COMPILATION OF EXPERT ASSESSMENTS

2023 REPORT ON THE STATE OF THE WORLD’S PREPAREDNESS
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Background and methodology

The Report on the State of the World’s Preparedness has been the flagship report of the GPMB. The report reviews progress on preparedness over the past year; examines challenges to preparedness; and sets out a roadmap for the following year. Past reports were informed by expert analysis from the Board and third parties, including specially commissioned consultations or analyses where appropriate. In May 2023, the GPMB launched its Monitoring Framework and decided to implement it for the first time in 2023 to develop its Report on the State of the World’s Preparedness, focusing on a prioritized set of indicators. This new process will rely on extensive collaboration and consultation with experts.

For its 2023 Report, the Board has prioritized three areas of prevention, preparedness and resilience: Leadership and Accountability, Equity and Coherence. These areas have been matched to a set of indicators of the Framework (see 1.1 below), which assess relevant issues such as research and development (R&D) and access to countermeasures, One Health systems, financing, governance and others. For each area the Board has identified experts to provide a preliminary assessment of the indicators (see 1.1 below). Evidence, data and analyses provided by the experts have been consolidated into this technical assessment report.

These assessments were used by the Board as the core evidence base for the development of its 2023 Report on the State of the World’s Preparedness. The GPMB would like to thank the experts for their contributions.

Indicators selected and experts consulted

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<th>MEASURING LEADERSHIP AND ACCOUNTABILITY</th>
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<td>Indicators</td>
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<td>Question</td>
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<td>Relevant expert</td>
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<th>Indicator ID</th>
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<tbody>
<tr>
<td>Indicators</td>
<td>Financing of WHO and other key institutions involved in preparedness and response</td>
</tr>
<tr>
<td>Question</td>
<td>Are WHO and other key institutions of the global health emergency ecosystem funded adequately, flexibly, and sustainably?</td>
</tr>
<tr>
<td>Relevant expert</td>
<td>Sarah England, Independent Consultant</td>
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<th>Indicator ID</th>
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<td>Indicator</td>
<td>Global surge financing for response</td>
</tr>
<tr>
<td>Question</td>
<td>Is there an effective global, adequately financed and sustainably replenished mechanism for rapid funding of the global health emergency response?</td>
</tr>
<tr>
<td>Relevant expert</td>
<td>Sarah England, Independent Consultant</td>
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<th>Indicator ID</th>
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<tr>
<td>Indicators</td>
<td>Funding immediate economic and socioeconomic response</td>
</tr>
<tr>
<td>Question</td>
<td>Is there a global financing mechanism to rapidly and adequately mitigate the economic and socioeconomic consequences of pandemics and major outbreaks?</td>
</tr>
<tr>
<td>Relevant expert</td>
<td>Sarah England, Independent Consultant</td>
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<th>Indicator ID</th>
<th>B.3.3.1</th>
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<tr>
<td>Indicators</td>
<td>National assessment of financing for preparedness and response: national preparedness is sufficiently, adequately and sustainably financed.</td>
</tr>
<tr>
<td>Question</td>
<td>Is national preparedness sufficiently, adequately and sustainably financed?</td>
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<tr>
<td>Relevant expert</td>
<td>Sarah England, Independent Consultant</td>
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<td>Indicator</td>
<td>Global platform to support leadership</td>
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<tr>
<td>Question</td>
<td>Is there a dedicated global platform for the governance of health emergency preparedness and response which brings cohesion, removes fragmentation and facilitates collective action, and where national, regional and global stakeholders can coordinate, plan, and agree on priorities, and that can be leveraged in the event of a health emergency?</td>
</tr>
<tr>
<td>Relevant expert</td>
<td>Adam Kamradt-Scott, Harvard University</td>
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<th>Indicator ID</th>
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<td>Indicator</td>
<td>Strategic plan</td>
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<tr>
<td>Question</td>
<td>Is there an agreed global, multisectoral, cross-agency and holistic strategic plan for health emergency preparedness and response?</td>
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<tr>
<td>Relevant expert</td>
<td>Adam Kamradt-Scott, Harvard University</td>
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<th>Indicator ID</th>
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<td>Indicator</td>
<td>International regulatory instrument</td>
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<td>Question</td>
<td>Relevant expert</td>
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<tr>
<td>Is there an international regulatory instrument with clear, enforceable</td>
<td>Gian Luca Burci, Graduate Institute of International and Development Studies</td>
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<tr>
<td>priorities and targets around preparedness and obligations related to</td>
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<tr>
<td>data sharing and equity during a health emergency response?</td>
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**MEASURING EQUITY**

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<tr>
<th>Indicator ID</th>
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<tr>
<td>Indicators</td>
<td>Global R&amp;D coordination and priority setting</td>
</tr>
<tr>
<td>Question</td>
<td>Is there an appropriate and inclusive global governance and coordination system for R&amp;D that supports priority setting, advanced planning, and capacity to rapidly mobilize resources to support end-to-end development, production, procurement, and equitable access to medical countermeasures for health emergencies?</td>
</tr>
<tr>
<td>Relevant expert</td>
<td>Suerie Moon, Graduate Institute of International and Development Studies</td>
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<th>Indicator ID</th>
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<td>Indicator</td>
<td>R&amp;D capacity-building</td>
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<tr>
<td>Question</td>
<td>Are there effective global mechanisms supporting technology transfers for vaccines, therapeutics, diagnostics, personal protection equipment and medical technologies as well as capacity building to develop research and development capacities at the regional and national levels?</td>
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<tr>
<td>Relevant experts</td>
<td>International Pandemic Preparedness Secretariat (IPPS) and IPPS Science and Technology Expert Group (STEG)</td>
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<td>Indicator</td>
<td>Coordination during health emergencies</td>
</tr>
<tr>
<td>Question</td>
<td>Is there a demonstrated capacity for the R&amp;D ecosystem to coordinate and rapidly switch to emergency mode, including for manufacturers to start R&amp;D and switch or scale up their production?</td>
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<tr>
<td>Relevant experts</td>
<td>International Pandemic Preparedness Secretariat (IPPS) and IPPS Science and Technology Expert Group (STEG)</td>
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<td>Indicator</td>
<td>Regional manufacturing capacity</td>
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<tr>
<td>Question</td>
<td>Is there sufficient regional manufacturing capacity for vaccines and therapeutics across WHO regions?</td>
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<td>Relevant experts</td>
<td>International Pandemic Preparedness Secretariat (IPPS) and IPPS Science and Technology Expert Group (STEG)</td>
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<tr>
<td>Indicators</td>
<td>Assessment of national R&amp;D innovation, development and access to medical countermeasures, including: adequate national emergency regulatory approval procedures/capacity, capacity to deploy medical countermeasures, equity in R&amp;D and access to countermeasures; involvement of communities in research and addressing the needs of different communities; access to medical countermeasures by vulnerable and marginalized communities.</td>
</tr>
<tr>
<td>Questions</td>
<td>Do countries have adequate national emergency regulatory approval procedures/capacity? Do countries’ health systems have the capacity to deploy medical countermeasures? Do countries ensure equity in R&amp;D and access to countermeasures? Do they involve communities in research and identify/address the needs of different communities? Do countries ensure access to medical</td>
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<td>B.1.2.2 (a)</td>
<td>Global mechanism to manage misinformation</td>
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<tr>
<td>B.1.2.2 (b)</td>
<td>Global spread and impact of misinformation during health emergencies</td>
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<td>B.1.2.2 (c)</td>
<td>Global platform to disseminate information and build knowledge</td>
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<th>Indicator ID</th>
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<th>Questions</th>
<th>Relevant expert</th>
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<tr>
<td>B.3.2.1</td>
<td>Assessment of communities and people at the national level, including having: 1. integrated and implemented minimum standards for community engagement in their preparedness plans, 2. an effective infodemic management plan and established communications channels to share accurate information transparently, including plans to utilize digital and social media.</td>
<td>1. Do countries have integrated and implemented minimum standards for community engagement in their preparedness plans, in terms of participation, ownership, inclusion, adaptability and building on local capacity? 2. Do countries have platforms in place that capture the views and experiences of citizens, including the most vulnerable in society, in order that these can be incorporated into preparedness? 3. Do countries have an effective infodemic management plan and established communications channels to share information transparently, including plans to utilize digital and social media?</td>
<td>Julie Leask, University of Sydney</td>
</tr>
<tr>
<td>B.1.2.1 (a)</td>
<td>Impact of health emergencies on women, youth, vulnerable and marginalized groups</td>
<td>Is there an effective, integrated global strategy to address the impacts of health emergencies on women, youth and vulnerable and marginalized groups, including a global monitoring mechanism and requirement to report on these impacts?</td>
<td>Clare Wenham, London School of Economics and Political Science</td>
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<tr>
<td>B.1.4.7 (a)</td>
<td>Inclusion of low- and middle-income countries</td>
<td>Do global decision-making bodies for preparedness and response effectively include LMICs?</td>
<td>Ngozi Erondu, The O’Neill-Lancet Commission on Racism, Structural Discrimination</td>
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<td>Indicator ID</td>
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<tr>
<td>B.1.4.7 (b)</td>
<td>Involvement of civil society, private sector and community representatives</td>
<td>Do decision-making bodies for preparedness and response effectively involve civil society, private sector and community representatives?</td>
<td>Ngozi Erondu, The O’Neill-Lancet Commission on Racism, Structural Discrimination and Global Health</td>
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<tr>
<td>B.1.1.2 (a)</td>
<td>Global mechanism for early warning and One Health surveillance</td>
<td>Is there an effective global mechanism for early warning, risk assessment and surveillance with data sharing (including standards), data management, analytics, modelling and real-time communication at the human health, animal health and environment interface to monitor emergence of potential new threats with open centralized access to data and rapid pathogen sharing, and grounded in equity?</td>
<td>David Hayman and Marion Koopmans, One Health High-Level Expert Panel</td>
</tr>
<tr>
<td>B.2.1.1.1</td>
<td>Regional laboratory capacity</td>
<td>Are there sufficiently resourced, globally-coordinated, regional laboratories with advanced capacities to support and provide assistance to national laboratories in advance of and during health emergencies?</td>
<td>Full Board with Lucille Blumberg as Chair, Strategic &amp; Technical Advisory Group on Infectious Hazards with Pandemic and Epidemic Potential (STAG-IH)</td>
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<tr>
<td>B.2.1.1.2</td>
<td>Assessment of national One Health and health systems preparedness, including: 1. the capacity to detect novel and emerging pathogens across the One Health spectrum, 2. health systems preparedness to respond to health emergencies, 3. adequate surge capacities.</td>
<td>Do countries have integrated capacity to detect novel and emerging pathogens across the One Health spectrum? Do they conduct comprehensive surveillance and rapidly report zoonotic pathogens in animal populations?</td>
<td>Strategic Technical and Advisory Group on Infectious Hazards</td>
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<tr>
<td>B.1.4.8</td>
<td>Coherence</td>
<td>Are priorities for preparedness aligned across the main international organizations working on different dimensions of health emergencies?</td>
<td>Rebecca Katz, Georgetown University</td>
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<tr>
<td>B.1.1.4.1 (a)</td>
<td>Trade coordination</td>
<td>Is there an effective global, multisectoral mechanism to support transparent coordination of trade measures in the context of a health emergency?</td>
<td>Joseph François, World Trade Institute</td>
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<td>Indicators</td>
<td>Involvement of relevant actors</td>
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<tr>
<td>Question</td>
<td>Are relevant sectors meaningfully involved in global health emergency preparedness and response?</td>
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<tr>
<td>Relevant expert</td>
<td>Adam Kamradt-Scott, Harvard University</td>
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Section 1 – Leadership and accountability

Expert assessments

Indicator B.1.4.5 (a) Independent monitoring

<table>
<thead>
<tr>
<th>Question</th>
<th>Are there global mechanisms to independently monitor and assess progress with preparedness and recommend action?</th>
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<tr>
<td>Expert</td>
<td>Clare Wenham, London School of Economics and Political Science</td>
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ANSWER TO INDICATOR QUESTION

Yes, there are multiple, each of which measuring a slightly different range of indicators and each of which using different methodologies.

SCORING

2/3

ANALYSIS

There are multiple mechanisms which have been developed both within the WHO and as research tools which assess and monitor country preparedness.

The most formal of these mechanisms is the IHR Monitoring and Evaluation Framework. This is to review implementation of public health capacities under IHR (2005), as prescribed at Article 54 and at Annex 1. There are four parts to this monitoring framework – the Joint External Evaluation (JEE), Simulation Exercises, Intra/After Action Review and State Party Self-Assessment Annual Report (SPAR). The JEE is a particularly important part of “independent” monitoring of IHR implementation as it is not self-reported, but is undertaken by country experts and an external evaluation team to assess state implementation of IHR. This is done over assessment of 19 technical areas (56 indicators) to establish a baseline assessment. These technical areas go beyond those of public health and includes broader multisectoral considerations. These are voluntary, but as of May 2022, 116 countries have undertaken a JEE, thus, whilst not global it has pretty good coverage and the findings of these are made public via WHO. Indeed, many countries have recently doubled down on undertaking JEEs, given that this is used as a baseline assessment for the results framework of the Pandemic Fund.

Conversely, the SPAR is a self-assessment tool for annual reporting to WHO, consisting of 24 indicators for the 13 IHR capacities. Given this is undertaken by states, these are not independent or free from political positioning of indicators and/or data.
For both of these, it is important to note that WHO lacks a mandate to verify scores, and therefore there are questions of quality and/or veracity of the data provided. Whilst for the most part this doesn’t seem to be a major issue of concern, there are of course different incentives for states to over-report capacities (e.g. for reputation and international standing) or to under-report (e.g. for increased opportunity for funding).

The current GPMB project to provide a monitoring framework at the global and national levels (i.e. this very exercise) will also provide an independent and universal monitoring mechanism for the broader strategic direction of pandemic preparedness and response.

Beyond WHO, there are different monitoring mechanisms established. The Global Health Security Index assesses and benchmarks countries’ health security and capabilities across six categories (prevent, detect, respond, health, norms, risks), 37 indicators, answering 171 questions of open source information and publicly available data. This includes both public health assessments, as well as broader social and political considerations. This is completely independent as it is run by research institutions, and all takes information from all states globally. It is able to score countries, and then use the low scoring indicators to advocate for capacity building and resource generation. It is updated every two years.

Importantly, however, none of these are supposed to be predictive as to how prepared a country may be, but a stock take on capacity of the current ability to manage and respond to an emerging health crisis should it arise. Indeed, there has been much made of the incongruence between those countries which scored highly on preparedness indices prior to COVID-19, and the real-world outcomes that occurred during the pandemic.

Moreover, not all issues which are important to pandemic preparedness can be measured in an indicator. The risk of placing such a focus on indicators is that the nuance can be lost – e.g. how a government might react at any particular time, what external or domestic factors may influence decision making are qualitative assessments which are not binary or indicatorisable. Not only may the focus on indicators not reveal the actual picture, but they can have the significant effect of complacency and/or being the only metric used for investment in preparedness, which is a limitation.

Finally, these pandemic preparedness assessments and monitoring predominantly focus on the technical public health indicators and assessments, with “success” measured by the ability to limit the spread of a pathogen. Little consideration in these indicators is given to the trade-offs in the political, social and structural arenas of such success – for example, if a country is effective at limiting the spread of a pathogen but this comes at the cost of human rights interventions, this isn’t captured in the monitoring and evaluation frameworks and indicators. Future iterations should be developed to ensure that the secondary effects of pandemic preparedness and response are also incorporated into the evaluation tools.

DATA SOURCES AND REFERENCES

2. Electronic IHR States Parties Self-Assessment Annual Reporting Tool (eSPAR), https://extranet.who.int/e-spar/#submission-details
Indicator B.1.4.5 (b) Independent, universal, periodic review mechanism

<table>
<thead>
<tr>
<th>Question</th>
<th>Is there an independent, universal, periodic mechanism to monitor IHR implementation and national action on preparedness and response measures?</th>
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<tr>
<td>Expert</td>
<td>Clare Wenham, London School of Economics and Political Science</td>
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ANSWER TO INDICATOR QUESTION

No

SCORING

1

ANALYSIS

The Universal Health & Preparedness Review (UHPR) has been developed since 2021, under the auspices of the WHO Health Emergencies (WHE) Programme. The UHPR is “a Member States-led intergovernmental mechanism in which countries agree to a voluntary, regular and transparent review of their comprehensive national health and preparedness capacities, elevates these to the highest levels of government, and commits to rapidly strengthen preparedness and response”. When this was created, it was amid broader conversations about why some countries seemingly performed better than others, and the lack of predictive nature of the indexes that already existed (e.g. Global Health Security Index). Conversations focused on the creation of a mechanism which could mirror the Universal Periodic Review from the UN Human Rights Council and/or Article 4 surveillance within the IMF.

The UHPR aims to result in:

- Prioritized improvements in health security, with leadership and commitment from the head of state, mobilizing a whole-of-government and whole-of-society approach beyond the health sector.
- Accountability to improve access to health services to prevent, detect, and respond to emergencies, including primary health care.
- Better compliance with commitments made under the International Health Regulations and related WHA resolutions in emergency preparedness, enabling a linkage to national and global funding in order to accelerate improved country capacity for preparedness.
- Prioritized actions that require immediate attention, in line with regional and global priorities.
- Mutual learning and pooling of best practices, solutions, and innovations.

In terms of universality, the proposed UHPR would score quite highly – in that it is available to all Member States to volunteer to be reviewed, and the proposed indicators cover a whole-of-government and multi-hazard/vulnerability approach to preparedness and response.
There is a challenge in the question and the way it is phrased, as the question/indicator asks for a UPR mechanism to monitor IHR implementation and national action plan on PPR measures. The UHPR is not supposed to monitor IHR implementation, or at least that is not its mandate, although it does use IHR-related data points. Monitoring IHR implementation and national action on PPR occurs through the IHR Monitoring and Evaluation Framework, comprising the State Parties Annual Reporting (SPAR) tool for mandatory annual reporting, and three voluntary components, the Joint External Evaluation, Simulation Exercises and Intra/After Action Review. These tools will continue to be the main mechanism for assessing preparedness in a particular state, as defined within the IHR. The UHPR will not replace these, but will have broader health system and governance-related metrics, structured around three core components: governance management and leadership; strong, agile and coordinated national and global systems for emergency preparedness; predictable and sustainable resources. On top of this broader scope, the UHPR is tasked to also provide a process to engage political actors in the process, rather than remaining a technical tool.

The question about independence is also important in considering the proposed UHPR. At present, the countries going through the review undertake a self-evaluation and compilation of a report on their own perceived performance against suggested indicators (suggested by WHO Secretariat). This uses a range of data sources, but predominantly as a government-led initiative, this will use government data, and thus not solely third-party data, and there is the real risk that there could be political manipulation of data. Moreover, there is yet to be a formal template, not all states that have thus far completed the process have used the same indicators, which offers some challenges to universality and independence.

Moreover, the second part of the UHPR is the peer review mechanism by other states. It is likely that this may bring political challenges as to who is being assessed by whom, etc. The peer review mechanism under the Global Peer Review Commission, is under development and will be piloted in due course by those countries that have already completed their country-level assessment. It should be noted that the GPRC will have significant resource needs for those Member States who are required to assess the reports of multiple countries at one time for consistency and rigor. This might mean that not all countries have the same capacity to partake, leading to political challenges in who is doing the reviewing, as well as challenges to independence and universality.

The periodic nature of the UHPR is also uncertain at present, given the significant burden placed on states both going through the review (it is estimated 12 weeks of work, and this will not replace the need to undertake other forms of IHR Monitoring and Evaluation), and those involved in the Global Peer Review Commission. This will likely limit the frequency of such activities.

It is also important to remember that the UHPR is a voluntary mechanism. Five voluntary pilots have taken place of the UHPR country reporting thus far: Central African Republic, Iraq, Portugal, Thailand and Sierra Leone. Thus, whilst this universal, periodic review mechanism exists, at present it is not adopted by WHA and is still in the pilot phase where different approaches to data collection, indicators used, and presentation of findings are being trialled, hence the low score at present.

However, there is discussion of inclusion of reference to a universal periodic review mechanism both
within the WGIHR and the proposed amendments at Article 5, and within the latest bureau text of the CA+. If this gets institutionalized in this way, then the score for this indicator can go up. It is unlikely that it will ever become a mandatory activity, however, and there is a sense that there is not complete buy-in from Member States as to this process, so it remains to be seen whether it gets formalized into treaty text, and how this then plays out in the next phases of the pilot.

It is also important to remember that part of the purpose of the UHPR as currently proposed is to drive high-level political buy-in from national leaders as part of the process through intergovernmental and expert-led dialogues. The purpose of such high-level dialogue is to ensure that there is political and resource commitment to build capacity in the identified gaps. Thus, the political nature of the process, which is inherently trying to foster national commitment, makes it hard to be completely independent.

**DATA SOURCES AND REFERENCES**

Indicator B.1.4.4 (a) Predictability of resources for global health emergency preparedness and response

**Question**

Is there long-term planning and predictability of sufficient and aligned resources for global health emergency preparedness and response?

**Expert**

Rebecca Katz, Georgetown University

**ANSWER TO INDICATOR QUESTION**

Incomplete

**SCORING**

*Capacity score*: 1
*Trend*: But hopefully improving: +1

**ANALYSIS**

Planning for emergency preparedness and response occurs on multiple levels, subnationally, nationally, regionally, and globally. Moreover, the extent of planning efforts varies significantly across geographic areas and across contexts. Is this measure intended to measure global (e.g. WHO and UN-level) planning efforts? Or does it also take into account country and/or local preparedness, which will vary substantially and may be impossible to reliably assess in a single measure?

Long-term planning, predictability and sufficiency need to be assessed at each of these levels. At the global scale, the Pandemic Fund and Global Fund, I believe, hope to eventually meet some of these needs, but the funds are far from there yet (the Pandemic Fund is just starting out and the Global Fund is just figuring out its future in PPR). Additionally, neither of these funds can rely on official development assistance (ODA) and the replenishment cycle is not necessarily sustainable.

The WHO is certainly trying to move towards more predictable financing through increased assessments, but the health emergencies program has traditionally relied very heavily on voluntary donations and the Contingency Fund for Emergencies seems to spend more than it can raise consistently.
Indicator B.1.3.1 Global financing of global public/common goods

**Question**
Are global common goods for prevention, preparedness and resilience fully financed?

**Expert**
Sarah England, Independent Consultant

**ANSWER TO INDICATOR QUESTION**
No

**SCORING**

**Score:** Current score is estimated at 0 in terms of international funding. At the peak of the COVID-19 crisis the score would have been 3 (average of 2020–mid 2023) if Operation Warp Speed were included. 

**Trend:** -1 Declining since the peak of the COVID-19 crisis.

**ANALYSIS**

**SUCCESSES**

USD 24.2 billion was contributed to the COVID-19 response through multilateral implementation agencies from 2020 to June 2023. This included USD 2.168 billion for WHO and USD 1.876 billion was awarded to CEPI for COVID-19 vaccine R&D from 2020 to June 2023.

The mRNA Technology Hub was launched in 2021 at Afrigen in South Africa. As of April 2023, there was financial support from donors of USD 117 million.

USD 18 billion was awarded to COVID-19 vaccine development in early 2020 through Operation Warp Speed (OWS), but there is debate as to whether this is a global public good as the USA had first priority on the product and the intellectual property was largely retained by the manufacturers.

The Oxford/AstraZeneca collaboration was intended to produce a COVID-19 vaccine for public health purposes as a global public good, to be sold at cost, but it appears that a 20% profit margin was eventually added to the price in some cases. Estimates of R&D funding to this vaccine are in the range of GBP 100 million to 225 million not counting the costs of clinical trials. Nevertheless, at a price of about USD 5 a dose, it was an affordable option for COVAX.

The EU Global Gateway strategy mobilized more than Euro 1 billion under the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies (TEI MAV+) adopted by the EU in October 2021. TEI provides support at “continental, regional and national levels to promote the supply and demand side as well as the enabling environment for local production of health products and technologies in Africa”. (This funding includes the EC contribution to the mRNA Hub.)
**PROGRESS**

The Pandemic Fund was established to support investments in preparedness, particularly in the area of surveillance. Although the Pandemic Fund finances proposals from countries, its investments in country level surveillance, etc., contribute to global health security.

**CHALLENGES**

The Oxford/AstraZeneca collaboration was intended to produce a COVID-19 vaccine for public health purposes as a global public good, to be sold at cost, but it appears that a 20% profit margin was eventually added to the price in some cases. Nevertheless, at a price of about USD 5 a dose, it was an affordable option. Export bans imposed by India impeded access to the Oxford/AstraZeneca vaccine.

Early investment of USD 18 billion from May 2020 by the USA in OWS established that the mRNA vaccines would be made available first to the USA.

The Pandemic Fund was founded on analyses by the International Monetary Fund (IMF) and others that indicated an annual need for USD 10 billion in external funding for pandemic preparedness, but as of early 2023 it had raised pledges and commitments of USD 1.6 billion. More than 100 countries submitted proposals in response to the first call, with requests for funding totalling USD 7 billion.

Although Afrigen was supported to produce COVID-19 vaccines and began production at laboratory scale by April 2023, demand for the vaccines collapsed, leaving Afrigen without a market. Similarly, generic manufacturers of COVID-19 antivirals found that by the time they were awarded licenses, there was little or no demand. The challenge is to keep “warm” manufacturing capacity in between peaks of demand.

There is a wide funding gap of approximately USD 6 billion per year for investment in preparedness at country level, particularly for surveillance including laboratory capacity, as shown by the high level of demand for support from the Pandemic Fund, and earlier pandemic prevention, preparedness and response funding gap estimates prepared by WHO and the World Bank for the G20 Joint Finance-Health Task Force.

There is a gap in funding for pandemic innovation as a global public good, as illustrated by the missed target of the CEPI replenishment. In 2022 it set its 5-year replenishment goal at USD 3.5 billion. As of March 2022, CEPI had raised about USD 1.5 billion towards this goal.

There is a gap in at-risk financing of medical countermeasures in the development pipeline for use in LICs and LMICs. This gap was estimated at USD billion at the start of the COVID-19 pandemic in an analysis by WHO on behalf of the G20 Joint Finance-Health Task Force.

**Total spend:** From 2020 to June 2023, a very rough estimate of international spending on global public goods for the COVID-19 response is USD 45 billion, or USD 15 billion per year on average (Access to COVID-19 Tools Accelerator: USD 24.2 billion, OWS: USD 18 billion, and other funding). This represents a peak level of spending during the crisis.
DATA SOURCES AND REFERENCES


5 Ibid.

6 Ibid.


Indicator B.1.3.2 Effectiveness and alignment of spending for preparedness

**Question**

Is international funding for preparedness adequate, provided efficiently, spent effectively and aligned with agreed priorities and leading to an improvement of global preparedness capacity?

**Expert**

Rebecca Katz, Georgetown University

**ANSWER TO INDICATOR QUESTION**

Incomplete

**SCORING**

Capacity score: 1

Trend score:

**ANALYSIS**

The concept of “preparedness needs” is open to interpretation and would benefit from additional clarification. What are the guiding principles for assessing this? In the parlance of the JEE, should experts consider these needs as equivalent to “sustainable capacity”? “Demonstrated capacity”? “Developed capacity”? Or are there other guidelines that should be considered? The cost requirements to meet these different thresholds will vary substantially, which will impact both results and interpretation.

There are a number of (sometimes competing) global strategies for financing and prioritizing health security efforts. Given misalignment between these strategies, which should be considered by the reviewers when assessing alignment? (This gets to the challenges of coherence.)

Given these points:

- **Adequate:** is funding sufficient to support needs? The easy answer on this is absolutely not. Our analysis finds that the world needs approximately $300bn over 5 years to get nations to build PPR capacity per the JEEs (earlier published findings linked below). Others estimate another ~$80bn for global manufacturing, R&D and supply chain. Thus, we have an almost $400bn problem. Yet the amount of funds available right now for PPR is miniscule. The Pandemic Fund will be giving out ~$300-350m this cycle (less than 1% of need).

- **Provided efficiently:** this depends on who is providing the funds. In our tracking.ghscosting.org costing tool, we track a multitude of donors (over 1,000), and over a million financial transactions since 2014. Each donor and each recipient have their own process for funding.

- **Spent effectively:** I am unable to comment on this. Each of those million plus transactions and 1,000 plus donors has their own monitoring and evaluation processes. We have, though, studied and published findings where we found an inverse relationship between the amount of global financing for a core capacity and sustained capacity over time. This finding points to the importance of the
nation itself setting the priority instead of external donors (see citation below).

- Aligned: in our tracking tool, we align the global financing to JEE indicators. If you believe that the JEEs are the global strategy, then you can map the spending back to that. But there is no prioritization within those indicators.

DATA SOURCES AND REFERENCES


Indicator B.1.3.3 Financing of WHO and other key institutions involved in preparedness and response

**Question**

Are WHO and other key institutions of the global health emergency ecosystem funded adequately, flexibly, and sustainably?

**Expert**

Sarah England, Independent Consultant

ANSWER TO INDICATOR QUESTION

Incomplete

SCORING

**Score:** 1: Overall significant funding was raised for the COVID-19 response, but there were gaps in the hundreds of millions for Day Zero rapid response funding. There was a gap in the tens of billions for rapid, at-risk financing of medical countermeasures in the development pipeline in order to make advance purchase agreements to secure volumes of these products for use in LICs and LMICs. Funding was not sustainable nor sufficiently flexible. As of July 2023, 74% of WHO’s emergencies and appeals budget is financed.

**Trend:** -1: Beginning in 2022, significant donor fatigue was in evidence and replenishment targets were missed including for CEPI. The Pandemic Fund request for proposals in January 2023 was oversubscribed by a factor of 23.

ANALYSIS

**SUCCESSES**

Regarding resource mobilization for the COVID-19 response through multilateral implementing agencies, donor engagement was strong, joint Access to COVID-19 Tools Accelerator instruments like the Strategic Plan and Budget and Commitment Tracker was very highly valued, its partner multilateral implementing agencies frequently spoke with one voice and an unprecedented USD 24 billion was raised by those agencies from 2020 to June 2023.

The WHO Contingency Fund for Emergencies (CFE) was highly effective in quickly releasing funds, with the first COVID-19 disbursement on 14th January 2020 and over USD 1.5 million released by the end of January. However, the CFE was limited in size and could not scale up quickly when a large number of countries had simultaneous crises. The size of the CFE could be limited by reluctance to have a pot of cash sitting idle in case of major emergency.

Appeal mechanisms set up by WHO, such as its COVID-19 Strategic Preparedness and Response Plan (SPRP), were able to fill this gap within 1–2 months, ultimately raising USD 4.3 billion over the course of
the crisis (with over USD 1 billion raised within 3 months). However, there were no predictable, pre-agreed Day Zero draw down mechanisms at sufficient scale to avoid the 1–2-month delay incurred in raising the funding required.\(^4\)

Similarly the UN Central Emergency Relief Fund (CERF)\(^3\) was able to very quickly disburse USD 225 million within one month of the declaration of the COVID-19 Public Health Emergency of International Concern, mainly to UN agencies for implementation in countries identified in the Global Humanitarian Response Plan for COVID-19. Current CERF capitalization is USD 500–700 million, and the target is USD 1 billion per year. There is a strong capacity to quickly move high quantities of funding. There is no cap on the amount but cash flow is a concern. CERF needs to keep a cash reserve in case of additional crises occurring concurrently.

Further fundraising could be feasible but is restricted by donor preferences and risk of idle cash. There is a low likelihood of big change in the contributions of current donors, in the absence of a new policy.

PROGRESS
The World Health Assembly in May 2023 agreed to increase the WHO assessed contributions by 20% and welcomed a replenishment mechanism.

CHALLENGES
Donors that redirected other ODA funds to health during the COVID-19 crisis are now rebounding to fund those development priorities that were relatively neglected during the pandemic. Regarding resource mobilization for the COVID-19 response through multilateral implementation agencies, an early, strong, well-resourced, joint resource mobilization campaign with shared branding and using pre-existing tools like a pooled fund with allocation mechanism, and front-loading financial mechanisms to spend against pledges would have changed the course of the COVID-19 pandemic.

GAPS
Throughout the COVID-19 crisis, the Access to COVID-19 Tools Accelerator consistently failed to meet the financing targets laid out in its strategic plans and budgets. Late financing may have played a key role in keeping LICs and LMICs from accessing vaccines.

Although loan financing from the development banks was available, 73 countries qualified for debt repayment relief during the crisis.\(^6\) From 2022 onward, there was a marked donor fatigue in contributions to the COVID-19 response and health emergency work more generally. Both the Global Fund and CEPI missed their replenishment targets in 2022. Funding was skewed towards vaccines, which may have been rational at the time, but resulted in significant funding gaps in areas like diagnostics and therapeutics (including oxygen), and there was insufficient support for the delivery of medical countermeasures.

The Access to COVID-19 Tools Accelerator issued a six-month transition period budget from November 1, 2022, which ended up extending to approximately the end of the COVID-19 Public Health Emergency of International Concern. As of June 1, 2023, of the USD 78 million that had been requested for therapeutics, there remained a gap of USD 56.4 million. For diagnostics, none of the USD 63 million budgeted had been raised. For health systems, of the USD 245 million budget, a funding gap of USD 147.7 million remained. Much of this funding is needed to keep “warm” those functions that would be required to be rapidly
ramped up in the event of a disease surge.

The Pandemic Fund was founded on analyses by the IMF and others that indicated an annual need for USD 10 billion in external funding for pandemic preparedness, but it raised pledges and commitments of USD 1.6 billion. More than 100 countries submitted proposals in response to the first call, totalling USD 7 billion.

Question: Two-thirds of the base programme budget is funded through sustainable funding such as assessed contributions, or a multi-year replenishment process, and is unearmarked:

- **WHO health emergency work**: Currently over 80% of WHO’s budget is from voluntary contributions, of which the great majority are earmarked. Member States have acknowledged that WHO needs more flexible, predictable and sustainable financing. Less than 5% of voluntary contributions are to be spent at WHO’s discretion. A replenishment mechanism is planned to start in late 2024. From the WHO 2022–23 biennial budget portal, as of June 2022 there was USD 2.3 billion approved for emergency operations and appeals, with a shortfall of negative USD 300,859,000. As of June 2023, USD 4 billion was approved for emergency operations and appeals, with a shortfall of USD 1 billion and only USD 141,841,000 of flexible funding was available. Nearly all of the emergency funds are specified.

- **UNICEF health emergency work**: UNICEF has a highly effective fundraising mechanism involving emergency appeals and the work of its national committees. It was able to mobilize over USD 50 million by the end of March 2020, and over USD 1 billion by August 2020, though not all of this was for the health sector. Core flexible funding is still only about 20% of the total.

- **Gavi health emergency work**: Gavi currently has USD 2.6 billion unspent funds for COVID-19 vaccines (a decision on reallocation of these funds will be made at the December 2023 Board meeting). It can be argued that had these funds been available faster, Gavi may have been able to make advance purchase commitments for COVID-19 vaccines in the pipeline, would have secured volumes of these vaccines for use by LICs and LMICs, and would not have had unspent funds. The vaccines became available in large part after the demand for them dropped. There is still a substantive funding gap for very rapid, large-scale, at-risk financing for the advance purchase of vaccines that are in the development pipeline in the event of a major health emergency.

- **The Global Fund** is not an emergency fund. However, as a channel experienced in managing funding at the scale of billions for pandemic response, it created the COVID-19 Response Mechanism (C19RM) with streamlined approval processes. Nevertheless, the mechanism was country-driven, relying on proposals from countries to drive disbursement, with development rather than emergency standard operating procedures. This may explain the need from August 2022 to reprogramme roughly USD 800 million in financing that had not been implemented during the peak of the crisis. The Global Fund has a multi-year replenishment cycle for support to HIV/AIDS, TB and malaria, which includes some health system investment that benefits health emergency preparedness. Reprogramming of unspent Global Fund COVID-19 Response Mechanisms funding is aimed at “(i) maximizing people-centered, integrated systems for health to deliver impact, resilience, and sustainability, and (ii) contributing to pandemic preparedness and response”. In the period 2023–2025, the Global Fund is encouraging its
clients to make proposals for Resilient and Sustainable Systems for Health (RSSH) investments that are “essential to ending AIDS, TB and malaria as epidemics and which enable the delivery of individual and population health services in an efficient, effective, equitable and sustainable way”\textsuperscript{10}. These investments may also promote health emergency preparedness. The proportion of grants that will be used for RSSH is country demand-driven.

- For the current replenishment cycle there was a target of USD 18 billion and USD 15.7 billion was raised. This means that some funding from the US that needed to be matched 2:1 was left on the table.

- CEPI health emergency work: CEPI has a multi-year replenishment process. In 2022 it set its replenishment goal at USD 3.5 billion. As of March 2022, CEPI had raised about USD 1.5 billion towards this goal. This missed target could reflect donor fatigue that had set in at that point in the pandemic.

- FIND health emergency work: During the COVID-19 crisis, the Global Fund teamed up with FIND to successfully widen its access to donors. However, FIND faces a challenge in raising the relatively small amounts of money it needs to keep key catalytic functions active.

- Unitaid health emergency work: Unitaid and the Global Fund co-chair the Global Oxygen Alliance with one objective being resource mobilization for increasing access to medical oxygen. This is a critically neglected area that is chronically underfunded. A strategic plan and budget are expected in early 2024 that will include financial needs for Unitaid, UNICEF, WHO and other partners.

- The World Organization for Animal Health (WOAH) operates with statutory donations from its members, as well as voluntary donations from member organizations. According to its 2022 financial report\textsuperscript{11}: “2022 signals a record year for income received for the World Fund (Euro 30.06 million); this positive result, coupled with new grants signed in 2022 (Euro 25.56 million), demonstrates confirmed interest and investment in the World Fund. ...Overall, fully flexible investments remain lower than needed to allow resources to efficiently deliver programmatic activities across the Organisation.” In 2022 WOAH members agreed to increase statutory contributions by 30% over three years (2023–2025).

- In 2022 the IFRC regular resources income was 113 million Swiss francs, over 80% of which is for core functions. This support enabled raising an additional 1.1 billion Swiss francs for the national Red Cross societies. 29% of the regular resources are statutory contributions from national societies, 22% is from voluntary contributions, and 50% is cost recovery from operations. This funding includes emergency appeals. They aim to increase regular resources income to 150 million Swiss francs per year by 2025. The IFRC has doubled allocations at the country level since 2020: increasing from 7 million Swiss francs in 2020 to 14 million Swiss francs in 2022\textsuperscript{12}. In terms of preparedness: “In 2022, regular resources allowed the IFRC to work with National Societies on initiatives related to community and institutional epidemic preparedness, immunization for COVID-19 and other vaccine-preventable diseases, the provision of water sanitation and hygiene facilities, community-based surveillance, and community engagement and accountability.”
DATA SOURCES AND REFERENCES


3. According to the WHO web site, the CFE had contributions of USD 16 million in 2023 and allocations of USD 48 million in 2023 as of June 15. The current balance is not indicated. Source accessed July 21, 2023: https://www.who.int/emergencies/funding/contingency-fund-for-emergencies


5. CERF operates under the Office for the Coordination of Humanitarian Affairs (OCHA). For 2022, the OCHA financial need was $51.7 billion. By 31 December, donors had provided $29.5 billion against the year’s coordinated global humanitarian appeals (57.1 per cent), compared with $20.11 billion in 2021. Source: United Nations Office for the Coordination of Humanitarian Affairs, Annual Report 2022, https://annualreport.unocha.org, p.70. Accessed July 21, 2023.


Indicator B.1.3.4 Global surge financing for response

Question
Is there an effective global, adequately financed and sustainably replenished mechanism for rapid funding of the global health emergency response?

Expert
Sarah England, Independent Consultant

ANSWER TO INDICATOR QUESTION
Incomplete

SCORING
Score: 1
Trend: +1

ANALYSIS
SUCCESSES
The WHO CFE and the UN CERF are highly effective rapid mechanisms to deliver very early response funding, but the order of magnitude is too small to cope with multiple concurrent country emergencies as in a rapidly evolving pandemic scenario.

PROGRESS
Many multilateral development banks (MDBs) are now taking stock of their financing instruments for pandemic prevention, preparedness and response. For example, the World Bank is in the midst of a process known as the ‘Evolution Roadmap’. As part of this process, work is underway to explore options to enhance the World Bank Group’s Financial Capacity and Model including enhancing its crisis response toolkit. In addition, the G7, G20, and other relevant stakeholders have committed to addressing the governance and financing challenges, particularly in addressing gaps in financing ‘response’.

CHALLENGES
Despite the COVID-19 pandemic being unprecedented in terms of levels of financing and coordination across global health agencies, the system for response financing is poorly coordinated due to high fragmentation. During the COVID-19 response it suffered from a lack of transparency. For example, global medical countermeasures’ pooled procurement systems were not always aware of bilateral purchase deals, leading to an overestimation of country demand. Grant financing for countries and the availability of in-kind support was frequently not predictable, leading to countries hesitating to take up loan financing.

GAPS
At the global level, options like the WHO Contingency Fund for Emergencies (CFE), which were fast to respond in the COVID-19 crisis, could not channel adequate quantities of financing while modalities like appeals by multilateral implementing agencies and others mobilized tens of billions in support, but with
significant delay, resulting in lost opportunities to address peak demand for support including access to medical countermeasures (MCMs). At-risk financing of R&D and manufacturing as well as for the advance purchase of MCMs before regulatory approval was inadequate in LICs and LMICs and the sources and uses of available financing contributed to inequity in eventual access to medical countermeasures in the COVID-19 response. Had frontloading instruments been available at the start of the COVID-19 crisis, the delays in mobilizing donor pledges and commitments meant that they would have been inadequate. This suggests the need for a pre-agreed triggered instrument to be negotiated with donors, combined with frontloading, in order to secure adequate financing, including at-risk financing, in the first phase of the response.

Finally, reallocation of existing projects’ funds is a fast and effective way to make crisis financing available to countries but calls for replenishment of both the country development envelope that those funds were originally intended for, and replenishment at the level of the institution of the international financial institution (IFI) development funds that have been diverted to crisis financing.

At each financing level, the degree to which these instruments and channels function effectively together varies. Findings of the G20 Joint Finance-Health Task Force analysis include that in some cases funding was significant but was not allocated effectively across needs for the response. For example, funding for MCMs was skewed towards vaccines, while therapeutics (including oxygen) funding did not meet targets. A rational and equitable modality for allocation could address this issue.

Global: Accessible by all countries, UN and partner organizations
Initial contingency financing at global level is available to WHO through the CFE, and to UN agencies and some others through the UN Central Emergency Relief Fund (CERF). These funds can be used in most countries. For the CERF in the case of COVID-19 there were global blocks of funding rather than country pooled funds as there was a high level of uncertainty over where outbreaks would flare up. Reprogramming of existing allocated funds at country level by development banks (e.g. World Bank Contingency Emergency Response Components, CERCs) and the Global Fund depended on country decisions to make use of these resources based on priorities for the use of those funds, and on the existence of those funds in a country. CERC use may require declaration of an emergency. In the COVID-19 crisis there was a low level of reprogramming relative to the potentially reprogrammable funds available. CEPI was able to use its balance sheet flexibility to make approximately USD 400 million available to COVAX very early in the crisis. WHO and UNICEF can also use budget sheet flexibility.

At least USD 100 million available for surge financing within 24 hours
No. Furthermore, it is likely that USD 100 million would not be enough resources from Day Zero to enable effective response to multiple health emergencies that are concurrent, as in a pandemic situation. It is likely that in the order of USD 500 million from Day Zero for the global level response would be needed in a pandemic scenario. The WHO Contingency Fund for Emergencies can disburse up to USD 500,000 for WHO use in the first 24 hours of an emergency with potentially USD 50 million available in 48 hours.

Funding available within one week
Partially. There was a funding gap of about USD 500 million for the global response in the first week to address multiple concurrent emergencies.

- CERF funds of USD 225 million were available by March 2020, mainly for use at country level but also
for global coordination (through World Food Programme).

- CFE funds of USD 129 million were implemented by February 2020.
- Reprogramming of existing allocated funding from development banks, UNICEF and the Global Fund resulted in implementation by March 2020 of USD 580 million.
- The WHO Solidarity Fund jointly established with the UN Foundation made available USD 242 million by March 2020.

USD 1 billion available to support the first 6 months

Yes, but this is inadequate. By June 2020 there was about USD 2 billion of funding available to multilateral implementing agencies for the COVID-19 response. In order to secure volumes of medical countermeasures in the development pipeline for use by LICs and LMICs, it is necessary to secure in the order of 10 billion of at-risk financing for advance purchases. By May of 2020 the USA had already invested USD 18 billion in Operation Warp Speed, ultimately securing access to Moderna and Pfizer mRNA vaccines. Given that HICs have ongoing relationships with pharmaceutical manufacturers, global public health interests need to act very quickly and with substantial resources in order to compete and to ensure equitable access to new products. This means very rapid, high levels of at-risk financing are needed.

Question: Funds are usually replenished on a continuous basis

Replenishment of the WHO CFE and CERF were continuous but of very limited magnitude. Other grant funds were appeals based and depended on donor willingness to contribute and their preferences as to the use the funds could be put to. CERF current capitalization is USD 500–700 million with a target of USD 1 billion per year. It has the capacity to quickly move large quantities of funding. There is no cap on the amount of a grant but cash flow is a concern as CERF needs to keep reserve funds in case of additional concurrent crises. In 2023, CFE contributions as of June 15 were USD 16 million with allocations at USD 48 million. It is assumed that the shortfall is covered by the WHO emergencies budget.

During 2020 and 2021, appeals for funding for the COVID-19 response through multilateral implementing agencies had substantial support though financial targets were not met. In 2020–21 the target was USD 38.1 billion and 17.8 billion was raised. The 2021–2022 Access to COVID-19 Tools Accelerator strategic plan and budget financial target of USD 16.9 billion was not met, with USD 6.3 billion raised by the end of the planning cycle in October 2022. Replenishment campaigns by the Global Fund and CEPI did not meet targets in 2022.

Question: Early funds are available within 24 hours of detection

Yes, but only at the level of USD 500,000 for WHO through the CFE. This is inadequate. Day Zero funding of about USD 500 million is needed at global level in the event of multi-country concurrent health emergencies.

Question: The mechanism can ensure that global response plans can be implemented effectively

No. The biggest gaps are in substantial funding for global and domestic responses from Day Zero, in the order of hundreds of millions for the global Day Zero response, and the need for tens of billions of at-risk financing in the first three months of a major health emergency involving a novel pathogen in order to secure volumes of future medical countermeasures for use by LICs and LMICs and others that have challenges in accessing markets for these products.
DATA SOURCES AND REFERENCES

   https://www.g20.org/content/dam/gtwenty/gtwenty_new/document/aug_docs/JFHTF%20Response%20Financing.pdf

Indicator B.1.3.5 (a) Funding immediate economic and socioeconomic response

**Question**
Is there a global financing mechanism to rapidly and adequately mitigate the economic and socioeconomic consequences of pandemics and major outbreaks?

**Expert**
Sarah England, Independent Consultant

**ANSWER TO INDICATOR QUESTION**

**SCORING**

*Score: 1*
*Trend: +1*

**ANALYSIS**

**SUCCESSES**

As reported by WHO and the World Bank to the G20 Joint Finance-Health Task Force

“MDBs have a mix of financing instruments with pre-arranged approaches to provide valuable quick-disbursing funds in the immediate aftermath of a crisis. Setting up ex-ante contingent lines of credit enables governments to access external finance in foreign currency (such as US dollars) at prearranged borrowing rates immediately after a disaster or a pandemic to meet emergency needs. Contingent credit or grant financing provides access to quick but limited liquidity.

The World Bank has offered ex-ante crisis risk financing through contingent financing products, like the Development Policy Financing (DPF) with a Deferred Drawdown Option (DDO), the DPF with a DDO for catastrophic risk (“DPF Cat DDO”), Contingent Emergency Response Components (“CERCs”) in Investment Project Financing (IPFs), and IPFs with DDO. Other IFIs offer ex-ante crisis risk financing for health-related emergencies. The Inter-American Development Bank offers a Contingent Credit Facility that provides ex-ante coverage for pandemics and epidemics.

Those pre-arranged financing mechanisms would lead to disbursements as soon as disbursement criteria for activation are met (which can be after Day Zero but before a Public Health Emergency of International Concern [PHEIC] or pandemic is declared) depending on agreement conditions and willingness to reprogram.”

The International Monetary Fund, the World Bank and regional development banks responded quickly to provide crisis financing and debt service relief within the first three months after the declaration of the COVID-19 Public Health Emergency of International Concern or very shortly thereafter.

**PROGRESS**

The World Bank is undertaking an exercise to enhance their toolbox of instruments including for health emergency preparedness and response as laid out in their evolution roadmap. Both the G7 and G20 are
exploring how to better provide rapid access to financing at adequate levels and through the right channels for health emergency response, particularly for pandemics. The G20 is also undertaking the development of a set of indexes to show vulnerability of countries’ economic systems to health emergency shocks.

**CHALLENGES**

According to an analysis by WHO and the World Bank for the G20 Joint Finance-Health Task Force, development banks made USD 200 billion available across 10 MDBs across pre-arranged contingency and external new financing over the course of the COVID-19 pandemic. However, uptake was slow, as a result of competing priorities, unpredictability, debt pressure, country capacity for response planning, and proposal processes better suited for development financing than emergencies. MDBs interviewed also cited slow disbursement of resources once they were made available (committed) to countries (e.g. ~4 months between approval and disbursement of financing from their crisis response financing facilities). Additionally, challenges with coordination and predictability of grant financing also impacted uptake. Furthermore, not all countries qualified for debt service relief through the IMF or the World Bank/G20 or for crisis financing instruments due to conditionalities.

**GAPS**

The amount of crisis financing drawn from the IMF by the end of April 2020 was in the order of USD 15 billion, which is far from the USD 50–100 billion prescribed by this indicator. However, the pool of financing available may have been greater than USD 15 billion, in which case, the delay may have been due to issues other than availability of financing.

**Question:** The mechanism provides USD 50–100 billion in funding within 90 days of the trigger.

No.

In the COVID-19 crisis there were several mechanisms that together provided substantial financing within 90 days of the declaration of the Public Health Emergency of International Concern on January 30, 2020, or shortly thereafter. These included fast financing and debt relief by the IMF starting March 2020\(^3\), and by the World Bank and the G20 through the Debt Service Suspension Initiative starting May 2020, and through a number of financial instruments from March. Only about USD 15 billion in financing appears to have been taken up through the International Monetary Fund (IMF) by the end of April 2020\(^4\), but the potential amount available may have been substantially higher. According to the IMF COVID-19 lending tracker, from March 2020 to March 2022, the IMF provided financing of approximately USD 171 billion to 90 countries. Overall debt service relief by the IMF from March 2020 to March 2022 amounted to USD 965.29 million. The G20 offered debt service relief to 73 countries through the World Bank from May 2020\(^5\) via the Debt Service Suspension Initiative, which resulted in USD 12.9 billion in suspended payments in the period up to December 2021. Regional development banks also provided crisis financing, but not in this order of magnitude.

**Question:** There are clear triggers at appropriate times to mitigate impact as early as possible.

IMF, World Bank and regional development bank support are triggered by a request from a country.

**Question:** It covers all countries in need of support.

No.
IMF: As part of its early response to the COVID-19 crisis, the IMF doubled access to its Rapid Credit Facility and Rapid Financing Instrument. To qualify for these instruments, countries must have sustainable debt (or on track to being sustainable), urgent balance of payment issues and appropriate relevant policies.

Reprogramming of allocated funding and balance sheet flexibility: Altogether, the reprogrammed funding from the Global Fund, UNICEF and World Bank in the first three months of the COVID-19 crisis totalled approximately USD 400 million.

UNICEF and the Global Fund provided the possibility of reprogramming of already allocated financing or in the case of UNICEF, used balance sheet flexibility to provide crisis financing for COVID-19 including needs beyond the health sector.

World Bank: World Bank Development Policy Financing is conditional on an adequate macroeconomic policy framework, satisfactory implementation of the reform programme, completion of critical policy and institutional actions, and alignment of the Development Policy Financing with the goals of the Paris agreement.

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Median Times in Months</th>
<th>Minimum Times in Months</th>
<th>First Disbursement Month and Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 Contingent Emergency Response Component (CERC)</td>
<td>1.0</td>
<td>1.0</td>
<td>March 2020</td>
</tr>
<tr>
<td>Catastrophe Deferred Drawdown Option (CAT DDO)</td>
<td>1.0</td>
<td>1.0</td>
<td>March 2020</td>
</tr>
<tr>
<td>Regional</td>
<td>1.0</td>
<td>1.0</td>
<td>March 2020</td>
</tr>
<tr>
<td>Repurposed Investment Project Financing (IPF)</td>
<td>2.0</td>
<td>1.0</td>
<td>March 2020</td>
</tr>
<tr>
<td>New IPF (additional financing)</td>
<td>2.6</td>
<td>1.1</td>
<td>March 2020</td>
</tr>
<tr>
<td>Multiphase Programmatic Approach (MPA)</td>
<td>4.1</td>
<td>2.2</td>
<td>April 2020</td>
</tr>
<tr>
<td>New Development Policy Loan (DPL)</td>
<td>7.6</td>
<td>3.5</td>
<td>May 2020</td>
</tr>
<tr>
<td>New IPF</td>
<td>10.5</td>
<td>5.2</td>
<td>July 2020</td>
</tr>
</tbody>
</table>


In addition, the World Bank Pandemic Emergency Finance Facility provided USD 195 million to eligible countries in the first 3 months of the COVID-19 crisis.

Regarding bilateral aid, according to the OECD:

“Initial estimates indicate that within total Official Development Assistance, Development
Assistance Committee countries spent USD 12 billion in 2020 on COVID-19 related activities. ... Providers indicated that in the short-term, their response was guided in managing the spread and consequences of the virus, thus focusing mostly on health systems, humanitarian aid and food security. Some indicated that they would focus in the medium-term on making diagnostics and vaccines available to countries most in need. Many indicated they would also provide support to address the economic and social repercussions of the pandemic.”

DATA SOURCES AND REFERENCES


4 Ibid.


Indicator B.3.3.1 National assessment of financing for preparedness and response

**Question**
Is national preparedness sufficiently, adequately and sustainably financed? Do countries have government-wide, adequately financed contingency funds to support the national response to health emergencies?

**Expert**
Sarah England, Independent Consultant

**ANSWER TO INDICATOR QUESTION**

**SCORING**

**ANALYSIS**

**SUCCESSES**
The Pandemic Fund was created to support countries in health emergencies preparedness with an initial capitalization of approximately USD 600 billion with additional funds pledged.

**PROGRESS**
The World Bank is undertaking an exercise to enhance their toolbox of instruments including for health emergency preparedness and response as laid out in their evolution roadmap. Both the G7 and G20 are exploring how to better provide rapid access to financing at adequate levels and through the right channels for health emergency response, particularly for pandemics. The G20 is also undertaking the development of a set of indexes to show vulnerability of countries’ economic systems to health emergency shocks. The Global Fund has facilitated use of approximately USD 800 million of COVID-19 Response Mechanism funding that was not implemented during the COVID-19 crisis to be used for health systems strengthening including investments like oxygen systems that contribute to health emergency preparedness.

**CHALLENGES**
The pendulum of political attention is swinging away from public health towards areas that were relatively neglected during the COVID-19 crisis, such as climate change and migration. It is unlikely that the Pandemic Fund will be sustainably financed at the levels needed to address preparedness gaps. The Global Fund is not mobilizing further resources for the COVID-19 Response Mechanism (C19RM), and it is anticipated that this funding source will not be replenished. In the COVID-19 crisis, countries did not fully take up available concessional loan financing for emergency response.

**GAPS**
The requests for funding from countries to the Pandemic Fund in its first round of financing exceeded the USD 300 million available by a factor of 23. Approximately USD 7 billion was requested. The actual need is likely to be substantially higher given that the request for proposals did not cover all needs for preparedness. The substantial investments made through grant financing in emergency response infrastructure during the COVID-19 crisis, such as oxygen concentrators and cold chain, will need to be
replaced over the next few years, but it is unlikely that the same order of magnitude of public health grants will be forthcoming. In general, international investment in implementing countries during the COVID-19 crisis emphasized capital expenditure with relatively less spending on human resources, operations, maintenance and repairs. It is therefore a risk that equipment purchased during the COVID-19 crisis may not be put into effective operation and/or may have a more limited lifespan than it could have had.

**Is national preparedness sufficiently, adequately and sustainably financed?**

No.

The oversubscription by a factor of 23 to the Pandemic Fund January 2023 request for proposals indicates a huge unmet need. Sustainability of the Pandemic Fund is not assured and the preparedness funding from the Global Fund C19RM is not expected to be replenished. Domestic funding is key to preparedness, but the COVID-19 crisis demonstrated that countries have not chosen to take up all available concessional financing for health emergency response.

According to the Global Health Security Index findings for 2021, “all countries remain dangerously unprepared for meeting future epidemic and pandemic threats... the overall average score for national-level financing is 35.2 out of 100”.

According to the International Health Regulations (2005) Joint External Evaluation results for 2023, the average global scores per capacity were 24% for prevention, 23% for response, 31% for detection and 31% for other hazards. For capacity C1, P1 national legislation, policy and financing, the global average was 8%. For capacity C12 R1, emergency preparedness, the global average score was 5%.

**Do countries have government-wide, adequately financed contingency funds to support the national response to health emergencies?**

A survey of G20 countries conducted by Ruchir Agarwal in early 2023 indicated that only 40% of countries surveyed had domestic contingency funds that could be deployed in a health emergency.

During the COVID-19 crisis, the Global Fund and the World Bank and some regional development banks provided options for rapid reprogramming of already allocated grant and loan financing for use in the COVID-19 response. In the case of the Global Fund, this amounted to about USD 500 million in funding. However, this reprogramming was not taken up as quickly as would have been hoped. This is likely because of competing demands for those funds for HIV/TB/malaria or for other development priorities, and possible reluctance of ministries of finance to use loan financing for emergency response when grant financing was anticipated. In addition, at the institutional level (e.g. IDA and Global Fund), support for the original target of those reprogrammed funds had to be replenished.

In the case of the World Bank, 26 Contingency Emergency Response Components (CERCs) were activated to support the COVID-19 response across the world, demonstrating a limited number of World Bank contingent instruments that could be immediately employed by countries at the onset of a crisis. In magnitude, tens of millions of these funds were implemented by June 2020 and a quarter of a billion dollars by December 2020. Challenges were described in an evaluation by the Independent Evaluation Group (IEG). CERCs activation required countries to declare an emergency in order to make resources
available. As a result, the IEG evaluation found that it:

“was not possible to access funds for planning activities before the crisis struck - adjusting this requirement could be important to improve the flexibility of CERCs to provide immediate resources for prevention activities to avert a future crisis”.5

In an analysis carried out by WHO for the G20 Finance-Health Task Force6, it was found that seven financing options for national level financing of pandemic response were mapped across six organizations. Financing for the COVID-19 response was unprecedented, with instruments like the World Bank Multi-phase Programmatic Approach (MPA) quickly put in place. However, uptake by countries was low with financing first available from months 4–6 of the response. The low uptake was a result of competing priorities, unpredictable availability of development assistance from various sources, debt pressure and requirements more consistent with development rather than with emergency standard operating procedures.

For example, the World Bank established the Fast Track COVID-19 Facility in April 2020. There was initial success with many countries quick to draw down funding, and USD 3 billion implemented by the end of April 2020. However, this amount quickly plateaued with a total of just over USD 4 billion implemented by the end of December 2020, and less than USD 6 billion implemented by Q1 20227.

Is preparedness included in national medium-term expenditure frameworks and are the right elements of preparedness included?

I did not have research findings on countries’ medium-term expenditure frameworks available for this analysis.

DATA SOURCES AND REFERENCES


6 Mapping Pandemic Response Financing Options and Gaps, prepared by WHO and the World Bank for
the G20 Joint Finance-Health Task Force, August 2023. [https://www.g20.org/content/dam/gtwenty/gtwenty_new/document/aug_docs/JFHTF%20Response%20Financing.pdf](https://www.g20.org/content/dam/gtwenty/gtwenty_new/document/aug_docs/JFHTF%20Response%20Financing.pdf)

Indicator B.1.4.1 (a) Global platform to support leadership

**Question**

Is there a dedicated global platform for the governance of health emergency preparedness and response, which brings cohesion, removes fragmentation and facilitates collective action and where national, regional and global stakeholders can coordinate, plan, and agree on priorities and that can be leveraged in the event of a health emergency?

**Expert**

Adam Kamradt-Scott, Harvard University, T.H. Chan School of Public Health

**ANSWER TO INDICATOR QUESTION**

The short answer is “no”. Currently, there is no global platform to support leadership as envisaged or described by this indicator. Nor, it must be said, would the proposed platform/model ever be realized using the criteria that are currently listed in the indicator.

**SCORING**

Capacity Score: Incomplete (i.e. a score of “1”; recommend reconsider indicator and assessment)

Trend: +1

**ANALYSIS**

Although I recognize the below comments are probably not what the GPMB are requesting in terms of an analysis, the question that I would pose back to the designers of this indicator is: how realistic is this indicator intended to be? To be more precise, given there is no “global platform to support leadership” or the beginnings of one, and it is unlikely to ever be feasible given the expansive nature of the suggested criteria, to what extent would the GPMB be prepared to have this indicator being consistently listed as “Incomplete” or scored as “1”? For, as currently described, it would likely be dismissed as improbable by the majority of policymakers and leaders.

The closest global “platform” we currently have is the World Health Organization, and while it may be tempting to suggest that agency could be extensively reformed to serve as the envisaged “platform to support leadership”, the reality is it is currently far from fit-for-purpose, and fails to meet several of the criteria such as space for civil society, private industry and other non-state actors to “participate meaningfully”. Admittedly, there have been attempts to strengthen participation and collaboration through initiatives such as the Framework of Engagement with Non-State Actors (FENSA) (WHO 2016), and the WHO is currently establishing a new Civil Society Commission (WHO 2023). But Member States have repeatedly declined proposals to reform the intergovernmental agency to allow for more participatory governance that might otherwise undermine their authority. In addition, how would “participate meaningfully” be evaluated? Would meaningful participation be considered achieved if non-state actors have equal voting
rights? The ability to speak to an agenda item? Or just a seat at the table? How would the non-state actors be selected for inclusion? The questions this particular indicator raises are numerous, and the criteria as currently listed are unlikely to ever be implementable. For that reason, I would recommend an alternative indicator and related set of criteria are developed that offer a more realistic framework for preparedness.

With respect to reducing fragmentation, this again is an ambitious and laudable objective. It would, however, necessitate a change in government behavior away from creating new entities and global health partnerships, and require extensive reforms of existing state-based platforms (such as WHO) in order to encourage increased trust in those existing institutions. Arguably the WHO is the only entity that might be assessed to be closest to the listed indicator, but it would require most of the 194 Member States to agree to major reforms of the organization. That is considered unlikely given current geopolitical tensions and the fact that while many WHO Member States have commended the intergovernmental organization on its management of the COVID-19 pandemic, the agency has also become unhelpfully politicized.

For these reasons, it may be more feasible to reduce the scope of the envisaged platform, limiting the objectives to creating a forum for heads of state/leaders if the intention is for a body to meet rapidly following identification of an international public health threat/emergency. There are proposals that have been put forward, for example, for a new “Global Health Threats Council” but it has currently received a mixed reaction, and the connection that any new body would have to existing governance mechanisms (i.e. UN Security Council, UN General Assembly, World Health Assembly, etc.) would need to be resolved to avoid further fragmentation and duplication. In this context, the proposal by the current WHO Director-General that the Global Health Threats Council should be folded into and under the WHO does not reduce the fragmentation and is politically unrealistic given the envisaged composition of the Council is heads of state (and WHO is restricted to working with health ministries), so an alternative “home” would need to be found.

The singular cause for a small measure of optimism relating to improved coordination of health emergency response over the previous year has been the creation of the Standing Committee on Health Emergency Prevention, Preparedness and Response (SCHREPR) in May 2022 (WHO 2022). The creation of the Committee, which has been designated as a standing committee of the Executive Board, provides some scope for enhanced intergovernmental response to future health crises; however, it must also be acknowledged that the Committee suffers from the same limitations as the World Health Assembly (i.e. composed of governments only with limited means for non-state actors to participate meaningfully), and also only comprises representatives from either foreign affairs departments or health ministries (as opposed to a leadership forum suggested by the indicator). In addition, as per the Committee’s terms of reference, the entity only convenes once a public health emergency of international concern has been declared, leaving limited scope for the Committee to consider matters of preparedness. The authority of the Committee to affect meaningful change in how governments respond to future health emergencies (i.e. issue unwarranted travel restrictions) is also untested. Accordingly, while it warrants recognition that some progress has conceivably been made over the previous year, it remains glacial at best and unproven.
What I would propose here is the GPMB carefully considers what is the objective they are trying to realize here, as the platform as currently worded is impractical. Is the GPMB seeking a consultative body that would be inclusive, participatory, and deliberative that considers what is needed for strengthening preparedness which then advises leaders and decision-makers to agree on measures? Or is it a body that helps coordinate international and regional capacity building (with the commensurate capability to have its decisions actioned in a timely manner)? Or is it simply a further extension to the WHO following the declaration of a PHEIC? These are different objectives and lead to different structures and governance arrangements.

DATA SOURCES AND REFERENCES

Indicator B.1.4.1 (b) Strategic plan

**Question**

Is there an agreed global, multisectoral, cross-agency and holistic strategic plan for health emergency preparedness and response?

**Expert**

Adam Kamradt-Scott, Harvard University, T.H. Chan School of Public Health

**ANSWER TO INDICATOR QUESTION**

As with other indicators, the concise answer to the indicator question is a “no”; it would seem, however, that efforts are at least underway to enhance the existing arrangements. At the same time, it should be acknowledged that any attempt to develop a global strategic plan must be approached with caution, with due regard given to the marked variation across the international community in terms of capabilities.

**SCORING**

*Capacity status:* Incomplete (i.e. score of “1”)

*Trend:* Improving (+1)

**ANALYSIS**

In response to the COVID-19 pandemic the international community has agreed to commence work on developing a new “pandemic treaty” (hereafter the “WHO CA+ instrument”) that might yet offer a more comprehensive framework and the basis for a global strategic plan to strengthen pandemic prevention, preparedness and response efforts. Having said this, the WHO CA+ instrument – even if successfully negotiated – is still unlikely to fully address the criteria as outlined in the indicator. More precisely, while the treaty may serve to strengthen and enhance multisectoral collaboration between governments and intergovernmental organizations, as well as some cross-agency cooperation in pandemic prevention, preparedness and response capacities, the instrument is not currently anticipated to address the economic and socioeconomic dimensions of pandemic prevention, preparedness, response and/or resilience. This may change given the intergovernmental negotiations underway, however it is considered unlikely. Still, the WHO CA+ instrument is likely to build on existing arrangements that are currently largely predicated on the International Health Regulations (2005) and thus it does potentially offer promise.

The major caveat to the above is that the WHO CA+ instrument, even if it is successfully negotiated, may not be ratified by every WHO Member State, leaving gaps in global capabilities. Even where countries do ratify the instrument, considerable work will be needed to develop action plans for how the instrument will be practically implemented, including where and how additional resources will be located to support countries building and strengthening their pandemic prevention, preparedness and response capacities. While it is important to acknowledge that progress is incrementally being made in the development of a more comprehensive “plan”,

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broadly defined, there remains extensive work yet to be undertaken.

DATA SOURCES AND REFERENCES.
No additional data sources.
Indicator B.1.4.2 International regulatory instrument

**Question**

Is there an international regulatory instrument with clear, enforceable priorities and targets around preparedness and obligations related to data sharing and equity during a health emergency response?

**Expert**

Gian Luca Burci, Graduate Institute of International and Development Studies

**ANSWER TO INDICATOR QUESTION**

**Methodological considerations**

1. From a methodological perspective, it would be important to clarify what is meant by “international regulatory instrument”: does it refer to legally binding instruments or also to non-binding normative instruments such as WHO’s Codes? The scope of the question and the range of possible answers changes dramatically. Moreover, the indicator and question imply that there should be a single instrument performing all the functions as a desirable situation. However, given the fragmentation and siloes of international law and governance, that is not necessarily a realistic prospect and possibly not even a desirable one since functions should be located institutionally and legally where they can be performed best.

2. “Prevention” has undergone a change in interpretation since the COVID-19 pandemic and the negotiations in WHO, and a clarification of what is intended by that term in the indicator is warranted. In particular, the concept of “deep prevention” has gained attention from a One Health perspective – preventing zoonotic spillovers rather than preventing an outbreak once the spillover has occurred.

Subject to the proviso above, there is no single international regulatory instrument addressing all the issues raised in the question and listed in the scope.

At the same time, a number of international regulatory instruments address directly or indirectly prevention, preparedness and response to health emergencies. These are in part specifically related to human health and mostly falling within WHO’s framework, while others deal with different issues and have been adopted by other organizations, but they influence health outcomes due to the complex and intersectoral nature of health emergencies. This plurality reflects the fragmentation of international law and governance.

The closest the international community is to the assumption expressed in the question is the current negotiation of a WHO pandemic accord, in parallel with the proposed amendments to the International Health Regulations (IHR). Many of the issues addressed in the indicator appear in the current Bureau Draft and in the proposed IHR amendments. However, whether and in what form they may remain in the final texts to be adopted in May 2024 is a speculative question.

**SCORING**
Capacity: 1-2: incomplete or partial based on the indicator question of a single instrument.

Trend: + 1: Improving from the 2022 baseline due to the ongoing processes of negotiation of a pandemic accord and amendments to the IHR as well as the increasing awareness of the role played by other institutions and instruments on PPPR.

ANALYSIS

A non-exhaustive list of applicable instruments is as follows:

1. **The International Health Regulations (2005)**, the sole global binding international legal instrument to address international disease outbreaks. The IHR (2005) focus on preparedness through their core capacities requirements; surveillance by States Parties as well as WHO; alert, containment and coordination through the declaration of a PHEIC, the issuance of temporary recommendations that serve as a benchmark for national actions, and more generally WHO’s analysis, risk assessment and guidance. States Parties hold a number of obligations but retain wide discretion to adopt unilateral national measures. The IHR lack an institutionalized compliance and accountability mechanism and are largely based on self-assessment, even though the WHO secretariat has adopted a number of tools to support States and ensure some uniformity (IHR Monitoring Framework, Joint External Evaluation Tool). They also lack dedicated provisions on financing and Article 44 on cooperation is quite general. Despite difficulties in implementation and political controversies, the IHR secure WHO’s leadership in PPPR and meets some of the criteria listed in the indicator.

2. **Multilateral Environmental Agreements (MEA)** that address aspects of deep prevention – e.g. protection of particular ecosystems such as wetlands or water bodies – or influence access to pathogens and potentially their genetic sequences – in particular the Convention on Biological Diversity (CBD) and its Nagoya Protocol. The most relevant is CBD/Nagoya that serves as default for the international sharing of pathogens and the benefits derived from their utilization. Even though MEAs are not directly health-related, the increasing realization of the interactions between environmental factors and human health are influencing policy decisions within their governance, e.g. with regard to the conditions for sharing genetic sequence data.

3. **WTO’s TRIPS Agreement** as the quasi-global default treaty regulating intellectual property rights (IPR), with a decisive influence on access to medicines. Despite the discretion given to States Parties to interpret and implement its provisions, TRIPS is enforceable through WTO’s mandates dispute settlement system. TRIPS’s implementation has generated important and at times controversial decisions, such as the 2001 Doha Declaration, the 2005 amendment to facilitate supply to developing countries, and the 2022 partial IPR waiver with regard to COVID-19 vaccines.

4. **WHO’s non-binding Pandemic Influenza Preparedness (PIP) Framework**, the sole international access and benefit sharing instrument in the health field, however limited to pandemic influenza. It has generated substantial resources for WHO’s role in it as well as for preparedness activities by Member States.

5. **Standards and surveillance framework developed by the World Organization for Animal Health (WOAH)** to detect animal outbreaks and facilitate deep prevention, such as the Terrestrial and
Aquatic Animal Codes.

6. **Standards, guidelines and recommendations of the FAO/WHO Codex Alimentarius Commission** related to food contamination. Despite their non-binding nature, such instruments acquire a harder legal nature through their reference as the international standards for food safety in WTO’s Agreement on Sanitary and Phytosanitary Measures (SPS).

7. **The 2022 One Health Joint Plan of Action** adopted by the organizations forming the “Quadripartite” (FAO, UNEP, WHO, WOAH). It provides a framework for action and proposes a set of activities the four organizations can offer together to advance and sustainably scale up One Health.

Even though the instruments listed under 4) to 7) are formally not binding and (with the exception of the SPS Agreement) non-enforceable, they produce a demonstrable normative and practical effect on PPPR measures and policies by states as well as other stakeholders.

While many areas of preparedness are covered by regulatory instruments, the most important gap is the One Health approach, in particular primary prevention to reduce the risk of zoonotic spillover. There is no international instrument that covers this area.

The Bureau’s draft of the pandemic accord released in May 2023 addresses a number of points covered by the indicator, in particular equitable access to countermeasures, transfer of technology, access and benefit-sharing as well as financing. It addresses compliance and accountability through a universal peer review process as well as an expert implementation and compliance committee. Textual negotiations have not really started yet and positions for the moment seem far apart, in particular on the proper balance between prevention and equity.

**DATA SOURCES AND REFERENCES**

1. International Health Regulations (2005) and compilation of amendments to the IHR

2. Bureau’s text of the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO CA+)

3. Pandemic Influenza Preparedness (PIP) Framework
   https://www.who.int/initiatives/pandemic-influenza-preparedness-framework

4. UN Framework Convention on Climate Change and Paris Agreement
   https://unfccc.int/ and https://unfccc.int/process-and-meetings/the-paris-agreement

5. UN Convention on Biological Diversity and Nagoya Protocol
   https://www.cbd.int/ and https://www.cbd.int/abs/about/

6. WOAH Terrestrial Animal Code and Aquatic Animal Code

7. Codex Alimentarius standards, guidelines and recommendations

8. TRIPS Agreement, 2001 Doha Declaration, 2005 amendment to TRIPS (Article 31 bis) and 2022 waiver on COVID-19 vaccines.
https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm;
https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm;
https://www.wto.org/english/tratop_e/trips_e/wti641_e.htm;
https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True
Section 2 – Equity

Expert assessments

Indicator B.1.1.2.1 Global R&D coordination and priority setting

**Question**

*Is there an appropriate and inclusive global governance and coordination system for R&D that supports priority setting, advanced planning, and capacity to rapidly mobilize resources to support end-to-end development, production, procurement, and equitable access to medical countermeasures for health emergencies?*

**Expert**

Suerie Moon, Graduate Institute of International and Development Studies

**ANSWER TO INDICATOR QUESTION**

No, there is not an appropriate and inclusive global governance and coordination system for R&D that supports priority setting and advanced planning. There are very few investments in building capacity. In principle, resources can be rapidly mobilized during a crisis from governments and philanthropic funders, but in reality, such mobilization is uncoordinated and siloed. Institutional arrangements to ensure end-to-end development are insufficient, as are arrangements for production, procurement and equitable access to medical countermeasures for health emergencies.

**SCORING**

*Score:* 0 Meets no or a few criteria

*Trend (since 2022 baseline):* 0 No change

**ANALYSIS**

**SUCCESSES AND PROGRESS**

A clear and important success has been the development of the WHO R&D Blueprint for emerging infectious disease, initially developed in response to the 2014–16 West African Ebola crisis. The Blueprint helps the global R&D community set priorities by identifying the pathogens likely to cause international health emergencies and for which existing health technologies are insufficient, and therefore, for which further R&D is required. The current list of priority pathogens is: COVID-19; Crimean-Congo haemorrhagic fever; Ebola virus disease and Marburg virus disease; Lassa fever; Middle East respiratory syndrome coronavirus (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS); Nipah and henipaviral diseases; Rift Valley fever; Zika; “Disease X.” The Blueprint team develops an R&D roadmap and target product profiles for each pathogen on the list, providing further guidance to product developers. While WHO cannot compel any research funder or research institution to follow these priorities, there is some evidence that the list has influenced R&D decision-making. For example, the Coalition for Epidemic Preparedness Innovations (CEPI) makes reference to the R&D Blueprint in its own
list of priority pathogens, and its investment includes seven of the diseases on the WHO priority list. The
Blueprint is currently undergoing review, and has shifted towards focusing on viral families rather than
on single viruses alone, with a new list expected to be published in 2023.

Another success and sign of progress is WHO’s capacity to convene upon short notice the international
scientific community to discuss and seek to reach agreement on R&D priorities during crises. It convened
multiple scientific meetings during the COVID-19 PHEIC, starting as early as February 2020, in a meeting
of over 300 scientists and research funders, jointly convened with the Global Research Collaboration for
Infectious Disease Preparedness (GLoPID-R).

The WHO Global Observatory on Health R&D is an important step forward in making more legible a vast,
diverse and global set of R&D activities. It aims to track global R&D activities in order to identify gaps and
enable priority-setting through monitoring and analysis. Established in 2016 in response to the Global
Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, it compiles data from
multiple sources.

A number of public and philanthropic R&D funders have begun placing access conditions on their
funding, which helps to plant the seeds of equitable access further down the line when a product is fully
developed. Such conditions usually require grantees to develop a product through regulatory approval;
to share data openly; to commit to manufacturing and adequate supply in specified countries; and to
commit to affordable pricing. Funders frequently retain licenses on intellectual property rights as a lever
for enforcement, in case the grantee does not fulfil these commitments. While contracts between
funders and grantees for health emergency R&D have generally been kept confidential, there has been
a growing number of instances of such contracts being made publicly available, a welcome albeit slow
shift towards greater transparency.

**CHALLENGES AND GAPS**

An important challenge is that there is no entity with the authority to coordinate research institutions or
research funders. This means that priorities can be established and agreed, but researchers and/or
funders may not actually work on or invest in those priorities. At best, WHO can monitor progress against
the priorities it has identified. Even the resources it has to do so seem insufficient for the task. For
example, the Global R&D Observatory compiles and relies on data collected by other actors, and can
offer limited analysis or follow-up on identified gaps. Funders are reluctant to give up autonomy in how
they set their own priorities, and seem likely to remain so.

R&D for emerging infectious diseases (EID) is primarily funded with public money, since it is too risky for
the private sector. This provides an important point of leverage to achieve equitable access to
countermeasures, as governments can tie equitable access conditions to the public funding they grant
to private firms, universities and other research institutions. The use of such access conditions, as noted
above, has been demonstrated to be effective for delivering equitable access in a number of
internationally-funded R&D projects, and has become a more frequently-deployed practice. However,
implementing such conditions is very rare for national governments, who remain the main R&D
investors.
Most government research funders prioritize narrowly-conceived national self-interest in their R&D investments for health emergencies. For example, during COVID-19, most government grants for vaccine R&D were given to research entities within one’s own territory. Perhaps this is to be expected, as pandemic product R&D emerged from national biosecurity R&D systems in a handful of countries. However, with growing global interdependence, counteracting disease outbreaks abroad is consistent with serving the national self-interest. While there is a strong rationale for governments to invest in R&D so that the end products can be made equitably accessible to all who need them, they are very very far from doing so. Current negotiations towards a Pandemic Accord are considering whether governments will commit to place equitable access conditions on their R&D funding, but there is opposition from some countries to doing so. Without a clear commitment to ensuring the fruits of publicly-financed R&D are accessible to all, there is unlikely to be equitable access to countermeasures in an end-to-end system.

R&D investments for countermeasures are decided by public and philanthropic funders, largely concentrated in the Global North. While this is slowly beginning to change, with increased interest in R&D investment by some governments in the Global South, the majority of funding is likely to continue to come from the Global North for some time. Governance of these investments does not systematically include representatives from LMICs, as they are largely made by national governments focused on national interests. There is more space for inclusive governance in international funding entities, such as CEPI, the Pandemic Fund or philanthropic funders (e.g. Gates Foundation, Wellcome), but these will always compete with national R&D funders.

Note: I did not include an assessment here of arrangements for production, procurement and equitable access EXCEPT as they relate to R&D, since these topics are also separately listed in the GPMB framework. The main way diversified production and equitable access could be delivered is through conditions on public funding of R&D, which I address above.

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**Indicator B.1.1.2.4 R&D capacity-building**

**Question**
Are there effective global mechanisms supporting technology transfers for vaccines, therapeutics, diagnostics, personal protection equipment and medical technologies as well as capacity building to develop research and development capacities at the regional and national levels?

**Experts**
International Pandemic Preparedness Secretariat (IPPS) Science and Technology Expert Group and implementation partners

**ANSWER TO INDICATOR QUESTION**

**INTRODUCTION**
R&D capacity building is a significant preparedness measure that can be undertaken in interpandemic periods to ensure the mechanisms, networks, and processes are in place ahead of a pandemic threat. Estimating the status of R&D capacity is difficult, and we present an analysis of two key components: technology transfer (Section A, drawing on key exemplar initiatives) and R&D capacity building activities (Section B, assessing the inputs, outputs and modalities for building capacity).

In summary, there is insufficient R&D funding being spent on the WHO’s R&D Blueprint pathogens, and there is a significant lack of funding for research in LMIC settings. There are some promising tech transfer programmes (e.g. MPP, C-TAP, DCVMN and the mRNA tech transfer programme), but these could be more widely adopted. Finally, more coordination is required to enable efficient use of limited resources for infectious disease with mechanisms to identify and align industry, academia and funders’ activities.

**A. Technology transfer**
Technology transfer refers to the process of sharing knowledge, intellectual property (IP), expertise, and technical know-how related to medical countermeasures such as vaccines, therapeutics, diagnostics, personal protective equipment (PPE), and other medical technologies. It involves the exchange of scientific information, manufacturing processes, research methodologies, and best practices between different entities, including countries, organizations, and industries. Five global initiatives of the most relevance to note here, which are described further below as examples: the COVID-19 Technology Access Pool, the Pandemic Influence Preparedness Framework and the Medicines Patent Pool, the Developing Countries Vaccine Manufacturing Network and the mRNA technology transfer programme.

Overall, tech transfer initiatives have proven successful in improving access to different types of technologies, particularly during COVID-19. Partnerships between academia and industry which have different models of intellectual property (IP) sharing, such as the Oxford AstraZeneca vaccine partnership, have proven effective during the pandemic, as well as tech transfer via public health organizations (with the licenses provided by Pfizer, Merck and Shionogi to multiple manufacturers via the Medicines Patent Pool). There are, however, still barriers in place. A major challenge is having capacity and skilled personnel to participate in tech transfers (receiving and adapting technology to local
use), especially in LMICs. This does present an opportunity for future investment in regional capacity building hubs as well as building off existing initiatives such as the Developing Countries Manufacturing Network (DCVMN), which has provided training specifically for this\(^1\). It can also be difficult to incentivize pharmaceutical companies to participate and more capacity is needed (within countries and initiatives) to manage licenses, transferring and accessing these tools. Also, the tech transfer programs which have been successful have been disease-specific, and have struggled at times when other outbreaks present competing priorities and tech transfer platforms are unable to diversify their scope.

**Example: COVID-19 Technology Access Pool**

The COVID-19 Technology Access Pool (C-TAP) is a WHO initiative that provides a “single global platform for the developers of COVID-19 therapeutics, diagnostics, vaccines and other health products to share their intellectual property, knowledge, and data with quality-assured manufacturers through public health-driven, transparent, voluntary, non-exclusive and transparent licenses. It also provides support for technology transfer agreements. Through voluntary licensing and patent pooling, patent holders can reach new markets and scale up production using untapped capacity of manufacturers around the world, while securing appropriate royalties”.

The main advantage of C-TAP is that it ensures transparent and non-exclusive licenses, it is voluntary and public-health driven. As of September 2022, 44 member states had joined\(^2\). It encompasses several types of technologies including vaccines, therapeutics and diagnostics, and its main focus is to improve access for developing countries. For example, in November 2021, the Spanish National Research Council (CSIC) was the first organization to share its IP rights and details of COVID-19 diagnostic tools globally through C-TAP, whilst the US National Institutes of Health (NIH) shared therapeutics, early-stage vaccines and diagnostics through C-TAP deals in May 2022. These benefited qualified manufacturers globally by allowing them to produce these shared technologies\(^3\). C-TAP licences are done via one of its operational partners, the Medicines Patent Pool (MPP), which is further explained below.

However, whilst its voluntary nature provides some advantages, it does mean there are some challenges as pharmaceutical companies producing the leading vaccines, therapeutics and diagnostics against COVID-19, such as Pfizer and Moderna, have not participated\(^4\). Some leading HICs have also not actively supported the initiative, which in 2022 included the UK, Japan and EU, whilst other pharmaceuticals established only bilateral tech transfer agreements instead (such as the AstraZeneca partnering with Oxford University, Fiocruz and the Serum Institute of India).

**Example: Pandemic Influenza Preparedness Framework**

The Pandemic Influenza Preparedness (PIP) Framework brings together WHO Member States, industry, other stakeholders and WHO to implement a global approach to pandemic influenza preparedness and response. Its key goals include: to improve and strengthen the sharing of influenza viruses with human pandemic potential; and to increase the access of developing countries to vaccines and other pandemic related supplies.

One key benefit of the PIP Framework is the Partnership Contribution (PC). According to the PIP Framework evaluation published in 2022, since 2012 USD256million has been contributed by pharmaceutical manufacturers that use the Global Influenza Surveillance and Response System (GISRS)
– a network of laboratories conducting surveillance of influenza viruses. The PC can then allocate funds for pandemic preparedness capacity building, response activities and the PIP secretariat. Member States are actively engaged in developing or updating their vaccination policies, regulatory processes and there have been marked improvements in pandemic preparedness activities at the country level.

The main challenges of the PIP Framework include the fact that it has taken time for some countries to share surveillance data with regional or global platforms (such as FluNET or FluiD). WHO has worked with countries closely to support them in doing this though. Also, other emergencies happening throughout the year prevent countries participating actively and consistently with the PIP, and it is affected by lack of capacity on the ground within countries at times (for example, there can be high staff turnover and trained staff are spread thinly).

**Example: Medicines Patent Pool**

The Medicines Patent Pool (MPP) is a “United Nations-backed public health organization working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries. Through its innovative business model, MPP partners with civil society, governments, international organizations, industry, patient groups, and other stakeholders, to prioritize and license needed medicines and pool intellectual property to enable generic manufacture and the development of new formulations”. The MPP is also an operational partner for C-TAP and all C-TAP licences are done via MPP.

The 2021 evaluation of the MPP showed that the MPP is widely recognized to provide unique and important services in global health by facilitating voluntary licensing and technology transfer for medicines and other health technologies with both health and economic benefits for people in LMICs. MPP has obtained licences on three key antivirals for COVID-19 and provided sublicences to multiple manufacturers across all regions of the world, which have enabled quality assured generic versions to be developed and become available for procurement by over 100 LMICs. As of December 2021, 26.91 billion doses of generic products providing 71.76 million patient-years of treatments facilitated by MPP have been supplied to more than 140 LMICs. MPP's work has also resulted in over USD$1.2 billion savings for the global public health community.

As a result, voluntary licensing has increased. MPP adds value to originator companies by monitoring compliance with license obligations (removing that burden from companies), and these companies gain reputational advantages from working with MPP. Also, generics companies gain access to licenses that they may not be able to obtain otherwise through the patent pool. Finally, the MPP works with diverse stakeholders from a range of sectors including public health, procurement agencies, national governments, and civil society organizations to ensure complementarity when trying to improve access to medicines in LMICs.

Over the years, MPP’s disease scope has expanded starting with HIV where the majority of its impact has been to date, and gradually expanding to hepatitis C, tuberculosis, noncommunicable diseases (NCDs), and COVID-19, with licences established across all these areas. Some of the biggest challenges have been in relation to NCDs, where industry access strategies (and advocacy for access from other stakeholders) are the weakest. MPP’s licensing work can deliver best results where they can work in partnership with
governments and other global health stakeholders to accelerate update of licensed products.”

**Example: Developing Countries Vaccine Manufacturing Network (DCVMN)**
The Developing Countries Vaccine Manufacturing Network (DCVMN) is “a voluntary alliance of over 40 vaccine manufacturers from 15 developing countries, firmly engaged in innovation, research, development, manufacturing, and supply of high-quality vaccines to 170 countries striving to enable equitable access to vaccines”. During the COVID-19 pandemic, 60% of global vaccine manufacturing was from DCVMN members and it demonstrated some success by accelerating tech transfer between its members to 170 countries\(^9\). For example, the transfer of the AstraZeneca vaccine to LMIC vaccine producers in Brazil, India and Thailand was supported by the UK government, CEPI and Covax\(^10\). The DCVMN also enables capacity building by providing training on tech transfer, in collaboration with the Hilleman Laboratories, to its LMIC partners and supporting the development of partnerships to enable it\(^11\).

**Example: mRNA technology transfer programme (South Africa)**
Finally, the mRNA technology transfer programme launched in July 2021 in South Africa aims to share technology and technical know-how on the manufacturing of mRNA vaccines with local producers across 15 countries. The initiative is co-convened by WHO and the MPP and has partnerships across the 15 governments involved, regional organizations (e.g. Africa CDC and PAHO), academia and industry. The programme aims to enable equitable access to mRNA vaccines by increasing the distribution of sustainable manufacturing capacity across LMICs, enhancing regional and inter-regional collaborations, and developing and empowering a local workforce through tailored and inclusive training and expert support. What is unique in the mRNA technology transfer model is the multilateral process that allows sharing of technologies to multiple recipients so that through local and regional production those in need can be reached rapidly\(^12\). The programme’s initial focus is on COVID-19 but over time the technology platform will be used by programme partners to explore the development of mRNA vaccines for other disease areas.

**B. R&D capacity building activities**
To assess R&D capacity building, we have focused on:

1. **Inputs:** Funding for R&D by expenditure of a country and for priority pathogens
2. **Outputs:** numbers of researchers and scientific publications within a country, products in pipeline, IP generated, capacities built in terms of skilled HR and infrastructure
3. **Modalities:** equitable partnerships, and networks to build R&D capacity

Overall, the main successes have been a growing appreciation for the need for investment in LMIC R&D capacities, as has been established through networks and equitable partnerships. These initiatives enable tech transfer as well as shared knowledge and resource pooling.

There are still challenges, particularly around ensuring research capacities are built sustainably in LMIC settings, and increasing capacity for trials and product development in Africa. Part of this comes through having a strong health research workforce, but investment is also needed in the underlying infrastructure that enables R&D to happen. There is certainly still a significant discrepancy between disease burden and research capacities in-country.
Inputs: R&D expenditure
In most high-income countries, research and development capacity would be considered well-developed. According to UNESCO, global spending on R&D has reached a record high of almost USD$1.7 trillion, but about 10 countries account for 80% of this spending\textsuperscript{13}. Countries with the highest R&D resources and investments, as assessed through percentage of GDP devoted to R&D activities, are typically in high income countries, with the USA, China and many countries in Europe spending over 2% of the GDP on R&D compared to countries in Africa and Southeast Asia often spending less than 0.25% (from the UNESCO Institute for Statistics 2020). This investment is closely linked with R&D performance, including a country’s capabilities for drug discovery and pharmaceutical patents\textsuperscript{14}.

Investments in priority pathogen R&D are collated by G Finder\textsuperscript{15}. Coronavirus funding in 2020 and 2021 dominates the infectious disease landscape, but up until then filoviruses (including Ebola and Marburg) had seen the most significant investments. In terms of medical countermeasures for R&D, vaccines averaged 42% of investments between 2014-21, in comparison to diagnostics which saw 3.9% of investment, whilst therapeutics and biologics had 23% of investment on average.

Outputs: Numbers of researchers and scientific publications within a country
There are noticeably higher numbers of researchers within HICs and more publications. According to the WHO Global Observatory on Health R&D, on average HICs had 353 full time equivalent health researchers per million inhabitants in 2023, compared to 62 in LMICs, equivalent to HICs having roughly 59 times more FTE health researchers per million inhabitants than the low-income group, ranging from 1,204 in Singapore to 0.2 in Zimbabwe (based on data from 82 countries). Health researchers represent between 10-14% of all researchers across all income groups (with Africa having the highest proportion of researchers working in health)\textsuperscript{16}.

According to Our World In Data, the number of scientific publications per capita is considerably higher in HICs than LMICs\textsuperscript{17}. Also, North America and Europe have published over 3,000 randomized controlled trials (RCTs) in high-impact medical journals, an indicator of a country’s ability to assess the effectiveness of medical countermeasures, whereas countries in Africa and South East Asia typically have under 300 (in 2017).

Outputs: Products in pipeline and intellectual property generated
There are currently more than 61,000 unique products in the pipeline for more than 118,000 indications. The vast majority (81%) of products are for noncommunicable diseases, with only 3% of products targeting a R&D Blueprint pathogen, and 0.5% targeted a neglected tropical disease. Most of these active products are therapeutics, whilst relatively few are diagnostics. Of the active products, 12%, 22% and 6% are in phase I, II and II studies respectively, with a following 1% in preregistration phase\textsuperscript{18}. Future analyses should aim to assess the location and geographic spread of products in the pipeline, but that was not possible at this time.

A 2018 study showed that approximately 83% of 784,585 trial sites were in 25 HIC OECD countries, whereas <5% had been conducted in 91 LMICs. Despite the challenges with conducting trials in LMICs, these countries saw the most growth between 2007-2012, particularly for latter stages of development.
(LMICs operated 19% of phase 3 trial sites, compared to only 6% of phase 1 trial sites)\textsuperscript{19}. A 2021 analysis of WHO’s International Clinical Trial Registration Platform (ICTRP) also showed that on 12,533 COVID-19 trials, only 4% were conducted in the African continent (which has approximately 20% of the world’s population), and most of these studies were conducted in either Egypt or South Africa involving the testing of therapeutics\textsuperscript{20}. Whilst these metrics highlight the lack of clinical trials in LMICs (particularly in Africa), they don’t translate to products in the pipeline, IP generated, or sustainable clinical trial sites in place as the success rate of these trials is unknown.

Outputs from R&D can also be assessed by the intellectual property generated, using statistics on patents. China has the highest patent applications in 2021 with 1.59 million applications, followed by the US (591,000 applications), Japan (289,000 applications), the Republic of Korea (238,000 applications) and the European Patent Office (189,000). The top 10 national patent offices accounted for 91.6% of the world total in 2021\textsuperscript{21}. This does not represent health-specific patents, but rather patent applications from all sectors.

Whilst the number of patent applications is increasing from lower middle-income countries (in 2012, there were 83,000 applications whereas 2021 saw 110,700 applications), only 3.5% of applications in 2021 were from low or lower middle-income countries. In 2021, 64% of patent applications were from Asia (mostly China and India), 21% from North America, and 12% from Europe\textsuperscript{22}.

**Outputs: Skilled workforce & infrastructure**
Key to building health research capacity is having skilled human resources and infrastructure to deliver R&D. Health research capacity development for healthcare workers has been recognized as critical for building capacities in LMICs, often documented through training programmes which enable local teams to participate in externally sponsored trials which creates a “false appearance of growth and generating dependence on foreign support”\textsuperscript{23}. Investments are needed in the training and scientific capacity of researchers at local institutions to build a workforce who are best positioned to address the health challenges of their local communities, and ensuring the solutions are more sustainable over time. Such capacity building initiatives should include long-term planning and collaboration with multisectoral partners, including researchers, implementers and policy makers and local, state and national levels\textsuperscript{24}. Most research funding however goes to answer specific questions or topics over a 3-4 year period, rather than supporting the broader ecosystem. Of USD$37,000 million spent on biomedical research in 2020, 16% of it went on training, 7% on core support and 1% on capacity strengthening\textsuperscript{25}.

**Modalities: Research partnerships**
Partnerships are one way of increasing R&D capacity, both between academic institutions in different countries as well as academia-industry partnerships (as was seen with COVID-19 vaccines). Globally, partnerships allow the spread of innovations across borders, and many funders (CEPI, Wellcome, Gates, NIH) specifically aim to fund partnerships that span multiple countries. Most collaborations receiving grant funding in 2020 occurred between HIC partners – 98% of grants that resulted in collaborations had been awarded to HIC recipients and of these, 83% of collaborations were with others in HICs\textsuperscript{26}. Initiatives to increase LMIC partnerships have historically been established as ‘north-south’ partnerships, but there is increasing effort being placed on ‘south-south’ partnerships as well now. Quantitative data is limited for this, however key initiatives include the Global Code of Conduct for Research in Resource-Poor
Settings to ensure research is carried out ethically, sustainably and without ‘helicopter research’ (extractive research where HIC teams are temporarily based in LMIC settings and extract data for their own purposes but which do not result in long term capabilities in these LMICs)\textsuperscript{27}.

Examples of research partnerships:

- CEPI has made investments in vaccine candidates R&D for priority pathogens and disease X. Many of these have involved partnerships in some way, including partnerships between academia and industry as well as collaborations between HIC and LMIC institutions. For example, CEPI co-chairs the Regional Vaccine Manufacturing Collaborative (RVMC) with the US National Academy of Medicine, and is an active participant in Africa CDC’s Partnerships for African Vaccine Manufacturing (PAVM), and also has targeted investments in a network of vaccine manufacturers in the Global South which will expand sustainable routine and outbreak vaccine manufacturing capacity in those regions\textsuperscript{28}.

- FIND, the global diagnostics alliance, is accelerating access to diagnostics by having active partnerships with 150 organizations. During COVID-19, they worked with partners and local communities across the full value chain to address key barriers around testing (e.g. quality issues, cost and geographic distance)\textsuperscript{29}. FIND actively champions global manufacturing equity, and have invested in technology transfer and local production for COVID-19 rapid diagnostic tests (RDTs) in Brazil, India, Senegal and South Africa. They’ve also supported LMICs to expand genomic surveillance capacities which helped identify the Omicron variant in Botswana.

- UK Collaborative on Development Research is a group of government departments and research funders who work to promote joint action in research\textsuperscript{30}. However, despite these efforts to increase R&D capacity in LMIC settings, there is still a large disparity in R&D capabilities between the global north and south research and funding.

- The G7 and G20 are also actively engaging and developing research partnerships, such as the Global Vaccine Research Collaborative. The ambition is to facilitate effective global and regional vaccine research to address gaps, establish structures and principles for better R&D preparedness and create a mechanism for promoting coordination for R&D. It aims to reduce duplication of effort, linking into other existing efforts such as the Medical Countermeasures Platform. Since most major R&D funders are in the G20, they can make a substantial impact in this space.

- Academic-industry partnerships have been powerful in COVID-19, such as the Oxford-AstraZeneca vaccine which enabled Oxford to create a vaccine candidate and AstraZeneca to be the commercial partner for regulatory approvals and supply agreements\textsuperscript{31}.

**Modalities: Networks**

Networks and consortia for research have been around since the 2000s and are now very popular with funders as they are considered advantageous for encouraging less hierarchical leadership models and individualistic attitudes\textsuperscript{32}. They help to pool resources, enable common research foci, increased knowledge exchange, sustainability and speed of diffusion of innovations which proved particularly
beneficial during the COVID-19 pandemic. Some notable networks are listed below.

- ISARIC, the International Severe Acute Respiratory and emerging Infection Consortium, provides a “platform through which global, patient-oriented clinical studies can be developed, executed and shared”\(^{33}\). It represents 52 networks from across the world, built on the principle of collaboration and local action to enable rapid clinical research in response to outbreaks. They have also developed a portfolio of research capacity building initiatives to support research in LMICs, including career development fellowship schemes, and training curriculums.

- In terms of epidemiological R&D, the ARTIC network and COG-UK (C-19 Genomics UK) are examples of networks established during the pandemic to enable pathogen genomic sequencing. They had global reach to share protocols, knowledge and resources (e.g. the Oxford Nanopore Technology MinION is creating a ‘lab-in-a-suitcase’ that can be deployed to remote and resource-limited location)\(^{34}\).

**SCORING**

*Capacity status for tech transfer:* 1  
*Capacity status of R&D capacity building:* 1  
*Trend:* +1 (improving)

**ANALYSIS**

**SUCCESSES AND PROGRESS**

- Tech transfer: a variety of technologies are now included in tech transfer programs including vaccines, diagnostics and therapeutics. These have been particularly beneficial during COVID-19 to enable access to tools and medicines to LMICs.

- Research capacity: large amounts of research funding were mobilized during the COVID pandemic compared to other disease outbreaks. There is also a growing appreciation for networks and collaborations to build R&D capacity in LMIC settings that proved valuable during the COVID-19 pandemic.

**CHALLENGES AND GAPS**

- Tech transfer: there is limited capacity for tech transfer in LMICs (and limited data available to demonstrate progress in this space). Programs are often siloed and disease-specific, meaning they are limited by capacity issues, particularly when there are other competing demands, or they struggle to expand to other disease areas beyond their known stakeholder network. Also, it can be difficult to incentivize pharmaceutical companies to participate in voluntary patent pools over bilateral agreements.

- Research capacity: There is limited infrastructure and capacity to conduct and produce high-impact research from LMICs, with R&D funding and expenditure dominated by HICs.

- Coordination: more could be done to ensure the limited R&D resources for R&D blueprint pathogens are being well coordinated amongst donors, in order to highlight gaps in our global R&D arsenal and incentivize investment in the ‘gaps’.
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Indicator B.1.1.2.7 (a) Coordination during health emergencies

**Question**

Is there a demonstrated capacity for the R&D ecosystem to coordinate and rapidly switch to emergency mode, including for manufacturers to start R&D and switch or scale up their production?

**Experts**

International Pandemic Preparedness Secretariat (IPPS) Science and Technology Expert Group and implementation partners

**ANSWER TO INDICATOR QUESTION**

**INTRODUCTION**

During a health emergency, rapid R&D coordination saves lives. Whilst significant progress and partnerships have been made during the COVID-19 pandemic and as has been demonstrated in the recent Sudan Ebolavirus outbreak, the R&D ecosystem is not yet coordinated enough to rapidly switch into emergency mode when needed. Further investment is particularly needed for therapeutics R&D and more rapid diagnostic approval pathways as these two areas are lagging behind the progress that has been made in vaccines. Also, more work is needed to agree R&D coordination trigger points before a Public Health Emergency of International Concern (PHIEC) is declared as this is too late to stand up any new mechanisms or pre-agreed response protocols.

To answer the question, we have focused on evidence of R&D rapidity (through quantifiable metrics such as time to approval); evidence of ability to pivot manufacturing (through qualitative case studies); and the future opportunities to advance E&D coordination and capacity.

It’s also worth noting that to help drive the R&D ecosystem forward, the 100 Days Mission is providing a unifying goal for countries, industry and global health organizations to align behind the aim for medical countermeasures to be developed within the first 100 days of a pandemic threat. The rationale behind the mission is that the first 100 days of a pandemic are crucial to changing its course and bringing it under control, which is only possible with the right tools. This requires further investment to fill the gaps in our R&D arsenal (coordinated against the WHO R&D Blueprint priority pathogens, and emphasizing diagnostics and therapeutics); embedding more efficient ways of product development and approval as learned during COVID-19 during inter-pandemic periods; and agreeing in advance how product development, approval and manufacture will be coordinated in an emergency. This is a global effort, with CEPI leading the vaccine 100 Days Mission, FIND leading diagnostics and Unitaid leading therapeutics with an alliance of other partners.

**EVIDENCE OF R&D RAPIDITY**

It is difficult to identify countries with demonstrated capacity to coordinate research in an emergency using the criteria for the question as in recent years, only mpox and COVID-19 have been declared PHEICs. Much of the R&D coordination begins well in advance of an emergency being declared a PHEIC, and is the result of significant funding before an outbreak occurs.
Overall, we are still far from having a coordinated R&D or response system for medical countermeasures, so if a pandemic or major outbreak were to occur today, we would likely see market forces dominate, which would not lead to equitable distribution. Much of the progress cited below depended heavily on the pathogens being prioritized, and thus R&D conducted, due to decades of biodefense funding such as that for Ebola and mpox (e.g. due to concerns over smallpox use as a bioweapon). Also, there isn’t currently a global actor who can coordinate and convene a response within 48 hours of a PHEIC declaration (but this signal implies a role for WHO, which is not currently happening). Some countries can coordinate their own response, as well as smaller groups of countries (e.g. G7, possibly G20 or regions), in addition to a global actor.

Nevertheless, see below a narrative description of three recent health emergencies (COVID-19, mpox, Sudan Ebolavirus) to demonstrate the speed of R&D coordination.

- **COVID-19.** For COVID-19, there were two key diagnostic products: PCR testing in laboratories and rapid diagnostic testing. Both types of diagnostic tests follow relatively standard production processes, which can be readily adapted and switched in an emergency. A third type of product, decentralized molecular testing, which was made available at later stages of the pandemic, is also manufactured in production lines that can be readily switched in case of emergencies.

  Diagnostic PCR tests were under development in all high income countries (HICs) with tests ready in public health labs 3-5 days after the genomic sequence was released. Rapid lateral flow tests were developed later (not approved for use until December 2020 in the UK, for example). However, there was a long delay by WHO for COVID-19 self-testing guidance well after self-tests were on the market and being used. For the development and emergency use authorization of SARS-Cov-2 diagnostics, a Korean supplier (SD Biosensor) took 42 days (for laboratory-based PCR) and 236 days (for rapid antigen RDTs) for accurate and authorized diagnostics to be developed, validated, authorized for emergency use by a regulator, scaled to low-to-moderate manufacturing volumes from a single manufacturing facility, and made available for export from the manufacturer of record. The Binax Now card from Abbott was the first instrument-free antigen rapid test to receive US FDA EUA on 26th August 2020, 208 days after the declaration of PHEIC. However, by the time the first commercial PCR kit obtained WHO EUL, there were already 1 million cases confirmed, the virus had spread across the globe, and countries were in lockdown.

  Vaccine efforts also mobilized quickly in HICs, with pre-clinical studies of mRNA vaccines starting in January 2020, phase I/II clinical trials in April and Phase II/III beginning in July 2020. COVID-19 therapeutics phase III clinical trials (e.g. Recovery by Oxford University, Solidarity by WHO) were launched after 40-50 days of a PEHIC being declared.

- **mpox.** mpox was declared a PHEIC on 23rd July 2022. 86 diagnostic tests have achieved regulatory approval of which 73 have been developed in China, 9 in the USA and 1 in each of Hong Kong and the UK. Smallpox vaccines had already been tested since the late 1980s, so could be mobilized subject to further testing, as well as manufacturing and supply chain limitations. Three vaccines have been used, all of which were developed and initially approved to treat smallpox (ACAM2000, JYNNEOS or otherwise known as Imvamimmune or Imvanex and LC16).
Whilst clinical trials are ongoing for mpox therapeutics in the USA, Canada, Brazil, Switzerland, UK and Democratic Republic of Congo, there are no licensed therapeutics for treating mpox although some medications have been authorized for emergency use\textsuperscript{iv}. 

- **Sudan Ebolavirus.** Although not a PHEIC, for the Sudan Ebolavirus outbreak (declared in Uganda on 20\textsuperscript{th} September 2022), R&D was mobilized within 44 days by WHO and other global health partners, leading to a roadmap and the establishment of the Tokomeza Ebola trial for three candidate vaccines (led by the Sabin Vaccine Institute in the USA, Oxford University in the UK and the International AIDS Vaccine Initiative, IAVI, in the USA and Merckin Germany)\textsuperscript{v}. WHO announced the first doses of a vaccine candidate against Sudan ebolavirus strain arrived in Uganda for safety testing 79 days after the outbreak was declared, although, the outbreak was declared over before trials for vaccines and therapeutics had been started\textsuperscript{vi}.

- **Other outbreaks.** Resolve to Save Lives’ assessment of outbreak response in Brazil, Ethiopia, Liberia, Nigeria and Uganda between 2018-22 identified that less than 50% of outbreaks had an early response (which includes initial laboratory diagnostics) completed within seven days\textsuperscript{vii}.

**EVIDENCE OF MANUFACTURING ABILITY TO PIVOT TO EMERGENCIES**

*Regional manufacturing capacity is covered by a separate indicator. Here, we describe recent health emergencies to demonstrate the ability to mobilise manufacturing and R&D during an outbreak.*

There has been progress in recent years. COVID-19 demonstrated that vaccines can be developed quickly through large public investments, joint planning of clinical development, regulation and manufacturing capacity and leveraging innovative platforms. In LMICs, key successes include the Africa Union COVID-19 vaccine strategy and scalable regional governance structures like the African Vaccine Delivery Alliance (AVDA). The World Economic Forum launched the Regionalized Vaccine Manufacturing Collaborative (RVMC) in May 2022, with CEPI and US National Academy of Medicine as co-chairs. Also, the African Union established the Partnership for African Vaccine Manufacturing (PAVM, hosted by Africa CDC) which aims to produce 60% of vaccines needed for Africa through continental vaccine manufacturing facilities. Finally, the Serum Institute of India (SSI) is the world’s largest vaccines manufacturer, and offers a model for bringing together physical infrastructure and an enabling environment that other geographies can learn from. Such a model has shown to be highly effective during the Sudan Ebolavirus outbreak which SSI developed with Oxford University within 79 days.

Whilst progress has been demonstrated with the Sudan ebolavirus outbreak, this virus did not affect HICs in the same way that COVID-19 or mpox threatened North America and Europe. In these situations, competition rather than collaboration threatens progress, as currently manufacturing in emergency situations is not equitable as few countries have R&D manufacturing capabilities. Even if manufacturing is available, HICs are more likely to have resources to stockpile or order large amounts of medical countermeasures, and unfortunately these issues faced during COVID-19 were still apparent during the mpox emergency. LMICs often do not have the capacity to develop countermeasures outside of an emergency (due to limited manufacturing capabilities, personnel, cold chain equipment for vaccine distribution), so are even more disadvantaged at the time of an emergency. For this reason, ACT-A, through FIND & Unitaid, supported an increase in manufacturing capacity by increasing capacity in China and India (committing to supply a minimum volume of the product to LMICs at a ceiling price) and
increasing manufacturing capacity in Senegal and Brazil.

Finally, more emphasis has been placed on vaccine manufacturing and coordination in recent outbreaks, rather than therapeutics or diagnostics.

**COVID-19 vaccines and coordination**

- According to the WHO Global Vaccine Market Report 2022, COVID-19 vaccines distributed in 2021 came from 19 manufacturers, 10 (52%) of which have no other marketed vaccine, and which collectively supplied 15% of the volume of COVID-19 vaccines. Only four COVID-19 vaccine manufacturers are in the top 10 in non-COVID-19 vaccine volumes, indicating that a significant portion of manufacturers of COVID-19 vaccines had limited prior experience in producing large volumes of vaccines.

- COVAX was established to avoid repeating the 2009 H1N1 situation where HICs bought most of the global supply of pandemic influenza vaccines, leaving inadequate resources for the worst affected LMICs. Many LMICs were reliant on COVAX to get vaccine doses, however COVAX itself faced challenges due to manufacturers’ purchase agreements with higher-paying countries and export bans, leading to delayed and sporadic procurement. In December 2021 more than 100 million COVAX vaccines were rejected by countries for being too close to the expiry date.

- The Norwegian Institute of Public Health and ECRIN established the COVID-19 Trials Coordination Board which includes investigators of large trials internationally, regulatory bodies (EMA), industry partners and experts from across sectors. The TCB now coordinates trials beyond COVID-19 therapeutics and vaccines, including mpox response trials. The TCB works to promote partnership and synergy within Europe and with WHO. During COVID-19, it was a trusted forum for the research community, investigators and stakeholders. However, there was declining involvement after the peak of the pandemic, some components took some time to operationalise, and as with other initiatives, there is low interest outside of pandemic periods.

**COVID-19 diagnostics**

- Manufacturers were able to rapidly expand manufacturing capacity to meet the demand. However, this capacity was highly centralised, and supply chain disruptions hampered the ability to translate manufacturing capacity into test availability worldwide. Through conversations with manufacturers, both bilaterally and in roundtables, it was clear that the main hurdles to access to diagnostic tests were not the speed of R&D and manufacturing capacity development, but rather, the access to samples for validation and the slow regulatory processes. Production capacity for RDTs rapidly improved between 2019-2021, (from 207 million tests per year in 2020 to 1866 million in 2022), but this has remained largely limited to a few countries and did not address the needs of LMICs adequately.

**Sudan Ebolavirus vaccine**

- On 15th December 2022, Oxford University reported that more than 40,000 doses of their Ebola vaccine had been manufactured by SII (Serum Institute of India) in just 60 days and doses shipped to Uganda. IPPS is conducting further work with SII and CEPI to understand the specific factors which enabled rapid manufacturing response and how this could be improved and replicated.
mpox vaccine

- There have been significant challenges with manufacturing of mpox vaccines due to Bavarian Nordic, the leading manufacturer of the Jynneos vaccine, announcing it was closing its production line due to the small market for the vaccine for its use in smallpox just before a PHEIC was declared in 2022. During this time, most of the available doses were stockpiled or ordered for use in the USA and Europe whilst nearly 30 million doses delivered to the US prior to 2022 had expired. Similarly to COVID, LMICs were unable to independently access large quantities of vaccines and had to rely on vaccine donations.

- The Jynneos vaccine was developed and manufactured for preparedness for smallpox, and therefore contracted to countries that had prioritized to stockpile a new smallpox vaccine. If there had not been an already approved vaccine for smallpox, the Mpox case would have been different and slower given low market opportunities.

mpox therapeutics and vaccines coordination

- The new European Medicines Agency (EMA) Clinical Trials Information System (CTIS) came into full effect on 31 January 2022 and was intended to provide an easier, more streamlined approach to the registration of clinical trials taking place in Europe. One of the studies included in this new application process was MOSAIC (a multi-center, multi-country cohort study for mpox therapeutics), submitted on 22nd June 2022 when mpox cases were escalating. MOSAIC had been approved by the British and Swiss authorities before mpox was declared a PHEIC. However, the approval procedure in CTIS has taken so long that approvals for several countries were only received once their respective outbreaks were tailing off.

FUTURE OPPORTUNITIES TO ENHANCE COORDINATION OF R&D COORDINATION AND CAPACITY

The 100 Days Mission aims to prepare as much as possible, so that within the first 100 days of a pandemic threat being identified, safe, effective and affordable diagnostic tests, therapeutics, and vaccines are ready to be produced at scale. This requires further investment to fill the gaps in our R&D arsenal (coordinated against the WHO R&D Blueprint priority pathogens, and emphasizing diagnostics and therapeutics); embedding more efficient ways of product development and approval as learned during COVID-19 during inter-pandemic periods; and agreeing in advance how product development, approval and manufacture will be coordinated in an emergency. The International Pandemic Preparedness Secretariat, an independent entity to support delivery of the 100 Days Mission has also captured progress against 25 recommendations for optimizing R&D coordination in their second annual implementation report.

Further work is still needed in some specific activities, as recommended by IPPS implementation partners. This includes addressing knowledge gaps in the R&D coordination ecosystem (e.g. through landscaping manufacturing capacity and pipelines), improving regional governance and coordination mechanisms, addressing regulatory barriers for diagnostics (e.g. test validation networks, improving the lag in guidance, plans for stockpiling and preparedness funding), and developing pan-family diagnostic tests during inter-pandemic periods.
SCORING

Capacity status: 1

Rationale:
- Discussions about R&D and manufacturing have been mobilized quickly during recent emergencies irrespective of whether they are declared a PHEIC.
- However, capacity is not equitable yet with LMICs not having capabilities or the mechanisms to acquire medical countermeasures. Furthermore, coordination mechanisms are important to avoid duplication, pool knowledge, enable tech transfer and share resources but there is currently no coordination mechanism for this. Regional initiatives are starting to emerge.

Trend: +1

Rationale:
- Improvements have been seen in the speed of vaccine development, e.g. for Sudan Ebolavirus compared to COVID-19 and the speed of regulatory approval for mpox vaccines, however further information is required to assess this trend for diagnostics and therapeutics.
- Also, Sudan Ebolavirus and mpox are not like-for-like comparisons with COVID because:
  o Ebola was not declared a PHEIC and did not affect HICs,
  o mpox had vaccines already approved for smallpox that could be repurposed, and approval has only been achieved by 5 HIC regulatory bodies.

ANALYSIS

The declaration of a PHEIC is not a good start point for this indicator. R&D coordination starts well in advance of a PHEIC and an earlier trigger point will be needed to encourage progress. For R&D, there is a need to take the "risk" of starting and then stop if the emergency does not evolve. A summary of the main points is described below.

QUALITATIVE ASSESSMENT

SUCCESSES AND PROGRESS

COVID-19 proved that medical countermeasures can be developed faster through large public investments, joint planning of clinical development, regulation and manufacturing capacity and leveraging innovative platforms, in high income settings. Coordination efforts include the WHO R&D Blueprint convened in February 2020 and the WHO-led Research and Innovation Forum on COVID-19 in July 2020 in order to map existing knowledge gaps and emerging research priorities. The Sudan Ebolavirus also demonstrated the capabilities of India, working in partnership with Oxford University and CEPI, to develop and manufacture vaccines rapidly.

CHALLENGES AND GAPS

Despite increasing coordination during health emergencies, high-income countries still manage to secure large supplies of medical countermeasures (e.g. as was the case in mpox and COVID-19), whilst LMICs are dependent on donations from HICs. LMICs often do not have the capacity to develop countermeasures outside of an emergency (limited manufacturing capabilities, personnel, cold chain equipment for vaccine distribution), so are even more disadvantaged at the time of an emergency.
QUANTITATIVE INDICATORS

SPEED OF DEVELOPMENT OF NEW COUNTERMEASURES

Vaccine rapidity
- COVID-19
  - 119 days: candidates were manufactured & available for phase 3 clinical trials (AstraZeneca/Oxford University ChAdOx1)xvii
  - 336 days: WHO issued its first EUL for a COVID-19 vaccine
  - 365 daysxviii: Average no. days for a country to approve its first vaccine
  - Total no. vaccines approved: 57 (1072 approvals across 192 countries)
- mpox
  - No phase 3 trials underwayxix. (Some observational data is available now but only because there already was a vaccine with cross protection approved.)
  - 18th days: Average no. days for a country/region to approve its first vaccine
  - Total no. vaccines approved: 3 (5 approvals across Japan, USA, EU and Canada)
- Sudan Ebolavirus
  - 79 days: candidates were manufactured & available for phase 3 clinical trials (Tokomeza trial - Sabin institute vaccine, with others shortly after)xii
  - No vaccines approved yet, clinical trials underway

Diagnostics rapidity
- COVID-19
  - 64 days: first real-time PCR test granted WHO EUL (data from FIND)
  - 236 days: first rapid diagnostic test granted WHO EUL (data from FIND)
  - Total no. diagnostics approved: 1504xxii
- mpox: No data on rapidity. Total no. diagnostics approved: 84xxiii
- Sudan Ebolavirus: No data on rapidity

Therapeutics rapidity
- COVID-19:
  - 49 days: candidates were manufactured & available for phase 3 clinical trials (RECOVERY trial)
- Mpox: no phase 3 trials
- Sudan Ebolavirus: no phase 3 trials

DATA SOURCES AND REFERENCES
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Indicator B.2.1.2.2 Regional manufacturing capacity

**Question**

Is there sufficient regional manufacturing capacity for vaccines and therapeutics across WHO regions?

**Experts**

International Pandemic Preparedness Secretariat (IPPS) Science and Technology Expert Group and implementation partners

**ANSWER TO INDICATOR QUESTION**

**INTRODUCTION**

Effective vaccines are the best defense in our arsenal against infectious diseases, especially pandemic pathogens like influenza or SARS-COV-2, because they are unsurpassed for safe, cost-effective prophylactic protection of entire at-risk populations. Augmenting global vaccine and therapeutic manufacturing capacity are the best preparedness measures global stakeholders can undertake in the inter-pandemic period. Estimating or measuring global pandemic vaccine manufacturing capacity is a complex theoretical exercise to translate the promise from estimate to reality. Currently the estimates of influenza or COVID-19 vaccine capacity can be used as a proxy but this will have many caveats when trying to extrapolate it to other WHO R&D Blueprint pathogen or Disease X vaccines.

In this paper, we present the best estimates of global vaccine manufacturing available with the underlying assumptions, caveats for extrapolation, and the new initiatives undertaken to augment the capacity, research and technology innovations contributing to vaccine access during next pandemic. While it is recognized that the original question also covered therapeutics manufacturing, we have not had access to the data or networks to assess therapeutics capacity accurately so have focused on vaccines, but this should be rectified in future years if more time was allowed for analysis. This short note will justify our assessment scores for WHO regional vaccine manufacturing capacity.

**Status of vaccine production capacity for pandemic pathogens**

1. **Global estimates**

There are no absolute global estimates available which could be extrapolated easily to any vaccine against a pandemic pathogen. Global vaccine (including therapeutics and other biologics) manufacturing capacity is not uniformly distributed globally but concentrated in certain regions like South-East Asia, Europe, and North America. Some regions like Africa and the Middle East have relatively low vaccine manufacturing capacity. Globally, 10 manufacturers alone provide 70% of vaccine doses (excluding COVID-19 vaccines) and 85% of the global value of vaccines. In 2022, more than 90 manufacturers supplied vaccines to WHO Member States, 10 of which entered the market in response to the COVID-19 pandemic. When looking at individual vaccines, often only two or three suppliers provide more than 80% of supply. More than half of suppliers globally produce only a few vaccines and only serve local markets. This global capacity of producing routine vaccines could theoretically be available for future pandemic response but will have lots of issues related to switch and surge capacity for a pandemic vaccine. There are no publicly available estimates available to quantify Drug Substance, Drug Product or Fill Finish capacity as well as the related material supply chains critical for vaccine production.
2. Influenza vaccines

In the pre-COVID era, the best estimates of global production capacity for pandemic vaccines were based on estimates of production capacity of seasonal influenza vaccines. In 2019, global vaccine manufacturers had estimated capacity to produce 1.48 billion doses of seasonal influenza vaccines over a 12-month period if they were to operate at full capability. Translating this for an influenza (monovalent) pandemic vaccine, WHO calculated that an estimated 8.31 billion doses of pandemic vaccine (best-case scenario) and 4.15 billion doses (a moderate-case scenario), could be produced in a 12-month period. Production time estimates are 4 weeks for inactivated influenza vaccines (IIV) (representing 89% pandemic capacity) and 21 weeks for live attenuated influenza vaccines (LAIV) (3.4% pandemic capacity) from recommendation of pandemic influenza strain to availability of first batches. Currently, 79% of ‘flu vaccines are made using egg-based production technology (IIV and LAIV), the remainder utilizes cell culture-based technologies (for IIV and recombinant). Newer technologies include mRNA or vectored vaccines, capacity estimates are not available.

Main challenges with influenza vaccine production include:
- The inactivated virus vaccine technology could face a major challenge due to lack of BSL3 manufacturing facilities as required for pandemic-potential vaccine production.
- The timing and time taken to switch from seasonal to pandemic vaccine remains a critical limitation in extrapolating these estimates to next pandemic.
- In case of future pandemic strain requiring two doses of vaccine to elicit and sustain an adequate immune response, there would only be enough vaccine to cover just over half of the world’s population, even in the best case scenario.
- Lack of geographically diversified vaccine capacity (concentrated in HICs, with minimal capacity in Africa) poses a challenge for global vaccine access equity.\(^3\)

1. COVID-19 vaccines

The recent COVID-19 pandemic provides an excellent opportunity to understand the global pandemic vaccine technology development, manufacturing, and distribution capacity. The COVID-19 pandemic revolutionized vaccine development using novel approaches including mRNA, next-gen self-amplifying mRNA, viral vector, virus-like particle and recombinant protein technologies. COVID-19 vaccine manufacturers ramped up their own manufacturing in parallel to clinical development (“scale-up”) from zero to billions of doses with a cumulative supply target of up to 14 billion doses\(^1\) by the end of 2021, via more than 150 partnerships with contract development and manufacturing organizations (CDMOs) and other multinational biopharmaceutical companies to transfer their technology and increase their overall production (“scale-out”)\(^4\).

The first COVID-19 pandemic vaccine was developed fully in 326 days’ time using new mRNA technology and within less than a year, 11 vaccines were already in clinical use in the countries (with emergency/limited authorization), more than 80 additional candidates in clinical trials, and hundreds of candidates are in the pre-clinical phase.\(^5\) However, this did not address the challenge of equitable distribution. Countries that had the vaccine manufacturing capacity, such as the United States, Germany, China, India, and the United Kingdom, exceeded 100 doses per 100 people. Currently, around 55% of capacity is in East Asia, 40% in Europe and North America, and less than 5% in Africa and South America. The African region in 2021 received just 3% of all COVID-19 vaccine doses and only 1% of COVID-19 vaccines administered in Africa were produced in the region as of April 2021.\(^6\)
With newer technologies the manufacturing time has been reduced to 90 to 120 days for the manufacturing, testing and release of a single batch of COVID-19 vaccine. Initiatives to reduce production lead times have been announced, e.g. Pfizer-BioNTech has launched ‘Project Light Speed’ to reduce production time of its mRNA vaccine from 110 days to 60.

The majority of current global COVID-19 vaccine capacity is due to mRNA technology requiring dose concentration of 30 or 100 mcg RNA to be effective. Self-amplifying mRNA technology has the potential to elicit a higher amount of antibodies lasting for longer duration, with a smaller amount of vaccine injected. Arcturus Therapeutics demonstrated the effectiveness of a 2-dose series requiring only 5 mcg of RNA vaccine. If such vaccine technology platform gets regulatory approval, it could mean a multifold increase to global capacity estimates for future pandemics.8,9

2. R&D blueprint/Pathogen X vaccines
Whether COVID-19 mRNA global manufacturing capacity translates to each of the WHO R&D blueprint pathogens or Disease X remains to be seen. Technical and regulatory probability of success for mRNA-based vaccines for these pathogens are yet to be evaluated, but the world cannot remain focused on a single technology platform. To enable preparedness and equitable access, the world will need a system to establish the major tech platforms regionally and create markets for the production of routine vaccines and allied products so that facilities can be sustainable and agile enough to quickly respond to outbreaks or pandemics. Each vaccine product, disease target and production technology poses its own challenges which need to be considered for future planning. WHO SAGE currently recommend a global Ebola (Zaire) vaccine stockpile containing 500,000 doses, deemed sufficient to avert outbreaks of similar scale as the one experienced in 2014-2016. The global Ebola (Zaire) vaccine stockpile has been operational since 2021. UNICEF manages the stockpile on behalf of the ICG and delivers vaccines to countries.10 Investigational stockpiles for other Ebola strains such as the Sudan virus should be considered, perhaps using material produced for the outbreak response in Q4 2022.

Opportunities for global manufacturing capacity: regional initiatives
Realizing these challenges, many regions and countries have embarked upon several initiatives towards vaccine self-sufficiency and reliance which will likely augment availability of vaccines for the next pandemic.

1. Regionalized Vaccine Manufacturing Collaborative (RVMC)
Recognizing the need to close the global gap in vaccine equity as experienced during the COVID-19 pandemic, the World Economic Forum launched the RVMC at its Annual Meeting in Davos in May 2022, with leaders from the Coalition for Epidemic Preparedness Innovations (CEPI) and the US National Academy of Medicine as co-chairs.11 RVMC is currently developing Global Framework, a playbook for the implementation of regional initiatives for geo-diversified vaccine manufacturing capacity based on seven pillars for building a regional vaccine production eco-system.

2. Partnership for Africa Vaccine Manufacturing (PAVM)
In April 2021, the African Union announced the plan for enhancing vaccine self-reliance and security by establishing the PAVM initiative hosted by Africa Centers for Disease Control and Prevention (Africa CDC), which aims to produce 60% of vaccines needed for Africa by 2040, by building a vaccine eco-system
for local vaccine manufacturing facilities. There are 10 manufacturers with existing vaccine production in Africa, whilst a further 17 additional organizations have publicly announced plans to begin manufacturing on the continent. While the majority of plans state Fill-Finish as the entry point to vaccine production, selected suppliers plan to also embark on drug substance and bulk drug product manufacturing, with manufacturers looking to leapfrog to next-generation technology platforms to be in a stronger position in new vaccine and therapeutic markets.

Figure 1: Map of current and planned vaccine manufacturing on the African continent, including ownership structure and value chain capabilities

3. Association of Southeast Asian Nations (ASEAN) region vaccine manufacturing plan
ASEAN has announced the Regional Strategic and Action Plan for ASEAN Vaccine Security and Self-Reliance (AVSSR) 2021-2025 with the aim of enhancing realizing vaccine security and self-reliance for all: ensuring healthy ASEAN through timely, equitable access to affordable and quality-assured vaccines.

4. Pan American Health Organization (PAHO) Regional Vaccine Manufacturing Platform
PAHO has announced a regional platform to advance the manufacturing of COVID-19 vaccines and other health technologies in the Latin American and Caribbean regions, through convening public and private stakeholders to foster research and incentivize development and manufacturing of essential and strategic health technologies. This is likely to expand regional manufacturing capabilities and capacities for pandemic preparedness.

5. Middle Eastern regions’ vaccine manufacturing initiatives
Similar efforts are ongoing in the other (geographic) regions including the Middle Eastern region. For example, after participating in global clinical trials of Russian and Chinese COVID-19 vaccines, the United Arab Emirates (UAE) aspires to become a regional hub in the global vaccine production and distribution chain by strengthening its collaborations with the pharmaceutical industry through technology transfer and fostering cooperation in vaccine production and distribution in the region.
Research agenda for future pandemic manufacturing capacity

There are several areas where research and development is needed to make safe, effective, affordable vaccines available in an accelerated manner to mitigate the impact of the next pandemic. Innovation research needs to be promoted, and investments into new product-type and formulation vaccines, plus manufacturing innovations such as container-based manufacturing units, multidose vaccine delivery pouch for mass vaccination campaigns, microarray patches and other needle-free methods for vaccine delivery, RNA printer technologies, etc. are required to enable quality vaccines to be made available for the control of outbreaks and pandemic preparedness.

1. **100 Days Mission**

The 100 Days mission for vaccines to be ready for emergency use authorization and manufacturing at scale within 100 days of recognition of a pandemic pathogen was originally conceived by CEPI for the UK G7 presidency. Focus on innovative vaccine technologies, use of technology platform regulatory pathways, early insights into development of vaccine libraries against major (pandemic potential) virus families, pre-approved protocols for global clinical trials, manufacturing innovations facilitating acceleration in scale-up operations, innovative public private partnerships with hybrid finance model might make this mission successful.

2. **G7 100 Day mission PLUS**

The 2023 Hiroshima G7 Global Health Task Force (GHTF) emphasizes in its draft recommendation the importance of strengthening the “end-to-end” structure of medical countermeasures, from R&D, manufacturing, procurement, delivery, to more equitable access (uptake) called the 100 Days Mission “PLUS”. The PLUS component enhances vaccine access and delivery through regionalized vaccine manufacturing and licensure initiatives.

3. **WHO mRNA network for vaccine development**

WHO and Medicines Patent Pool established an mRNA technology transfer hub in June 2021, with the objective of developing an accessible mRNA vaccine production platform, and building mRNA product capacity in low- and middle-income countries from a center of excellence via tech transfers and training.

4. **G20 Global Vaccine Research Collaborative (GVRC)**

The current India G20 Presidency called for the establishment of GVRC to promote international cooperation to advance vaccine development for emerging pathogens, utilizing G20 as a vital platform to facilitate collaboration between governments, research organizations, pharmaceutical companies, and other stakeholders. It is essential to link this platform to regional vaccine manufacturing.

5. **CEPI’s Global Vaccine Libraries Development**

CEPI aims to develop prototype vaccines against the different virus families that have the potential to infect humans. These prototype vaccines will be based on rapid response platforms such as mRNA, which can be adapted in a matter of weeks once a new virus has been identified. These will form a ‘library’ of vaccine candidates or precursors that are ready to be pulled off the shelf and swiftly adapted if a “Disease X” emerges. This initiative needs to be linked to manufacturing process platform development as well.
SCORING

Global Vaccine Manufacturing Capacity: Incomplete 1

What actions have been taken in the last year? Improving (+1) with all the regional initiatives announced.

ANALYSIS

SUCCESSES

The global pandemic vaccine manufacturing capacity has increased significantly in recent years, due in large part to the COVID-19 pandemic. This successful increase in capacity has been driven by several factors, including:

• The development of new vaccine technologies and manufacturing innovations.
• The investment of public and private sector funds in vaccine manufacturing capacity.
• The collaboration of vaccine manufacturers and governments to scale up and scale out production.
• Wider acceptance of public-private partnership and voluntary outlicensing models during the COVID-19 pandemic.

CHALLENGES

Despite this increase in capacity, there are still challenges that need to be addressed to mitigate the impact of future pandemics. These challenges include:

• The concentration of vaccine manufacturing in a few countries. This concentration of capacity makes equitable supply vulnerable to disruptions, such as national lockdowns during COVID-19, vaccine nationalism, export bans, and/or political instability.
• Production of inactivated viral vaccines could face a major challenge due to lack of high biocontainment manufacturing facilities as required for production and testing.
• The time taken to switch (from routine vaccines to pandemic vaccine) and scale up surge, and the number of doses required for adequate immune response would be important criteria to be factored in for estimating pandemic vaccines capacity.
• The high cost of some vaccines and inequalities of procurement mechanisms make it difficult for LMICs to access vaccines for emerging infectious diseases.
• The lack of regulatory capacity in some countries can slow down the approval and roll-out of new vaccines.
• The development of sustainable markets for products developed in these facilities so that they might have viable business models between major outbreaks.

OPPORTUNITIES

The main opportunities to catalyze vaccine manufacturing capacity are:

• Investing in sustainable regional manufacturing capacity in LMICs.
• Further investments in research and development of innovative vaccine manufacturing technologies.

The current research agenda initiatives (GVRC, 100 Days Mission PLUS, Global Vaccine Libraries) are
important from a preparedness point of view and to help focus R&D efforts. Additional areas which could be opportunities for improvement of global vaccine manufacturing capabilities include:

- Development and measurement against a global vaccine manufacturing roadmap that identifies the specific capacity needs/gaps/research agenda that need to be addressed.
- Investments into more efficient and scalable manufacturing platform processes e.g. implementing automation, robotics and digital technologies.
- Improvement of training and education of vaccine manufacturing and testing workforces, including recognizing them as essential workers in pandemics.
- Standardization and ensuring supply chain robustness for components and materials.
- Support of sustainable, regional vaccine manufacturing capabilities, that can also be used to manufacture other products.
- Facilitation of sharing of open-source technologies, data and best practices amongst vaccine manufacturers.
- Strengthening of the regulatory framework for vaccine manufacturing aspects.

Thus, the current pandemic vaccine manufacturing capacity estimates need to be evaluated with assumptions, caveats, gaps, challenges, and opportunities to build global capacity for the next pandemic.

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Indicator B.3.1.2.1 Assessment of national R&D innovation, development, and access to medical countermeasures

**Questions**

Do countries have adequate national emergency regulatory approval procedures/capacity? Do countries’ health systems have the capacity to deploy medical countermeasures? Do countries ensure equity in R&D and access to countermeasures? Do they involve communities in research and identify/address the needs of different communities? Do countries ensure access to medical countermeasures by vulnerable and marginalized communities?

**Experts**

International Pandemic Preparedness Secretariat (IPPS) Science and Technology Expert Group and implementation partners

**ANSWER TO INDICATOR QUESTION**

**INTRODUCTION**

The ability to approve medical countermeasures in an emergency; the capacity to deploy these countermeasures; and the equitable development and distribution of these countermeasures are all critical components of global pandemic preparedness. It is only by ensuring a high quality and equitable product development, approval and delivery pipeline that the world will be able to suitably respond to future pandemic threats.

To answer this question, we have used qualitative examples and quantitative data (where available) to assess emergency regulatory approval procedures, capacity to deploy countermeasures and equity in access to countermeasures.

While each of these components of the preparedness ecosystem is very broad and challenging to assess on a global scale, here we study a number of aggregated data sources and analyses to support a judgement on each of the components. On emergency regulatory approval capacity, we find most countries lack mature regulatory systems but do possess the ability for expedited approval of countermeasures during public health emergencies, via support of WHO prequalification and Emergency Use Listing (EUL) procedures. Regarding the capacity of health systems to deploy medical countermeasures, while this is a very challenging topic to summarize, high-level data and reports from the COVID-19 pandemic suggest insufficient global capacity. When it comes to equity in R&D and access to countermeasures, while there are many nations and regions delivering successfully here, global challenges persist, particularly evident in the difficulties of delivering routine healthcare and achieving universal health coverage in sub-Saharan Africa and Southeast Asia.

Ultimately, we find insufficient preparedness with respect to these three components of the indicator.

*Do countries have adequate national emergency regulatory approval procedures and capacity?*

There is great variety in global procedures and capacity for emergency regulatory approval for medical
countermeasures. The most useful way to consider a response to this question is to assess whether countries have emergency regulatory approvals procedures in place.

Global Health Security Index findings


Based on qualitative assessment of official national sources (which vary by country), in 2021 the Index reported that: “73% of countries do not have the ability to provide expedited approval for medical countermeasures, such as vaccines and antiviral drugs, during a public health emergency.”

WHO assessments of emergency use procedures and regulatory system maturity

The gold standard for assessing the response to this question would be the World Health Organization Global Benchmarking Tool (GBT) for Evaluation of National Regulatory System of Medical Products, particularly subindicator MA01.12: “There are established guidelines that cover circumstances under which the routine MA procedures may not be followed (e.g. for public health interest)”. However, GBT subindicator assessment results are not publicly available on a national basis, and many countries have not undertaken a formal GBT assessment.

Given that GBT results are not public, the closest proxy from the WHO for whether regulatory systems have emergency regulatory approval procedures in place may be assessment of national regulatory system maturity levels. As of 2020, the WHO noted:

“...the World Health Organization (WHO) regulatory systems strengthening database showed that among its 194 Member States, only 50 countries (26%) have what are considered to be mature regulatory agencies (the top or second-highest level of maturity), whilst 144 countries have suboptimal regulatory systems. Just over half, 51% (99 countries) are at the lowest level of maturity, whilst 23% (45 countries) are at the second lowest level of maturity. Although not all countries were benchmarked against WHO GBT, but the maturity level status of remaining countries have been estimated based on previous assessments done by WHO using other tools or being a Stringent Regulatory Authority (SRA).”

This is not a direct indicator however. All countries that are considered mature will have emergency regulatory approval procedures in place, but it is notable that a country may have other procedures to allow the entry of products into their territory regardless of their maturity level (see below).

National and global approaches to emergency use authorization

There are numerous examples of developed countries with effectively functioning emergency use authorization procedures – for example, during the COVID-19 pandemic the United Kingdom was the first country to approve the Pfizer-BioNTech COVID-19 Vaccine via a temporary authorization for emergency use. The UK Medicines and Healthcare products Regulatory Agency began the evaluation process for the vaccine on 1 October 2020 with an approval granted by 2 December 2020, facilitated through rolling data submission – where the vaccine developer was allowed to submit the data related to product efficacy and safety in batches as it became available.
Many nations not considered as having a functionable regulatory authority based on WHO’s GBT (maturity levels 3 or 4) do still however have routes to provide emergency use authorization, based on the WHO prequalification or EUL procedure. The EUL is a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostics with the aim of expediting the availability of these products to people affected by a public health emergency, and was first developed in response to the 2014-2016 Ebola Virus Disease outbreak. The EUL assists UN procurement agencies and Member States in determining the acceptability of using specific products, based on an essential set of available quality, safety, and efficacy and performance data⁴.

Conclusion
Overall, based on the GHS Index and WHO’s assessment of regulatory systems, the majority of countries do not have mature regulatory systems yet, but do have the autonomous ability for expedited approval of countermeasures during a public health emergency. In fact, in the event of a public health emergency of international concern (PHEIC), many countries without mature regulatory systems will be able to approve vaccines via support of the WHO prequalification and EUL procedures.

Do countries’ health systems have the capacity to deploy medical countermeasures?
There is great variety in the capacity of global health systems for deploying medical countermeasures, and given the broad nature of the question, without an extensive new study there are limited sources from which to draw on aggregated data to support the answer to this question.

Global Health Security Index findings
One assessment of aggregate global capacity of health systems is found as part of the Global Health Security (GHS) Index, an assessment and benchmarking of health security and related capabilities across 195 countries. The GHS Index contains a category looking specifically at health system capacity in the context of pandemic preparedness, and to assess this utilizes a number of different indicators, including:

- health capacity in clinics, hospitals and community care centres;
- supply chain or health systems and healthcare workers;
- medical countermeasures and personnel deployment;
- healthcare access;
- communication with healthcare workers during a public healthcare emergency;
- infection control practices; and
- the capacity to test and approve new countermeasures.

Looking at this category, the most recent 2021 GHS Index report finds that:

“The average score in the health system category is 31.5 out of 100, with 73 countries scoring in the bottom tier. Sixty-nine countries have insufficient capacity at health clinics, hospitals, and community centers. Ninety-one percent of countries do not have a plan, program, or guidelines in place for dispensing medical countermeasures, such as vaccines and antiviral drugs, for national use during a public health emergency. Altogether, the health systems category shows little progress since 2019 and identifies serious gaps in capacity in national-level medical workforce, facilities, and healthcare access.”

and that:
"[Between the 2019 and 2021 GHS Index reports] most countries saw little or no improvement in maintaining a robust, capable, and accessible health system for outbreak detection and response. Seventy percent of countries show insufficient health capacity in clinics, hospitals, and community health centers, including human resources and facilities capacity. Only 25% of countries, or 49, have published an updated health workforce strategy over the past five years to address staffing shortages."

The GHS Index is only one source of this information, and its result should be taken with some caution – one study has shown that the 2019 GHS Index (in entirety) did not serve as a faithful predictor of coronavirus pandemic responses.

WHO Joint External Evaluation

A WHO Joint External Evaluation (JEE) is a voluntary, collaborative, multisectoral process to assess country capacities to prevent, detect and rapidly respond to public health risks whether occurring naturally or due to deliberate or accidental events. The JEE helps countries identify the most critical gaps within their human and animal health systems in order to prioritize opportunities for enhanced preparedness and response.

While the JEE framework has a relevant category “Medical countermeasures and personnel deployment”, and three indicators for this (see Table 1 below, taken from the JEE framework), there is insufficient global data resulting from JEEs to come to a suitable conclusion on the global state of health system preparedness. Many reports are from as early as 2016 and 2017, meaning they are likely outdated. Further, while a JEE Dashboard exists, there is no current aggregation of the specific indicator scores to facilitate global aggregation.

Ultimately, JEEs are insufficient to use in coming to an aggregated view of the global capacity for healthcare systems to deploy medical countermeasures.

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Table 1: Indicators for medical countermeasures and personnel deployment (from https://extranet.who.int/sph/sites/default/files/document-library/document/9789241550222-eng.pdf)
**COVID-19 vaccine delivery**

One approach to examining this question may be to examine to what degree countries have been successful in their ability to deliver COVID-19 vaccines. Assuming sufficient supply, a low rate of delivery is likely to represent a failure in the healthcare system to deliver medical countermeasures. This is however confounded by other factors beyond the delivery capability of the healthcare system itself – including vaccine hesitancy and political factors, as well as the dynamics of vaccine supply (if vaccines arrived in country ‘late’ following a surge of cases, there is unlikely to be the same drive to vaccinate; or if vaccines arrived in a country with limited shelf life, there may still be a lot of wastage).

Quantitative data on this topic is challenging to identify. While the [Global COVID-19 Access Tracker](https://www.globalcovidaccess.com) does contain some relevant data, it is challenging to come to a useful quantitative conclusion based on this alone, particularly due to a need for such an analysis to consider how these statistics change over time. Qualitatively, during the COVID-19 pandemic there were multiple reports that many countries, particularly developing countries, were struggling to use vaccination stocks as a result of logistical deployment challenges – in some cases leading to large quantities of expired vaccines going to waste.

**Conclusion**

Ultimately there is limited data to draw upon to provide a comprehensive response to this question. The most comprehensive and relevant quantitative source, the GHS Index, alongside qualitative evidence on vaccine delivery, suggests that globally there is insufficient health system capacity to deploy some more complex medical countermeasures, requiring extensive support from international organizations.

*Do countries ensure equity in R&D and access to countermeasures? Do they involve communities in research, and identify and address the needs of different communities? Do countries ensure access to medical countermeasures by vulnerable and marginalized communities?*

There is great variety in global approaches to equity in R&D and access to countermeasures, including the involvement of vulnerable and marginalized communities in research and access to countermeasures. Since equity is such a multifaceted concern (race, gender, age, socioeconomic status), it is challenging to present a single assessment of equity across the board.

R&D participation and access to countermeasures are related in some situations – without effective participation in clinical trials, some groups are unlikely to be able to have good access to medical countermeasures.

**Equity in R&D and community engagement in research**

Equity in R&D is a challenging factor to measure on a global scale – primarily because the vast majority of countries do not engage in R&D for health products.

One successful example of effective equity being developed in R&D and access to countermeasures for infectious disease is the [DolPHIN 2 Clinical trial](https://www.dolphin2clinicaltrial.org), studying the efficacy and safety of the HIV drug dolutegravir in late presenting pregnant women in sub-Saharan Africa. As pregnant women are often excluded from clinical trials, there are restrictions on their ability to access medical countermeasures. Trials such as this are essential to ensure that vulnerable communities are able to access life-saving drugs, and establishing strong infrastructure and best practices during inter-pandemic periods allows...
infrastructure to be strengthened and procedures to be ready for adaption in the case of a pandemic.

The COVID-19 pandemic in many countries saw marginalized communities subject to a disproportionate number of cases and deaths, and highlighted the need to involve community stakeholders in the research process\(^9\). Many COVID-19 vaccine trials faced challenges with enrolling participants in both a rapid, yet equitable and diverse manner\(^10\). According to IQVIA’s 2023 report on the status of R&D, clinical research inclusiveness has declined over the last 10 years, particularly in the US where Black/African American participation in trials represented 43% of the US population demographic levels and Hispanic participation was at 53%\(^11\). Also, as a significant proportion of clinical trials are conducted in Europe and North America, research leaders from geographies with the highest burden of disease are under-represented\(^12\). As a result, research funders and institutions have been making a more active effort to improve R&D diversity, and increase participation and diversity research funding. For example, the NIH Clinical and Translational Science Awards (CTSA) require a community engagement program, and the US Food and Drug Administration (FDA) has actively updated policies and reviewed regulations to increase diversity in trials\(^13\).

Another perspective to equity in R&D would be to understand the characteristics of those conducting research, rather than participating in it. While this is a multifaceted issue, gender is one characteristic for which there is good data available: according to the WHO Global Observatory on Health R&D, whilst globally the average proportion of women employed as full time health researchers is 50%, data from 75 (out of 82) countries shows the proportion ranges from approximately 52% in the high income group to only 24% in the low income group\(^14\).

**Equity in access to countermeasures including vulnerable and marginalized communities**

We have looked at 4 areas to assess equity in access to countermeasures: (1) access during COVID-19, (2) equity in routine immunization programmes, (3) legislation to protect vulnerable populations, and (4) provision of universal health coverage.

1. **Approach for providing equitable access to medical countermeasures during the COVID-19 pandemic globally and particularly for vulnerable and marginalized communities**

Globally, the Access to COVID-19 Tools (ACT) Accelerator aims to develop, produce and enable equitable access to COVID-19 tests, treatments and vaccines. Its delivered 176 million tests to 184 countries, allocated over 300,000 therapeutics to countries, and through COVAX delivered 1.96 billion vaccine doses to 146 countries\(^15\). The ‘Roadmap for prioritizing uses of COVID-19 vaccines’ issued by the WHO Strategic Advisory Group of Experts on Immunization\(^16\), is also an example of a guidance-based approach to ensuring effective prioritization of COVID-19 vaccinations, taking into account a wide range of evidence to issue guidance on how countries should immunize different groups to equitably deliver vaccines.

2. **Routine immunization programmes outside of pandemics**

Having equity approaches in place for routine immunization would likely translate to an effective approach in pandemics. Polio, for example, remains endemic in only Afghanistan and Pakistan and GAVI’s evaluation of the Research Every District/Community Strategy has identified that whilst it is an effective strategy, there is more that can be done to ensure vulnerable populations are able to get a vaccine. This includes having female polio workers being accompanied by male workers due to social
views in some districts, ensuring religious leaders are engaged from the outset, and using hotspot mapping to target communities most in need first\textsuperscript{17}.

3. **Legislation in place that protects different groups and characteristics, particularly in ensuring equity in access to healthcare**

It is not possible to provide a comprehensive assessment across all characteristics, but one example would be the criminalization of homosexuality – there are 66 jurisdictions that criminalize private consensual same-sex sexual activity\textsuperscript{18} (11 of these for which the act would lead to the death penalty). In countries with these laws, it is highly unlikely that gay people receive equitable access to care and countermeasures, particularly when treatment has the potential to reveal their sexuality, for example, infection of mpox was significantly higher in groups of men who have sex with men\textsuperscript{19}.

4. **Provision of universal health coverage, to ensure that the nation is offering equitable access to routine healthcare to all**

A good indicator here is the progress against Sustainable Development Goal indicator 3.8.1 on the coverage of essential health services. The latest data on universal health coverage from the WHO demonstrates that while in many developed nations there is coverage of over 80%, much of the world does not have such access – in much of sub-Saharan Africa and Southeast Asia in particular there are many countries with less than 50% coverage (see Figure 1).

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{UHC_Service_Coverage_Index_SDG_3.8.1_from_the_WHO_Global_Health_Observatory.png}
\caption{UHC Service Coverage Index (SDG 3.8.1) – from the WHO Global Health Observatory\textsuperscript{20}}
\end{figure}
Conclusion
While there are a number of strong examples of efforts to improve equity in R&D and access to countermeasures, it is clear that there are great challenges in delivering equitable approaches on the global scale. This is particularly clear when looking at universal health coverage, which demonstrates that there are clear challenges in delivering routine healthcare to all in sub-Saharan Africa and Southeast Asia.

SCORING
Score: 7/15 (insufficient) - on a global scale, considering only components 3–5 of the indicator, and the response and analysis above.

ANALYSIS
As noted above, there is limited appropriate data available to confidently come to a score. Given the above comments, it is clear that while there are examples of strong levels of preparedness (particularly in the developed world), the preparedness levels on a global scale with reference to this indicator are insufficient, and as such should score between 5 and 9. While there are many individual countries that have little to no capacity for the measures in the metric, there are some global and regional approaches and support in place to support less developed countries in these preparations. Given that there is so much variability, a score in the middle of this range would best reflect the global preparedness levels.

DATA SOURCES AND REFERENCES
challenges-today-futureproof-africas-vaccine-infrastructure#challenge-logistical-issues-around-vaccine-infrastructure
Indicator B.1.2.2 (a) Global mechanism to manage misinformation

**Question**

Is there an effective global mechanism to monitor digital/social information sources on health emergencies and public health issues, to coordinate fact-checking initiatives and slow the spread of disinformation?

**Expert**

Heidi Larson, London School of Hygiene & Tropical Medicine

**ANSWER TO INDICATOR QUESTION**

Regarding an answer to the indicator question “Is there an effective global mechanism to monitor digital and social information sources on health emergencies and public health issues, to coordinate fact-checking initiatives and slow the spread of disinformation”, there are multiple questions packed in one here, but for each of them 1) monitoring information sources (assuming monitoring to identify mis- and disinformation); 2) coordinating fact-checking initiatives; and 3) slowing the spread of disinformation (assuming you mean both misinformation and disinformation), I would say that there are various efforts around the world, but no single global mechanism.

**SCORING**

Capacity score: 1 – Meets a few criteria  
Trend: 0 – While increasing attention was focused on these issues during COVID, there has been no significant change in the past year in terms of building one comprehensive global mechanism.

**ANALYSIS**

**SUCCESSES AND PROGRESS**

Although there is no single global mechanism addressing all the points in the question, there are a number of positive initiatives, both global and regional, that can be valuable resources. I would consider, for instance, the Africa Infodemic Response Alliance (AIRA) network “to share safe, proven facts on health and to counter dangerous health misinformation” as being successful in identifying issues and giving guidance (see examples of others in the “Data resources and references” section below.) But, whether this resource is actually used by countries and the guidance acted on is unclear.

**CHALLENGES**

While monitoring trends and identifying new emerging mis- and disinformation at a global level is important, monitoring, fact-checking and slowing the spread will need regional and local efforts also – especially in consideration of different languages and the proliferation of different local platforms for information sharing. Even considering major global platforms such as Facebook (Meta), Twitter (X) and Instagram, different countries use some platforms more than others (see Vincos Blog: World Map of Social Networks as one example.)
An additional key challenge is that with growing restrictions on social media, and more people moving into private groups e.g. by using WhatsApp, access to monitoring social media has become more limited.

**DATA SOURCES AND REFERENCES**


Indicator B.1.2.2 (b) Global spread and impact of misinformation during health emergencies

Question | What is the impact of misinformation and disinformation during health emergencies?
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Expert | Heidi Larson, London School of Hygiene & Tropical Medicine

**ANSWER TO INDICATOR QUESTION**

In recent years, there has been a surge in publications on misinformation, in general, and specifically in the context of COVID as well as other disease outbreaks and humanitarian crises. In terms of the relevance to this indicator on 1) the spread and 2) the impact of misinformation in health emergencies, there is a lot more on the spread — which is easier to track (although increasingly difficult to track on some platforms with increasingly stringent regulations). Additionally, any global tracking needs multilingual capacity or will miss the most important trajectories of spread.

Measuring the impact of misinformation in an emergency is a complex task, as it is difficult to attribute the impact to misinformation alone to an outcome as it is often entwined with other issues.

We have done some control trials exposing people to different types of misinformation and there was (in the USA and UK cohorts) over a 6% drop in willingness to accept a COVID-19 vaccine. (We are analyzing data now for similar trials done in multiple other countries.) But, these results are in the context of a trial and maybe different, even higher, in real-life situations where there are multiple sources, and levers of misinformation.

There are different types of impacts which need to be considered, including (among others):
1. impact on attitude — mis- and disinformation can steer people away from positive health behaviours by influencing their perceptions and attitudes;
2. impact on actual individual or group behaviour — drinking salt water to cure Ebola, or ingesting hydroxychloroquine to “cure” COVID-19; and
3. impact on policy and decision-making (when mis- and disinformation influences high-level decision-makers. There are others, but these give examples of the range of “impact” (another would be the impact on the spread of diseases, for instance, as a result of the behaviours — and the need to look at proximal and distal impacts.

**SCORING**

**Score:** 0, based on our own research and others. Mis- and disinformation are widely accessible and can have a significant impact on individual, institutional and political decisions in health emergencies, with serious impacts on morbidity and mortality.
DATA SOURCES AND REFERENCES


Indicator B.1.2.2 (c) Global platform to disseminate information and build knowledge

Question

Is there an effective global platform to measure and build knowledge of relevant communities, including marginalized and vulnerable groups, and to produce and disseminate information on health emergencies, educate the public and build scientific literacy?

Expert

Julie Leask, University of Sydney

ANSWER TO INDICATOR QUESTION

INTRODUCTION

At the global level, two platforms measure health knowledge and literacy:

1. **Social Behaviour Dashboard on Public Health Emergency**
   Collective Service developed this platform in response to the COVID-19 pandemic. The platform collects social and behavioural data, including knowledge of individuals at the global level. The data can be searched by disease outbreak, region, country and indicator. The dashboard includes 13 indicators related to knowledge about COVID-19 symptoms, transmission, prevention and seeking health information.

2. **COVID Behaviors Dashboard**
   The Johns Hopkins Center for Communication Programs COVID Behaviors Dashboard presents data from a global survey of knowledge, attitudes and practices around COVID-19. The data presented was collected from the COVID-19 Trends Impact Survey developed by Facebook in collaboration with the Delphi Group at Carnegie Mellon University in the US and the University of Maryland Social Data Science Center. The dashboard displays vaccine information, COVID-19 behavior, testing, and knowledge. Knowledge indicators include COVID-19 transmission and topics that people search for related to COVID-19.

Globally, there are three platforms building Health Literacy/Health Knowledge:

1. **WHO platforms**
   WHO has several platforms that produce and disseminate information on health emergencies, educate the public and build scientific literacy including News Room, Disease Outbreak News and WHO Health Emergency Dashboard. All these platforms are updated regularly from days to weeks based on the confirmed acute public health events or potential events of concern. Additionally, The Vaccine Safety Net (VSN) is a global network of websites, established by the World Health Organization, that provides reliable information on vaccine safety. This network has accredited approximately 104 websites in 36 languages in 44 countries worldwide.

2. **Our World in Data**
   Our World in Data is a collaborative project between researchers at the University of Oxford who contribute to the website's content. The non-profit organization Global Change Data Lab produces and maintains the website and data tools since 2011. It provides visualized data in different topics including poverty, disease, hunger, climate change, war, existential risks, and inequality.
3. **Wikipedia**
Wikipedia and the other Wikimedia free knowledge projects are operated by the Wikimedia Foundation, a non-profit organization. A collaboration between WHO and Wikimedia was announced in October 2020 to expand the public’s access to the updated and most reliable information about COVID-19.

**SCORING**

*Score:* Capacity status: 2  
*Trend:* +1

**ANALYSIS**

Generally, the global platforms that measure health knowledge and literacy during health emergencies are considered ad-hoc activities during global public health emergencies.

**CHALLENGES AND GAPS**

One of the limitations of the Social Behaviour Dashboard on Public Health Emergency is that data cannot be compared over time across the countries due to the extraction of data from academic and peer-reviewed research articles and other publicly available studies, as well as risk communication and community engagement (RCCE) partner-led KAP surveys and field assessments. Additionally, the sample size and sampling differ from one country to another.

Data on the COVID Behaviors Dashboard can be compared across countries as the data was collected globally using a unified questionnaire. However, the data visualized is about COVID-19 only, with the last updated version in 2022. The survey was limited to recruiting participants exclusively from Facebook, therefore the findings should be interpreted with caution and may not be generalizable to the larger population.

The global platforms that contribute to building health literacy/health knowledge during health emergencies especially developed by WHO are updated regularly from days to weeks based on the confirmed acute public health events or potential events of concern. The credibility of WHO makes these platforms trusted sources of reliable information about global public health emergencies. One of the limitations is its availability only in UN languages, which delays access for speakers of other languages.

Wikipedia is the most frequently accessed resource by individuals seeking health information online in different global languages. Our World in Data utilizes credible sources, including official data from government sources, international institutions or statistical agencies and research articles. A notable drawback of this platform is that it only presents data in English and that it relies on the quality of surveillance of data sources.

**DATA SOURCES AND REFERENCES**

The data sources are provided as links in the analysis. This response was provided by Majdi Dafallah with assistance from Adeline Tinessia, University of Sydney.
Indicator B.3.2.1 Assessment of communities and people at the national level

**Question**

Is there an effective global platform to measure and build knowledge of relevant communities, including marginalized and vulnerable groups, and to produce and disseminate information on health emergencies, educate the public and build scientific literacy?

**Expert**

Julie Leask, University of Sydney

**ANSWER TO INDICATOR QUESTION**

(1) *Do countries have integrated and implemented minimum standards for community engagement in their preparedness plans, in terms of participation, ownership, inclusion, adaptability, and building on local capacity?*

**Overall assessment**

Globally, there is moderate implementation of minimum standards for community engagement in preparedness plans. There is evidence that most countries recognize the importance of community engagement in health emergencies and have taken steps to integrate and implement minimum standards in their preparedness plans. The quality and implementation of these standards will vary in practice. The inclusion of marginalized population groups is sub-optimal, as emphasized in examples from countries in Africa and from India.

**Basis of assessment**

State Parties Self-Assessment Annual Reporting Tool (SPAR) reports country self-assessment of mechanisms for systematic community engagement in public health emergencies as part of IHR reporting obligations. Five levels of scoring cover the degree to which countries have mechanisms for systematic community engagement. Level 1 is where such activities are under development or implemented on an ad hoc basis. Level 5 is where the activities are implemented and supported at all levels and include socio-behavioural research with engagement activities exercised, reviewed, evaluated and updated on a regular basis. The 2022 e-SPAR C10.3 scored average global capacity for community engagement at 66 out of a maximum score of 100. Regional scores ranged from 60 in EMRO to 81 in WPRO. For specific countries, two scored 0/100, 27 scored 20/100, 15 scored 40/100, 36 scored 60/100, 74 scored 80/100 and 30 scored a full 100/100. Eleven countries had no data.

The WHO Joint External Evaluation global score reported in 2018 was 51% for risk communication community engagement, based on 124 assessments made between 2016 and 2019. The JEE scores community engagement with affected communities at five levels, from no capacity (1), where there is no arrangement to systematically engage populations at community levels for emergencies, through to sustainable capacity (5), where communities are equal partners in the risk communication process as evidenced by “review of a simulation exercise or tested during a real health emergency”. The 2023 score was only 5% however, the basis of this is unclear and unlikely to reflect actual efforts during the COVID-19 global health emergency.
Do countries have platforms in place that capture the views and experiences of citizens including the most vulnerable in society, in order that these can be incorporated into preparedness?

The majority of countries have platforms with the potential to incorporate the views and experiences of citizens into preparedness. Platforms include surveys, artificial intelligence (AI) listening tools, and in-person community and health worker engagement. Evidence of these mechanisms comes in multiple forms related to disease-specific factors and prevention-specific factors, along with social and demographic factors. There are multiple and varied platforms related to COVID-19 that include relevant prevention behaviours, but fewer that collect data for future preparedness in a routine, systematic, rigorous and standardized way over time.

Generalised preparedness-relevant platforms

These platforms include: The Collective Service provides a Social Behaviour Dashboard on Public Health Emergency. It includes dimensions of communication, knowledge, perceptions, practices, social and structural factors. The dashboard lists country-specific surveys related to the dimensions. The Wellcome Global Monitor has collected data from up to 140 countries since 2018 about people’s interest and trust in science. The World Values Survey collects data on social and religious values, political interest and participation, ethical values and norms, security, trust and corruption, with the most recent wave in 2017-2022.

COVID-19-specific platforms

These platforms have included in-country assessments of social and behavioural trends related to the COVID-19 response, sponsored by UNICEF in collaboration with academic partners. Multiple other platforms exist, run by global agencies, academic organisations and businesses.

Vaccination-specific platforms

These platforms include: the WHO Behavioural and Social Drivers of Vaccination tools for data collection, which include surveys and interview guides that measure the main influences on vaccine uptake from the perspective of caregivers/vaccinees. The tools cover domains of thinking/feeling, social processes and practical issues. Designed originally for routine immunization of children, they have been adapted for COVID-19 and now malaria vaccination. Fully launched in 2022, the tools have been used in at least 59 countries. The Vaccine Confidence Index collects data from over 55 countries on dimensions related to vaccine confidence. Its operationalization since 2015 starting in five countries provides a baseline on which to measure changes over time.

Citizens’ views and experiences

Specific countries provide exemplars of community engagement that can inform preparedness and response, including India; citizen score card approaches in Zambia, Tajikistan, Malawi, Tanzania, Ethiopia, Rwanda and Egypt; use of community health workers to provide feedback mechanisms in Kenya and India; and community health committees (CHCs) in some east and southern African countries.

Most countries have an effective risk communication management plan, including infodemics. It is difficult to assess their levels of transparency in sharing information. The SPAR Risk Communication indicator C10.2 measures “mechanisms for public communication and/or media relations, including infodemics”
and the 2022 global average was 72 out of a possible 100. Data is collected from 185 state parties with 184 having at least a minimum score. Levels 4 and 5 are considered to be effective and 108 countries (58%) have a score of 80 or above.

Notwithstanding country performance, there is a global effort to address the infodemic. Since COVID-19, WHO has used digital listening to analyse and quantify information associated with COVID-19, with relevant keywords tracked to identify trends. The Early AI-supported Response with Social Listening (EARS) is an AI-powered tool for automated digital listening. It provides real-time analysis of narratives of the public and has been piloted in 30 countries with data collected through English, French, Spanish, and Portuguese languages. The Vaccine Demand Observatory conducts social listening across multiple countries.

The specific effectiveness of each country’s infodemic management plan varies. An exemplar is Ghana’s multi-sectoral National Misinformation Task Force who used Talkwalker to identify instances of misinformation and rumours. Talkwalker has also been used by the UNICEF Middle East and North Africa (MENA) office to leverage conversational data to combat the spread of vaccine misinformation during COVID-19.

**SCORING**

*Good 6.5*

**ANALYSIS**

**Question 1**

External assessments of community engagement in preparedness plans are often based on historical evidence. Since the COVID-19 pandemic, community engagement efforts have intensified in most countries. The translation of such experiences to new preparedness plans is likely to be slow and would require a systematic country-by-country evaluation of new plans. Self-assessment encourages country ownership and accountability; however, external assessments are also recommended to provide greater standardization. With the new hindsight of a pandemic to inform planning, an additional interim consideration is whether countries have evaluated their COVID-19 community engagement responses and used these to inform planning.

**Question 2**

Since COVID-19, several different global platforms have captured multiple variables. However, most relate to response to the current pandemic rather than metrics related to preparedness for new emergencies. As such, there have been many new initiatives for COVID-19, with duplication and fragmentation of their use, and a lack of ability to compare to a pre-pandemic baseline. Studies often require high levels of technical support with associated workforce and funding limitations in non-emergency periods. It is not clear how invested countries are in surveys conducted by global and external agencies, nor levels of ownership in data collected. Survey samples often rely on population groups who have the capacity to respond and common data collection methods, such online panels or mobile-based responses, systematically miss those experiencing systemic disadvantage, such as people with a disability, people living in poverty, and females. For capturing the views and experiences of citizens relevant to
preparedness, GPMB indicator 3.2.1 would be easier to assess with named variables. The most relevant psychological variable would be trust – both government and interpersonal, based on its high predictive value for lower infection and fatality rates in a recent assessment.

**Question 3**
This question currently captures a collection of different ideas and would benefit from clearer conceptualization. ‘Infodemics’ – an over-abundance of information – is a recent and popular term but it has been critiqued for problematizing information and its multiple meanings make operationalization difficult. ‘Transparency’ is an essential component of trustworthiness but challenging to measure and does not account for timeliness of information, which is also crucial. Digital and social media are channels of communication among multiple important ones. An alternative is whether countries have established communication channels with a range of stakeholders that are in place prior to the emergency and fully rehearsed. Such an indicator should account for digital and social channels along with other relevant modes that are most relevant to the multiple stakeholders.

**DATA SOURCES AND REFERENCES**
Most data sources are provided as links in the analysis.


Indicator B.1.4.7 (a) Inclusion of low- and middle-income countries

Question

Do global decision-making bodies for preparedness and response effectively include LMICs?

Expert

Ngozi Erondu, Georgetown University & The O’Neill-Lancet Commission on Racism, Structural Discrimination and Global Health

ANSWER TO INDICATOR QUESTION

While there are not validated data sources to monitor progress and monitor any quantitative measure of change of LMIC inclusion within PPR decision-making bodies, there is evidence that participation and coalition building of LMICs has increased in decision-making processes such as post-pandemic negotiations around the WHO CA+ and the IHR (2005) revisions. WHO-led processes, in theory, include engagement and inclusion of all 196 state parties, but the process of how this participation happens has historically not been transparent. In 2023 we are in a situation where there is increased visibility of global level decision-making processes and the backlash after the non-solidaric actions of Industry and HICs towards LMICs, especially regarding vaccine access and distribution—but also other governance actions from multilateral organizations. Within the process of developing the WHO CA+, for example, there have been several reports about the intergovernmental negotiating body (INB)-led negotiating process and LMICs suggested conditions around data sharing and promoted a Common but Differentiated Responsibility approach to funding preparedness across LMICs—this language received substantive deliberation. Additionally, there has been a coalition on equity led by LMICs within the WHO CA+ process and LMICs have been clear within the IHR revisions of which instrument is best placed to hold suggested language and provisions.

Still, World Health Assembly and subsequent meeting reports suggest that HICs have heavily influenced the language resulting in less binding and potent commitments from their part. That begs the question if allegations of LMIC participation not being adequate are true. Adequate does not just refer to representation or presence in the room, which can meet the vague interpretation of “but is inadequate to meet the criterion of a more robust definition of ‘effectively’ ”. For example, a cause for inadequate participation includes the wrong LMIC representative participating in the room. So, while there is plenty of work towards this indicator, it is difficult to measure qualitatively or quantitatively based on the lack of systematic data collection.

SCORING

Capacity status: Potentially Incomplete or N/A Information unavailable

Trend: -1; declining

Many of the new instruments, funds and processes were developed in 2022 and have been developed on an ongoing basis since then. In many cases, the heightened visibility of the ongoing pandemic and the injustices around global collaboration/solidarity, meant that LMICs were more effectively included in 2022. Anecdotally there are reports that in 2023 the interest of some LMICs and HICs in continuing to
ensure meaningful equitable inclusion of LMICs has already declined, though this depends on the process. Though pre-pandemic and post-pandemic measurement of this marker is most likely an improvement, if 2022 is the baseline then I would score the trend as ‘-1’ declining. As mentioned, moving forward this score will need to include both quantitative and qualitative components.

**ANALYSIS**

**PROGRESS**

Currently this indicator cannot be answered, there is no institutional body that regularly collects this data and the existing data sources do not allow for a quantitative score to attribute to this question. Still, this indicator asks for effective inclusion as defined by involvement in decision-making, implementation, and negotiation and this can be demonstrated in some ways by examining current global health governance processes e.g. the WHO CA+, the IHR revisions. Also in other governing bodies, including GPMB, there does not seem to be any systematic measurement for this indicator, at least not one that is publicly available. Without a specific survey and intentional review of this indicator, existing and new bodies and processes will count LMIC membership rather than effective (and meaningful) inclusion.

**CHALLENGES**

- This is not a systematically collected or monitored indicator.
- Effective is defined as mere involvement. Any survey that assesses this indicator will also need to ask about meaningful participation (and that would need to be defined as well). Otherwise, entities will consider having a seat at the table as good enough.
- Due to the high seniority levels of government officials participating in many of these formal discussions, it is more difficult for non-state actors to glean anecdotal information about perceived meaningful involvement (unless civil society is also present).
- Another challenge in properly assessing this indicator is the strain on time of LMIC participants who normally have many more responsibilities than HIC counterparts—so participation and involvement in issues may not always reflect lack of interest but lack of time and human resources. This issue was articulated by some LMIC representatives regarding the number of informal meetings and expert consultations required for the WHO CA+.

**GAPS**

A large gap is that this indicator needs qualitative and quantitative measures, meaning that this data can be collected through surveys and questionnaires but also must include interviews, focus groups, and open-ended responses. A document review of some of the sources listed below could also be beneficial if the documents included are from trusted sources.

There is a need to capture the appropriate levels of representatives that participate and engage in decision-making processes. Sometimes those with the technical expertise AND those with appropriate seniority and organizational influence are not the ones in the decision-making chair. This obstructs meaningful and effective involvement in decision-making.
DATA SOURCES AND REFERENCES

There are existing assessments that could potentially incorporate collection and monitoring of this data. These include:

1. **Global Health 50/50**: [https://globalhealth5050.org/](https://globalhealth5050.org/)

   Since 2018, Global Health 50/50 has produced annual reports of index performance reviews on gender and health. Its aim is to influence policy and practices across three domains: the workplace, health outcomes, and ideological discourse. It is an independently registered UK charity and is funded by the Bill and Melinda Gates Foundation. While this imitative focuses on gender, it may be worth replicating a model to support a global equity version of this.

2. **Global Health Decolonisation Movement in Africa (GHDM-Africa)**: [https://ghdmafrica.org/](https://ghdmafrica.org/)

   In 2021 GHDM-Africa published a framework of decolonization of global public health leaders led by researchers and public health practitioners from (and based in) low- and middle-income countries. This work was closely developed with **Network of Impact Evaluation Researchers in Africa** ([https://nieraglobal.org/](https://nieraglobal.org/)), Nairobi, Kenya – and this institution should be approached if there is funding provided to support such an endeavor. Read more at: Oti SO, Ncayiyana J. Decolonising global health: where are the Southern voices? BMJ Glob Health. 2021 Jul;6(7):e006576. PMID: 34244206; PMCID: PMC8268905, [https://doi.org/10.1136/bmjgh-2021-006576](https://doi.org/10.1136/bmjgh-2021-006576)

3. **Independent monitoring board**

   There have been proposals for an **independent monitoring board** to regularly assess and monitor the progress and implementation of the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO CA+). This would be especially pertinent as an aim for the WHO CA+, as reported in earlier **drafts**, to achieve greater equity and effectiveness for pandemic prevention, preparedness and response through the fullest national and international cooperation. In order to ensure that this is being achieved and that signatories are implementing agreed upon actions, an independent monitoring board can include an indicator of meaningful LMIC participation. An independent body was also a recommendation of the Lancet-University of Oslo Commission on Global Governance for Health, and a paper I recently co-authored regarding lessons learned from The Framework Convention for Tobacco Control. See Ottersen, Ole Petter, et al. "The political origins of health inequity: prospects for change." The Lancet 383.9917 (2014): 630-667; Equity and the Pandemic Instrument: Lessons From The Framework Convention For Tobacco Control", Health Affairs Forefront, August 16, 2022. [https://www.healthaffairs.org/content/forefront/equity-and-pandemic-instrument-lessons-framework-convention-tobacco-control](https://www.healthaffairs.org/content/forefront/equity-and-pandemic-instrument-lessons-framework-convention-tobacco-control)

4. **Qualitative assessments**

   Qualitative assessments of the process can be found in official reports from high level meetings that include Member States and from global institutions such as the WHO and UNICEF. Additionally, there are trusted independent civil society entities such as Global Health Files, a global health journalistic organisation that scrutinizes, assesses, and engages with global governance processes for pandemic preparedness and response and beyond.
Indicator B.1.4.7 (b) Involvement of civil society, private sector and community representatives

**Question**

*Do decision-making bodies for preparedness and response effectively involve civil society, private sector and community representatives?*

**Expert**

Ngozi Erondu, Georgetown University & The O’Neill-Lancet Commission on Racism, Structural Discrimination and Global Health

**ANSWER TO INDICATOR QUESTION**

During an active global response to the COVID-19 pandemic, there were global platforms that ensured that civil society, private sector, and community representatives were integral to PPR decision-making, for example, the ACT-accelerator at the global level, but also regional bodies within ASEAN and Africa CDC (e.g. the Africa Task Force for Coronavirus). After 2022, this trend has continued within some processes/entities and attenuated in others.

This indicator, while not having a body or institution that regularly collects and monitors it, is one that can be validated since the criteria definition is so clear. Still, there is not one central point that lists all processes, coalitions, boards, and convenings where civil society have or have not been invited to contribute. Still, situational awareness and participation in civil society can provide some insight (though still inadequate as it is not balanced).

*Please note that this assessment mainly covers civil society organizations (CSOs) and community representatives (often working in tandem with or alongside CSOs); there is limited reflection on private sector participation.*

**SCORING**

*Capacity status: Incomplete = 1*

*Trend: +1 ‘improving’*

**ANALYSIS**

**PROGRESS**

There have been several areas of progress. One example is that civil society representatives successfully advocated to gain two seats on the Pandemic Fund governing board and these seats are equally divided between the Global South and North. Additionally, WHO announced the establishment of the Civil Society Commission, which aims to boost engagement with WHO and CSOs at national, regional, and global levels of the institutions. Also, the INB-led process to develop the pandemic accord (now the WHO CA+) included public informal consultations with civil society, consultations with experts on specific domains, and opportunities to provide comments and feedback on the zero draft.

Still, when it came to active negotiation processes with Member States, civil society (bar a few
representatives) has been largely excluded. Fortunately, some Member States independently held sessions to ensure civil society informed their language and other points that were brought to these negotiations. The Working Group on amending the IHR (WG-IHR) also has not set official modalities for including civil society within their processes either. There seems to be opposition with some Member States to formally incorporate civil society representatives in this process. There are some instances where countries actively block civil society participation, this is clear in the G20 meetings, but it seems that this trend mirrors country-specific domestic issues and general geo-political shifts towards reduced democracy and less empowerment of non-governmental entities. There are many more expert critiques that describe the “edging out” of civil society in several global health processes and platforms (see Data sources and references below).

As a trend analysis across the past three years, I will say that this indicator has progressed, with hard-won but fragile gains. The gains are not consistent or uniform and there seems to be more restrictions on civil society participation in formal processes than there was in recent years. What is worrying is that personalities rather than processes seem to dictate how much or how little civil society is involved. Anecdotally, the direction of this indicator is thought largely to hinge on certain individuals who have impactful roles at multilateral and bilateral organizations or are leading the processes of developing new instruments/mechanisms. For example, one of the INB co-Chairs actively sought gender experts to draft language that incorporated gender in the zero-draft report. This contrasts with some of the technical working groups where civil society may not be as valued by other members or by the leading organization itself.

For the private sector—the most engagement seems to be in fora regarding localizing medicines and vaccines production. CEPI works with several global pharmaceutical companies and other industry experts. GAVI has also increased involvement with these groups. However, in this area it does not seem that wider civil society is consulted or involved. A recommendation is that the board suggests more systems and structures to be put in place for engaging CSOs, the private sector, and community representatives.

**CHALLENGES**

There is no central source (e.g. spreadsheet) that i) lists all the ongoing negotiations, platforms, working groups and other relevant organizations; ii) monitors which invitations have been offered to civil society (communities and private sector) to provide input and feedback and iii) assesses the level of integration of the feedback within these processes. This information is largely scattered across press releases, blogs, opinion and research articles, or found through speaking with civil society representatives who are close to these processes. This makes collecting this information/data extremely time-consuming.

**GAPS**

There is not one entity that rallies all civil society and community groups specifically and coordinates PPR input. The Pandemic Action Network does a great job of bringing together voices and advocating for inclusion; it is not really their objective to be a neutral platform for civil society exchange and coordination. A PPR group analogous to PEPFAR Watch could be a helpful mechanism to ensure that there is more CSO involvement, accountability, and participation across processes. I think that this gap was evident regarding the CSO input for the PPPR High-level meeting. The coordination efforts and preparation of TB and UHC High-level meetings were of a higher standard.
The above gap allows for barriers in access to information and being informed. Some of the calls for new working groups or opportunities to input are not widely distributed or known to CSOs, especially those in the global south. The lack of consistent systems or structures in place to ensure wide dissemination of information in addition to appropriate funding to support CSO representatives for in-person meetings, will continue to result in access being a barrier for this indicator. This must be captured qualitatively as part of monitoring this indicator.

DATA SOURCES AND REFERENCES

1. Background Research Report: Meaningful & Effective Civil Society Participation in the Pandemic Accord & IHR Amendment Negotiations

2. Terms of reference WHO Civil Society Commission

3. India’s G20 presidency proves need for better civil society engagement
   https://www.diplomaticourier.com/posts/indias-g20-presidency-proves-need-for-better-civil-society-engagement

4. The Systematic Edging out of Civil Society in WHO Governing Body Meetings
   https://genevahealthfiles.substack.com/p/the-systematic-edging-out-of-civil

Indicator B.1.2.1 (a) Impact of health emergencies on women, youth, vulnerable and marginalized groups

Question
Is there an effective, integrated global strategy to address the impacts of health emergencies on women, youth and vulnerable and marginalized groups, including a global monitoring mechanism and requirement to report on these impacts?

Expert
Clare Wenham, London School of Economics and Political Science

ANSWER TO INDICATOR QUESTION
No – quite simply not, with efforts to try and change this, albeit limited or without evidence as yet.

SCORING
1 (at best)

ANALYSIS
The consideration of the secondary disproportionate impacts of health emergencies on women is something which only came to be recognized during the COVID-19 pandemic, despite the wealth of evidence which pre-dates this from prior emergencies. There is no over-arching strategy to mitigate these gendered impacts per se – within the legal frameworks for consideration gender is absent from the WGIHR negotiations apart from in consideration of elite representation within committees, and in the INB gender inclusion has continued to have been watered down in the sequential draft texts of the INB. The HLM PPPR declaration has some efforts to be gender responsive, including recognition of the gendered impacts of health emergencies, the feminized workforce within the health sector, and the need for gender perspectives in all policies and programmes. However, these are all in flux, and so it is not yet possible to call these "global strategies". To a certain extent Sustainable Development Goal (SDG) 5 offers some coverage of ensuring a strategy for gender equality, but this is not limited to health emergencies. The impact of these mixed processes in terms of being able to quantify, monitor or report on gendered impacts is thus lacking.

Changes emerged as a consequence of COVID-19. This included both the creation of a Gender Working Group within the Health Emergencies Programme of WHO, which has been a forum for discussing and progressing activity in this space, and has led to the inclusion of gender indicators within the Joint External Evaluation (JEE). The updated JEE tool (2022) includes a number of gender measurements and requirements. These include P1.2 Gender equity and equality in health emergencies, which considers the legal and capacity mechanisms to support equity at a national level, such as through requirements for disaggregated data, understanding differential gendered exposures and risks of infection, differential engagement strategies, consideration of gendered workforces, addressing structural barriers to access to care and medical countermeasures, etc. Gender also appears in P.3.1 National IHR Focal Point functionality; R1.4 Activation and coordination of health personnel in a health emergency; R3.3 continuity of routine essential health services, as well as information on the mechanisms by which to assess such
needs, such as gender action plans, gender assessments, etc. These gender indicators are new (2022) and thus to date have only been used in a few JEE missions to date, and thus there is no assessment of their utility and whether they have been implemented fully to date, and to what effect. However, it is important to recognize that even if gender is sparingly considered in legal terms (such as within the WGIHR and INB), it is being operationalised through WHO efforts across the health emergencies landscape.

As I understand it, the governance indicators for the Universal Health Preparedness Review (UHPR) have one area of gender inclusion, related to the distribution within the workforce. However, it is unclear whether this has been included in the UHPR pilots to date.

There are a number of other mechanisms which seek to analyze gender inequality more broadly across societies and states, such as the gender data portal from the World Bank, gender indicators from OECD and the UN Women Data hub, to name but a few. However, these are not specific to the impact of health emergencies, but can provide some proxy data points to understand the differentials in gender equality and equity in differing locations. Moreover, there will likely be a range of indicators related to the specific domains of gendered impact as outlined in the criteria, e.g., on education through UNESCO, development from the United Nations Development Programme (UNDP)/UNICEF, nutrition through the Food and Agriculture Organization (FAO), etc. These are beyond my knowledge base, but they might be disaggregated and contribute to the global monitoring of such effects.

The criteria definitions also require some greater consideration. Yes, getting sex and gender disaggregated data is important and will be vital in allowing trends in epidemiology and clinical care to be understood, but this is not sufficient to be able to understand the impact of health emergencies of women and other vulnerable groups. For this you require feminist methods to be able to get the everyday life stories from those at the margins. This can include participatory methods, qualitative interviews, focus groups, oral histories and participant observation. For many, particularly those who work in the biomedical field, such data points can be at odds with the concept of “evidence” but this is where real understanding of issues which cannot be quantified, but which women experience every day, can be better understood—for example, domestic violence, which is notoriously underreported in statistics.

**DATA SOURCES AND REFERENCES**

7. UN Women Data, United Nations. [https://data.unwomen.org/](https://data.unwomen.org/)
Section 3 – Coherence

Expert assessments

Indicator B.1.1.1.2 (a) Global mechanism for early warning and One Health surveillance

<table>
<thead>
<tr>
<th>Question</th>
<th>Is there an effective global mechanism for early warning, risk assessment and surveillance with data sharing (including standards), data management, analytics, modelling and real time communication at the human health, animal health and environment interface to monitor emergence of potential new threats with open centralized access to data and rapid pathogen sharing, and grounded in equity?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expert</td>
<td>One Health High-Level Expert Panel</td>
</tr>
</tbody>
</table>

ANSWER TO INDICATOR QUESTION

Incomplete and fragmented

SCORING

Capacity: Incomplete (1)
Trend: improving (+1)

ANALYSIS

There have been several recent assessments of a global mechanism for early warning and One Health surveillance, including by the One Health High Level Expert Panel (OHHLEP) and Quadripartite One Health Intelligence Scoping Study, at the request of the Quadripartite of FAO, WOAH, WHO and UNEP.

PROGRESS

There are components of such systems that have been developed or are in development, including the Joint FAO–WOAH–WHO Global Early Warning System for health threats and emerging risks at the human–animal–ecosystems interface [GLEWS], the WHO Global Antimicrobial Resistance and Use Surveillance System [GLASS], The WHO Global Outbreak And Response Network [GOARN], FAO’s Global Animal Diseases Surveillance and Early Warning System. There are systems in place for data sharing for some necessary aspects, such as viral genomes via the Global Initiative on Sharing All Influenza Data (GISAID), but there are numerous challenges and gaps.

CHALLENGES AND GAPS

Challenges and gaps include: agreement on the scope for events and One Health surveillance; defining what data are required; developing integrated systems that are flexible, but coordinated; recording timely and
standardized data that can accommodate technological advances and big data (e.g. whole genome sequencing, citizen science-based surveillance); developing governance systems that overcome political, ethical, administrative, regulatory and legal (PEARL) barriers; developing protocols for surveillance overviews and outputs, including the implications for reporting results that lead to equitable and appropriate responses; and developing implementation plans that account for current capacities, and mechanisms to enforce enhanced surveillance with potential changes in risk.

DATA SOURCES AND REFERENCES

1. One Health High Level Expert Panel White paper (under submission)
2. Global Initiative on Sharing All Influenza Data https://gisaid.org/
5. Epidemic Intelligence from Open Sources (WHO) https://www.who.int/initiatives/eios
9. Infectious Diseases Data Observatory https://www.iddo.org/
11. Quadripartite One Health Intelligence Scoping Study https://www.who.int/publications/m/item/quadripartite-one-health-intelligence-scoping-study

Examples that informed the assessment

The recent outbreaks of avian influenza involving cats in Poland and Korea, and fur farms in Finland have raised questions about potential common source exposures. These were barely addressed, and there does not seem to be a mechanism for true open discussion and sharing of information. The message seems to be “we got this, no need for involvement of public health actors”, yet, there is a critical need for information.
Indicator B.2.1.1.1 (a) Regional laboratory capacity

**Question**
Are there sufficiently resourced, globally-coordinated, regional laboratories with advanced capacities to support and provide assistance to national laboratories in advance and during health emergencies?

**Expert**
Strategic & Technical Advisory Group on Infectious Hazards with Pandemic and Epidemic Potential (STAG-IH)

**ANSWER TO INDICATOR QUESTION**
A regional laboratory meeting all the above-mentioned criteria is notional. There are regional laboratories but not for multi-pathogen testing even though some are designated for vaccine-preventable diseases and certain viruses.

The capacity of these laboratories varies across different regions. Also, the structure, functions, and collaborations of regional laboratory networks vary across the regions. It is uncertain how scalable the capacity of the regional laboratories would be, given that many would also be supporting their own national response in a crisis, although several collaboration cases were made during the COVID pandemic.

Due to a lack of clarity regarding the definition of the criteria, the assessment was challenging. To ensure accurate scoring and assessment of the indicator, further clarification is required. It is worth noting that the Global Health Security Index and Joint External Evaluation score for health preparedness are not correlated with countries’ COVID-19 detection response time and mortality outcome (https://pubmed.ncbi.nlm.nih.gov/32892793/). With that caveat in mind, we should exercise caution when scoring, as it has the potential to create a misleading impression when trying to understand the situation. It is also important that the criteria align with the priorities we aim to highlight and achieve.

**STATUS AND NETWORKS OF REGIONAL LABORATORIES**
Below is a map of WHO Collaborating Centres (CCs) (see Figure 1). The Eastern Mediterranean Regional Office (EURO), Pan American Health Organization (PAHO), and Western Pacific Regional Office (WPRO) have fairly established well-resourced multi-function labs and associated networks. The South-East Asia Regional Office (SEARO) has some endemic disease-focused labs and lab networks. EMRO has only MERS-focused and some influenza CCs. The Regional Office for Africa (AFRO) has several strong labs but pathogen-focused labs and the number of CCs are small compared to the other regions.
Figure 1: National Influenza Centres and WHO Collaborating Centres for Epidemic and Pandemic Preparedness and Response

- **PAHO:** No designated regional lab for multi-pathogens but there is a well-structured regional lab (CDC) for flu. For further information, please visit PAHO Laboratories: [https://www.paho.org/en/laboratories](https://www.paho.org/en/laboratories)

- **WPRO:** The lab network exists across the different programmes – a vaccine preventable disease lab network (polio, measles and rubella, rotavirus etc.), AMR network lab, and public health lab network for emergencies. Furthermore, the Pacific Island countries have their own surveillance and lab network. WPRO is trying to expand wastewater surveillance for polio and other diseases, including COVID-19. For further information, please visit:
  - Western Pacific Coordination laboratory networks: [https://www.who.int/westernpacific/activities/coordinating-laboratory-network](https://www.who.int/westernpacific/activities/coordinating-laboratory-network)
  - Pacific Public Health Surveillance Network LabNet: [https://www.pphsn.net/services/labnet](https://www.pphsn.net/services/labnet)

- **EMRO:** There are designated laboratories for vaccine-preventable diseases and a certain virus. No designated regional laboratory for multi-pathogen testing that is globally connected. For details, please visit Eastern Mediterranean Regional Office Public Health laboratories: [https://www.emro.who.int/entity/laboratories/index.html](https://www.emro.who.int/entity/laboratories/index.html)

- **EURO:** The “Better Labs for Better Health” initiative supports countries in strengthening the core laboratory capacities required under the International Health Regulations (2005). Intersectoral national laboratory working groups (NLWGs) hold regular meetings to advance the Better Labs for Better Health objectives, discuss laboratory-related activities, provide advice at the national level, and identify synergies with other laboratory-related initiatives. For more information, please visit:
How the Better Labs for Better Health initiative improves laboratories.
https://www.who.int/europe/initiatives/better-labs-for-better-health/how-the-better-labs-for-better-health-initiative-improves-laboratories

WHO/EURO established the European Laboratory Task Force for Emerging and Re-emerging Pathogens (Lab Task Force) in January 2019. The 2nd meeting of the European Regional Laboratory Task Force for High Threat Pathogens was held in Antalya, Türkiye, 21–23 June 2022. For further information, please visit the following link:
  https://apps.who.int/iris/handle/10665/366510

• **SEARO**: WHO supported laboratory strengthening activities during the COVID-19 pandemic to improve diagnostic capacity and bio-risk management, provide guidance to Member Countries, undertake regional networking and deploy relevant human resources and laboratory supplies, where required. For details, please visit the following links:
  o WHO South-East Asia Region’s efforts to strengthen national laboratories during the COVID-19 pandemic.
  o Establishment of public health laboratories in South-East Asia.
    https://apps.who.int/iris/handle/10665/274288

• **AFRO**: Laboratories and Health Technology:
  https://www.afro.who.int/health-topics/laboratories-and-health-technology

**SCORING**

**Capacity Status**: 2 (Partial)

**Trend**: +1 (improving compared to 2022)

**ANALYSIS**

Laboratory is one of the core capacities that countries must develop for the implementation of the International Health Regulations (IHR) because laboratory services play a major role in all the key processes of detection, assessment, response, notification, and monitoring of outbreaks.

A lot of capacities were developed, and networks expanded during the COVID pandemic. Nevertheless, a lack of resources remains an obstacle to strengthening laboratory capacity even though gaps were identified.

This high-level indicator may create a wrong impression regarding the actual capacity of regional laboratories. Merely having regional laboratories doesn't guarantee quality and safety of the laboratories. With this caveat, we should carefully assess this indicator. It is necessary to consider the quality assurance component in evaluating this indicator.
This indicator is too high-level to identify gaps and strengthen capacity. Another more in-depth assessment may be required. Utilizing more sophisticated tools will help enhance prequalification and regulatory capacity.

The indicator could be re-named “Regional Laboratory Capacity and Global Coordination”, given the importance of global coordination in tackling pandemics.

DATA SOURCES AND REFERENCES
Links to the relevant sources are provided above.
Indicator B.3.1.1.1 Assessment of National One Health and health systems preparedness

Questions

Do countries have integrated capacity to detect novel and emerging pathogens across the One Health spectrum? Do they conduct comprehensive surveillance and rapidly report zoonotic pathogens in animal populations?

Expert

Strategic & Technical Advisory Group on Infectious Hazards with Pandemic and Epidemic Potential (STAG-IH)

ANSWER TO INDICATOR QUESTION

According to SPAR (State Party self-assessment Annual Reporting, States Party self-assessment Annual Reporting tool Second Edition – WHO website), about 70% of countries report that there are some One Health activities, but in fact most of them are quite premature. In particular, most countries don’t have an integrated platform and capacity to detect a novel or emerging pathogens across the One Health spectrum. That requires significant effort on standardization of methodologies, data sharing, inter-operability, etc. (For instance, the recent H5N1 outbreak in the UK can be a starting point we can look into as one example. The UKHSA risk assessment report on avian influenza H5N1 can be found at: https://www.gov.uk/government/publications/avian-influenza-influenza-a-h5n1-technical-briefings)

Lack of clarity on the terms in the questions poses challenges to the assessment. We request clarifications regarding the definitions of integrated capacity, comprehensive surveillance, and rapid reporting. Establishing minimum criteria is crucial to address this issue. The context will play a significant role as spillover risks can vary widely across different geographies, degrees of encroachment on wildlife reservoirs, agricultural practices, population density, and connectedness.

It is also recommended that the criteria align with what we want to get out of this indicator and what we want countries to do so that we can translate a result of assessment into actions.

SCORING

Score: 9

Scoring was challenging due to the indicator’s lack of clarity. For instance, it is challenging to define "well prepared" since preparedness has different dimensions. Another comment refers to the different range of scoring of this indicator. Harmonizing the range of scores with that of other indicators needs to be considered.

ANALYSIS

The global level coordination mechanism of One Health (WHO, FAO, World Organisation for Animal Health) promotes multi-sectoral mechanism and tools at national level. For further information, please visit the following links:

- One Health Joint Plan of Action (2022-2026)
However, One Health is not fully integrated into the country-level system. The relevant sectors often operate in silos (e.g. AMR programme), with separate facilities and funding for the One Health programme. The challenges extend beyond just capacity and involve issues related to financing. It is necessary to consider this situation while assessing this indicator.

Additionally, the current One Health programme is primarily focused on addressing one specific disease such as flu. This narrow focus emphasizes human diseases over animals. It is crucial to broaden our scope and look into diverse reservoirs to better prepare for future pandemics.

The indicator is too broad and high level to pinpoint specific bottlenecks and determine the necessary actions or solutions.

DATA SOURCES AND REFERENCES

Relevant source links are provided above.
Indicator B.1.4.8 Coherence

**Question**

*Are priorities for preparedness aligned across the main international organizations working on different dimensions of health emergencies?*

**Expert**

Rebecca Katz, Georgetown University

**ANSWER TO INDICATOR QUESTION**

Partially

**SCORING**

**Score:** 1.5

**ANALYSIS**

We are assuming this question is solely aligned to international organizations (IOs), although it is not entirely clear.

There are certainly efforts to try to align priorities at the national level (one example being the National Action Plans for Health Security), and this is often forced by a budgetary process. There has also been at least a nominal effort to align One Health priorities between UNEP, FAO, WOAH and WHO. And some organizations have tried to align metrics of success (such as the Global Fund integrating JEE and SPAR metrics when relevant to assess their PPR funding efforts).

These efforts, though, are around high-level coordination and do not necessarily mean that preparedness priorities are aligned across all IOs. And nor should it, necessarily. Each IO has its own equities, which focus on different parts of preparedness, and at times when there is clear overlap, it leads to multiple approaches to preparedness working with varying stakeholders.

In some IOs that are governed by Member States, the different negotiating partners have chosen to emphasize different approaches to preparedness, such as in sharing sequence data (see CBD/Nagoya/GISRS/IHR and INB negotiations/IPSN at WHO).

These structural challenges in the IOs mean that there are some areas that are coordinated and many that are not. This is also an odd time to assess this, as there are multiple negotiations underway (including IHR revisions, Pandemic Accord and UNGA resolution), as well as a newly created Pandemic Fund, all of which may help guide other IOs in priorities. This may be particularly relevant for the Pandemic Fund, which currently utilizes 13 Implementing Entities, which may serve as a forcing function for aligning priorities.

Therefore overall, there are currently some partial activities to move towards coherence, but we are far from there.
DATA SOURCES AND REFERENCES


Indicator B.1.1.4.1 (a) Trade coordination

<table>
<thead>
<tr>
<th>Question</th>
<th>Is there an effective global, multisectoral mechanism to support transparent coordination of trade measures in the context of a health emergency?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expert</td>
<td>Joseph François, World Trade Institute</td>
</tr>
</tbody>
</table>

**ANSWER TO INDICATOR QUESTION**

There are institutions that exist for coordination of trade-related policy in times of crisis, but these are not specific to health emergencies. The starting point here is the World Trade Organization. During the COVID-19 pandemic, the WTO Members negotiated (with mixed results) on waivers to facilitate access to vaccines that were otherwise protected intellectual property. At the same time, WTO Members individually engaged both in export bans on critical medical supplies, and also on trade barriers reductions (tariffs in particular) for critical medical supplies. In the end, the overall process was chaotic. Many of the measures implemented by WTO Members violated WTO commitments, though they were claimed to be justified given the public health emergency. Even within integrated markets (the European Union in particular), individual Members took unilateral actions with respect to cross-border movement of both goods and people. As such, in the sense of having an effective mechanism defined as “there are no restrictions on the movement of essential medical goods and raw materials during health emergencies as well as other essential goods such as food and energy”, it does not exist.

**SCORING**

**Capacity Status:** 1 (Incomplete)

**Trend:** Improving (there is some progress, for example further support for TFA implementation)

**ANALYSIS**

At the same time, any assessment must consider that there were related disruptions to global supply chains due to local lockdowns (affecting production and shipment of a broad range of goods) and border closures (see Moosavi et al. 2022 for a review of recent literature). Measures deemed necessary to slow the spread of the virus also led to disruption of the cross-border flow of goods, which in turn created shortages for a wide range of goods outside those deemed medically necessary. International organizations like the WTO and the OECD did provide platforms for discussion and coordination, but it is not clear how one balances the risk of disruption to both local and global supply chains against the possible need to impose closure in future health emergencies. What is clear is that the present system is not built for this purpose.

One mechanism that may help in this regard is the Trade Facilitation Agreement (TFA) signed by WTO Members. In theory, when fully implemented, this agreement is designed to make cross-border flow of goods smoother, whether in normal times or during crisis. However, many low- and middle-income countries lack resources to benefit fully from the aims of the TFA (see Figure 1 below). There has been substantial monetary support provided for TFA implementation within the framework of the agreement. Further monetary and technical assistance may help the world trading system to be more resilient in future medical (or other) crises, helping to better ensure the flow of essential goods.
Another complication, to put it bluntly, is lobbying and politics. With respect to vaccine access, there was a second process at play. Generic drug manufacturers were on the one hand seen as pressing their governments to use the crisis to attempt a forced transfer of intellectual property (IP) beyond the scope needed to manage the immediate crisis. On the other side of the equation, drug companies with IP relevant to managing the crisis were also seen as lobbying heavily to prevent transfer of proprietary technology. This interplay between pharmaceutical multinational enterprises (MNEs), through proxies in government, signals a need for cooperation on competition policy and regulation of lobbying in the sector that goes well beyond pandemic preparedness (see the WTO action list below).

The offer to supply vaccines purchased by industrial countries was one response to this political constraint. Similar to the challenge of treatment for neglected diseases in tropical countries, the heavy subsidies and rapid approval of vaccines focused on new technologies that required distribution systems and (ultra-low temperature) storage, which is less suitable outside the health systems of high-income countries. This interplay between vaccine production, suitability, and production capacity (linked to IP) are all reflected in the pattern of trade in COVID-19 vaccines during the pandemic (see Figure 2 below).
Figure 2: Trade in COVID-19 vaccines grew at an accelerated pace, but distribution was unequal. Source: World Bank and WTO (2022). Source: Data from the WTO and International Monetary Fund’s COVID-19 Vaccine Tracker (accessed April 2022).

https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm
The fact that there were negotiations within the WTO means that at least we have a framework for meeting and discussion. However, much work needs to be done in this regard. Beyond more investment under the TFA, the WTO (WTO 2022) has outlined a set of recommended steps under the guise of the medical goods trade agreement to improve the responsiveness of the trading system in future emergencies. These are:

- An agreement to lower barriers to trade in medical goods and supporting services.
- An agreement on trade and health could include commitments to limit the duration of restrictions on exports of critical goods during a pandemic.
- Regulatory cooperation can improve the resilience and functioning of supply chains and reduce the risks of illicit trade.
- An improved global IP system.
- Reduction of services trade barriers and improvement of regulatory systems could expand access to medical services.
- Rules in trade agreements on subsidies, public procurement, and competition specific to health emergencies and health policies.

This is a challenging list and will require WTO Member commitment and real resources for implementation. Some elements will also require a great deal of time, while others may be pursued more rapidly. Linking them in joint negotiations may ensure the pace of reaching an agreement follows the most difficult elements.

**DATA SOURCES AND REFERENCES**

Indicator B.1.1.4.2 Involvement of relevant actors

**Question**

Are relevant sectors meaningfully involved in global health emergency preparedness and response?

**Expert**

Adam Kamradt-Scott, Harvard University, T.H. Chan School of Public Health

**ANSWER TO INDICATOR QUESTION**

The short answer to the B.1.1.4.2 question is “no”. It is a good question, but the two critical words in the indicator are “relevant” and “meaningfully” and what is meant by these terms/how they are assessed. Determining who are relevant actors and the extent to which they are meaningfully or comprehensively engaged remains a contested issue, and will largely continue to be influenced by who holds the convening power.

**SCORING**

*Capacity Score*: Incomplete (i.e. a score of “1”)

*Trend*: No change (0)

**ANALYSIS**

For example, the security sector is one set of actors identified in the indicator. Military actors have a long history of collaborating on health issues (Michaud et al 2019). One study has recently claimed that 95 per cent of the world’s countries utilized their security forces in some way during the COVID-19 pandemic (Erickson et al 2023). My own as-yet unpublished research revealed that at least 53 per cent of the world’s governments called on their armed forces in the first year of the pandemic to support civilian efforts or assume leadership of their national COVID response. What is clear from both of these studies is that militaries played an important function in the pandemic response, but many public health professionals still classify the involvement of any military personnel in health-related activities as undesirable and would dismiss their inclusion as being inappropriate or irrelevant. Conversely, military commanders/leadership often view ‘military operations other than war’ (MOOTWs) pejoratively and a distraction from their primary function of warfighting (Bernard 2013). While they may begrudgingly accept they have a role in prevention and preparedness at the national level, they are more likely to resist being called upon to assist with these functions at the regional or global level. Further, how they are engaged and the mechanisms by which this occurs are still under-developed to non-existent.

The World Health Organization did release the first edition of new guidelines in 2021 that speak to engaging the security sector at the national level, within the context of a domestic crisis (WHO 2021); while these guidelines for national military involvement continue to remain under-developed, the development of guidelines for how foreign military assistance is utilized in health emergencies has not even been attempted by leading intergovernmental agencies, in part due to continued resistance from the humanitarian sector and public health community (including within WHO).
A further example is the animal health sector. While COVID-19 has emphasized again the importance of more integrated, One Health approaches to pandemic prevention, preparedness and response, the existing institutions are not sufficiently fit-for-purpose to engage the animal health sector in a meaningful way. While the separation of human-animal-environmental fields into two distinct international organizations (WHO, WOAH) and a program (UNEP) – only two of which are UN entities – contributes to this disjunction, the animal health sector continues to be marginalized in pandemic prevention, preparedness and response efforts. A current example involves the negotiations around the development of a new pandemic treaty instrument – while WOAH has been consulted at various points, a turf war still seems to be playing out with WOAH being sidelined in important deliberations that involve One Health and specifically animal health considerations. Part of the reason for this phenomenon appears to derive from professional attitudes, particularly amongst public (human) health professionals who view veterinary health considerations as secondary to human health (Fasina et al 2021; Kolla et al 2021; Otu et al 2021). While this may be the case from a human public health perspective, it fails to acknowledge the interdependent relationships between humans, animals and the environment, and is impeding effective collaboration in pandemic prevention, preparedness and response.

In sum, while these are just two examples, what is apparent is that some actors are considered to have a legitimate role to play in pandemic prevention, preparedness and response, whereas others are marginalized, viewed negatively and/or with distrust. It may be helpful to consider actors along a spectrum of legitimacy and appropriateness, particularly when considering their roles, functions and activities in a regional or global context, but that spectrum and where actors sit along it will be influenced by who is asking the question.

DATA SOURCES AND REFERENCES

About the GPMB

The Global Preparedness Monitoring Board (GPMB) is an independent monitoring and accountability body to ensure preparedness for global health crises. Co-convened by the Director-General of the World Health Organization and the President of the World Bank, the GPMB comprises globally recognized leaders and experts from a wide range of sectors, including health, animal health, environment, human rights, economics, law, gender, and development.

The GPMB is tasked with providing an independent and comprehensive appraisal for policy makers and the world about progress towards increased preparedness and response capacity for disease outbreaks and other emergencies with health consequences. In short, the work of the GPMB is to chart a roadmap for a safer world.