



## Consultation response

# Preparing for, and responding to, future pandemics and other international health emergencies

September 2023

## **Q1: How can international cooperation be improved to more effectively prevent, prepare for, and respond to, future pandemics and other international health emergencies?**

This submission is made on behalf of the foundation partners of the Australian Institute for Infectious Disease (AIID) – the University of Melbourne, the Burnet Institute and the Peter Doherty Institute for Infection and Immunity.

The COVID-19 pandemic is one of the greatest global challenges in human history. System changes to prevent and facilitate early detection and response to future pandemics and other international health emergencies are essential to avoid repetition of inequitable and fragmented responses. The proposed reform of the International Health Regulations (IHR) and development of a pandemic instrument are critical steps to improve global pandemic prevention, preparedness and response (PPPR), and we support the need for ambitious and meaningful change.

There are significant limitations of the current IHR. The IHR do not address some of the most important aspects of health emergency/pandemic response, in particular including access to countermeasures. They do not cover the sharing of pathogen samples or genomic sequences, nor access to the benefits arising from their use. There is little capacity to ensure governments comply with their obligations under the IHR and there is limited global oversight and co-ordination. Data from surveillance and monitoring are essential to underpin effective evidence-based responses and have played too small a role in unsuccessful ones. The foundation of PPPR should be timely data for decision-making and evidence-based action. Both the IHR and a potential pandemic instrument should enhance and support these capacities, recognising the central importance of international and cross-sectoral cooperation and ensuring equity.

We support Australia's full participation in the current negotiations for development and reform of the International Health Regulations and a pandemic instrument. We encourage Australia to play a continued leadership role, including with a focus on the Asia-Pacific region, in particular in support of Pacific Island states. We also support full Australian participation in the meetings of governing and subsidiary bodies once the pandemic instrument and changes to the IHR have entered into force.

We recognise that there are many ways in which international cooperation can be improved other than through inclusion of new obligations, commitments, processes and bodies in legally binding international instruments. Some improvements might be made in the implementation of the new pandemic instrument/amended IHR – e.g. adopted by their governing bodies through decisions taken to support implementation rather than included in the text itself. Others can be made without requiring changes to international legal frameworks – e.g. activities that WHO or other international agencies are already empowered to perform, or that states or non-states actors are already equipped and able to carry out. While the primary focus of this consultation is on the

new pandemic instrument and changes to the IHR, our responses are in some instances about international cooperation more broadly, recognising that the pandemic instrument and changes to the IHR are an important – but not the only – vehicle for improvements in international cooperation for pandemic prevention, preparedness and response.

This section provides specific recommended actions based on our collective expertise in prevention, preparedness and response to health emergencies around themes identified in the consultation document as being under active discussion in current negotiations.

## **Surveillance, laboratory strengthening and timely notification of outbreaks:**

- **Require** states to share surveillance and notification data (including genomics data). Promote the need for and benefits of information sharing and notification and consider enablers e.g. performance-based and non-pandemic financing. Expectations and rewards should be tiered for LMICs and HICs to promote equity. Non-sharing should be actively discouraged, and, in appropriate cases, highlighted.
- **Promote** the sharing and interpretation of surveillance data at a regional level to support specific containment objectives and decision-making.
- **Ensure** an independent global monitoring mechanism (e.g. Global Preparedness Monitoring Board, Polio International Monitoring Board) to support surveillance and international sharing. Monitoring should be nuanced to distinguish between wilful non-compliance and non-compliance due to lack of resourcing, systems or capacity.
- **Promote** the development and use of surveillance and preparedness indicators that can be used in country self-assessments as well as contributing to regional and international monitoring.
- **Require, encourage and reward** national, regional and international simulation exercises to test capacities and communication and provide opportunity for relevant capacity development.
- **Define** a set of more nuanced triggers for alerts or formal declarations of health emergencies requiring international co-operation and collaboration. These triggers should include scenarios for new and re-emerging pathogens of pandemic potential.
- **Actively support** surveillance and diagnostic activities through the provision of equitable access to reagents and other consumables for laboratory testing (such as WHO International Reference Reagents, rapid diagnostic tests) and the provision of training including in basic microbiology, indicator-based surveillance and response capacity. Link to other laboratory strengthening initiatives to enhance IHR capacities including those around antimicrobial resistance, tuberculosis, HIV and malaria (e.g. those run by the Global Fund to Fight AIDS, Tuberculosis and Malaria, Fleming Fund, World Bank).
- **Promote** surveillance and notification capacities that not only support international co-operation, but also strengthen domestic health responses.
- **Develop** ways to quantify the value of data and facilitate the return of equivalent value to data providers (at all levels – community, sub-national, national) e.g. in the provision of access to support and countermeasures.
- **Encourage** adherence to common data standards and security e.g. through groups such as PHA4GE to facilitate better data sharing and integration.
- **Promote** transparent and safe mechanisms for data sharing, including details of how data are managed, accessed and funded.
- **Endorse** and promote international harmonisation of protocols and ethics for connecting anonymised clinical and genomics data.
- **Protect** against potential negative consequences of data and sample sharing (e.g., do not name strains after sharing locations, do not impose travel or trade restrictions on sharing states).



- **Provide** clearer guidelines on when pathogens can be downgraded peri/post-pandemic (e.g., SARS-CoV-2 as a BSL2 not BSL3 pathogen) to facilitate specimen sharing and research.
- **Establish** a WHO Pathogen Access and Benefit-Sharing System (the “PABS System”), drawing on the WHO Pandemic Influenza Preparedness (PIP) Framework and its lessons. This could enable capacity building and access and benefit sharing that is financially supported by vaccine/antiviral manufacturers.

## One Health:

**One Health is a critical lens** and area for uplift in **considering prevention, preparation and response to international health emergencies** across different sectors, intersecting with many of the themes addressed elsewhere in this submission. Supporting the recommendations of the Quadripartite and One Health High-Level Expert Panel, we further recommend to:

- **Support** a One Health approach to disease surveillance, including the development of minimum datasets and capacities for varied settings including human, animal and environmental sampling frames and indicators.
- **Implement** surveillance strategies that are framed to encapsulate cross-species/sectoral systems and interactions including progression from species-specific events towards a focus on ‘communities of risk’. This should include the development of shared protocols with required minimum capacities and data specifications.
- **Reduce** spill over risk at the interface of human and animal habitats including wildlife, agricultural and domestic contexts. Governments in high-risk areas should be supported to implement interventions that explicitly reduce this risk including targeted sentinel surveillance and other approaches to reducing cross-species transmission e.g., restrictions on wildlife trade, promotion of sustainable agricultural practices and promoting best-practice approaches to natural resource management. Recognise the potential synergistic benefits in addressing other global issues such as climate change and biodiversity loss with implications for animal-human interface exposures and the link to other instruments e.g. the Convention on Biodiversity, the Paris Agreement and the WTO Agreement on the Application of Sanitary and Phytosanitary Measures.
- **Promote** mechanisms for sharing samples and data across sectors e.g., animal health, agriculture, human health, and environment, recognising the challenges of cross sectoral governance and appropriate interpretation of data in the context from which it was sourced.
- **Implement** a cross-sectoral One Health approach in LMICs and HICs through ministries other than health, ensuring informed assessment of risk, resource requirements and delivery of co-benefits across species and sectors.

## Access to countermeasures:

- **Ensure** the equitable supply and distribution of countermeasures, both globally and within countries.
- **Maintain** international and regional stockpiles of personal protective equipment, vaccines and therapeutics to promote early containment objectives and support rapid and effective outbreak response.
- **Build** on the learnings from existing vaccine initiatives e.g., the ACT-Accelerator, COVAX and the International Coordinating Group (ICG) on Vaccine Provision to address vaccine access issues, particularly for LMICs. All aspects of vaccine access need to be addressed, including development, financing, licensing, distribution, administration, monitoring and benefit sharing.
- **Co-ordinate** the development of distributed, adaptable vaccine manufacturing platforms, including open access technology provisions to promote regional manufacturing capacity (e.g., for mRNA-LNP and other vaccines, adjuvants, and treatments).
- **Support** geographical diversification and regional manufacturing capacities and sharing arrangements to reduce reliance on global supply chains and resource competition. Include regionally accessible stockpiles of raw materials for manufacture of mRNA platform products.
- **Promote** the inclusion of countermeasure access pipelines, arrangements and agreements in preparedness plans. Link early reporting to early access to countermeasures, optimising prospects of limiting the spread and impact of an emergent infectious disease.
- **Ensure** investment in the development of low-cost point-of-care diagnostics and systems. This should include comprehensive approaches for deployment and implementation, including staff training, community outreach and task shifting arrangements for surge response.

## Global capacity development (support for region and LMICs):

- **Promote** and enhance regional networks as a mechanism to increase capability and capacity through co-ordination and trust-building. These networks can facilitate resource sharing, training, and knowledge and technology transfer, including the supply and distribution of countermeasures. System harmonisation through these networks would enable seamless regional workforce expansion in case of a contained outbreak, supported by trained rapid response teams. These networks would also enable collaboration to share learnings, information and best-practice approaches.
- **Prioritise** investment in baseline capacity to fulfil IHR requirements across diagnostic microbiology, surveillance and response, with clear triggers and mechanisms for further support including training and finance.
- **Strengthen** intra-sectoral capacity in diagnostics and surveillance to promote co-benefits for human and animal welfare. This could include promoting better animal diagnostic capacity as a way to maintain and extend international trade and market access for the agricultural sector.
- **Promote** investment in the development and/or technology transfer of electronic data systems and automated extraction, data linkage capabilities to enable low cost and sustainable monitoring and evaluation in LMICs and across regions.
- **Strengthen** public health and research laboratory capacity and capability in diagnostic testing and genomics. This should include establishing a minimum acceptable set of competencies and standards and provide follow-up, monitoring and training for longer term sustainability.
- **Support** the development of a diverse health workforce, including rapid response teams, surveillance, field epidemiology and operational research training (through global networks such as GOARN, TEPHINET and SORT-IT), policy and communications programs for prompt responses to outbreaks and implementation of local and population level countermeasures.
- **Provide** recommended core capacities for response to pandemics and other health emergencies, including health workers, research, data management, informatics capacity, and governance and regulation.



Development of an integrated One Health workforce will be supported by identification and fostering of network brokers who can build relationships between sectors and organisations.

## Research and Development:

- **Establish** systems to (rapidly) fund directed research that can inform public health or policy decisions including epidemiological, clinical and social research.
- **Create** and reinforce mechanisms to enable co-ordinated, rapid and large-scale clinical and observational trials e.g., on re-purposed drugs. These mechanisms should include, for example, expedited ethics and governance approvals, expedited funding and nationally and internationally co-ordinated recruitment strategies.
- **Strengthen** research platforms and partnerships to enable early operationalisation of studies to inform emergency response.
- **Encourage** R&D on technologies to enable cheaper, more equitable production and distribution of vaccines and other countermeasures e.g., heat stable vaccine formulations.

## Health promotion, community engagement and communication:

**Health promotion, community engagement and communications** are fundamental mechanisms for the **development of sustainable public trust** within and between countries. These functions also underpin the ability to make **evidence-based decisions** and to avoid the spread of misinformation. To build these capacities, we recommend to:

- **Include** communications expertise within core preparedness capacities and advisory groups.
- **Recognise** that community engagement is critical to pandemic prevention, preparedness and response and should be embedded as a priority in planning, resourcing, workforce training and response implementation. This engagement should be inclusive (e.g., of language, audience, and location) and should align with existing community health needs, including the need for participatory and co-designed approaches to prevention.
- **Acknowledge** there is no one-size-fits-all approach to community engagement and risk communication. Strategies should leverage existing local and/or regional expertise as required.
- **Assist** countries to provide contextually appropriate materials before rollout of any vaccine, countermeasure or new technology at a rapid pace to the whole population.
- **Provide** additional support for governments and health services to meaningfully engage with and target communication to priority communities including First Nations and marginalised groups to reduce the potential for inequitable health outcomes.
- **Strengthen** strategies to distribute communications materials - conduct training, encourage varied media campaigns to reach different groups of people (including local information and engagement sessions).
- **Ensure** there is local translation of communications, e.g. in countries with different dialects or First Nations populations, including provision of cultural awareness training to ensure these communications are appropriate.
- **Encourage** two-way communication between those providing, analysing and reporting data to provide incentives to data sharing, build trust and to improve communication between different health sector stakeholders.
- **Promote** greater transparency in government through public data sharing e.g. of surveillance trends, case numbers, and deaths.

## **Q2: What issues do you think need to be prioritised to guide the world's future preparation for, and responses to, future pandemics and other international health emergencies?**

### **Equitable access to countermeasures**

- An international system that delivers equitable access to medical countermeasures (including diagnostics, therapeutics, vaccines, personal protective equipment and oxygen) must be established and effectively implemented. Such a system is essential for the development and maintenance of mutual trust, particularly between countries of different capacities and resources. There can be no expectation of effective, trust-based international cooperation on health emergency/pandemic prevention, preparedness and response without such a system. Beyond delivery of such interventions, equity of population access requires corresponding efforts to support sustainable development of infrastructure, people and research capacity for discovery and implementation of timely and effective interventions.

### **Access and benefit-sharing**

- It is essential that an international access and benefit-sharing system for pathogen samples and genomic sequences be established. Such a system must be established in either the amended IHR or the pandemic instrument, with details of the system to be developed and agreed as a matter of priority by the relevant governing body, i.e. the system should not be left to be established by the relevant governing body (as is one of the proposals in the 2 June 2023 *Bureau's text of the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response*). The system should be recognised as a 'specialized international access and benefit-sharing instrument' for the purposes of Article 4.4 of the Nagoya Protocol to the Convention on Biological Diversity.

### **Incentives for surveillance, notification and sharing**

- Timely, best practice surveillance, notification and sharing by countries need to be supported and rewarded, with effective measures in place to prevent any disincentives (such as the naming of strains after the notifying/sharing location, and the imposition of travel and trade restrictions.). Informative surveillance systems require development of sustainable infrastructure, workforce and skills across all stages of the data management life cycle to ensure actionable knowledge for evidence-informed prevention, preparedness and response.

### **One Health**

- One Health approaches across prevention, preparedness and response must be fully embraced and supported in a way that creates synergies at international levels (in particular through the One Health Quadripartite) and at regional and national levels, with effective coordination across sectors, and activities performed by those agencies best placed (through mandate, expertise and resources) to perform them. Minimum requirements of One Health approaches to surveillance, prevention, preparedness and response must be established with recognition of heterogeneity of risk drivers and capacities across settings.

### **Research and development, technology and know-how**

- Greater co-ordination of research and development efforts is needed within and between countries to support timely and cost-efficient generation of evidence applicable to disparate settings. This includes prioritisation of key questions by response phase, fair and efficient distribution of available resources, harmonisation and rapid adaptation of multi-centre protocols, and timely data and knowledge sharing. Such co-ordination will reduce research duplication, wasted effort and avoidable delays to generation of actionable knowledge and effective countermeasures. Support for health emergency/pandemic research



- and development should enhance and synergise with baseline domestic and regional capacities rather than shifting funding, capacity or attention from existing health priorities, particularly where already constrained.
- Manufacturers of countermeasures should be required to grant licences to use their intellectual property and actively share their technology, know-how, information and knowledge in particular with manufacturers in developing countries. Public funding of private research and development activity should be transparent and include conditions that contribute to equitable global access to countermeasures.
  - Governments should be encouraged and supported to apply and implement to the full the flexibilities provided in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights as recognised in the Doha Declaration on the TRIPS Agreement and Public Health.

## Strengthening WHO

- WHO should be strengthened, both in its powers and the resources provided to it, and in a way that empowers and strengthens its collaboration with other international organisations, respects both the breadth and the limits of WHO's mandate and expertise and does not require or expect WHO to undertake responsibilities or functions that are better performed by other international organisations.

## International and regional cooperation, capacity-building and financing

- Regional approaches across prevention, preparedness and response should be strengthened including, in particular, the development of regionalised arrangements for production and distribution of countermeasures including supply chains, manufacturing capacity, and advance market agreements.
- International and regional capacity-building and support should take systems approaches, which are informed by genuine partnerships that are responsive to need, appropriate to context and sustainable over the longer term.
- Secure and sustainable international and regional financing based on need must be available to supplement domestic financing and support international, regional and national activity across prevention, preparedness and response. Financing for implementation of a new pandemic instrument/amended IHR should be provided in synergy and complementarity with the activities of major funding agencies including multilateral development banks.

## Whole-of-government and whole-of-society collaboration

- The development of mutual trust and understanding between sectors and jurisdictions is essential to enabling the sharing of skills, information, know-how, and specimens required to respond to health emergencies/pandemics and must be developed and maintained at all times, including between health emergencies/pandemics.
- The ongoing community engagement, and continuous upskilling in communication within and between sectors, that are essential to ensuring prepared and resilient communities, and supporting prevention efforts, must be developed and consistently maintained and invested in.
- Whole-of-society engagement across prevention, preparedness and response must be developed and consistently maintained and invested in – across disciplines, private and public sectors, and communities, including vulnerable and marginalised groups.
- The resources and expertise of the private sector should be harnessed across prevention, preparedness and response, while appropriately regulating their activities and avoiding and/or managing any potential or actual conflicts of interest.

## Pandemic instrument/amended IHR governance and accountability

- Effective monitoring, compliance and accountability mechanisms should be established for both a new pandemic instrument and amended IHR. Such mechanisms should both encourage and support compliance and hold governments accountable for non-compliance, in ways that can appropriately distinguish between, for example, cases where non-compliance may be due to a lack of resources or knowledge and those where non-compliance is deliberate or wilful.
- Governance arrangements adopted for both a new pandemic instrument and amended IHR should ensure transparency of the proceedings and activities of governing and subsidiary bodies, and the effective participation of civil society and academia.

### **Universal Health Coverage and human rights**

- Action should be taken at all levels – international, regional and national –to improve prevention, preparedness and response to pandemics and other international health emergencies. These efforts should align and support the push for universal health coverage, and protect and promote human rights, including the right to the highest attainable standard of health for all, requiring particular attention to those with lower underlying health status and access, including First Nations and priority populations.





## Q.3 Is there any other information you would like to provide that might help to guide Australia's engagement on a new international pandemic instrument and changes to the IHR?

- Australia's leadership, through the UN, WHO, other international organisations and with our regional partners will be critical in advancing successful outcomes in the design and negotiation of a new international pandemic instrument, changes to the IHR and other international and regional efforts to improve health emergency/pandemic prevention, preparedness and response.
- This would align with Australia's International Development Policy which aims to advance an Indo-Pacific that is peaceful, stable, and prosperous. In particular through the stated approaches of building accountable states, enhancing community resilience, connecting with regional architecture and generating collective action on global challenges. Strengthened primary health systems, universal health coverage and equitable health systems (through gender equity, disability inclusion and a human rights approach) and embedding the perspectives of communities and in particular, First Nations communities, are fundamental to enhanced prevention, preparedness and response to health emergencies/pandemics.
- Further, enhanced health emergency/pandemic prevention, preparedness and response will strengthen responses to other communicable disease threats such as TB, HIV and malaria.
- It is critical that both a new international pandemic instrument and changes to the IHR build on, support and strengthen the IHR, rather than undermine the IHR or create counterproductive overlaps or fragmentation. Noting the differences between Articles 19 and 21 of the WHO Constitution – in particular, the 'opt-out' nature of Article 21 Regulations, and the broader scope of Article 19 compared to Article 21 – where legally and politically feasible, new arrangements should be included in amended IHR rather than a new pandemic instrument, both because these will inherently build on the IHR, and because there are ultimately likely to be more States Parties to the IHR than Parties to a new pandemic instrument.