Summary of the Jan 9 consultation-
A Scientific Framework for Epidemic & Pandemic Preparedness

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Objectives of January 9 Meeting

A scientific framework for epidemic and pandemic research preparedness

• To discuss the scientific opportunities and challenges for all viral and bacterial families, regardless of perceived pandemic potential
  • Define the scope of emerging virus threats through discovery
  • Discuss generalizable basic research that supports the development of vaccines for future threats
• To outline cross-cutting scientific actions that are needed, globally and at the country-level, to address development challenges including global collaboration to coordinate basic and translational research as part of pandemic preparedness
Emerging infections are a large but finite problem
- 150 viruses from 26 families recognized as human pathogens with potential for person-to-person spread
- Pandemic Preparedness research requires generalizable solutions for the viral families that pose risk
- Research activities that are fundamental to PP
  - Bio-surveillance and viral discovery
  - Fundamental research (pathogenesis, immunology, antigen design, delivery, reagents and assays)
  - Research and Development of vaccines, therapeutics and diagnostics
  - Mechanisms to produce and deploy rapidly interventions on global scale
- Science and technology can help solve many problems BUT we need consensus on global coordination, communication, and governance
- Equitable distribution of discoveries and manufacturing is critical to address local problems before they become global
Process for prioritizing the world’s greatest pathogen threats- Marie-Paule Kieny

**Phase 1: Scientific Prioritization**
- **Process:** 30 independent viral family and 1 bacterial Working Groups
  200+ international experts
- **Output:** Not shortlisted and shortlisted viral and bacterial families
  (incl. prototype pathogen(s))

Dec 2022 – early 2024

**Phase 2: Public Health Prioritization**
- **Process:** Prioritization Advisory Committee (PAC)
  40 – 50 experts (including Chairs of WGs)
- **Output:** Final shortlist of viral and bacterial families with pandemic potential
  (incl. prototype pathogen(s))

Early 2024
Strategies to promote collaboration and universal values—Phil Krause

- 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.
Methods for Virus Detection and Discovery- Ian Lipkin

• **Capture sequencing**
  • Rapid, sensitive, inexpensive, straightforward platform for discovery, surveillance, and differential diagnosis
  • Sample Receipt to Pathogen Identification in less than 8 hours
  • Several new pathogens identified

• **Agnostic serological assays**
  • To detect footprint of past infections in the immune system, elucidate causes of outbreaks (e.g. AFM and ED 68) and provide early evidence of cross species transmission
  • Microarrays and Multiplex Phage Display

• **GAPP, the Global Alliance for Preventing Pandemics**
  • international collaborative public health research center to establishes sustainable infrastructure for infectious disease discovery, surveillance, diagnostics, and response
Environmental sampling

Advantages:
- Cost effective, Rapid
- Convenient, Flexible
- Wider net at high-risk interfaces
- Biosafety, biosecurity
- Animal welfare

Disadvantages:
- Sensitivity
- Sample types
- No individual level (meta/epi)data
- Bioinformatics
- PCR inhibition, sample degradation
- SOP
Understanding cell tropism and receptor requirements
Vincent Munster

- Wealth of genetic data, but limited full genome data
- Limited connection between surveillance / discovery and mechanistic work
- Mechanistic work currently limited by absence of generizable high throughput tools
New Technologies to Define the Atomic-level Details of Surface Proteins Likely to be Vaccine Targets - Jason McLellan

- New advances in cryo-EM have enabled higher resolution and higher throughput than ever before
- High-throughput synthetic biology accelerates antigen engineering by enabling rapid design-build-validate cycles for many new protein designs
- AI/ML combined with high-throughput screening is allowing accelerated development of vaccine antigens for important human pathogens
Rapid development of monoclonal antibody and protein reagents to guide and facilitate vaccine development- Emanuele Andreano

COVID mAbs were the first molecules to be discovered and approved for emergency use authorization (94 days from discovery to first human dose)

Developing humanized models with an eye on potential for generalizability—
Simon Funnell, Mark Johnson, Lenny Schultz, Alexander Mosig, Alireza Mashaghi

Key needs

- Sharing data and resources, especially standards, reagents, pathology data, clinical samples and methodology
- Simultaneous development of animal models refined for each of the known high-risk groups of pathogens along with simultaneous development of microphysiological systems which may complement or support in vivo approaches
Developing immunological assays with an eye on potential for generalizability - Bill Dowling

- The WHO Assays working group was established to coordinate the development and standardization of immune assays to support vaccine development for COVID-19, and then later for other WHO priority pathogens.

- Continued sharing of protocols, methods, and results will help to advance the development of immunoassays for Disease X vaccines.

- Research done in advance of an epidemic or pandemic, as well as pre-established partnerships and processes, will shorten the time needed for implementation.

- Use of novel, high-throughput platform technologies applied to viral or bacterial systems will allow rapid adaptation to newly emergent pathogens.
New Division & WHO Hub for Pandemic and Epidemic Intelligence - Sara Hersey

Three critical objectives targeting the development of capabilities for collaborative surveillance

Obj. 1
Strengthened national integrated disease, threat & vulnerability surveillance

Obj. 2
Increased diagnostics and lab capacity for pathogen and genomic surveillance

Obj. 3
Collaborative approaches for event detection, risk assessment and response monitoring

Better decisions

Underpinned by:
- Enablers (governance, sustainable financing, culture of trust, workforce)
- Detailed sets of capabilities
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

2. Availability
   - Agreement on availability and access to candidate vaccines and therapeutics

3. Clinical trials
   - CORE protocols and platforms to promptly initiate trials with equitable access to research

4. Agreements
   - Prior agreement on legal collaboration, insurance, indemnity and liability

5. Funding
   - Access to readily available funding through committed financing mechanism

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

   - R&D Blueprint: Powering research to prevent epidemics

   - For internal use - not for distribution