COVID-19 Pandemic: The World in Disorder

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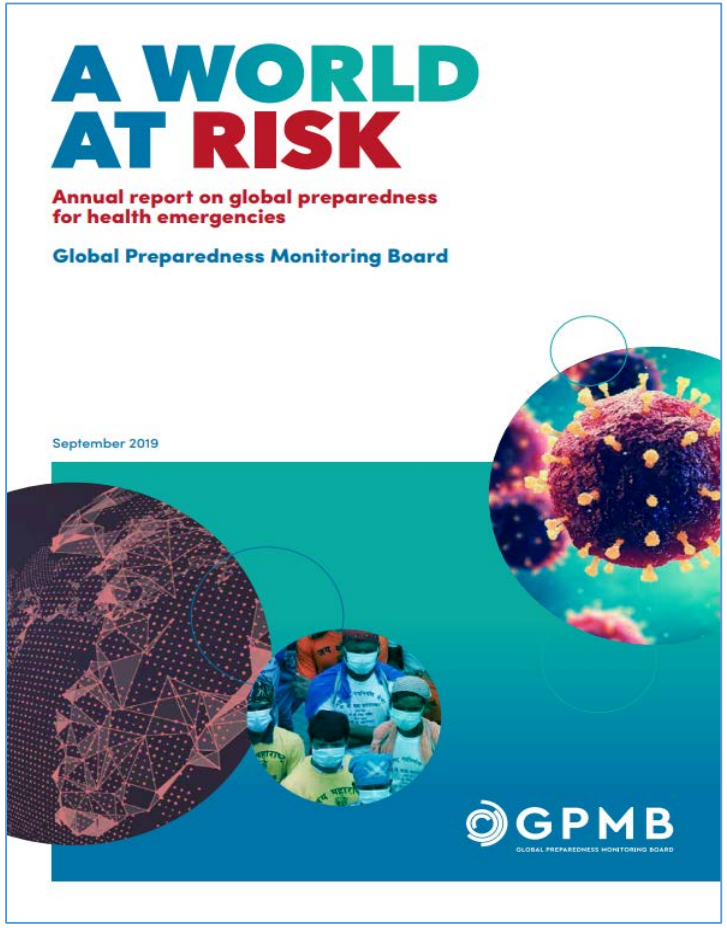
President, US National Academy of Medicine

February 4, 2021
NASEM Aeronautics and Space Engineering Board

NATIONAL ACADEMY of MEDICINE

Founded in 1970 as the Institute of Medicine

GPMB 2019 Annual Report: '*A World at Risk*'



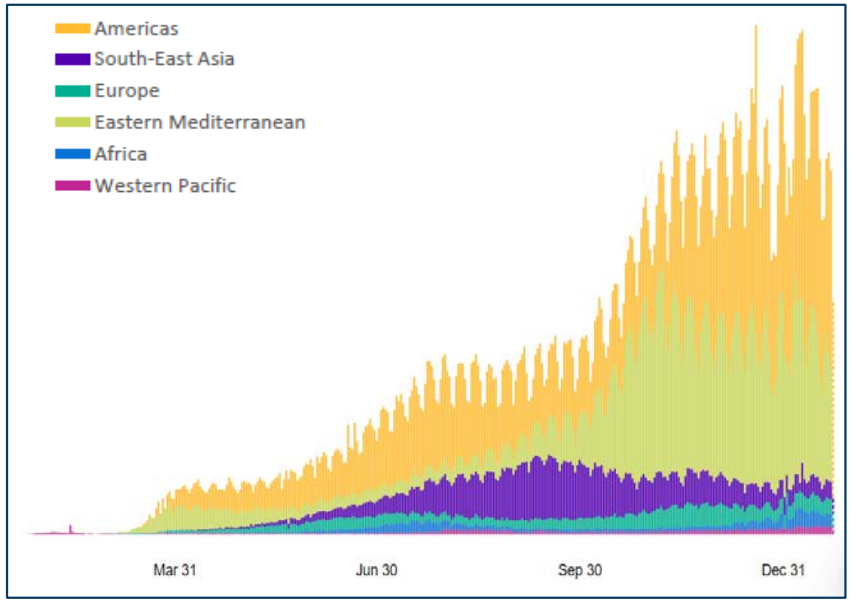
- The report warned of the very real threat of 'a rapidly spreading pandemic due to a lethal respiratory pathogen', and the need for determined political leadership at national and global levels.
- We called for urgent actions to prepare the world for health emergencies

Today: an escalating pandemic with an evolving virus

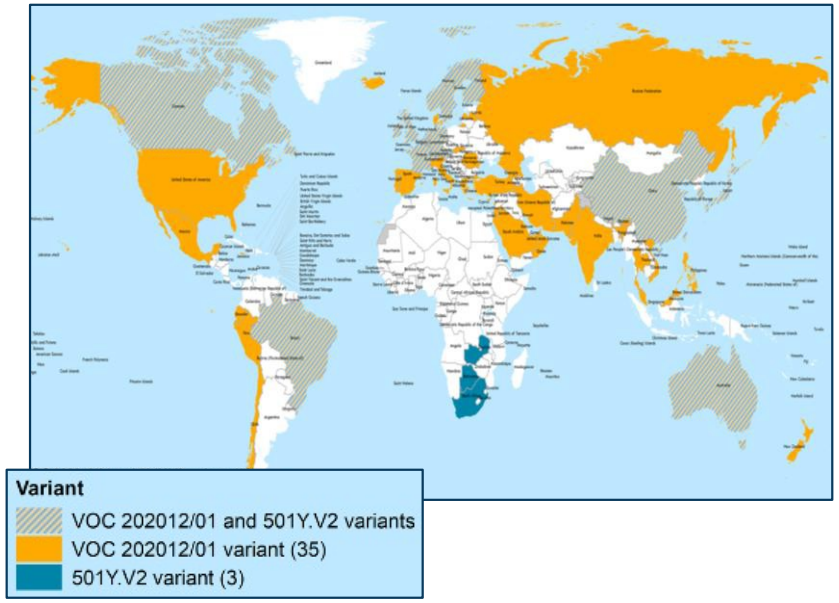
Cumulative (February 3):

- 104 million confirmed cases.
- 2.3 million deaths.
- US: 26.5 million cases; 449,000 deaths

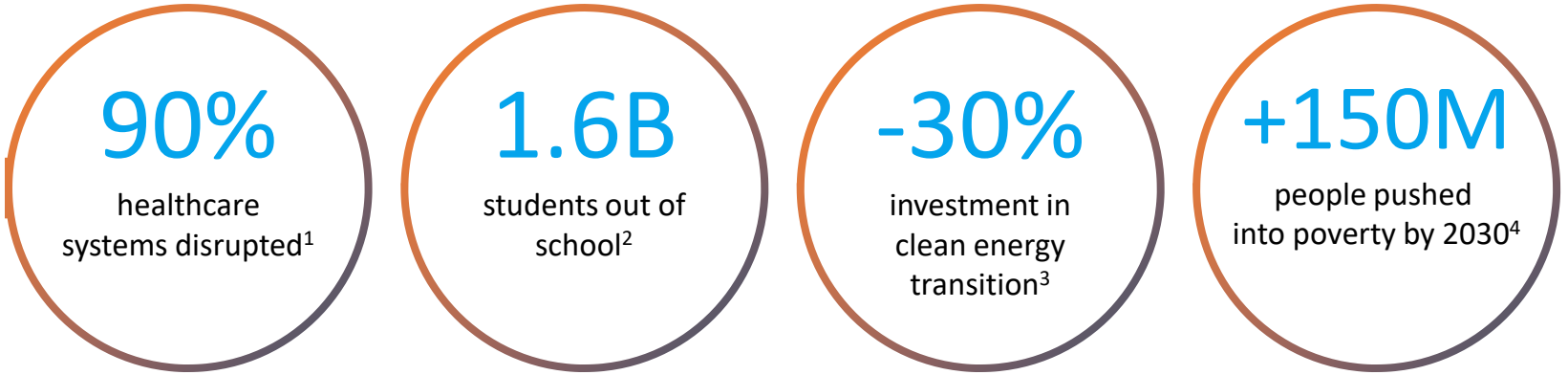
100 million cases & 2 million deaths



Variants of Concern in at least 70 countries



COVID-19 impact | The pandemic endangers all populations and is undermining all of the Sustainable Development Goals



Global Health

As of August 31, 2020

Education

As of April 30, 2020

Climate

Poverty

1. Worldwide disruption of healthcare system due to Covid-19, WHO; 2. World bank; 3. Market intelligence ; 4. Effect of covid-19 only, UN

Lessons learned from COVID-19 (GPMB 2020 Annual Report)

- COVID-19 has revealed a collective failure to take pandemic prevention, preparedness and response seriously and prioritize it accordingly.
- We live in a world where a shock anywhere can become a catastrophe everywhere, which means we are interconnected.
- The impact of Covid-19 is well beyond health
- The human dimension of preparedness has been overlooked. Responsible leadership matters most and citizens have a critical role to play.
- Current measures of preparedness are not predictive.
- Health emergency preparedness requires effective, agile systems
- Pandemic preparedness is a common good
- No one is safe until all are safe
  - Global preparedness is not simply the sum of national preparedness.
  - The world of pandemic preparedness needs consolidation, not further fragmentation
- The return on investment for global health security is immense

A 23-Nation Comparative Study of COVID-19 Response, with Lessons for the Future of Public Health

- Purpose: Studied how public trust, leadership, and political culture have impacted the COVID-19 response in 23 nations on six continents
- The politics of implementing public health interventions, not their policy soundness, drove outcomes
- Leaders must think about the complex political, economic, and public health tradeoffs involved in response actions in their local contexts.
- Three broad patterns of pandemic response that have emerged across the 23 countries:
  - 1. Control countries (i.e. Taiwan, China, Singapore, South Korea)
  - 2. Consensus countries (i.e. Germany, Australia, Japan, Sweden)
  - 3. Chaos countries (i.e. the US, Brazil, India, United Kingdom)
- One of the most important “pre-existing conditions” shaping pandemic response has been trust, cohesion and solidarity.
  - This solidarity and cohesion can come from more authoritarian, top-down force and also from trust and idealism in democratic government

Schmidt Futures, Harvard, Cornell, and Columbia Universities, 2021

Conditions for Success

- **Important pre-existing condition shaping pandemic response has been trust, cohesion and solidarity.**

- **Countries that succeeded in controlling the virus invariably had a coordinated national strategy**

- **An effective global collective response is absolutely necessary to stop the pandemic**

US Preparedness & Response

- **Leadership & citizenship**
  - Lack of strong, coordinated federal response: states have primary responsibility
  - Politicization of public health measures;
  - False dichotomy – economy vs public health
  - Lack of responsible citizenship (individualism vs public good - social & moral responsibility)
- **Nationalism**
  - Withdrawal from WHO; Failure to engage in global efforts
  - Securing vaccines, therapeutics for own citizens without regard for global equity

US Response: Lack of National strategy & coordination

- Nonpharmaceutical Interventions: Lack of public health mandate and consistent messaging, resulting in extreme variation across states
- Testing:
  - Guidance changing often about who should get tested
  - Slow and inconsistent implementation of widespread testing
- Digital: many digital innovations, but no national strategy and coordination
- PPE and ventilators: initial widespread shortages; failure to invoke Defense Production Act
- Therapeutics:
  - Quick to adopt new therapeutics without sufficient data (e.g., remdesivir).
  - EUA without plans for implementation
- Vaccine: record-setting race to develop, study and approve vaccines, but challenges with supply, distribution and administration
- Data and sequencing

Vaccine

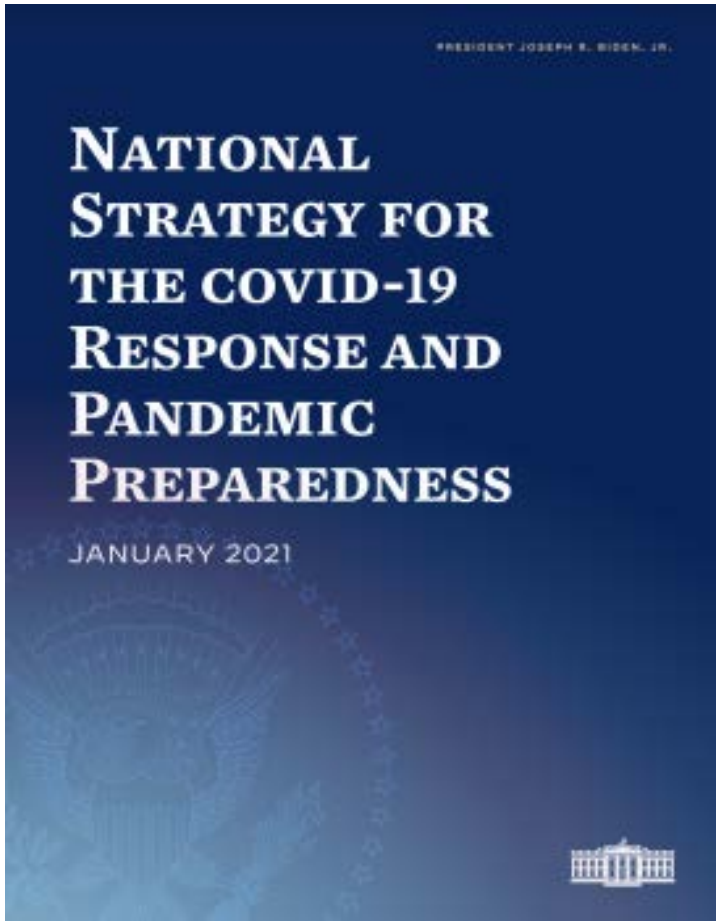
- Record setting pace to develop and approve vaccine
- NASEM and CDC Framework for Equitable Allocation of Vaccine for the Novel Coronavirus
- Major challenges with supply, distribution, and administration
- Logistical and coordination challenges, e.g., supply chain, equipment malfunctions; workforce shortages; scheduling challenges
  - “federal officials have left many of the details of the final stage of the vaccine distribution process, such as scheduling and staffing, to overstretched local health officials and hospitals (NYT)”
- US officials promised 20 million vaccinated against coronavirus by the end of 2020
  - 4.6 million Americans vaccinated (January 5, 2021)
  - 33.9 million doses have been administered, reaching ~10% of the total U.S. population (February 3, 2021)
- Distribution uneven: communities of color receiving far fewer COVID-19 vaccinations than white counterparts despite higher risks

Monoclonal Antibody Therapy

- EUA with inadequate plans for implementation
- Significantly challenges in doses available, potential demand and slow uptake
  - As of February 2, HHS had allocated more than 738k treatment courses to states.
  - Given the nation is facing 140k new cases per day (7 day average, as of Feb. 1), this is insufficient to meet potential demand.
  - However, only 25% of treatment courses have been utilized to date.
- Lack of clear guidance, but robust data is not yet available to help triage which patients are treated in what order
  - Early evidence available showing mAB reduces viral load in outpatients
- Complex logistical challenges (IV infusion)
- Access, equity, cost, and allocation
- NASEM workshop (December 2020) & REC Allocation of COVID-19 Monoclonal Antibody Therapies and Other Novel Therapeutics (January 2021)

Biden-Harris plan to beat COVID-19

1. Restore trust with the American people.
2. Mount a safe, effective, and comprehensive vaccination campaign.
3. Mitigate spread through expanding masking, testing, data, treatments, health care workforce, and clear public health standards.
4. Immediately expand emergency relief and exercise the Defense Production Act.
5. Safely reopen schools, businesses, and travel while protecting workers.
6. Protect those most at risk and advance equity, including across racial, ethnic and rural/urban lines.
7. Restore U.S. leadership globally and build better preparedness for future threats.



https://www.whitehouse.gov/priorities/covid-19/

Global Response

- **Lack of global strategy and coordination**
  - No global strategy for preparedness and response
  - No global entities with a mandate, financing arrangements, or the ability to coordinate multiple independent actors
  - WHO – monitors & supports member states in developing capacity (IHR), coordinates member states for pandemic preparedness and response, and responds to emergency [[like a fire department]]
  - but lack of funding, political constraints, etc hinder WHO ability to respond to emergencies
- **Global R&D ecosystem is fragmented and poorly coordinated**
  - Uncertain which components of ecosystem have responsibility and resources to support a global system
  - Only a few can support an end-to-end R&D system from basic research before a crisis to approved products during the response to an outbreak.
- **Every country taking care of own citizens- nationalism**.
- **Need for everyone coming together to address global equity and access**

GPMB called for global equitable effort in diagnostics, therapeutics & vaccines.

European Commission hosted the Coronavirus Global Response International Pledging Event

World Health Organization

Global leaders unite to ensure everyone everywhere can access new vaccines, tests and treatments for COVID-19

Unprecedented gathering of heads of government, institutions and industry cements commitment to accelerate development and delivery for all populations

24 April 2020 | News release

ACCESS TO COVID-19 TOOLS (ACT) ACCELERATOR

24 April 2020

A Global Collaboration to Accelerate the Development, Production and Equitable Access to New COVID-19 diagnostics, therapeutics and vaccines

COMMITMENT and CALL TO ACTION

Our Vision and Mission

Grounded in a vision of a planet protected from human suffering and the devastating social and economic consequences of COVID-19, we, an initial group of global health actors (BMGF, CEPI, Gavi, Global Fund, UNITAID, Wellcome Trust, WHO) and private sector partners and other stakeholders, are launching a landmark, global and time-limited collaboration to accelerate the development, production and equitable global access to new COVID-19 essential health technologies.

We know that as long as anyone is at risk from this virus, the entire world is at risk – every single person on the planet needs to be protected from this disease.

We agree that alongside evidence-based public health measures, against COVID-19, no one should be left behind.

We understand we cannot do this alone, and that we need to work together in unprecedented and inclusive partnership with all stakeholders – political leaders, public and private sector partners, civil society, academia, and all other stakeholders across society – jointly leveraging our comparative strengths and respective voices to drive towards collective solutions, an accelerated path, and access for all. We are stronger, faster and more effective working together.

Our Mission is not only accelerated development and availability of new COVID-19 tools – it is to accelerate equitable global access to safe, quality, effective, and affordable COVID-19 diagnostics, therapeutics and vaccines, and thus to ensure that in the fight against COVID-19, no one is left behind.

Our Commitment

1. We commit to the shared aim of equitable global access to innovative tools for COVID-19 for all.
2. We commit to an unprecedented level of partnership – proactively engaging stakeholders, aligning and coordinating efforts, building on existing collaborations, collectively devising solutions, and grounding

Our Call

We ask the global community and political leaders to support this landmark collaboration, and for donors to provide the necessary resources to accelerate achievement of the objectives of this global collaboration, capitalizing on the opportunity provided by the rolling pledging campaign that will start on 4 May 2020.

Bill & Melinda Gates foundation · dcvmn · The Global Fund · IGBA · Wellcome · CEPI · Gavi · IFPMA International Federation of Pharmaceutical Manufacturers & Associations · Unitaid · World Health Organization

ACT-Accelerator Global Response to Covid-19

[ACT-Accelerator Facilitation Council
(WHO + EC + Governments (26) + Non-government partners + Envoys & Invitees **]**

[Coordination hub and **ACT-Accelerator Principals]**

R&D

Manufacturing

Procurement

Deployment

Vaccine Partnership (COVAX)

Lead Actors
- CEPI
- GAVI
- WHO

Therapeutic Partnership

Lead Actors
- Wellcome
- UNITAID
- WHO

Diagnostics Partnership

Lead Actors
- FIND
- Global Fund
- WHO

Health Systems Connector
Lead Actors: World Bank and WHO

Goals

- Vaccines: 2 billion doses by the end of 2021
- Therapeutics: 245 million courses by mid-2021
- Diagnostics: 500 million tests by mid-2021

Why we need COVAX

The only solution that will deliver fair, equitable access to vaccines

Bilateral deals leave many countries behind

High risk of failure in vaccine development

Over 1.6 million deaths and counting

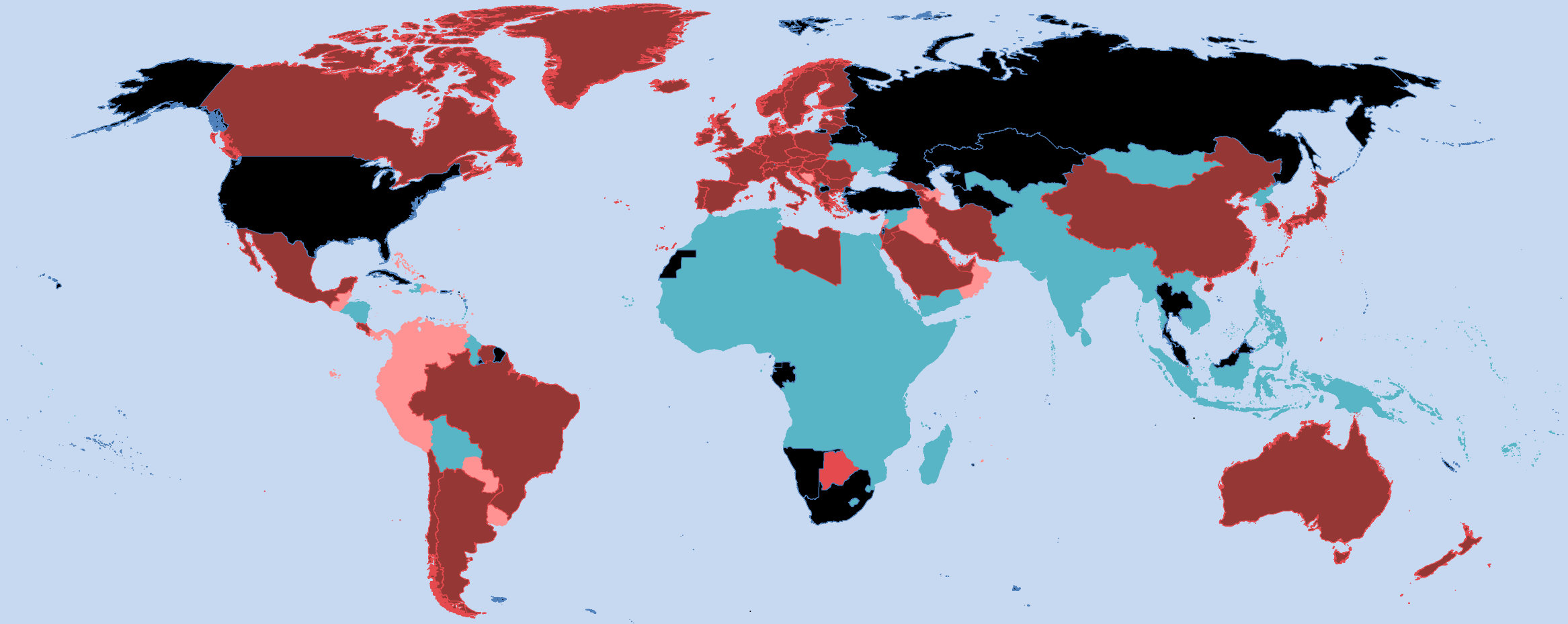
By working together, COVAX aims to provide an end-to-end solution to vaccine development, manufacturing and delivery.

COVAX pools financial resources to develop vaccines, purchase them at scale, and investing up-front in manufacturing so that vaccines are ready to be distributed as soon as licensed.

Ensures global access all countries at the same time, regardless of income.

One World Protected.

COVAX Facility consists of 92 Advance Market Commitment (AMC) economies and 98 self-financing participants (SFP) – 190 economies in total



AMC	92 economies 3.9 B people	**Self-financing committed purchasers**	27 economies 0.2 B people	**Self-financing optional purchasers**	67 economies 2.8 B people

3 big shifts are driving ACT-A priorities in 2021

High **vaccines demand** but sub-optimal uptake of other key tools

Evolving viral mutations & variable in-country response

Under investment in global solutions & increasing bilateral deals

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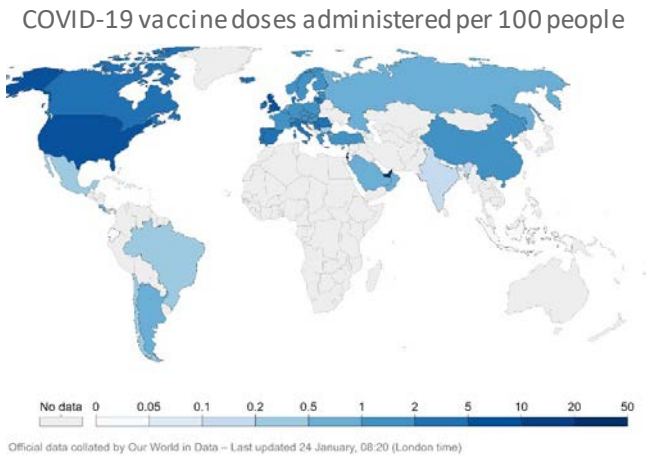


ACT-A funding gap by Pillar & Strategic Priority, 2021

Last update: 26 Jan 2021

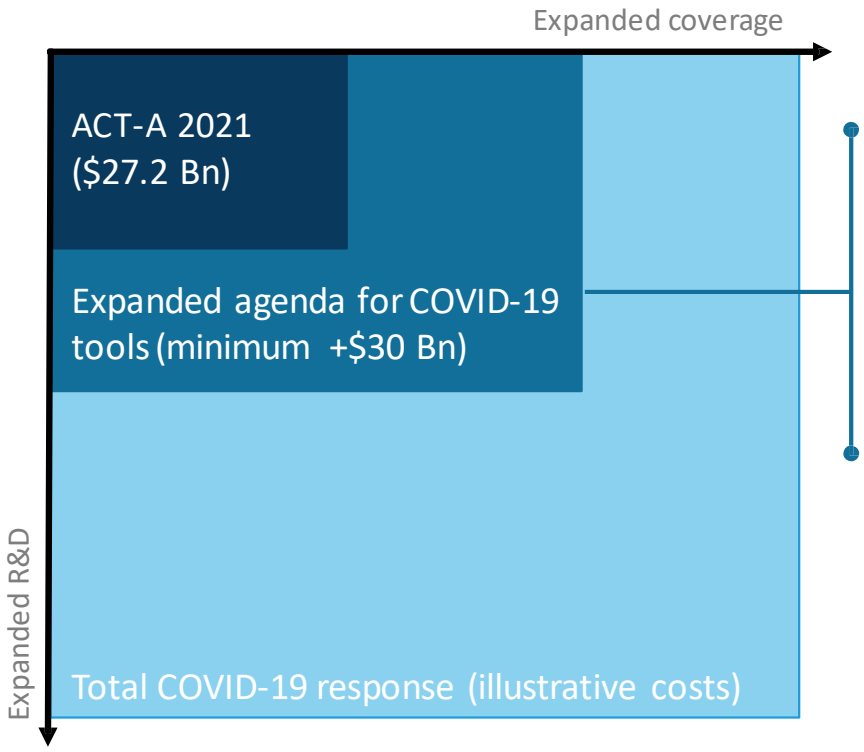
by Pillar
USD$ billions

	Q1/Q2 2021	Q3/Q4 2021	**Total 2021**
Diagnostics	1.8	7.1	**8.9**
Therapeutics	1.0	1.8	**2.7**
Vaccines	7.8	<0.1	**7.8**
Health Systems Connector	3.6	4.3	**7.9**
Total	**14.2**	**13.1**	**27.2**

Strategic Priorities

- Rapidly scale delivery of 2 billion vaccine doses through COVAX
- Bolster R&D, product evaluation & regulatory pathways
- Enhance use of diagnostics, therapeutics& PPE in LICs & LMICs
- Ensure robust supply pipeline of essential diagnostics, therapeutics& PPE for LICs & LMICs

ACT-Accelerator within a broader need for COVID-19 tools



Indicative estimates for an expanded agenda

Expanded R&D to address variants ($4 Bn)

Expanded coverage to enhance control ($26 Bn)[1]

- Vaccine coverage from 20% to 80% in the LICs/LMICs
- Testing in LICs/LMICs raised to 90% of HICs rates
- Treatment coverage raised in proportion to testing

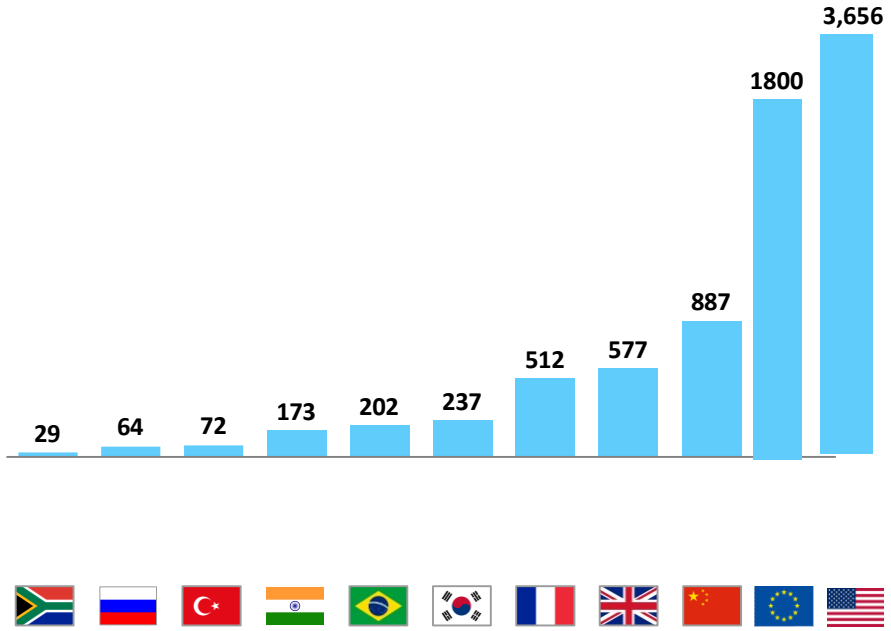
1. procurement estimates only

Case for Investment

We are calling on G20 & leaders around the world to ACT NOW to change the course of the COVID-19 pandemic.

~$13T of stimulus were unlocked by G20 countries to support businesses & economies (as of December 2020)

Size of stimulus package – in $B



For just 10 High Income Countries, investing the US$ 27.2 billion still needed by ACT-Accelerator would produce over US$ 466 billion in economic benefits over 5 years, with a higher return than investing in domestic economy

1. Source: OECD Data

Need for sustainable financing

- The scale, sources and instruments of financing currently available are too limited to support the development of global public goods for epidemic prevention, preparedness and response.
- The primary source of financial support of **Development Assistance is an inadequate model** for financing investment in preparedness
- This inadequacy of funding results in excessive economic and human costs internationally - vastly exceeding the required funding of the global health commons.
- Establish an **independent review to propose actionable reforms** for reliable and sustainable financing of global public goods for pandemic prevention, preparedness and response.
    - o propose solutions that leverage resources from public, private and philanthropic sectors and the international financial institutions.

Global Vaccine: Major Challenges

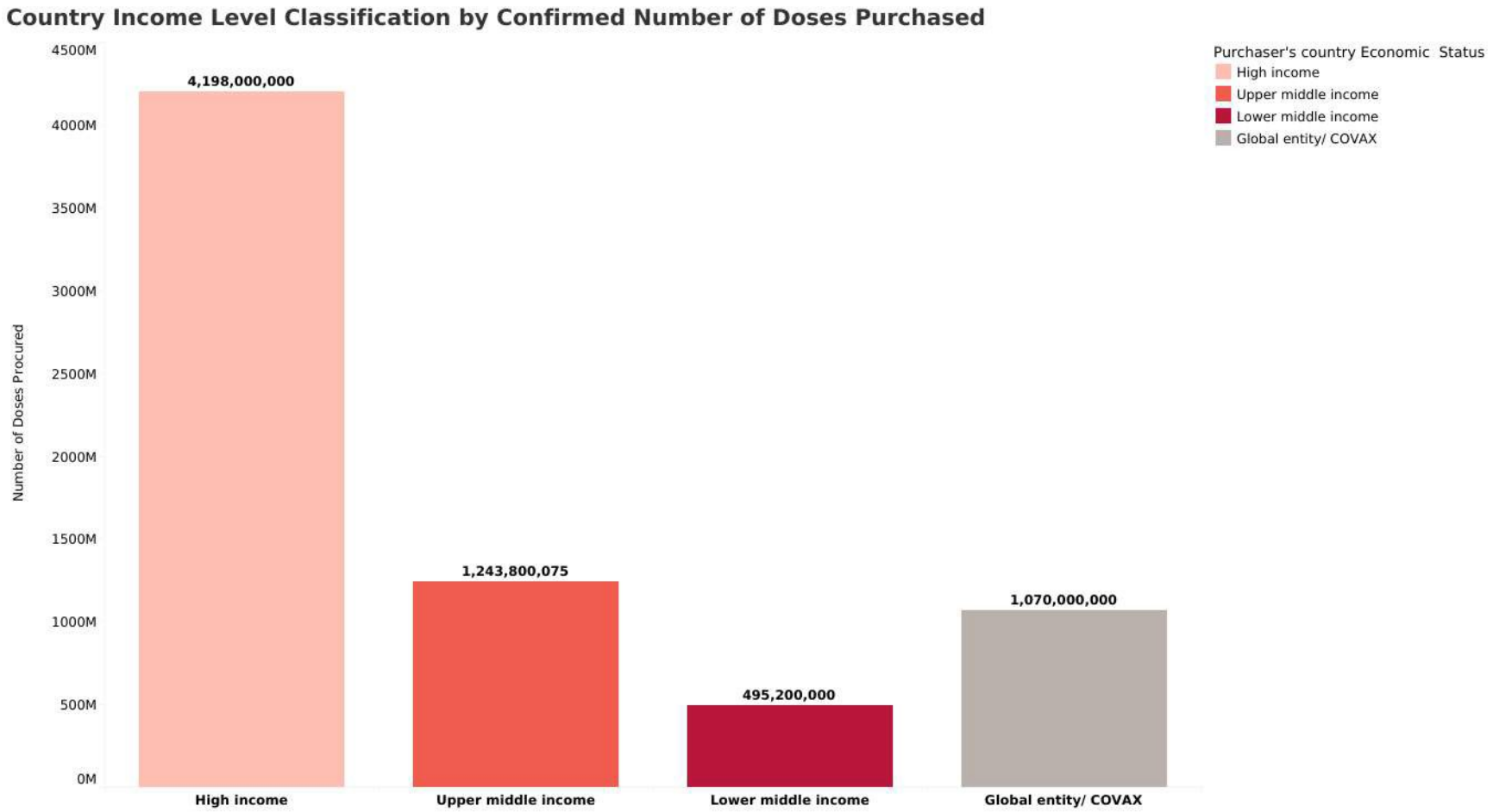
- Step change in financing to scale up for impact
- Need to engage all countries to work together for equitable access: multilateralism
  - Recent surge in vaccine bilateral deals threatens COVAX and has raised concern for vaccine apartheid
- New level of coordination for roll out of vaccines, diagnostics, and therapeutics
- Equitable distribution and ensuring public trust

Vaccine Advance Purchases by Income Category (January 14)

Over 7 billion vaccine doses purchased to date

- Over 4.1 billion doses by high-income countries
- Over 1.2 billion doses by upper middle-income countries
- 500 million doses by lower middle-income countries
- Over 1.0 billion doses by COVAX

Additional 5.5 billion doses under negotiation or optioned



Vaccine nationalism/apartheid

- High income countries (15% world's population) have purchased 60% of all vaccine doses
- 44 bilateral deals were signed in 2020, and at least 12 have already been signed in 2021
- Many high income countries will end up with many more doses than they actually need
  - E.g., Canada has purchased enough doses to vaccinate 600% of population
- EU Astrazeneca Dispute
  - AstraZeneca recently informed the EU it would not be able to supply the number of vaccines the EU had hoped for by the end of March. EU leaders are furious that the company appears to be fulfilling its deliveries for the UK market and not theirs.
- Globally equity
  - January 18, 2021: "More than 39 million doses of vaccine have now been administered in at least 49 higher-income countries. Just 25 doses have been given in one lowest-income country (Guinea)… the world is on the brink of a catastrophic moral failure – and the price of this failure will be paid with lives and livelihoods in the world's poorest countries." (Tedros Adhanom)
- Vaccine nationalism could lead to the unequal allocation of COVID-19 vaccines and cost the global economy up to $1.2 trillion a year in GDP terms (RAND)

Global distribution of COVID Vaccines

- Each country will get their share of vaccine doses, determine allocation (likely according to WHO – not mandatory) and distribution
- Very challenging – distribution
  - “In Gavi eligible countries, our experience shows that there are, in practice, two separate, often not well-connected, supply chains: the segment that *moves vaccines from suppliers to the receiving country*, and the segment that *moves vaccines in country from the port of entry through the national and local storage and distribution system to the health care provider*.” (HEALTH AFFAIRS 30, NO. 6 (2011): 1113–1121)
- Storage
  - Pfizer vaccine must be stored at -70 degrees and Moderna vaccine -20 degrees
- Supply chain
  - “The World Health Organization estimates that more than 50% of vaccines may be wasted globally every year because of temperature control, logistics and shipment-related issues.”
- Workforce (not enough healthcare workers, community workers, etc)

Challenges related to vaccine inventory, supply chain, and logistics: Countries have experienced inventory unpredictability, inadequate cold-chain capacity and insufficient funding

Inventory unpredictability	Inadequate cold-chain capacity	Insufficient Ffunding
• **Ethiopia 20121:** Average of 5 levels of inventory holding points *(1)*. • **Nigeria 2012:** In one month, 30% of states had no syringes, and 20% of states experienced vaccine stock-outs *(2)*. • **2011:** 50% of GAVI-eligible countries reported a vaccine wastage rate in excess of WHO recommendations *(3)*.	• **2011:** 2.8 million vaccine doses lost in five countries due to cold-chain failures *(4)*. • **Nigeria 2011:** 41% of refrigerators were non-functional *(5)*. • **Turkey 2008:** New vaccine introduction increased required storage capacity 20-fold *(6)*.	• **Ethiopia 2011:** Lack of maintenance leading to 30% of cold-chain equipment being non-functional *(7)*. • **Tanzania 2006:** Operating at 25% of required staffing levels *(8)*. • **Ukraine 2012:** Funding only sufficient for 60% of vaccine needs forecast. Reported DTP3[7] coverage in 2011 was 46% *(9)*. • **2013:** Less than 10% of countries meet WHO recommendations for effective vaccine management practices *(10)*.

WHO, 2011

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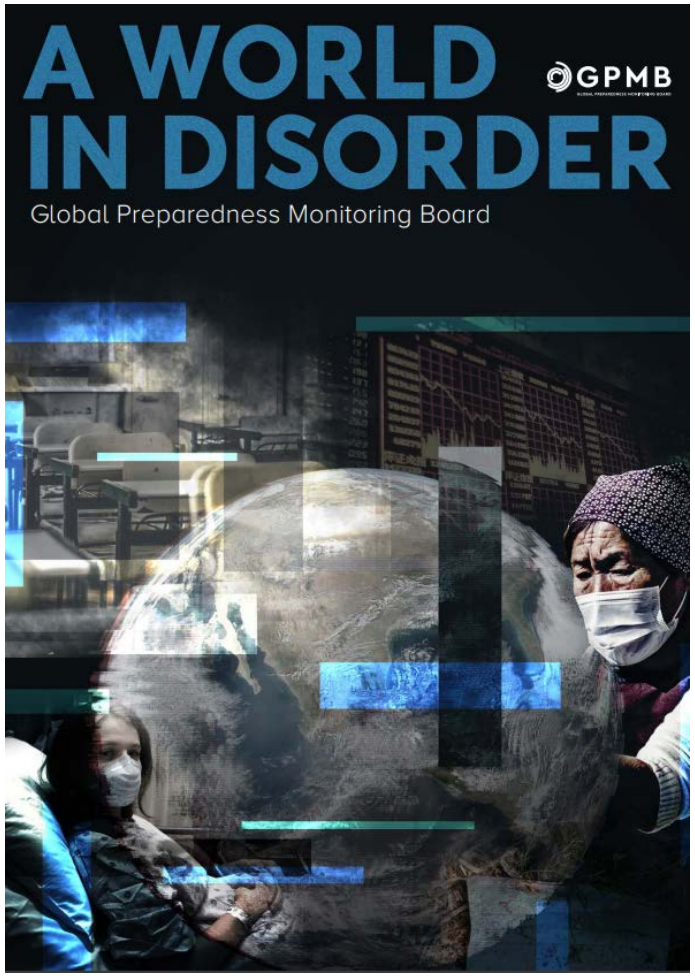

The GPMB calls for urgent actions to strengthen the current response to COVID-19 and better prepare the word for future pandemics and health emergencies; to bring order out of catastrophe and chaos.

1. Responsible leadership
2. Engaged citizenship
3. Strong and agile systems for health security
4. Robust global governance of preparedness
5. Sustained investment

GPMB 2020 Annual Report: Recommendations

1. Responsible leadership & engaged citizenship
2. Robust global governance of preparedness
   - propose amendments of the IHR to the World Health Assembly
   - develop an international framework of governance
3. Strong and agile systems for health security
   - **Heads of government**
     - strengthen national systems for preparedness (all of society approach)
     - strengthen WHO as an impartial international organization responsible for directing and coordinating pandemic preparedness and response
     - renew their commitment to the multilateral system
4. **Research sector, the private sector, governments, the World Health Organization and international organizations**
   - improve coordination and support for research and development in health emergencies
   - establish a sustainable mechanism to ensure rapid development and equitable access to novel vaccines, therapeutics, diagnostics and non-pharmaceutical interventions
5. Sustained investment
   - **G20 leaders, UN, WHO, and International Financing Institutions**
     - recognize preparedness as a global common good, and is not at the mercy of political and economic cycles
     - Nations ensure that adequate finance is made available now to mitigate the current and future economic and socioeconomic consequences of the pandemic.
     - develop a mechanism for sustainable financing of global health security (including vaccines, treatment, and diagnostics), which mobilizes resources in scale and in time, not reliant on development assistance.

Reviews of COVID preparedness and response

- GPMB
- WHO Independent Panel for Pandemic Preparedness and Response (IPPR)
- Lancet COVID-19 Commission
- G20 Health Summit
- G20 Sustainable Global Financing System for Global Common Good for Pandemic Prevention, Preparedness, and Response

National Academies: Next Steps

- Sustainable Global Financing System for Global Common Good for Pandemic Prevention, Preparedness, and Response
- Advancing Pandemic and Seasonal Influenza Vaccine Preparedness and Response
  - Consensus Study Committee on Vaccine Research and Development
  - Consensus Study on Distribution and Supply Chain
  - Consensus Study on Public Health Countermeasures
  - Consensus Study on International Coordination, Partnerships, and Financing
- Early Warning Surveillance Systems for Zoonotic Viruses of Pandemic Potential
- CDC request - vaccine safety monitoring

Lessons learned from COVID-19: Future Needs

- Strategy & coordination in public health interventions (detection, testing, contact tracing, data reporting and analysis), and digital innovations at national & global levels
- Global coordinated end-to-end R&D Preparedness and Response Ecosystem for vaccines, therapeutics and diagnostics
- Multilateralism: Need to engage all countries to work together - Global mechanism for coordination and equitable access
- No global equity without solidarity
- Governance: ensuring all can function coherently and effectively at all levels--local, national, regional and global
- Sustainable financing: long-term, predictable, reliable financing for global common good for pandemic prevention, preparedness and response

Thank You