



## COVID 19

# Public Health Emergency of International Concern (PHEIC)

Global research and innovation forum: towards a research roadmap

# Broad consensus on the need for research to focus on actions that can save lives now.

To ensure that those affected are promptly diagnosed and receive optimal care; while integrating innovation fully within each research thematic area.

To support research priorities in a way that leads to the development of global research platform(s) pre-prepared for the next disease X epidemic; thus, allowing for accelerated research, R&D for diagnostics, therapeutics and vaccines and their timely access.

11-12 February, 2020



### Powering research to control the epidemic

Over the first 6 weeks of the new decade, the novel coronavirus, known as COVID-19, has spread from the People's Republic of China to 20 other countries.

On 30 January 2020 following the recommendations of the Emergency Committee, the WHO Director General declared that the outbreak constitutes a Public Health Emergency of International Concern (PHEIC).

In view of the urgency of this outbreak, the international community is mobilising to find ways to significantly accelerate the development of interventions. The WHO R&D Blueprint is a global strategy and preparedness plan that allows the rapid activation of R&D activities during epidemics. Its aim is to fast-track the availability of effective tests, vaccines and medicines that can be used to save lives and avert large scale crisis.

World experts on COVID-19 met at the World Health Organization's Geneva headquarters from 11 to 12 February 2020 to assess the current level of knowledge about the new virus, agree on critical research questions that need to be answered urgently and ways to work together to accelerate and fund priority research that can contribute to curtail this outbreak and prepare for future outbreaks.

The global imperative for the research community is to maintain a high-level discussion platform which enables consensus on strategic directions, nurtures scientific collaborations and, supports optimal and rapid research to address crucial gaps, without duplication of efforts.

"We need our collective knowledge, insight and experience to answer the questions we don't have answers to, and to identify the questions we may not even realize we need to ask."

Dr Tedros WHO Director General

The meeting organized by the World Health Organization, in collaboration with the GloPID-R (the Global Research Collaboration for Infectious Disease Preparedness) brought together over 300 scientists, researchers, national public health experts from a large variety of disciplines as well as major research funders to discuss a research map for COVID 19.

Research topics discussed included: virus: natural history, transmission and diagnostics; animal and environmental research on the virus origin, and management measures at the human-animal interface, epidemiological studies; clinical characterization and management, infection prevention and control, including health care workers' protection; candidate therapeutics R&D; candidate vaccines R&D; ethical considerations for research and; integrating social sciences in the outbreak response.

Over 2 days of intense discussion, facilitated group work, research priorities were captured and distilled, and research priorities identified. Experts discussed a wide range of aspects of the outbreak and identified immediate concrete actions and priorities across the ten thematic areas.

Experts identified key knowledge gaps, and research priorities and shared scientific data on ongoing research, thereby accelerating the generation of critical scientific information to contribute to the control the COVID 19 emergency.



# An imperative for research to focus on actions that can save lives now.

## **Eight** immediate research actions were agreed as part of this Forum

- 1. Mobilize research on rapid point of care diagnostics for use at the community level this is critical to be able to quickly identify sick people, treat them and better estimate how widely the virus has spread.
- 2. Immediately assess available data to learn what standard of care approaches from China and elsewhere are the most effective there is an imperative to optimise standard of care given to patients at different stages of the disease and take advantages of all available technological innovations to improve survival and recovery.
- **3.** Evaluate as fast as possible the effect of adjunctive and supportive therapies. The global research community need to understand what other adjunctive treatments than currently being used we currently have at our disposal that may help with the standard of care provided to patients, including the quick evaluation of interventions such as steroids and high flow oxygen.
- **4.** Optimise use of protective equipment and other infection prevention and control measures in health care and community settings It is critical to protect health care workers and the community from transmission and create a safe working environment
- **5.** Review all evidence available to identify animal host(s), to prevent continued spill over and to better understand the virus transmissibility in different contexts over time, the severity of disease and who is more susceptible to infection- Understanding transmission dynamics would help us appreciate the full spectrum of the disease, in terms of at risk groups, and conditions that make the disease more severe as well as the effectiveness of certain public health interventions.
- **6.** Accelerate the evaluation of investigational therapeutics and vaccines by using "Master **Protocols**"- Rapidly developing master protocols for clinical trials will accelerate the potential to assess what works and what does not, improve collaboration and comparison across different studies, streamline ethics review and optimise the evaluation of new investigational drugs, vaccines and diagnostics.
- 7. Maintain a high degree of communication and interaction among funders so that critical research is implemented Funders reiterated their current financial commitments to tackling this outbreak and agreed that the priorities agreed at the Forum would help to coordinate existing investments and inform mobilisation of additional resources in the coming days, weeks and months.
- 8. Broadly and rapidly share virus materials, clinical samples and data for immediate public health purposes—It was agreed that virus materials, clinical samples and associated data should be rapidly shared for immediate public health purposes and that fair and equitable access to any medical products or innovations that are developed using the materials must be part of such sharing.



# A research roadmap with clearly defined priorities and governance framework to accelerate research that can contribute to contain the spread of the epidemic "WHO remains committed to equitable

"WHO remains committed to equitable access to health products for populations that need them and will work to ensure that access is always part of all R&D efforts."

Dr Tedros Director General, WHO

A To ensure that those affected are promptly diagnosed and receive optimal care; while integrating innovation fully within each research thematic area,

To support research priorities in a way that leads to the development of global research platform(s) pre-prepared for the next disease X epidemic (an unexpected epidemic by a known or previously unknown pathogen); thus, allowing for accelerated research, R&D for diagnostics, therapeutics and vaccines and their timely access.

## **OBJECTIVES**

- 1. Enable acceleration of research through global collaboration with solidarity and equity as principles.
- 2. Ensure transparent and effective evidencebased prioritization of research questions (as above) within and between the thematic areas.
- 3. Ensure that access to medical products is built into R&D pathways from the beginning of development.
- 4. Ensure resources are available for areas most likely to yield practical outcomes.
- 5. Maintain repositories of landscape analyses, prioritization, protocols, tools, SOP and information, and support enabling ethics and regulatory activities.
- 6. Ensure communication to media is accurate and coordinated to maintain trust in research activities.

#### The need for a cross-cutting approach

- Equitable access embedded from the start, so that the people at risk have timely access.
- Appropriate ethical oversight and collaboration to fast track review process.
- Combat stigmatisation of those affected, or perceived to be affected, by the disease.
- Critical social science to ensure communities engage and understand the value of proposed interventions.
- International solidarity is important, and we need to come together as one to tackle this global challenge.
- Build even closer partnerships with Chinese scientists and experts from countries with cases who are on the front line of tackling this outbreak.



# Targeted research priorities in each research thematic areas were identified

Beyond the immediate research actions, the Forum participants identified a comprehensive set of priority research areas and recognised the significant cross-over and co-dependencies between the different research areas.

WHO will play an important role in the coordination and development of governance frameworks.

"This meeting allowed us to identify the main urgent priorities for research. As a group of funders, we will continue to mobilize and coordinate to ensure support is in place for all critical research needed to tackle this crisis and stop the outbreak in partnership with WHO."

Yazdan Yazdanpanah Chair GLOPID-R

#### 1. Virus: natural history, transmission and diagnostics

- Understand the natural history of the virus and shedding of it from an infected person
- Support implementation of diagnostics and products to improve clinical processes
- Develop disease models, including animal models for infection, disease and transmission
- Develop tools and studies to monitor phenotypic change and potential adaptation of the virus
- Better understand the immune response and immunity

## 2. Animal and environmental research on the virus origin, and management measures at the human-animal interface

- Identify animal host(s) and any evidence of continued spill-over to humans
- Understand the socioeconomic and behavioural risk factors for this spill-over
- Design and test sustainable risk reduction strategies

#### 3. Epidemiological studies

- Understand the transmission dynamics of the virus, including the basic reproductive number, incubation period, serial interval, modes of transmission and environmental factors
- Define the severity of disease, including risk of fatality among symptomatic hospitalized patients, and high-risk patient groups
- Understand susceptibility of populations
- Identify what public health mitigation measures could be effective for control

#### 4. Clinical characterisation and management

- Define the natural history of disease to inform clinical care, public health interventions, infection prevention control, transmission, and clinical trials
- Develop a core clinical outcome set to maximize usability of data across a range of trials
- Determine adjunctive and supportive interventions that can improve the clinical outcomes of infected patients (e.g. steroids, high flow oxygen)



#### 5. Infection prevention and control, including health care workers' protection

- Understand effectiveness of movement control strategies to prevent secondary transmission in health care and community settings
- Optimise the effectiveness of personal protective equipment (PPE) and its usefulness to reduce risk of transmission in health care and community settings
- Minimise the role of the environment in transmission

#### 6. Candidate therapeutics R&D

- Develop animal models and standardise challenge studies
- Develop prophylaxis clinical studies and prioritise in healthcare workers
  Ensure adequate supply of investigational? therapeutics showing efficacy (address? cost/affordability, equitable access, production capacity and technology transfer

#### 7. Candidate vaccines R&D

- Optimize clinical trial design, including for Phase III/ prioritized candidates for testing
- Understand approaches to evaluate risk for enhanced disease after vaccination
- Develop assays to evaluate vaccine immune response and process development for vaccines, alongside suitable animal models [in conjunction with therapeutics]

#### 8. Ethical considerations for research

- Articulate and translate existing ethical principles and standards to salient issues in COVID-2019
- Embed ethics across all thematic areas, engage with novel ethical issues that arise and coordinate to minimise duplication of oversight
- Support sustained education, access, and capacity building in the area of ethics

#### 9. Social sciences in the outbreak response

- Establish a team at WHO that will be integrated within multidisciplinary research and operational platforms and that will connect with existing and expanded global networks of social sciences.
- Develop qualitative assessment frameworks to systematically collect information related to local barriers and enablers for the uptake and adherence to public health measures for prevention and control. This includes the rapid identification of the secondary impacts of these measures. (e.g. use of surgical masks, modification of health seeking behaviours for SRH, school closures)
- Identify how the burden of responding to the outbreak and implementing public health measures affects the physical and psychological health of those providing care for Covid-19 patients and identify the immediate needs that must be addressed.
- Identify the underlying drivers of fear, anxiety and stigma that fuel misinformation and rumour, particularly through social media.
- Contextually contribute to the design of research to ensure the involvement of communities throughout the process (in design, implementation and evaluation).



#### What is next?

In addition to the research actions ongoing, the Forum participants committed to a comprehensive collaborative research agenda. The implementation of this collaborative research agenda started immediately.

We now have a clear roadmap with immediate and mid and longer-term priorities to build a robust global research response. Importantly there is a decisive pledge to collaboration, solidarity and to equitable access to all innovations developed.

The full report of the Forum will provide a detailed account of the deliberations and the multidisciplinary approach taken for the co-creation of the global research map.

What?	When?
Summary of conclusions	February 14, 2020
Full report of this Forum	February 21, 2020
Research roadmap including detailed milestones and timelines	February 28, 2020

The detailed roadmap which will set out the path for the critical research and the development that the new interventions the world needs to end this epidemic.

**END**