

# COVID-19 Response Mechanism Information Note

Transition from the COVID-19 Response to Resilient and Sustainable Systems for Health, Community System Strengthening and Pandemic Preparedness

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# **Executive Summary**

The COVID-19 Response Mechanism (C19RM) was designed to support countries across three broad categories: COVID-19 control and containment interventions; activities to mitigate the effects of the pandemic on HIV, tuberculosis and malaria programs; and expanded reinforcement of key aspects of health and community systems. The original C19RM Technical Information Note (April 2021) covered direct COVID-19 recommended activities that could be funded under these three categories, further organized within the ten WHO response pillars which have been the basis of national COVID-19 response plans (Box 1).

**Transition planning.** Since 2022, epidemiologic trends in case notification, morbidity and mortality have prompted many countries to transition national COVID-19 responses. Transition planning and methods have varied greatly across countries. However, increased focus on integration of key response functions, and health systems' resilience and pandemic preparedness has been consistently emphasized. Updates to this document are intended to guide countries during the period of ongoing response, increasingly through integrated and mainstreamed approaches, and transition towards strengthening systems for health and pandemic preparedness.

**Preparedness** is intended to include both activities to prepare for new surges of future SARS-CoV-2 variants of concern (VOC), and/or of new and emerging pathogen threats. As several of the COVID-19 response pillars are also reflected in the normative technical frameworks applied by countries in implementing health systems and pandemic preparedness plans, such as the <u>Joint External Evaluation (JEE) and national action plans for health security (NAPHS)</u>, the content has been retained and, in some cases, extended where appropriate.

Health and community systems and pandemic preparedness programmatic priorities include the following:

**Surveillance system strengthening** is focused on early detection of and response to new outbreaks and monitoring the spread and transmission of these pathogens via a variety of surveillance modalities. This requires improvement of countries' data collection, analytic and response capacity so that problems can be detected early, investigated, verified and responded to appropriately.

**Laboratory and diagnostics** encompass activities to expand and strengthen laboratory and diagnostics capacity to enable rapid confirmatory testing of new outbreaks, including VOC, while building on and maintaining the established infrastructure and diagnostic capacity for other relevant diseases. Activities include specimen transportation networks, quality management systems, laboratory information systems and equipment management systems, human resource capacity as well as biosafety and biosecurity practices.

Human resources for health and community systems strengthening, including optimization of the health workforce to ensure equitable access to and scale up of integrated, people-centered health services, improved human resources for health (HRH) performance and quality of care via evidence-based innovative interventions, and strengthened primary health care (PHC) and community level integrated service delivery, including pandemic preparedness. This also includes infection prevention and control and the protection of the health workforce beyond PPE.

**Medical oxygen, respiratory care and therapeutics** includes developing appropriate care pathways to manage sudden surges in patient volume and to ensure those most in need can access care and treatment services immediately to limit transmission, morbidity and mortality. This also includes COVID-19 test and treat as part of surge preparedness.

**Health product and waste management systems** are needed to manage waste that is generated during response and/or as part of pandemic preparedness 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.

All interventions and activities described in this 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 Mechanism (CCM) engagement with national COVID-19 response coordinators and working groups, where they remain viable, to rapidly develop high quality, strategic and impactful C19RM funding requests. Where these national coordination bodies have been decommissioned, mainstreamed or otherwise ceased to function in a robust manner, it remains vital to ensure engagement with alternative governance bodies such as those for health systems and pandemic preparedness coordination, as appropriate. Finally, it is critical that community engagement in national health systems and pandemic preparedness and response governance bodies be considered broadly across all technical areas.

# Introduction

C19RM was designed to provide support across three broad categories:

- 1. COVID-19 control and containment interventions such as epidemiologic surveillance, contact tracing, testing and treatment, provision of PPE, and risk communications, as specified in <a href="https://www.who.guidance">WHO guidance</a>.
- 2. Activities to mitigate the effects of the pandemic on HIV, tuberculosis and malaria programs (referred to here as "mitigation").

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

# This updated information note:

- Aligns with current guidance, will continue to be updated and is complemented by other guidance.
  - Combines key COVID-19 response operational pillars with the new focus on health system resilience and related pandemic preparedness interventions.
  - Reflects the most current technical guidance based on the global COVID-19 response and pandemic preparedness.
  - Will continue to be updated based on emerging evidence, preparedness and response needs, and partner feedback.
  - Is complemented by more detailed guidance on essential HIV, TB, malaria, resilient and sustainable systems for health (RSSH), community, rights, and gender-related investments within GC7.
  - Should be supplemented with procurement-specific guidance contained in the <u>Guide</u> to Global Fund Policies on Procurement and Supply Management of Health Products, <u>Quality Assurance Policies for COVID-19 Health Products</u>, <u>Health Product</u> Segmentation Framework, and the Global Fund Budgeting Guidelines.
  - 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. These documents are being updated in February 2023.
- Promotes RSSH and PP interventions that are cross-cutting, multi-disease and that
  promote integration to boost and sustain HIV, TB and malaria outcomes, complementing
  Grant Cycle 7 (GC7) investments in: laboratory strengthening; community health workers
  (CHW)/ community systems and responses; multi-disease platforms for screening and
  diagnosis; and supporting integrated "end-to-end" surveillance which incorporates all of the
  above, as appropriate to country context.
- Moves beyond HIV, TB and malaria "mitigation" to "recovery" and integration. As a
  result, no longer supports single-disease and stand-alone HIV, TB or malaria interventions
  such as: TB cartridges, multi-month dispending (MMD) for HIV, and community responses
  for malaria interventions.
- Following the strategic shift to longer term investments in RSSH and PP, there are some
  interventions originally included in the C19RM 2021 TIN that still appear in the C19RM
  Modular Framework, but that are no longer included as priority investments in this technical
  information note (for example, HIV, TB and malaria mitigation). Applicants should discuss
  with Global Fund Country Teams before these areas are included in funding requests,
  depending on country context and need.
- **New Pandemic Fund.** Aligns with programmatic priorities defined within the first call for proposals of the new Pandemic Fund.

National Strategic Preparedness and Response Plan for COVID-19 (NSPRP) and Joint External Evaluation (JEE).<sup>1</sup> In order to align with national and global COVID-19 response strategic and operational planning, including for transition and sustainability, Global Fund C19RM funding requests that were previously based on select NSPRP pillars (NSPRP; Box 1) are now linked to core areas of health system resilience and pandemic preparedness domains (JEE; Box 2).

<u>The monitoring and evaluation (M&E) framework</u> has been updated to ensure comprehensive and relevant reporting, monitoring and evaluation of C19RM investments which in many countries will be programmed in parallel to GC7 resources.

# Box 1. Pillars of National Strategic Preparedness and Response Plan for COVID-19

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

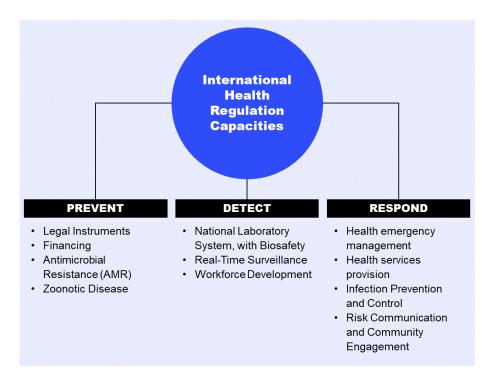
Pillar 9: Maintaining essential health services and systems\*

Pillar 10: Vaccination

\*Referred to as "mitigation" in C19RM.

<sup>&</sup>lt;sup>1</sup> Joint External Evaluation (JEE). WHO. https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/joint-external-evaluations.

Box 2. Select health system resilience and pandemic preparedness domains in WHO Joint External Evaluation framework



# **Key Considerations in Pandemic Preparedness and Response**

These key principles help guide the convening, consultation and integrated operational planning and prioritization required to develop technically robust and programmatically and financially aligned pandemic preparedness funding requests:

- 1. Strengthen pandemic preparedness through implementation of the International Health Regulations (IHRs). The Global Fund promotes integrated approaches while also recognizing and financing structures and systems that are specific to pandemic preparedness.
- 2. Finance pandemic preparedness national strategies e.g., NAPHS, and work in partnership with National Public Health Institutes (NPHIs) or equivalent government structures to develop and implement them. Where CCMs do not possess the specific expertise to develop robust funding requests they are advised to document their consultations with relevant bodies, per above.
- 3. Employ standardized, tested pandemic preparedness strategies and monitoring tools, tailored to the country context. The national government should define priority activities to be supported using available data, risk assessments, learning exercises, and local knowledge and these should be reflected in the NAPHS or equivalent pandemic preparedness strategy and operational plans.
- 4. Build on systems developed during COVID-19 and other public health emergencies to strengthen medium to longer-term preparedness.

- 5. Apply multisectoral and One Health approaches, e.g., human, animal and environmental sectors.
- 6. While building national capacity is critical, successful pandemic preparedness systems must also support complementary frontline capabilities, including human resources, at the primary health care and community levels. Including, but not limited to, maintaining essential health services, data collection and response, public health cadres, community health workers, early investigations, sample collection, limited diagnostic capacity, case management, infection prevention and control (IPC), local emergency management structures.
- 7. For CCMs, where appropriate, should consider how to adapt, modify or extend their governance model to support the effective coordination and oversight of pandemic preparedness programs. This will help ensure meaningful consultation and engagement with the specific and relevant government bodies, implementing partners and civil society organizations for pandemic preparedness and ensure active and direct participation in dialogue on national pandemic preparedness priorities at policy, strategy, operational and technical levels.
- 8. Effective response requires community trust and pandemic preparedness investments should focus on building their trust through holistic community engagement, including:
  - a) Encouraging proactive gender equity-based solutions, as pandemic responses often exacerbate gender inequalities and should address in PP strategic and operational plans.
  - b) Addressing barriers to health services.
  - c) Solving human rights and gender-related barriers and inequities that limit access to PHC services, including at community level.

Strengthened pandemic preparedness can only be achieved by including communities in the preparedness enterprise, including through country governance and direct implementation and oversight roles.

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 related funding. CCMs and country stakeholders are encouraged to engage national COVID-19 response bodies, where they continue to be viable and robust, as well as additional health system and pandemic preparedness governance bodies, such as those overseeing the annual operational planning for implementation of national action plans for health security, Laboratory and Epidemiologic Surveillance Directorates, and others. Holistic integrated planning should be employed 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.

# 1. Resilient Health and Community Systems, Preparedness and Response

Interventions related to RSSH, including community systems strengthening activities, are critical to transitioning the COVID-19 response in sustainable ways and building pandemic preparedness.

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,<sup>2</sup> WHO Benchmarks for IHR Capacities,<sup>3</sup> and, where available, National Action Plans for Health Security (NAPHS), IPC strategies and AMR roadmaps.

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 response transition and sustainability planning to enable greater impact, innovating around how to strengthen community roles in preparedness, prevention, early detection, and response, strengthen lab and supply chains, and engaging the private sector.

There is extensive evidence that COVID-19 and other disease outbreaks have exacerbated persistent health inequities, gender inequalities, and human rights impacts on already marginalized communities. Based on consideration of this evidence within WHO global consultations on updating of the JEE and SPAR in 2021, gender equity and equality were explicitly reflected as indicators for the first time. Health and community system investments in preparedness must therefore be intentionally designed as responsive to those factors and barriers that will hinder equitable access to critical services during disease outbreaks. There are also six interventions related to community systems and responses, addressing human rights and gender barriers in access 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 prevention, treatment and care. Community systems and responses and the engagement of communities at all levels, including key and vulnerable populations, are key to the COVID-19 response. For further information, refer to the list of activities below of necessary community, rights and gender-related investments during COVID-19 as well as the accompanying Community Systems and Responses Technical Information Note.

<sup>&</sup>lt;sup>2</sup>Joint External Evaluation (JEE). WHO. https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/joint-external-evaluations.

<sup>&</sup>lt;sup>3</sup> WHO benchmarks for International Health Regulations (IHR) capacities. WHO, 7 March 2019. https://www.who.int/publications/i/item/9789241515429

Finally, decisions on funding of infrastructure projects will only be made exceptionally as stated in the <u>Grant Budgeting Guidelines</u>. This exception applies to well-articulated infrastructure projects with a clear rationale and which are relevant to the national COVID-19 response.

- WHO IHR Joint External Evaluations (2022)
- WHO Benchmarks for IHR capacities (2019)
- WHO National Action Plans for Health Security (2018)

# 1.1 Surveillance system strengthening

A progressive transition from pandemic response to recovery and pandemic preparedness will require a renewed focus on building sustainable, resilient systems for health, informed by and building from the COVID-19 response. Countries are encouraged to invest in systems that can help transitioning from COVID-19 pandemic response mode (universal COVID-19 surveillance such as case investigation, contact tracing) to scale down and prepare mode.<sup>4</sup>

# **Box 3. Surveillance Systems**

- Indicator-based surveillance is the systematic (regular) identification, collection, monitoring, analysis and interpretation of structured data, such as indicators produced by well-identified, mostly health-based formal sources.
- Event-based surveillance is the organized and rapid capture of information about events that are of potential risk to public health. Information is initially captured as an alert, considered by the early warning and response system as representing a potential acute risk (such as an outbreak) to human health. All alerts may not necessarily become real events, and as such, need to be triaged and verified before a response is initiated.
- Per the <u>2019 WHO IDSR guidelines</u>, there are multiple types of Indicator-based surveillance, including facility-based, case-based, sentinel, syndromic, lab-based, disease-specific, community-based.

In this transition phase, surveillance systems are important to provide data to detect near real-time surges of COVID-19 (such as sentinel surveillance), identify hotspots (event-based surveillance) and detect emerging SARS-CoV-2 variants with different epidemiological characteristics causing outbreaks or increased disease severity (both indicator-based (including sentinel) and event-based surveillance). See Box 3 These routine (indicator- and event-based) surveillance systems should also be strategically expanded, integrated, and/or strengthened to test for multiple respiratory viruses including Influenza and respiratory syncytial virus (RSV) among others.

As countries continue to transition towards integration of COVID-19 surveillance into routine systems, investments to strengthen surveillance and response capacities and structures that can better prepare countries for ongoing epidemics and future pandemics are critical.

<sup>&</sup>lt;sup>4</sup> Technical Guidelines for Integrated Disease Surveillance and Response in the African Region: Third edition. WHO. March 2019. https://www.afro.who.int/publications/technical-guidelines-integrated-disease-surveillance-and-response-african-region-third

A core and fundamental element for strengthening health systems for pandemic preparedness is early warning surveillance and response systems. Optimal early warning surveillance and response interlinks and enhances functions of a country's existing overall surveillance. It includes strengthening of indicator- and event-based surveillance, linked to laboratory systems, community health and data systems and data utilization. Recognizing the utility of existing infrastructure and systems built for national health programs, including for HIV, tuberculosis and malaria, countries are encouraged to systematically evaluate, leverage and/or extend components of existing infrastructure to enhance early warning surveillance and response functions.

# Eligible elements include:

- Surveillance, including event- and indicator-based data systems and response. Event-based surveillance should focus on early recognition and reporting from communities and health facilities (both public and private), and on systems and capabilities that can manage reported events. Indicator-based surveillance can include systematic strengthening of notifiable disease and sentinel surveillance systems that contribute to early warning. Intentional leveraging of existing disease monitoring and response systems should be considered for early warning. See the 2022 WHO JEE tool,<sup>5</sup> 2019 WHO Benchmarks for IHR capacities,<sup>6</sup> 2022 WHO Mosaic Respiratory Surveillance Framework,<sup>7</sup> and/or WHO Pandemic Influenza Preparedness Framework,<sup>8</sup> for more information about specific activities supporting these capacities.
- Laboratory system elements that support early warning surveillance include specimen
  transport and referral systems, timely characterization of pathogens, data systems, and rapid
  return of results to enable appropriate response. Multipathogen detection methods and next
  generation sequencing that will guide public health surveillance should be considered. Refer
  to <u>Laboratories and Diagnostics section</u> (below) and <u>Briefing Note on Integrated Laboratory
  Systems Strengthening Catalytic Initiative</u> for further details.
- Data reporting, systems and use. A functional data system, also referred to as health management information system (HMIS), will allow events to be reported from both formal and informal sources: community-level key informants, prisons, workplaces, schools, clinicians from public and private health care facilities and others, and enable data storage and access. These investments should be linked to systems to receive, store, analyze, interpret and visualize data from multiple sources of information to provide a comprehensive picture of an epidemic or a disease under surveillance, including capacity for essential disaggregated analyses by gender, age, etc. Such data hubs could be situated at NPHIs, public health emergency operations centers (PHEOC) or similar. Data systems infrastructure built for HIV, TB, malaria and other national health programs can be assessed, enhanced and built on to support the needs of early warning systems as described above. These investments should link to national strategies for Routine HMIS and/or for Digital Health,

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<sup>&</sup>lt;sup>5</sup> Joint external evaluation tool: International Health Regulations (2005) - third edition. WHO, 23 June 2022. https://www.who.int/publications/i/item/9789240051980

<sup>6</sup> WHO benchmarks for International Health Regulations (IHR) capacities. WHO, 7 March 2019. https://apps.who.int/iris/handle/10665/311158.

<sup>&</sup>lt;sup>7</sup> "Crafting the Mosaic" a framework for resilient surveillance for respiratory virus and epidemic and pandemic potential. WHO, 8 March 2023. https://www.who.int/publications/m/item/crafting-the-mosaic-a-framework-for-resilient-surveillance-for-respiratory-virus-and-epidemic-and-pandemic-potential

<sup>&</sup>lt;sup>8</sup> Pandemic Influenza Preparedness (PIP) Framework. WHO. https://www.who.int/initiatives/pandemic-influenza-preparedness-framework

where possible. Key to the success of investing in data systems is to build human capacity to access, analyze, interpret and use of data for action. Finally, related HMIS/ digital health investments should be demonstrably linked to the essential early warning systems (EWS) modalities described above, and not used to support broad, fundamental HMIS/ digital health investments which do not specifically strengthen EWS capacities and capabilities.

- Workforce. Applicants should consider in-service and pre-service training of front-line workers (community health workers, clinicians and nurses), community members, subnational public health epidemiologists and periodic joint training of the laboratory and epidemiology workforce to increase understanding of the epi-lab linkages in order to build and sustain an early warning system. Established training programs such as Field Epidemiology Training Programs (FETP) should be included. Additionally, policies and defined processes to recognize, support, appropriately compensate, retain and manage community health workers and other front-line workers are key to institutionalize an early warning system (see <a href="https://example.com/hRRH section">hRRH section</a>).
- Response resources include training for investigation of and response to reported events, and capability and ability to routinely deploy simulation exercises to evaluate early warning functions.

# The following activities are recommended:

- Revision and/or development of national guidelines, standard operating procedures (SOPs), training materials for early warning surveillance.
- Implementation, strengthening and/or integration of early warning surveillance including:
  - Event-based surveillance in communities (community health workers (CHWs), communities at large, congregate settings) and health facilities (both public and private).
  - Indicator-based surveillance including sentinel site surveillance and notifiable disease surveillance. This includes strengthening sentinel surveillance systems for respiratory viruses (including laboratory capacity) with capabilities to improve understanding of disease transmission, signal surges and start of epidemic season and define thresholds for investigation and response.
  - Countries are encouraged to map private health facilities and develop policies, mechanisms and processes that intentionally include private health facilities in eventand indicator-based surveillance.
- Investments in foundational digital health and/or routine data systems (HMIS/CHIS, lab/epi linked systems) that will contribute to early warning surveillance capacity and capability.
- Capabilities that will ensure that early warning surveillance and response data (programmatic, lab, logistics, etc.) are analyzed, presented, interpreted and used for decision-making and mounting targeted and appropriate response.
- Institutional capacity building support to a health coordination bodies such as a public health emergency operation centers or national public health institutes (NPHIs), e.g., in response management.
- Development and implementation of joint external evaluations (JEE).
- Revision and/or development of a National Action Plan for Health Security (NAPHS).
- Support to civil society and community organizations to play a meaningful role in countrylevel co-ordination and planning.

- Intra-action and after-action reviews, including application of 7-1-7 metric, and simulation exercises to assess and remediate preparedness and response capabilities based on local outbreaks and epidemics.
- Support public financing systems which will enable governments to increase fund flows to local levels, including via social contracting, based on WHO recommendations on health emergency response and preparedness budgeting.

Specific surveillance activities related to antimicrobial resistance include:

- Assessment of existing surveillance systems or laboratory capacities for identification and antibiotic susceptibility testing of common bacteria.
- Definition of national AMR and One Health surveillance objectives and development of a national AMR surveillance strategy including priority specimens, bacteria, and drug-bug combinations for national reporting.
- Assignment of a national coordinating center to oversee the development and functioning of the national AMR surveillance system.
- Development of a national surveillance protocol including surveillance targets, laboratory standards, definitions, priority specimens, pathogens and drug-bug combinations, designated surveillance laboratories, defined datasets, metrics, data production, analysis and reporting, quality management, monitoring and evaluation.
- Develop and initiate training programs for data collection and reporting of AMR according to the national AMR and One Health surveillance system plan.
- Execution of AMR surveillance in line with methods outlined by the national surveillance strategy and WHO's global antimicrobial use and surveillance system (GLASS).
- Dissemination of reports relating to priority measures and outputs of the surveillance system, including measurement of the proportion of AMR pathogens among specimens or isolates, results from participation in international EQA rounds of the national reference laboratory, and incidence of infections caused by AMR pathogens at sentinel sites (community and hospital acquired).
- Identification of a health ministry lead for AMR and a national multisectoral AMR andor One
  Health coordinating committee with clear terms of reference and accountability for the
  coordination of activities of relevant ministries on AMR and stewardship.
- Development of a National Action Plan (NAP) to address AMR in line with the Global Action Plan (GAP) on AMR. Identification of priority actions (based on risk and feasibility) from the NAP, development of an implementation plan with responsible agencies with established timelines and implementation of these actions. Development and implementation of an AMR and/or One Health national action plan monitoring framework.
- Identifying national priority multi-drug resistant organisms (MDRO), using published or surveillance data, including presence and frequency of highly transmissible genotypes such as carbapenemase-producing or extended-spectrum beta-lactamase producing genotypes.
- Developing a national strategy or guidance for MDRO detection, reporting, and prevention that addresses colonization and transmission of MDRO, communication between laboratories and IPC, and public health authorities. Improving national, sub-national, or clinical facility ability to detect MDRO and transmissible genotypes, including genotyping or phenotypic measures.

The activities described within this intervention category may be mapped to the following JEE interventions and indicators: D2.1 Early warning surveillance function; D2.2 Event verification and investigation; D2.3 Analysis and information sharing; P4.2 Surveillance of AMR; P5.1 Surveillance of zoonotic disease; R4.2 Health Care Acquired Infection (HCAI) surveillance; JEE P1.1 Legal instruments; P3.1 National IHR Focal Point functions; P3.2 Multisectoral coordination mechanisms; P3.3 Strategic planning for IHR preparedness or health security; P5.2 Responding to zoonotic diseases; R1.1 Emergency risk assessment and readiness; R1.2 Public Health Emergency Operations Center (PHEOC); R1.3 Management of health emergency response.

# 1.2 Laboratories and diagnostics

Laboratories are the mainstay of health systems, as test results are critical for diagnosing diseases, guiding treatment, determining drug resistance, and identifying diseases of public health significance through surveillance. A functional, integrated, tiered laboratory system with level-appropriate diagnostic testing is necessary to address these health system requirements. The RSSH Laboratory Systems Strengthening module in the Modular Framework Handbook emphasizes integration and coordination across disease programs and proposes the development/updating of integrated National Laboratory Strategic Plans (NLSP). This requires consolidation and coordination of existing resources (e.g., facilities, multipathogen testing, equipment, personnel and supportive processes (i.e., specimen referral, test reporting, inventory management, quality management, post-market surveillance)) for multiple disease programs of public health importance, as per the Maputo declaration. The Laboratory Systems Strengthening module within the RSSH/Pandemic Preparedness intervention of the Modular Framework covers eight packages:

- 1. National laboratory governance and management structures
- 2. Quality management systems and accreditation
- 3. Laboratory information systems
- 4. Network optimization and geospatial analysis
- 5. Laboratory-based surveillance
- 6. Laboratory supply chain systems
- 7. Specimen referral and transport system
- 8. Biosafety and biosecurity, infrastructure, and equipment

A COVID-19 national testing strategy should include a clear structure and defined internal governance on integration/coordination of testing and how collaboration with stakeholders (including communities) is organized. Countries should continue to strengthen and sustain domestic diagnostic and laboratory capacity for COVID-19 at national and sub-national levels, while building on and maintaining the established infrastructure and diagnostic capacity for other relevant diseases and antimicrobial resistance. Decentralization of testing through use of antigen (Ag) rapid diagnostic tests for "Test and Treat" programs covering populations at high-risk for severe disease should be considered.

Applicants are encouraged to consider integration of COVID-19 testing into their existing diagnostic networks, leveraging past investments and equipment to strengthen the capacity to respond to COVID-19, HIV, TB and malaria, and other priority pathogens. 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 integrated

sample transportation systems, and laboratory information systems to facilitate delivery of test results.

Countries are encouraged to maintain and strengthen national laboratory information systems (LIS) for all diseases at all levels of the system, considering connectivity solutions for laboratory equipment. Interoperability with all digital health systems such as electronic medical records and HMIS will allow for integration of laboratory test results with associated clinical and epidemiologically relevant data, facilitating return of results to patients and physicians, and aggregating data for national-level dashboards.

Essential diagnostic testing includes molecular assays that have received regulatory approvals for priority pathogens (such as SARS-CoV-2) and Ag-RDTs allowing decentralization of testing capacities and supporting 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 <u>Laboratory Testing Strategy</u> and <u>Antigen Detection in the Diagnosis of SARS-COV2 infection</u>.

Specific activities which can be supported include:

- Laboratory surge capacity planning (infrastructure, staffing and operations) as part of pandemic preparedness allowing for large-scale testing:
  - Establish access to a designated international/national reference laboratory for priority diseases, identification of new and emerging pathogens and antimicrobial resistance testing.
  - Adopt and disseminate standard operating procedures (SOPs) as part of disease outbreak investigation protocols for specimen collection, management, and transportation for diagnostic testing.
- Integrated specimen transport networks, quality management systems (including pathogen specific external quality assessment (EQA) schemes), laboratory information systems, infrastructure, equipment, laboratory supply chain management systems and human resource capacity.
- Laboratory-based surveillance which could include genomic, AMR and zoonotic disease surveillance activities, multipathogen testing.
- Capabilities of laboratories to test and return results of specimens from outbreak and epidemic prone diseases, including investments that include electronic reporting from community level to national level.
- Biosafety and biosecurity practices, and waste management
  - Identify hazards and perform a biosafety risk assessment at participating laboratories; use appropriate biosafety measures to mitigate risks; (e.g., <u>WHO Assessment tool for laboratories implementing SARS-CoV-2 testing: interim guidance</u>).
  - Adopt standardized systems for molecular testing (including AMR, linked to One Health), with assured access to reagents and kits.
  - Develop and implement plans to link laboratory data with key epidemiological data for timely data analysis.
  - 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 pathogen transmission.
- Develop or update national genomic surveillance strategy as per <u>WHO guidelines</u>; implementation of genomic surveillance activities.
- Share sequence data according to established protocols.
- Monitor and evaluate diagnostics, data quality and staff performance, and incorporate findings into strategic review of national laboratory plan and share lessons learned.
- Develop quality assurance mechanisms for each testing methodology, including point-of-care.
- Technical assistance to support countries in the preparation of funding requests, with a proposed menu of interventions.
  - Development and implementation of guidelines and workflow SOPs to account for integrated testing and prioritization (e.g., COVID-19, HIV EID, HIV VL, TB, Hepatitis, HPV, STIs, testing on molecular multipathogen instruments).
  - Training, supervision and salary for staff supporting the above including at community level (e.g., contracting of community-based organizations for rapid testing of multiple pathogens).

The use of multipathogen testing instruments is encouraged as per the WHO information note (2017) Considerations for Adoption and Use Of Multi-disease Testing Devices moving towards integrated laboratory diagnostic networks that use common laboratory equipment to support multiple testing streams. Focus on integration of COVID-19 testing into existing national essential diagnostics services is recommended.

To facilitate the preparation of the funding applications, the <u>Modular Framework Handbook</u> covers laboratory components within the RSSH-PPR implementation packages which include:

- The Introduction and adoption of multipathogen testing as per developed country <u>Essential</u> <u>Diagnostic List</u> (EDL). This also supports priority disease molecular testing with linkages to pandemic preparedness with implementation of AMR testing is strongly encouraged.
- The scale-up of and decentralization of point of care (POC) diagnostics for multiple pathogen testing at the community level (e.g., single disease RDTs, dual/multi-disease RDTs, multipathogen POC instruments). Related activities accompanying the procurement of POC diagnostic tests should be considered including training, support to quality assurance, and technical assistance for the development of multi-disease testing and community testing strategies.

The activities described within this intervention category may be mapped to the following JEE interventions and indicators: D1.1 Specimen referral and transport system; D1.2 Laboratory quality system; D1.3 Laboratory testing capacity modalities; D1.4 Effective national diagnostic network; P7.1 Whole-of-government biosafety and biosecurity system is in place for human, animal and agriculture facilities; P7.2 Biosafety and biosecurity training and practices in all relevant sectors (including human, animal and agriculture).

# 1.3 Human resources for health and community systems strengthening

# (a) Human resources for health

The health workforce is critical to COVID-19 responses and pandemic preparedness and should be included in intervention planning. This includes interventions for health care workers (e.g., doctors, nurses, laboratory technicians, pharmacists, social workers), community health workers (CHWs), management and support staff (e.g., health managers, public health workers, epidemiologists, biomedical engineers, laboratory professionals, health data analysts, health financing managers and others) that may be involved in strengthening primary health care systems and public health functions such as surveillance, rapid response laboratory, infection prevention control measures, multipathogen case management, vaccination and other areas.

Support from Global Fund plays a catalytic role in strengthening human resources for health (HRH) development in a sustainable and evidence-based manner to improve quality of care, working with relevant ministries, technical partners and other donors, as formalized in the <a href="https://www.who.au/wh

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

HRH investments should be informed by the country context, periodic assessments (e.g., through a health labor market and workload optimization analyses), the evidence base and country dialogue including government HRH stakeholders, and other development partners supporting HRH to ensure complementarity. Compared to the previous funding cycle (GC6), applicants are encouraged to support three key shifts reflecting the new critical approaches to investing in HRH (See: RSSH Information Note Section 4.5 Human Resources and Quality of Care).

Critical approaches for investing in HRH:

- 1. More effective interventions to improve HRH performance.
- 2. Catalytic support for integrated HRH strategic planning supporting country workforce development, including CHWs.
- 3. Enhance system readiness to scale CHWs aligned with WHO guidance.

The RSSH Human Resource for Health section of the <u>Modular Framework Handbook</u> (pages 28 to 36) emphasizes integration and coordination of the primary health care (PHC) workforce.

Intervention areas for HRH and Quality of Care include:

- HRH planning, management and governance, including CHWs.
- Education and production of new health workers, excluding CHWs.
- Remuneration and deployment of existing/new staff, excluding CHWs.

- In-service training, excluding community health workers.
- Integrated supportive supervision for health workers, excluding CHWs.
- Quality improvement and capacity building for quality of care.
- Community health workers: selection, pre-service training and certification.
- Community health workers: contracting, remuneration and retention.
- Community health workers: In-service training.
- Community health workers: Integrated supportive supervision.

For CHWs please also refer to **Table 1** in the <u>RSSH Information Note</u> for a summary of eligible intervention areas for CHWs, excluding commodities (which are not eligible under C19RM). See the <u>Modular Framework Handbook</u> for a detailed list activities under each intervention area above.

# A sample of key activities include:

- HRH policy or strategic planning, such as development and monitoring of a national HRH strategy.
- Strategic framework to nationally prioritize resources and investments in One Health workforce development.
- Rapid responses for public health events, rapid workforce planning exercises/ analysis to inform workforce skills optimization and re-deployment.
- Pre-service education, including curriculum development and review.
- Certificate, Diploma, and Degree-conferring field epidemiology training programs, including advanced field epidemiology training program (FETP) that comprise trainees from human and animal health professionals, including development of curriculum, capacity building of health training institutions.
- Development or contribution to retention schemes.
- Temporary recruitment schemes for appropriately licensed health workers, (e.g., retired HRH, unemployed HRH) to support surge capacity for health emergency response.
- Skills and competence based, on-site in-service training with integrated technical content, combined with post- training follow up, through integrated supportive supervision or continuous collaborative quality improvement.
- Integration of pandemic preparedness in continuous professional development training of multi-disciplinary teams (e.g., frontline surveillance, epidemiology, biostatistics, laboratory and biosafety, veterinary, communication).
- Collaborative and innovative continuous quality improvement approaches including group problem solving.
- Leadership and management training for national, regional, district health managers, including measures to promote increased female leadership and gender equity.
- Capacity building of national or subnational health training institutions.
- Development or revision/updates to CHW contracting agreements specifying the roles and responsibilities, working conditions, remuneration package, career advancement and workers' rights.
- Gender-based violence (GBV) and stigma and discrimination-related training for all levels of health workforce.
- Salaries, incentives, benefits and eligible allowances for CHWs.

• Application, use and integration of digital health platforms and tools, including development of blended learning solutions for continuous professional development.

Long-term financial sustainability of investments should be considered at the activity development stage. Countries should ensure that they have appropriate technical assistance (TA) for surge and sustainability planning.

Surge capacity should complement existing staff size and should not undermine long-term planning and capacity strengthening 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 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 activities described within this intervention category may be mapped to the following JEE interventions and indicators: D3.1 Multisectoral workforce strategy; D3.2 Human resources for implementation of IHR; D.3.3 Workforce training; D.3.4 Workforce surge during a public health threat; R1.4 Activation and coordination of health personnel in a public health emergency.

# (b) Community Systems Strengthening – Community Led and Based Organizations

Strong, well planned, and resourced, community led responses are proven as critical in responding to disease outbreaks. All evidence emphasizes the unique and extensive role communities play in building trust across key actors and in the development of culturally and socially acceptable response strategies and programs, in reaching the most vulnerable and marginalized, in demand creation, in monitoring service accessibility and quality, and in advocacy, knowledge generation and research.

COVID-19 and other disease outbreaks have demonstrated the importance of community led and based organizations in their capacity to rapidly adapt as threats emerge and to act in support of whole of system responsiveness to changing community needs and challenges in access to critical services.

Sustained support from the Global Fund in systems strengthening for community led and based organizations will be critical in the transition from a COVID-19 emergency response setting to a focus on system preparedness for future disease outbreaks and emergencies.

Outlined below are intervention areas and example activities focused on sustaining and strengthening community led and based organizational capacities to engage in pandemic preparedness and disease outbreak readiness processes and the underlying systems necessary to rapidly respond and adapt when necessary.

Investments here should be aligned and complimentary with those proposed as part of GC7 where relevant. Applicants might use the Community Systems Strengthening Technical Brief as guidance.

# Community capacity building and leadership development:

- Strengthening community led organizational planning and leadership capacities to respond to disease outbreaks and emergencies (e.g., emergency planning for service disruptions, safety and security protocols and systems to maintain service access for marginalized and/or criminalized communities, surge planning to respond to increases in GBV and human rights violations.).
- Leadership, professional development, and resourcing to enable effective community representation in emergency response decision-making processes and platforms.
- 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 the Global Fund Guidelines for Grant Budgeting.

# Community-led monitoring:

- Activities that strengthen community led monitoring system capacities to adapt and respond to disease outbreaks and their impacts on service availability, accessibility, acceptability, and quality; monitor human rights and gender related impacts.
- Activities that strengthen community led monitoring of health policy, budget and resource decisions and development, health financing allocation decisions; and/or complaint and grievance mechanisms.
- Technical support, training and mentoring on community-led monitoring: collection, collation, cleaning, and analysis of data; and use of community data to inform programmatic decision making, policy development, and advocacy for social accountability.

# Community-led advocacy and research:

- Qualitative, quantitative, and operational community-led research on health system preparedness and resilience in the context of disease outbreaks including system capacities to assess and mitigate for potential human rights, health equity and gender related implications.
- o Community-led mapping and analysis of legal, policy and other barriers that hinder/limit community led and based responses in disease outbreaks.
- Budget advocacy for domestic resource mobilization for health and community systems in pandemic preparedness and responses

# Community engagement, linkages and coordination:

- Community engagement and representation in national policy processes, decisionmaking and accountability mechanisms, and in the development of local, regional and national strategies and plans (including JEE & NAPHS, IARs, AARs, and SIMEX; country level platforms/WGs/mechanisms with a role in preparedness).
- Support and reinforce community mobilization initiatives and approaches as agile and adaptable in the context of sudden disease outbreaks and health emergencies.
- Creation and/or strengthening of platforms that improve coordination, joint planning and effective linkages between community stakeholders and organizations and formal health systems in disease outbreak preparedness planning.

 Support to establish or strengthen community engagement in RCCE coordination mechanisms and working groups.

The activities described within this intervention category may be mapped to the following JEE interventions and indicators: P.1.2 Gender equity and equality in health emergencies; R5.1 RCCE system for emergencies; R5.2 Risk communication; R5.3 Community engagement.

# (c) Infection prevention and control, and protection of the health workforce beyond PPE

Infection Prevention and Control (IPC) is a cross-cutting clinical and public health specialty area that strengthens the health system to be more resilient against outbreaks and pandemics and helps to ensure continuity of essential health services. The COVID-19 pandemic has exposed weaknesses in healthcare systems globally that threaten the lives of healthcare workers, patients and the progress made in global health programs. Previous outbreaks such as the Ebola have highlighted the role that poor IPC can have in propagating disease transmission both within healthcare facilities and in community settings. This includes a wide range of service delivery venues, including prisons, drop-in centers, and other informal venues. Additionally, service disruptions due to healthcare-associated COVID-19 transmission has threatened the ability to essential health services, including providing care to people with HIV, TB and malaria.

IPC is a key strategy in the prevention of respiratory diseases including TB and COVID-19. The key framework to guide IPC activities is WHO's Minimum Requirements for IPC at National and Facility Levels.<sup>9</sup> This guidance outlines the minimum capacities and capabilities that are expected for the safe delivery of health care services. These core components have been incorporated into accepted measures such as the Joint External Evaluation (JEE)<sup>10</sup> and the State Party Self-Assessment Annual Reporting (SPAR) tool.<sup>11</sup>

Prior Global Fund investments in IPC in C19RM have primarily been through commodities, particularly the provision of personal protective equipment (PPE). However, IPC is much more than PPE. According to the hierarchy of controls, PPE is the least effective IPC and safety measure, and is the last line of defense against infectious diseases in healthcare. While early in the response this need was critical and likely life-saving, given the shift of C19RM toward preparedness and health systems, it is important to move beyond PPE toward strengthening IPC programs, including those outside of the formal health sector. Strong health systems rely on elimination, engineering, and administrative controls to keep health workers and patients safe; these measures require IPC programs for proper planning and integration within the health system.

It is crucial to engage IPC stakeholders in the planning and application writing process. Directors of national IPC programs are typically within Ministries of Health in the clinical services area, within epidemiology/ disease control programs, or within national public health institutes. Other key

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<sup>&</sup>lt;sup>9</sup> Minimum requirements for infection prevention and control programmes. WHO, 18 November 2019. https://www.who.int/publications/i/item/9789241516945.

<sup>&</sup>lt;sup>10</sup> Joint external evaluation tool: International Health Regulations (2005) - third edition. WHO, 23 June 2022. https://www.who.int/publications/i/item/9789240051980

<sup>&</sup>lt;sup>11</sup> IHR State Party Self-Assessment Annual Report (SPAR). WHO.https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/states-parties-self-assessment-annual-reporting

stakeholders include national laboratory directors, surveillance directors, national TB program managers, AMR focal persons, as well as community and prison health directors.

The establishment of a coordinated IPC approach for preparedness and emergency response activities at a national level is critical. National IPC programs should: (1) oversee IPC efforts at the national, sub-national and healthcare facility level; (2) establish country IPC policies, guidelines, and standards; and (3) ensure monitoring and improve adherence to appropriate IPC practices during healthcare delivery across multiple settings.

# Priority activities include:

- Support for a national IPC program. The IPC coordinator should have sufficient authority to engage the health sector, issue policies, and coordinate activities. The coordinator should engage across programs and departments as needed for coordination, planning, and implementation of IPC best practices.
- Development/revision and implementation of a national IPC strategy including guidelines, standards, training/ supportive supervision, quality improvement, and other policies for COVID-19 and other emerging diseases.
- Support for sub-national IPC programs. Sub-national coordinators should work with the national IPC coordinator and assist with implementing the national strategy, including monitoring and reporting of key IPC indicators.
- Development of a national M&E system for IPC, including key indicators. This system should ideally be a central reporting system that collects and reports data on IPC status of health facilities, PPE stock levels, or nosocomial health care workers or patient infections. Data should be used for quality improvement.
- Conducting a 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 or
  other emerging infectious diseases.
- Patient screening and triage to rapidly identify people with suspected infectious diseases including COVID-19 and TB; screening, identification, and management of healthcare worker exposures or illnesses; inpatient and healthcare staff cohorting and isolation; visitor management.
- Development or installation of isolation areas in healthcare facilities, including respiratory isolation for TB or other airborne pathogens, and contact isolation for hemorrhagic fevers or highly resistant bacteria.
- Implementing physical barriers and regulating patient flow to minimize crowding; ensuring adequate ventilation in patient care and waiting areas.
- Support for IPC training, supportive supervision, and/ or quality improvement in informal sectors, including CHWs.

### Additional activities and programs may include:

- Supporting implementation of strategies for health care associated infection or AMR surveillance to link with public health notification in line with national efforts for surveillance.
- Ensuring appropriate environmental cleaning and waste management practices (training, job aids, guidance, and protocols, use of indicators to monitor practices).

- Ensuring sufficient water/ sanitation infrastructure and supplies for hand hygiene.
- Improving facility level IPC response to MDRO detection, including colonization screening, isolation, environmental cleaning, and other IPC measures consistent with WHO guidelines.

The activities described within this intervention category may be mapped to the following JEE interventions and indicators: P3.2 Multisectoral coordination on AMR; R4.1 IPC programmes; R4.3 Safe environment in health facilities; P4.4 Optimal use of antimicrobial medicine in human health.

Please refer to the following WHO guidelines:

- WHO COVID-19 response operational guidelines.
- <a href="https://www.who.int/publications/i/item/WHO-2019-nCoV-PPE\_specifications-2020.1">https://www.who.int/publications/i/item/WHO-2019-nCoV-PPE\_specifications-2020.1</a>
- <a href="https://www.who.int/teams/risk-communication/health-workers-and-administrators">https://www.who.int/teams/risk-communication/health-workers-and-administrators</a>

# 1.4 Medical oxygen, respiratory care and therapeutics

In the transition from COVID-19-specific case management to more integrated approaches, health facility staff should be trained on the case definitions of suspected COVID-19 and other notifiable infectious diseases, including respiratory pathogens such as influenza. Outpatient and in-patient services should reflect the appropriate care pathways, 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 respiratory pathogen referral pathway, which designates appropriate care settings for mild and low-risk moderate 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.

Test and treat approaches focusing on high-risk groups with mild/moderate forms of COVID-19 should be piloted and implemented, promoting early testing (including rapid antigen test usage at health facility, community or home levels), and securing good linkages to the prescribing entities, to enable early access to oral COVID-19 antivirals (Nirmatrelvir/ritonavir and Molnupiravir), with adequate management of contra-indications and drug-to-drug interactions.

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 other WHO-recommended novel therapeutics), 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.

For proposed COVID-19 test and treat (T&T) investments, the following are encouraged:

# A. What is the focus of the funded T&T activities?

- Immediate clinical services (integrated management of COVID-19 cases within routine services) as part of on-going response.
- Surge preparedness, ensuring capacity to rapidly deploy and scale T&T services in event of surge.

# Ensure basic information has been gathered on:

- Governance of the T&T activities. (Who is the entity driving the T&T activities? What part(s) of the MoH are involved? who are key technical partners?)
- Regulatory status of oral antivirals e.g., Paxlovid/Pfizer, Lagevrio/MSD and/or generic versions of Nirmatrelvir/ritonavir and molnupiravir.
- Clinical guidelines. (Have relevant novel therapeutics been introduced in national guidelines? Are there specific COVID-19 T&T guidelines? Have the guidelines been disseminated and are relevant health workers trained, including CHWs where appropriate?)
- Service delivery model. (What is the target population(s)? Is this a pilot or phased implementation? Will model include health facility and/or community-based services, tiered referral? Is there a surge plan covering national deployment including marginalized and vulnerable populations?)
- Diagnostics. (RDTs via community-based or self-testing, overall strategy including clinical and surveillance, and related quantification & forecasting)

# Specific activities which can be supported include:

- Disseminate regularly updated information and evidence, train, and refresh the health workforce in management of COVID-19 and respiratory pathogens, 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, including novel therapeutics to address future variants of concern, including
  service and maintenance where appropriate to ensure continuous availability of equipment.
- Medical oxygen and respiratory care interventions that are eligible for Global Fund support include bulk oxygen supply, oxygen distribution and storage, oxygen delivery and respiratory care, oxygen support systems.
- 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). More information is available in the Global Fund Health Product Management Template (HMPT) and the HPMT User Guidelines.
- 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.
- 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.
- Implement national assessment of medical oxygen demand and gaps.
- Salary, training and supervision for temporary staff supporting the above.

- Support and coordinate novel therapeutics introduction (NPI) activities, for oral COVID-19
  antivirals, including generics (e.g., registration, update of national guidelines, dissemination
  of the guidelines including creation of job aids, training of health care workers including at
  community-level, demand generation activities, development of forecasting tools, integration
  into the supply chain and in the supply of monitoring tools).
- Pilot and implement Test and Treat activities, in coordination with new product introduction (NPI) activities and focused on surge preparedness.
- Medical equipment for integrated and multi-disease screening and diagnosis within respiratory care and case management services, such as digital x-rays with or without computer assistance. Per WHO guidance, optimal use of this technology needs to consider how it would fit within the clinical setting where it is going to be deployed (e.g., portable radiographic digital systems should not be used for patients whose location, clinical condition and/or isolation status would permit transport to hospital radiology departments).

The activities described within this intervention category may be mapped to the following JEE interventions and indicators: R3.1 Case management; R3.2 Utilization of health services; R3.3 Continuity of essential health services (EHS); and R4.3 Safe environment in health facilities.

Please refer to the <u>WHO COVID-19</u> response operational guidelines; <u>WHO Therapeutics and COVID-19</u>; and <u>WHO Portable Digital Radiography Systems: Technical Specifications.</u>

# 1.5 Health Product Management Systems

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, and operating costs in line with WHO guidance.

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

# (a) Quality Assurance

- Pre- and post-market surveillance activities of health products: as described in the <u>Guide to Global Fund Policies on Procurement and Supply Management of Health Products</u>, market intelligence/surveillance work should be implemented. 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 preand 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.

More information is available at: WHO 2020 guidance on post-market surveillance.

# (b) Supply Chain

- Flexible Capacity for Efficient Surge Management: Surge demand flexibility may include managing country specific strategic stockpile of critical health products through existing capacity or additional temporary capacities. It could also warrant distributing an increased throughput of health products, in-country logistics for new product introductions (NPIs) and managing in-country reverse logistics. These set of investments should also prioritize warehousing safety and security to prevent accidents, fires or loss of health products. Note: This does not relate to vaccines.
- Accelerating agility using data: Data-driven decision-making at all levels of the supply chain can help avert stock outs and other problems. The availability of high-quality data is however dependent on information systems that support the processes of the supply chain at all levels from central to community levels. C19RM funds can be used to support the implementation of WHO standards-based <a href="health product information systems">health product information systems</a> to enable the fulfilment of reporting requirements, such as stock and consumption reporting and analytics on the efficiency and effectiveness of downstream supply chain processes.
- Effective Supply Chain System Governance: Investments in supply chain governance
  including the creation, review and renewal of national supply chain strategic plans should
  include elements of pandemic preparedness that directly work to strengthen the oversight of
  key supply chain functions and governance bodies. These investments further support
  country stewardship and enable self-reliance and effective supply chain management.
  Naming, coding and unique device identifier (UDI) databases are important to track and trace
  health products ensuring that training, maintenance, calibration and operating costs and
  warranties are considered.

# (c) Maintenance of health equipment

• Eligible activities include regular preventive maintenance all medical equipment, such as laboratory diagnostic platforms, oxygen. All procured health equipment should include warranty and maintenance contracts<sup>12</sup>, appropriate training and eventually spare parts, as that equipment should not be consider a one-off expense but a long-term investment.

# (d) Medical and Laboratory Waste Management Systems

While the provision of high-quality health services improves health and well-being overall, health care waste (HCW) is an inevitable byproduct. If not managed properly, HCW can cause unintended harm to human health as well as significant environmental damage.

C19RM is an opportunity to expand waste management capacities to address issues highlighted by the pandemic, and for future surge capacity. However, disease programs are strongly encouraged to consider waste management as a part of core grants to address waste generated by these

<sup>&</sup>lt;sup>12</sup> The Global Fund will fund warranty and maintenance of health equipment within the same Allocation Utilization Period/IP, according to the Global Fund's Budgeting Guidelines.

programs and C19RM is not intended to address routine waste issues from HIV, TB, or malaria programs.

Grant applicants should ensure that the right technical in-country stakeholders (e.g., IPC and WASH focal points, Ministry of Environment) are actively engaged in the proposal, and that it is aligned with a national waste management strategy. Ad hoc proposals without consideration of sustainability and integration should be avoided.

For additional information, grant applicants should also consult the <u>Global Fund Technical Brief on</u> Sustainable Health Care Waste Management.

# Examples of activities include:

- Systematic assessment of health care waste and needs, to inform development of a national or subnational waste management strategy.
- Development of national, sub-national, and facility level policy frameworks, guidance or operational plans for management of health care and laboratory waste and/or supply chain wastage.
- Support of national waste management programs and engagement of key stakeholders including IPC, WASH, Environment, and communities.
- 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 in line with the national waste management system or strategy.
- Maintenance and servicing of waste treatment technologies.
- 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.

The activities described within this intervention category may be mapped to the following JEE interventions and indicators: R1.5 Emergency logistic and supply chain management.

### More detailed information:

- The Global Fund's Technical Brief on Sustainable Health Care Waste Management
- WHO guidelines for safe management of wastes from health-care activities
- WHO guidance on decommissioning medical devices

# 2. 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 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 <u>guidance on CCM engagement</u> and <u>Mitigation of HIV, TB, and malaria</u>, should also be reviewed to understand the full breadth of C19RM partner engagement.

# 2.1 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, and/or relevant health systems, and/or pandemic preparedness governance bodies. The application guidance strongly encourages effective engagement with response management entities that are steering COVID-19 responses and pandemic preparedness from start to finish of the new funding requests. Ideally this will include direct coordination with relevant national technical working groups or related technical bodies with specific responsibilities for epidemiologic surveillance, laboratory diagnostics, workforce, IPC, and case management, including oxygen.

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. Please note the distinction between funding TA needs for implementation and funding "the cost of funding request development" which is not covered by grant funds. 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, as necessary to find TA solutions.

Finally, TA may be sought from relevant external sources, i.e., global and regional institutions, supporting key aspects of C19RM via centrally managed and led investments, or CMLI, as well as fit-for-purpose set-aside TA resources. These include:

- Project BOXER: PSA plants for bulk oxygen production.
- Project STELLAR: Lab diagnostic and network optimization, including genomic sequencing.
- **Project TNT**: COVID-19 Test and Treat.
- End-to-End Surveillance and Response: Early Warning Surveillance.
- Project BIRCH: Community Health Worker programs.

US Government set-aside: USAID and US CDC.

# 2.2 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 and/or relevant health systems bodies, such as Epidemiologic Surveillance and Laboratory Directorates, Community Health/Human Resources for Health Units, and/or epidemic and pandemic preparedness coordination bodies, e.g., NPHIs, 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 preparedness and response, for example in disease surveillance, laboratory and diagnostics, IPC, and case management, including sub-groups on oxygen services, 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 donors, e.g., including concurrent operational planning, prioritization, and proposal development for the Pandemic Fund, the Global Health Security Agenda, or related processes.

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.

# **Acronyms**

ACT-A	Access to COVID-19 Tools - Accelerator
AAR	After-action Review
Ag RDT	Antigen rapid diagnostic tests
BSCII	Biosafety cabinet class II
C19RM	COVID-19 Response Mechanism
ССМ	Country Coordinating Mechanism
CLM	Community-led monitoring
COVID-19	Coronavirus disease 2019
COE	Challenging operating environment
DR-TB	Drug-resistant tuberculosis
EMR	Electronic medical records
EWARS	Early Warning Alert and Response System
EWS	Early Warning Surveillance
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
ICU	Intensive care unit
IDSR	Integrated Disease Surveillance and Response
IHR	International Health Regulations
IAR	Intra-action Review
IPC	Infection prevention and control
JEE	Joint External Evaluation
KP	Key population
LMIC	Low- and middle- income countries
LMIS	Logistics management information system

MDRO	Multi-drug resistance organisms
M&E	Monitoring and Evaluation
NAPHS	National Action Plan for Health Security
NDVP	National Deployment and Vaccination Plan
NPI	New Product Introduction
NSPRP	National Strategic Preparedness and Response Plan for COVID-19
O2	Medical oxygen
PCR	Polymerase chain reaction
PPM	Pooled Procurement Mechanism
PR	Principal Recipient
PSA	Pressure swing adsorption
PT	Proficiency testing
QA	Quality insurance
RCCE	Risk communication and community engagement
RSSH	Resilient and Sustainable Systems for Health
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SIMEX	Simulation exercises
SOP	Standard operating procedures
TA	Technical assistance
ТВ	Tuberculosis
тот	Training of trainers
UHC	Universal health coverage
UPS	Uninterruptible power supply
VIE	Vacuum insulated evaporator
WASH	Water, sanitation and hygiene
WHO	World Health Organization

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