World Health Organization

Strategies to promote collaboration and universal values
in development and evaluation of medical countermeasures

Philip Krause, MD
Advisor to WHO

R&DBlueprint
Powering research to prevent epidemics

Values for countermeasure development

Regarding access to candidate vaccines and therapeutics, 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 availability, and **trust** in the products safety and efficacy.

Values for countermeasure development

Speed **Cost** **Quality** **Equity** **Trust**

There are inevitable trade-offs in attempting to address these values

Overly focusing on some of them may sacrifice success with the others

Differences in opinion about what to do can often be traced to differences in values

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

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

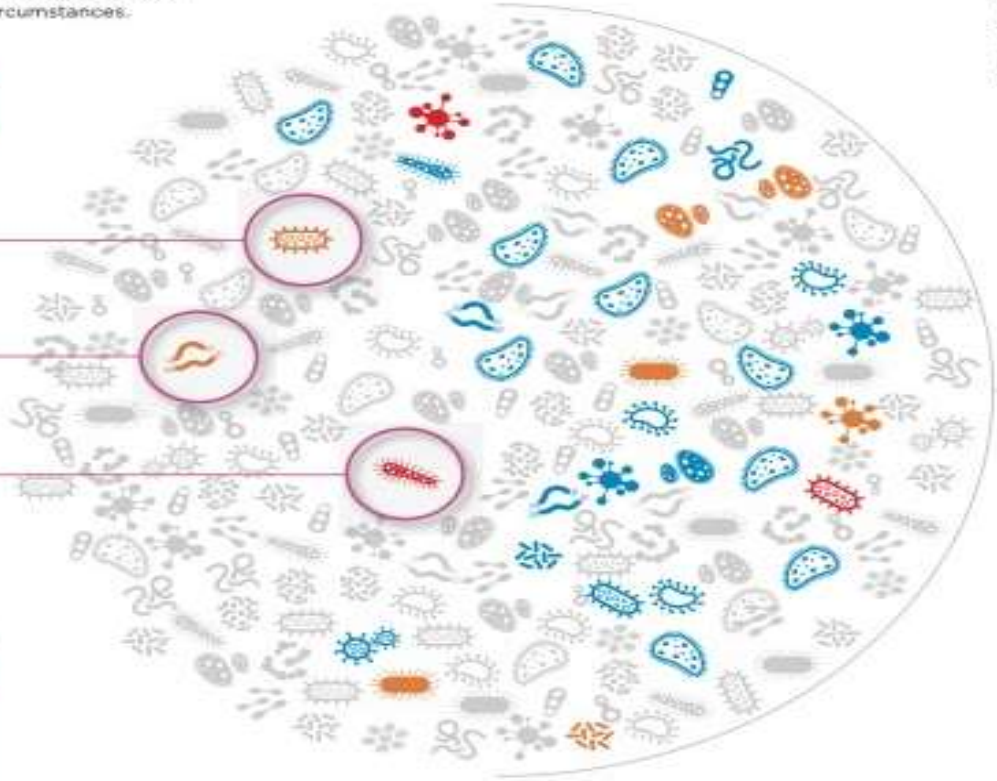
Disease X **Disease X** a pathogen/disease the world has not encountered yet but which has very high potential to cause outbreaks/pandemics

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.

Pathogens not being reviewed since evidence shows they have no potential to cause outbreaks/pandemics

Pathogens that, after expert review, are seen to have less potential to cause outbreaks/pandemics, and where we have adequate medical defences

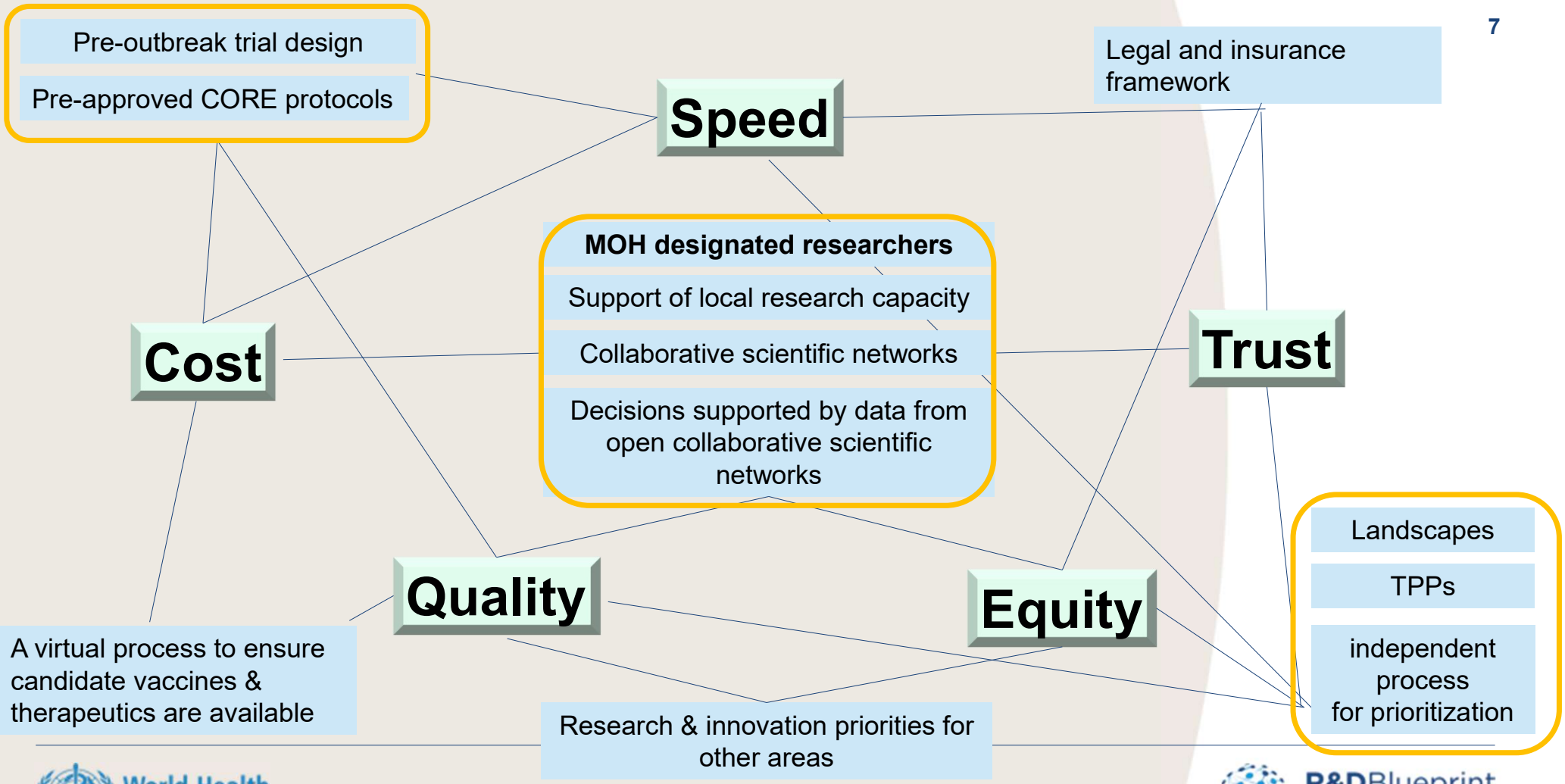
Pathogens that, after expert review, are seen to have high potential to cause outbreaks/pandemics, and where we have very limited or failing medical defences

Pathogens that, after expert review, are seen to have very high potential to cause outbreaks/pandemics, and where we have NO medical defences

Outbreak/future pandemic planning for key pathogens

For key viral and bacterial families identified as future outbreak/pandemic risks, WHO has convened and will convene expert consultations to **Develop Research and Development Roadmaps for vaccines, therapeutics, and diagnostics for each viral/bacterial family.**

In addition, research and innovation priorities for other areas will be outlined.



World Health Organization

R&DBlueprint
Powering research to prevent epidemics

Preparing for the inevitable

Global and regional level

Inter-epidemic period	Integrated in outbreak response
Landscape of candidate products in the pipeline and their status regarding development and evaluation	Updated list of prioritized vaccine and therapeutics candidates for inclusion in the specific outbreak.
TPPs outlining the public health perspective	
Pre-outbreak trial design consideration	
Independent process for prioritization of vaccine and therapeutic candidates	Activation of the process so that prioritized candidate vaccines and therapeutics are promptly deployed. Such studies are initiated within 2 weeks of the declaration of an outbreak
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	Prompt convening of the relevant collaborative scientific networks to update on the situation and mobilize support research during the specific outbreak
Research and innovation priorities for other areas will also be identified	Support for research and innovation priorities previously identified mobilized
Creation/maintenance of legal and insurance frameworks	Activation of legal and insurance frameworks needed to conduct studies of investigational vaccines and therapeutics

Studies start within 7-14 days of the declaration of the outbreak

Preparing for the inevitable

Sub-regional and country level

Inter-epidemic period	Integrated in outbreak response
A collaborative research framework driven by countries	MOH-designated researchers activated and engaged with relevant international scientific networks
MOH designated researchers and research institutions	
Clarity regarding national regulatory pathways	Final approval of CORE obtained- product information
Pre-approved CORE protocols	Support for implementation protocols mobilized to fill any remaining gaps
Support of national research capacity	

Studies start within 7-14 days of the declaration of the outbreak

World Health Organization

R&DBlueprint
Powering research to prevent epidemics

Filoviruses family response

Based on previous experience, WHO and the Ministries of Health of the affected countries have been developing and implementing **plans to speed the deployment of candidate vaccines and therapeutics for clinical studies in the context of future outbreaks.**

Although in the most recent outbreak of Sudan virus in Uganda, novel candidate vaccines were available for initiation of efficacy studies in record time (within 79 days), the goal is to make candidate vaccines and therapeutics available for clinical evaluation **within days 7-15 of outbreak identification in a subsequent outbreak.**

- For ZEBOV since 2016, ring vaccination started between 4-13 days after the outbreak was reported to WHO and data from over 320,000 vaccinees was collected

Acceleration of research to enable availability of countermeasures

Pathogen	R&D Roadmap	Vaccines					Therapeutics					Diagnostics					Research priorities for other areas of research and innovation.
		Landscape Candidate Vaccines	TPP Vaccines	Trial design Vaccines	Simple protocol available	Regulatory pathway consultations	Landscape Candidate Therapeutics	TPP Therapeutics	Trial design Therapeutics	Simple protocol available	Regulatory pathway consultations	Landscape Candidate Diagnostics	TPP Diagnostics	Trial design Diagnostics	Simple protocol available	Regulatory consultations	
COVID-19	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
MERS-CoV	✓	✓	✓	✓		✓	✓		✓			✓	✓				✓
Zika	✓	✓	✓	✓	✓	✓	✓	✓				✓	✓	✓		✓	✓
Nipah	✓	✓	✓	✓					✓	✓							✓
Lassa fever	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓		✓	✓
Ebola ZEBOV	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓
Ebola SUDV	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓
Marburg	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓
Crimean–Congo hemorrhagic fever	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓			✓	✓
Rift Valley fever	✓	✓	✓	✓		✓	✓		✓		✓	✓	✓				✓
Chikungunya	✓	✓	✓	✓			✓		✓								✓
Plague	✓	✓	✓	✓		✓	✓		✓		✓					✓	
Monkeypox	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓
Pathogen X	✓			✓					✓								

World Health Organization

R&DBlueprint
Powering research to prevent epidemics

CONCLUSIONS

In addition to considering speed and cost, preparation for the next pandemic must consider QUALITY, EQUITY, and TRUST as essential values

Preparations and implementation of pandemic response thus should be country-centered, transparent, and collaborative

Target product profiles will need to consider outputs of the virus/pathogen family prioritization process, with an eye towards generalizability

WHO will play an essential role in assuring a high quality, equitable, and trusted global response