What is WHO’s current proposal regarding R&D preparedness?
Human Impact of Global Outbreaks

- Ebola in West Africa: 30,000 reported cases, 3,500 deaths
- SARS in East Asia: 10,000 reported cases, 3,000 deaths

Economic Impact of Global Outbreaks

- Ebola in West Africa: $2.2 B
- SARS in East Asia: $54 B
- Expected Annual Losses from the Global Economy: $30 B

*Figures are in USD
In May 2015, the Sixty-Eighth World Health Assembly

“...welcomed the development of a blueprint, in consultation with Member States and relevant stakeholders, for accelerating research and development in epidemics or health emergency situations where there are no, or insufficient, preventive, and curative solutions, taking into account other relevant work streams within WHO”.
At the request of its 194 Member States in May 2015, WHO has convened a broad coalition of experts to develop an R&D Blueprint for Action to Prevent Epidemics.

WHO experts teams, an international Scientific Advisory Group and partners engaged through global forums are collaborating to formulate this novel R&D model.
The vision the Blueprint is a world in which our R&D response to PHEIC caused by emerging pathogens is faster and more effective than ever before and in which the global community is able to ensure a continuous effort aiming not only to accelerate the results of research but also to adapt to the scientific, logistical and social challenges that are specific to epidemics.

1. An inclusive process with a clear mandate and defined milestones
2. Building on the efforts of others in the community
3. A collaborative effort with the Member States in the affected countries at its core
4. Driven by scientific knowledge
Approaches currently being used to improve preparedness under the R&D Blueprint.

A. Improving coordination & fostering an enabling environment
   1. Building an effective governance & coordination framework
   2. Outlining innovative transparent and aligned funding processes
   3. Encouraging effective communication

B. Accelerating Research & Development processes
   1. Assessing epidemic threat & defining priority pathogens
   2. Developing R&D roadmaps to accelerate evaluation of diagnostics, therapeutics & vaccines
   3. Outlining appropriate regulatory & ethical pathways

C. Developing new norms and standards adapted to the epidemic context
   1. Supporting expansion of capacity to implement adequate study designs
   2. Developing guidance & tools to frame collaborations and exchanges
   3. Anticipating evidence needs to inform regulatory review and policy development
These 3 approaches are aligned with:

the lessons learned during the 2014–2016 Ebola epidemic and

the recommendations of the various reviews on the Ebola epidemic conducted to date
What would success look like?

The Blueprint aims to reduce the time between the declaration of a public health emergency of international concern and the availability of effective tests, vaccines and medicines that can be used to save lives and avert crisis.
First Blueprint deliverables
The initial list of disease priorities needing urgent R&D attention comprises: Crimean Congo haemorrhagic fever, Ebola virus disease and Marburg, Lassa fever, MERS and SARS coronavirus diseases, Nipah and Rift Valley fever. Chikungunya, severe fever with thrombocytopenia syndrome, and Zika designated as "serious". The list will be reviewed annually or when new diseases emerge.
Public consultation on ideas for potential platforms to support development and production of health technologies for priority infectious diseases with epidemic potential

The epidemic of Ebola in West Africa showed that the world is unable to develop effective interventions in a timely manner for control of severe emerging infectious diseases using current approaches to vaccine, drug and diagnostics development.

The World Health Organization (WHO) is inviting submission of structured ideas on how to improve R&D readiness for priority infectious disease threats. Specifically, propositions are requested for flexible development and production platform technologies.

Submission of platform ideas by Friday 5 February 2016, 17:00 Geneva time.

Read more... pdf, 220kb

Vaccines

Trials progressing

Treatments

Trials continue

Diagnostics

Novel tests
Development of R&D Roadmaps for priority pathogens

Roadmaps as a Vehicle for Addressing Large-Scale Public Health Challenges
Governance and coordination
Data Sharing
ICJME Recommendations, 2015

In the event of a public health emergency (as defined by public health officials), information with immediate implications for public health should be disseminated without concern that this will preclude subsequent consideration for publication in a journal.

An exception to this principle may occur when information that has immediate implications for public health needs to be disseminated, but when possible, early distribution of findings before publication should be discussed with and agreed upon by the editor in advance.
Monitoring and evaluation Framework

In the event of an Emergency

**Pre-WHA**

- W31: Mechanisms to prioritize pathogens for research and product development
- W32: Gap analysis and identification of research priorities for the priority diseases
- W33: Organization, coordination, and surveillance of the strengthening of capacities
- W34: Assessment of preparedness level and impact of interventions
- W35: Funding options for preparedness and emergency responses

**Post-WHA**

- Process in place to review and revise threats
- R&D road maps for other pathogens
- Mechanism established to collaborate over responses to MERS and other prioritized pathogens
- A system for funding R&D exists characterized by higher levels of funding and more coordination
- Procedures in place to rapidly evaluate new technologies in emergent and neglected热带 diseases at higher ethical standards

**ASUMPTION:** WHO coordinates blueprint work-streams effectively with good communication between work-streams

**The Problem**
The world is unable to develop effective interventions in a timely manner for control of some infectious diseases using current approaches particularly when they (i) are sporadic or unpredictable, (ii) occur largely in low and middle income countries, and (iii) are new diseases.
Outcome document
Financing of R&D Preparedness and Response to Epidemic Emergencies
October 29-30, 2015
Oslo, Norway

Background
This Outcome document summarizes discussions that took place during the Oslo consultation on Financing of R&D Preparedness and Response to Epidemic Emergencies (October 29-30, 2015). It reflects views expressed and the discussion that took place, but does not necessarily reflect all interventions. Names of representatives of countries and organizations participating in the Oslo consultation on Financing can be found on the webpage of the Norwegian Institute of Public Health. Stakeholders represented included government, industry, NGOs and academia as well as charitable foundations.
The R&D Blueprint represents WHO’s new start for a better R&D preparedness.

The current lack of R&D preparedness is a problem that can be solved.

Let’s solve it together!