



Promoting Global Solidarity to Advance Health System Resilience: Recommendations for the G7 Meetings in Japan

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Hiroshima G7 Global Health Task Force

Executive Committee on Global Health and Human Security

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Frequently Used Abbreviations

100DM	100 Days Mission
ACT-A	Access to COVID-19 Tools Accelerator
AMC	Advanced Market Commitment
AMR	Antimicrobial Resistance
BARDA	Biomedical Advanced Research and Development Authority
BSL	Biosafety Level
CDC	Centers for Disease Control and Prevention
CEPI	Coalition for Epidemic Preparedness Innovations
COP	Conference of Parties
CSO	Civil Society Organization
DALYs	Disability Adjusted Life Years
FIND	Foundation for Innovative New Diagnostics
G7	Group of Seven
Gavi	Gavi, the Vaccine Alliance
GFF	Global Financing Facility for Women, Children and Adolescents
GHIT Fund	Global Health Innovative Technology Fund
HERA	Health Emergency Preparedness and Response Authority
IHR	International Health Regulations
INB	Intergovernmental Negotiating Body
IPR	Intellectual Property Rights
JCIE	Japan Center for International Exchange
LMICs	Low- and Middle-Income Countries
MCMs	Medical Countermeasures
MDB	Multilateral Development Bank
MPP	Medicine Patent Pool
NCD	Noncommunicable Disease
Pact	Pact for Pandemic Readiness
PHC	Primary Healthcare
PPE	Personal Protective Equipment
PPR	Pandemic, Prevention, Preparedness and Response
R&D	Research and Development
RECOVERY	Randomised Evaluation of COVID-19 Therapy
SCARDA	Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response
UHC	Universal Health Coverage
WASH	Water, Sanitation, and Hygiene
WHO	World Health Organization
WMA	World Medical Association

1. Introduction

We are currently in an era of destabilization, challenged by multiple interconnected crises. These crises include climate change and the resulting increases in natural disasters, public health crises, inequality, military conflict, food shortages, high inflation, mounting debts, political unrest, and more. These increasing planetary pressures increase pandemic risk, with future epidemics likely to be zoonotic in origin.¹ COVID-19 has shown that health emergencies threaten social cohesion, economic stability, and national security.² Enhancing health system resilience to epidemics and other diverse threats is thus a central challenge for political leaders in this new era.

Each country has an obligation and self-interest to enhance its health system resilience to protect its people and address the security implications of public health emergencies as part of its national security agenda. In addition, promoting health and human security^a requires managing cross-border externalities and addressing global inequities in distributing resources and knowledge. Political leaders must also tackle the challenge of transforming and strengthening the global health architecture to ensure global solidarity for advancing health system resilience, especially given the current geopolitical tensions and shifts as well as the nationalism fueled during health emergencies.

In May 2023, Japan will host the Group of Seven (G7) Summit in Hiroshima and the G7 Health Ministers' Meeting in Nagasaki. These meetings provide a prime opportunity to advance discussions on ways to transform health governance systems at the national and global levels, drawing on the lessons learned from the COVID-19 pandemic. The G7, as a community with shared values, has a critical collective role to play in advancing global solidarity. The G7 countries gave 76% of the total ODA provided by the Development Assistance Committee countries in 2021, and occupy leading positions in science and technology, making them a source of significant external financial and technological support and partnership.³ The G7 should utilize human security as a guiding principle in global health efforts. They should work with relevant actors to catalyze the global health architecture to be more resilient and adaptable to meet the challenges of a new era. Additionally, the G7 should aim to decentralize the research and development (R&D) ecosystem to ensure faster and more equitable delivery of medical products, including medical countermeasures (MCMs). The concept of human security—a people-centered approach that integrates systemic and multisectoral responses to structural vulnerability and inequality, focusing on root causes of interconnected threats—would guide political leaders to engage all stakeholders in decision-making and collective actions to ensure solidarity at the community, national, regional, and global levels.^{4,5,6}

In July 2022, the Executive Committee on Global Health and Human Security of the Japan Center for International Exchange (JCIE) launched the Hiroshima G7 Global Health Task Force to inform discussions on the global health agenda for the Summit. (See **Appendix 1** for further information on the Task Force and its organizers.) The Task Force identified three vital current

^a Human security: the activities required, both proactive and reactive, to minimize the danger and impact of acute public health events that endanger people's health across geographical regions and international boundaries.

challenges in global health and developed a set of recommended actions for the upcoming G7 Summit and Ministerial Meetings in Japan. The three challenges are (1) Universal Health Coverage (UHC) which is resilient to health emergencies and diverse health threats⁷; (2) the 100 Days Mission (100DM) PLUS^b; and (3) the global health architecture. The Task Force selected these topics based on the following principles: that UHC should be viewed as an overarching goal, building on Japan's strengths and legacy; that the 100DM PLUS is a critical way to ensure timely and equitable access to MCMs; and that an enhanced global health architecture is an essential basis in achieving those two policy goals.

2. Three interconnected issues for the Hiroshima G7

During the United Kingdom's G7 presidency in 2021, it launched the 100DM to reduce the impact of future pandemics by making diagnostics, therapeutics, and vaccines (known collectively as MCMs) available within 100 days.⁸ This initiative continues to be championed by the UK and should be a priority for Japan to uphold during its presidency, along with Germany's Pact for Pandemic Readiness (Pact), which seeks to advance a global surveillance network for animals and humans and explore what is needed for an enhanced and better-coordinated emergency workforce.⁹ However, the Task Force recognized gaps in these efforts, particularly regarding implementation, and stressed that these initiatives should also be linked to and translated into national systems to attain UHC and help low- and middle-income countries (LMICs) access MCMs—i.e., through an enhanced 100DM process, or what is referred to as 100DM PLUS. The emergency workforce should also be empowered and mobilized beyond national boundaries to protect communities from emerging and re-emerging epidemics.

As defined at the Ise-Shima G7 Summit in 2016, health security and UHC are two sides of the same coin, but the Task Force noted that progress is lacking in connecting these two dimensions.¹⁰ In adjusting to a new era, pandemic prevention, preparedness, and response (PPR) capacities must be positioned as an essential dimension for attaining UHC. Concrete ways to synergize health security and UHC are needed in order to make PPR efforts more sustainable.

This section summarizes the Task Force's views on these three challenges. For a more extensive discussion of each, please see **Appendix 2**.

UHC

Human security demands that the health of all people be protected, indicating that UHC is an essential component of human security.¹¹ The experience with COVID-19 has served to

^b 100DM PLUS: In addition to the "100 days mission" to develop and supply medical countermeasures (MCMs) within 100 days of an outbreak, the "100 days mission PLUS" covers the entire process from accessibility-focused R&D of MCM to prompt and equitable delivery to the final beneficiary at the global level.

reinforce the importance of UHC. To date, the progress toward UHC has been evaluated mainly in terms of whether essential healthcare services are universally provided and whether financial risk protection structures have been established to ensure affordable access to those services. However, UHC should also incorporate the resilience needed to respond to health emergencies without disrupting the delivery of essential health services and to address the ever-changing interconnected threats to health. Considering the linkage between public health, health security, and social and environmental determinants, the Essential Public Health Functions^c should be further strengthened as the basis for UHC. Particularly in light of the fact that the negative impacts of the COVID-19 pandemic have disproportionately affected the vulnerable, and continue to do so with long COVID, structural inequality and inequity should be further addressed to make systems more resilient by strengthening primary healthcare (PHC)^d and community systems and by promoting social inclusion.

The key challenges related to UHC that the Task Force identified include the following:

- a. [False dichotomy between health security and UHC](#)
- b. [Need for improved collaborative surveillance and public health leadership coordination](#)
- c. [The global crisis of noncommunicable diseases and the failure of public health to address the risk factors](#)
- d. [Insufficient basic infrastructure development for healthcare facilities](#)
- e. [Unequal pandemic impact and inadequate social security leaving the vulnerable behind](#)
- f. [Need to protect gains made in gender equality over the past decades](#)
- g. [Need to exploit the benefits of digital health technologies](#)

100DM PLUS

The success of MCM R&D must be assessed based on the speed of development and the adequate coverage of the products. MCMs should be accessible to every person in need. Without access to new innovations, lives will be lost to health emergencies, and it will take years to control

c Essential Public Health Functions Lists: A list of public health functions identified as common and fundamental based on a crosswalk analysis includes: 1. Monitoring and evaluating the population's health status, health service utilization and surveillance of risk factors and threats to health; 2. Public health emergency management; 3. Assuring effective public health governance, regulation and legislation; 4. Supporting efficient and effective health systems and multisectoral planning, financing and management for population health; 5. Protecting populations against health threats, including environment and occupational hazards, communicable disease threats, food safety, chemical and radiation hazards; 6. Promoting prevention and early detection of diseases, including non-communicable and communicable diseases; 7. Promoting health and well-being and actions to address the wider determinants of health and inequity; 8. Ensuring community engagement, participation and social mobilization for health and well-being; 9. Ensuring adequate quantity and quality of public health workforce; 10. Assuring quality of and access to health services; 11. Advancing public health research; and 12. Ensuring equitable access to and rational use of essential medicines and other health technologies.

d Primary healthcare (PHC): a whole-of-society approach to health that aims to ensure the highest possible level of health and wellbeing and their equitable distribution by focusing on people's needs and as early as possible along the continuum from health promotion and disease prevention to treatment, rehabilitation, and palliative care, and as close as feasible to people's everyday environment.

emerging and re-emerging infectious diseases. The addition of “PLUS” to 100DM intends to emphasize the importance of equitable access to MCMs. Since R&D capacity is unevenly centered around the G7 and—to a lesser extent—G20 countries, global and regional mechanisms should be set up to ensure coordination among nations with R&D capacity for MCMs and access by the people in need globally. Based on the external evaluation of the Access to COVID-19 Tools Accelerator (ACT-A) and the second implementation report of 100DM, more flexible mechanisms are necessary to realize 100DM, better respond to regional and local needs, and collaborate with the private sector and regional organizations to ensure equitable access to innovations.^{12,13} We must also recognize that innovation, spawned from long-term public investment in R&D and dedication from the private sector and academia to tackle the existing threats, made the rapid production of COVID-19 vaccines possible. To strengthen resilience to public health threats and improve health equity, a comprehensive approach to advance timely and equitable access to life-saving MCMs throughout the entirety of the MCM value chain should be taken, recognizing MCMs as global common goods.¹⁴

The Task Force identified the following issues related to 100DM PLUS:

- a. [Insufficient global coordination among R&D systems for MCMs](#)
- b. [Lack of a collaborative network among regional R&D financing organizations](#)
- c. [Insufficient alignment of regulatory decision-making](#)
- d. [Difficulties meeting high-income countries’ national interests and LMICs’ needs through global mechanisms](#)
- e. [Lack of risk hedge plan for research, manufacturing, and supply of MCMs](#)

Global health architecture

In order to promote UHC and 100DM PLUS, the global health architecture, including financing mechanisms, should be further transformed by enabling a multilayered governance structure that facilitates effective collaboration among state and nonstate actors beyond the health sector at the global and regional levels. There should be a global consensus on norms, procedures, principles, and guidelines. At the same time, actions and infrastructures should be decentralized to ensure agile and inclusive responses to health emergencies at the regional and national levels. Transformation requires the meaningful participation of LMICs and civil society organizations (CSOs) in service delivery, policy development, and review processes to ensure UHC and access to technological innovations by vulnerable populations. Such social participation is critical not only to ensure that “no one is left behind,” but also to ensure accountability and transparency. The private sector is also a critical partner and source of innovation. The global community should proactively promote voluntary partnerships across the private, public, academic, and nonprofit sectors to ensure equitable access to technological innovations contributing to global health, especially in terms of MCMs.

The Task Force focused on the following issues that must be addressed in enhancing the global health architecture:

- a. [Insufficient effective legal regimes and norms to tackle the broader scope of health threats](#)

- b. [Need for enhanced governing mechanisms for coordinated global action against pandemics and other multifaceted health threats](#)
- c. [Insufficient health prioritization by governments and inadequate domestic and international financing for health and health emergencies](#)
- d. [Limited global efforts to avoid fragmentation and secure comprehensiveness while realizing a tailored commitment to the regional level](#)

3. Recommendations for the G7 agenda

In light of its analysis of the challenges to attaining UHC, 100DM PLUS, and the transformation of the global health architecture, the Hiroshima G7 Global Health Task Force recommends the following policy options for the G7 this year. These recommendations aim to promote the ongoing evolution of health policy and further catalyze agile and coordinated responses to future health emergencies. Key goals of these recommendations include promoting adaptation to a new era and exploring the future global health architecture to become more resilient to the ever-changing interconnected threats.

RECOMMENDATION 1. Boost country-led efforts to achieve UHC

1-1. Integrate PPR into national UHC strategies, with a focus on PHC

EMPHASIZE PPR WITHIN UHC AND PHC FRAMEWORKS

The G7 nations must reevaluate their commitment to the global movement to attain UHC in order to avoid creating a false dichotomy between UHC and health security. They should promote the integration of investments in core health security capacities, such as surveillance, laboratories, healthcare workforce, inspection, tracking, monitoring, and risk communication, into national UHC strategies, while fostering access to innovative and affordable products and technology. PHC should serve as the common foundation for UHC and health security, with PPR capacity building purposefully integrated into ongoing health projects under the overarching goal of UHC.

The G7 should recognize that countries adapted and innovated in response to COVID-19, leveraging synergies between existing investments to fight HIV/AIDS, tuberculosis, malaria, neglected tropical diseases (NTDs), antimicrobial resistance (AMR), and others. Integrating PPR capacity building into the ongoing health projects within the broader scope of UHC is essential. To enhance the resilience of UHC, ensuring stewardship or appropriate use of medicines—especially antibiotics—should also be prioritized in capacity building.

The G7 should establish a mechanism to ensure that donors and partnerships for existing infectious diseases (e.g., the Global Fund to Fight AIDS, Tuberculosis and Malaria [Global Fund], the Gavi, the Vaccine Alliance [Gavi] and the Global Polio Eradication Initiative), noncommunicable diseases (NCDs), and sexual, reproductive, maternal, newborn, child and adolescent health (e.g., Global Financing Facility [GFF], United Nations Children's Fund [UNICEF], and United Nations Population Fund [UNFPA]) encourage and support countries to increase investments in PHC strengthening. The G7 should also lead the global efforts to redefine the core capacities of PHC required for PPR enhancement in collaboration with relevant international organizations and encourage each agency to set a target ratio of PHC support.

The G7 must encourage the World Health Organization (WHO), World Bank, UHC2030, and other international organizations to develop and improve upon legitimate governing mechanisms, such as mechanisms to track and assess the progress of PHC systems (e.g., the Universal Health and Preparedness Review), in order to highlight synergies between PPR and the UHC.

ENHANCE COMMUNITY SYSTEMS FOR RESILIENT HEALTH SYSTEMS AND FOSTER SOCIAL PARTICIPATION

Lessons from the global HIV response have highlighted community-led organizations and networks' crucial role in addressing pandemics and other health emergencies. These entities can improve health outcomes by promoting service demand, reaching hard-to-reach populations, mobilizing political leadership, transforming social attitudes and norms, and fostering an environment that encourages equal access.

Community system strengthening focuses on nurturing informed, robust, and coordinated communities, as well as developing the capacity of community-led and -based organizations and networks. The G7 should increase investments in community system strengthening in their external assistance and encourage international organizations to facilitate further community-led responses, including community-led monitoring, research and advocacy, capacity building and leadership development, and engagement and coordination.

In addition, the G7 should help ensure the active and meaningful participation of diverse stakeholders—communities, CSOs, and local community leadership—in the governance and implementation of social policies, including health policies. They can ensure this by increasing investment in capacity building and funding for community stakeholders, strengthening global and regional initiatives to promote UHC, and institutionalizing mechanisms of social participation and participatory governance at the national level.

STRENGTHEN INTEGRATED DISEASE SURVEILLANCE AND HEALTH EMERGENCY WORKFORCE

The G7 should reaffirm its commitment to bolstering integrated disease surveillance and health emergency workforce, which is crucial for effectively preventing, detecting, and mitigating the spread of current and emerging health threats.

In addressing COVID-19, governments have utilized existing surveillance systems for HIV and other infectious diseases and engaged with grassroots organizations to reach vulnerable

populations. Leveraging existing infrastructure, such as laboratories, increased trust between decision-makers and community members, and promoted community health literacy. Integrating these proven strategies into future responses to pandemics and other public health concerns is recommended.

Improved coordination among leadership at all levels of governance—from community to global—is essential for delivering well-coordinated and decisive responses. Considering the capacity limitations and brain drain issues faced by LMICs, the G7 should support international organizations in creating an international network of strong and collaborative health emergency leaders. These leaders should be able to support each other in preparing and preventing health emergencies and should help countries in need to develop and finance motivated and trained health workforces. Establishing emergency policy measures and temporary recruitment schemes to optimize the skills mix of health workers and ensure workforce surge capacity during non-pandemic periods is essential.

ADVANCE DIGITAL TRANSFORMATION AS NEXT-GENERATION HEALTH CRISIS MANAGEMENT

The COVID-19 pandemic showcased the effective use of digital technologies and platforms for delivering tailored prevention and outreach services to at-risk communities. The G7 should prioritize digital transformation in healthcare and advocate for its integration into national health strategies. The G7 should work to create a digitally symbiotic society that ensures no one is left behind. This includes promoting investment in real-time syndromic surveillance and tracking systems, as well as human resource development through the use of Internet of Things (IoT) devices and social media.

The G7 can reaffirm its support for the efforts of international organizations such as the International Digital Health and AI Research Collaborative (I-DAIR), UNDP, UNICEF, and WHO, among others, to promote the use of digital tools in LMICs. The efforts include expanding internet broadband access, strengthening capacities to use digital tools, and ensuring access to digital health services for people with disabilities and those with relatively low health and digital literacy. These tools can be used to empower health workers to collect disease-related information, such as vaccination history, adverse reaction occurrences, and post-vaccination infection status, while also delivering prevention and outreach services to vulnerable populations in LMICs. The G7 should also promote the expansion of the digital transformation of health systems.

The G7 should encourage developing and implementing interoperable registries and databases capable of linking and integrating disease-related information and other healthcare data into personal health records through close collaboration with the G20. Each country's legislation and digital transformation promotion plans should include this next-generation approach to health risk management.

1-2. Address interactions among NCDs, infectious diseases, and social determinants of health

PROMOTE GLOBAL EFFORTS TO CONTROL NCDs

The G7 should urgently address the growing burden of NCDs and mental health issues, including dementia, depression, and neurocognitive conditions. To overcome the syndemics^e of the COVID-19 pandemic, the G7 must adequately address interactions between NCDs and infectious diseases and confront deeply embedded structural inequities in society and communities through a rights-based approach.

The G7 should address metabolic risks such as hypertension and high blood sugar; and behavioral risks, including smoking, alcohol, and unhealthy eating (as highlighted at the 2021 Tokyo Nutrition Summit). A multistakeholder collaborative framework is critical for addressing NCDs. The G7 should work to create an environment that fosters partnerships across the private sector, government, civil society, and academia. This includes developing, adopting, and scaling solutions and smart technologies, such as digital health tools, which empower diverse communities and promote individual behavior change. The G7 should also support adherence and continuity of individual-level public health measures with proven effectiveness, such as promoting obesity reduction and salt reduction in chronic disease control. In addition, the G7 should actively encourage policy packages that have been proven effective in reducing risk factors, such as health taxes, product labeling, and advertising regulations.

PRIORITIZE HEALTHCARE FACILITIES IN THE G7/G20 “QUALITY INFRASTRUCTURE INVESTMENT”

Within the context of the G7/G20 “Quality Infrastructure Investment,” the G7 should prioritize the development of healthcare facilities and social infrastructure, such as clean water and electricity, particularly in rural and marginalized areas. Environmental considerations should be integrated throughout a project’s life cycle. In addition to infrastructure, the G7 should support countries in integrating water, sanitation, and hygiene (WASH) in healthcare facilities as a core component for maternal, child, and newborn health, AMR, PPR programs, and UHC strategies. This should align with the strategic directions proposed by the Global Taskforce for WASH in Health Care Facilities.¹⁵ Providing grants at scale to catalyze private investment, such as blended finance projects, to build and strengthen health infrastructure, especially in rural and marginalized areas in LMICs, can promote collaboration between multilateral/regional development banks and international organizations.

^e Syndemic: a set of closely intertwined and mutual enhancing health problems that significantly affect the overall health status of a population within the context of a perpetuating configuration of noxious social conditions (Source: Singer M. A dose of drugs, a touch of violence, a case of Aids: conceptualizing the Sava Syndemic. *Free Inq Creat Sociol.* 1996; 24: 99-110)

TACKLE SOCIAL BARRIERS AND ENSURE ACCESS TO HEALTHCARE AND WELFARE SERVICES

The G7 should address social barriers hindering access to health services, including stigma, discrimination, and lack of sexual and reproductive health and rights, and invest in programs that change gender and social norms while addressing the broader social determinants of health. This requires ongoing support from CSOs and international organizations such as UNFPA. Disaggregated data by gender, income level, race, age, and other factors help identify, understand, and address the specific needs of different groups. The G7 should promote the establishment of a system that enables everyone to access healthcare and welfare services, including mental health services, through various social security menus. These measures can act as a safety net to protect the health and wellbeing of vulnerable groups during health crises. In order to ensure that hard-to-reach populations have access to services, a universal service delivery infrastructure must be made available to marginalized communities, including community systems often best positioned to reach these populations. Developing tailored and multisectoral strategies to address the communities' barriers, including gender barriers, that often extend beyond the health sector, is essential. The G7 should support initiatives for hard-to-reach populations in LMICs under its commitment to UHC.

The G7 should also strive to create a healthy environment that enables individuals to maintain their wellbeing regardless of social circumstances. This entails establishing and strengthening mechanisms for social security, market regulations, and incentives necessary to promote disease prevention and treatment, as well as improving living conditions, including environmental risks like climate change and biodiversity loss; and psychosocial risks.

PROMOTE GENDER TRANSFORMATION IN HEALTH SYSTEMS

A gender-transformative approach^f must be mainstreamed in UHC and health security endeavors to avoid excluding those needing services the most and worsening existing health-related care financial burdens that disproportionately affect women. Gender plays a crucial role in health systems and must not be disregarded, as it influences health system needs, experiences, and outcomes at all levels. The G7 should acknowledge, address, and eradicate disparities in access to resources, distribution of labor and roles, social norms and values, and decision-making processes based on gender.¹⁶

^f “A gender-transformative approach is concerned with redressing gender inequalities, removing structural barriers, such as unequal roles and rights and empowering disadvantaged populations. In practice, this means working for change in laws and policies, systems and services; distribution of resources; norms, beliefs and stereotypes; and behaviour and practices.” (UNICEF. 2022. A Review of Gender-Transformative Approaches and Promising Practices in Health, Nutrition and HIV Programming in Africa: From Theory to Practice.)

1-3. Facilitate investments in UHC through harmonized external assistance and domestic financing

REAFFIRM THE SIGNIFICANCE OF DOMESTIC HEALTH FINANCING

Following the 2019 UN High-Level Meeting on UHC, country commitments to UHC almost doubled between 2019 and 2021. However, in 2022, this positive trend stagnated and even reversed in some countries. The G7 should reaffirm the importance of mobilizing domestic financing for health by providing incentives and strategic support at the highest levels of government. Potential measures include advocating for the multiple benefits of UHC to government leaders; promoting collaboration between finance and health ministries; assessing economic return on investments; implementing grant financing conditional on domestic resource mobilization for health; and offering incentives and support for mobilizing resources during fiscal consolidation.

The G7 should also encourage international organizations such as the Global Fund, Gavi, GFF, and others to act as catalysts for domestic resource mobilization through co-financing requirements, advocacy, and technical assistance.

Current inflationary and debt pressures remain a challenge in many LMICs. Therefore, the G7 should facilitate access to international capital markets and concessional finance for these countries without increasing their sovereign debt burden. The G7 should support regional initiatives for mobilizing domestic resources for health, such as the Abuja Declaration, which sets a target of allocating at least 15% of the annual budget of the African Union's member states to the health sector.

HARMONIZE SUPPORT FOR COUNTRY-LED UHC EFFORTS IN LMICS

Achieving UHC in LMICs requires the G7 members and global health agencies to harmonize their external assistance. The G7 should recognize that support from international organizations and multilateral development banks (MDBs) must be managed more effectively to achieve a more significant impact. Transaction costs for LMICs should be reduced through better coordination, alignment with country systems, and harmonization among bilateral and multilateral assistance.

There have been efforts to enhance harmonization among the donors and international organizations in the health sector, such as IHP+/UHC2030, UHC Partnership, Global Action Plan for Healthy Lives and Wellbeing for All (SDG3 GAP), and GFF Alignment Working Group. Based on the lessons learned from these experiences and aligning with discussions from the Future of Global Health Initiatives process, the G7 should facilitate harmonization among G7 members and the partner agencies of the SDG3 GAP.

We recommend the G7 promote harmonization and streamline initiatives, supporting LMICs to align efforts at the country level. In order to provide strong external and mutual incentives for harmonization, the G7 should consider creating an accountability mechanism to monitor progress. G7 members and global health agencies should share a long-term vision for aid independence and transition, as well as a unified voice on domestic resource mobilization for each country.

INVESTIGATE THE FEASIBILITY OF CREATING A GLOBAL KNOWLEDGE HUB ON UHC FINANCING

We recommend that the G7 explore the possibility of creating a global knowledge hub on sustainable and efficient UHC financing, including domestic resource mobilization. This hub (a “Center for UHC Financing”) would serve as a mutual learning platform and an open-source database for information required for sustainable and efficient UHC financing, such as resource mapping, disease burden, demographic trends, and the economic outlook of LMICs. International organizations, bilateral donors, CSOs, the private sector, and others should align themselves based on financial conditions and each country’s long-term UHC financing strategy. Based on country analyses, technical assistance should be provided to strengthen financial administration capacities at the central and local levels. Collecting evidence of health return on investment is crucial to demonstrate the impact of investing in health and to make a case for continued collaboration between health and finance ministries.

This hub can be explored through close collaboration with the G20 Joint Finance and Health Taskforce and public-private collaboration, including international organizations such as the WHO and World Bank.

RECOMMENDATION 2. Ensure a comprehensive approach to advance timely and equitable access to life-saving MCMs

2-1. Accelerate R&D for MCMs

STRENGTHEN THE GLOBAL NETWORK OF R&D FUNDING AGENCIES FOCUSED ON PRIORITIZED PATHOGENS

The G7 is expected to increase investment in research to identify high-risk microorganisms and pathogens and to coordinate efforts to mitigate various risks, including pandemics, epidemics, AMR, zoonotic diseases, especially climate-sensitive diseases, and biosecurity risks. The Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) has existed as a global network of funders for R&D for epidemic and pandemic preparedness and response, and its network has contributed to diverse R&D efforts.¹⁷ However, preparing for and responding to these multifaceted risks requires more diverse endeavors beyond the mandate of GloPID-R. To achieve this, the G7 should strengthen the global network through collaboration among key regional organizations, aligning with but not limited to the GloPID-R mandate and membership. Key regional organizations include the US’s Biomedical Advanced Research and Development Authority (BARDA) and the EU’s Health Emergency Preparedness and Response Authority (HERA). Although their mandates and scopes are not exactly the same as those of BARDA or HERA, the Indian Council of Medical Research, Japan’s Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA) under the Japan Agency for Medical Research and Development, and the Partnerships for African Vaccine Manufacturing can also help accelerate research and preparedness for potential infectious diseases.¹⁸

The Coalition for Epidemic Preparedness Innovations (CEPI) and the Global Antibiotic Research and Development Partnership (GARDP) can serve as global hubs to connect regional efforts for vaccines and AMR, respectively. The G7 should call on support for CEPI's and GARDP's R&D programs to accelerate vaccine and treatment development, reduce the threat posed by future epidemics and pandemics, and enable equitable access to life-saving innovations for the most vulnerable populations.^{19,20}

STRENGTHEN ECOSYSTEMS FOR DIAGNOSTICS AND THERAPEUTICS

The R&D of diagnostics, therapeutics, and vaccines should not be siloed, as all three areas are crucial for effective PPR. The G7 should promote the 100DM plan in diagnostics and therapeutics and support efforts to ensure that the knowledge on prioritized targets is utilized to inform future R&D across those areas as well as vaccines. R&D in diagnostics and therapeutics is lagging behind vaccines, especially in the case of COVID-19. Therefore, global/regional partnerships and cooperation should be further promoted, particularly with the Global Health Innovative Technology Fund (GHIT Fund), Foundation for Innovative New Diagnostics (FIND), and the Rapidly Emerging Antiviral Drug Development Initiative (READDI). Active private sector engagement for all R&D efforts is also essential to catalyze innovation by multiple sectors. The G7 should support initiatives such as FIND's exploration of prototype diagnostic libraries in coordination with key diagnostic players, including the pharmaceutical industry and public-private partnerships.¹³

ACCELERATE NATIONAL AND GLOBAL EFFORTS TO ADDRESS AMR

Similar challenges and recommendations can also be applied to the issue of AMR. Ensuring timely and quality access to appropriate antimicrobials, as well as financing National Action Plans, are important groundwork for the 2024 UN High-Level Meeting on AMR.

First, the G7 should encourage donors to provide technical and financial assistance to develop and implement national-, regional-, and global-level AMR action plans by better leveraging MDBs and global health organizations. This includes monitoring the mobilization of funds more effectively. Action plans should also be developed based on better-quality surveillance data. Therefore, the G7 should promote the strengthening of integrated surveillance, which also covers AMR, and propose periodical reporting to an appropriate entity to monitor the AMR situation, in keeping with the framework for utilizing Joint External Evaluation tools in the Global Health Security Agenda.²¹

Second, to encourage the R&D of new and repurposed antimicrobial agents under international partnerships, the G7 should stimulate innovative push-and-pull incentives that do not adversely affect the affordability of the final products and strengthen innovation on behalf of highly affected populations, particularly children and neonates. These incentives should be based on actionable member commitments and transparent selection criteria for products eligible for those pull incentives. Although several innovative financing mechanisms to incentivize R&D exist, none of them are globally applicable, and none fit the situation of LMICs.^{22,23}

The G7 should promote the development of innovative ecosystems to facilitate timely development and sustainable access. This issue cannot be solved solely by market mechanisms alone. Therefore, it is essential to incorporate the private sector, including commercial companies, non-profit organizations (e.g., the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator [CARB-X], GARDP, and the SECURE initiative), and CSOs into these efforts.^{24,25} In addition, a multifaceted evaluation of social impact using the One Health⁸ lens, such as the Collier FAIRR Protein Producer Index, would be helpful to encourage the private sector beyond the medical and pharmaceutical sectors to minimize adverse environmental externalities.²⁶

2-2. Promote timely access to MCMs

ENHANCE REGIONAL INNOVATION AND MANUFACTURING CAPACITIES

The World Economic Forum, in collaboration with CEPI and the US National Academy of Medicine, launched the Regional Vaccine Manufacturing Collaborative in May 2022 as a broad multisectoral partnership to increase regional vaccine manufacturing capacity, primarily in the Global South. G7 governments should work in close collaboration with the G20 with the goal of enhancing regional manufacturing capacities in LMICs. They should leverage existing work in this area, including WHO/South Africa mRNA vaccine technology transfer hub and Gavi's first regional vaccine manufacturing white paper. Additionally, they should support and coordinate with initiatives by ASEAN and the Africa Centres for Disease Control and Prevention (Africa CDCs) to strengthen regional manufacturing capacities for MCMs in LMICs.^{27,28}

PROMOTE MARKET SHAPING AND SYNERGIZE WITH PUBLIC HEALTH INTERVENTIONS

Production of MCMs typically requires large R&D investments. However, the market size for MCMs tends to be unclear due to uncertainties about the spread of infection (with regards to infectious diseases), supply chains, affordability (especially in lower-income countries), and others. To address these market failures, market-shaping interventions are needed to reduce risks for suppliers and purchasers and to align supply and demand.^{29,30} Market shaping is important at the early stages of R&D and manufacturing. The German G7 Presidency in 2022 called on Gavi to present a Market Shaping Strategy to support sustainable local and regional vaccine production, particularly in Africa.³¹ Diversifying and expanding vaccine manufacturing in emerging and low-income economies to increase global vaccine supply security is crucial to prepare for the next pandemic. From the standpoint of public health interventions, life-course immunization is important in the context of healthy aging.³² Simultaneously, life-course immunization also contributes to shaping a stable vaccine market. Market shaping of diagnostics and therapeutics is also important. For example, antigen rapid diagnostic test kits can be useful tools for testing outside of a health facility, such as self-tests or community-based tests. Expanding testing outside of

⁸ One Health: a collaborative, multisectoral, and transdisciplinary approach—working at the local, regional, national, and global levels—with the goal of achieving optimal health outcomes recognizing the interconnection between people, animals, plants, and their shared environment.

health facilities can contribute to wider test coverage with lower costs and potential market shaping at the same time.³³ The G7 should promote these public health interventions, which can also contribute to sustainable market-shaping efforts, leveraging existing strategies and tools from global health organizations while stimulating further R&D efforts for MCMs.

DEVELOP REGIONAL PRE-NEGOTIATED COLLECTIVE PROCUREMENT SYSTEMS FOR LMICs

Regional bodies, such as HERA or the African Vaccine Acquisition Trust, have tried to secure sufficient MCMs for their regions to address the COVID-19 pandemic. Initially, COVAX was established as a global collective procurement system with an ambitious goal and scope, but its ability to play that role was restricted by various external factors, including funding shortages from day-zero, undersupply of vaccines as a result of export bans, and vaccine nationalism, to name a few.^{12,34} Hence, regional pre-negotiated collective procurement systems for LMICs should be developed that are complementary to the multilateral procurement system led by experienced current pooled procurement agencies in order to diversify manufacturing and procurement capacities. Regional bodies should be strengthened to play a more proactive role as regional hubs in implementing each element of the MCM value chain. However, while this type of regional collaboration is useful, it may have limitations when faced with global undersupply, especially in emergency phases. Hence, resource mapping of ingredients/raw materials and mutual coordination in trade during non-pandemic/inter-crisis periods is also critical in order to prepare for excessive demand in an emergency phase.

ENSURE UNRESTRICTED TRADE FOR MCMs

Based on global resource mapping, materials required to manufacture MCMs must be mobilized promptly without any trade barriers. The G7 should also consider supporting the establishment of mechanisms to ensure unrestricted trade in pandemic products and their ingredients/raw materials as prerequisites of R&D and manufacturing of MCMs, but not at the expense of each country's/region's action to protect the right to health of its people. The G7 can encourage further discussion to explore better trade policies involving multiple stakeholders, including the World Trade Organization and the WHO.³⁵

PROMOTE REGULATORY ALIGNMENT AND STRENGTHEN CLINICAL TRIAL PLATFORMS WITH LMICs

The G7 should support the development of adaptive clinical trial platforms³⁶ involving LMICs and involve LMIC regulators in discussions to support them in achieving the maturity level 3 standards for their own MCM candidates. The inclusion of LMICs embeds an access lens into the R&D process. This includes the generation of clinical data and medical evidence to guide the use of MCMs in affected populations in LMICs. Additionally, this inclusion satisfies the ethical imperative to provide benefits back to the LMIC participants/communities involved in the clinical trials, especially in accordance with the World Medical Association (WMA) Declaration of Helsinki.³⁷ To better prepare for the next pandemic and tackle existing health threats, it is crucial

to strengthen clinical trial infrastructure, networks, and human resources. The dual-purpose potential of clinical trial infrastructure should also be explored and leveraged for R&D funding. For example, the utilization of R&D infrastructure based in LMICs for existing health threats (e.g., the PANdemic preparedness plATform for Health and Emerging infections Response [PANTHER], regional and global clinical trial networks to address AMR, etc.) during inter-crisis periods can contribute to capacity development for R&D and the strengthening of clinical trial networking in LMICs based on the LMIC's own needs.³⁸

The International Coalition of Medicines Regulatory Authorities should play a more significant role in driving global alignment and accelerating R&D, such as driving the global R&D agenda for the global priority pathogens (e.g., virus families, fungi, etc.), as mentioned in Recommendation 2-1.³⁹ This would support the necessary technical assistance for inspections or complex adaptive clinical trial designs and actively explore rapid methods to accelerate clinical trials, such as master protocols and platform trials. The G7 can call on its members' R&D funders and regulators to agree on a detailed collaboration plan for facilitating R&D, clinical trials, and approval processes for MCMs.

2-3. Promote equitable access to MCMs

INCORPORATING A UHC PERSPECTIVE INTO THE R&D ECOSYSTEM TO ENSURE EQUITABLE ACCESS

It is crucial to incorporate UHC perspectives into the R&D ecosystem in order to address the global inequity in access to MCMs during pandemics. The phrase “from lab to jab” symbolizes that MCMs can only fulfill their objectives if they reach the people who need them, i.e., with “shots in arms.”⁴⁰ Therefore, the 100DM PLUS initiatives should adopt an “end-to-end” approach that includes access considerations in the very early stages of R&D.¹⁴ Developing access conditions or commitments in R&D funding and procurement agreements, as well as adopting common principles, norms, and policies to plan for access during the R&D process, can ensure effective integration of access considerations. The G7 can encourage businesses and research institutions to design accessibility into their proposals for public R&D funding, fostering partnerships with nonprofit organizations that have contributed to market-shaping, introduction, and scale-up of affordable quality-assured products in LMICs. Major R&D funders should prioritize shaping flexible target product profiles, even in low-resource settings, and patient-friendly, such as thermostable vaccines, orally active therapeutic drugs, and child-friendly formulations and dosing. When considering this point, the Access to Medicine Index can be a useful analytic tool providing comprehensive analysis to assess accessibility, including availability, affordability, and supply.⁴¹ For accessibility-oriented R&D funding, the funding partnership model between public and nonprofit organizations should be developed based on principles of transparency and accountability by all parties to one another and, when funding is from public sources, to the taxpayers or the citizens of the donor countries.

The Biotechnology Innovation Organization (BIO), Developing Countries Vaccine Manufacturers' Network, and the International Federation of Pharmaceutical Manufacturers and

Associations adopted the Berlin Declaration in July 2022, demonstrating the industry's commitment to the timely production of and equitable access to MCMs for priority groups (e.g., healthcare workers and high-risk individuals), especially in LMICs.⁴² Although this is very promising, several CSOs do not support the declaration as a way to achieve truly equitable access to MCMs.^{43,44} Further dialogues among the stakeholders are required to develop a shared vision for promoting equitable access.

EXPLORE INNOVATIVE WAYS TO MANAGE INTELLECTUAL PROPERTY RIGHTS TO ENSURE INNOVATION AND EQUITABLE ACCESS

Intellectual property rights (IPR) incentivize the development of new knowledge and technologies.⁴⁵ Therefore, if public funds finance R&D to mitigate risk, the public sector that provided the funding at its own risk should receive due consideration both in terms of pricing and access. This ensures that public interest is adequately addressed once the final product becomes available. To make actionable norms for equitable access, the G7 can develop a common access framework for public R&D funding that stipulates best practices for public access requirements for the resulting products. Supporting open innovation approaches to knowledge sharing will enhance the effectiveness of R&D and ensure the affordability, accessibility, and availability of resulting health tools rather than inhibiting innovation.⁴⁶

Without financial risk-taking and access, innovation is impossible or meaningless. The G7 should engage with the private sector to ensure a coherent balance between risk remuneration and expedited market access conditions provided by public intervention, in addition to access strategies (e.g., tiered pricing, voluntary licenses, donations, etc.) that are in place for products that have been developed with significant public funding. Various alternative methods have been discussed to overcome barriers to access to essential MCMs.^{47,48} To implement the World Health Assembly resolution 72.8 (2019), the G7 should call on diverse stakeholders to accelerate discussions and explore innovative alternative incentive mechanisms that can overcome the barriers created by traditional IPR.⁴⁹

EXPAND TECHNOLOGY TRANSFER AND MANUFACTURING CAPACITIES IN LMICs

Technology transfer and capacity-building in LMICs should be expanded to increase long-term sustainable global innovation and manufacturing capacity and diversify manufacturing platforms (e.g., geo-diversification and supply chain diversification). This will be achieved by promoting an enabling environment for voluntary partnerships across the private, public, and academic sectors, as well as for voluntary technology transfer utilizing various mechanisms such as the Medicines Patent Pool (MPP), the WHO Technology Access Pool (C-TAP), the WHO mRNA Vaccine Technology Transfer Hub, joint ventures, nonprofit partnerships such as Drugs for Neglected Diseases Initiative, and others.

Given the limited resources and materials, this technology transfer should target manufacturing and be carefully planned, based on an access and sustainability lens, to generate synergy by enhancing the MCM supply chain management capacity in LMICs. Notably, these voluntary

licensing schemes should be promoted in the early stage of R&D, at the latest by Phase 2 clinical trials, to ensure more efficient and faster development and manufacturing of MCMs.

The G7 also needs to stimulate discussions on improving the MPP mechanism, examine how to further promote equitable pricing and nonexclusive voluntary licensing, and incentivize knowledge sharing. Knowledge sharing through C-TAP was insufficient due to an absence of incentives. For example, middle-income countries have been excluded from access to generic oral antivirals through the MPP despite COVID-19's enormous impact on those countries.⁵⁰ The MPP mechanism should be improved to expand access to generic drugs in middle-income countries.

An end-to-end approach also necessitates implementing access and delivery strategies at national and regional levels. The G7 should recognize the importance of end-to-end approaches that connect R&D investments with access strategies (e.g., the GHIT Fund-UNDP/Access and Delivery Partnership, which links R&D with enhanced health systems capacities) for access preparedness at the national and regional level. This includes national capacities to select, approve, procure, and deliver health technologies.

SHARE A BROAD RANGE OF TECHNOLOGIES/KNOWLEDGE REQUIRED FOR MCM R&D

Along with manufacturing technologies, other related technologies and knowledge necessary for MCM R&D and production should be shared proactively. First, to conduct efficient clinical trials, various human resources are required. For example, research nurses in National Health Service facilities in England contributed to the effective recruitment of participants for the RECOVERY (Randomised Evaluation of COVID-19 Therapy) trial.⁵¹ Second, to set up appropriate manufacturing, it is essential to have specialists in developing antibodies, vaccines, and other biologics, as well as knowledge about good manufacturing practices. In addition, traditional pharmaceutical companies and other emerging actors have essential roles to play. For example, small biotech ventures contributed to developing a variety of novel seeds financially supported by venture capital. In addition, the modularization of the MCM value chain by contract manufacturing organizations and contract development manufacturing organizations contributed to accelerating MCM supply. This support for technology transfer can also generate positive spillover effects on the economic environment in LMICs.

2-4. Promote an “always-on” approach

PROMOTE DUAL-PURPOSE TECHNOLOGIES FOR CRISIS AND INTER-CRISIS PHASES

Infrastructure and workforce in R&D need to be strengthened to ensure surge capacity that can respond to existing health threats and future pandemics. To guarantee the readiness of these areas during inter-crisis periods—i.e., an “always-on” approach—it is essential to promote the dual use of technologies to respond to health emergencies. Dual-purpose technologies are expected to promote synergy and coordination of R&D for PPR and fight against existing health threats

such as high-impact infectious diseases such as tuberculosis, HIV/AIDS, NTDs, hepatitis, waterborne diseases, re-emerging infectious diseases, and AMR diseases.

Transitioning from a non-pandemic/inter-crisis period to a pandemic/crisis period is challenging for the pharmaceutical industry and the health sector. It requires coordinated efforts from multiple sectors, including start-up companies, venture capital firms, and nonprofit entities. The G7 should agree on the necessity of developing supportive policies to promote the dual purpose of technologies and human networks and explore a new approach to de-risk the transition.

As seen in the example of the innovative dual-purpose diagnostic systems for tuberculosis and COVID-19, building surge capacities on the back of PHC and disease interventions will be more cost-effective and sustainable.⁵² R&D that utilizes these existing tools and pursues solutions for multiple health threats should be further supported. For example, investments in COVID-19 tests resulted in the advancement of point-of-care (POC) diagnostics. FIND and Unitaid grants have improved access to tuberculosis diagnostics, including POC diagnostics technologies. The G7 should recognize those synergy-generating examples and support innovative R&D across diagnostics, therapeutics, and vaccines.⁵³

PROMOTE THE USE OF EXISTING MECHANISMS AND INITIATIVES TO ENSURE EQUITABLE ACCESS AND DELIVERY

While ACT-A has contributed to promoting timely and equitable access to MCMs globally, improvements are required. The G7 should recognize global partnerships and foundations such as Unitaid, the Global Fund, WHO, Gavi, FIND, Bill & Melinda Gates Foundation, and Clinton Health Access Initiative. These all played a catalytic role in expediting the market introduction, manufacturing, and procurement of countermeasures for COVID-19 and underlined the importance of their partnership and cooperation.

Existing mechanisms created for other infectious diseases can be utilized to improve procurement and delivery. For example, the Gavi Advanced Market Commitment (AMC) financing instrument, originally designed for equitable access to pneumococcal vaccines, contributed to equal access to COVID-19 vaccines in low-income countries. The Global Fund's existing grant-making process and procurement channels were utilized to procure and deliver diagnostics, treatments, and personal protective equipment (PPE) for COVID-19 and mobilize health workers at the community level. Although these mechanisms were initially developed for equitable access and delivery of MCMs for existing diseases other than COVID-19, they can be utilized to address various persistent health threats, including malaria, tuberculosis, HIV/AIDS, NTDs, COVID-19, AMR, and others. The G7 should promote resource and capability mapping of the existing mechanisms to accelerate immediate action against these health threats.

PROMOTE OPERATIONAL READINESS

To ensure preparedness during inter-crisis periods, it is crucial to maintain the MCM value chain "always on" in the "end-to-end" approach. This involves promoting dual purpose and sustainable R&D and ensuring the availability of elements of health system strengthening and UHC, especially downstream of the value chain. The G7 should support efforts to specify and conceptualize

a package of investments needed for “operational readiness” for public health emergencies. For example, components such as maintaining stockpiles of PPE, mobile refrigeration systems, safe injection equipment, and medical oxygen are not typically part of standard UHC schemes and systems. G7 countries should work closely with partners such as the WHO, regional bodies, and national health authorities to determine the key components and resources required to secure them worldwide.

2-5. Launch a globally inclusive “access initiative” to link R&D with delivery and access

The G7 should launch an “access initiative” that facilitates discussions on how to link accelerated R&D with timely delivery and equitable access to MCMs, including financing arrangements and the formalizing of delivery partnerships. This initiative must be inclusive, engaging international organizations, industry, academia, the Global South, and CSOs, and be done in close alignment with the G20 and other partners.⁵⁴ To emphasize the appropriate stakeholder access lens in the R&D ecosystem, the Global South and nonstate actors, including NGOs and CSOs, should be substantively involved in the global discussion of the 100DM. The G7 can consider establishing a Task Force that includes LMICs and NGOs/CSOs to address the procurement and delivery of MCMs in LMICs.

RECOMMENDATION 3. Promote multilayered global health governance to facilitate effective collaboration among state and nonstate actors at the global and regional level

3-1. Ensure global solidarity in terms of norm-setting, financing, and governance

ESTABLISH A GLOBAL AGREEMENT ON NORMS FOR PPR

In light of the various issues revealed by the COVID-19 pandemic, member countries of the Pandemic Treaty Intergovernmental Negotiating Body (INB) should clarify norms related to UHC, One Health, equity, and inclusiveness, and should work to build consensus among relevant parties. Within the global consensus-building process, the G7 should agree on the importance of the following norms in negotiations on the WHO accord on PPR and the International Health Regulations (IHR) amendment.

The first norm to be emphasized is UHC. Recognizing that PPR is an integral part of essential health systems, the G7 should agree on the necessity of linking PPR strengthening to global UHC efforts with an emphasis on strong PHC. In addition, they should facilitate interaction among the High-Level UN meetings on UHC, PPR, and tuberculosis.

The second norm to be emphasized is the concept of One Health and the related concept of Planetary Health.^h COVID-19 was originally an infectious disease of animal origin that spread to humans. The importance of a perspective that captures animal, environmental, and human health in one dimension should be reaffirmed to prevent the next pandemic. It is critical to emphasize early detection and rapid sharing of pathogens and genetic sequence data under health emergencies as part of the norm-setting of One Health as the foundation for response in all stages of PPR, including surveillance, vaccines, and drug development. In addition, climate change has increased the fragility of the global systems that health depends on, including the food system.⁵⁵ Cross-disciplinary measures from the perspective of planetary health are therefore necessary.

The third norm to be emphasized is equity and inclusiveness. The preamble to the WHO Constitution states that “unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger.”⁵⁶ Despite this statement, the pandemic has created significant disparities, particularly in access to diagnosis, treatment, vaccines, and other medical equipment. It has also demonstrated that the fates of high-income countries and LMICs are intertwined and starkly inequitable. Transnational infectious diseases need to be addressed globally, and the G7 should commit to ensuring equitable access, equity, and inclusiveness in the decision-making process.

EXPLORE INNOVATIVE WAYS TO SECURE SUSTAINABLE FUNDING FOR PPR, INCLUDING SURGE FINANCING

Considering the increased need for investments in PPR capacity, resource mobilization through organized financing measures before and during pandemics is essential. As mentioned in recommendation 1-3, mobilizing more domestic resources for health, including PPR, and strengthening collaboration between finance and health ministries is crucial. External assistance should be provided based on a long-term vision for sustainable health financing, with enhanced accountability and transparency through social participation and strengthening CSOs. However, existing global funding mechanisms, such as the Global Fund, Gavi, and the Pandemic Fund, should fill the gap. We propose conducting a gap analysis of the global health architecture and improving resource allocation under the finance and health coordination arrangement, leveraging financial innovations to catalyze resources from the private sector and capital markets. Diversifying sources and ownership of global public funding for health through the Global Public Investment initiative is also advised.

To respond to pandemics, the G7 should create an enabling environment for LMICs to mobilize resources through MDB loans and capital markets without increasing fiscal pressure. Other methods include improved insurance schemes based on lessons from the Pandemic Emergency Financing Facility and contingency or pooled funds, like the WHO Contingency Fund for Emergencies. Strengthening surge financing mechanisms for rapid, large-scale funding disbursement

^h Planetary Health: recognizes that human health and the health of our planet are inextricably linked, and that our civilization depends on human health, flourishing natural systems, and the wise stewardship of natural resources. With natural systems being degraded to an extent unprecedented in human history, both our health and that of our planet are in peril.

after an outbreak is essential for appropriate response measures, including ensuring equitable distribution of vaccines and medicines, mitigating associated social and economic impacts, and accelerating the R&D of MCMs.

SUPPORT THE CREATION OF A HIGH-LEVEL GOVERNANCE MECHANISM TO ADDRESS MULTIFACETED THREATS TO HEALTH

Given the growing need to systematically address health, climate change, and other global challenges, a governance mechanism engaging state and nonstate actors at all levels is crucial. The magnitude of the problem and the variety of pandemic-related issues necessitate effective intervention against health threats through coordinated governance systems. The G7 can affirm its support for creating a high-level governance mechanism engaging political leaders to address global health threats to give impetus to productive discussions toward the United Nations High-Level Meetings on UHC, PPR, and tuberculosis. The WHO should play a significant role, but collaboration with other UN agencies, international organizations and initiatives, MDBs, the private sector, CSOs, and academia is vital for a multisectoral and inclusive response. MDBs will play a particularly critical role in mobilizing the financial resources for implementing the decisions made through this high-level governance mechanism.

DEVELOP A STANDARDIZED, INTEROPERABLE DIGITAL PLATFORM

To facilitate global collaboration and coordination, standardized and interoperable data systems and processes at the regional level are essential. Establishing a web-based, standardized, interoperable national digital platform—one that is gender-sensitive as well—for healthcare information and creating a robust legal framework for the cross-border use of personal health records should be prioritized. The G7 should promote international discussions on rules-based criteria for cross-border healthcare data use, especially regarding handling personal health information for public interest purposes during pandemics, following the European Data Act and the proposed European Health Data Space.

3-2. Strengthen regional hubs for PPR as a regional security strategy

SUPPORT REGIONAL INITIATIVES AND BOLSTER REGIONAL HUBS FOR TAILORED RESPONSES

Based on the lessons learned from ACT-A, global coordination for a pandemic response should be enhanced by strengthening connections with existing regional organizations. Despite COVID-19 being a pandemic, its prevalence and impact differ across regions, as does the ability to respond to it and other diseases. Efforts such as establishing regional Centers for Disease Control and Prevention (CDCs) are being reinforced. We urge the G7 to assist regional leaders in developing support ecosystems and achieving their regional health-related targets. To improve regional capacity across all domains, the G7 should also collaborate with regional and subregional actors (e.g., the East, Central and Southern Africa Health Community [ECSA-HC],

Africa CDC, ASEAN Centre for Public Health Emergencies and Emerging Diseases [ACPHEED], and the Pan-American Health Organization [PAHO]) to improve regional capacity across all domains. This is particularly crucial for MCM manufacturing, distribution, and surveillance capacity. The role and coverage areas of ACPHEED, established in November 2022, should be meticulously planned to ensure efficiency and avoid duplication and fragmentation. Collaboration with regional and international MDBs is vital for capacity development, especially for this newly launched hub.

To prevent regional efforts from causing excessive decentralization of governance, the G7 should foster global solidarity, ensuring consistency among global, regional, national, and local initiatives by strengthening the WHO's role as a global norm setter. The G7 should improve coordination among public health leaders to ensure agile and coordinated responses to health emergencies and enhance harmonization of emergency response capabilities and preparedness standards. Continuous improvements in coordinating inter- and intra-regional bodies are essential to minimize duplicative efforts and fragmentation and to ensure long-term sustainability.

ENHANCING REGIONAL SURVEILLANCE CAPACITY AS A COMPONENT OF NATIONAL SECURITY

Several WHO-led surveillance initiatives exist, such as the WHO Hub for Pandemic and Epidemic Intelligence, the WHO BioHub System, and the Global Influenza Surveillance and Response System (GISRS+). The WHO should play a central role in fortifying the global network and collaborating for integrated surveillance among these mechanisms. Additionally, building regional hub capacity is critical. The US CDC, European CDC, Africa CDC, ECSA-HC, and ACPHEED should enhance collaboration with WHO-led mechanisms. The G7 can explore utilizing regional biosafety level 4 or 3 (BSL-4 or -3) facilities to strengthen surveillance systems and R&D capacities by collaborating with regional biosafety and biosecurity. The G7 countries can support developing and implementing regional surveillance and R&D capacity plans as part of their national health and security strategies.

ADOPT A FLEXIBLE APPROACH TO MCMs TO ADDRESS REGIONAL NEEDS

Demand for MCMs varies significantly. Regional bodies should proactively enhance R&D, joint clinical trials, pharmacovigilance, manufacturing, procurement, and distribution. G7 countries, leveraging research facilities with advanced BSL ratings, can establish research networks with neighboring countries and, ultimately, with worldwide research facilities, aiming to create a global research network.

One lesson from the ACT-A experience is the need for greater flexibility and coordination regarding structure and countries. Consequently, the G7, in close collaboration with the G20, should promote a multilayered coordination platform with global equity at its core that is better suited for responding to future pandemics. Global, regional, and national MCM responses are all needed, but not at the expense of global capabilities for effective epidemic and outbreak preparedness. The G7 should communicate this message clearly and recognize this approach as a standard policy in all its engagements with PPR.

3-3. Promote a multisectoral approach to comprehensive and interdisciplinary health solutions

EXPLORE CONCRETE ACTIONS FOR MULTISECTORAL APPROACHES

The G7 should explore concrete actions for addressing comprehensive and interdisciplinary aspects of health, such as One Health and Planetary Health, and preparing and organizing a dialogue platform, whether formal or informal, between various relevant actors is essential for achieving this. Given the connections between food security, nutrition, warfare, urbanization, and health threats, we propose the active adoption of a multisectoral approach—involving states, international organizations, the private sector, and CSOs—working collaboratively for efficient and accountable solutions.

STRENGTHEN HEALTH SECTOR EFFORTS TO ADDRESS CLIMATE CHANGE

Climate change increases the vulnerability of the global systems on which health depends.⁵⁷ The G7 should strengthen its commitment to climate-resilient and low-carbon health systems, as advocated in the Conference of Parties (COP26).⁵⁸ To enhance health system resilience against climate change, the G7 countries and their respective public health institutes can leverage networks, such as the International Association of National Public Health Institutes (IANPHI), which has published a roadmap for action on health and climate change, to advance health sector climate adaptation and mitigation.

ADDRESS INTERCONNECTIONS BETWEEN HUMAN, ANIMAL, PLANT, AND ENVIRONMENTAL HEALTH

To address the interconnections between human, animal, plant, and environmental health, the G7 can establish a One Health track to monitor and promote multisectoral collaboration under the One Health Joint Plan of Action. It is essential to integrate various testing modalities (including genomic analysis) of AMR, tuberculosis, HIV, vaccine-preventable diseases, emerging infectious diseases, zoonoses, and other public health concerns when strengthening collaborative surveillance systems through the One Health approach. Information management should stress interoperability to facilitate global coordination of infectious disease control, including pandemics, by promoting digital transformation for data sharing.

ENHANCE INCLUSIVENESS AND EQUITY IN HEALTH GOVERNANCE

The G7 should reaffirm its commitment to enhanced inclusiveness and equity in health governance mechanisms, particularly for increasing engagement of governments representing LMICs, regional organizations representing governments across the Global South and nonstate actors, including CSOs, diverse and vulnerable communities, the private sector, and other funding sources. We propose rebalancing public and private stakeholders to ensure fair decision-making processes support equitable access to quality health services. The G7 can further engage the Global South and nonstate actors in discussions and implementation of the 100DM and the Pact, leading to their incorporation into the WHO's INB discussions. To sustain the global

commitment to PPR, countries must protect everyone, everywhere, from both the deadliest existing diseases and future unknown pathogens.

The G7 should promote public-private partnerships, reflecting the private sector's increasing importance in global health strategies, and ensure ongoing discussions after formulating those strategies. The "access initiative" proposed in Recommendation 2-5 should engage LMICs, industry, and NGOs/CSOs to address timely and equitable procurement and delivery of MCMs in LMICs.

Conclusion

The selection of Hiroshima and Nagasaki as the venues for the G7 Summit and Health Ministers' Meeting expresses Japan's commitment to peace and human security, and these meetings will likely deliver commitments leading to a more peaceful future. The Task Force believes that the G7 should affirm that the promotion of health and wellbeing under any condition, including conflicts, is an inalienable human right. We also believe that investments in health can lead to more peaceful, prosperous, and stable societies, given UHC's vital role as a safety net, and the role of health as a source of productivity.

The year 2023 represents a critical juncture for developing a global system that can respond effectively to future health emergencies. The Task Force hopes that Japan's 2023 G7 presidency will provide a driving force for fully implementing the G7's past commitments on PPR and for catalyzing collective action by a broad and inclusive range of stakeholders to make our world more resilient to future health emergencies.

✧ The views expressed here are solely those of the G7 Hiroshima Global Health Task Force members based on literature reviews and input from international advisors and other informants.

Appendix 1. About the Task Force and Organizers

Hiroshima G7 Global Health Task Force

In light of Japan's presidency of the G7 Summit in 2023, the Hiroshima G7 Global Health Task Force was established in July 2022 under the Executive Committee on Global Health and Human Security—a public-private policy platform on global health chaired by Keizo Takemi, Member of the House of Councillors, and directed by Akio Okawara, President & CEO of the Japan Center for International Exchange (JCIE).ⁱ The objective of the Task Force was to serve as a platform for Japan to exercise effective leadership toward the 2023 G7 Summit by leveraging international networks across various sectors, including the political, governmental, academic, and private sectors. JCIE managed this Task Force under a grant from the Bill & Melinda Gates Foundation. The Task Force worked through close collaboration with research contributing to global health policy supporting Japan's effective presence at the 2023 G7 health-related meeting and responding to pressing issues funded by the Ministry of Health, Labour and Welfare Research Grant.

The Task Force established working groups in Japan on UHC, the 100 Days Mission Plus, and the global health architecture, with relevant experts selected for each topic. Working groups were convened to discuss challenges and formulate recommendations. Additionally, key global health experts were asked to serve as domestic and international advisors and provide input through a series of consultations and hearings in the last quarter of 2022 and the first quarter of 2023. The Task Force is grateful to the many experts who offered comments and insights throughout this process. For a full list of those who contributed to these recommendations, please visit our website at <https://bit.ly/g7-global-health-task-force>.

Executive Committee on Global Health and Human Security

The Executive Committee on Global Health and Human Security is a high-level, public-private platform that facilitates the Japanese government's policymaking on global health and public-private collaboration in that field. Under the chairmanship of Professor Keizo Takemi, the committee holds quarterly meetings to provide a venue for unofficial exchanges of views and information-sharing among senior representatives from government ministries, academia, private companies, and CSOs in Japan. Relevant global health experts are invited to speak at the meetings to offer their knowledge and advice. The committee is an integral part of JCIE's Global Health and Human Security Program, which manages all aspects of the committee's work.

ⁱ Mr. Okawara served as president and CEO through March 31, 2023.

Japan Center for International Exchange (JCIE)

Founded in 1970, JCIE is one of Japan's leading foreign policy institutes. Consisting of partner organizations in Tokyo and New York, it organizes legislative exchanges and policy dialogues that bring together key figures from diverse sectors of society, both in Japan and overseas. During the 1990s, it played a leading role in encouraging the adoption of human security as a pillar of Japanese foreign policy, leading to the launch of a series of major initiatives on global health. The Friends of the Global Fund, Japan, was created in 2004, the Global Health and Human Security program in 2008, and the Healthy and Active Aging in Asia program in 2017 to strengthen public-private partnerships and Japan's role in global health.

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Appendix 2. Major global health challenges

The following represents the analysis of the three global health challenges identified by the Task Force. As the recommendations listed in this report are interlinked and overlapping, they have been synthesized, rather than aligned, with each specifically identified challenge below. The Task Force performed a prioritization exercise, asking each member to rate the recommendations on a three-point scale considering impact, feasibility, and timeliness. Based on these results and subsequent discussions with working group leaders, the recommendations were further organized into the final form presented above.

1. UHC

CHALLENGE 1-A: FALSE DICHOTOMY BETWEEN HEALTH SECURITY AND UHC

A 2021 WHO survey found that about 90% of the 126 countries analyzed experienced disruptions in essential health services during the COVID-19 pandemic.⁵⁹ Immunization rates for diphtheria, measles, polio, and other communicable diseases declined in many LMICs.^{60,61,62} Diagnosis and treatment of tuberculosis, which was the deadliest infectious disease until 2020, also suffered significant disruptions.

Fewer than half of the world's countries incorporated the maintenance of essential health services in their national COVID-19 strategic plans.⁶³ Treating health security and UHC strategy independently can lead to policy decisions that only invest in one or the other. This false dichotomy overlooks the interconnectedness of the two and the central role of health systems in achieving UHC that is resilient to health emergencies. In order to bridge health security and UHC, it is critical to focus on PHC as a common foundation. Strengthening PHC is crucial for crisis prevention, epidemic surveillance, preparedness, and response. It supports vital health system functions like well-trained frontline community health workers, interoperable data systems, accessible health infrastructures, water and sanitation, and reliable health-related supply chains.^{64,65}

Countries that reported progress in the UHC monitoring indicators jointly developed by the WHO and the World Bank did not necessarily minimize the health consequences of the COVID-19 pandemic.⁶⁶ This suggests that the WHO's current UHC monitoring indicators do not reflect the capacities needed to effectively prevent and respond to health emergencies, such as pandemics.

CHALLENGE 1-B. NEED FOR IMPROVED COLLABORATIVE SURVEILLANCE AND PUBLIC HEALTH LEADERSHIP COORDINATION

The capacity of early detection and warning systems and networking for data sharing was insufficient to prevent the further spread of COVID-19. The Pact emphasized the importance of strengthening integrated, interoperable, and interdisciplinary cross-sector surveillance capabilities and capacities, following the One Health approach to increase system resilience to epidemics. In LMICs, the surveillance workforce primarily relies on PHC workers, such as community health workers. Capacity building based on a coordinated strategy across various disciplines,

including epidemiologists and laboratory personnel, is necessary to strengthen surveillance mechanisms and ensure the functionality of intelligence functions. This approach helps avoid siloed thinking and enhances effective and comprehensive PHC services supported by accurate epidemiological information. Goals should include improved access to and quality of healthcare services while building surge capacity based on routine PHC and disease interventions. This involves increasing human resources for health, adequate test coverage on the frontline, accurate and speedy laboratory diagnostics, faster digital transformation for data sharing, and more efficient utilization of data and biosamples for R&D.

At the global level, multiple ongoing efforts exist to strengthen surveillance systems and biosafety intelligence functions, such as the WHO Hub for Pandemic and Epidemic Intelligence in Berlin, Germany, the WHO BioHub System, and the GISRS+. ^{67,68,69,70} However, the concrete linkages and modes of collaboration among these WHO mechanisms remain unclear.

CHALLENGE 1-C: GLOBAL CRISIS OF NONCOMMUNICABLE DISEASES AND THE FAILURE OF PUBLIC HEALTH TO ADDRESS THE RISK FACTORS

The COVID-19 pandemic is a "syndemic," as it interacts with a worldwide NCD epidemic in the context of steep inequalities. ⁷¹ NCDs increase the risk of hospitalization or death from COVID-19, demonstrating the failure of health systems to cope with the risk factors related to the increased disease burden of major chronic diseases. This failure has resulted in vulnerable populations and increased the pandemic's health burden. ⁷² Further, chronic diseases are a consequence of the lack of UHC. COVID-19 starkly demonstrated that underserved populations had higher rates of chronic disease and a higher risk of sickness and death in countries of all economic status.

The lack of progress worldwide in building health systems and intervention approaches that can respond flexibly to changes in disease structure, including the increased disease burden of NCDs and secular demographic changes such as population aging and declining fertility, is concerning. ^{73,74} Accurate information to discuss healthcare demands and resource availability, such as disease prevalence, treatments, and access to healthcare, is inadequate in many countries. ⁷⁵ In addition, the distribution of health financing from domestic sources and donor countries does not always sufficiently consider increasing health threats coming on top of existing epidemics. For example, NCDs currently account for 33.9% of the disease burden (measured in disability adjusted life years [DALYs]) in low-income countries and 55.2% in lower-middle-income countries in 2019. However, only about 2% of health sector ODA from major donor countries (including both bilateral and multilateral aid) goes toward addressing NCDs. ^{76,77} Health sector ODA needs to be responsive to epidemiological and demographic changes and encourage investments in preventative measures to address risk factors.

CHALLENGE 1-D: INSUFFICIENT BASIC INFRASTRUCTURE DEVELOPMENT FOR HEALTHCARE FACILITIES

The infrastructure of healthcare facilities is critical for quality care and protection of healthcare workers, particularly during emergencies. The functions of these facilities rely on resources such as electricity, water and sanitation, and oxygen. However, the situation is serious globally: 11%

of healthcare facilities have no water, and 11% have limited water services, leaving 1.7 billion people to receive care in facilities without water. Additionally, in 2021, 10% of healthcare facilities had no sanitation services at all, and many had no electricity.^{78,79}

When infrastructure is strengthened, consideration should be given to reducing greenhouse gas emissions, proper waste management, and improved resilience to extreme weather events. At the same time, bringing health services closer to where they are needed can contribute to decarbonizing the health system. The mitigation of and adaptation to climate change is an obligation for all sectors. Though the health sector is responsible for an average of 4.4–4.6% of worldwide emissions, efforts to reduce greenhouse gas emissions in the healthcare sector are still in their infancy.⁸⁰ The G7 needs to commit to climate-resilient and low-carbon health systems, as advocated in the COP26.

CHALLENGE 1-E: UNEQUAL PANDEMIC IMPACT AND INADEQUATE SOCIAL SECURITY LEAVING THE VULNERABLE BEHIND

The COVID-19 pandemic has had an extremely unequal impact on countries worldwide, both within and between nations. Vulnerable populations, including people living in poverty, older persons, persons with disabilities, youth, indigenous peoples, refugees, and women and children (especially girls), have experienced particularly severe effects, including high infection rates, fatality, and mortality.⁸¹

Vulnerable groups face financial barriers to accessing high-quality healthcare due to job loss and reduced income due to the pandemic. Additionally, they could not practice basic sanitization in environments with limited access to safe water and sanitation. Access to nutritious food was also difficult to achieve. Furthermore, social security safety nets, including social welfare and livelihood protection, were not adequately developed to address the social determinants of health. Legal barriers, stigma, and discrimination also hindered certain groups' access to social services and healthcare.

CHALLENGE 1-F: NEED TO PROTECT GAINS IN GENDER EQUALITY OVER THE PAST DECADES

While the COVID-19 outbreak affected all members of society, women and girls bore the brunt of the pandemic's impact, pushing them out of employment and reversing decades of progress in their participation in the labor force. The loss of jobs, especially in sectors where women dominate, including the informal economy, and the increase in unpaid work have had a significant impact. Women and girls have reported reduced access to sexual and reproductive health services, increasing the risk of unwanted pregnancies, sexually transmitted diseases, and complications during pregnancies, delivery, and abortion. Violence against women and girls has risen rapidly during the pandemic, with some countries reporting a 33% increase in intimate partner violence due to movement restrictions.⁸²

CHALLENGE 1-G: NEED TO EXPLOIT THE BENEFITS OF DIGITAL HEALTH TECHNOLOGIES

During the COVID-19 pandemic, numerous innovative digital health technologies were developed to share timely and high-quality information with professionals and policymakers and to provide a wide range of services to the public. Extensive testing and timely diagnosis are essential for pandemic control and preparedness. Health information management systems, digital platforms, and technologies such as online screening, self-testing and treatment adherence facilitation, telemedicine, and sharing information on prevention, infection cases, and treatment via social media and messenger apps have demonstrated their potential to enhance countries' ability to monitor the epidemic's evolution and mount an effective response, despite resource shortages.

However, there has been mixed success with these digital health technologies due to data collection challenges such as non-electronic and non-standardized data collection, lack of a legal basis for data sharing, and challenges in ensuring data transaction reliability, trustworthiness, and authenticity. This has created knowledge gaps and reduced the potential of these data and technologies.⁸³ Incomplete implementation of data standardization delays the reporting of case information and laboratory results and limits the integration of public health data with clinical treatment and demographic information, further delaying policy responses.⁸⁴ This is also critical for the agile initiation of R&D on MCMs. The digital divide is another issue that must be addressed. Therefore, the rollout and scale-up of these technologies must be done through a rights-based approach, with digital literacy programs implemented alongside them.

2. Innovative R&D, access, and delivery with a focus on the 100DM

CHALLENGE 2-A. INSUFFICIENT GLOBAL COORDINATION AMONG R&D SYSTEMS FOR MCMs

Global coordination for R&D is a part of ACT-A's mandate. Due in part to ACT-A's efforts, vaccines, diagnostic tools, and therapeutics for COVID-19 treatment have been developed at an unprecedented speed. However, the external evaluation of ACT-A identified insufficient R&D coordination and leadership in each pillar, with the therapeutics pillar lacking a leading organization in R&D coordination and investment corresponding to CEPI or the Foundation for Innovative New Diagnostics (FIND).¹² Although global platforms for clinical trials, such as RECOVERY and the WHO COVID-19 Solidarity Therapeutics Trial, were established in March 2020, fragmentation and duplication of trials presented challenges, especially in the early stage of the pandemic. Many trials were small-scale and poorly designed.^{13,85,86,87,88} Further, resource mobilization was heavily skewed toward the vaccine pillar. While CEPI and Gavi received donors' financial commitments and substantially invested in vaccine R&D, ACT-A's other pillars suffered from chronic underfunding.^{12,89,90}

Regarding therapeutics, multiple organizations worked in a siloed manner, and there was no straightforward, prioritized approach.¹² Although CEPI conducted a production capacity survey for vaccines, there appears to have been no clear analysis and mapping of R&D capacity and distribution at the global level across diagnostics, therapeutics, and vaccines. The lack of attention

to global accessibility when designing the R&D of MCMs was also an issue. Although the development of the mRNA vaccine was innovative, it requires cold chain storage that makes distribution in low-resource settings a challenge.⁹¹ The insufficient involvement of LMICs and the most affected communities/populations in R&D decision-making and collaboration contributed to the lack of attention to global accessibility. Due in part to the uncoordinated R&D system and less attention to accessibility, the global community failed to achieve efficient supply of and equitable access to MCMs during the pandemic.

CHALLENGE 2-B. LACK OF A COLLABORATIVE NETWORK AMONG REGIONAL R&D FINANCING ORGANIZATIONS

As the leading R&D agency in the vaccine pillar, CEPI has strengthened partnerships with regional and country-level agencies such as the United States' BARDA and the EU's HERA, and is exploring the possibility of a partnership with SCARDA in Japan.⁹² However, it remains unclear how to coordinate these regional initiatives to avoid inefficiencies such as duplication, geographic imbalance/gap, or formation of silos within a global framework.

CHALLENGE 2-C. INSUFFICIENT ALIGNMENT OF REGULATORY DECISION MAKING

The vaccine approval process was accelerated, with regulatory agencies reviewing dossiers on a rolling basis as developers provided data and regulators reviewed in real-time. Regulatory agencies of sufficient maturity also conducted independent reviews and approvals. The WHO implemented a reworked Emergency Use Listing (EUL) procedure to assess dossiers licensed by a reference regulatory agency. Once a vaccine received EUL designation, many LMICs could use national recognition procedures to license these vaccines for deployment. However, in some cases, the approval process was delayed, particularly in areas where the reference regulatory agency was not stringent. As a result, access to vaccines slowed, causing confusion when certain WHO EULs were approved in some countries but not others. This fueled vaccine hesitancy and led to uncertainty for travelers required to present a digital vaccination certificate. Alignment in the regulatory review process is necessary to promote consistency in the quality of product review and the speed at which individual countries can access products. This would involve multiple stringent regulatory agencies aligning on their assessment of a submitted dossier and producing a single assessment report that would allow the WHO to issue a EUL quickly. Importantly, countries would need to make a final decision on whether the aligned assessment could be approved based on their local benefit-risk assessment, which depends on many local considerations including epidemiology, other approvals, the effectiveness of public health measures, etc.

CHALLENGE 2-D. DIFFICULTIES IN MEETING HIGH-INCOME COUNTRIES' NATIONAL INTERESTS AND LMICs' NEEDS THROUGH GLOBAL MECHANISMS

During the COVID-19 pandemic, the development and distribution of vaccines have become crucial for controlling the spread of the virus. COVAX was established as a global effort to provide both R&D incentives for pharmaceutical companies and equitable access to vaccines

through collective purchase and the AMC mechanism. However, the effectiveness of COVAX was hindered by some high-income countries directly purchasing more vaccines than needed from manufacturers, as well as the global vaccine manufacturing capacity falling short of demand, especially in 2021.^{93,94} As a result, inequity in vaccination coverage remains, especially in low-income countries, with primary series vaccination coverage at only 24%, as of the latest data on January 6, 2023.⁹⁵

Moreover, the deployment of COVID-19 vaccines in low-income countries has been affected by inadequate delivery systems, including insufficient infrastructure, personnel, and equipment. These deficiencies can hinder the effective distribution and storage of vaccines, leading to limited acceptance of vaccine doses and, in some instances, wastage. Thus, effective and adequately funded coordination of vaccine deployment within the country is essential. While a global coordination mechanism is necessary, strengthening regional and national infrastructure and capacities to meet regional/national needs more effectively is also critical.

CHALLENGE 2-E. LACK OF RISK HEDGE PLAN FOR MANUFACTURING AND SUPPLY OF MCMs

While there has been notable progress in technology transfer initiatives, such as the mRNA vaccine technology transfer hub, and several emerging countries like India and South Africa have shown promising vaccine manufacturing capacity, the COVID-19 pandemic has exposed the challenges in the manufacturing and supply of MCMs.^{96,97} COVAX, for instance, has heavily relied on India, resulting in serious undersupply during the surge of the Delta variant from April to October 2021.⁹⁸ Insufficient manufacturing capacity and uneven distribution of MCMs are not the only challenges, as securing the necessary raw materials and equipment for manufacturing is also critical.⁹⁹

Access to MCMs, including oral antivirals and diagnostics, is still inequitable, despite voluntary licensing by pharmaceutical companies and the MPP for oral antiviral therapeutics.¹⁰⁰ Moreover, the MPP did not cover some of the upper-middle-income countries hugely affected by COVID-19, and the voluntary licensing agreement between MPP and licensor companies included a termination-upon-challenge clause.¹⁰¹ IPR and fair pricing of vaccines have also been controversial in LMICs, especially given the challenges with limited supply through the end of 2021.⁸⁰ In addition, trade restrictions imposed by governments have impeded the flow of pandemic-essential goods across borders, affecting both raw materials and commodities, as well as COVID-19-related drug samples and finished products.

3. Global health architecture

CHALLENGE 3-A: INSUFFICIENT EFFECTIVE LEGAL REGIMES AND NORMS TO TACKLE THE BROADER SCOPE OF HEALTH THREATS¹⁰²

The current global health governance system is fragile, relying on voluntary compliance with various norms and rules by each actor. Due to increasing geopolitical tensions, this framework has been breaking down in recent years. It is necessary to review and reconstruct the norms and legal

framework of the global health architecture to address unprecedented and multifaceted challenges in the Anthropocene epoch.

The existing IHRs have established various rules and norms for PPR. However, the COVID-19 pandemic has revealed their insufficiencies in dealing with new health threats. For example, there is a recognized close connection between war and infectious diseases, given the collapse of the health infrastructure in Ukraine and the spread of various infectious diseases such as COVID-19 and cholera. Additionally, PHC has been acknowledged as the foundation of health systems, contributing to UHC and health security. Existing frameworks and norms have not adequately addressed the linkages between PPR, existing disease threats, equity capacities, and other security issues such as war, climate change, or trade. To strengthen existing frameworks and norms, human rights norms must be explicitly incorporated, and new norms must be established to capture PPR from a more comprehensive perspective.

Existing legal regimes, including the IHR (2005), have significantly advanced the role of health regimes. However, the urgent threat of COVID-19 has necessitated more comprehensive and effective legal governance to improve global oversight and coordination, including early alert and response.^{103,104} The current regime primarily addresses capacities at a national level. However, there remains a need to integrate health matters across all relevant sectors and policy areas such as climate change, food security/nutrition, WASH, social infrastructure, and education, and to promote One Health and Planetary Health approaches. Fundamental concepts underlying the necessary responses to pandemics, such as equity, solidarity, inclusiveness, human rights, community engagement, and UHC, are not explicitly delineated under existing legal norms. Any new system should complement and leverage existing instruments, including clarifications on how it relates to other existing frameworks, rather than create pathways where proven ones already exist.

CHALLENGE 3-B: NEED FOR ENHANCED GOVERNING MECHANISMS FOR COORDINATED GLOBAL ACTION AGAINST PANDEMICS AND OTHER MULTIFACETED HEALTH THREATS

COVID-19 has underscored the multifaceted and interdisciplinary nature of health crises, impacting areas such as economy, trade, supply chain management, intellectual property, and politics. However, few mechanisms effectively address these multifaceted aspects regarding strategic direction, coordination, and implementation.

The pandemic has highlighted the limitations of static, rigid, and single-issue interventions dependent on a limited number of actors. Effective responses required the engagement of numerous relevant actors, including community organizations. However, there was a lack of coordination mechanisms to delineate an appropriate division of labor. Although existing and emerging networked mechanisms for collaboration are in place, challenges persist in their effectiveness, including the successful implementation of policies.

There has been an emphasized need for improved communication processes among various actors and the institutionalization of a forum for coordinating these actors under strong political leadership. For example, the May 2021 Report of the Independent Panel for Pandemic Preparedness and Response (IPPPR) proposed a Global Health Threats Council for high-level

governance coordination among governments and relevant actors to ensure a lasting commitment to PPR.¹⁰⁵ Additionally, the 75th World Health Assembly proposed the establishment of a Global Health Emergency Council to complement the Standing Committee of the Executive Board.¹⁰⁶ Critical partners in establishing effective mechanisms include global partnerships such as the Global Fund and Gavi, the UN agencies, MDBs like the World Bank, and private or semi-private actors like the Gates Foundation, pharmaceutical companies, and CSOs. Furthermore, collaboration with companies is essential for promoting innovative technological solutions, including digital health and medical tools. Establishing a high-level governance mechanism for strategic direction, coordination, and implementation is vital to address global health threats beyond the health sector.¹⁰⁷

CHALLENGE 3-C: INSUFFICIENT HEALTH PRIORITIZATION BY GOVERNMENTS, AND INADEQUATE DOMESTIC AND INTERNATIONAL FINANCING FOR HEALTH AND HEALTH EMERGENCIES

Enhancing health system resilience requires long-term global and national investment. Even during non-pandemic periods, domestic financing for health in LMICs has been insufficient. In low-income countries, as defined by the World Bank, 29% of health expenditures are financed by external funding, compared to 12% in lower-middle-income countries in 2019.¹⁰⁸ Additionally, the fiscal space for health is projected to face increased pressure due to the consequences of COVID-19, inflationary pressures, other policy agendas, and the current geopolitical environment. This underscores the need for rapid access to external aid in future pandemics, particularly in low-income countries.

Although the Pandemic Fund has been established, securing sustainable financing remains challenging. Since the Fund primarily targets the “prevention and preparedness” parts of PPR, response financing insufficiencies persist in terms of the net amount, timeliness of response, and coordination and governance, which has global implications for all economies.^{109,110} The lack of fully coordinated, sufficient, and timely funding has exacerbated the situation, including the distribution of MCMs and PPE. While ACT-A unites governments, health organizations, scientists, businesses, civil society, and foundations to accelerate the development, equitable allocation, and scale-up of new COVID-19 tools, it relies primarily on donor countries and foundations for funding, which may not be sustainable. Furthermore, the roles of existing and emerging financing mechanisms (e.g., MDBs [World Bank/International Development Aid], regional development banks, development financing institutions, the Pandemic Fund, the Global Fund, CEPI, Gavi, and domestic financing) have not been fully designated and coordinated, especially in the early phase of the pandemic. Addressing fragmentation in global health is essential to enhance efficiency.¹¹¹ Further, sustainable increased collaboration with and leveraging of private funding and mechanisms is required.

CHALLENGE 3-D: LIMITED GLOBAL EFFORTS TO AVOID FRAGMENTATION AND SECURE COMPREHENSIVENESS WHILE REALIZING A TAILORED COMMITMENT TO THE REGIONAL LEVEL

As geopolitical tensions intensify, efforts are underway to expand the substantial capacity for PPR at the regional level.¹¹² Historically, regional health cooperation has progressed more rapidly than global health cooperation, as neighboring countries often share similar health challenges.¹¹³ Progress in regional cooperation during the pandemic, such as establishing the African Medicines Agency, the Africa CDC Consortium for COVID-19 Vaccine Clinical Trials, and the European Health Union, is promising.

However, ACT-A failed to assure equitable access in LMICs, as noted in an evaluation report on the initiative. Possible reasons include excessive influence by donors and inadequate involvement of LMICs in the conceptualization process.¹¹⁴ Solutions include working to regain trust, providing incentives, and collaborating with new actors, including regional organizations.

The current challenge lies in maintaining consistency and coherence in health governance, which is becoming more multilayered. Disparities between regions or groups may arise if each region develops substantive health cooperation.¹¹¹ Without proper coordination at the global level, the development of regional health cooperation can also lead to the decentralization and fragmentation of global health governance.

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