply a combination of strategies, including both through formal sector as well as through community-led outreach. In countries where certain populations experience difficulty accessing programs and services, CSOs and community health workers have often played a key role in strengthening national programs and overall service coverage.

The Global Fund, as well as other donors, provides significant support to countries to reach the most vulnerable and those at higher risk groups for the HIV, TB and malaria. When external resources are significantly reduced or discontinued, one of the main identified risks is the disruption of programs that specifically address the needs of key and vulnerable populations. Interruption in the delivery of essential services for these groups risks backsliding on quality, coverage and equity of HIV, TB and malaria service delivery. To ensure continuity and sufficient scale of programs for key and vulnerable populations, it is important that countries proactively plan how these services will be sustainably delivered and funded. This may require making primary health care more responsive to those groups’ needs; improving policies and systems that allow community health workers to operate efficiently; and/or strengthening public financing of CSOs for the provision of services. This annex focuses on the last item and includes both an explanation on key considerations as well as an overview of how Global Fund support can be leveraged in this effort.

### **Public financing of CSO service delivery – i.e., “social contracting”**

Many countries, regardless of their income level, use health service delivery models that engage CSOs to implement country health policies and increase access to health services. This ranges from offering maternal and child health services in rural areas to providing HIV prevention services among high-risk groups. From a government perspective, reasons behind this decision vary but may include: a) a recognition that CSOs are closer to the beneficiaries and the problems they experience, strengthening responsiveness to community needs and improving service quality; b) a recognition that CSOs may be more flexible and with stronger potential for innovation; c) CSOs may have expertise that is not sufficient in the public sector; d) Government may face constraints—including human resources, budgetary, etc. – that require engagement of other, non-governmental actors. From the CSO perspective, advantages may include: 1) greater ability to fulfill their missions; 2) increased stability of funding or increased capabilities resulting from expanded resources and staffing.

## Definitions/key concepts

*Public financing of CSO service delivery (also known as “social contracting”)*

Particularly in the field of HIV, the term “social contracting” is often used to describe the public financing and contracting of CSOs to provide health services. As an emerging concept, its definition remains fluid and can be used to mean slightly different things. The Global Fund (and this guidance) uses both the terms “social contracting” as well as “public financing for CSO service delivery”. But more important than terminology is the definition of what is meant. In summary, “social contracting” involves the process of governments bringing civil society organizations into the provision of health services, by providing them with funding and the responsibility of service delivery.

The concept of “social contracting” includes two main elements: a) the government agrees to pay with domestic resources a CSO for a service rendered; b) a CSO agrees to provide a service in exchange. This definition excludes the hiring of individual community health workers by public entities to deliver services to specific populations and/or the use of donor resources, channelled through governments to compensate CSOs.<sup>31</sup> The population to be reached and the services to be delivered are defined based on the country context. In some cases, contracting of CSOs will prioritize specific key populations. In other contexts, other vulnerable groups among the general population (i.e., migrants) may be the primary recipient of services. Services can also include facility based and non-facility based, such as peer education, awareness raising, community-based treatment care and support, etc.

## Key elements to consider when it comes to establishing “social contracting” mechanisms

### Understand the country context

Supporting “social contracting” requires a strong understanding of country context, including:

- What is the legal and policy context for civil society and for the collaboration between government and civil society (overall and particularly for HIV, TB and malaria)?
- What is the legal and policy context for public funding of CSO service delivery? Is the public sector (at central or local level) financing CSOs to provide services (overall and particularly for HIV, TB and malaria)? In which sector/s? which services? what is their experience?
- What is the capacity of the public sector to set up and effectively manage service delivery agreements with CSOs (overall and particularly for HIV, TB and malaria)? What is the capacity of the CSOs to deliver the requested services with the expected quality?
- What is the current support of the government and CSOs for social contracting (overall and particularly for HIV, TB and malaria)?

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<sup>31</sup> In some cases, countries may use donor funding to pilot “social contracting” mechanisms. This implies using the national policy framework for the allocation, implementation and monitoring of those resources (which might differ from standard Principal Recipient and Sub-recipient arrangements) but financing them with external resources (as opposed to domestic resources). For the purpose of this guidance this is excluded from the definition but may be an important starting point for development of contracting mechanisms.



The Global Fund supported the development of a “*Diagnostic Tool on Public Financing of CSOs for Health Service Delivery*”. The tool includes a comprehensive set of questions to examine country context and help assess the ability/experience in transferring public resources to CSO for the delivery of services. It also helps map the range of domestic opportunities at national and subnational level that may exist. The tool provides a list of questions that can be then tailored to different contexts and scenarios (i.e., rapid assessment vs in-depth assessment).

The likelihood of “social contracting” for HIV, TB or malaria services in a specific country and the accompanying strategy for support will depend on this initial analysis. In some cases, the opposition to outsourcing services to CSOs is deeply rooted at all levels of the government. In these situations, “social contracting” may not be the best placed solution and other alternatives should also be explored. In other cases, resistance is found at certain places (i.e., national level) but there are opportunities elsewhere (i.e., local or municipal level). Also, “social contracting” might not be used for HIV, TB or malaria services but may have been used within other health programs or sectors. In such cases, building from existing experience may be very valuable.

### **Enabling environment and political support**

To enable “social contracting”, national legal frameworks should allow CSO to register and provide (certain) health services and should allow for the transfer of public funding to CSOs to pay for the provision of health services. In some cases, general procurement laws may be used, but they are often not suitable or adequate for the purchasing of social services provided by CSOs. The most prominent distinction is that in the case of “social contracting”, price alone should not be the only or key factor in selecting a provider. Quality of service and other factors that determine the best VfM should take precedence.

Political support, ownership, and willingness to compromise (across all actors) are crucial for implementation. Building political support often starts by building government awareness of the role and added value of CSOs. In many cases, community systems have often been supported outside the formal health sector. Efforts to build awareness on the work of CSOs, the contribution CSOs make to national disease responses or health systems, and opportunities to build relationships with government should be strengthened.

### **Key considerations for operationalizing “social contracting”**

Governments choose different models to partner with civil society for the delivery of services. The level of detail in the procedures established also varies greatly. Defining clear regulations may help facilitate trust, guide expectations and enhance the enforceability of agreements.

#### **Setting the principles**

Embedding certain principles in the general policy framework for “social contracting” is important, and may include:

- *Goal oriented* – Public financing should be allocated for clearly defined goals and priorities in line with government policies and public health needs. Evaluation should be driven by indicators to measure achievement of these goals.
- *Transparency* – Application and selection procedures should be clear and transparent and provide maximum clarity and openness for the tendering and contracting process.

- *Equal treatment of applications* – A set of pre-established clear and objective criteria, which ensure non-discrimination and selection of the most qualified applicants based on the merit of the proposal.
- *Accountability* – Accountability in spending of public funds is key, including spending the allocated funds in an agreed way and with clear reporting obligations is fundamental.
- *Proportionality* – Procedures for application, documentation, reporting requirements, oversight and supervision should be proportionate to the program activities and funding provided.
- *Participation of beneficiaries* – Rights and needs of beneficiaries should have a central role. They should be involved in the design as well as in the monitoring and subsequent evaluation of the services provided.

## Design of the objectives and targets

Frequently, national plans define overall targets for the responses. The services to be implemented by CSOs should contribute to those targets. The process of contracting must start with a clear definition of the objectives, which are explicit and measurable. The objectives, targets, services or service location may change over time to respond to the changes in the epidemics or in the health system.

Definition of the specific services to be purchased (i.e., standardized care based on international guidelines) and the geographic area of intervention is also critical. To inform this decision, governments may need to understand better where CSOs are already engaged and whether the CSOs have enough institutional capacity to undertake additional tasks. Affected communities and CSOs should be actively involved in these discussions.

## Costing and financing

Countries need to estimate the costs of the services to be contracted out, identify the funding source and define the payment mechanism. In this area, based on international experiences, it is important to highlight several elements:

- *Costing* – A good understanding of the cost of delivering services by CSOs is important to inform budget allocations. Some existing tools have been used in several contexts, while many countries have also used an ad-hoc approach.<sup>32</sup>
- *Funding source* – Funding to contract services from CSOs may come from different sources, including national or local budgets, specific pre-defined financing mechanisms (such as lottery proceeds), private sector contributions, etc.
- *Predictable funding* – Predictability enhances continuity of services and better planning. Predictable funding is more likely when the government has a policy that supports contracting of CSOs and when there is a distinctive budget line item. Multi-year agreements are helpful to CSOs because it allows for a strengthened focus on programs, with less energy and time spent on fundraising. However, many governments can only provide annual funding. In this

<sup>32</sup> Costing tools may include: <https://www.healthpolicyproject.com/index.cfm?ID=publications&get=pubID&pubID=442>; [http://data.unaids.org/publications/irc-pub05/jc412-costguidel\\_en.pdf](http://data.unaids.org/publications/irc-pub05/jc412-costguidel_en.pdf); <https://www.msh.org/resources/community-health-services-costing-tool>

case, it is important to think about strategies to avoid interruption of services in the beginning of the fiscal year.

- *Price and competition* – One concern noted when funding decisions are primarily based on price is the potential for a “race to the bottom” that may put the quality of the services and financial stability of implementing CSOs at risk.
- *Recognize organizational costs* – Some institutional funding to cover organizational costs is important for increasing capacity of the sector and investing in its longer-term viability.
- *Payment structure* – To reinforce the attention to achieving the expected results, paying for performance is being used by some countries in some “social contracting” mechanisms. In this case, agreements specify quantitative outputs and link those to financial disbursements. When defining the payment mechanism, it is important to bear in mind the amount of time that dealing with certain technical and financial reporting requirements will imply and the potential for implementation delays and reduced attention from technical concerns during contract implementation. It is also necessary to consider the capacity of the public sector to monitor performance-based contracting.
- *Payment schedule*: As most CSOs cannot advance payments, long delays in receiving funds may mean that CSOs have few if any resources available to initiate programs in a timely manner.

### **Tendering and selection of contractors**

In most countries, the government invites CSOs to bid for services, normally through an open call or tender (although in some cases the government may invite a limited number of qualified providers). To participate in a tender for the public contracting of services, CSOs are often required to be legally registered in line with national regulations. Furthermore, if there are criteria for the provision of specific services, CSOs will be required to have the relevant accreditation/certification. When designing the tender/call for proposal it is important to consider how the process may restrict participation of smaller CSOs who will find it difficult to compete. In general, simplifying the procedures and allowing for more CSOs to be included in the contracting process may yield longer-term benefits. However, sometimes contracting to an umbrella organization, at least in the short term, may be the more realistic approach.

Open competition with clear selection criteria developed and published in advance is recommended. Some examples of criteria used for the evaluation of proposals include: understanding the needs of the target population and geographical context; experience of the CSO implementing similar interventions; linkages with government and other programs or robustness of the M&E plan. An evaluation committee comprised of independent experts from various institutions is an important part of the process.

### **Monitoring, reporting and evaluation**

Existing information and M&E systems in many countries do not adequately capture or reflect the disease-response work undertaken by many CSOs. This information may be only available in the reporting system used by donors who have historically provided support. A critical initial step for countries to recognize the role of CSOs is adjusting the reporting and evaluation systems to capture the unique contributions of CSOs.

Furthermore, for governments it is essential to monitor the effectiveness of the delivery of services. A M&E system should be put in place to carry out technical and financial monitoring of the specific

contracted services. Clear definition of who is responsible for implementing the M&E plan and sufficient budget allocated to ensure that the plan can actually be implemented, is essential. Agreement on the indicators to be used and the timelines for when data will be collected is important to ensuring clarity between all parties. Some of the common M&E activities include technical reports submitted by the CSO and reviewed by the responsible entity (who ideally should provide feedback to the CSO to guide them in implementation and subsequent planning); site visits to check project activities and systems (i.e., records and registers); and evaluations. The evaluation should cover not only the changes in service utilization but also quality, equity and costs aspects of this service delivery model. Finally, impact studies can help assess if the program is having the desired impact.

### **Capacity building**

Experience has demonstrated the importance of building and ensuring governmental capability to monitor and supervise CSO operations and oversee the process of contracting civil society with public funding. This requires a change in role from that used with the direct management of service provision. Ensuring strong capacity for contract management and experience in working with CSOs is important. In some cases, given capacity constraints, the government may choose to hire an independent agency for contracting or to be in charge of technical management of contracting.

When CSOs constitute a key component of the service delivery system, the government plays an important role in supporting them to perform well as implementers. Understanding the current capacity of CSOs to undertake specific health services and manage contracts is necessary. Investing in technical and management training and other improvements is important and should be budgeted as part of the overall strengthening of contracting and service deliver.

The pace and scale of contracting should be decided based on institutional and CSO capacity. Time for learning and adjustments should be expected. If there are few experienced CSOs or governmental capacities are weak, it may be beneficial to approach contracting incrementally, with fewer/smaller contracts to allow testing and development of capacity. If government starts using social contracting while donor funding is still in country, their support can often be leveraged to build capacity of both contractual parties.

### **Common difficulties/concerns in strengthening/developing “social contracting” mechanisms<sup>33</sup>**

In addition to some of the issues mentioned above, it is important to be aware of the most common difficulties experienced by countries when using “social contracting” mechanisms:

- *Weak legal and/or policy framework to allow for “social contracting”* – The most common issues include: a) ambiguous laws and policies governing CSO legal formation and operations, which may be combined with individual discretion to interpret the policy; b) rigid or excessively demanding requirements that overburden community, less formalized organizations; c) unclear or inconsistently applied rules governing CSO eligibility to participate in contracts; d) heavy restrictions on services to be provided by CSOs; e) accreditation and licensing policies sometimes include education qualifications and infrastructure requirements unrealistic for community-based organizations.

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<sup>33</sup> The main source of information for this section comes from reports from the Global Consultation in 2017. *Social Contracting: working toward sustainable responses to HIV, TB and Malaria through government financing of programs implemented by civil society. Background paper for a global consultation convened by the Open Society Foundations, the United Nations Development Programme, and The Global Fund to Fight AIDS, Tuberculosis and Malaria, 5 - 6 October 2017, New York*

- *Narrow set of outcomes* – CSOs are sometimes frustrated that governments may only want to purchase a narrow set of outcomes in relation to testing, treatment and care, whilst they have a philosophy of working more broadly on social determinants of health in their target populations.
- *Inefficient management* – Weak systems can make contracting difficult and can impede efficient financial and HR management for CSOs – i.e., holding up payments and providing short-term contracts that make attracting and maintaining highly-qualified staff difficult.
- *Lack of awareness/understanding from control/auditing bodies* – Authorities in charge of controlling public administration may not be familiar with the particularities of the public health interventions implemented by CSOs and block the transfer of public funding or make burdensome requests. Engaging public control authorities in the design of the mechanism as well as maintaining dialogue with them is recommended to mitigate these challenges.
- *Mismanagement or bad performance* – As in other types of service delivery models, there may be cases of financial misappropriation of funds, diversion of project funds or repeated poor performance. Contracts usually include provisions that allow the government to close the contract in those cases. These practices harm the reputation of CSOs and may have lasting consequences in the support provided to “social contracting” in a given country. To avoid or reduce that risk, it is important that government and CSO collaborate in the definition of rules and sanctions.
- *Changes in government* – Changes in government may lead to changes in the interest in or desire to engage in “social contracting”; abrupt or sudden financing decisions could have lasting consequences for CSOs and the populations they serve. For that reason, building support from multiple stakeholders and developing a solid policy framework is essential.
- *Integration* – “Social contracting” for HIV, TB and malaria should be, as much as possible, embedded in national well-established policies than can apply to other social sectors.
- *Service providers vs advocates* – Some CSOs, particularly those who work on the rights of marginalized populations, may fear that being contracted by Government to implement public health programs could result in them being co-opted by government and weaken their ability to advocate on behalf of their constituencies. However, examples exist of contexts where civil society groups have largely maintained their independence, autonomy and voice while engaged in “social contracting”. Elements that usually help to maintain a constructive engagement where CSOs engage in both service provision and advocacy include: a) when CSOs consistently provide efficient, high quality services and conduct evidence-based advocacy; b) when countries have an overall enabling legal environment in which CSO can operate easily; c) where Governments are genuinely interested in ensuring adequate service coverage for the selected populations and understand the CSOs watchdog role as a source of useful information for their action. In addition, some countries use an independent purchasing agency to facilitate a more neutral interface with CSOs.

## Leveraging Global Fund support to support strengthened “social contracting”

For those countries supported by the Global Fund where “social contracting” is deemed an adequate strategy to expand access to services, the Global Fund can provide different types of support (based on country context). Where basic conditions to start implementing “social contracting” are not in place, Global Fund support is likely to aim to establish a better enabling environment and set the groundwork for the future. Where there are existing mechanisms in place or opportunities to expand on more informal arrangements, Global Fund support – including via grant funds, technical assistance, negotiation of co-financing commitments, etc. – can be instrumental. Examples may include those items listed below.

Strengthening enabling environment and setting the stage	Building on and/or further developing mechanisms
<ul style="list-style-type: none"> <li>• Align as much as possible contracting mechanism of existing sub-recipients to public contracting rules.</li> <li>• Support trust building activities between government and CSOs.</li> <li>• Support strengthening CSO linkages with government services.</li> <li>• Support integration of community services within the national health management information system.</li> <li>• Support integration of prevention indicators in the national M&amp;E framework, ensuring data from services delivered by CSOs are well captured in data systems.</li> <li>• Support advocacy to achieve the needed policy changes and budget for contracting CSOs and/or for delivery of certain services (i.e., needles and syringe exchange).</li> <li>• Support CSOs to be effective and cost-efficient, as well as to show the results of their work.</li> <li>• Support implementation of initial contextual analysis: i.e., implementation of the diagnosis tool on public financing for CSO health service delivery.</li> <li>• Support systematization of the roles, services provided and added value of CSO in national responses.</li> <li>• Support strong engagement of civil society in design and implementation of service delivery mechanisms.</li> <li>• Work in partnerships with other donors to support normative enabling frameworks for government and civil society collaboration.</li> <li>• Support mapping of CSOs and their capacities.</li> </ul>	<ul style="list-style-type: none"> <li>• Negotiate co-financing commitments focused on domestic uptake of those interventions for key and vulnerable populations with higher donor dependency.</li> <li>• Support piloting “social contracting” mechanisms with Global Fund financing.</li> <li>• Support tailored technical assistance for the design and implementation of the mechanism.</li> <li>• Support south to south exchanges.</li> <li>• Support country stakeholders dialogue on public financing mechanisms for CSO service delivery in order to understand stakeholders’ views / concerns and discuss ways to resolve these.</li> <li>• Support capacity building of Government authorities and CSOs for “social contracting.”</li> <li>• Support robust assessments and monitoring systems.</li> <li>• Support accountability mechanisms for all involved parties (i.e., patients scorecards or community led monitoring).</li> <li>• Map what other institutions (domestic and external) can provide in terms of support, such as capacity building for CSO or government.</li> </ul>