Preparing for the next pandemic threat

Advancing viral & bacterial families approach

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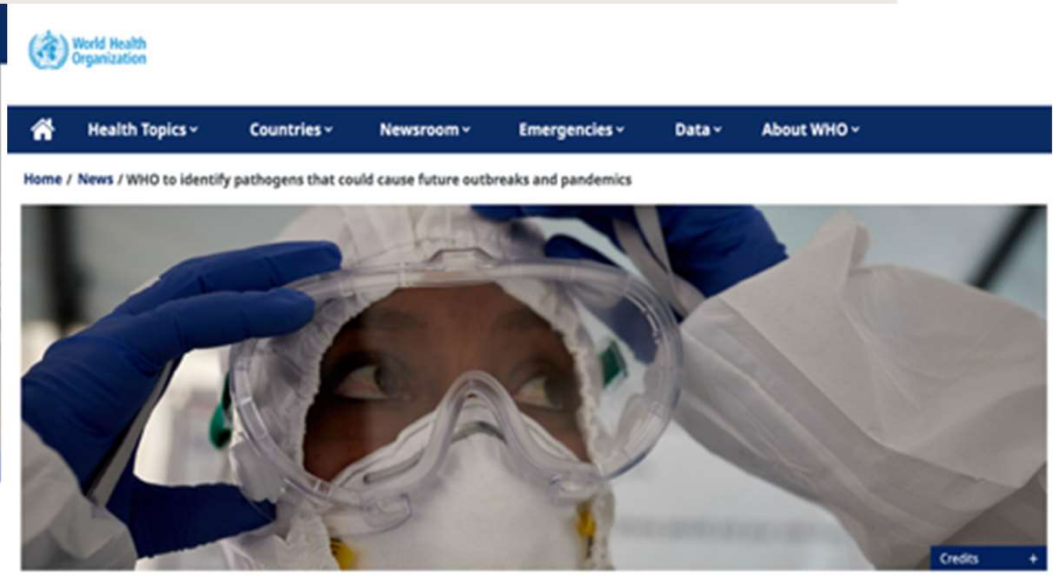
R&DBlueprint
Powering research to prevent epidemics

New strategic components steering future global research agenda

Countries begin negotiations on global agreement to protect world from future pandemic emergencies

3 March 2023 | News release | Geneva |Reading time: 2 min (464 words)

Media Contacts



WHO to identify pathogens that could cause future outbreaks and pandemics

21 November 2022 | News release | Geneva |Reading time: 1 min (388 words)

Media Contacts

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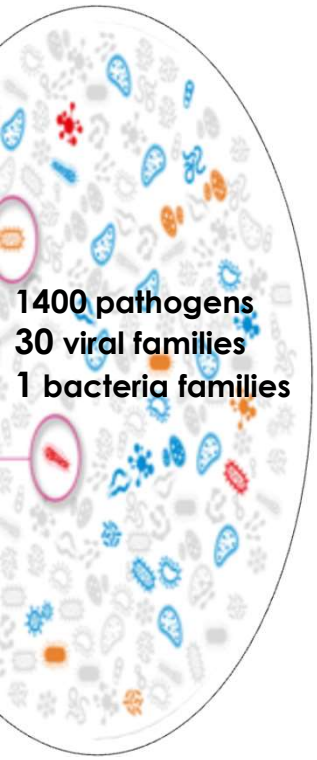
Coordinating and accelerating global research must promote universal values

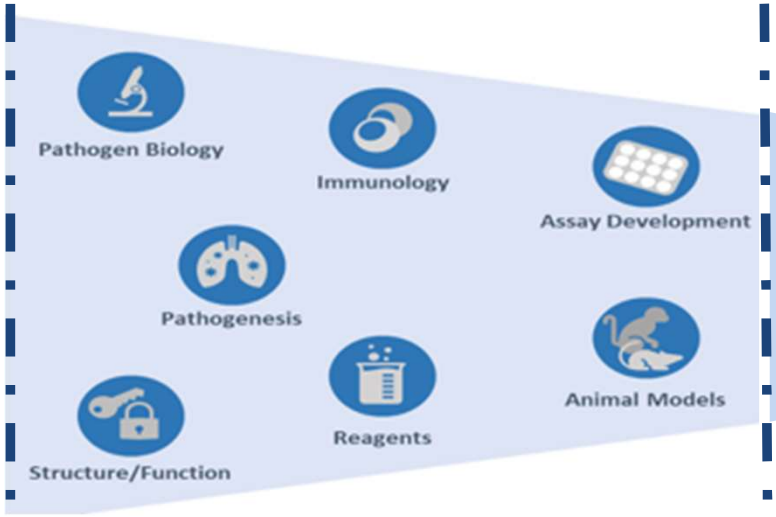
Regarding a collaborative effort to ensure access to MCMs during pandemics, some have emphasized the importance of **speed** and sometimes **cost** in responding to future pandemics.

It is equally important to take a broader view that recognizes the primary importance of **quality**, **equity** in access, and **trust** in the products safety and efficacy.

Research and Innovation for Epidemics

NOW… Viral and Bacterial Family approach





Trials integrated into the outbreak response

MCMs – prototype vaccines & therapeutics/Family

- R&D Roadmaps
- TPPs
- Landscape of MCMs
- CORE protocols /family trial design

Broader **Research and Innovation**

Collaborative **networks**

Trials to reduce **UNCERTAINTY** for important public health questions

Seamless trial design

Simple trial
Randomization during deployment

Priority Families
Prototype pathogens

ALL Families regardless of perceived pandemic potential

Phase 1- 2

Phase 3

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A scientific approach to pandemic preparedness

Scientific opportunities to achieve fast and equitable access to high-quality and trusted vaccines for future pandemics.

Scientific research priorities for all viral and bacterial families, regardless of perceived pandemic potential

- Defining the scope of **emerging virus treats** through the discovery
- Expanding generalizable **basic research** that would support the development of vaccines and therapeutics for future threats
- **Translational research** and product development with an eye on the potential for **generalizability**
- **Large, simple randomized trials** CORE protocols per family

Additional scientific research priorities for viral and bacterial families with pandemic potential

- Monitoring transmission of **pathogens known to cause outbreaks**
- Translational research and **product developmen**t with an eye on potential for **generalizability**
- **Continue R&D projects** for identified pathogens with **generalizability** in mind
- Large, **simple** randomized **trials integrated into the outbreak response**

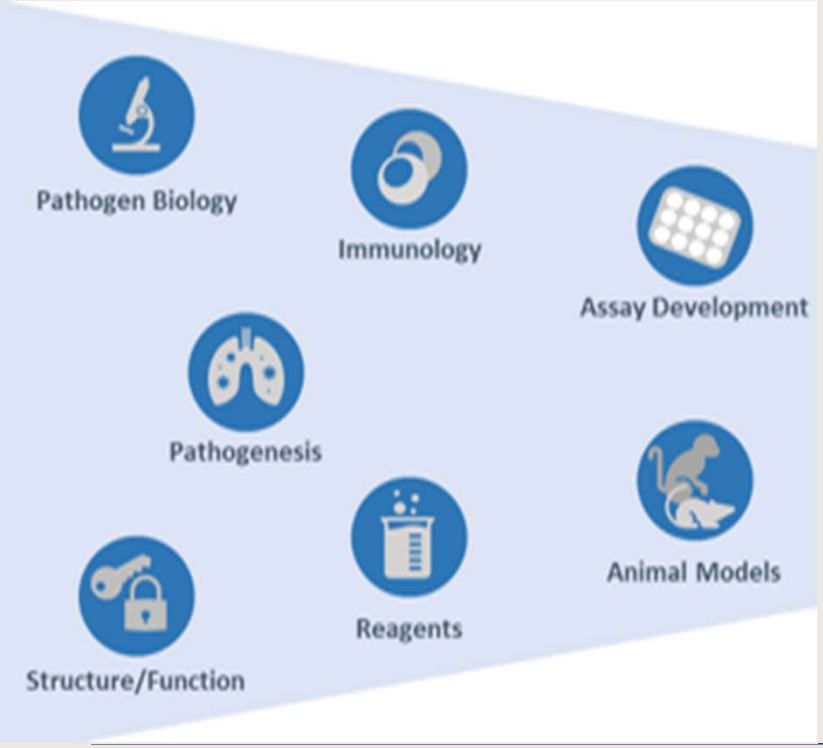
Additional scientific research priorities for an unknown pathogen (disease x) causing a pandemic

- Contemporary viral isolates that have been well characterized.
- Identifying antigens: scientific challenges
- Collaborative basic research to study viral structures for MCM development
- Evaluation of candidate MCMs using simple trials OR randomization during deployment, integrated into the outbreak response

GLOBAL COLLABORATION TO RESPOND TO AN UNKNOWN PATHOGEN (DISEASE X) CAUSING A PANDEMIC

In 2024…

Each viral and bacterial families regardless of pandemic potential



Succinct LIVE R&D Roadmaps

(knowledge gaps and critical research, with generalizability in mind)

To study selected prototypes within a given family and to apply knowledge and strategies to inform the design of MCMs for related viruses/bacteria within that family.

In addition, Research and Innovation priorities for other areas of research will be identified.

In 2024...

Target Product Profiles/Viral Family - Vaccines example

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 the development of vaccines against related pathogens
- **Other attributes:** Longer lasting vaccines; vaccines that are easier to administer and reduce the spread of the virus; innovative solutions for faster, cheaper, rapidly deployable technologies
- **Readily manufacturable** at a reasonable cost

In 2024…

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

In 2024…

Study design options to reduce UNCERTAINTY during an epidemic

For candidate products that may have evidence on **safety** and may likely be **effective** against **outcomes important for public health**, but for which there is **remaining uncertainty**

Studies of biomarkers

Animal Rule

Immunobridging

Comparisons using immunomarkers

Randomized clinical trials

Placebo controlled trials

Simple large randomized trials

Open-label randomized trials

Randomization during deployment

Observational studies

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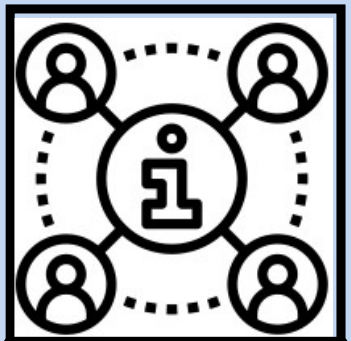
Collaborate



Facilitate access

Expand capacity

- Global **Consortia** to promote international collaboration
- **Hubs. Collaboration** To seek views from ALL and not just a few

- **Landscapes** of candidate MCMs
- **Criteria** - for key research projects, for evaluation….
- Facilitate **access** (protocols, antigens, reagents, data…)

- **Updates live** and regularly
- Specific consultations to **address emerging questions**

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An approach to fast-track assessment of candidate MCMs

and support pandemic prevention and control

1 Prioritization

WHO Independent expert process to prioritize candidate vaccines

A WHO process for prioritization of candidate vaccines by an independent WHO Technical Advisory Groups on candidate vaccine and treatments prioritization

2 Availability

Agreement on availability and access to candidate vaccines and therapeutics

Decisions are informed by outcomes of the prioritization process on minimum number of candidate product doses required for research during outbreaks and that need to be available.

3 Clinical trials

CORE protocols and platforms to promptly initiate trials with equitable access to research

Ministries and researchers in affected countries are in the driving seat and integrated into the response. CORE protocols for viral and bacterial families design and approved in advance

4 Agreements

Prior agreement on legal collaboration, insurance, indemnity and liability

A partnership model and signed agreements with Ministries of Health and developers with **access** to MCMs considered, and a framework for insurance and liability arrangements.

5 Funding

Access to readily available funding through committed financing mechanism

Signed agreements with contributors; aimed at a simple approval process for releasing of funds and simplifying financial reporting.

6 Collaborative approach

To foster an open flexible collaborative mechanism that allows a variety of contributors

Including pathogen and trial experts, local researchers, and outbreak response teams to help adjust and implement research as needed

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In summary, be prepared for future epidemics & pandemics

- **Continue to foster collaboration** for evaluating candidate vaccines and therapeutics within epidemic responses, led by Ministries of Health and national research teams.
- **Continue to involve national researchers and authorities to contribute to design of CORE protocols** for each vral and bacterial family towards final consensus on key trial design attributes.
- **Expand to develop viral and bacterial families' roadmaps via collaborative global networks** of designated researchers in "at risk" countries via engagement in a framework for clinical research preparedness to ensure clinical research is promptly integrated into future epidemic responses.

The current challenges of Research and Innovation are a problem that can be solved.

Let's solve it <u>together!</u>