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COVID-19 Response Mechanism Information Note

Considerations for Global Fund Support to the COVID-19 Response, including Health and Community System Strengthening, and Mitigation of COVID-19 effects on HIV, TB and Malaria Services and Programs

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Contents

Acronyms

ACT-A	Access to COVID-19 Tools - Accelerator
ARV	Antiretroviral
Ag-RDT	Antigen rapid diagnostic tests
BSCII	Biosafety cabinet class II
C19RM	COVID-19 Response Mechanism
CCM	Country coordinating mechanism
CLM	Community-led monitoring
COVID-19	Coronavirus disease 2019
COE	Challenging operating environment
DHIS2	District Health Information Software 2
DR-TB	Drug-resistant tuberculosis
EMR	Electronic medical records
EWARS	Early Warning Alert and Response System
EQC	External quality control
FE(L)TP	Field Epidemiology (and Laboratory) Training Programs
GAVI	Global Alliance for Vaccines and Immunization
GBV	Gender-based violence
GHTF	Global Harmonization Task Force
GLLP	Global Laboratory Leadership Programs
HCW	Healthcare worker
HIV	Human immunodeficiency virus
HMIS	Health management information system
HRH	Human resources for health
ICE	Information, communication and education
ICU	Intensive care unit
IDSR	Integrated Disease Surveillance and Response
IHR	International Health Regulations
IPC	Infection prevention and control
IRS	Indoor residual spraying
ITN	Insecticide treated nets
KP	Key population
LMIC	Low- and middle- income countries
LMIS	Logistics management information system
M&E	Monitoring and Evaluation
NAPHS	National Action Plan for Health Security
O2	Medical oxygen
PCR	Polymerase Chain Reaction
PHSM	Public health and social measures
PPE	Personal protective equipment
PPM	Pooled Procurement Mechanism
PR	Principal Recipient
PSA	Pressure swing adsorption

PT	Proficiency testing
QA	Quality assurance
RCCE	Risk communication and community engagement
RSSH	Resilient and Sustainable Systems for Health
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SMC	Seasonal malaria campaigns
SOP	Standard operating procedures
NSPRP	National Strategic Preparedness and Response Plan for COVID-19
TA	Technical assistance
TB	Tuberculosis
TOT	Training of trainers
UHC	Universal health coverage
UPS	Uninterruptible power supply
VIE	Vacuum insulated evaporator
WASH	Water, sanitation and hygiene
WHO	World Health Organization

Acknowledgements

Executive Summary

The COVID-19 Response Mechanism (C19RM) was designed to support countries across three broad categories: **COVID-19 control and containment interventions**, including testing, treatment, such as medical oxygen, provision of personal protective equipment (PPE), communications and other health and social measures; activities to **mitigate the effects of the pandemic on HIV/AIDS, tuberculosis and malaria**; and expanded **reinforcement of key aspects of health and community systems**, including disease surveillance and laboratory systems and community mobilization. This Technical Information Note delineates direct COVID-19 recommended activities that can be funded under C19RM across these three categories, which are further organized within the10 response Pillars which are the basis of national COVID-19 response plans.

The first category for C19RM funding in this Technical Information Note concerns the **control and containment of the virus**. Firstly, to maximize operational and financial efficiency, **country-level co-ordination and planning (Pillar 1)** activities are critical to ensure response effectiveness, as well as to support countries in aligning coordination, planning, and financing for the COVID-19 response with any other health emergencies that they may be facing. The **risk communication and community engagement Pillar (Pillar 2)** focuses on understanding people's perceptions and behaviors surrounding COVID-19, in order to help communicate health risks and related public health and social measures in a clear and timely manner through appropriate and credible channels. This is a crucial part of a national response and plays an important role in overcoming challenges such as vaccine hesitancy.

The third Pillar concerns activities that contribute to **surveillance, including epidemiological investigation and contact tracing**. Detecting cases and monitoring the spread and transmission of the virus is necessary to adjust public health and social measures, as well as adapt to new developments such as vaccine introduction and evolution of virus variants. Contact tracing is a key strategy for stopping the spread of COVID-19, along with rapid testing, isolation and care of identified cases. Moreover, testing remains one of the most important ways to inform response strategy and subsequently limit the spread of COVID-19. The **laboratory and diagnostics Pillar (Pillar 5)** encompasses activities to expand and strengthen laboratory and diagnostics capacity to manage large-scale testing for SARS-CoV-2, while building on and maintaining the established infrastructure and diagnostic capacity for other relevant diseases.

Infection prevention and control, and protection of the health workforce (Pillar 6) is a priority area that includes identifying and managing patients infected with COVID-19 to prevent the transmission of the virus to and among health workers, visitors, caregivers and the wider community. Part of the activities in this Pillar are directed towards ensuring access to safely managed water, sanitation, and hygiene, particularly for vulnerable communities and those populations affected by humanitarian crisis. Pillar 7 covers activities that fall under **case management, clinical operations, and therapeutics.** This includes developing appropriate care pathways to manage sudden surges in patient volume and to ensure those most in need can access treatment – such as corticosteroids and medical oxygen – immediately.

The second broad category for C19RM funding is the **mitigation of effects of COVID-19 on essential HIV, TB and malaria services.** This category is encompassed in the **Mitigation for Disease Programs (Pillar 9)**, which focuses on adapting and restoring health services for HIV, TB and malaria. This section represents abridged guidance content from the separate consolidated information note on mitigation of HIV, TB and malaria services. For HIV, this includes (but is not limited to) providing continued access to testing and treatment, using digital health platforms where possible, as well as ensuring the social protection and human rights of patients. For TB, activities include interventions and innovations that should be prioritized to restore and accelerate TB services, adapting TB Programming to the context of COVID-19 (by integrating these services within the wider health system for instance, and using digital technologies to support TB diagnosis, treatment and prevention), and activities sustaining commitment and resources to end TB. Malaria-focused mitigation activities include guarding against stock outs of medicines and malaria case management commodities, campaigns for malaria prevention such as the distribution of mosquito

nets, and service uptake activities that ensure the continued uptake of diagnosis, treatment and prevention services.

The third broad category of C19RM concerns Pillars and activities that fall under **health and community system strengthening.** Interventions related to resilient and sustainable systems for health (RSSH), including community systems strengthening activities, are critical to improving and underpinning the COVID-19 response, and applicants are strongly encouraged to prioritize activities included in this section for support. Cross-cutting interventions that strengthen the underlying health system are organized under four Pillars and other targeted activities.

Interventions under **Surveillance Systems (Pillar 3)** will contribute to improving countries' data collection, analytic and response capacity so that problems can be detected early, mitigation measures put in place, and the effectiveness of the mitigation measures monitored.

Laboratory Systems (Pillar 5) groups together activities that include specimen transportation networks, quality management systems, lab information systems and equipment management systems, as well as biosafety practices. In addition, while vaccination is not a primary feature of C19RM and countries are encouraged to look to either domestic resources or other donors such as GAVI and World Bank, **support to vaccine delivery services (Pillar 10)** may be requested for urgent, targeted system strengthening activities to contribute to vaccine delivery services, where these are not being supported by other partners. These include social mobilization and engagement strategies to address vaccine hesitancy, training community health workers, and identifying and reaching those excluded or not covered by the public health system.

Another cross-cutting and important aspect of countries' pandemic response are the **health product and waste management systems (Pillar 6)**, to be able to deal with the huge amount of waste that is generated (PPE, single-use commodities, and so forth) and to strengthen end-to-end health product management systems, including selection, quality assurance and regulatory approval, procurement supply chains, training, maintenance, post-market surveillance, operating costs, consumables and waste management systems, in line with WHO guidance.

In addition, specific activities can be supported under a number of crucial interventions, such as responding to human rights and gender related barriers to services, community-led monitoring, community-led advocacy and research, social mobilization, building community linkages and coordination, institutional capacity building, planning and leadership development, and gender-based violence (GBV) prevention and care.

All of the interventions and Pillars described in this Technical Information Note rest upon essential **in-country Partner Engagement** at every level, from the development of C19RM funding requests to grant implementation. This document emphasizes the critical importance of Country Coordinating Mechanisms (CCMs) engagement with national COVID-19 response coordinators to rapidly develop high quality, strategic and impactful C19RM Funding Requests. It also covers the importance of leveraging partner engagement for ongoing country dialogue during the implementation of these grants, including issues of oversight, alignment and quality assurance, based on application of Global Fund's Budgeting Guidelines. Finally, it is critical that community engagement in national COVID-19 responses be extended broadly across all response Pillars.

1. Introduction

The COVID-19 Response Mechanism (C19RM) was designed to provide support across three broad categories:

> 1. COVID-19 control and containment interventions, such as testing and treatment, provision of personal protective equipment (PPE), communications and other public health and social measures (PHSM) as specified in WHO guidance;

> 2. activities to mitigate the effects of the pandemic on HIV/AIDS, tuberculosis and malaria (referred to here as "mitigation"); and

> 3. expanded reinforcement of key aspects of health and community systems, including laboratory systems and community mobilization.

This consolidated information note:

- Covers all three priority areas and is intended for use in development of C19RM funding requests.
- Reflects the most current technical guidance based on the global COVID-19 response to date, and interim evidence, including programmatic information from country stakeholders;
- Will continue to be updated based on emerging evidence, response needs, and partner feedback/
- It is complemented by more detailed operational guidance for select domains such as COVID-19 PCR and antigen rapid diagnostic tests (Ag-RDTs) and medical oxygen, and also linked to more detailed guidance on essential HIV, TB and malaria mitigation and Community, Rights and Gender-related investments within COVID-19 responses; Supply Operations documents on product eligibility, information on product availability, reference prices for budgeting, and differentiated procurement channels; CCM engagement; and the COVID-19 Modular Framework, which details the anticipated outputs, outcomes, and impact of these investments across all three investment categories.
- Should be read in conjunction with the C19RM Funding Request Instructions, which has further details on how to fill in the C19RM Funding Request, as well as the C19RM Guidelines.

In order to align with national and global COVID-19 response strategic and operational planning, Global Fund C19RM funding requests are based on the National Strategic Preparedness and Response Plan for COVID-19 Pillars (NSPRP[1]; see Box).

The Modular Framework has been updated to reflect this approach through the addition of a 'COVID-19' module and multiple interventions that are aligned with the relevant NSPRP pillars. Interventions supporting COVID-19 control and containment include protection, diagnostics, treatment and rehabilitation of COVID-19, as well as other relevant aspects of the NSPRP reflected in the Pillar framework below. Interventions that cover the mitigation of disease programs are included under the maintenance of essential health services Pillar (9) and are covered under the three disease-specific "Mitigation" Interventions. Health and Community Systems interventions components are distributed among multiple direct COVID-19 interventions and Pillars, based on a functional distinction between direct "support" and broader "system "strengthening" activities. The latter are covered under separate health systems and community systems strengthening interventions.

An M&E framework has been developed for C19RM to ensure there is comprehensive reporting, monitoring and evaluation of C19RM investments, acknowledging the challenges of measuring results and setting targets within an emergency response to a rapidly evolving pandemic. Countries are encouraged to strengthen their data collection systems to track progress more frequently and accurately. Reinforced health management information systems (HMIS), rapid health facility assessments and household-level surveys will provide valuable information needed to manage the response and evaluate the effects and impact of C19RM investments.

Box. National Strategic Preparedness and Response Plan for COVID-19 Pillars[1]

Pillar 1: Country-level coordination, planning, and monitoring
Pillar 2: Risk communication and community engagement, including infodemic management
Pillar 3: Surveillance, including Epidemiological Investigation and Contact Tracing
Pillar 4: Ports of Entry, International Travel and Transport
Pillar 5: Laboratory and diagnostics
Pillar 6: Infection Prevention and Control, and Protection of the Health Workforce
Pillar 7: Case management, Clinical Operations, and Therapeutics
Pillar 8: Operational support and logistics
Pillar 9: Maintaining essential health services and systems (Referred to as "Mitigation" in C19RM)
Pillar 10: Vaccination

This information note also addresses partnership arrangements, covering the role of technical partners and civil society and communities in the development of C19RM Funding Requests and the implementation of the grants. CCMs and country stakeholders are encouraged to engage national COVID-19 response committees as soon as possible to define current gaps, needs and priorities to be addressed in the requests, and should engage all relevant technical and donor partners and civil society and communities in monitoring and oversight of implementation. The COVID-19 Partners Platform supports transparency, collaboration, and efficiency for countries, UN agencies, implementing partners, and donors in their COVID-19 response, and may be a helpful in planning.

2. Scope

All activities described in this document are considered within scope and eligible for support within C19RM Funding Requests, assuming they are relevant, strategically formulated and feasible for a particular context.

Based on known and expected country needs, it is anticipated that the greater portion of any additional funding will be directed towards addressing critical needs in countries' responses to COVID-19, including scaled-up procurement, regulatory approval and distribution, operational costs, training, maintenance and waste management of diagnostics, monitoring, and treatment medical equipment, and PPE based on full product life cycle use.

Health and community responses are also key to the COVID-19 response, especially through ensuring stronger surveillance and lab systems. It is critical that community engagement in national COVID-19 responses be extended broadly across all response Pillars. Specifically, full consideration should be given to effective community-led and community-based service delivery models.

Immediate health and non-health product needs should be balanced against short- and medium-term health and community systems goals.

While Principal Recipients will be able to use established reprogramming flexibilities and any grant savings reinvested through portfolio optimization for HIV, TB and malaria mitigation and catch-up plans, such resources will not be available for direct COVID-19 needs, such as COVID-19 diagnostics and therapeutics.

Given the importance of PPE both as a fundamental COVID-19 intervention and key component of mitigation activities, PPE can be flexibly funded under either C19RM or existing grants.

Mitigation activities including health commodities

For mitigation-related activities supported under C19RM, CCMs are requested to first review existing grants to determine financing availability for mitigation activities, including through reprogramming, re-budgeting, use of savings and potentially future portfolio optimization. If funding in the core grants is unavailable, CCMs should determine whether financing needs are consistent with C19RM mitigation criteria below and, if so, include these activities in the C19RM funding request, as follows:

Review Existing Grants to Determine Financing Availability	Determine if Financing Needs Consistent with C19RM Mitigation	Include Mitigation activities within C19RM funding request
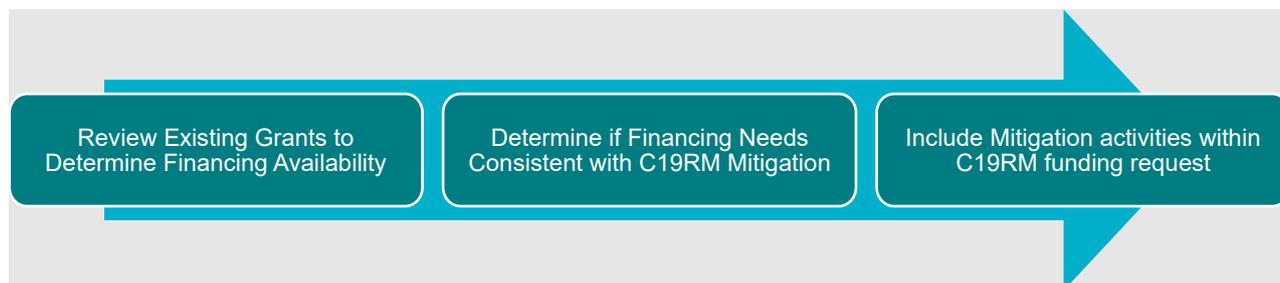
Mitigation activities are intended to prevent or limit the disruption of or access to quality HIV, TB and malaria services due to the direct or indirect effects of COVID-19. They should only be requested through C19RM if there is no grant funding available.* Eligible mitigation activities include those which:

- Involve changes to standard service delivery models to prevent or limit disruption, or
- Simultaneously support HIV, TB and malaria objectives and help contain COVID-19.

An example of a TB mitigation activity is simultaneous testing of the same patient, e.g. for both TB and COVID-19, which refers to integrated diagnostic testing service delivery models (see Diagnostics and testing section below) and community-led initiatives on infection prevention and control. Where mitigation activities require additional HIV, TB and malaria commodities, the Global Fund will work with CCMs and PRs to source those items through the existing grants, as this will be more operationally efficient than financing through C19RM. Additional HIV, TB and malaria commodities should not be included in C19RM funding requests. CCMs are requested to avoid using C19RM funding to compensate for shortfalls in domestic procurement of HIV, TB and malaria commodities. 'Catch-up' activities (i.e. those intended to improve coverage and access to HIV, TB and malaria service where they are lagging due to COVID-19) should be funded by existing grants.

* PPE for HIV, TB and malaria mitigation is not subject to this requirement and can be requested through C19RM.

These activities include measures which are intended to re-establish pre-COVID-19 service coverage and quality levels and trajectories, including towards national targets and impact goals. The following definitions are provided to facilitate planning discussions:

Mitigation (of the effects of COVID-19 on essential HIV, TB and malaria services): measures which are intended to mitigate the effects of the COVID-19 pandemic on disruption of access to quality HIV, TB and malaria services.

Adaptation (of services): one of the sub-categories of Mitigation measures which involves changes to standard HIV, TB and malaria service delivery models intended to prevent or limit the disruption of access to quality HIV, TB and malaria services due to the direct or indirect effects of COVID-19. Also referred to as program mitigation.

Catch-up: scale-up measures which are intended to recover the lost ground against HIV, TB and malaria targets of grants from the 2020-2022 allocation period, and performance trajectories due to direct or indirect effects of COVID-19.

Human Resources for Health (HRH)

The health workforce is critical to COVID-19 responses and should be included under the relevant interventions in the direct COVID-19, Mitigation, and Health and Community Systems areas. This includes support for health care workers, community health workers, and support staff that may be involved in surveillance, contact tracing, referrals, infection prevention control, case management, vaccination and others.

Dedicated procurement and supply management of health products (medicines, in vitro diagnostics, PPE, medical equipment and consumables) and lab staff might also be needed for Principal Recipient coordination and reporting to Global Fund. Health workers that have numerous functions should be included under the intervention they will provide the most support for.

Safeguarding of front-line health workers is critically important through infection prevention and control (IPC) measures including availability of IPC guidelines, training, PPE, IPC programs, amongst other interventions.

In countries where lockdown restrictions remain, health workers should follow host government guidance on home visits, leveraging telemedicine where feasible, restricting in-person care/interactions to those that cannot be virtually conducted. IPC trainings and supportive supervision should be provided virtually using online platforms, using established, standardized international and national sources whenever possible, e.g. OpenWHO COVID-19 trainings.

Countries are encouraged to employ digital applications for regular and routine information sharing with staff and to develop innovations that enable more integrated, supportive training and supervision to enhance effectiveness of health worker performance, for instance web-enabled training and supervision platforms, consistent with national and other partner guidelines.[3]

All staff hired with C19RM funding are expected to be temporary. Countries should ensure that they have appropriate TA for surge planning and there should be a financing strategy in place with a clear, timebound exit plan.

Surge capacity should complement existing staff capacity and should not undermine long-term planning and capacity building of the health workforce. In any instances where the intent is to hire non-temporary staff, the medium to long-term costs and consequences of hiring additional government staff should be carefully considered and justified, including impact on resilient health systems and preparedness for future outbreaks.

Appropriate funding should be allocated to knowledge transfer, initiated by C19RM activities, from temporary staff to existing staff related to the procurement, installation, and steady state operations of medical technologies. The Global Fund Guidelines for Grant Budgeting apply to all HRH requests, including the required sustainability plan for how additional costs will be absorbed by the government.

Health Products

As health products will remain a major feature of C19RM financing based on country response needs, the Global Fund has developed a health product segmentation framework for health products to control and contain COVID-19. Product eligibility and procurement considerations which are reflected within this framework are also aligned with C19RM Fast-track Funding Requests. Specifically, the products designated here as "Optimal" are also eligible under the Fast-track Funding Request, along with the costs associated with their effective deployment.

Procurement of "Limited use/specialized" products is expected to remain restrictive and to require sufficient justification in the C19RM Funding Request, e.g., equipment for gene sequencing. The non-exhaustive list of products indicated in the non-recommended category are items that are not recommended by WHO to control COVID-19 and are thus not eligible for funding via C19RM. If recommended by WHO outside of the COVID-19 context, the latter should be proposed for grant funding, as appropriate in the local context.

Annex 1 contains additional considerations and information on health products.

Table. Health Product Segmentation Framework

Intervention/Health Product Category	Optimal	Limited Use / Specialized	Not Recommended
Laboratory and Diagnostics	SARS-CoV-2 Ag RDTs, SARS-CoV-2 molecular tests with swabs and control material. Consumables for sample transport.	Equipment and consumables for genomic sequencing. Antibody testing for surveillance purposes only. Low throughput molecular testing platform for multi-disease testing (HIV/TB and COVID-19 tests conducted on the same equipment). Automated extractors. Procurement of ancillary equipment (i.e. biosafety cabinet class II, refrigerators, incinerators, centrifuges, pipettes, vortexes, etc.)	N/A
Infection Prevention and Control (IPC)	Core PPE (apron protection, examination and surgical gloves, face shields, masks, respirators, fit test kits, gowns and protective goggles); Scrubs; Core IPC supplies: soap, sanitizers, safety boxes, chlorine, biohazard bags, etc.	Other PPE/IPC supplies including aprons (coveralls), rubber boots, heavy duty gloves.	N/A
Case Management and Therapeutics*	Concentrators; distribution systems (i.e. cylinders, piping); select liquid Oxygen (tanks), PSA/plants; masks, tubing, nasal cannulas, face mask, and related Patient monitors (pulse oximetry), infusion pumps, and consumables for respiratory care Dexamethasone; low dose heparin or low molecular weight heparin	Select liquid Oxygen (tanks) and PSA/plants	Medicines not recommended by WHO to treat COVID-19, including lopinavir/ritonavir; hydroxychloroquine; and remdesivir

*__See Annex 4 for detailed information regarding liquid O2 and PSA Plant packages meeting Optimal (Fast Track-eligible) and Limited Use/Specialized categories. Fast-Track Funding Requests should reference these packages as much as possible to facilitate eligibility determinations.__

For procurement of laboratory equipment such as molecular PCR machines - with the exception of low throughput instruments such as near-POC instruments for TB or HIV testing where appropriate, countries should consider reagent rental contracts which may decrease capital costs and leverage "all-inclusive" pricing offers, including options for vendor managed inventory, maintenance and service, to optimize value for money. More information on contracting models is available here.

For procurement of oxygen-related equipment, consideration should be given to ensuring that consumables and accessories are purchased concomitantly to ensure at least six-months supply (avoiding stock out); and that appropriate technical assistance (biomedical and clinical) and warranties are available to ensure proper operations.

Quality assurance (QA) requirements for health product eligibility

For the selection and procurement of any health product (e.g. diagnostics, PPE and treatment, including oxygen-related equipment), Global Fund Quality Assurance policies will apply.[78] For operational guidance, see the Guide to Global Fund Policies on Procurement and Supply Management of Health Products,[8] which includes quality assurance requirements for PPE which take effect on 1 July 2021. Additional operational guidance regarding product eligibility, including the list of SARS-CoV-2 diagnostic test kits and equipment eligible for procurement, is available on the Global Fund's website.[9]

Additional guidance on health products can be found in Annex 1, and more information, including a detailed mapping of health products against the above health product segmentation framework is available here.

3. COVID-19 Control and Containment

The direct COVID-19 recommended activities are based on the updated 2021 WHO COVID-19 Strategic preparedness and response plan: Operational planning guideline. As the official Pillar titles have been aligned with the Intervention categories within the C19RM Modular Framework, some of the titles herein have been modified to reflect this alignment.

Country-level co-ordination and planning (Pillar 1)

Inclusive multi-sectoral and multi-partner mechanisms for coordination, planning, financing and monitoring at national and sub-national level are essential to avoid duplication of efforts within and among the Pillars of the response, ensure there are no gaps in preparedness and response efforts, maximize availability and efficient allocation of resources including new COVID-19 vaccines, and support strengthening of health and community systems. More than one year into the COVID-19 pandemic, many countries now face or are at risk of concurrent health emergencies from multiple causes. To support multiple emergency responses, especially in challenging operating environments (COEs), countries should align coordination, planning, financing, and monitoring for the COVID-19 response with broader emergency coordination mechanisms. Capacities to be operationally ready for and respond to concurrent emergencies should be evaluated at national and sub-national levels and national COVID-19 preparedness and response operational plans should be updated accordingly. All countries and partners are strongly encouraged to utilize the WHO COVID-19 Partners Platform to plan and coordinate their response with real-time, transparent information sharing.

Specific activities which can be supported under this Intervention category (Pillar) include:

- Meetings related to governance of COVID-19 response, e.g. planning to support inter-sectoral or cross-border collaboration.

- Support to civil society and community organizations in order to play a meaningful part in country-level co-ordination.

- Intra-action reviews and simulation exercises to assess and remediate response Pillars based on local gaps, needs and priorities.

- Institutional capacity building support to a health coordination body such as a Public Health Emergency Operation Centre, e.g. in program management.

- Support public financing systems which will enable governments to increase fund flows to local levels, including via social contracting, based on WHO recommendations on COVID-19 response budgeting.

Please refer to the WHO COVID-19 Strategic preparedness and response plan: Operational planning guideline for detailed information on prioritized actions. Countries should use this framework to assess current gaps and needs and define priority activities.

Risk Communication (Pillar 2)

The risk communication and community engagement (RCCE) pillar aims to prevent and reduce the negative impacts of COVID-19 on individuals and communities by using evidenced-based approaches to understand people's perceptions and behaviors, communicate risk through timely, credible and relevant information and channels (e.g. community-based organizations).

Slowing the transmission of COVID-19 and protecting communities requires a whole-of-society approach with the participation of every member of every community to take action and prevent transmission.

People's behaviors, and their willingness and ability to follow public health and social measures remain the most powerful means to stop the spread of the virus. Consequently, there is an unprecedented opportunity to leverage RCCE in breaking the chains of transmission and mitigating the impact of the pandemic. Understanding communities and adapting to reflect those insights will look different for every community.

New challenges in 2021 include the need to overcome vaccine hesitancy, and to counter and build resilience to deliberate anti-vaccine misinformation in a context of increasing pandemic fatigue. Evidence-driven, people-centered and community-led approaches have proven successful in many countries.

Specific activities which can be supported include:

- Develop/update national COVID-19 RCCE action plans using social data analysis of context and communities, e.g. on gender responsiveness. Plans should reflect community input to effective public health and social measures while addressing community readiness for vaccines, treatments and tests.

- Identify and map marginalized and at-risk populations to engage with culturally appropriate messages using relevant channels and community networks/influencers.

- Pilot messages through participatory processes. Prepare contextualized messages with communities based on latest evidence and pilot messages through a participatory process that specifically targets key stakeholders and, where possible, all sub-population groups.

- Establish mechanisms to embed the voice of communities into decision-making for emergency response (i.e. by nominating community representatives to participate in response planning and implementation, addressing diversity and gender parity, etc.).

- Activate or strengthen RCCE coordination mechanisms and working groups in coordination with UN agencies, levels of government, civil society and partners to ensure the efficient use of each organization's strength and audience. Ensure participation of community and vulnerable groups.

- Develop and implement information materials and campaigns, including on COVID-19-related community mobilization and sensitization messages including SMS/text messages, radio messages, and/or announcements in the site.

- Support community mobilization activities that involve affected communities, key and vulnerable populations, women and girls, men or other groups in the development of Information, Communication and Education (ICE) materials on COVID-19.

- Build on RCCE experiences and capacities built during the response to strengthen the role of communities in support of longer-term preparedness and emergency risk management functions.

- Salary, training and supervision for temporary staff supporting the above, including at community level.

Please refer to the WHO COVID-19 response operational guidelines.

Surveillance, including Epidemiological Investigation and Contact Tracing (Pillar 3)

COVID-19 surveillance data are essential to detect cases, monitor geographical spread and transmission intensity of the virus, track trends in age, gender and vulnerable population and settings, assess impacts on health-care services, and adjust appropriate and proportionate public health and social measures (PHSM), and to adapt to new developments such as vaccine introduction and evolution of virus variants.

Contact tracing – along with rapid testing, isolation and care of identified cases – is a key strategy for interrupting chains of transmission of SARS-CoV-2 and reducing COVID-19-associated mortality. It can also be used to find a source of infection by identifying settings or events where infection may have occurred, allowing for targeted public health and social measures. Community-based organizations and digital tools can enhance contact tracing for COVID-19, but ethical issues around accessibility, privacy, and security need to be considered as they are designed and implemented.

Specific activities which can be supported include:

- Conduct capacity assessment and risk analysis for specific settings, including mapping of vulnerable populations or events such as mass gatherings, as appropriate.

- Identify needs to strengthen contact tracing, active case finding, isolation, cluster investigation, as well as testing at all levels.

- Identify needs to strengthen diagnostic capacity at all levels. If capacity is insufficient, prioritize testing and measures that can reduce spread (e.g. isolation of cases, quarantine of contacts).

- Assess need to include in surveillance strategy use of genetic and serological surveillance or sero-epi studies, with aim to measure the effective extent of infection in the general population or sub-populations and the proportion of undetected or unreported infections (e.g. asymptomatic infections, insufficient testing capacity, or people who do not seek or cannot afford to seek care).

- Engage with multisectoral household or community surveys that monitor adherence to PHSM, socio-economic impacts, and COVID-19-induced barriers to basic needs including health.

- Conduct a risk–benefit analysis using defined indicators adapted to the existing systems and local context to decide when control measures need to be adjusted, per WHO guidance. Develop thresholds to scale up and down PHSM.

- Use local situation assessments (transmission level and response capacity and performance) to guide actions or changes to response strategy, particularly with respect to adjustment of PHSM.

- On the basis of assessments above, new knowledge and lessons learned, develop and/or regularly update: a) COVID-19 national surveillance strategy / guidelines including on public health and social measures; and b) COVID-19 national contact tracing strategy including international contact tracing; as well as case definition and investigation protocols per WHO guidance.

- Salary, training and supervision for temporary staff supporting the above, including at community level.

Genomic sequencing has been critical in detecting and responding to new SARS-CoV-2 variants. Increasing sequencing capacity and access to existing capacity across the world is a high priority during 2021. A diagnostic implementation package, Package 4: "Support for genomic surveillance / sequencing activities", aims at developing genomic surveillance plans and sampling strategies, expanding capacities leveraging existing integrated surveillance networks, and training for country staff. These activities are not proposed to support individual patient management or clinical care. See Annex 2 for details.

Systems aspects of COVID surveillance are reflected below in the section on Health and Community Systems. Please refer to the WHO COVID-19 response operational guidelines.

Diagnostics and Testing (Pillar 5)

Testing remains one of the most important ways to inform response strategy and subsequently limit the spread of COVID-19. Extensive, systematic, and strategy-based testing can be used to inform public health and social measures such as contact tracing, quarantining of suspected cases and isolation of confirmed cases, and avoid extensive repeated lockdowns.

Countries should continue to strengthen and sustain domestic diagnostic and laboratory capacity to manage large-scale testing for SARS-CoV-2 at national and sub-national levels, while building on and maintaining the established infrastructure and diagnostic capacity for other relevant diseases.

In addition, countries are encouraged to use national data platforms to document critical clinical, epidemiological and virus data that facilitates overall response management, including related to the detection and assessment of new SARS-CoV-2 variants. A national testing strategy should be available that includes a clear structure and defined internal governance on coordination and how collaboration with stakeholders (including communities) is organized.

There should be a national plan that provides clarity on how laboratories and diagnostics are integrated with the other measures in the response. In the event of widespread community transmission, surge plans should be activated to manage the increased volume of samples from suspected cases.

Essential diagnostic testing includes the following:
   a. Molecular testing, as the gold standard for diagnosis and with multiple technologies that have received regulatory approvals for COVID-19 testing; and
   b. Antigen (Ag) rapid testing for SARS- CoV-2, which is being introduced and scaled-up allowing decentralization of testing capacities and support patient management and public health measures.

Use cases for each testing type and specifications for tests to be procured should be aligned with WHO recommendations on Laboratory Testing Strategy and Antigen Detection in the Diagnosis of SARS-COV2 infection.

Specific activities which can be supported include:

- Choice of interventions aimed at expanding laboratory capacity to manage large-scale testing for COVID-19 — either domestically, or through international reference laboratories:

   o Establish access to a designated international COVID-19 reference laboratory;

   o Adopt and disseminate standard operating procedures (SOPS; as part of disease outbreak investigation protocols) for specimen collection, management, and transportation for COVID-19 diagnostic testing;

   o Identify hazards and perform a biosafety risk assessment at participating laboratories; use appropriate biosafety measures to mitigate risks; More information is available on the WHO Assessment tool for laboratories implementing SARS-CoV-2 testing: interim guidance.

   o Adopt standardized systems for molecular testing, with assured access to reagents and kits;

   o Develop and implement plans to link laboratory data with key epidemiological data for timely data analysis;

   o Develop and implement surge plans to manage increased testing demand; consider measures to maintain essential lab services, e.g. limiting testing to people at high risk of poor outcomes and based on establishing key epidemiologic trends, if needed, in anticipation of possible widespread COVID-19 transmission;

   o Share genetic sequence data and virus materials according to established protocols;

   o Monitor and evaluate diagnostics, data quality and staff performance, and incorporate findings into strategic review of national laboratory plan and share lessons learned;

o Develop quality assurance mechanisms for each testing methodology, including point-of-care.

- Technical assistance for adoption of packages (below) devised to support countries in the preparation of funding requests, with a proposed menu of interventions.
  - Development of guidelines and SOPs to account for integrated testing, prioritization (e.g. COVID-19, EID, VL, TB testing on molecular multi-testing platforms and workflow; and
  - Salary, training and supervision for temporary staff supporting the above including at community level (e.g. contracting of community-based organizations for rapid testing at community level).

As recommended by WHO since 2017, multi-disease testing devices (also known as polyvalent testing platforms or multianalyte analyzers) refer to common lab equipment and capacity to support multiple testing streams. Such devices support integration of COVID-19 testing into existing testing systems.

WHO also recommends "simultaneous testing" of the same patient, e.g. for both TB and COVID-19, which refers to integrated diagnostic testing service delivery models (also called "bi-directional" testing in India). Such approaches are not implemented at laboratory level but rather at testing sites, per clinical guidelines.

To facilitate the preparation of the funding applications, diagnostic implementation packages include:

- Package 1A - *Introduction and adoption of Antigen SARS-CoV-2 testing* and
- Package 1B - *Scale-up of Antigen SARS-CoV-2 testing for countries already implementing Ag-RDTs.*

The packages also refer to related activities accompanying the procurement of SARS-CoV-2 Rapid diagnostic tests (RDTs), such as procurement of PPE, training, support to quality assurance, and technical assistance supporting the development of testing strategy.

Package 2 - *Scale-up of Implementation of SARS-CoV-2 Molecular Testing* (including Low- and High-Throughput molecular testing platforms) refers to activities related to implementation of molecular testing. Requests for molecular testing platforms should be justified with submission of evidence related to the pre-requisites, as indicated in the detailed lab packages; and approval of funding requests will be dependent on availability of supporting documents.

These packages can be submitted for Fast-Track review with the exception of low throughput molecular testing platforms and automated extractors which will be submitted for full review. Detailed descriptions are provided in Annex 2. Also please refer to the WHO COVID-19 response operational guidelines.

World Health Organization (WHO) Information Note. Tuberculosis and COVID-19; 12 May 2020

World Health Organization (WHO) Information Note. Considerations for adoption and use of multi-disease testing devices in integrated laboratory networks. 2017.

Stop TB Partnership Briefing on COVID-19 and TB Bi-directional Testing

Infection Prevention and Control, and Protection of the Health Workforce (Pillar 6)

In the context of COVID-19, Infection prevention and control (IPC) measures and practices in health facilities and communities should be evaluated using existing standardized tools (e.g. IPC health-care facility response for COVID-19 core components), enhanced for identification and management of patients infected with SARS-Cov-2, and to ensure prevention of transmission to staff, among staff, between staff and patients/visitors/caregivers, and in the community. This includes monitoring at national, sub-national and facility level to prevent health care associated infections during provision of care in non-COVID-19 health services (or settings).

Enabling IPC measures is dependent on access to safely managed water, sanitation, and hygiene (WASH), particularly for vulnerable communities and those populations affected by humanitarian crisis.

It will be critical to incorporate preparedness and readiness in the central coordination mechanism at health facility level to reduce avoidable mortality from COVID-19 and other concurrent emergencies, with particular focus on safety and security of health care personnel and all essential workers (including community volunteers and outreach workers).

Specific activities which can be supported within health facilities and community settings include:

- Assess health facility IPC capacity for COVID-19, ensuring WHO-recommended minimum requirements for IPC programs; these include IPC focal point, functional triage system and isolation rooms, sufficient IPC (PPE and WASH services) supplies, trained staff, sufficient staff-patient ratio;

- Adapt, disseminate and implement IPC guidance such as the use of standard and additional precautions for health care settings including home and community care providers.

- Provision of sufficient IPC supplies including Personal Protective Equipment (PPE) and WASH items for COVID-19; masks, respirators, gowns, gloves, goggles, face shields, hand sanitizer, etc., based on implementation of national and sub-national policies and strategies per WHO guidelines. **Note that all COVID-related PPE needs for HIV, TB and malaria mitigation activities should also be included here, where not supported within existing grants**;

- Encourage international collaboration for the development of practical, robust and sustainable PPE, compatible with patient-centered care;

- Development of "PPE" for community settings, primarily aimed at mitigating transmission and decreasing burden of waste for relatively low-risk community transmission scenarios (e.g., where social distancing permits);

- Provide training to health workers and essential staff, including volunteers, peer educators, etc., according to national strategy, on IPC measures and on rational use of PPE in COVID-19 context;

- Implement strategies and tools for preventing, identification, management and monitoring of health workers COVID-19 exposure or infections at work or in the community;

- Implement improvements to health facility water and sanitation according to road maps;

- Conduct health facility and IPC tabletop exercise that aims to examine implementation of IPC strategies required to prevent or limit intra-facility transmission of SARS-CoV-2;

- Support access to WASH services in public places and community spaces most at risk, with special considerations for vulnerable populations;

- Plan and procure waste management supplies and equipment for appropriate implementation of waste management protocols;

- Apply IPC measures including practices for hand hygiene and safe injections, appropriate and rational use of PPE, safe waste management and training of health workers involved in the delivery of the COVID-19 vaccine program;

- Monitor and evaluate IPC guidance dissemination, implementation and impact;

- Ensure hand hygiene stations are available, supplied and functioning at all gathering places (markets, clinics, places of worship, public facilities and transport stations) in COVID-19 affected areas, high-risk areas and humanitarian settings in line with the "Hand Hygiene for All" initiative;

- Salary, training and supervision for temporary staff supporting the above.

Please refer to the following WHO guidelines:
- [WHO COVID-19 response operational guidelines](#).
- https://www.who.int/publications/i/item/WHO-2019-nCoV-PPE_specifications-2020.1
- https://www.who.int/teams/risk-communication/health-workers-and-administrators

Case management, Clinical Operations, and Therapeutics (Pillar 7)

Adaption to health services due to large increases in patients with suspected or confirmed COVID-19 at national and sub-national levels should be implemented. In all health facilities, staff should be familiar with the suspected COVID-19 case definitions and must be able to deliver the appropriate COVID-19 care pathway, ensuring that patients with, or at risk of, severe illness are treated and referred immediately. A high volume of cases will put staff, facilities, and supplies under pressure. This pressure can be minimized with appropriate surge planning. A COVID-19 referral pathway, which designates appropriate care settings for mild and low-risk moderate COVID-19 patients, may allow for care in the community, at a community facility or at home, particularly through use of pulse oximetry for triage and referral from community to hospital settings. For those with severe or critical disease, this includes care areas in hospitals that have capacity to give basic emergency and critical care (i.e. monitoring, oxygen therapy and advanced respiratory support) and therapeutics (i.e. corticosteroids), and in any part of health facilities, primary care/outpatient clinics, as well as pre-hospital settings and ad hoc community facilities, that may receive patients with severe COVID-19. Finally, care after acute illness, for all patients that have had COVID-19, should be implemented in case patients experience persistent or waxing and waning symptoms of Post COVID-19 condition.

Specific activities which can be supported include:

- Disseminate regularly updated information and evidence, train, and refresh the health workforce in management of COVID-19, using protocols based on international standards and WHO guidance;

- Ensure availability of and access to quality, safe and cost-effective pharmaceuticals, medical devices, oxygen and other health technologies considered essential for the treatment of COVID-19, according to level of care and context, including service and maintenance where appropriate to ensure continuous availability of equipment. These include provision of the following:

  o Provide pulse oximeters, medical oxygen cylinders, cannister, and systems, including disposable, single-use, oxygen-delivering interfaces (nasal cannula, Venturi mask and mask with reservoir bag); generators; dexamethasone/steroids, anticoagulants, intensive care beds, physiological parameters monitors, infusion pumps and IV sets, invasive and non-invasive ventilators, and imaging equipment (ultrasound, chest X ray (including digital) and CT, to complement IVD diagnosis; [13,14,15] and investments to ensure device use (e.g., generators); [see Annex 3 and Annex 5 for details]

- Set up screening and triage areas at all health care facilities with capacity for isolation of suspected and confirmed cases; and set up screening capacities in the community;

- Establish medical surge capacity according to epidemiological scenario and health services network context. Surge should take into account maintenance of essential health services to avoid excess mortality; as well as biomedical technicians and clinicians with capacities to manage oxygen systems and provide care of severely ill patients. Surge also needs to take into

account safe hospital spaces with engineering and administrative controls to care for COVID-19 patients (see IPC);

- Apply steps to monitor and control indoor ventilation in the context of COVID-19;

- Integrate training packages developed for the management of sudden increased health needs into curricula for different occupations of health workers and managers;

- Monitor performance indicators at patient level to assess whether processes of care are improved. For example, did patients with severe or critical COVID-19 receive oxygen and corticosteroids? If not, then explain why. Use this information to improve quality of care;

- Evaluate implementation and effectiveness of case management procedures and protocols (including for pregnant women, children, elderly patients, and immunocompromised patients), and adjust guidance and/or address implementation gaps as necessary;

- Enhance capacity of informal caregivers in community to provide social support and outreach;[13]

- Implement national assessment of medical oxygen demand and gaps (see Annexes 3 and 4); and

- Salary, training and supervision for temporary staff supporting the above.

Please refer to the [WHO COVID-19 response operational guidelines](#); and [WHO Priority medical devices list for the COVID-19 response and associated technical specifications](#).

4. Mitigation for Disease Programs (Pillar 9)

More details on the range of mitigation measures that may be needed, as well as for HIV, TB, and malaria services in the context of COVID-19 can be found in this consolidated HIV, TB and Malaria mitigation Information note, which includes links to the key technical guidance developed by partners. Section 2, above, of this C19RM Technical Information Note provides a decision tree to assist country stakeholders in determining which funding source can and should be used to support disease-specific mitigation-related interventions. Priority intervention areas are listed below – but do not substitute the more detailed and consolidated HIV, TB and Malaria information note.

HIV

- HIV prevention: Restart, adapt and accelerate integrated HIV prevention services, prioritizing those populations with greatest needs (key populations in all locations and AGYW and their sexual partners in high HIV incidence locations).

- HIV testing: Remain focused on early diagnosis - prioritize differentiated testing strategies, scale up of HIV self-testing especially for populations not coming forward or being reached by facility testing. Continue testing at ANC and EID. Ensure linkage to ART.

- HIV treatment and care: Focus on early initiation of ART following diagnosis and continuation of ART, ensuring continuous supply of ARVs to achieve/maintain viral suppression. PLHIV with advanced disease should be cared for by qualified providers. Consider the needs of different populations, including children and adolescents.

- COVID-19 management for PLHIV (protection, testing and vaccination) should be in line with respective local guidance.

- Commodity security: Anticipate challenges in procurement and supply, such as delays of shipments, potential increased needs, and adaptations required to deliver essential health products to people affected by HIV.

- Health care workers: Protect the safety and morale of health care workers for all cadres delivering HIV services and support them to execute new tasks where reassigned.

- Social protection and human rights: strengthen current service delivery platforms to address human rights violations, including gender-based violence (GBV).

- Community response: Support the development, adaptation and delivery of additional services through CBOs and expansion of CLM.

- Permanent adaptation of service delivery for pandemic resilient services: Adopt people-centered models using pharmacies and alternative delivery channels for services and commodities. Accelerate the use of digital health platforms, digital tools and mobile apps for communication, data visualization and service delivery for HIV prevention, testing and treatment.

TB

Interventions and innovations that should be prioritized to restore and accelerate TB services:

- Diagnosis: campaigns, active and intensified case finding, bi-directional screening/testing for TB and COVID-19, using X-rays with computer-aided detection (CAD), access to rapid molecular diagnostic tests, sample transportation, integrated TB/COVID-19 contact investigations.

- Treatment: community/home delivery of medicines, e-pharmacy, multi-month drug dispensing, all-oral regimens for DR-TB, digital adherence technologies, community engagement, social protection for high-risk groups including nutritional and psychosocial support.

- Prevention: Airborne Infection Prevention and Control (IPC) especially in health care and congregate settings, scale up use of new regimens for TB prevention among contacts, PLHIV and other high-risk groups.

- Adapting TB Programming to the COVID-19 situation: shift to community, home-based and people-centered models, strengthen linkages between the community and facility-based interventions, promote integration with wider health system including COVID-19 responses, train and protect health and community workers from COVID-19 and TB. Interventions to address the long-term sequelae of TB and COVID-19 and activities to address community (population) fear of both COVID-19 and TB and to address the associated stigma and discrimination.

- Enhanced surveillance with real-time case-based reporting and use of digital technologies to improve programmatic reporting and use of data for agile and responsive decision-making.

- Private Sector Engagement: contracting, scaling up innovative approaches to increase TB diagnosis, notifications, and treatment support of private patients.

- Sustaining commitment and resources to End TB: Communication campaigns and multi-sectoral response; Step-up proactive advocacy efforts in countries to highlight consequences of TB budget shifts.

Malaria

Interventions that should be prioritized to maintain access to and uptake of malaria services include:

- Malaria case management: Review quantification of malaria case management commodities. Plan early for additional commodities, waste management transport and storage if necessary. Consider adapting the case management model if needed, including decentralization with CHW expansion if not included elsewhere. Ensure PPE for CHWs as well as health facility workers are included in the wider health system PPE planning.

- Malaria vector control and chemoprevention: Ensure Insecticide Treated Nets (ITN), Indoor Residual Spraying (IRS), and Seasonal Malaria Campaigns (SMC) go ahead on time, planning and procuring as early as possible. Plan adaptations to campaign distribution models, including consideration of digitization, with PPE procurements planned as needed. Maintain routine ITN and malaria in pregnancy services, adjusting as needed.

- Surveillance, monitoring and evaluation: Consider how surveillance, monitoring and evaluation can be adapted to the COVID-19 context, improving data for planning and intervention as well as enabling continuation of key data collection in line with local restrictions.

- SBCC: plan adaptations to or expansion of messaging as appropriate to support continued, equitable update of case management and prevention services. Particular attention may be needed on care seeking for fever.

- CRG and specific groups: Assess whether the COVID-19 has altered equity of access, with particular consideration to gender (pregnancy) and age vulnerabilities of malaria as well to migrants, refugees and mobile populations. Consider needs of ensuring equity of access in all groups during planning and implementation. Ensure meaningful involvement of these communities throughout.

- Technical Assistance: Consider accessing technical assistance for the development or implementation of costed COVID-19 mitigation plans for malaria, or components thereof.

5. Health and Community System Strengthening

Interventions related to resilient and sustainable systems for health (RSSH), including community systems strengthening activities, are critical to improving and underpinning the COVID-19 response.

As noted in the scope section above, **applicants are strongly encouraged to prioritize activities included in this section for support**. They are critical to the continuity of essential health services and can help ensure that direct COVID-19 responses are embedded into the health system to enable a more sustainable response.

Where health systems investments contribute to future pandemic preparedness, CCMs will be requested to ensure appropriate:

1. involvement of relevant actors, such as national International Health Regulation (IHR) focal points and epidemic preparedness coordinating bodies; and

2. alignment with relevant technical frameworks including the International Health Regulations (IHR), the Global Health Security Agenda/Joint External Evaluations, WHO Benchmarks for IHR Capacities, and, where available, National Action Plans for Health Security (NAPHS).

This engagement will strengthen country-level accountability and ensure more rigorous alignment with other domestic and donor funding. The Global Fund encourages countries to explore innovations in their COVID-19 responses to enable greater impact, innovating around how to strengthen community responses, strengthen lab and supply chains, and make better use of the private sector.

The interventions and activities listed below focus on activities that are more cross-cutting than those listed in the direct COVID-19 response section above, in that they are meant to strengthen the underlying health system. They are organized in alignment with select components of the national COVID-19 Response Pillar (SPRP) framework to make it easier to request funding based on the national COVID-19 response plans. The interventions include surveillance systems, laboratory systems, health products and waste management, which are all important components of the health system, and which need to be strengthened to enable a better COVID-19 response. Together, alignment with prioritized national COVID-19 response plans and existing epidemic preparedness plans will enable investments that embody "value for money", a concept that defines how to maximize and sustain equitable and quality health outputs, outcomes and impact for a given level of resources.

There are also six interventions related to community systems and responses, related to human rights and gender barriers, community-led monitoring, community-led advocacy and research, social mobilization, building community linkages and coordination, institutional capacity building, planning and leadership development, and gender-based violence prevention and care. Community systems and responses engagement of communities including key and vulnerable populations are key to the COVID-19 response. For further information, please refer to the list of activities below of necessary community, rights and gender-related investments during COVID-19 as well as the accompanying CSS information note.

As noted above in the Scope Section, human resources for health are critical to the response and, where appropriate, should be included under the relevant interventions in the direct COVID-19, Mitigation, and Health and Community Systems areas. This includes support for facility- and community-based health care workers that may be involved in surveillance, contact tracing, referrals, and case management, including home-based care for COVID-19 patients using pulse oximeter and oxygen tanks or concentrators with nasal prongs. Dedicated procurement and supply management, engineers and technicians, and lab staff might also be needed for PR coordination/reporting to Global Fund. Health workers that have numerous functions should be included under the intervention they will provide the most support for.

The medium to long-term costs, risk-benefits, and consequences of hiring additional government staff should be carefully considered, and the Global Fund's Budgeting Guidelines apply to all HRH requests, including the requirement to present a sustainability plan for how additional costs will be absorbed by the government. For all HRH activities related to training and supervision, innovations to enable more integrated, supportive training and supervision to enhance effectiveness of health worker performance are encouraged. C19RM funding cannot be used for 'risk/hazard incentives/payments' to health workers due to COVID-19. Training and capacity building for clinicians, nurses, engineers, and laboratory staff should be prioritized.

Finally, decisions on funding of infrastructure projects will be made only exceptionally. Section 7.5 of the Global Fund Budgeting Guidelines applies to this type of project. Well-articulated infrastructure projects with a clear rationale and which are relevant to the national COVID-19 response can be approved in exceptional cases within C19RM Funding Requests.

More information can be found in the document: Value for Money concept and measures and:

- WHO IHR Joint External Evaluations
- WHO Benchmarks for IHR capacities (2019)
- WHO National Action Plans for Health Security

Surveillance Systems (Pillar 3)

There is an overall need to improve country analytical capacity given the many challenges and uncertainties associated with COVID-19. It has become even more pressing to have frequent and reliable data on the key indicators so that problems can be detected early, mitigation measures put in place, and the effectiveness of the mitigation measures monitored. Routine HMIS, health facility data and household level data will all need to be enhanced, and intra-action assessments will help ensure data are used appropriately.

Where new digital health tools are proposed, CCMs and national response managers are encouraged to map these against the Health System Challenges, Digital Health Interventions, and System Categories from the WHO Classification of Digital Health Interventions. Furthermore, the best suited digital health solutions are those that are mature Global Goods as assessed by the Global Goods Maturity assessment framework.

Specific activities that can be supported under this intervention include:

- Integration of COVID-19 surveillance and routine reporting, including for contact tracing, in existing HMIS platforms. These may include national HMIS, Early Warning Alert and Response System (EWARS), event-based surveillance, influenza, vaccine-preventable disease and/or Integrated Disease Surveillance and Response (IDSR). Use digital platforms where possible for real-time information sharing.

- Activities to ensure availability and use of disaggregated data at all levels for planning and programmatic decision making.

- Investments for cross-cutting/integrated data systems for routine reporting and surveillance that require more funds than originally funded in the grants due to COVID-19:

  o Update assessment, review or situational analysis of HMIS, e.g. digital health roadmaps, to incorporate COVID-19 routine reporting and surveillance, or other activities specific to COVID-19;

  o Update national digital Health Information Systems strategies or implementation plans, including for patient-level data systems, e.g. electronic medical records, to incorporate COVID-19;

  o Integrate routine reporting and surveillance of community-level COVID-19 health services into existing Community Health Information Systems;

- o Technical support for Geographic Information Systems, analysis and use geographic data, including georeferenced master health facility list and CHWs/community-based services; and decentralized (e.g. district, sub-district) planning based on master lists, for COVID-19 response activities.

- o Additional data systems governance or coordination support that is needed given the COVID-19 context and associated new data system proposals and funding, e.g. for conducting/updating inventories of the data systems in country; for a stakeholder group or other governance mechanism to serve as a 'clearinghouse' and coordination for new data system proposals and funding during COVID-19; for developing and/or implementing policies on patient data privacy, data security, and data sharing;

- o Additional data quality improvement activities due to COVID-19 including data quality assurance, supervision, assessments, and validation;

- o Additional temporary human resources, training, and/or technical assistance needed for data collection, reporting, analysis and use due to COVID-19, including digital workforce.

- Implementation of Field Epidemiology (and Laboratory) Training Programs (FETP/FELTP) – also known as Global Laboratory Leadership Programs (GLLP) - which produce front-line epidemiologists and laboratory leaders at sub-national and facility levels to support data analysis and use.

Laboratory Systems (Pillar 5)

Specific activities which can be supported under this intervention include:

- Specimen transport networks, quality management systems, lab information systems and equipment management systems

- Biosafety practices, as any COVID-19 testing should be performed in appropriately equipped laboratories, or facility- and community-based venues, by staff trained in relevant technical and safety procedures

A dedicated package - Package 3: *Strengthening Integrated Laboratory Systems* - has been developed with activities aiming at strengthening key aspects of laboratory services. (See Annex 2 for details) Applicants are encouraged to consider integration of COVID-19 testing into their existing laboratory system, leveraging past investments and installed equipment to strengthen the overall capacity to respond to COVID-19 and HIV, TB and malaria needs. Shortening the turnaround time for results is a key consideration to improve patient management and public health measures, therefore the procurement of diagnostic products and equipment should be coupled with innovative approaches such as integrated sample transportation systems, and laboratory information systems to facilitate delivery of test results.

Systems Support Contributing to Vaccine Delivery Services (Pillar 10)

Vaccination is not a component of the Global Fund Strategy nor is it a primary feature of C19RM. The Global Fund acknowledges the primary financial, operational and technical roles of other development partners in supporting governments this area, including but not limited to Gavi, World Bank, UNICEF, and WHO. The Global Fund expects that funding from other partners (e.g. grants and loans from Gavi and the World Bank) will be the principle sources of external support to countries' vaccine deployment efforts. Vaccine procurement is firmly outside the scope of C19RM. However, funding requests may be used to request support for urgent, targeted system strengthening activities to contribute to vaccine delivery services, where these are not being fully supported by other partners and where they support both COVID-19 and HIV, TB, and malaria responses.

In addition to national COVID-19 response plans, it is critical to align any vaccine delivery-related activities with National Deployment & Vaccination Plans (NDVP), which are the basis for financial

planning. Any Global Fund investments in this area should be part of the NDVP and integrated budget to optimize alignment. In addition to essential coordination with national COVID-19 response entities, CCMs are encouraged to engage national Inter-agency Coordination Committee (ICC) on immunization where related support is proposed in funding requests.

Specific activities which can be supported under this Intervention category (Pillar)[17] include:

- Design social mobilization and engagement strategy/demand plan and information awareness program to address COVID-19 testing, treatment and vaccine hesitancy in communities.

- Apply IPC measures and provide COVID-19 response-related training of community HCWs that also support vaccine delivery.

- Planning activities for how to identify and reach those excluded or not covered by the public health system, e.g. detainees, migrants and refugees, and stigmatized populations, with COVID-19-related testing, treatment, and prevention services, that may support vaccination services, as appropriate.

- As part of national COVID-19 response activities under Pillar 1, conduct COVID-19 vaccine table-top (simulation) exercises to test on-going country readiness.

- Adapt and apply existing surveillance and monitoring frameworks to address vaccination coverage, acceptability, adverse events reporting, etc.) for COVID-19 vaccine, including information from facilities and contractors participating in vaccine delivery.

- Adapt and apply existing HMIS/DHIS2 electronic and/or paper-based monitoring tools and appropriate institutional arrangements (e.g. vaccination cards/certificates, facility-based nominal registers, etc.) to monitor progress and coverage among different at-risk and marginalized groups in order to facilitate vaccine delivery and timely reporting.

Health Product Management Systems (Pillar 6)

Given the disruptions that in-country supply chains have experienced due to COVID-19, it will be vital for countries to have proactive mitigation measures to reduce the risk of disruption to key functional areas including quality assurance, storage and distribution capacity in country. To support planning processes, information systems so that in-country supply chains can swiftly adapt and respond to dynamically changing demand and supply. As such, there will be a need to strengthen end-to-end health product management systems, including selection, regulatory approval, procurement, supply chain, installation, training, maintenance, post-market surveillance, operating costs and consumables in line with WHO guidance. See Annex 1 for details.

Specific activities that can be supported under this intervention include quality assurance, supply chain, maintenance and capacity enhancement, as follows:

Quality Assurance

- Pre- and post-market surveillance activities: As described in the Guide to Global Fund Policies on Procurement and Supply Management of Health Products, market intelligence/surveillance work should be implemented, including for core personal protective equipment (PPE) and oxygen delivery interfaces. This includes randomized pre-shipment sampling and testing and monitoring of the quality of core PPE throughout the supply chain, in line with relevant WHO post market surveillance guidance or International Medical Device Regulators Forum (IMDRF) guidelines on Post-Market Surveillance of PPE and medical devices, including for respiratory care. Monitoring activities should be performed in close collaboration with the relevant national regulatory authority, who should be cognizant of medical devices regulations/donations. Budget support to address both pre- and post-market surveillance requirements (e.g., sampling, transportation and testing, including outside of the country when necessary), including training for Principal Recipients, can be requested for this.

- Regulatory strengthening: If needed, funding may be requested for ensuring that regulators and procurement agencies and recipients of donations, which should be regulated, in countries are trained on minimum quality assurance requirements for pre-market and primary post-market

verification work. This may also include strengthening of Regulatory Information Systems to increase efficiency for storing and sharing critical regulatory data.

WHO 2020 guidance on post-market surveillance

Supply Chain

- Augment Warehousing and Distribution Capacity: Given the increasing volumes of COVID-19 related health products that countries will have to manage, there will be an increasing need to augment existing warehousing and distribution capacity in some countries to effectively manage that additional throughput. Budget support would allow for the contracting of additional services for logistics capacity, such as temperature-controlled storage for PCR assays and control materials, and distribution vehicles, across various countries. [NB. This does not relate to vaccines.]

- Supply chain information systems: Managers of supply chains depend on timely and accurate data to make informed and effective decisions about routine operations like forecasting demand and resupplying health facilities. Data also informs strategic decisions to make supply chain design, processes and workforce more efficient and cost-effective. Introducing or enhancing a digital logistics management information system (LMIS) in a country's health supply chain improves the collection, analysis, communication and use of accurate data for effective decision-making. More information can be found on the Qualified Software Solutions for Logistics Management Information Systems (LMIS).

- Track and Trace: To mitigate against the threat of falsification and illegal diversion of health products including legitimate COVID-19 related products including diagnostics, medical equipment, PPE, therapeutics and vaccines, countries will need to accelerate the use of traceability and verification systems. Budget support requests can be made to enhance the verification of COVID-19 related health products in support of broader supply chain efforts of evolution towards full traceability.

- Naming, coding and unique device identifier (UDI) databases are important to track and trace products ensuring that training, maintenance, calibration and operating costs and warranties are considered.

- Building COVID-19 Forecasting Capacity: The ability to ensure the consistent availability of COVID-19 related health products will be enabled through timely and comprehensive forecasting processes. Given the new set of health product lines, with fast changing assumptions around the exact needs for diagnostics, oxygen, PPE, and therapeutics products budgetary support should be planned to facilitate robust quantifications. Please also refer to WHO COVID-19 Essential Supplies Forecasting Tool.

- Maintenance and assurance of safe and appropriate operation of all medical and laboratory and oxygen related equipment is indispensable. Therefor all procured equipment should include maintenance contracts, warranty, training and spare parts. These are investments and should not be consider a one-off expense but a long-term investment.

Medical Waste Management Systems (Pillar 6)

It is anticipated that with the increased use of single-use PPE, testing volume, single-use devices, vaccine delivery, medical equipment and oxygen supply systems, there will be a need to strengthen waste management systems, in line with WHO guidance. See Annex 1 for details.

Waste Management

- Assessment and development of policy frameworks, guidance and operational plans for management of health care waste and/or supply chain wastage;

- Risk assessment and development of sustainable, safe and environmentally friendly interventions for the management and/or disposal of specific health products (e.g. PPE, diagnostics, lab material, vaccines, etc.) as well as non-health products as part of the national waste management system;

- Consider outsourcing as an immediate stop gap measure while exploring options to and set up and strengthen national waste management systems including the safe collection, classification and segregation, handling, return transportation, recycling and/or treatment as well as disposal of waste;

- Training of human resources across all tiers in the public and private sector to increase awareness and improve competency in waste management practices including the Return Supply chain;

- Infrastructure and equipment for the collection, transport, treatment and disposal of health care waste that are compliant with environmental and occupational health standards;

- Evaluation of carbon footprint of 'End to End' Supply Chain, especially waste management and disposal options and promotion of climate-smart waste management systems and practices, including via public-private partnerships, engagement with communities and civil society, and innovative methods.

More detailed information:

- [The Global Fund's Technical Brief on Sustainable Health Care Waste Management](#)
- [WHO guidance on decommissioning medical devices](#)

Respond to human rights and gender related barriers to services

Specific activities which can be supported under this intervention can include:

- Rapid assessments of safety and security of key population (KP) program clients and implementers given COVID-19 restrictions, and support to adjusting program delivery based on such findings;

- Adapting COVID-19 prevention information to minorities and indigenous people to improve access to health services;

- Online trainings and sensitization – of communities as well as of law enforcement and Health Care Workers – require support in converting the content and approach so that it works for online trainings, as well as internet access;

- Scaling-up support for community-led monitoring (CLM) of human rights violations and equitable distribution and access of C19RM funded tools – be it through expanding existent systems and apps or instituting harmonized paper-based/e-mail based quick reporting forms. CLM may need to be expanded in scope, to capture access to PPE, non-discriminatory food support, etc.

- Linking cases of human rights violations to support and redress, including through expanded community paralegal programs, with provision of PPE, transportation and enhanced internet access;

- Support engagement with community leaders and raise awareness on the potential rights-violations in the context of COVID-19 against key and vulnerable populations, and engage them as part of the CLM and rapid response;

- Strengthening engagement with the journalists on non-stigmatizing messaging; and

- Trainings of law enforcement officers on responsive policing, including responding to and addressing intimate partner and gender-based violence.

Specific activities related to the stigmatization of TB patients exacerbated by the COVID-19 pandemic:

- Stigma reduction (both at facilities level and in communities);

- Policy review and revision to allow easier access to TB services, including multi-months dispensing and allowing third-party collection of the treatment; and

- Scaling-up community mobilization/treatment support groups for treatment support, monitoring and strengthen the linkage to TB services for the management of side-effects.

Community-led monitoring

Specific activities which are supported under this intervention can include:

- Development, support and strengthening of community-based mechanisms that monitor: availability, accessibility, acceptability and quality of services (e.g. observatories, alert systems, scorecards); health policy, budget and resource tracking, and monitoring of health financing allocation decisions; and/or complaint and grievance mechanisms;

- Community-led and/or -based monitoring of barriers to accessing services (e.g. human rights violations, including stigma and discrimination and confidentiality; age and gender-based inequities; geographical and other barriers) for purposes of emergency response, redress, research and/or advocacy to improve programs and policies;

- Tools and equipment for community-led and/or -based monitoring (including appropriate technologies);

- Technical support and training on community-based monitoring: collection, collation, cleaning and analysis of data; and using community data to inform programmatic decision making and advocacy for social accountability and policy development; and

- Community engagement and representation in relevant governance and oversight mechanisms;

- CBO monitoring of the impact of COVID-19 on health service providers in their communities;

- Support communities to monitor and report stock-outs, quality of services and human rights violations.

Community-led advocacy and research

Specific activities which can be supported under this intervention can include:

- Qualitative, quantitative and operational community-led research that takes into account human rights, gender and age considerations; and the production, publication and dissemination of reports and communication materials;

- Community-led mapping of legal, policy and other barriers that hinder/limit community responses (including barriers that impede registration, funding of community organizations);

- Data collection and analysis to inform development and/or improvement of key and vulnerable population programs;

- Research and advocacy to sustain/scale-up access to services by key and vulnerable populations, including public financing for the provision of services by community-led and based organizations (e.g. costing of services and implementation arrangements; analysis of the legal and policy context, tendering and selection processes, and monitoring of implementation);

- Capacity building to develop and undertake campaigns, advocacy and lobbying, for improved availability, accessibility, acceptability and quality of services and social accountability;

- Capacity building to develop and implement advocacy campaigns for domestic resource mobilization for COVID-19 and the three diseases and Universal Health Coverage (UHC); and

- Advocacy activities, including conducting situational analysis, engagement and representation in policy processes, decision-making and accountability mechanisms and processes, and in the development of local, regional and national strategies and plans (including national health; disease-specific; community health and UHC);

- Finance development of simple advocacy materials on the importance of preserving access to HIV, TB and malaria services and reproductive health services.

Social mobilization, building community linkages and coordination

Specific activities which can be supported under this intervention include:

- Community-led participatory needs assessments;

- Building capacity on use of appropriate new information communication tools and technologies;

- Community-led development/revision of strategies, plans, tools, resources and messages for social mobilization;

- Mapping of community-led and community-based organizations and networks and their service packages as basis for improved planning, resourcing, integration and coordination of service delivery and advocacy; and

- Creation and/or strengthening of platforms that improve coordination, joint planning and effective linkages between communities and formal health systems, other health actors and broader movements such as human rights and women's movements;

- Procuring data packs/IT support for communities to foster engagement in all processes;

- Strengthen existing community platforms (drop-in centers, safe spaces, community-based clinics) as well as community networks to deliver services.

Institutional capacity building, planning and leadership development

Specific activities which can be supported under this intervention include:

- Capacity building and mentorship of community organizations and networks in a range of areas necessary for them to fulfil their roles in social mobilization, community-based monitoring and advocacy;

- Technical and programmatic development to ensure high quality delivery of integrated community-based services;

- Development and/or revision of tools and other forms of support for community-led and community-based organizations and networks for: assessing capacity and developing appropriate capacity building plans, institutional and organizational capacity including governance, financial management, sustainability planning, internal policies, leadership development, program management, monitoring, evaluation and learning and reporting, partnerships, community organizing and advocacy, technical capacity to respond to human rights, gender and legal and policy barriers to services; and

- Infrastructure and associated program management costs of community-led and community-based organizations and networks to support/strengthen their capacity for service provision, social mobilization, community monitoring and advocacy, in line with Global Fund Budgeting guidelines.

Gender-based violence (GBV) prevention and care

During the pandemic, lockdowns, curfews and other restrictions on movement have saved millions of lives. For women and girls, however, they can also be sources of increased risk of violence and death. More GBV has been reported against the backdrop of the COVID-19 pandemic, so it is important to include measures to address this.

Specific activities that can be supported under this area include:

- Trainings for frontline staff and volunteers during COVID-19 response on psychological first aid, GBV referral pathways, and how to support a survivor and relay information on available GBV services, including remote modalities, such as hotlines;

- Support existing GBV hotlines (temporary staff, training materials, communication tools, etc.);

- Post violence counseling, referral and linkages to provision of post exposure prophylaxis (PEP), clinical investigations, medical management, clinical care, forensics management and medical-legal linkages, psychosocial support, including mental health services and counselling required as a result of COVID-19 restrictions;

- Development and implementation of systems for linkages to protection services (i.e. police, neighborhood watch, peer counsellors); and

- Support women and affected key populations with linkages to access justice interventions or to legal redress for human rights violations experienced as a result of COVID-19 restrictions.

6. In-country Partner Engagement

The purpose of this section is to highlight the essential in-country partner engagement touchpoints for development of C19RM funding requests and grant implementation, including technical assistance (TA) for CCMs to rapidly develop high quality, strategic and impactful C19RM Funding Requests, and implementation oversight, alignment and quality assurance, based on application of Global Fund's Budgeting Guidelines. Separate guidance on CCM engagement and Mitigation of HIV, TB, and malaria, should also be reviewed to understand the full breadth of C19RM partner engagement.

Technical assistance during funding request development process

As in all Global Fund grant processes, country ownership, inclusiveness and accountability are fundamental. This extends to partner engagement and TA activities which are generally country-led and often coordinated by CCMs. In the case of development of C19RM funding requests, standard and traditional partnerships will be extended and strengthened through direct engagement with national COVID-19 response coordination bodies. The application guidance strongly encourages effective engagement with response management entities that are steering COVID-19 responses from start to finish of the new funding requests. Ideally this will include direct coordination with relevant national response Pillar working groups or related technical bodies with specific responsibilities for COVID-19 lab diagnostics, infection prevention and control, e.g. PPE, and medical therapeutics, including oxygen. Ultimately, all COVID-19 control and containment aspects of C19RM Funding Requests must be endorsed by the national COVID-19 response coordinator.

The identification of TA needs is also country-led, and often CCM-mediated, including the search for consultants, dialogue with partners, development of terms of reference, TA requests and coordination of TA. For C19RM, streamlined funding request guidance and application tools will help to identify areas requiring specialized TA, such as medical oxygen. Where suitable, local TA has not been identified via national COVID-19 structures and in-country technical partners, timely communication regarding new TA needs is critical. Specifically, early communication with in-country partners and Global Fund country teams is essential. CCMs should alert Global Fund country teams as soon as possible regarding unmet TA needs, such as failure to identify TA provider/consultant with the right expertise, skills and/or resources. Country teams should alert Global Fund C19RM Technical Teams as appropriate as these teams can engage ACT-A partners and partner networks, e.g. Biomedical Consortium/O2 Taskforce, as necessary to find TA solutions.

It is possible that additional priority technical areas may be added to existing Global Fund TA pool(s). Regardless of TA source (in-country technical partner, external, etc.) support for the direct engagement of those most impacted by and vulnerable to COVID-19 in the development and implementation of C19RM interventions, including for specialized services, will be maintained, consistent with response Pillar 2 on Risk Communication and Community Engagement. Finally, TA may be sought from relevant external sources, i.e. global and regional institutions, supporting COVID-19 response implementation in relatively new and evolving technical areas, e.g. medical oxygen, where expertise both in-country and external capacity is limited.

Leveraging partner engagement for ongoing country dialogue during implementation

As with all Global Fund investments, once C19RM funding requests have been approved, CCMs have an oversight duty to ensure that resources are being used efficiently and effectively.

It is thus critical for CCMs to continue to engage appropriate national COVID-19 response structures on an ongoing basis to be able to determine if the activities being implemented are addressing the relevant needs, gaps and priorities.

Ideally this will include routine coordination among appropriate CCM constituencies and representatives of technical bodies of the response, for example in disease surveillance, laboratory and diagnostics, infection prevention and control, and case management, including sub-groups on oxygen services, for COVID-19, as well as the national disease programs and partners involved in HIV, TB and malaria programming.

Through this regular engagement with technical partners, CCMs and PRs will be best able to ensure that the C19RM resources are optimally aligned with response needs and financing from domestic and external donor, e.g. WB, sources.

Furthermore, it is through this engagement, and inclusive of community, civil society, and non-state actor constituencies, that emerging TA needs will be identified and responded to in a coordinated manner, as well as in monitoring and evaluation of supported activities.

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Annex 1. Additional Health Product Considerations

Beyond the scope and eligibility requirements described in Section 2 and Section 5 above, the additional guidance below and related considerations should inform activity planning to maximize impact from investments in health products. Updated information on product categories, market availability, reference pricing and lead-times, will be posted in the Global Fund website.

Procurement Channels

Health and non-health products needed for the COVID-19 response include a diverse set of products with different market characteristics, which require deliberate approaches to secure better market outcomes (such as lower prices or improved lead times). A three-category framework for health products has been developed to articulate this:

- **Strategic:** products that are scarce on the global market. For such products, pooling of demand or coordination of order placement is needed to be able to secure volume that, if not done in a coordinated and timely way, may be lost to high income country markets. This may include very close and timely coordination for an ACT-A partner volume agreement that had to be made to secure volumes for low- and middle-income countries;

- **Mainstream:** products with specific quality assurance requirements, which may require enhanced visibility to have assurances that volumes secured and delivered; and

- **Local sourcing advised:** products which are generally low value bulky and/or hazardous products, such as alcohol and bleach, or those for which contracting of a local contractor is preferred, for example, for supply of some oxygen interventions.

For strategic products, as described in Section 2 of the Guide to Global Fund Policies on Procurement

And Supply Management of Health Products, countries may be required to use the Global Fund's Pooled Procurement Mechanism (PPM)/wambo.org for as long as the supply dynamics and constraints remain as described above.

For mainstream products, countries are highly encouraged to use the Global Fund's PPM/wambo.org. This will allow for countries to benefit from negotiated terms and pricing while simplifying orders, especially for those products currently scarce on the global market.

The prevailing details of which products fall into each category can be found at https://www.theglobalfund.org/en/covid-19/health-product-supply/procurement-advice.

Procurement Guidance

- Beyond procurement channel guidance, additional information for planning purposes, including reference pricing, is available on the following:
  - [SARS-CoV-2 diagnostics](#)
  - [COVID-19 Treatment and Oxygen Equipment](#)
  - [Personal Protective Equipment](#)
  - [Procurement advice, including indicative lead times](#)
  - Product container/volume estimations [6]
  - Contracting models for diagnostic platforms
    - For procurement of laboratory equipment such as molecular PCR machines, where appropriate countries should consider reagent rental contracts which may decrease capital costs and leverage "all-inclusive" pricing offers, including options for vendor managed inventory, maintenance and service, to optimize value for money. More information on contracting models is available [here](#).

Temperature Considerations

- Consistent evaluation of existing cold chain capacity needs and policies will be critical to ensuring effective storage and handling of health products throughout the supply chain to maintain their quality and efficacy. More information on operational guidelines is available [here](#) from WHO. If needed, additional capacity can be sourced to ensure effective supply chain capacity exists; see additional comments in Supply chain section.

- All COVID-19 products should be stored in line with storages conditions listed in the manufacturers' instructions for use.

- Currently only some PCR/controls have special conditions – cool/frozen.

- Ag-RDT kits should generally be stored 2-30°C / 36-86°F and out of direct sunlight. Manufacturers' guidance should be followed but improved upon where necessary.

- PPE: The storage should be adequate to protect the PPE from contamination, loss, damage or deterioration. Extremes in heat and cold should be avoided for the area where PPE garments are stored. Manufacturers' guidance should be followed but improved upon where necessary.

- Some novel therapeutics may have special storage considerations

Quantification

- WHO has made a [COVID-19 Essential Supplies Forecasting Tool](#) available to help estimate potential requirements for essential supplies to respond to COVID-19.

Quality Assurance

Overview of Global Fund Quality Assurance Requirements for COVID-19 Health Products[1]

	Pharmaceutical products*	Diagnostic products[2]	Core Personal Protective Equipment	Medical Devices (exclusive of PPE and condoms)[3]
Clinical requirements	Current national, institutional and/or WHO Standard Treatment Guidelines and/or Essential Medicines Lists	National guidelines and/or conformity with WHO guidance	National policy/guidelines on infection prevention and control and/or conformity with WHO guidance**	National policy/guidelines on infection prevention and control and/or conformity with WHO guidance
Quality requirement	(1) Approved by national regulators; and (2) Approved by any Stringent Regulatory Authority as defined under the Global Fund QA Policy for Pharmaceutical Products, including through WHO Emergency Use and Listing procedures or other emergency procedures set up by these SRAs.	(1) Approved by national regulators; (2) Is manufactured at a site that complies with relevant quality management system requirements; and (3) Approved by any Stringent Regulatory Authority (SRA) as defined under the Global Fund QA Policy for Diagnostic Products including through WHO Emergency Use and Listing procedures or other emergency procedures set up by these SRAs.	(1) Approved by national regulators; and (2) Approved by Stringent Regulatory Authorities (Founding Members of the Global Harmonization Task), WHO Prequalification Programme or Expert Review Panel	(1) Approved by national regulators; and (2) Approved by Stringent Regulatory Authorities (Founding Members of the Global Harmonization Task), WHO Prequalification Programme or Expert Review Panel

*This category is exclusive of essential medicines used for the management of patients with suspected or confirmed COVID-19 diagnosis. Quality assurance requirements for essential medicines are specified in Global Fund's Quality Assurance Policy for Pharmaceutical Products.

**The Global Fund recommends, and Global Fund funds can be used for, the procurement of PPE items approved for medical use, including surgical and non-surgical masks that meet Global Fund quality assurance requirements. If any request is made for non-medical (fabric) masks, which are not considered PPE, as part of a C19RM Full Funding Request, it will be reviewed by the Global Fund on a case-by-case basis. However, as there is currently sufficient production capacity and no supply constraints for medical masks, the Global Fund does not expect to receive requests for funding for non-medical (fabric) masks.

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[1] See the Guide to Global Fund Policies on Procurement and Supply Management of Health Products for more information, including definitions of Stringent Regulatory Authorities: https://www.theglobalfund.org/en/sourcing-management/

[2] For COVID-19 diagnostic tests, Quality Requirements include WHO Emergency Use Listing procedures and emergency procedures set up by a Regulatory Authority defined in the QA Policy.

[3] This is a preliminary statement which will be confirmed through the next update to Global Fund Quality Assurance Policy and Guide to Global Fund Policies on Procurement and Supply Management of Health Products.

Annex 2. COVID-19 Laboratory Packages

Activities in Packages 1A, 1B and 2 are specific to COVID-19 response:

Package 1A: Introduction and adoption of Antigen SARS-CoV-2 testing

Procurement of Ag-RDTs for SARS-CoV-2 (with swabs included)

TA Support for developing/revision of COVID -19 diagnostic scale-up plans and testing strategies to include Ag RDT

Support to small-scale verification studies for introduction of RDTs *(only if mandated by national regulatory authorities)*

Procurement of PPE

Training of end-users, facility level staff (on-site training) and training of trainers (TOT, on-site training)

Procurement of external quality assurance scheme (EQA)/proficiency testing (PT) panels and external quality control (EQC) material

Package 1B: Scale-up of Antigen SARS-CoV-2 testing for countries already implementing Ag-RDTs

Procurement of Ag-RDTs for SARS-CoV-2 (with swabs included)

Procurement of PPE

Training of end-users, facility level staff (on-site training) and training of trainers (TOT, on-site training)

Procurement of external quality assurance scheme (EQA)/proficiency testing (PT) panels and external quality control (EQC) material

Package 2: Scale-up of Implementation of SARS-CoV-2 Molecular Testing, including Low- and High-Throughput Molecular Testing Platforms

Package Content	Prerequisites for procurement of specific equipment
Procurement of SARS-CoV-2 molecular assays	
Procurement of consumables, swabs, control material	
Training and refresher sessions on SARS-CoV-2 molecular Assays	
TA support for conducting Diagnostic Network Assessment considering national public and private sector capacities	
Procurement of PPE	
Minor rehabilitation of laboratory site infrastructure	Please provide supporting documents such as: Assessment report for site level readiness (assessing unidirectional workflow, air

	conditioning, power supply and generator backup/ solar panels, water supply, space, available biosafety cabinets)
Upgrade of equipment for continuous electrical supply (i.e. solar, UPS, generator, fuel)	
Procurement of EQA/proficiency testing (PT) panels and external quality control (EQC) material	
Procurement of molecular testing platforms (low throughput equipment only)*	Please provide supporting documents on: •Endorsed plan for integration of testing for HIV, TB, SARS-CoV-2 with projected numbers of tests for HIV/TB as established in NFM3; • Data on utilization rate for equipment already in use and justification for request for additional equipment; • Diagnostics network scale up plan to include plans to scale up i) Functional sample transportation system; ii) Laboratory Information Management system iii); Waste management system; • Availability of trained and certified staff.
Procurement of ancillary equipment (automated extractors)*	Updated mapping of existing equipment

* Procurement of high throughput automated equipment should be considered with grant savings and/or flexibilities. Where appropriate, countries should consider a contracting strategy for leasing (vs. direct purchase) with options for reagent rental, as per country demand. More information on contracting models is available here.

Health and Community System Strengthening Packages

Activities in Package 3 are related to COVID response and also address broader health system needs.

Package 3: Strengthening Integrated Laboratory Systems

Core Competency	Package Content
HRH	Hiring additional temporary human resources to support surge sampling, testing, test result reporting (consider contracting and "pay for performance" modalities)
Lab Information System	TA support to develop and implement plans to link laboratory data with key epidemiological data for timely data analysis interconnectivity with EMR, LMIS and HMIS
	Procurement of IT equipment and software
	TA support for data analysis
Sample Transportation System	TA for review of transportation routes, design for expansion of existing network, costing exercise, contracting private sector
	Payment for transportation based on performance contracts
	Hiring additional (temporary) drivers and sample collectors

	Procurement of consumables for transportation (swabs, labels, PPE, UN boxes, etc.)
	Training delivered on-site on safe handling and packaging for collecting staff / drivers
Biosecurity/Biosafety	TA support to conduct biosafety risk assessment at laboratories and testing sites
	Procurement of biosafety cabinet, spill kits, access control showers
Quality Management System	TA support with establishing / maintaining national/regional /international accreditation schemes
Generic equipment	Procurement of ancillary equipment (centrifuges, fridges, freezers, pipettes, vortex, heat blocks)
Procurement and Supply Management	TA supporting efficient stock management, including consumables, controls and calibrators sourced
	TA support to improve robustness of supply chain systems, including cold chain capacity, shelf life

Activities in Package 4 are related to COVID response and also address broader health system needs.

Package 4: Support for genomic surveillance / sequencing activities

Applicants should prioritize buying services from fully equipped and functional laboratories, specialized in genomic sequencing activities, leveraging existing regional networks.

Package Content	Prerequisites for specific activities
TA support for development of a SARS-CoV-2 sequencing strategy (incl. assessment of country readiness, surveillance of variants and sharing of genetic sequences)	
Payment of fees for sequencing services (consider pay for performance modalities)	Leverage existing networks (i.e. Africa CDC Pathogen Genomics Initiative, PAHO, Europe CDC, etc.)
Procurement of Sample Transport services, national or international (consider private sector engagement, or joint funding for existing system to be expanded)	
Procurement of consumables for transportation of samples (Triple packaging UN boxes, labels, PPE, etc.)	
Procurement of reagents or software for sequencing activities	A sampling plan must be available and testing platforms for initial extraction/PCR testing must be functional in country)
Procurement of ancillary equipment	
Hiring and training temporary human resources to meet surge capacity	
Training for bio-informatics	Bio-informatics software and capacity must be available in-country

Annex 3: Detailed Medical Oxygen Operational Guidance

Demand for medical oxygen supplies and services is surging in LMICs based on current COVID-19 epidemiological trends. Although many gaps and needs remain unquantified, there are numerous reports of acute oxygen shortages caused by COVID-19. Also, WHO and implementing partners such as CHAI and PATH have carried out structured oxygen needs assessments in almost 20 countries. Through the work of the ACT-A emergency task force on oxygen, technical and donor partners have come together to define approaches to rapidly respond to existing demands for these life-saving interventions, including financial and country operational aspects. All elements of country funding requests need to be supported by evidence, however given the complexities of O2 we have included this Annex to provide additional guidance and key considerations in characterizing local oxygen needs, gaps, and priorities as defined within the Case Management Pillar (7) of national response plans. This information - along with the following Annex 4 which describes various packages for oxygen generation and storage - is intended to aid in the development of maximally effective and impactful funding requests.

CCMs and national COVID-19 response managers will want to ensure their response plans accurately assess current needs and forecast future oxygen and respiratory care equipment needs, identify best-fit solutions, and leverage available in-country expertise. Most countries will want to pursue a combination of 1) optimizing existing oxygen supply at facilities; 2) identifying non-functional equipment for potential recommissioning; and 3) securing additional required oxygen supplies and related services. Where countries have existing (or are developing) oxygen policies or broader respiratory care capacity strengthening strategies, plans should describe how emergency response investments for COVID-19 align with these broader, longer-term approaches. Oxygen services should be included in the strengthening of supply chain information systems as mentioned above in Pillar 6. While improving oxygen system, efforts also should be made to ensure access to life saving corticosteroids are also in place for severe and critical COVID-19.

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

Conduct a rapid respiratory care stakeholder mapping exercise

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

Conduct rapid capacity assessments of designated, planned, and/or potential COVID-19 treatment centers

Scope / purpose: Quickly determine the current availability of respiratory care equipment and oxygen supplies at priority health facilities within the COVID-19 response, identify non-functional equipment for potential repairs, and identify facilities with capacity to absorb bulk oxygen supply options (e.g. facilities with piping, cylinder manifolds, etc.).***Available tools***: WHO Biomedical Medical Equipment assessment tool & phone survey guidance

Rapid oxygen and respiratory care equipment Gap assessment for designated, planned, and/or potential COVID-19 treatment centers

Scope / purpose: Forecast patient need for oxygen and respiratory care equipment at priority health facilities within the COVID-19 response, determine the presence and size of oxygen and respiratory care equipment gaps at priority facilities and overall.

Available tools / resources: WHO Essential Supplies Forecasting Tool; WFSA Oxygen Supply & Demand Calculator; Unicef Oxygen System Planning Tool; WHO disease commodity package for COVID-19 and Technical specifications Pressure Swing Adsorption

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

Scope / purpose: Compile a rapid listing of in-country oxygen, equipment, and maintenance suppliers; Identify local sources (manufacturers and/or distributors) of suitable respiratory care equipment and oxygen supplies; Reveal constraints in local supply chains impacting product availability and suitability; Identify constraints in local service markets impacting maintenance and operation of key equipment; Identify suitable short- and long-term oxygen supply solutions and operating models.

Available tools / resources: PATH/CHAI supplier questionnaires; PATH/CHAI Sub-Saharan Africa distributor listing; [Every Breath Counts partner mapping matrix](#)

Develop Robust procurement requests

Scope / purpose: Determine best-fit oxygen supply options for priority facilities based on gap assessment and in-country supply landscape; Produce costed estimates of equipment and consumable needs by facility and overall; Develop allocation plans based on current equipment distribution; Identify post-response equipment re-allocation priorities, as appropriate, and opportunities in line with broader national strategies for oxygen or respiratory care capacity strengthening.

Available tools / resources: [WHO Essential Supplies Forecasting Tool](#); [WFSA Oxygen Supply & Demand Calculator](#); [Unicef Oxygen System Planning Tool](#)

Develop targeted training plans

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

Available tools / resources: [WHO Health Workforce Estimator; OpenWHO clinical training channel: https://openwho.org/channels/clinical-management](#)

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

Scope / purpose: Identify ongoing service and maintenance requirements for equipment; Forecast recurrent costs associated with ongoing equipment operation and maintenance; Identify domestic financing channels with the potential to cover recurrent costs. This should include HR costing as well as warranties and service agreements.

Available tools / resources: Pending

Also see PATH's [COVID-19 oxygen resource library](#) and [COVID-19 Training Catalogue](#) for training resources.

Annex 4. Detailed Medical Oxygen Packages, Products, and Activities for Bulk Oxygen Supply, Generation, and Storage

Use Case / Supply Option	Operational criteria for optimal vs. limited designation				Optimal (O) or Limited (L)
	Required Equipment - Existing	Required Equipment – Purchase	Required Service (w/suitable local supplier)	Other Recommended Services	
1. Source bulk liquid deliveries	Bulk liquid tank, VIE, piping and/or cylinder filling capacity, cylinder manifold (ideal)	None	None	None	O
2. Source bulk gas cylinder deliveries	Cylinder manifold w/piping (ideal), cylinder trolleys	Additional cylinders as required	Cylinder and accessories management (optional?)	None	O
3. New bulk liquid storage for onsite cylinder filling	Cylinders, cylinder trolleys, delivery trucks (if for distribution to multiple facilities)	Bulk liquid storage tank(s), VIE; If not already owned: Cylinders, cylinder trolleys, delivery trucks (if for distribution to multiple facilities)	Source bulk liquid deliveries	Cylinder distribution (if for distribution to multiple facilities)	O
4. New bulk liquid storage and piping	Cylinders (back-up), cylinder trolleys	Bulk liquid storage tank(s), VIE, piping installation; If not already owned: Cylinders (back-up), cylinder trolleys	Source bulk liquid deliveries, contract for piping installation	None	L
5. Temporary staffing increase at existing PSA plant(s)	Existing PSA plant - fully functional but with low runtime	Additional cylinders and ancillary equipment as required	None	None	O
6. Refurbishing existing PSA plant(s)	Existing PSA plant in need of repair	Necessary tools, parts, supplies; additional cylinders as required	Skilled PSA maintenance	None	O
7. Add PSA plant(s) to piped facility	Piping, cylinder manifold (ideal), back-up generator, suitable land / housing for plant	PSA plant (containerized or skid mounted); manifold & piping connections if piped; booster compressor for cylinder filling if not piped; additional cylinders as required	PSA installation	PSA operation & maintenance	O
8. Containerized PSA plant(s) for cylinder filling	Suitable land for plant(s), cylinders, cylinder trolleys	PSA plant; booster compressor for cylinder filling; additional cylinders as required	PSA installation	PSA operation & maintenance	L*
9. Skid-mounted PSA plant(s) for cylinder filling	Suitable land / housing for plant(s), cylinders, cylinder trolleys	PSA plant; booster compressor for cylinder filling; additional cylinders as required	PSA installation	PSA operation & maintenance	L*
10. Containerized PSA plant(s) for piped supply	Suitable land for plant(s), cylinders (ideal), cylinder trolleys (ideal)	PSA plant; manifold & piping connections; booster compressor for cylinder filling (optional - back-up) with additional cylinders as required	PSA installation, piping installation	PSA operation & maintenance	L
11. Skid-mounted PSA plant(s) for piped supply	Suitable land / housing for plant(s), cylinders (ideal), cylinder trolleys (ideal)	PSA plant; manifold & piping connections; booster compressor for cylinder filling (optional - back-up) with additional cylinders as required	PSA installation, piping installation	PSA operation & maintenance	L
12. Oxygen concentrators	None	Delivery interfaces (nasal cannulas, masks, tubing, flow splitters). Oxygen analyzer (~ 1 per 20 concentrators) In settings where power is unreliable: voltage stabilizers, uninterruptible power source (UPS), alternative source of power (diesel back-up generator or solar panel + battery pack + inverter)	Service and maintenance	None	O

*These package descriptions should be referenced as specifically as possible, e.g. by number, within Funding Requests in order to facilitate determination as to eligibility and operational alignment.

Technical assistance framework for provision of medical oxygen services

Phase 1: Assessment of Oxygen Need-Gap

1. Oxygen needs baseline assessment to understand, select solution and estimate costs for appropriate oxygen sources (e.g., bedside concentrators, PSA plants, liquid suppliers), distribution and/or delivery systems.
2. Development of a facility, sub-national or national oxygen scale up end-to-end project considering the country readiness and absorptive capacity.
3. Establishing partnerships for long term sustainability of the project.

Phase 2: Procurement and Implementation

1. Procurement and contracting support.
2. Preparation of site (including infrastructure, human resources, power supply and other ancillary services).
3. Commissioning of goods and services.
4. Initial trainings (clinical and technical).

Phase 3: Capacity building and knowledge transfer

1. Quality improvement for priority medical programs involving oxygen therapy.
2. Programmatic use/case management for COVID-19 and/or child pneumonia (healthcare worker capacity building and training).
3. Technical (biomedical) training.
4. Preventative maintenance program.
5. Support on incorporation of appropriate monitoring and evaluation indicators.