Strengthening health emergency prevention, preparedness, response and resilience



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Foreword



On 5 May, 2023, I acted on the advice of the fifteenth meeting of the International Health Regulations (2005) (IHR) Emergency Committee regarding the coronavirus 2019 disease (COVID-19) pandemic, and declared that COVID-19 no longer constituted a public health emergency of international concern (PHEIC). After 3 years of the COVID-19 emergency the declaration is a welcome milestone, and it coincides with a growing sense that consensus and momentum is building behind efforts to ensure that in the wake of the COVID-19 emergency we are better able to prevent, prepare for and respond effectively to the health emergencies of the future.

Over the past 3 years, numerous expert reviews have analysed the successes and shortcomings of the global response to the COVID-19, and

the architecture for health emergency prevention, preparedness, response and resilience (HEPR) that underpinned it. After considering more than 300 recommendations, WHO is now working intensively with Member States and partners to translate these ideas into concrete and concerted action to save lives and reduce morbidity.

Expanding on my report to the World Health Assembly in May 2023, this paper provides a two-part summary of the initiatives that are now underway to strengthen the global HEPR architecture. Part I provides an overview of the Member-State driven processes to reform the governance of HEPR at the global level; new mechanisms to secure sustainable financing for health emergency preparedness and response; and introduces a new concept – the five Cs – that will guide the strengthening of the national, regional and global operational systems of HEPR. Part II provides a more detailed exploration of each of the five Cs, and the next steps that we must take to accelerate the implementation of the HEPR framework at the national level, in order to meet the pressing needs of communities affected by and at risk of health emergencies now and in the years to come.

The time has come to translate policy into action to save lives and protect the most vulnerable. The initiatives described in this paper give us the best chance to get back on track towards the Sustainable Development Goals by investing in the core national capacities and capabilities that sit at the intersection of health security, primary health care, and health promotion – capacities that can benefit everyone everywhere no matter what threats to health they may face now or in the future.

Dr Tedros Adhanom Ghebreyesus

WHO Director-General

PART I

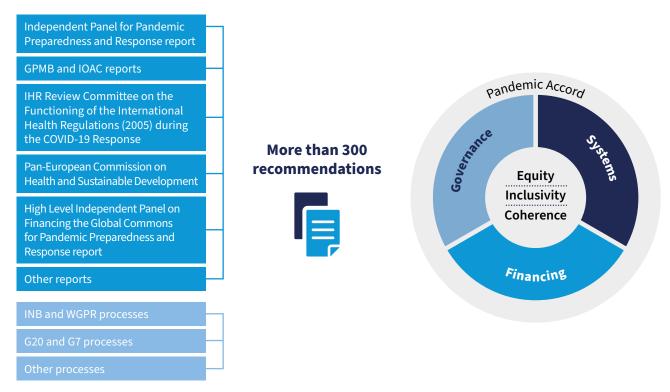
Progress and challenges

Context and purpose

The devastation caused by the pandemic of coronavirus disease (COVID-19) has brought urgency to efforts to strengthen the way countries and the world prepare for, prevent, detect and respond to health emergencies. But while it is vital for the world to seize the chance to do things differently, it is nonetheless essential that national, regional and global efforts are coordinated and coherent, reflective of a broad consensus and inclusive of participation by all stakeholders, including community stakeholders, and that all efforts have equity at their heart. During the three years that have passed since the onset of the pandemic, WHO has worked with Member States and diverse partners to provide that coherence and coordination, and to ensure that every Member State's voice is heard with a view to achieving a safer future for all (figure 1).

This work of strengthening the global architecture for health emergency preparedness, prevention, response and resilience (HEPR) has never been more important or more pressing. And although the COVID-19 pandemic has been a catalyst for action, efforts to strengthen national and global capacities for HEPR must be about more than just preparing for and preventing the next pandemic. Multiple threats to health are proliferating, compounded by systemic vulnerabilities that interact with, and reinforce, one another. There is now an urgent need for action to protect communities and strengthen national HEPR capacities to prepare for and respond to current and future health crises.

Figure 1. Reviews, reports and processes that have contributed to the framework for a strengthened global architecture for health emergency prevention, preparedness, response and resilience



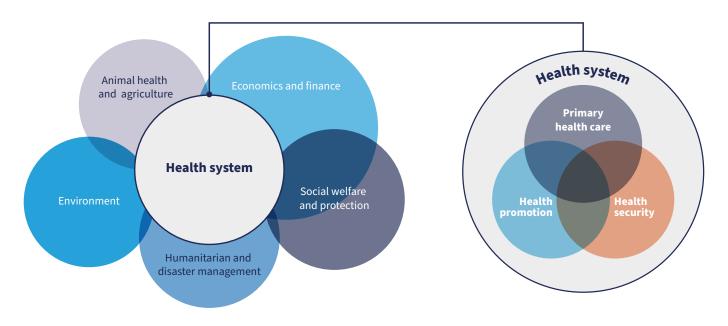
GPMB: Global Preparedness Monitoring Board; Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response; IOAC: Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme; WGPR: Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies.

The emergence and re-emergence of epidemic-prone diseases continues to accelerate; hunger and shortages of essential goods are caused by and exacerbate geopolitical conflict; ecological degradation and climate change continue to intensify; and social and economic inequalities continue to widen. This affects everyone, but those living in fragile, conflict-affected and vulnerable settings are at the highest risk. More than 339 million people living in such settings – almost 1 in 20 of the world's population –need urgent humanitarian assistance throughout 2023. This is an increase of 25% compared with 2022, and is more than double the number of 135 million people who needed humanitarian assistance in 2018.

If the threats to health are interlinked and self-reinforcing, so must be the solutions. WHO's strategic framework for HEPR can guide, inform and resource collective efforts to strengthen the key interlinked national, regional and global multisectoral capacities and capabilities that sit at the intersection of health security, primary health care and health promotion (figure 2).

Part I of this paper describes the ongoing efforts, including Member State negotiations, to strengthen HEPR, along with key challenges, under three main thematic headings: global governance, financing and HEPR systems.

Figure 2. Effective health emergency preparedness and response revolves around core capabilities at the intersection of health security, primary health care and health promotion, and their interface with other sectors



Strengthening global governance of HEPR: leadership, inclusivity and accountability

Effective governance enables governments and partners to achieve the collective goals of HEPR, galvanized by political will and with the resources to sustain positive changes. Several key initiatives are already under way to strengthen the global governance of HEPR, cognizant of the lessons of the COVID-19 pandemic and based on agreed rules and norms.

International legal instruments

At the heart of efforts to strengthen global HEPR governance are two aligned processes driven by WHO Member States. The first of these processes is the work of the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (the INB). The INB is mandated to submit its outcome for consideration by the Seventy-seventh World Health Assembly, and its work is well under way, as summarized in its progress report to the Seventy-sixth World Health Assembly.¹

In addition to the INB process, WHO Member States are also engaged in the process of considering targeted amendments to the International Health Regulations (2005), through the Working Group on Amendments to the International Health Regulations (2005) (WGIHR). The WGIHR was provided with the report of the Review Committee regarding amendments to the International Health Regulations (2005) and has started its consideration of the proposed amendments. Intersessional meetings have also been held to facilitate consideration of the proposed amendments. The INB's zero draft instrument and the proposed targeted amendments to the International Health Regulations (2005) being considered by the WGIHR address several common, cross-cutting themes, including equity, transparency, trust, sovereignty, collaboration and assistance.

Sustained political leadership

The Standing Committee on Health Emergency Prevention, Preparedness and Response, was established by the Executive Board at its 151st session in May 2022² to immediately strengthen WHOs ability to prepare for and respond to health emergencies. The Committee has two core remits: (a) in the event that a public health emergency of international concern ("PHEIC") is determined, to consider information provided by the Director-General and, as appropriate, provide guidance to the Executive Board and advice to the Director-General, through the Executive Board; and (b) to review, provide guidance and, as appropriate, make recommendations to the Executive Board regarding the strengthening and oversight of the WHO Health Emergencies Programme and for effective health emergency prevention, preparedness and response.

Proposals have been made for the establishment of a global health threats or health emergencies council, comprising Heads of State. The establishment of a global health threats council could enhance our collective capacity and accountability for systematic, sustained, inclusive and multisectoral preparedness and response. Such a council should be anchored in WHO's Constitutional mandate and the Health Assembly, thereby maintaining the vital link between empowered health ministers and Heads of State that proved itself to be a powerful platform in a number of Member States during the pandemic. Such a close alignment allowed for a more effective all-ofgovernment, whole-of-society approach, driven by the best real time health and scientific evidence. This link must remain in place if rapid, coherent, trusted, sustained and evidence-based multisectoral action is to be generated at international level.

¹ Document A76/37 Add.1.

² See decision EB151(2) (2022).

The forthcoming high-level meeting of the United Nations General Assembly on pandemic prevention, preparedness and response will provide an opportunity for Member States, through a political declaration, to affirm their commitment to a coherent, equitable and inclusive approach to strengthening national, regional and global pandemic and health emergency preparedness, prevention and response, with WHO at the centre.

Driving accountability

Several key questions identified in both the INB and the WGIHR processes to date relate to the need to balance sovereignty with the promotion of mutual accountability among the 196 States Parties to the International Health Regulations (2005), including all WHO Member States, for building and maintaining effective capacities and systems for the prevention and detection of, preparedness for and response to public health emergencies, and for adherence to relevant international rules.

In November 2020, at the request of Member States, the WHO Director-General announced the launch of the voluntary pilot phase of the Universal Health and Preparedness Review as a way of achieving that balance through a voluntary, transparent, Member State-led peer review mechanism that establishes regular high-level and multisectoral intergovernmental dialogue between Member States on their national HEPR capacities.

The piloting of the Universal Health and Preparedness Review is part of a broader ongoing effort to transition to more dynamic assessments of threats and vulnerabilities in order to drive action, as capacity assessments evolve to put greater emphasis on functional capacities and outcomes. Collective health security also depends on the tailoring of these approaches for application in areas that are characterized by a reduced presence of the State, or which are under the control of local de facto authorities, as is often the case in humanitarian and conflict-affected settings.

Independent monitoring of the state of global preparedness for health emergencies should continue to complement national-level self-assessment and peer review, with strengthened roles for existing monitoring mechanisms, such as the Global Preparedness Monitoring Board and the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme.

Sustainable, coordinated and innovative financing for HEPR

Financing effective national, regional and global health emergency preparedness alone will require approximately US\$ 30 billion per year, with a gap of US\$ 10 billion per year, according to WHO–World Bank analyses. But effective financing for HEPR not only depends on making more funds available – it also requires more effective mechanisms to ensure that funds are allocated rapidly, scaled appropriately and targeted to fill critical gaps. Such effective financing is crucial for reducing risks, not only to health but also to economic and financial stability.

Rapid progress on financing over the past two years is now bearing fruit, with the launch of the Pandemic Fund and deliberations as part of the G20 joint health and finance track beginning to forge consensus on the scale of needs and potential mechanisms to administer surge financing for large-scale pandemic and health emergency response.

The Pandemic Fund: catalytic financing to transform national HEPR capacities

The launch of the Pandemic Fund in November 2022 promises to be a transformative moment in the effort to strengthen national HEPR capacities. The Fund has already secured more than US\$ 1.6 billion in donations to strengthen HEPR in low-income and middle-income countries, and has moved rapidly to constitute its Governing Board and Technical Advisory Panel.

In early 2023, the Fund issued its first call for expressions of interest. After receiving an overwhelming response (more than 650 expressions of interest at a value of more than US\$ 6 billion), the Fund opened its first call for proposals on 3 March, which closed on 19 May 2023. WHO and partners have provided intensive support for eligible countries, regional entities and implementing entities to develop full proposals for potential projects to be supported by the initial tranche of funding. WHO, in collaboration with the World Bank, the United Nations Children's Fund, the Food and Agriculture Organization of the United Nations, the Global Fund and Gavi, the Vaccine Alliance, held a series of webinars starting in March 2023 to outline the tools and approaches countries can take to develop Pandemic Fund proposals as part of broader national plans to strengthen HEPR. The initial funding window

of US\$ 300 million will provide catalytic funding for HEPR investments that will operate alongside and be coordinated with funding from other international and domestic sources.

Expanding surge financing to save lives during health emergencies

As part of its work to understand, monitor and mitigate pandemic risks to global economic stability and growth, the G20 Joint Finance and Health Task Force has adopted a multiyear rolling agenda up to 2025. Delivering on the mandate of the G20 Rome Leaders' Declaration, in 2023 the Task Force will continue developing coordination arrangements between finance and health ministries, and will share best practices and experiences from previous finance-health coordination to develop joint responses to pandemics, as appropriate. To ensure that the voices of low-income and middle-income countries are heard and considered, the G20 Task Force members extended invitations to regional economic and political organizations. The Task Force has collaborated with the World Bank, International Monetary Fund and the European Investment Bank to better understand economic risks and vulnerabilities from pandemics and how to mitigate them.

There remains a fundamental mismatch between the scale and speed at which funds are required to finance large-scale operations and ensure access to medical countermeasures during global and regional health emergencies, and the scope of current financing mechanisms. Mechanisms that were able to release money quickly during the COVID-19 crisis were unable to do so at sufficient scale. Other mechanisms that were able to call on a greater magnitude of funding were unable to move with the required speed or to direct funding through the most effective channels.

Clearly a new approach is needed to rapidly mobilize and coordinate sufficient large-scale financing for an international response in the event of a pandemic or other global health emergency, complementary to the Pandemic Fund's focus on investments in national HEPR capacities. As part of its work for the G20 Joint Finance and Health Task Force, WHO reviewed experiences from the COVID-19, H1N1 and other outbreaks, and found that in order for outbreak containment and control measures to be effective, substantial surge response financing is needed within the first one to six months of the onset of a pandemic or potential pandemic. Using the magnitude of financing that was channelled through international implementing agencies in response to the COVID-19 pandemic as a benchmark, it was estimated that this minimum financing requirement would be of the order of US \$ 30 billion.

WHO will continue to work with Member States and other stakeholders, especially the World Bank and other partners, including through the G20 Joint Finance and Health Task Force, to advance discussions around a number of key areas, including the need for an agreed approach to accelerate and coordinate existing funding streams for the greatest possible impact; strategies for accessing and channelling other potential funding sources and new mechanisms to complement existing financing; and how to integrate pathfinding work on surge financing with other ongoing work, including through relevant G20 working groups, on the design of a new coordination platform for access to medical countermeasures, which comprise a significant proportion of estimated surge financing costs (see also the five core HEPR systems described below).

Strengthening HEPR systems

Realizing the world's potential, and rising to the challenges of the future, means investing in collaboration, coordination and strengthened multi-sectoral capacities at the intersection of health security, primary health care, and health promotion.

The frequency, scale and complexity of health emergencies continues to increase year on year, driven by many of the same long-term trends that continue to accelerate the emergence and re-emergence of epidemic-prone diseases: geopolitical conflict; the collapse of trade leading to famine and shortages of essential goods; the intensification of ecological degradation and climate change; weakened health systems; and widening health, economic and social inequalities. The evidence of the past few decades tells us that these trends are increasingly interacting – in complex and unpredictable ways – to drive health emergencies. Sustainable solutions and the attainment of the health-related sustainable development goals will depend on giving more weight to proactive preventive, readiness and resilience-building measures even as we respond to ongoing crises.

To respond effectively to the ever-increasing scale of health emergencies, particularly in fragile, conflict-affected and vulnerable settings, countries and health emergency stakeholders must adopt a strategic shift towards an ecosystem approach to health emergencies prevention, preparedness and response. This shift should focus on strengthening five (figure 3) core health emergency components:

- collaborative surveillance;
- community protection;
- safe and scalable care;
- access to countermeasures; and
- emergency coordination.

These five interlinked systems described above, which encompass and complement all the core capacities required by the International Health Regulations (2005), are explicitly multi-stakeholder and whole-of-government systems and extend into every area of HEPR. The five Cs are explicitly aligned with the One Health approach that underpins zoonotic disease prevention and response strategies, with multidisciplinary and intersectoral efforts focusing on the understanding and investigation of the multiple drivers, patterns and dynamics that lead to the emergence and re-emergence of zoonotic diseases. But as the five Cs extend to all hazards to health, they apply the same coordinated, multifactorial One Health approach to health emergencies more broadly.

Part 2 of this document sets out a framework comprising the vision, objectives, capabilities and subcapabilities necessary for the effective and sustainable implementation of each of the five Cs at the national level, supported where appropriate by regional and global capacities.

Figure 3. The five Cs of health emergency prevention, preparedeness, response and resilience





Strengthened workforce capacity for health emergencies

Strengthening health emergency preparedness, readiness, and resilience

Health emergency alert and response coordination



Collaborative surveillance

Strong national integrated disease, threat, and vulnerability surveillance

Effective diagnostics and **laboratory** capacity for pathogen and genomic surveillance

Collaborative approaches for event detection, risk assessment, and response monitoring



Community protection

Community engagement, risk communication and infodemic management

Population and environmental **public health** interventions

Multisectoral action for **social and economic** protection



Safe and scalable care

Scalable clinical care during emergencies

Protection of health workers and patients

Maintenance of essential health services





Fast tracked **R&D**

Scalable manufacturing platforms

Coordinated **supply chains** & emergency distribution

PART 2

The five Cs of health emergency prevention, preparedness, response, and resilience

Part II of this paper outlines the scope and ambition of each of the five Cs, and proposes an ambitious set of capabilities required for their effective implementation at national, regional and global levels. However, the starting points will differ for each country. The steps countries will need to take to develop these capabilities will vary, and require targeted and tailored investments and technical support to adapt, prioritize, and resource capabilities.

Each of the five Cs is structured in a similar way, with three key objectives that can be achieved through the development of a number of core capabilities and sub-capabilities.

Collaborative surveillance

Collaborative surveillance is the systematic strengthening of capacity and collaboration among diverse stakeholders, both within and beyond the health sector, with the ultimate goal of enhancing public health intelligence and improving evidence for decision-making.

This concept builds upon the foundations of robust public health surveillance, health service monitoring, and laboratory surveillance, drawing insights from other data sources and applying advanced data and analytical approaches to enable the generation of contextualized intelligence. Collaborative surveillance emphasizes collaboration itself as a key capability – building intentional collaboration across four key dimensions.

- Disease and threat surveillance systems: Enabling a comprehensive understanding of the epidemiological situation across systems for monitoring hazards, threats, and vulnerabilities, with the ability to mobilize disease and threat-specific capabilities to respond to emerging events.
- Sectors: Building multisectoral contextual understanding and operationalizing collaboration across sectors, organizations, fields of expertise, and disciplines.
- Emergency cycles: Addressing both routine monitoring and emergency surveillance objectives throughout the cycle of prevention, preparedness, response, and recovery.
- Geographic levels: Ensuring local capacities to respond to local events and the flow of relevant data, information and intelligence across subnational, national, cross-border, regional, and global administrative levels.

Nurturing an effective system of collaborative surveillance will involve working collectively towards three critical objectives:

- 1.1. strong national integrated disease, threat, and vulnerability surveillance
- 1.2 effective diagnostics and laboratory capacity for pathogen and genomic surveillance
- 1.3 collaborative approaches for event detection, risk assessment, and response monitoring.

While the first two objectives address capacity development and collaboration across core public health surveillance sources, the third seeks to maximize the application of these and other sources through innovative and multidisciplinary capabilities and public health intelligence processes, which collectively generate actionable insights.

Each of the three key objectives for collaborative surveillance, along with the critical capabilities required to achieve them, are described below.

1.1 Strong national integrated disease, threat, and vulnerability surveillance

Strong capabilities are required for public health surveillance in tandem with the monitoring of health service capacity, access, and usage. Data derived from these capabilities should be systematically integrated with contextual insights, including insights on risk and vulnerability, derived from other diverse sources of data. Thus, achieving the objective of strong national integrated disease, threat, and vulnerability surveillance hinges on four key capabilities:

1.1.1 Strong public health surveillance

Informed decision-making for action first requires timely and appropriate routine public health surveillance, including analytical and communications capacities, founded on three sub-capabilities:

- Timely and appropriate routine public health surveillance capacity
- Integration of routine surveillance capacities across disease and threat-specific verticals, and interconnection with response mechanisms, including flexibility to respond to early warning signals with enhanced surveillance capabilities and surge during emergency
- Limitations in routine surveillance capacity understood and corrected where possible, and contingency tools prepositioned to fill anticipated gaps

1.1.2 Health service capacity, access, and usage monitoring

In addition to primary routine monitoring, facility management and service provision objectives, health service monitoring complements public health surveillance for emergency preparedness and response by providing a dynamic picture of the resilience of health systems, founded on two sub-capabilities:

- Regular monitoring and reporting of key metrics on health service capacities, access, and usage to provide a dynamic picture of contemporary and projected system resilience
- Health service monitoring capacities interconnected with response mechanisms, with the necessary flexibility to surge

and adapt surveillance to all types of emergencies, including capacity to rapidly assess impacts of major disasters

1.1.3 Contextual, community, and One Health insights

Advanced public health practice requires the use of multiple surveillance systems and other health and non-health data sources to comprehensively assess and understand risk, founded on two sub-capabilities:

- Continuous exchange of information between One Health partners, enabling joint risk assessments and response for high-risk situations
- Multisectoral understanding of vulnerabilities demographic, environmental, social and economic drivers of health risks, based on local contexts – established and applied towards both the design of surveillance (e.g., prioritization of risks and vulnerable populations) and interpretation of surveillance findings

1.1.4 Collaboration: governance, innovation, and integration

Surveillance approaches must be coordinated to meet the full range of routine surveillance and emergencyrelated objectives and be designed for flexibility to address shifting needs, founded on three subcapabilities.

- Surveillance approaches selected and coordinated to collectively meet the full range of objectives for locally prioritized risks, with flexibility to address shifting emergency needs
- Systematic routine evaluations of the constellation ("Mosaic")
 of surveillance systems, with lessons shared to inform strategic
 investments in capacity strengthening, based on evidence of
 surveillance best practices, including context-specific cost-benefit
 analyses
- Digitization of surveillance data and processes from the point of data collection, to promote integration, interoperability, and flexibility

1.2 Effective diagnostics and laboratory capacity for pathogen and genomic surveillance

With increased diagnostic and laboratory capacity, collaborative surveillance aims for the early detection and verification of signals to provide insights at all levels while limiting biorisks. This means developing decentralized testing capabilities at or near the point of care, better equipping laboratory systems, ensuring timely sharing of data and biological material across networks, and promoting sound biosafety and biosecurity practices

1.2.1 Decentralized testing capabilities at or near the point of care

Access to diagnostics and laboratory services is often limited at the peripheral level, particularly for hard-to-reach areas and populations. To leverage decentralized testing opportunities, national distribution plans for point-of-care diagnostics should be developed and aligned with public health surveillance and clinical care strategies and guidelines, with clearly outlined responsibilities at each appropriate subnational level. The capability comprises four sub-capabilities:

- National distribution plans for point-of-care diagnostics developed and aligned with public health surveillance and clinical care strategies and guidelines, with clearly outlined responsibilities at each appropriate subnational level
- Routinely updated and validated central register of public and private diagnostic capacity, and a stock management system linked to replenishment mechanisms
- Quality management systems for point-of-care testing
- Integration of point-of-care diagnostic results into national surveillance systems for priority diseases

1.2.2 Expanded laboratory capacity and collaboration, including genomics

Robust diagnostics and laboratory capacity must be established and maintained, with the ability to surge to respond to emergencies, leveraging all sectors as part of

a One Health approach. The capability comprises four sub-capabilities.

- Sufficient, fit-for-purpose laboratory capacity with the ability to surge, leveraging all sectors across One Health dimensions
- Quality management systems for laboratory testing
- Access to genomic and phenotypic characterization of pathogens, either in-country or abroad, with findings integrated into surveillance and risk assessment activities
- Innovation and research ecosystem that responds to local, national, and global needs for affordable, scalable technologies which laboratory systems sustainably implement as contextually appropriate

1.2.3 Risk-based biosafety and biosecurity practices to manage biorisks

Ensuring biosafety and biosecurity begins with agreed pathogen-control measures, including standards for inventory, containment, equipment operation and maintenance, personal protective equipment, operational handling, and proper management of high-consequence research. The capability comprises four sub-capabilities.

- Agreed pathogen control measures, including standards for inventory, containment, equipment operation and maintenance, operational handling, and proper management of high consequence research
- Implementation and observance of guidelines and protocols, underpinned by workforce competencies and governance
- Risk-based biosafety guidelines, standards, and regulation for safe and secure national and global specimen, reagent, pathogen, material, and genetic sequence data sharing
- Rigorous incident reporting, response and monitoring in activities involving high-consequence pathogens, both inside and outside safe and secure facilities

1.2.4 Integrated laboratory networks, including data and sample sharing

Tiered national laboratory and diagnostics networks, connected to networks of international partners, must be established to generate, report, and share high-quality data from subnational facilities to public health and reference laboratories. The capability comprises four sub-capabilities:

- Tiered national laboratory and diagnostics networks established to generate, report, and share data from subnational facilities to high-quality public health and reference laboratories, connected to networks of international partners
- National and international systems for access and benefit sharing of biological materials, supported by rapid transportation capacity

1.3 Collaborative approaches to event detection, risk assessment, and response monitoring

Collaboration requires mechanisms that draw upon the key surveillance dimensions to generate actionable intelligence for decision-makers. These surveillance mechanisms are powered by innovative and multidisciplinary capabilities at national and subnational levels to forecast, detect, and assess risks and monitor risk-informed response actions. By understanding risks and potential health consequences, countries can apply evidence to inform their plans and prioritize key actions to prepare for emergencies, scale up anticipatory actions, and mitigate the impacts of events. The capabilities required to enable this collaborative approach include:

1.3.1 Scalable architecture for integration

Integration and collaboration will benefit from establishing modern infrastructure across national public health delivery bodies (e.g., national surveillance hubs managed by national public health agencies or equivalent entities) and in other sectors. The capability comprises four sub-capabilities:

- Integrated modern infrastructure across national public health delivery bodies
- Scalable, distributed, and evolving technical interfaces for secure data linkage, integration, and intelligence sharing between systems
- Established norms and standards on data quality routinely applied with clearly derived benefits
- Developed focal points (nodes) for intelligence sharing between multisectoral partners to triangulate findings from different data sources as emergencies unfold

1.3.2 Tools for data collection, analysis, and sharing

A global collaborative agenda should be established to continuously inform the development of data collection, management, analysis and modelling tools based upon national and local needs. The capability comprises three sub-capabilities:

- A global collaborative agenda to continuously inform the development of data collection, management, analysis, and modelling tools based upon national and local needs
- A global 'marketplace' of tools available to countries and adaptable to various contexts
- Technical support for countries to build, customize or adapt, and use advanced analytical tools

1.3.3 Information and data visualization for interpretation

Robust risk assessment for decision-making requires strong and well-sourced analytical capacities, which must integrate contextual insights from statistical analyses and modelling. Intelligence generated, including community and behavioural insights, should be shared and fed back through appropriate mechanisms. The capability comprises four sub-capabilities:

- Analytics capacity, integrating contextual understanding and insights from modelling for strengthened risk assessment, with resources and intelligence shared and feedback mechanisms
- Real-time interfaces and dashboards, incorporating insights drawn from collaboration, leveraged for decision making
- Access for policy makers and public to multisectoral data sources, tailored to target audiences and the national or local context, to generate actionable insights
- Open communication with surveillance outputs routinely published, complemented by mechanisms established to leverage intelligence for mutual benefit and coordinated action

1.3.4 Networks for enhanced information sharing and collaboration

National networks across partners, sectors, organizations, and fields of expertise are needed to build relationships and establish protocols for enabling secure access to data; sharing information,

intelligence, and capacities in a timely manner; and leveraging synergies. The capability comprises two subcapabilities:

- National network across sectors, organizations, and fields of expertise to build strong relationships, establish necessary protocols to share data, information, intelligence and capacities in a timely manner, and leverage synergies
- Regional and global platforms to define longer-term objectives and a shared agenda for global surveillance networks, supporting knowledge exchange, and building trust within the community

Community protection

In the context of HEPR, Community Protection refers to community-centred actions that protect the health and wellbeing of those affected, such as vaccination to protect from an infectious disease. Community-centred approaches can be seen as (i) "bottom up" i.e., those that arise through community-led action, including through advocacy, activism, and volunteering, (ii) "top-down" i.e. those led by governments or response actors, or (iii) "intermediary" i.e., those by organisations or institutions to interpret top-down strategies while being responsive to the communities they serve. "Top-down" strategies can be community-centred when they are informed by and responsive to community feedback and input regarding their design, implementation, and evaluation.

Health emergencies begin and end in communities. Any effective health emergency response must have communities and their interests at its heart; therefore, communities must be at the centre of efforts to prepare for, prevent and respond to health emergencies. Whether we are talking about population-based interventions such as vaccination or emergency nutrition, or environmental interventions such as vector control and WASH (Water, Sanitation and Hygiene) measures, to be most effective these interventions must be co-created with affected communities and, crucially, combined with multisectoral actions at local, national and global levels that ensure that health protection is indivisible from the protection of social and economic welfare, mental health, livelihoods, food security and dignity.

Effective community protection hinges on the achievement of three objectives:

- 2.1 Community engagement, risk communication and infodemic management to guide priority actions and strengthen community resilience
- 2.2 Population and environmental public health interventions
- 2.3 Multisectoral action to respond to community concerns and ensure community welfare

2.1 Community engagement, risk communication and infodemic management to guide priority actions and strengthen community resilience

Ensuring that communities are listened to, provided with the right information at the right time, and are involved in the development of multisectoral protection plans is critical to build the resilience of communities to health emergencies. Four capabilities are crucial for achieving this objective:

2.1.1 Listening to and understanding communities, and synthesizing insights

Effective community engagement, data utilization, and inclusion drives effective strategies and decision-making for preparedness and response efforts, and depends on three sub-capbilities:

- Establishment of listening channels and development and delivery of strategies and activities
- Validation and analysis of data to derive insights, and to systematically share data and feedback with communities
- Integration of data and insights from communities into strategic response planning processes and real-time decision-making during preparedness planning and response coordination

2.1.2 Risk communication and community engagement

Community resilience can be enhanced by involving communities in the design of activities and messaging, employing evidence-based communication strategies, and empowering communities with the tools and knowledge to combat misinformation and enhance health literacy. Effective risk communication and comunity engagement requires the following three subcapabilities:

- Engagement with and involvement of communities to codesign activities, advice, and messaging
- Communication of risk and distilling science, through coordinated and evidence-based multi-channel communication with affected populations and through trusted channels and tailored messages

 Tools and trainings to build health literacy and resilience to mis/disinformation including risk communication platforms and infodemic management systems

2.1.3 Community capacities, services and coordination

Empowered communities, enhanced coordination, and strengthened health emergency management can be achieved through the development of the following five sub-capabilities:

- Development of capacities for community health emergency risk management, including community risk assessment, vulnerability and capacity mapping, risk management, emergency planning, and simulations
- Community-driven detection, warning, surveillance, and response, and essential community health services, integrated with primary health care
- Strengthening the community health workforce and other key community workforces (incl. social, educational, media) and their connections to local leaders
- Development and update of a community-driven and owned research agenda to gather insights through participatory approaches
- Identification and integration of best practice community engagement into governance, coordination, and partnership with relevant sectors, CSOs, and at and between all jurisdictional levels

2.1.4 Multisectoral community engagement

We can understand and minimise the negative consequences of response measures, promote adherence to and participation in public health interventions, and ensure effective collaboration during health emergencies through the development of the following three sub-capabilities:

- Development of plans, including business continuity plans, through multisectoral engagement to address anticipated potential negative health, economic and social consequences of response measures
- Systematic approach to acceptance, adherence, and trust, with impacts tracked and insights fed into decision-making
- Maintenance of cross-sectoral decision-making and coordination mechanisms, supported by health literacy programmes and decision-making tools

2.2 Population and environmental public health interventions

Increasing the acceptance and uptake of interventions is decisive in determining whether an intervention succeeds or fails to protect health and wellbeing, so the co-creation with communities of services, planning, design and delivery of interventions is crucial. Capabilities for key interventions include:

2.2.1 Prevent, detect and contain zoonotic spillover

Understanding risk pathways, raising awareness, implementing targeted interventions, and establishing effective coordination mechanisms in a One Health context are essential to protect public health, and can be achieved through the development of the following three sub-capabilities:

- Understanding of risk pathways and raising awareness
- Identification, co-design and implementation of targeted interventions including food safety, animal health, and environment interventions to manage risks
- Development and maintenance of effective One Health coordination mechanisms across sectors, including monitoring and evaluation to track improvements

2.2.2 Vector control

To effectively combat vector-borne diseases, it is crucial to develop the following three sub-capabilities to leverage local knowledge and data, mobilize communities, and review and evaluate vector-control efforts.

- Harnessing of local knowledge and data to actively inform planning, design, development, and scaling of vector control tools and interventions
- Mobilisation and supporting communities to develop and implement local vector control interventions
- Continuous review, lessons learned, and monitoring and evaluation of interventions

2.2.3 Community access to water, sanitation, and hygiene

Improved access to safe water, sanitation, and hygiene facilities leads to better health outcomes and can be achieved by developing the following three subcapabilities:

- Planning of community WASH interventions together with communities according to guidelines, best practice, available tools, and adapted to local context
- Implementation of basic community WASH and safely managed services, including provision of safe drinking water, toilets and hygiene facilities, and hygiene promotion training
- Monitoring and evaluation of community WASH services, through development of standards, provision of monitoring training, and gathering of feedback

2.2.4 Public health and social measures

Public health risks can be effectively managed through the development and application of the following three sub-capabilities:

- Acceleration of an evidence-informed approach to public health and social measures
- Promotion of safe travel and trade, through routine and emergency capacities at points of entry and in border communities
- Strengthening routine preparedness, readiness and response and scaling up of capacities for gatherings and for hosting and attending communities, and the implementation of a riskbased approach for gatherings

2.2.5 Vaccination

The effective and equitable use of vaccines has ultimately been central to the control of infectious diseases throughout history, and new technologies suggest an even more crucial role in the future. The effective deployment of vaccines in emergency contexts depends on the development of evidence-based policy development, inclusive planning and coordination, community engagement, microplanning, effective targetting of and access to populations in fragile, conflict-affected and vulnerable settings, and robust and rigorous monitoring and evaluation, broken down into the following six sub-capabilities:

• Development of evidence driven policy for vaccine prioritization, target population, product choice, schedules

- and delivery
- Establish inclusive vaccine delvery, planning, and coordination mechanism
- Engagement of communities, and all level political leadership to support vaccine implementation and promote vaccine equity
- Establish subnational microplanning and plan for vaccines to be co-delivered with other health services
- Plan and implement vaccination of vulnerable populations in humanitarian settings in collaboration with humanitarian actors
- Monitor and evaluate vaccine rollout

2.3 Multisectoral action for social and economic protection

Effective public health interventions often entail disruptions to the normal social, educational and economic life of individuals and communities.

Minimizing the impacts of these disruptions is central to ensuring the success of public health interventions, and the economic, social and mental wellbeing of individuals and communities. Five key multisectoral capabilities are required to ensure social and economic protection for communities:

2.3.1 Strengthening social welfare and protection

Essential health services must be provided, and health systems maintained and strengthened before, during and after emergencies. Achieving this ambition depends on the development of three capabilities:

- Development of social protection policies to address health, economic and social impacts, based on regular risk and vulnerability assessments
- Delivery of goods and services for social welfare and protection, including procurement systems pre-response and delivering essential goods and services to communities
- Development and maintenance of infrastructure to implement social protection policies and deliver essential goods and services

2.3.2 Protection of livelihoods and business continuity

Effectively addressing the health, economic, and social impacts of health emergencies means planning and delivering the necessary support and assistance to affected populations, and depends on the development of three sub-capabilities:

- Legislation and social standards to encourage formal employment, reduce precariousness, facilitate flexible work, and accountability of governments, businesses, and other organisations
- Creation, management and allocating of funds to support affected communities and communities at-risk of being most affected by health emergencies
- Physical and digital infrastructure to ensure business continuity and livelihoods through provision of financial support

2.3.3 Continuity of education and learning

Inclusive and effective learning opportunities for all individuals can be maintained during health emergencies through the development and application of the following three sub-capabilities:

- Development and implementation of relevant curriculum and evaluation tools to ensure quality education for children, adolescents, and adults
- Policies and services to provide education-based social support and food security for children
- Development and maintenance of infrastructure for remote, hybrid, and in-person learning

2.3.4 Ensuring food security

Food security is a right, and enhancing the resilience of food production and distribution systems to cope with health emergencies can be achieved through the development and application of the following three sub-capabilities:

- Establishment of systems to procure and distribute food, nutrition, and raw materials for food production during health emergencies
- Development and implementation of policies for responsible stockpiling, assurance of rights for workers, and regulation of trade and tariffs

• Development and maintenance of infrastructure to ensure resilient food production systems that provide sufficient quantities to meet local demand

2.3.5 Addressing indirect health and mental health impacts

Enhancing and protecting community health and mental well-being before and during emergencies can be achieved through the development and application of the following two sub-capabilities:

- Design of mechanism to scale community health and mental health services pre-response, established procurement systems, and providing health and mental health services
- Development and maintenance of physical and digital infrastructure pre-response for providing community health and mental health services

Safe and scalable care

An effective global architecture for HEPR must be built on health systems that are prepared and ready to respond rapidly to emergencies, and to ensure communities have access to high-quality health services in safe and functional settings during and after emergencies. As COVID-19 and other health emergencies have shown, such resilient health systems are based on strong primary health care, and have the resources and capacity to re-organize and deploy existing resources in response to increased demands imposed by health emergencies with agility and flexibility, while maintaining essential health services and protecting and supporting health workers and patients. Resilient health systems should promote equitable access to care and mitigate financial, contextual, and cultural barriers.

Safe and scalable care must be equitable, inclusive, and deliver three key objectives:

- 3.1 Scalable clinical care during emergencies
- 3.2 Protection of health workers and patients
- 3.3 Maintenance of essential health services

3.1 Scalable clinical care during emergencies

When health emergencies hit, health systems must have the plans, people, and infrastructure to scale up to meet the sudden surge in clinical need. Meeting this need for scalable clinical care depends on four key capabilities.:

3.1.1 Scalable clinical care pathways

Defined clinical pathways based on dynamic risk and vulnerability analyses are key to appropriate and quality clinical care during health emergencies, and require the following five sub-capabilities.

- Allocation of resources for clinical surge, supported by hazardspecific contingency plans and capacity assessments
- Development of functional and adaptable clinical care pathways spanning the end-to-end patient journey that can be adapted to specific hazards, patient populations and care settings
- Integration of clinical research and care innovation into clinical surge mechanisms and pathways through development of data infrastructure platforms and governance mechanisms
- Monitoring, evaluation and improvement of clinical pathways and operations using quality performance indicators
- Supporting post-response transition and recovery of clinical services and pathways through risk and vulnerability assessments, prioritization of key services and engagement of multisectoral stakeholders

3.1.2 Scalable infrastructure for safe clinical surge

Safe, accessible, resilient and sustainable infrastructure and health facilities that are adaptable to health emergencies and flexible to meet changing demands during health emergencies, can be ensured through the development and application of the following five subcapabilities.

- Development of quality standards for health facilities and infrastructure, including for specific requirements for prioritized hazards
- Allocation of resources for the reinforcement of existing infrastructure based on assessment of vulnerability, safety and resilience against defined standards

- Development and reinforcement of resilient critical services (including shelter, water, food, electricity, medical oxygen, and information and communication technology) for the delivery of safe and quality clinical surge through cross-sectoral coordination and collaboration with relevant sectors and the use of sustainable technologies where appropriate
- Identification and prepositioning of key clinical surge sites, services and systems for response to prioritized hazards
- Review and improvement of infrastructure for surge based on monitoring and evaluation, lessons learnt and after-action reviews

3.1.3 Stockpiles and supply chain for clinical care during emergencies

An uninterrupted supply of required medicines and supplies, rapidly distributed to affected patients, health workers and facilities, is essential for effective health emergency response, and can be ensured through the development and application of the following four subcapabilities:

- Definition of a list of essential medicines, supplies and prioritized investigational products for priority hazards
- Forecasting and mapping of needs for essential medicines and supplies through established inventory management and control systems at facility level based on capacity assessments
- Optimization of supply chain and responsive stockpile management processes to ensure equitable access to essential medicines and supplies, including processes for replenishing supplies post-response
- Ensuring safe and equitable deployment of investigational products through development of protocols and appropriate workforce training

3.2 Protection of health workers and patients

Within health facilities, infection, prevention and control (IPC), water, sanitation and hygiene (WASH) services and other measures for the protection of patients and health workers are essential during and between health emergencies.

3.2.1 Water, sanitation, and hygiene (WASH) services in health facilities

Water, sanitation, and hygiene (WASH), including waste management, and engineering controls such as ventilation are essential to minimize the risk that health facilities amplify outbreaks, and ensure safety, and require the development of the following subcapabilities:

- Development of systems, plans and protocols for WASH and waste management, including the procurement, management and handling of supplies, and treatment of waste
- Development of indicators and tools for regular assessment of WASH systems and engineering controls
- Maintenance (including reinforcement where appropriate)
 of critical infrastructure, engineering controls, supplies and
 equipment in health facilities to ensure access to safe water,
 safe movement and processing of clinical waste and storage
 of required equipment
- Provision of training to health workforce and key personnel in WASH practice and processes, and in the maintenance and handling equipment

3.2.2 Infection Prevention and Control (IPC) in the context of Health Emergencies

Infection prevention and control (IPC) is essential during all stages of preparedness, readiness and response to epidemic and pandemic events caused by infectious diseases to minimize the risk of health and care facilities amplifying community outbreaks, as well as to ensure protection for both health workers and patients. Effective IPC for health emergencies depends on the development of the following five sub-capabilities:

• Development of evidence-based standards, guidance and

protocols for IPC and occupational safety and health (OSH)-related practices, including for individual and site-level risk assessments, and the safe reception, movement and care of patients in isolation

- Implementation of alternative service models such as telemedicine to minimize risk of spread and support containment efforts
- Development of capacities of health workers to perform continuous risk assessments, ensure appropriate flow of patient care, and detect and report health care associated infections through development of competency standards and creation of appropriate training modules
- Development of responsive stockpiling processes to ensure adequate supply of PPE and IPC equipment
- Tools for monitoring adherence to IPC processes and detection and reporting of healthcare-associated infections

3.2.3 Patient and workforce safety during health emergencies

In the context of health emergencies, patient and workforce safety is the absence of preventable harm to a patient or health worker and reduction of risk of unnecessary harm associated with patient care to an acceptable minimum. Addressing safety gaps in the health care system is critical to ensuring patient and workforce safety for effective preparedness, readiness and response to health emergencies. This entails implementing interventions that consistently and sustainably lower risk, reduce the occurrence of avoidable harm, make error less likely and reduce the impact of harm when it does occur. Patient and workforce safety in the context of health emergencies depends on the following five sub-capabilities:

- Development of legislation and policies to ensure patient and workforce safety, outlining hazard-specific minimum standards and best practice in assessment, infrastructure planning and service design
- Reinforcement of health facilities to ensure safety and security of patients and staff based on risk and vulnerability assessments and defined safety standards
- Development of protocols, tools and systems for risk assessment identification, reporting, and investigation of patient and staff safety events and incidents that are integrated into clinical pathways and existing data infrastructure
- Capacity building of the health workforce and relevant personnel in protecting patient and staff safety through dedicated training, defined competencies, knowledge sharing and regular

- communications to health services
- Integration of patient and staff safety policies and standards into existing governance mechanisms, including through dedicated roles for safety officers

3.3 Maintain essential health services

Essential health services must be provided, and health systems maintained and strengthened before, during and after emergencies. Achieving this ambition depends on the development of three capabilities:

- Assessment of essential health service needs, capacities and gaps
- Adaptation and augmentation of resources to deliver essential health services
- Resilient infrastructure and workforce for health service delivery

3.3.1 Assessment of essential health service needs, capacities and gaps

Countries may need to make difficult decisions to balance the demands of responding directly to a health emergency, while simultaneously engaging in strategic planning and coordinated action to maintain essential health service delivery. Success requires a comprehensive approach to community, primary and secondary levels of care, and requires particular attention to the linkages across these levels. Essential health services are country-specific and context-specific, and high-priority categories include those where limited-term disruptions have substantial health impact. Effective assessment of essential health service needs depends on the development of three sub-capabilities:

- Identification and mapping of essential health service needs, capacities and gaps
- Design and optimisation of service delivery plan to remove barriers to access and to establish safe and efficient patient flow
- Mapping and identification of resource requirements to deliver essential health services

3.3.2 Adaptation and augmentation of resources to deliver essential health services

Dynamic monitoring of the availability, accessibility and utilization of essential health services during emergencies is critical for effective decision-making across all phases of a crisis. This includes adaptation of available resources and mobilization of additional requirements tailored to the health emergency. This should be followed by strategies for adapting and maintaining systematic and standardized data collection during emergencies that should be integrated with and build on routine monitoring approaches. Systems should be in place to ensure that monitoring approaches are appropriate and data available to support timely decision-making. The following three sub-capabilities are required:

- Mobilization of additional appropriate technical and operational resources
- Implementation of alternative service delivery models
- Improvement and adaptation of service delivery through monitoring and evaluation, intra- and after action reviews, and lessons learned

3.3.3 Resilient infrastructure and workforce for health service delivery

Health systems should be well prepared for health emergencies, be able to adapt to evolving conditions during an emergency and leverage response efforts for sustained health system improvements as health emergencies subside. Some adaptations in service delivery may be reversed, some continued for a limited time, and others that are found to be safe and beneficial, incorporated into routine practice. The following three sub-capabilities are required:

- Develop Essential Health Service continuity plans at health facility level, informed by risk and vulnerability analyses
- Foster health workforce resilience through training, standard operating procedures, and support structures for workforce health and wellbeing
- Harden health facilities and critical health infrastructure to increase resilience, informed by risk and vulnerability assessments

Access to countermeasures

Testing, treating and protecting communities during health emergencies depends on timely, sufficient and equitable access to medical countermeasures, such as diagnostics, therapeutics, vaccines, medical devices and medical equipment.

The medical countermeasures ecosystem is diverse, encompassing a broad and complex network of potential collaborations that span distinct functional areas (such as research and development, manufacturing and procurement), geographical regions and phases across the health emergency cycle. Harnessing and aligning the collective capabilities of these various actors in a coordinated manner is critical in order to better prepare for and respond to future health emergencies, and it necessitates the creation of a medical countermeasures coordination platform to support coordination efforts across different stakeholders. Global health stakeholders should focus efforts on achieving three key objectives to increase access to countermeasures:

- 4.1 fast-track research and development;
- 4.2 scalable manufacturing; and
- 4.3 end-to-end health emergency supply chains.

Access to countermeasures should be part of an integrated system for health emergency preparedness and response, with strong links to collaborative surveillance; safe and scalable clinical care; community protection; and emergency coordination.

Due the urgent need for an interim coordination platform for countermeasures, and pending the conclusions of the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response and the Working Group on Amendments to the International Health Regulations (2005), WHO is convening partners and connecting key countermeasure networks and actors.

4.1 Fast-track research and development

Accelerating R&D timelines is essential if we are to ensure timely and equitable access to the medical countermeasures needed to mitigate the impact of future health emergencies – impacts that disproportionately affect the poor, marginalized and vulnerable. To achieve this acceleration, and to ensure it delivers equity, the global community should cultivate the collaborative and enabling environments required to develop and deliver a well-resourced, globally aligned roadmap to accelerate research and development into globally agreed priorities. Fast-tracking research and development will require the development of four key capabilities:

4.1.1 Coordinated research built on a shared global R&D agenda

Effective strategies to enhance research coordination, prioritise critical areas, and facilitate the development of effective medical countermeasures depend on the following sub-capabilities:

- Prioritization of research efforts through the development and periodic revision of a list of viral families and bacteria with epidemic and pandemic potential
- Global coordination of independent Scientific Advisory Groups and research groups
- Research roadmaps to advance scientific understanding and fill research gaps, and target product profiles to guide development of medical countermeasures
- Mapping of candidate medical countermeasures to identify gaps and streamline efforts
- Established networks for systematic sharing of clinical information data to inform clinical research priorities
- National research plans informed by a mapping of hazards and threats, and the identification of clinical research priorities and medical countermeasure needs, linked through collaborative platforms to global research efforts where applicable

4.1.2 Enabling environment for research and discovery

Efficient, innovative, and collaborative research and development efforts require the following enabling subcapabilities:

- Candidate development by global research community supported by standardized early-stage research methods and forums for research data sharing
- Adaptation of global ethics pathways and processes to local norms, to enable rapid discovery and guide product development throughout all R&D stages
- National funding for discovery programs, aligned with the national research plans
- Global and regional R&D funding mechanism to finance rapid R&D efforts when an outbreak is declared, incorporating sufficient risk tolerance and flexibility to allocate R&D resources as needed
- Mechanisms, protocols, and infrastructure for the safe sharing of biological samples and pathogen data, linked to access and benefits sharing agreements

4.1.3 Standardized platforms for equitable and scalable clinical trials

Strengthened research capacity, efficient and agile trial implementation, and inclusive and equitable participation of all stakeholders in outbreak research efforts can be ensured through the following six subcapabilities:

- National research capability assessment to guide capacity strengthening
- Strengthened capacity to conduct research in outbreaks through use of platform trials that enable faster data gathering and increased statistical power of results
- Global and regional technical and operational support for national trial implementation through training on good clinical practice, and initial set-up and support for essential trial infrastructure
- Standardized trial designs and core protocols for each pathogen and outbreak
- Mapping of planned, completed, and in-progress clinical trials and latest evidence base relevant to candidate medical countermeasures against priority diseases
- Recruitment of patients into trials and sharing of productspecific research outcomes through community engagement

activities as defined by the Good Participatory Practice (GPP) guidelines

4.1.4 Adapted regulatory and legal frameworks to enable timely trials, product review and approval

Timely access to crucial medical products and an efficient regulatory response during emergencies depend on the following six sub-capabilities:

- Global benchmarking tool for the evaluation of national regulatory authority (NRA) capabilities to assess efficacy and quality prior to issuing marketing authorizations, as well as conduct post-marketing pharmacovigilance
- Technical assistance to implement institutional development plan (following evaluation)
- Agile product regulatory requirements and procedures during emergencies
- Coordination mechanisms between regulators, and between regulators and researchers during emergencies
- Accelerated countermeasures review and approval through increased regulatory reliance, harmonization and convergence
- Expedited Emergency Use Listing (EUL) and Performance Qualification (PQ) processes by WHO to rapidly evaluate and approve critical products for emergencies

4.2 Scalable manufacturing

Improving access to countermeasures means improving the global distribution of manufacturing capacity, which at present is concentrated in a small number of countries. But broadening participation in and access to manufacturing is a complex process that requires much more than simply building or adapting new manufacturing facilities. Enablers such as effective and agile policy environments, stable access to input materials and a qualified workforce, readily available financing, and access to continued technical support from global and regional authorities and technology providers are all additional crucial factors. The following four capabilities can aid in accelerating the transition to a world with a more agile, resilient and equitable manufacturing base for countermeasures:

4.2.1 Adaptable manufacturing platforms

The following two sub-capabilities are essential to ensure that manufacturing efforts align with specific requirements, optimize regional production capacities, and meet the different demands of different regions and contexts:

- National manufacturing plan informed by national needs (threat and vulnerability mapping, demand forecasting) and capability and capacity mapping
- Prioritization of technologies for regional manufacturing scale-up, considering forecast aggregate regional demands and technical feasibility study

4.2.2 Distributed manufacturing supported by pre-negotiated agreements

Production and equitable distribution of sufficient quantities of high-priority, quality-assured medical countermeasures depends on the following five subcapabilities:

- Set-up of manufacturing platforms supported by technology transfer
- Access and benefits sharing agreements for priority pathogens
- Transfer of intellectual property (IP) rights through licensing

- agreements and patent waivers to manufacturers seeking to produce high-priority, strategic medical countermeasures
- Manufacturing facility set-up (capital expenditure) and ongoing operations (operating expenditure) funded by at-risk capital financing mechanisms
- Development of national policies to implement prenegotiated technology transfer, access and benefit sharing, licensing, and financing agreements

4.2.3 Ever-ready capability for rapid mobilization

The following four sub-capabilities are required to optimize manufacturing capabilities, enhance preparedness, and incentivize the production of medical countermeasures during emergencies:

- Dual-purpose manufacturing through the integration of emergency capacity into the production of non-emergency products
- Technical assistance to operate dual-purpose production lines
- Stable access to production inputs, such as raw materials and utilities
- Procurement from local and regional manufacturers prioritized to create demand-side incentives

4.2.4 Strengthened regulatory framework to oversee set-up and scale-up of manufacturing platforms

The following six sub-capabilities are essential to ensure the efficient, reliable and timely manufacture of and access to medical countermeasures at the same time as maintaining stringent regulatory standards:

- Robust regulatory systems with oversight of licensing of Good Manufacturing Practice compliance
- Global and regional technical support and guidance for national regulatory system strengthening
- Adaptable manufacturing regulatory requirements and procedures during emergencies
- Emergency coordination mechanisms between regulators, and between regulators and manufacturers
- Accelerated production of medical countermeasures enabled by increased regulatory reliance, harmonization and convergence
- Expedited EUL and PQ processes by WHO to rapidly evaluate and approve manufacturers for emergencies

4.3 End-to-end health emergency supply chains

An agile, equitable, and risk risk-tolerant global system for the procurement and distribution of medical countermeasures for pandemic threats demands requires end-to-end partnerships along the medical countermeasure value chain, built on trust and collaborative relationships and processes among core partners and new participants. Building an effective and resilient end-to-end supply chains will require the development of the following five key capabilities:

4.3.1 Essential medical countermeasures and their associated standards, policies and enablers are established for priority hazards

Achieving the goal of equitable access will depend on the establishment of pre-defined lists and technical standards, evidence-guided policy, regular review of definitions and standards, and market assessments:

- Pre-defined lists of essential countermeasures and technical standards are in place for priority hazards
- Policy on use of medical countermeasures is timely and guided by best available evidence
- Mechanisms for the routine and rapid updating of definitions, norms, standards and policies based on emerging hazards and availability of new medical countermeasures
- Market assessments inform action plans to drive equitable access

4.3.2 Coordinated demand aggregation

The following sub-capabilities are essential in order for decision-makers to anticipate and meet demand for medical countermeasures during emergencies:

- Risk-based demand analysis, including a rapid assessment of needs at the onset of an emergency
- Demand forecasts to inform initial push of supplies at response onset
- Aggregated demand forecasts across multiple countries and regions, including populations (e.g. refugees) at risk of being excluded from national estimates,
- Robust methodologies to forecast demand for medical

countermeasures by response pillar and hazards are available; guidance on factors that drive demand for novel medical countermeasures are rapidly made available

4.3.3 Coordinated supply and procurement

Effective decision-making, coordination and collaboration for supply and procurement of medical countermeasures depends on the following four subcapabilities::

- Analytics capacity, integrating contextual understanding and insights from modelling for strengthened risk assessment
- Real-time interfaces and dashboards, incorporating insights drawn from collaboration, leveraged for decision making
- Access for policy makers and public to multisectoral data sources, tailored to target audiences and the national or local context, to generate actionable insights
- Open communication with surveillance outputs routinely published, complemented by mechanisms established to leverage intelligence for mutual benefit and coordinated action

4.3.4 Equitable and transparent needs-based allocations

The fair, equitable, and efficient distribution of medical countermeasures during emergencies is central to global health security, and depends on the following sub-capabilities:

- Needs-based allocation frameworks and principles that can be rapidly adapted
- A global allocation process that manages conflicts of interest and ensures that allocation decisions are transparent, driven by public health goals, and based on an ethical framework
- Allocation decisions take account of commitment to use medical countermeasures appropriately according to established guidance
- Allocations are timely, efficient, transparent and underpinned by collective agreements, international instruments and political commitment to equitable access to appropriate medical countermeasures

4.3.5 Resilient logistics and distribution

The availability, integrity, and efficient distribution of medical countermeasures during health emergencies can be ensured through the development and application of the following sub-capabilities:

- Strategic stockpiles of medical countermeasures are established and provide for rapid response, prevention, response and stopgap needs.
- Potential barriers to the delivery of medical countermeasures and their raw materials during emergencies are addressed through pre-negotiated plans.
- Export and import processes for medical countermeasures streamlined.
- Supply chains monitored against counterfeit and falsified products as a part of robust regulatory oversight
- A cooperartive network of health emergency supply chain actors

Emergency coordination

Coordination of HEPR systems is critical to systematically marshal and deploy the appropriate resources (knowledge and data, financial, materiel, technical and operational) to prepare for, prevent, detect, alert, and respond rapidly to any health emergency. At all levels of organization, accountable leadership must be underpinned by effective multisectoral and multidisciplinary coordination, particularly in incident management of acute response and broader health emergency workforce development.

The Emergency Coordination subsystem enables all the other subsystems to deliver on their capabilities at the global, regional, national, and sub-national level through coordination. Effective emergency coordination hinges on developing the capabilities to deliver three key objectives:

- **5.1** Strengthened workforce capacities for health emergencies
- 5.2 Health emergency preparedness, readiness and resilience
- 5.3 Health emergency alert and response coordination

5.1 Strengthened workforce capacities for health emergencies

Recent health emergencies have revealed that current national, regional, and global response coordination mechanisms are not well-equipped to rapidly detect and mount a decisive and coordinated response.

Gaps in crucial capacities for coordination are often compounded by under-equipped and understaffed rapid response teams and gaps in public health and emergency workforce capacities. To enable national, regional, and global health systems to deploy an effective and coordinated multisectoral response, strong and coordinated health emergency leadership is essential. At the global level, connected health emergency leadership will require the engagement of health emergency leaders and experts at the strategic and tactical level of operations through established coordinating platforms and mechanisms.

The backbone of all emergency operations is the public health and emergency workforce. Effective emergency response requires an inter-disciplinary and multisectoral team that executes the response operations and engages in service delivery to the affected populations.

By expanding and professionalising the pool of national-level expertise, developing a collaborative platform to link existing mechanisms for rapid surge deployment, and connecting those mechanisms to strategic and technical national, regional and global health emergency leadership, strengthened national health emergency workforce capacities can be leveraged into a globally deployable health emergency corps. Achieving the above goals will require the development of four key capabilities:

5.1.1 Public health and emergency workforce

Every country should be able to draw on a professional multi-disciplinary workforce to prevent, prepare for and respond to health emergencies, based on the following four sub-capabilities:

- Scope of emergency preparedness and response functions, practice activities and the associated competencies aligned with the Essential Public Health Functions (EPHFs)
- Competency-based education and learning pathways strengthened and informing capacity development of public health and emergency workforce
- Mapping and measurement of all occupations that perform EPHFs, and estimates of multidisciplinary workforce needs based on risk, vulnerability and capacity assessments
- Action plans define workforce education, development and retention strategies based on service needs, gap assessments and national health workforce policies

5.1.2 Health emergency corps

A dedicated, trained and scalabale health emergency corps can be developed through the application of the following four sub-capabilities:

- Clarified institutional accountabilities for health emergency leadership, coordination and response, including surge capacities
- Dedicated personnel with the right size, expertise and skills to enable timely detection, alert and response to new events, as well as preparedness, prevention and readiness assessment, planning, resource mobilization and implementation (right number of people, in the right role at the right time)
- Sufficient operational support capacity through adequate supplies, space, systems and financing
- Continuous specialized & interdisciplinary learning through regular trainings and simulations based on local hazard profile
- Support to enable participation in connected health emergency leadership

health threats

and regions

• Established and predictable triggers and mechanism(s) for

gathering leaders across countries and regions to enable

common situational awareness and collective decisionmaking to prevent, contain and respond to regional/global

Regular networking, simulation exercises and experience

sharing amongst health emergency leaders across countries

5.1.3 Interoperable surge deployment

Sustainable, high-quality and interoperable surge capacity can be developed through the following five sub-capabilities:

- National and international minimum standards for rapid response capacities
- Sustainable development of surge capacity covering all key domains of HR & team management, technical expertise, data & reporting, operations, coordination, learning, health & welfare, training and simulation exercises
- Integrated and coherent activation, coordination and information exchange protocols, tools and platforms across surge deployment mechanisms at national, regional and global level
- Quality assurance mechanisms and processes for emergency surge capacities, including for domestic and international deployment
- Joint and interdisciplinary learning, cooperation and experience sharing at national, regional and global levels between surge mechanisms and actors

5.1.4 Connected health emergency leadership

Effective health emergency leasdership requires strong leadership structures, collaboration and knowledge exchange, and support through the development of the following four sub-capabilities:

 Trusted and supported health emergency leadership embedded within the competent national structure (NPHA or equivalent)

5.2 Strengthening health emergency preparedness, readiness, and resilience

Underfunding has led to many countries being unable to deliver services that meet both the routine and emergency needs of their populations. The further weakening of health systems by the COVID-19 pandemic and concurrent emergencies, and weak links to key multi-sectoral actors, have led to a renewed focus on building capacities for health emergency response that sit at the intersection of health security, health systems strengthening and universal health coverage.

In tandem with the need for a broadly multisectoral planning process for HEPR, there is a growing realisation that planning processes must be agile and dynamic, capable of responding to risks and vulnerabilities as they evolve and change over time.

Achieving national, regional and global health security requires national planning processes informed by dynamic and holistic capacity assessments (including current IHR assessments such as IHR State Party Annual Reporting (SPAR), Joint External Evaluation (JEE), IHR-Performance of Veterinary Services (IHR-PVS) National Bridging Workshops (NBW) and Tripartite operational tools) and risk and vulnerability assessments, feeding into a clear multi-sectoral national plan for health emergency prevention, preparedness, response and resilience backed by domestic and international resources. Achieving this goal will require the development of four key capabilities:

5.2.1 Capacity, risk and vulnerability assessment

A thorough and dynamic understanding of evolving capabilities and vulnerabilities is needed in order to develop targeted strategies to strengthen health emergency preparedness and response. Such an understanding requires the development of the following three sub-capabilities:

- Assessment of preparedness and response capacities, building on existing frameworks
- Comprehensive and up-to-date threat and vulnerability analysis and readiness assessments

 Updated risk profile and agreement of strategic objectives based on capacity assessments and threat and vulnerability analysis

5.2.2 Prioritized and costed plans

Effective prioritization of needs, and accurate and dynamic estimations of resource needs are essential to accelerate health emergency preparedness and response capacity strengthening, and require the following three sub-capabilities:

- Development of prioritized action and readiness plans to achieve strategic objectives
- Development of service delivery and operational plans integrated into existing strategies and programmes
- Costing of operational plans and estimating resource requirements

5.2.3 Resource mapping and mobilization

Efficient and comprehensive strengthening of health emergency capacities depends on the identification and effective utilisation of available financial and technical resources and support, based on the following three sub-capabilities:

- Mapping of existing financial resources for prioritized actions and identification of gaps
- Mobilization of additional financial resources and development of funding proposals
- Identification of technical and operational delivery partners and assignment of roles and responsibilities

5.2.4 Implementation, monitoring and review

A rapidly changing world demands a dynamic and evolving assessment of capacities, efforts, and risks, based on the following three sub-capabilities:

- Establish monitoring mechanisms to track implementation against plans
- Periodic review of capabilities and system performance through intra-action and after-action reviews and simulation exercises
- Continuous adjustment and update of plans based on results of periodic review and evolving threats and vulnerabilities

5.3 Health emergency alert and response coordination

Efficient coordination among stakeholders is a critical component of effective emergency response. Coordination mechanisms should facilitate whole-of-government and whole-of-society responses to emergencies. Strengthened and scalable health emergency alert and response coordination at the national level, and more effective international coordination for response, can be achieved through the development of four key capabilities:

5.3.1 Standardized triggers and rapid resources for immediate response

Effective emergency response depends on established and clearly defined triggers for action, seamless and rapid information sharing, and effective coordination among stakeholders based on the following three subcapabilities:

- Standardized methods for hazard identification, alert, rapid risk assessment and grading to declare onset of emergency
- Rapid deployment mechanisms for the release of available contingency resources (human, financial, technical) for immediate initial response on a no-regrets basis
- Established multisectoral response coordination mechanism and coordination infrastructure (such as public health emergency operations centres), activated in line with emergency categorization and grading and in line with global guidance

5.3.2 Timely, evidence-based and resourced response strategies

An effective response strategy depends on the rapid translation of evidence and knowledge into practical actions to address a well-defined and understood threat, which can be achieved through the development and application of the following three sub-capabilities:

- Situational needs analysis and assessment
- Rapid development of evidence-based, multisectoral emergency response plans and technical strategies for operational response

 Sustainable, rapidly disbursed and flexible funding mechanisms for agile, scalable and sustained emergency response

5.3.3 Operational support and logistics platform

Effective operational support and logistics are essential to translate strategies into practice, and require the following three sub-capabilities:

- Staff safety and security, and safeguarding of staff and affected communities, including protection from sexual exploitation, abuse and harassment
- Operational logistics including establishment and maintenance of key infrastructure and processes, including accommodation, health emergency logistics and procurement
- Operational support and management, including financial administration and human resources

5.3.4 Monitoring, review and adjustments to response

Health emergencies change rapidly, and response strategies must adapt and adjust accordingly, which can be facilitated by the following three sub-capabilities:

- Monitoring mechanisms to track delivery and impact against emergency response plans
- Periodic strategic and operational review, utilizing intra-action review methodologies
- Adaptation and course correction of health emergency response plan in accordance with findings of intra-action reviews and evolving risks

Next Steps

Setting out the scope and ambition of the five Cs is a first but significant step towards building the HEPR systems that the world needs. Defining, refining and syndicating the HEPR capabilities the world requires is a multi-stage process.

The scope and structure of each of the Cs was defined and refined through extensive landscape analyses, with initiatives, strategies, and frameworks reviewed to identify key trends, critical gaps, and the most salient lessons from major emergencies. Technical working groups convened by WHO developed each concept over a series of working sessions, drawing extensively on input from Member States and partners. Each of the five Cs encompasses core IHR capacities, alongside complementary multi-sector and One Health capacities crucial for an effective whole-of-society approach to health emergency prevention, preparedness, response and resilience

In addition to systematically applying cross-cutting principles of equity, inclusivity, and coherence, the specific capabilities listed above that are required to meet the overarching objectives of each C must be underpinned by:

- clear institutional arrangements, responsibilities, and accountabilities, with strong governance and legislation;
- sustainable funding for the establishment and maintenance of capabilities that can adjust to evolving priorities and technologies;
- a culture of trust through systematic feedback and transparency; and
- a well-resourced and effective workforce with the ability to scale up, and with established expertise and mechanisms for coordination and collaboration across all required disciplines.

Work to refine and contextualise each of the five Cs will continue. In addition, WHO will accelerate its work with partners to provide intensive support to national efforts to formulate detailed investment plans to strengthen

capacities across the five Cs, based on a thorough appraisal of existing capabilities, risks, vulnerabilities, and an understanding of available technical and financial resources, including new streams of funding available through the Pandemic Fund and other funding sources.

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