
Guidance Note

Sustainability, Transition and Co-financing

15 May 2020¹

¹ The STC Guidance Note was originally published in Dec. 2019. This updated version of the Guidance Note now includes an additional annex on HIV (Annex 2). No other material changes have been made in this updated version.

Background

The Global Fund's Sustainability, Transition, and Co-Financing Policy ([STC Policy](#)) was approved in April 2016² and implemented for the first time during the 2017-2019 funding cycle. Although sustainability has always been an element of the Global Fund's work, the STC Policy formalized the overall approach to strengthening sustainability, increasing domestic financing and co-financing, and supporting countries to better prepare for transition from Global Fund financing through national planning. The policy has the goal of better investing external financing and catalysing domestic resources to strengthen health systems and support countries to address critical sustainability and transition challenges, in order to maintain and scale service coverage and accelerate the end of the three diseases.



FIGURE 1: THREE ELEMENTS OF THE STC POLICY

This document is intended to support countries to strengthen sustainability, increase domestic financing, and enhance preparations for transition from Global Fund support as they develop funding requests, implement Global Fund grants, and manage national [HIV](#), [TB](#), and [malaria](#) programs.³ Due to the distinct challenges related to the sustainability of HIV, tuberculosis and malaria programs and a variety of technical areas (including [health product management](#), [health information systems](#), and [public financing of civil society service provision](#)), the document also includes specific, more detailed considerations in the annexes.

Contents of this guidance note

- **Recommendations** for countries to [embed sustainability considerations](#) into national planning, program, and grant design.
- **Additional recommendations** for countries [to prepare for transition](#), including assessing transition readiness and undertaking transition planning.
- **An overview of requirements** for countries to align with the STC Policy, including transition work-plans (when applying for “transition funding”), co-financing, and application focus requirements.
- **Additional considerations (annexes)** related to sustainability and transition for specific diseases and technical areas, including: 1) [HIV](#), 2) [TB](#), 3) [Malaria](#), 4) [Health Product Management \(HPM\)](#), 5) [Health Management Information Systems \(HMIS\) and Monitoring and Evaluation \(M&E\)](#), and 6) [Public Financing of Civil Society Service Provision](#) (also known as “Social Contracting.”)
- **Links to other [Global Fund guidance](#)** to support countries, including information notes on HIV, TB, malaria, and resilient and sustainable systems for health (RSSH) and technical guidance notes on human rights, gender, and key and vulnerable populations, the Value for Money Technical Brief.

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

³ 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.

Overview of Global Fund Approach

Sustainability

The Global Fund's 2017-2022 Strategy⁴ recognizes that ending the HIV and TB epidemics and eliminating malaria requires sustainable national responses to the three diseases and resilient systems for health. 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 support efforts for elimination of the three diseases, even after funding from the Global Fund or other major external donors comes to an end.*⁵ Sustainability includes many dimensions such as financial, epidemiological, programmatic, systems-related, governance, human rights, and political. Individual focus areas for specific countries will vary, influenced heavily by country and regional context.

To minimize the risk of programmatic disruption and mitigate potential negative impacts that could result from a decrease or absence of Global Fund financing, countries are strongly encouraged to strengthen attention to sustainability in their national planning and program design, with support from the Global Fund and partners as necessary. A sustainable approach to program planning and implementation should consider how to maximize impact while balancing short and long-term results; not only with the view of financing available today through donor support, but also considering what domestic financing will need to take up in the future.

Sustainability considerations often include: robust national planning (either for specific diseases or the health sector), enhancing domestic resource mobilization to progressively increase domestic financing for health and the three diseases, enhancing Value for Money, investing in resilient and sustainable systems for health (RSSH), enhancing alignment and implementing Global Fund activities through national systems, increasing efforts to address human rights and gender-related barriers to access, and strengthening national governance.

Transition

Eligibility for Global Fund funding is determined by a country's income classification⁶ and disease burden as defined in the Eligibility Policy.⁷ As countries move upwards in income classification and/or experience a decline in disease burden, considerations around the sustainability of Global Fund financed 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.⁸ In line with this definition, the Global Fund considers a transition to have been successful where national health programs are able to at least maintain and preferably improve, equitable coverage and uptake of services through resilient and sustainable systems for health even after Global Fund support has ended.

While the timeframe for receiving Global Fund financing and the total amount of financing will vary by country, all Upper Middle Income (UMI) countries (regardless of disease burden) and Lower Middle Income (LMI) countries (with disease components that have "Not High" disease burden) are strongly encouraged to design, develop and implement Global Fund funding requests, grants, co-

⁴ As set forth in GF/B35/02 – Revision 1 and approved by the Board in April 2016 under decision point GF/B35/DP04.

⁵ The Global Fund Sustainability, Transition and Co-financing Policy.

⁶ 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>

⁷ GF/B39/02, Annex 2.

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

financing commitments, and national programs with the aim of eventual and full transition to domestically funded and managed responses.

For these disease components, the Global Fund encourages strengthened national planning, ideally 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).

Transition funding

Once a country disease component funded under an existing grant becomes ineligible, the component may receive up to one allocation period of transition funding following their change in eligibility.⁹ The funding request for a transition funding grant must be based on a detailed transition work-plan and is subject to tailored review by the Technical Review Panel (TRP).

Co-financing

Increasing domestic financing is an integral aspect of strengthening sustainability and fostering successful transitions. The Global Fund has co-financing requirements designed as a strategic tool to catalyze increased domestic financing for health and the three diseases. Co-financing requirements in the STC Policy are differentiated by income classification and disease burden.¹⁰

Application Focus Requirements

To strengthen the overall impact and sustainability of Global Fund investments, the Global Fund’s “application focus requirements” (included as part of the STC Policy) outline how countries should invest Global Fund financing, differentiated by income classification.

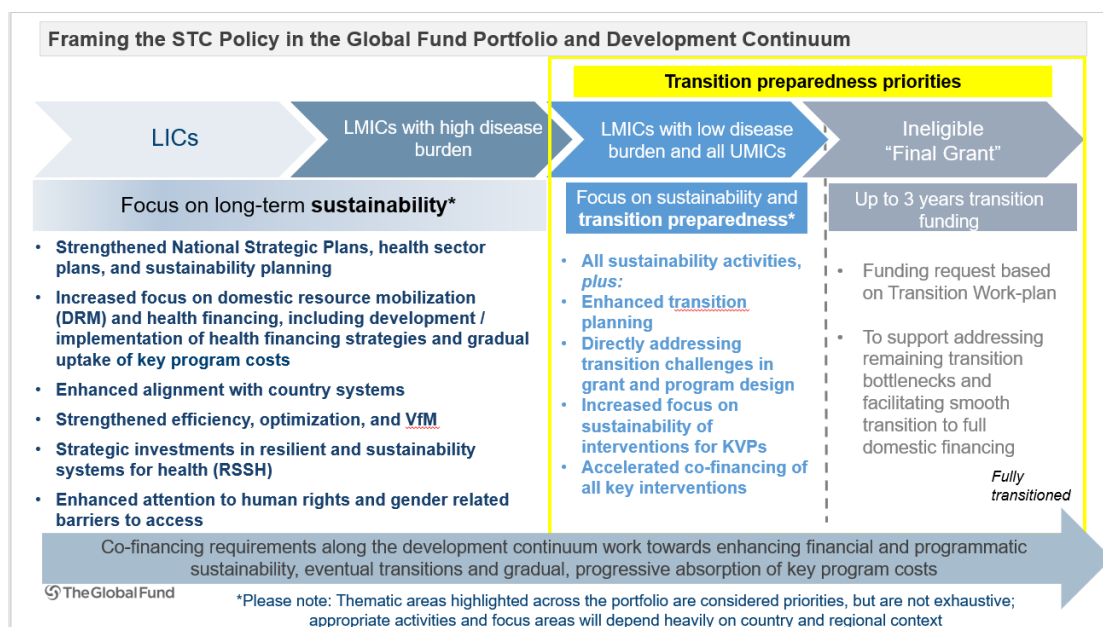


FIGURE 2: STC AND THE DEVELOPMENT CONTINUUM

⁹ 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 UMI with less than an ‘extreme’ disease burden, or c) become members of the Organization for Economic Co-operation (OECD) and Development’s Development Assistance Committee.

¹⁰ The Global Fund [Sustainability, Transition and Co-financing policy](#). See also the [Global Fund Operational Policy Note on Co-Financing](#).

A) Key Considerations for Strengthening Sustainability

Sustainability considerations should be included in program planning, funding request development, grant design, and implementation **for all countries, regardless of their stage of development or their proximity to transition from Global Fund financing.** These considerations may take many forms or cut across many thematic areas, including financial, epidemiological, programmatic, systems-related, governance, human rights, and political¹¹. They 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, sustainability planning should be conducted through inclusive, country-led processes that involve governments, multilateral and bilateral agencies, civil society organizations, the private sector, representatives of key and vulnerable populations, and people living with the diseases. Communities most impacted by the three diseases, including key and vulnerable populations, bring to these processes critical expertise to develop and implement programs appropriate for and accessible to marginalized groups, including activities to reduce human rights and gender related barriers, and monitoring and reporting on issues of access and quality.

There are several focus areas and activities that the Global Fund recommends all countries consider when working to enhance the sustainability of HIV, TB, and malaria programs as well as the overall health sector.¹² They include:

1. **Strengthened national planning, including development of robust, costed and prioritized National Strategic Plans (NSP).** The Global Fund encourages applicants to base their funding requests on robust and costed NSPs for the health sector and specific diseases. While the planning process is country-specific, key considerations recommended for countries include:
 - a. *Defining short and long-term program goals:* since NSPs provide the overall strategic direction for a country's health sector or disease program, the process of creating the NSP should encourage decision-making on how to financially and programmatically sustain impact. For example, when implementing the latest guidance from technical partners, including on new technologies, countries are encouraged to plan not only with the view of financing available today but also consider what the government will need to take over at some point in the future. The NSP process should also consider frontloading efforts to remove human rights and gender-related barriers to services.¹³ Effective planning should consider all activities that contribute to the disease response, including private sector and civil society organizations.
 - b. *Priority setting:* program planners should use available funds to maximize and sustain equitable and quality health outputs, outcome and impact. This can be achieved by allocating resources to the most cost-effective interventions, providing them with quality at minimum cost and achieving desired health outcomes. In the event of declining funds from major external donors, including reduced allocations from the Global Fund, a cost-impact analysis supported by the application of allocative efficiency tools can help policy makers identify the

¹¹ 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?](#)

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

¹³ The Global Fund "Value for Money Technical Brief" (2019).

opportunities for efficiency gains and allocate resources across interventions, geographies and population groups to maximize impact. By linking investments to health and economic gains, cost-impact analysis can also support advocacy efforts towards Ministries of Health and Ministries of Finance for mobilizing increased domestic financing for health and the three diseases. It is important that resource allocation discussions include interventions that cannot be easily quantified in a cost-impact analysis (such as health systems strengthening activities or human rights interventions) and take into account the challenges of conducting accurate priority setting for interventions with limited reliable data (such as key and vulnerable population size estimates).

- c. *Costing*: interventions and systems to achieve program goals should be costed to define the full funding need over the period of the NSP, following appropriate methodology and using suitable tools.¹⁴
- d. *Financing*: disease-specific NSPs should be accompanied by plans detailing how they will be financed. Resources from all funders should be mapped against the funding need to provide a financial gap analysis,¹⁵ a key input to determining by how much domestic investments need to increase to progressively take up program costs.

If countries do not have an NSP that is sufficiently robust, inclusive (including key and vulnerable populations), evidence-informed or accurately costed, the Global Fund may in coordination with relevant partners support countries to strengthen the development of the NSP to ensure that it provides the appropriate strategic direction. Relevant activities may also be funded through Global Fund grants, as appropriate. 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. [Annex 1](#) to this document provides a table of the costing and resource allocation tools that countries have previously implemented to inform the development of NSPs and Global Fund funding requests.

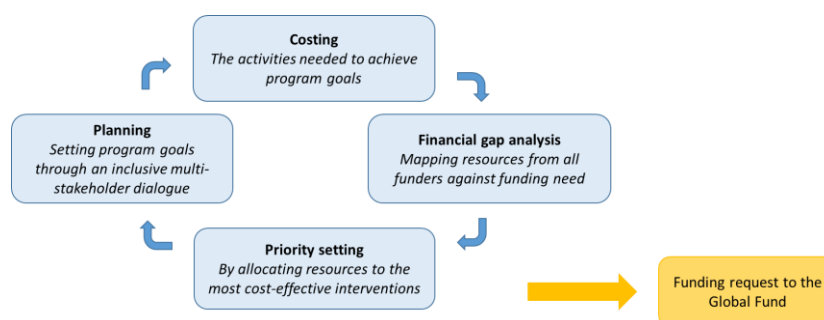


FIGURE 3: THE ITERATIVE PLANNING PROCESS FOR NATIONAL STRATEGIC PLANS

As part of and in the context of overall national planning, the Global Fund recommends that countries specifically enhance their attention to key, long-term sustainability challenges, including undertaking assessments of these challenges (where deemed necessary and relevant). Specific consideration for key long-term sustainability challenges can help strengthen country ownership to address them. Where relevant, the Global Fund encourages that these assessments and planning are done in collaboration with other financing and technical partners, to enhance alignment and consensus on key long-term challenges facing the health sector and national disease responses.

¹⁴ Countries are encouraged to consult with technical agencies (ie WHO, UNAIDS, etc.) to appropriately cost NSPs, applying costing tools such as OneHealth.

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

2. Strengthening domestic resource mobilization for health and the three diseases.

Recognizing the importance of increased domestic resource mobilization to meet national program and strategic goals, countries are strongly encouraged to take a comprehensive approach to strengthening the financing of the health system and national responses to the three diseases. This includes:

- a. *Development and implementation of health financing strategies:* countries are encouraged to dialogue on long term strategies to sustain program financing with increased domestic investments. As a measure to progressively raise domestic revenues to finance the health sector and the three disease programs, the Global Fund encourages countries to have in place or further implement existing health financing strategies or plans, which provide a framework for developing and advancing health financing towards Universal Health Coverage. These strategies should provide a detailed overview of how health care will be financed, including sources of financing (e.g. external, domestic public, domestic private) and revenue type (e.g. unmarked public spending, earmarked public spending, tax subsidies, voluntary prepayment, out-of-pocket spending).¹⁶ They should consider the government's fiscal situation 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 implement social health insurance. In order to remain useful, it is important that strategies for health financing be frequently reviewed and updated.

The Global Fund will engage with countries, where appropriate, by working with partners to support the development or operationalization of strategies for health financing. 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 such as the Global Financing Facility¹⁷.

- b. *Tracking health and disease program spending:* relevant and updated data on health and disease program spending is essential to inform overall country planning, NSPs and health financing strategies. The Global Fund encourages countries to have institutionalized national health accounts processes to track domestic expenditure on health, so that data on past spending can be used regularly to inform health sector policy-making.¹⁸ It is recommended that programs have processes in place to track spending, ideally by intervention and major sources of funding, to inform program planning, costing and budgeting. Countries can request that Global Fund grant funds are used to invest in resource tracking efforts.
- c. *Gradual uptake of key program costs:* as part of the Global Fund's co-financing approach, all countries are encouraged to gradually pick up key program costs, including those currently funded by external financing. Gradual uptake 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. Deciding which program costs and the scope of program costs will be taken up domestically will depend on country context but should consider those areas that have been traditionally supported by external financing.

¹⁶ WHO guidance on developing Health Financing Strategies: http://www.who.int/health_financing/tools/developing-health-financing-strategy/en/

¹⁷ <http://globalfinancingfacility.org/>

¹⁸ 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.

When certain interventions require enhanced national capacity, technical skills to maintain overall quality and cost-effectiveness, or have not traditionally been financed by domestic financing (such as the procurement of health products, delivery of services to key and vulnerable populations, or investments to reduce human rights or gender-related barriers to access), ensuring a gradual and early approach to phased uptake can help build capacity and avoid sudden disruptions to key interventions. For health products in particular, lessons learned indicate that gradual uptake combined with significant up-front planning is essential, since some countries may face challenges to accessing quality, affordable health products with domestic financing. In addition, it is essential for efforts to be in place early on to ensure the scale and quality of comprehensive packages of services for populations most affected by the diseases, such as adolescent girls and young women in specific settings or other key and vulnerable populations.

- 3. Implementing through and strengthening alignment with national systems.** Global Fund financed programs should be implemented through country systems whenever possible, including using national health information systems, national procurement and supply chain systems and public financial management systems. It should be noted that “national systems” are not necessarily government systems. They may also include community systems, or instances when government contracts or otherwise works with non-governmental organizations (NGOs) to provide critical health services. Applicants are encouraged to include systems strengthening measures in their funding requests so that national systems can be increasingly used to implement interventions. When grants are currently implemented through parallel structures, countries should articulate plans to enhance implementation of donor-financed programs through country systems.

As countries work to enhance alignment, two important areas to consider are national salaries and the institutionalization of trainings. In accordance with the Global Fund’s [Guidelines for Grant Budgeting](#), salaries supported by the Global Fund should be in line with national human resources procedures and salary scales.¹⁹ Budget requests that include human resource costs should be able to provide plans for the sustainability of these costs beyond Global Fund support.²⁰ Government workforce trainings supported by the Global Fund (including prevention, advocacy, sensitization, gender and human rights trainings) should be progressively institutionalized into the national health curriculum and capacity development programs, with specific domestic funding included in appropriate budgets.

- 4. Enhancing strategic investments in resilient and sustainable systems for health (RSSH).** The Global Fund strongly encourages countries to include activities to strengthen health systems in funding requests and enhance domestic investments for these activities. While specific investments will vary, applicants should:

- focus on results for the three diseases while improving health system coverage and quality of care, to be measured robustly;
- have an increased appetite for innovation and ensure the innovative approaches are properly evaluated to maximize learning;
- employ a systems perspective that employs cross-cutting health systems interventions (e.g. decentralized facility financing or performance-based financing), uses integration to increase efficiency and effectiveness, and recognizes the importance of the private sector and community systems; and
- address equity by ensuring the poor and other vulnerable, under-served communities receive responsive care.

¹⁹ For more information on salaries and other human resource investments, see the Briefing Note for Global Fund applicants on Strategic Support for Human Resources for Health.

²⁰ [Global Fund Guidelines for Grant Budgeting](#) 2019.

There are several systems-related needs that are common across the three diseases, including community systems, human resources, procurement and supply chain systems, health information systems and financial management systems. Based on lessons learned from early implementation of the STC Policy,²¹ systems weaknesses that impact the sustainability of disease outcomes are particularly acute in the areas of procurement and supply chain, public financial management, and integration of programs, systems, and services. 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.

- 5. Developing strong Health Management Information (HMIS) and monitoring and evaluation (M&E) systems.** Country level health information and monitoring and evaluation systems should be robust enough to generate reliable data related to the epidemiology of the three diseases. Having the right information and institutionalizing the appropriate processes to obtain this data is imperative to ensuring that a disease program is appropriately tailored to the epidemic. As such, investing in robust HMIS, routine disease data, surveillance, surveys, and population size estimates at national and subnational levels on a routine basis is necessary to ensure that the disease program is structured in a way that ensures that the right populations are being targeted with the right interventions. These systems should capture data inputs such as disease incidence and disease prevalence, disaggregated by gender and age, and amongst specific key and vulnerable populations. Having transparent, good quality and timely data on program performance, enhancing private sector and civil society participation in program planning and ensuring their accountability is essential.

All countries, regardless of their proximity to transition, should consider:

- investing in key national data systems (such as HMIS), surveillance systems, population-based surveys, administrative and financial data sources, while making sure that Global Fund specific data reporting systems and service quality assurance and improvement are integrated into national routine processes;
- including priority interventions for building and improving in-country national monitoring and evaluation systems in funding requests. The Global Fund recommends that grants allocate between five and ten percent of their budget to monitoring and evaluation activities to address any gaps in M&E;
- mitigating challenges and bottlenecks in developing and using national HMIS and M&E systems.

To support countries, this guidance includes a specific [HMIS and M&E annex](#) outlining a variety of challenges that countries may face across these areas, and considerations to address those challenges.

- 6. Maintaining and strengthening access to affordable, 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 products 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, certain challenges may arise in some contexts, particularly when countries using Global Fund financing or pooled

²¹ TERG STC Policy Review, 2019. Forthcoming.

procurement mechanisms take greater responsibility for domestic procurement, financing and management. These challenges may include: inadequate financing or misalignment of domestic financing with the procurement cycle; legislative or regulatory barriers that limit access to international pooled procurement mechanisms; weaknesses or gaps in country quality standards; outdated procurement or national guidelines that may create barriers for new products to enter the market or slow uptake of new products; limited registration, 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 using international pooled procurement mechanisms (like Wambo.org, UNICEF, or the Global Drug Facility for TB health products, etc.) to maintain quality and increase efficiency, or leveraging technical assistance to proactively address country specific barriers to effective procurement.

In addition, where parallel procurement and supply chain management systems (PSM) are being used, these should be transferred to national systems in a step-wise fashion well before a country stops receiving Global Fund support.²² 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 value for money, 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.

- 7. Strengthening value for money.** Given the substantial funding gaps that exist in global plans for HIV, TB, and malaria, it is imperative to maximize the impact of available resources. Countries should make the best possible use of resources and maximize the value for money of Global Fund investments. The Global Fund has recently published a [Value for Money Technical Brief](#) that provides further details, including activities countries can take to strengthen the impact of available resources.
- 8. Human rights and gender.** Human rights and gender-related barriers undermine countries efforts to scale up quality service coverage. NSP development, national planning, and domestic financing strategies 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 malaria provide information on the comprehensive intervention packages and approaches to using

²² 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.

data, including quality assessments, to ensure an equitable approach to health system planning and budgeting.

9. Evolving the role of the CCM and strengthening the health governance architecture.

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 country dialogue, including identifying and assessing key sustainability challenges and gaps. CCMs may also consider modifying the composition of their membership to ensure appropriate engagement of actors particularly relevant to sustainability (including Ministry of Finance or Planning, development banks, the private sector, and others, as outlined in detail in the [CCM Policy](#)), and take a more proactive role in monitoring efforts to strengthen sustainability, including the realization of co-financing commitments, implementation of recommendations from assessments of sustainability, etc.

B) Preparing for Transition from Global Fund financing

As countries move along the development continuum, it's essential that they increasingly focus on planning for 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.²³ 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 disease 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 regardless of proximity to transition.

Lessons learned suggest that successful transitions take time and require resources, and therefore early and proactive planning is a key part of enhancing transition preparedness. All UMI countries regardless of disease burden and all LMI countries with “not high” disease burden are encouraged to prepare as early as possible for eventual transition from Global Fund support. This does not imply that all UMICs (regardless of disease burden) and LMICs (with “not high” disease burden) are exiting from Global Fund financing. But it does mean that planning for eventual transition should be a priority, and considerations for transition should be built into country dialogue, co-financing commitments, grant design, and program design. For the 2020-2022 Global Fund allocation period, these components are listed in the table below.

Transition preparedness priorities: Components with existing grants and classified as LMI with “not-high” disease burden or UMI²⁴

UMI countries	Azerbaijan (HIV, TB), Belarus (HIV, TB), Belize (HIV), Botswana (HIV, TB), Colombia (HIV), Costa Rica (HIV), Cuba (HIV), Dominica** (HIV, TB), Dominican Republic (HIV), Ecuador (HIV), Gabon (TB), Grenada** (HIV, TB), Guatemala (HIV, Malaria*, TB*), Guyana (HIV, Malaria*, TB), Iran (HIV), Iraq (TB), Jamaica (HIV), Jordan (TB), Kazakhstan (HIV, TB), Kosovo (HIV*, TB*), Lebanon (HIV), Malaysia (HIV), Marshall Islands** (HIV, TB), Mauritius (HIV), Montenegro (HIV), Namibia (HIV, Malaria, TB), Paraguay (HIV), Peru (HIV, TB), Russian Federation (HIV), St. Lucia** (HIV, TB), St.
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²³ www.theglobalfund.org/documents/core/eligibility/Core_ProtectedTransitions2016_List_en/

²⁴ Source: Global Fund 2020 Eligibility List. Includes countries receiving funding via multi-country grants. Please note that in addition to the components listed above, the following components received transition funding in 2017-2019: Albania (HIV, TB), Algeria (HIV), Belize (TB), Botswana (malaria), Dominican Republic (TB), Paraguay (TB), Panama (TB), and Sri Lanka (malaria). As they continue implementing grants, these components are strongly encouraged to continue the focus on transition preparedness and planning priorities.

* These components are newly ineligible as per the 2018-2020 lists and have received Transition Funding in 2020-2022.

** Small island economies. These countries are encouraged to plan for transition even though UMI countries in this group are eligible for all components regardless of disease burden as per the Global Fund's Eligibility Policy

	Vincent and the Grenadines** (HIV, TB), Samoa** (HIV, TB), Serbia (HIV), South Africa (HIV, TB), Suriname (HIV, Malaria), Thailand (HIV, Malaria, TB), Tonga** (HIV, TB), Turkmenistan (TB), Tuvalu** (HIV, TB)
LMI countries with Not High burden classification	Armenia (HIV*, TB), Bangladesh (Malaria), Bhutan (HIV, Malaria), Bolivia (Malaria), Cabo Verde** (HIV, Malaria, TB), Comoros** (HIV, TB), Djibouti (Malaria), Egypt (TB), Eswatini (Malaria), Honduras (Malaria, TB), Kiribati** (HIV), Lao PDR (HIV), Mauritania (HIV), Micronesia** (HIV), Nicaragua (Malaria, TB), Pakistan (Malaria), Palestine (HIV, TB), Papua New Guinea (HIV), Philippines (Malaria), Sao Tome and Principe** (HIV), Sri Lanka (HIV), Sudan (HIV), Timor-Leste** (HIV), Vanuatu** (HIV, TB), Yemen (HIV, Malaria, TB)

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.²⁵ These [transition projections](#) are estimates based on 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 immediate short term, potentially through reprogramming of non-essential activities.

1) Assessing readiness and transition planning

Countries preparing for transition should assess their readiness and strengthen national planning to manage transitions from Global Fund financing. Readiness assessments and related 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 a phased plan for domestic take-up or integration of Global Fund financed activities and plan to address any critical transition challenges.

Countries have the flexibility to decide what form readiness assessments and/or transition 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 well-coordinated with other donor plans and partners. Moreover, it should be developed through a rigorous, transparent and inclusive process, including full engagement of community and civil society actors. High-level political and financial commitment is also important to enable a successful transition process.

Transition Readiness Assessments

As a first step in preparing for transition, countries are encouraged to conduct transition readiness assessments. These readiness assessments are strongly encouraged but not required, particularly in cases where there already exists sufficient, detailed analysis of the sustainability and transition challenges at the country level. Whether the assessment is carried out by country stakeholders or with external support, it is crucial that the process involves inclusive dialogue among key country stakeholders, so that the outcomes of the assessment reflects the inputs of a variety of stakeholders and are country owned.

Transition readiness assessments will differ (often substantially) based on country context. Countries may use as guidance the thematic areas below to consider key factors that affect the future sustainability and transition readiness of the health system and disease program:

- *Epidemiological context*: the drivers of infection, including key and vulnerable populations (especially when these are currently heavily supported by external partners) and other populations due to age, gender related disparities, and/or other vulnerabilities.

²⁵ <https://www.theglobalfund.org/en/funding-model/before-applying/eligibility/>

- *Economic situation*: the country's macroeconomic outlook and the fiscal capacity of the government to increase public sector financing, with a particular focus on meeting national strategic goals and absorbing financing previously available from external resources.
- *Political context*: the government's commitment to managing and financing the disease response, including specific components 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.
- *Governance*: 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.
- *Policy and legal environment*: the policy and legal issues that may impact transition, and the on-going quality of service delivery, particularly for key and vulnerable populations.
- *Human rights and gender*: the human rights and gender-related barriers to access services and how these will be addressed in transition planning. This includes, 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.
- *Programmatic*: an analysis of the future programming needs to enable the country to maintain and scale up coverage to provide for the continued control of the diseases, as well as whether service delivery will be programmatically feasible for national governments to take over in the future.²⁶ This includes: analysis of the current interventions implemented; service delivery coverage by gender and age (including for key and vulnerable populations) and an analysis of where scale-up is needed to achieve policy objectives; the key services needed and for which population groups and geographical areas; how services are delivered, including the ability for civil society organizations to continue providing services (where relevant); capacity needs, and the enabling environment to support program implementation.
- *Health systems*: the capacity and quality of health systems elements that are critical for transition, including data systems, human resources, labs, 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; what systems components present roadblocks to transition.
- *Financing*: current and projected funding landscape; 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; whether key services of the disease program are currently or should be included in national health insurance; any progress or bottlenecks in the implementation of health financing strategies; etc.
- *Support and TA*: identification of any needs for technical assistance and resources available to support transition planning.

²⁶ Global Fund "Value for Money Technical Brief" (2019).

Findings from transition readiness assessments should inform a country's overall national planning for transition and/or a transition work-plan and be used to evaluate where additional effort and investment is needed to enable a successful transition from Global Fund support. 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.

As countries engage in transition planning, it is important to consider the governance of the process, and which decision makers and influencers should be included to ensure strong country ownership. This includes the role of communities and civil society, private sector and other stakeholders, as well as how information can be transparently shared and monitored along the way. The CCM can play an important role in convening key stakeholders for transition planning, but it is essential that all key ministries are engaged in the process, even when they are not part of the CCM.

A significant amount of countries undertook the development of *transition readiness assessments* or equivalent analyses and *transition work-plans* or other equivalent planning in the 2017-2019 funding cycle. Actively using these work-plans or equivalent planning to inform funding requests, Global Fund grants, and ongoing implementation of national programs in the 2020-2022 funding cycle will be key to continue strengthening transition preparedness.

2) Consider enabling factors for transition

Preparing for transition depends on specific country context, the level of reliance on donor funding, the national disease strategy, and other factors. However, in addition to the sustainability considerations outlined in previous sections of this document (all of which are relevant for countries preparing for transition), there are several enabling factors and activities that are often particularly important as countries face reductions in external financing and/or 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 planning. They include:

- **Providing an enabling environment to continue programs for key and vulnerable populations.** 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 programs 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, including critical interventions to remove human rights and gender-related barriers to access, often lack adequate domestic financing or political commitment. In order to safeguard against disruptions to these critical interventions when disease components transition from Global Fund support, key and vulnerable populations must be central in all transition processes, 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.
- **The critical role of non-state actors.** In many national programs, non-state actors (particularly civil society) play an essential role in the implementation of key activities. The Global Fund has encouraged the use of dual track financing 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, community groups and the private sector) 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, especially those targeting key and vulnerable populations. As such, activities that enable or facilitate working with civil society organizations and non-state implementers to ensure strengthened capacity and sustainability in program design and service delivery should be prioritized.

Public financing of civil society service delivery (also known as “social contracting”). A critical factor in sustaining and scaling effective responses is the capacity of governments to fund non-state actors with public financing. A number of factors – including fiscal, legal, and political – may make it difficult to maintain funding for these organizations and continue their role in national responses. One way to mitigate this is to set up or strengthen appropriate mechanisms to use public financing to support services provided by civil society. This type of system change often takes time to put in place. 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 is now included in this guidance.

Enhanced capacity for advocacy and resource mobilization. Civil society also plays 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 programs, including after transition from Global Fund financing. This may include supporting civil society organizations to develop and implement strategies for resource mobilization. Where governments may not fund these types of activities, other stakeholders could support them, such as the private sector or national / international philanthropy.

- **Accelerated co-financing of all key interventions.** While the Global Fund encourages all countries to gradually assume program costs, accelerated co-financing of interventions financed by the Global Fund is particularly important in contexts where countries are preparing for transition. Gradually accelerating co-financing of critical programs that need to be maintained may help avoid service disruption and continued progress against the three diseases.
- **Selection of implementers for Global Fund grants.** In preparing for successful transitions, the Global Fund encourages CCMs to consider which entity is the most appropriate to strengthen transition preparedness and implement transition activities and grants and 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.

- **The role of CCMs in transition processes.** CCMs can play a key role in supporting the transition preparedness process and overseeing the transition away from Global Fund support and towards full domestic financing. 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, including 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 work-plans, 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.

C) Transition Funding

Once a country disease component becomes ineligible for Global Fund financing, the respective country *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.²⁷ For components receiving “transition funding”, the funding request should focus exclusively on 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.

The funding request for “transition funding” components will be subject to a tailored review by the Technical Review Panel (TRP), and applicants applying for transition funding are required to submit a *transition work-plan* along with their funding request. While there is no prescribed format, the *transition work-plan* should be derived from findings in transition readiness assessments or equivalent analysis, be aligned with the NSP and health sector planning, be practical, measurable, costed and include a detailed outline of the steps that the country will take to transition to fully funding programs from domestic resources over the three-year transition funding period. The work-plan should consider including the following:

- An overview of activities currently financed by the Global Fund, and the activities that require financing or integration to enable a successful transition.
- A phased financing plan towards full government uptake of all activities (or full integration of those activities) by the end of the final grant.
- Description of which activities are specific to the transition process (such as technical assistance) and would therefore cease by the end of the grant implementation period.
- Where applicable, options and strategies for reprogramming existing funds and/or seeking additional funds from new sources to fill existing gaps.
- Description and budget of any activities essential for enabling a successful transition that are not financed by the Global Fund transition funding grant.

²⁷ 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 UMI with less than an ‘extreme’ disease burden, or c) become members of the Organization for Economic Co-operation (OECD) and Development’s Development Assistance Committee.

Requests for transition funding should focus on activities described in the transition work-plan and as prioritized during the country dialogue process. While country context will strongly influence the content, they should generally address key sustainability and transition challenges, including those outlined in this guidance note, and include:

- 1) Activities that enhance the sustainability and support the transition of effective and evidence-informed services for key and vulnerable populations, or address human rights, gender, or other enabling environment-related barriers to access to services.
- 2) 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 civil society organizations; activities to secure the availability of robust programmatic and financial data for program planning and monitoring (e.g.: building capacity for data collection and analysis, strengthening national HMIS and surveillance systems); 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, as well as strengthen supply chains; etc.
- 3) Activities to ensure the financial sustainability of Global Fund supported programs (e.g. integrating service provision into national health insurance 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.).

It is important to note that transition funding is not expected to be used to maintain the status quo of current grants or to extend for additional time 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 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 complementary activities 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 populations and prevention. 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

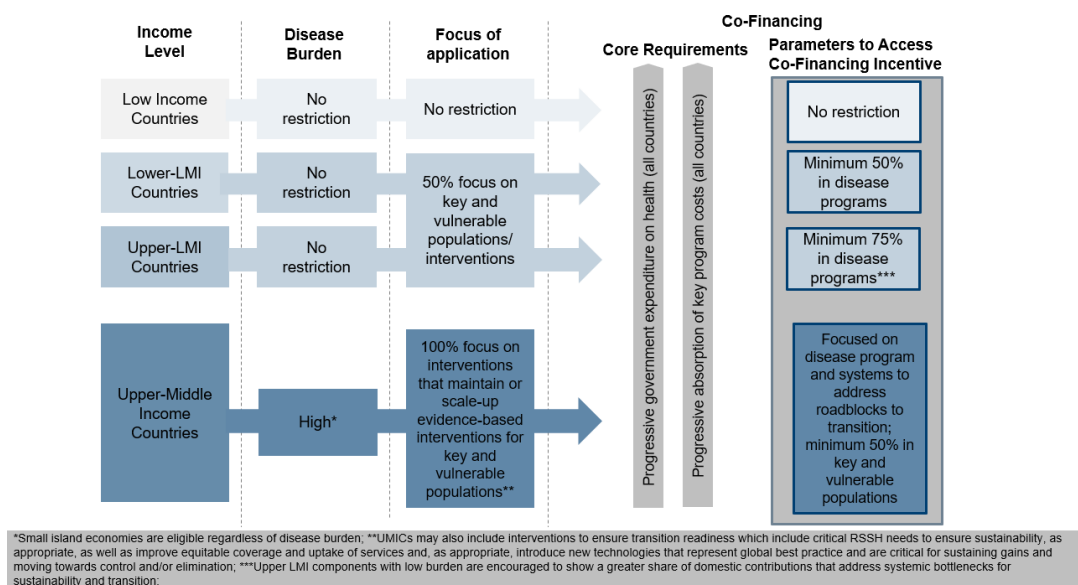
all necessary procurement to maintain coverage in line with national strategic plans and the complementary activities necessary to achieve this goal should be included in the funding request.²⁸

- 3) *Human resources and other recurrent operational costs.* The majority of recurrent costs for the management of disease programs 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 Funds’ overall approach of integrating into grants sustainability considerations regarding human resources for health.²⁹ 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, in discussion with the Global Fund, should evaluate how best to use transition funding and agree on a performance framework for the transition funding grant that maintains the 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. work-plan tracking measures – is essential.

D) Co-financing

A critical enabler of sustainability is increased domestic financing. As countries move along the development continuum and expand their fiscal capacity, they are expected to take on greater ownership of the national response to the three diseases by increasingly contributing to disease programs and health systems. The STC policy includes specific co-financing requirements aimed at incentivizing greater domestic resources for health and the three diseases. The requirements are differentiated by income to encourage additional domestic investments to be more ambitious and progressively focused on specific activities and thematic areas as a country prepares for transition. Overall, the co-financing requirements aim to encourage increases in overall health spending and progressive domestic uptake of key program costs.



²⁸ 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](#)

²⁹ [Briefing Note for Global Fund applicants on Strategic Support for Human Resources for Health](#)

Figure 4: Application focus and co-financing requirements

In order to access a Global Fund allocation, countries should meet two core co-financing requirements: 1) show progressive government expenditure on health and 2) show progressive uptake of key program costs, including those supported by the Global Fund.

In addition, to further encourage domestic investment, **at least** 15% of a country's allocation (but in some cases more) is a **co-financing incentive** made available if countries make – and eventually realize – additional domestic commitments over the implementation period (relative to expenditures over the previous implementation period). The scope of these additional investments should be:

- For low income (LIC) countries, additional domestic investments should be at least 50% of the total co-financing incentive amount;
- For middle income (MIC) countries, additional domestic investments should be at least 100% of the total co-financing incentive.³⁰

Factors that may influence co-financing incentives to be greater than 15% include but are not limited to: if the share of government spending on health is less than 8%; if the country is a UMI (regardless of disease burden) or LMI with “Not High” disease burden and will need to proactively plan for transition; or other country specific contextual factors. For more details on the co-financing incentive, countries should consult the Global Fund [Co-Financing Operational Policy Note](#).

In addition, the requirements for these commitments are differentiated by income (as described in Figure 3):

- **Low income countries:** Low income countries have the flexibility to make additional investments either in disease programs and/or RSSH activities.
- **Lower middle-income countries:** As countries move along the development continuum, additional co-financing commitments must be invested increasingly in disease programs 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 disease program. *For Upper-LMI countries*, a minimum 75% of co-financing contributions should be in line with identified priority areas within the disease program. *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 upper middle-income countries must focus on the disease program 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 relevant to the country context. Applicants for transition funding are also required to meet the co-financing commitments.

During the funding request and grant-making process for the 2020-2022 funding cycle, countries will need to show evidence of having met their previous co-financing commitments from the 2017-2019 allocation period. Failure to realize previous commitments or provide evidence of realizing commitments may result in the reduction of grant funds and/or reductions in future allocations. The

³⁰ [Sustainability, Transition, and Co-Financing \(STC\) Policy](#)

realization of previous commitments will be verified throughout the funding cycle. Further details

Illustrative co-financing incentive examples:

Country A is a UMI and has received an allocation for HIV only. It receives an allocation of \$10 million for 2020-2022, 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 \$2 million more than what it spent over the previous three years. Of the \$2 million, at least \$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 \$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 \$7.5 million more than what was spent over the previous three years. Country B has the flexibility to invest all of the additional \$7.5 million in either disease programs or RSSH activities.

can be found in the Global Fund [Co-Financing Operational Policy Note](#).

Lessons learned during the early stages of co-financing implementation indicate a number of focus areas that may be important for countries to pay particular attention to as they are developing co-financing commitments. In addition to those highlighted in the sustainability considerations above, these include:

- proactive planning to ensure that co-financing commitments are backed by formal, approved financial commitments, including from relevant national ministries (like the Ministry of Finance);
- enhanced attention to any risks associated with commitments, 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);
- greater attention to and up-front documentation of strategies for how commitments will be formally monitored, tracked, and reported to the Global Fund; and
- greater CCM engagement in supporting realization and monitoring of commitments.

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 programs to maximize impact against HIV, TB and malaria; and contribute towards building resilient and sustainable systems for health. 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 program 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.
- **Transition Funding:** As described above and as per the STC Policy, transition funding should be used to fund activities included in the country's transition work-plan. In addition, applicants should take into account the broader application focus requirements for upper-middle income countries as described above.

Annex I: Resources to support sustainability and preparations for transition

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

A. Main allocative efficiency tools (by alphabetical order) to inform resource allocation:

Disease program/System	Tool	Tool developer ³¹	
Disease program	HIV	AIM/Goals model	Avenir Health
		AIDs Epidemic Model (AEM)	East-West Center
		Optima HIV	Burnet Institute
	TB	Australian Tuberculosis Modelling Network (AuTuMN)	James Cook University
		Imperial TB model	Imperial College London
		Optima TB	Burnet Institute
		TB Impact and Modelling Estimates (TIME)	London School of Hygiene and Tropical Medicine
	Malaria	Elimination Scenario Planning	Imperial College London
		Epidemiological MODelling (EMOD) malaria modelling	Institute of Disease Modelling
		Malaria Elimination Transmission and Costing (MEMTC) (in the Asia Pacific)	Mahidol Oxford Tropical Medicine Research Unit
		OpenMalaria	Swiss TPH
		Optima Malaria	Burnet Institute
Spectrum Malaria		Avenir Health	
Health Systems	Health Intervention Prioritization (HIP) Tool	University College London	
	OneHealth	WHO and others	
	Socio-Technical Allocation of Resources (STAR)	London School of Economics	
	WHO-CHOICE	WHO	

B. Partner resources that can be used to inform sustainability and transition planning

PEPFAR: Sustainability Index and Dashboard (SID)

World Bank: checklist for transition planning of national HIV responses

USAID and PEPFAR Health Policy Project: Readiness assessment – moving towards a country-led and financed HIV response for key populations

<i>What is it?</i>	Used to assess the sustainability of national HIV programs where PEPFAR has investments.	A checklist to provide an analytical framework to support countries in undertaking transition planning to ensure programmatic sustainability of their national HIV responses.	A guide to assess the ability of a country's stakeholders to lead and sustain HIV epidemic control among key populations as donors transition to different levels and types of funding.
<i>For more information:</i>	http://www.pepfar.gov/countries/cop/c71524.htm	http://documents.worldbank.org/curated/en/645871473879098475/pdf/108266-NEWS-WBChecklistforTransitionPlanning-PUBLIC.pdf	http://www.healthpolicyproject.com/index.cfm?id=publications&get=pubID&pubID=462

³¹Co-developers or collaborators of some of the tools can be found on the website of the tools.

C: Global Fund Supported tools to support sustainability and transition planning:

Curatio: Transition preparedness framework

Aceso Global/APMG: Guidance for Analysis of Country Readiness for Global Fund Transition

APMG: Diagnostic Tool on Public Financing of CSOs for Health Service Delivery (PFC)

UCSF: Transition Readiness Assessment for Malaria

<i>What is it?</i>	Tool to support transition planning process by identifying strategic and operational issues that will assure the sustainability of programs currently supported by the Global Fund and other donors. Used primarily in Eastern European contexts.	Tool to support countries to identify 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;	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	Tool intended to be a first step in the transition planning process. It provides a guided assessment of five key domains: malaria program financing, management, workforce, supply chain, and programming, to determine where challenges may occur. Available here .
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For more information: Contact the Global Fund Secretariat

D. Other relevant resources (non-exhaustive): To be updated

Annex II – HIV and Sustainability

HIV Specific Annex to the STC Guidance Note

Background to the HIV Annex

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 to move towards epidemic control requires continual attention to issues of sustainability and the effective use of limited resources. Reducing new infections and achieving and sustaining epidemic control is a primary factor in laying the groundwork for a sustainable national response. Efficient and effective national programs lead to greater epidemic control, while at the same time epidemic control enables leaner programs and reduces fiscal burden of national governments.

Through its Sustainability, Transition and Co-Financing (STC) policy, 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 HIV programs and strong health systems that can support an HIV response, 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.

- This annex to the STC Guidance Note outlines **HIV-specific** sustainability and transition considerations for use in national planning, program, and grant design.
- **Considerations** are organized around selected thematic areas: leadership and governance, program implementation and service delivery, health systems and HIV, human rights and equity, and financing.
- Under each theme are principal **challenges** countries may experience, and **potential responses** to mitigate them and strengthen long-term program sustainability.
- This annex is intended to build on the **Global Fund's STC Guidance Note** and used in conjunction with 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.
- It is also intended to complement other **HIV technical notes** and **RSSH specific information** notes, technical guidance notes on human rights, gender, and key and vulnerable populations, and the Value for Money Technical Brief.

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. In all contexts, however, reducing new infections, achieving and sustaining epidemic control is a primary factor in laying the groundwork for a sustainable national response. 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 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 HIV prevalence is low or concentrated in key and vulnerable populations, which external financing often helps bring attention to.
- *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, and which should be retained within a vertical HIV program approach. Once these technical determinations are made, it can be difficult for HIV programs to plug into the broader health system 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, health, 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 has gained support at the central level but encountered implementation problems at local levels.

Key Considerations

- *Broaden HIV leadership and ownership:* Engage multi-stakeholder groups that include a broad range of ministries, parliamentarians, policy-makers 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 with the introduction of UHC approaches. 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, cervical cancer screening and treatment, and routine antenatal and postnatal services). 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.

Program Implementation and Service Delivery

The pathway to a sustainable HIV response depends on reducing new infections and ensuring effective life-long treatment for people living with HIV. Countries must implement quality treatment and prevention strategies at scale to reach populations at risk for and affected by HIV. This requires understanding where new infections are occurring, who is being left behind in current programming, and putting in place real-time feedback loops on quality of services. It is also essential that HIV programs link program effectiveness with efficiency. Streamlining program approaches for greater efficiency relies on measuring cost in relation to impact and coverage.

Key Challenges

- *Key and vulnerable populations are often not reached through general health services:* Populations affected by HIV are diverse (e.g., adolescent girls and young women (AGYW), youth, men, MSM, transgender persons, and other key and vulnerable populations), and require tailored, multi-sector strategies to reach and engage individuals in prevention, treatment, and long-term care for successful health outcomes. For example, in reducing vulnerabilities of AGYW, interventions to promote completion of secondary education, provide economic and livelihood opportunities, and avert early marriage complement access to accurate health information and SRH services. Reaching these diverse populations may require tailored strategies that go beyond general health services.
- *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 willingness to tackle challenging human rights issues and discriminatory policies or laws that impede marginalized populations access to essential prevention 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 at scale.
- *Poor quality of care:* Investments in health services including testing, drugs, and diagnostics may be ineffective when follow up care and support for retention is absent, with high rates of lost to follow up. 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). Poor quality of care can jeopardize long-term sustainability.
- *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 continued dependencies on external finance:* In some countries, civil society organizations (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 particularly 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 HIV interventions, such as pre-exposure prophylaxis (PrEP) and self-testing. 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 or enabling community health workers to play a role in ARV distribution.

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 (ie, 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 1). For more information, see Annex VII on “Public Financing of Civil Society Service Provision in the STC Guidance Note”.
- *Streamline program activities and enhance value for money:* Undertake activities to strengthen overall value for money of the HIV program, including analyzing program activities for impact and linking with cost data to inform program implementation and decision-making.
- *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](#).

Box 1: 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.

Health Systems and HIV

Procurement, laboratory, and information systems are key functions of the larger health system that require special attention for HIV sustainability and transition planning.

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 2nd and 3rd line regimens. Procurement may be additionally hindered by poor alignment between country procurement guidelines and evolving WHO guidance, as well as poor 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 biobehavioral 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 have the opportunity to increase the quality, efficiency, and cost-effectiveness of the HIV response through the development of a strong national laboratory system that serves all disease areas and levels of care. (See Technical Brief: [Laboratory Systems Strengthening](#)). A national strategic plan for laboratory services should include HIV services and address HIV priorities, such as optimizing timely access to tests and results and determining appropriate and timely diagnostic technologies. (See country example in Box 2)
- *Consider adopting multi-disease diagnostic platforms:* Multi-disease testing devices can help countries achieve greater technical and financial efficiencies across disease programs. “All in” contracting models in which the manufacturer is responsible for the maintenance of laboratory equipment and supplies can help countries streamline system maintenance and quality management processes.
- *Update procurement policies:* Countries are advised to improve responsiveness to changes in global treatment guidelines and develop policies that avoid barriers to leveraging external purchasing platforms to maximize efficiency and quality, particularly for specialized HIV treatments.

Box 2: Building an integrated laboratory system

Achieving HIV targets requires creating efficient and reliable national laboratory systems where HIV laboratory services are integrated with other programs and sectors. For example, in one East African country, the Minister of Health recognized the inefficiencies and costs created by multiple, fragmented laboratory systems and led efforts to create an integrated national laboratory system. This included creating a national leadership position to oversee laboratory services across all diseases and meet International Health Regulations. It also included development of a national lab strategic plan and re-organizing lab activities by functional areas (e.g., specimen transport, molecular testing) rather than disease areas. Dismantling parallel laboratory systems is challenging, and strong high-level leadership was key to the country’s success. It was critical to have a multi-stakeholder process to develop the strategic plan, in order to ensure full country ownership. In addition, the Global Fund, PEPFAR, and other partners coordinated to support the country-led process.

Human Rights and Equity

Central to strengthening epidemic control is ensuring that prevention and treatment interventions reach all those affected by HIV. This requires addressing barriers to access to services and employing effective interventions to reduce stigma and discrimination. 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 social health insurance programs 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 focus attention and funding on evidence-based programs that strengthen planning for sustainability and future transition from Global Fund support. 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 in order 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.
- *Reduce health workforce discriminatory attitudes and behaviors:* 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 vulnerable populations out-of-pocket costs as a barrier to care:* Engage in and help inform health system financing dialogues with the ministries of health and finance in order 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 social health insurance programs and expand equitable access to health services regardless of employment status. Monitoring and quantifying out-of-pocket expenditure for people living with HIV is critical information to support advocacy around financial protection.

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:* Unlike some other diseases, HIV patients need to remain on treatment for life. Therefore, countries should plan for long-term investments in prevention and treatment activities. 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 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 Principal Recipient, 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 3)
- *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; mechanisms to address common bottlenecks in service delivery, such as stockouts or health worker constraints, for example, through task-shifting; and/or efforts to deliver quality services through efficient modalities, for example, through scaling up patient-centered, differentiated service delivery (DSD) models along the HIV cascade. 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 3: 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.

Annex III – Tuberculosis and Sustainability

TB Specific Annex to STC Guidance Note³²

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.
- 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

³² This TB and sustainability annex was completed with the support, partnership, and collaboration of USAID.

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. These new sectors and populations may not be a priority for the public sector once external financing begins to decrease, and countries may not have established domestic mechanisms to provide support for the continued provision of recommended services / interventions by civil society and non-governmental organizations (NGOs).

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.
- 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 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.
- Analyze whether existing or proposed health payment mechanisms align with the needs of TB care.
- Ensure that TB is included in discussions about how to reach Universal Health Coverage. 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 Universal Health Coverage 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 protocols for 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 medicines needed for public 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 by the 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 and value for money.
- 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). Consider using, where applicable, external financing to institutionalize contracting of CSOs and ensure that they are on-budget and flow through government systems.
- 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 IV – Malaria and Sustainability *Malaria Specific Annex to STC Guidance Note*³³

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 and management 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 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

³³ This Malaria sustainability annex was completed in collaboration with UCSF-Malaria Elimination Initiative.

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 a lack of civil society 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, which they frequently do not have sufficient capacity to take on.
- *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 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 political will 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 advocacy efforts. 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.
- *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.

- *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.

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 positions not included in human resource plans (e.g., malaria information system staff), short-term hires (e.g., for indoor residual spraying), or positions that receive compensation higher than government rates.
- *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:

- *Develop or strengthen malaria human resource plans:* 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. This can include determining which of functions can be integrated in the health system and which require a vertical malaria response. An updated, costed human resource plan for malaria 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. 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:* Ensure that front-line health providers are knowledgeable about malaria case management throughout malaria elimination and POR phases.

- *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. When facing reduced funding, often the first cuts made to malaria programs are in information systems, quality assurance, management, and supervision. However, these functions are crucial to maintain because they can help increase efficiency, particularly as malaria programs become increasingly targeted and tailored in response to changing epidemics in low-burden contexts.
- *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 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., DHIS) to ensure integrated systems, are often better positioned to strengthen program management and efficiency. Programs should consider using technical assistance to improve data quality, access, and usability, and take steps to assess and plan for integration of vertical systems, as applicable.
- *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 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:* Ensuring 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. This can include, for example, designing vector control packages at district level, rather than national LLIN distribution.
- *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 indoor residual spray and other 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 V - 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:

Policy, legislation, and regulation -- 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.
<i>Selection and Rational Use</i> – 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.
<i>Procurement and Sourcing</i> – This includes products procured efficiently and supplied reliably, ensuring evaluation beyond unit price (i.e. best value for money); 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).
<i>Supply Chain</i> – 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.
<i>Organization and Management</i> – 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; 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
Policy, Legislation and Regulation	
<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"> • <i>Products of Public Health Interest</i> – Key products for HIV, TB, 	<p>To address these challenges, countries may consider:</p> <ul style="list-style-type: none"> • 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. • Introducing flexibility in national legislation that allows at least an option of access to

<p>and malaria programs are not always prioritized for funding and/or included in a national essential medicines lists, which may negatively impact proper procurement, registration, and tax exemption.</p> <ul style="list-style-type: none"> • <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 and limited or no alignment with internationally recognized stringent quality standards could impact quality and safety of procured products. Weaknesses and gaps in some country 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 • <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. 	<p>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.</p> <ul style="list-style-type: none"> • Promoting that WHO recommended optimal products are used by disease programs, including development or update and use of clinical guidelines and national essential medicines lists. These products are also generally easier to procure. • 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. • 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 products circulate in the market and reach end users. • Leveraging global and regional quality assurance mechanisms and standards, including the WHO collaborative procedure for accelerated national registration. • Conducting market research (with special consideration of what is available locally vs. on international market)
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Selection and Rational Use

<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"> • <i>Outdated guidelines</i> -- If treatment and diagnostic guidelines are not updated regularly and in line with WHO or other international recognized clinical standards, this may lead to selection and use of sub-optimal products, that may lead to undesirable treatment outcomes. • <i>Outdated guidelines</i> – May also lead to unnecessary prescriptions and hence encourage the unrequired use of products. 	<p>To address these challenges countries may:</p> <ul style="list-style-type: none"> • 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). • Work towards the alignment of national treatment guidelines and essential medicines’ lists (EML) with WHO guidelines, optimal regimens, and EML. • Support the procurement of optimal regimens and FDCs (where applicable) regardless of funding source; • 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
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<ul style="list-style-type: none"> • <i>Financing</i> – There may be a lack of financing to introduce or expand access to new and modern diagnostic products and technologies 	<p>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 will be transitioned to government budgets.</p> <ul style="list-style-type: none"> • Consider using external financing, where available, to strengthen the capacity and capability of implementing and monitoring the rational use of health products.
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Procurement and Sourcing

<ul style="list-style-type: none"> • <i>Procurement Processes</i> -- Procurement processes and practices may be restrictive, inefficient, and/or outdated, which may lead to suboptimal 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. • <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. • <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 	<ul style="list-style-type: none"> • 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. • Ensure procurement systems and processes consider quality, and reliable on-time supply in addition to price. • Ensure procurement requirements and specifications are non-restrictive and responsive to market conditions. • 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.).
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sources, reference prices (to benchmark the procurement outcomes) and other relevant information.	
In-country supply chain	
<p>There may be challenges related to efficient and responsive in-country supply chains, including:</p> <ul style="list-style-type: none"> • When and where parallel systems have been used, reverting to inadequate country systems may result in the disruption of supply or may have negative effect on quality of supplied products. • Poor shape and capacity and/or under prioritization of relevant infrastructure essential for storing, distributing, and managing health products / medicines. 	<ul style="list-style-type: none"> • Well before transition, consider opportunities for using grant funds for investing into and strengthening/optimizing of health product supply chains. • 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. • 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. • In cases where treatment disruptions are likely, countries can plan for stop-gap measures such as Rapid Supply Mechanisms. • Identify opportunities for RHSS activities – e.g. to strengthen LMIS, forecasting and quantification tools and develop SOPs for inventory management.
Organization and Management	
<p>There may be organization and management challenges, including:</p> <ul style="list-style-type: none"> • 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. • Insufficient human resources and or limited capability to 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. • If elements of management information systems have not been embedded in country 	<ul style="list-style-type: none"> • 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. • 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 systems necessary to be fully integrated and compatible with national systems. • Where relevant and applicable, countries may consider out-sourcing various activities to non-government entities.

<p>systems, these may be discontinued when external financing ends, decreasing overall availability and quality of data.</p> <ul style="list-style-type: none"> • Routine monitoring may not be inclusive of 'availability' of health products. 	
Additional Considerations Related to Diagnostics and Laboratory Services	
<p>Additional challenges specifically related to diagnostics and lab services may include:</p> <ul style="list-style-type: none"> • Delays in adopting and making available to patients new technologies and diagnostic methods. • In the absence of external financing, reverting to outdated, less accurate or efficient but cheaper diagnostic products and methods. • In the absence of external financing, reverting to less frequent monitoring treatment outcome or effectiveness • Lack of routine maintenance of health equipment, which may lead to inaccurate test results, malfunction of equipment, downtime, waste of reagents. • Lack of maintenance of biosafety standards and requirements, including a failure to secure necessary accreditations, risk of environmental contamination. • 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. • Weaknesses in samples referral and transportation network. 	<ul style="list-style-type: none"> • 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. • Consider financing of relevant activities, including equipment, reagents, training, to address lab related issues • Consider greater focus on how to more efficiently use existing infrastructure, such as strengthening the sample transport network rather than opening additional laboratories.

Annex VI: HMIS, M&E, and Sustainability

HMIS and M&E Specific Annex to STC Guidance Note

1. Introduction and background

The Global Fund supports country data systems through its grants investments and catalytic funding. The Global Fund aims to strengthen and build sustainable Health Management Information Systems (HMIS) and Monitoring and Evaluation (M&E) systems in close collaboration with partners under the umbrella of the Global Health Data Collaborative (HDC), involving more than 40 international organizations, donors and partner countries. The Global Fund has specified six key areas of investment in HMIS and M&E, as follows: i) routine reporting including HMIS; ii) program and data quality assessments; iii) surveys (population-based and among risk groups); iv) administrative, and finance data sources; v) civil registration & vital statistics (CRVS) system; and vi) analysis, evaluation and review. These areas are included under the Management Information and Monitoring and Evaluation module in the RSSH [Modular Framework Handbook](#), which provides an illustrative list of activities that could be budgeted under each intervention.

2. Global Fund 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 and analyze and use of 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:

1. *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.
2. *Using national M&E and HMIS 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 eventually integrating the implementation of donor-financed M&E activities through country systems. This should also include supporting national HMIS/routine reporting systems for : a) use of digital 'global public health goods', such as software to collect, manage, visualize and explore data; b) Setting, rolling and 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-based reporting and private sector data; d) Interoperability with other data systems such as Logistics Management and Information Systems (LMIS), laboratory systems, and financial data systems.
3. *Building resilient and sustainable M&E systems:* Planning and funding for building sustainable M&E systems should be aligned with the national M&E plan. These include investing in routine reporting, surveillance, population size estimates, surveys, and others, while integrating data and service quality assurance and improvement mechanisms into their routine processes.
4. *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.
5. *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.

3. HMIS and M&E sustainability challenges and considerations

Potential Challenges	Key considerations
Policy, Legislation and Governance	
<ol style="list-style-type: none"> 1. Lack of national health information policy and strategy 2. Funding for data systems and activities not always aligned with country priorities. 3. Inadequate information sharing among stakeholders regarding investments in country M&E systems. 	<ol style="list-style-type: none"> 1. Provide technical assistance and/or political/advocacy support for development of national health information policy and strategy 2. Strengthen in-country coordination through HMIS and M&E Technical Working Group that will coordinate the national and donor funding. 3. Advocate for and convene stakeholders to support one M&E platform and M&E investments plan.
Financing	
<ol style="list-style-type: none"> 1. Insufficient funding for HIS and M&E (global M&E public goods) that form the basis of country data systems 	<ol style="list-style-type: none"> 1. Work through governance structures to mobilize, coordinate and use more efficiently all stakeholder support in HIS and M&E.
Routine reporting and HMIS system	
<ol style="list-style-type: none"> 1. Project-based data systems investments leading to duplication of data collection, with no attention to data quality and future system sustainability. 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. 	<ol style="list-style-type: none"> 1. Ensure funding requests submitted to the Global Fund include activities related to building national and sustainable HMIS and M&E systems and frameworks, while engaging and coordinating with the private sector and communities. 2. Guide countries in developing one single M&E platform and interoperable HMIS and linking private sector and community-based data collection and reporting systems into the national HMIS.
Program Review and Evaluations	
<ol style="list-style-type: none"> 1. Insufficient national capacity for carrying out quality national program reviews and evaluations. 	<ol style="list-style-type: none"> 1. Engaging and building the capacities of local or regional research institutions. At global level, Global Fund plans to provide TA for carrying out quality national program reviews and evaluations in selected countries.
Data analysis and use	
<ol style="list-style-type: none"> 1. Lack of analysis and regular use of available data for decision making at all levels (central, regional and district) for program planning, resource allocation, program improvement. 2. No regular downstream feedback from higher to lower levels of data collection and reporting. 	<ol style="list-style-type: none"> 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 countries in dissemination of analyses and recommendations upstream and downstream at all levels.

Further details on the Global Fund's approach to investment in data systems and M&E are provided in the [Global Fund Data Use for Action and Improvement \(DUFAl\) Framework](#). Specific guidance on prioritizing M&E system investments in these areas is provided in the [Guidance Note on Essential Set of Data System Investments](#).

Annex VII: 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 – ie, “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, channeled through governments to compensate CSOs.³⁴ 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)?

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 (ie, 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

³⁴ 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.

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 value for money 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 (ie, 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.³⁵
- *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 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.

³⁵ 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; <https://www.msh.org/resources/community-health-services-costing-tool>

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” mechanisms³⁶

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.
- *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 – ie, 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

³⁶ 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*

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