

AN R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS

Progress update - February 2017

Progressing towards an effective preparedness plan and response mechanism for R&D in emergencies.

A. Improving coordination and fostering an enabling environment

A Global Mechanism to improve coordination.

What are the anticipated benefits?

Global response efforts are faster, more consistent, transparent, better coordinated, effective. Ownership and buy-in from key stakeholders and communities are increased.

- A first scoping meeting co-hosted by Chatham House, the Wellcome Trust and WHO brought together key stakeholders in global R&D in November 2016. The participants reached consensus on the need to establish a Global Coordination Mechanism (GCM) and on the request that WHO – through the Blueprint – should take the lead in facilitating the work of this mechanism.
- Terms of reference for the GCM will be discussed at the 1st official meeting of the GCM scheduled for March 2017.
- Plans are underway for a first practical application of the GCM through a prioritization exercise of Zika vaccine efficacy trials to be conducted at various sites throughout the world.
- Mapping of groups working on each of the Blueprint priority diseases has been completed and a visual application to allow easy access to the information is under development.

B. Accelerating R&D processes

Assessing epidemic threats and defining priority pathogens

What are the anticipated benefits?

The global R&D community can focus efforts on identified priority pathogens. A decision tree is available for determining when a novel disease should trigger an interim prioritization assessment.

- Jointly with experts, in December 2016 the Blueprint team refined its original pathogen prioritisation methodology (which informed the priority pathogen list of 2015). The methodology is currently in peer-review phase and will be published shortly.
- Based on this improved methodology, the priority list of pathogens was updated in January 2017. The list now includes the following pathogens*: Arenaviral hemorrhagic fevers (including Lassa Fever); Crimean Congo Haemorrhagic Fever (CCHF); Filoviral diseases (including Ebola and Marburg); Middle East Respiratory Syndrome Coronavirus (MERS-CoV); other highly pathogenic coronaviral diseases (such as Severe Acute Respiratory Syndrome, (SARS); Nipah and related henipaviral diseases; Rift Valley Fever (RVF); Severe Fever with Thrombocytopenia Syndrome (SFTS); and Zika.

*There was agreement that Chikungunya, while not in the priority list, still warrants attention and further research and development.

Developing R&D roadmaps to accelerate development of diagnostics, therapeutics and vaccines

What are the anticipated benefits?

The Roadmaps identify R&D gaps and help prioritize where investments should be channeled to initiate R&D activities; this will hopefully translate into interest from funders.

Developing R&D Roadmaps

- The R&D Blueprint has adopted this approach to clearly communicate direction and foster collaborative multi-partner efforts to accelerate R&D of medical countermeasures for each of the priority pathogens. A prototype R&D roadmap for MERS-CoV has already been published, and a methodology to design and implement R&D roadmaps has been drafted to guide future efforts.
- Efforts are currently underway to develop roadmaps for Ebola/Marburg, Crimean-Congo haemorrhagic fever, Lassa fever and Zika.

Developing Target product profiles (TPPs)

- The following TPPs have been finalised: Ebola Zaire vaccines (outbreak response and long-term protection); multivalent filovirus vaccines (long-term protection); Zika vaccine (in emergencies); Ebola diagnostics; Zika diagnostics; MERS-CoV vaccines (2 human profiles and 1 camel vaccination profile).
- The following TPPs are under development: Lassa and Nipah vaccines (in support of the CEPI priorities).

Outlining appropriate regulatory and ethical pathways

- Work has begun to define regulatory pathways for clinical trial approval and emergency use, including an update of the Emergency Use Assessment and Listing (EUAL) procedure, following lessons learned from experience with Ebola diagnostics and vaccines, and Zika diagnostics.

C. Developing new norms and standards adapted to the epidemic context

What are the anticipated benefits?

Clinical trial designs for testing efficacy of vaccines and therapies against priority diseases are discussed and agreed before an outbreak. This allows quick implementation in case of need, country ownership and fosters partners' coordination.

Supporting expansion of capacity to implement adequate study designs

- Work is underway with three expert groups on a decision-making tool and annotated protocols for Phase III vaccine trials for the Blueprint priority diseases. Completion of this work is expected by the third quarter of 2017.
- A future phase of this work will focus on efficacy trial protocols for therapeutics.

Developing guidance & tools to frame collaborations and exchanges

What are the anticipated benefits?

Guidance and tools enable barriers to data and sample sharing to be incrementally addressed, so that timelines are accelerated in future outbreaks. This allows control measures to be better implemented, available interventions to be more effectively

deployed, and experimental interventions to be evaluated efficiently.

- **Data sharing:** WHO held a consultation in Geneva on 1-2 September 2015 to advance the development of data sharing norms in the context of public health emergencies. Following the recommendations of this consultation, ICMJE changed its guidelines to start publishing in real time new data and evidence from R&D during public health emergencies to facilitate collaboration. This area of work is now spearheaded by the Wellcome Trust for the GCM.
- **Sample sharing:** A web-based capacity tool is under development to facilitate the use of Material Transfer Agreements. The tool should be available for pilot testing in the second quarter of 2017.

D. Working with partners

- The Blueprint recently signed a memorandum of understanding (MoU) with the Coalition for Epidemic Preparedness Innovation (CEPI). The MOU includes CEPI's agreement to follow WHO normative guidance on disease priorities, target product profiles and regulatory strengthening, to cite just the main points. WHO, in turn, has observer status on the CEPI Executive Board and its Scientific Advisory Board.
- GloPID-R is contemplating entering into a similar arrangement with the Blueprint. WHO is an observer on the GloPID-R steering committee.

E. Value for money

The WHO R&D Blueprint represents a high-return on low investment initiative – approximately US\$ 15 million are needed over three years, 50% of which is already secured, to make the world outbreak ready in the area of R&D. This is because WHO does not actually carry out R&D activities, rather, it sets the principles for innovative ways to conduct rigorous R&D activities to avert large-scale epidemics and places those tools, resources, networks and partnerships at the disposal of the international R&D community. WHO also aims to ensure that, in the event of a public health emergency, that community works in a coordinated and collaborative way to advance science and public health.

F. Integration of the R&D Blueprint within the official WHO structure

An internal steering committee - composed of the heads of the three relevant WHO clusters - is now established to ensure coordination and institutional buy-in. Technical teams will soon be hosted in the three clusters under a single coordination mechanism.