Building Resilience Against Outbreaks & Pandemics

Research to identify sustainable solutions

The 3rd Global Research and Innovation Forum
Critical research to ensure equitable and fast access to high-quality and affordable vaccines while ensuring people’s trust

Update and priorities

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Maximizing our research efforts to inform strategic actions is critical to control outbreaks and prevent future pandemics.

“A systematic approach that studies prototype pathogens from viral families with known pandemic potential to develop MCMs against emerging or reemerging viruses”.

Innovative approaches and emerging technologies can help selecting among available vaccine and therapeutics candidates for prototype pathogens.
Principles for pandemic vaccines

- Quality
- Equity
- Speed
- Cost
- Trust
Pivotal research and innovation to improve global protection against deadly pathogens that can cause outbreaks

Country-centered

Transparent

Objective

Collaborative

Preparation and research integrated into outbreak response
Integrating elements of the response

**Speed**
- Pre-outbreak trial design
- Pre-approved CORE protocols
- MOH designated researchers
  - Support of local research capacity
  - Collaborative scientific networks
  - Decisions supported by data from open collaborative scientific networks

**Cost**
- A virtual process to ensure candidate vaccines & therapeutics are available

**Quality**
- MOH designated researchers

**Trust**
- Legal and insurance framework
- Landscapes
- TPPs
- Independent process for prioritization

**Equity**
- MOH designated researchers
  - Support of local research capacity
  - Collaborative scientific networks
  - Decisions supported by data from open collaborative scientific networks
Prioritizing the world’s greatest pathogen threats

There are over 1,400 species of human pathogens in the world. These include viruses, bacteria and fungi.

Most of the time they are harmless but some can be very dangerous.

This is why the World Health Organization (WHO) R&D Blueprint produces a list of the priority pathogens that have the greatest potential to cause a global public health emergency. The list is updated periodically to take into account new evidence and circumstances.

### How are the most dangerous pathogens shortlisted?

#### 300

Global experts are involved in the shortlisting process and they review:

#### 25

Viral families that pose the greatest threat

#### 1

Key group of bacteria that pose the greatest threat

### Disease X

Disease X is a pathogen/disease the world has not encountered yet but which has very high potential to cause outbreaks/pandemics.

### Key criteria for prioritizing the pathogens

- How transmissible are they?
- How virulent are they?
- What is the state of our current defences against them (with medical countermeasures)?

The final WHO global list of priority pathogens

The pathogens on the final priority list have the most potential to cause outbreaks and pandemics, and are those for which the world has no, or limited, countermeasures against them.

The list has become the cornerstone of prioritizing the global R&D response to prevent and combat outbreaks and pandemics.
Target product profiles for viral family vaccines

Special features

Development of the vaccine should (at least) provide information that will enable higher quality/more rapid/less expensive/more equitable/more trustworthy vaccines against related pathogens to be developed for pandemic use

➢ Safety: could platform safety be extrapolated to related pathogens?
➢ Efficacy against severe disease is a minimum requirement
➢ Breadth of protection, to cover more pathogens in a given family
➢ Where breadth of protection isn’t feasible, mechanism of protection/correlates of protection may facilitate development of vaccines against related pathogens
➢ Readily manufacturable at reasonable cost
# Preparing for the inevitable

## Global and regional level

### Inter-epidemic period
- Landscape of candidate products in the pipeline and their status regarding development and evaluation
- TPPs outlining the public health perspective
- Pre-outbreak trial design consideration
- Independent process for prioritization of vaccine and therapeutic candidates

A virtual process to assure that candidate vaccines and therapeutics are funded and available for rapid international delivery in vials so deployment for use in studies that will collect needed data

An open convening of collaborative scientific networks to rapidly conduct/support research during outbreaks

Research and innovation priorities for other areas will also be identified

Creation/maintenance of legal and insurance framework

### Integrated in outbreak response
- Updated list of prioritized vaccine and therapeutics candidates for inclusion in the specific outbreak.

Activation of the process so that prioritized candidate vaccines and therapeutics are promptly deployed.

Prompt convening of the relevant collaborative scientific networks to update on the situation and mobilize research during the specific outbreak

Support mobilized for previously identified research and innovation priorities

Legal and insurance frameworks needed to conduct studies of investigational vaccines and therapeutics activated

Studies start within 7-14 days of the declaration of the outbreak
### Preparing for the inevitable

#### Inter-epidemic period

| A collaborative research framework driven by countries |
| MOH-designated researchers and research institutions |
| Clarity regarding national regulatory pathways |
| Pre-approved CORE protocols |
| Support of National Research Capacity |

#### Integrated in outbreak response

| MOH-designated researchers activated and engaged with relevant international scientific networks |
| Final approval of CORE protocols based on inclusion of product information |
| Support for implementation protocols mobilized to fill any remaining gaps |

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**Studies start within 7-14 days of the declaration of the outbreak**
Status Filoviruses

1. TWO vaccines licensed for EVD caused by Zaire strain

2. PROTOCOLS

CORE Protocol for vaccines evaluation (Phase 1, 2 and 3)
- Conditional approval from WHO ERC

CORE protocol for therapeutics
- Conditional approval from WHO ERC

3. PRIORITIZATION

- Process and expert independent committee established for vaccines and therapeutics
- List of priorities for both Sudan and Marburg candidate vaccines

3. CANDIDATE VACCINE DOSES

- Sudan
- Marburg

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Correlates of protection: filovirus example

- We know that VSV-ZEBOV is effective against Zaire EBOV
- While sequences diverge, filoviruses share common pathogenesis, genomic structure, other features
- What do we need to know about other filoviruses (e.g., Sudan, Marburg) for it to be “reasonably likely” that a different VSV vectored vaccine that induced similar immune responses would be effective against other filoviruses?
- Definition of “reasonably likely” may be different for different people

This type of question will need to be answered for multiple virus families
Prototype vaccines may help to answer these questions and speed availability of vaccines in a pandemic
## Acceleration of research to enable availability of countermeasures
### Status as of August 2023

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A coordinated global approach is critical
How can we collaborate for improved outcomes?

WHO global forums facilitate discussion and prioritization of research needs, and sharing of best methods and results

- Network of networks
- Transparency (including availability of recordings and summaries)
- Accepting of input from all stakeholders in a way to assure that conflicts of interest do not influence outcomes

WHO R&D Blueprint has been doing this for priority pathogens since 2015

- Hundreds of research consultations
- Guidance, protocols, tools available . . . .

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