

## The Challenge of Epidemics

Epidemics of emerging infectious diseases are a significant and growing threat to life, health and prosperity. They can arise anywhere at any time, but disproportionately affect low-income countries where needs are often greatest. In a world of denser cities, increased mobility and ecological change, their disruptive impact is increasing, making epidemics among the most pressing health security issues facing the world today.

Recent outbreaks, such as Ebola and SARS, have claimed thousands of lives and cost billions of dollars, both to countries that were directly affected and those that contributed to responding. Similarly, ongoing outbreaks of Zika will pose devastating health and economic impacts for years to come.

*All these events have exposed serious flaws in the world's capacity to prepare for epidemics, and to react when they strike. The time is right for action.*

## The Role of Vaccines

A suite of public health capacities and global health reforms are needed to increase the world's resilience and capacity to prepare, detect and respond to epidemic threats. In addition, we need the toolset that better biomedical countermeasures can offer. Vaccines can play a critical role in containing epidemics to help avert humanitarian crises, but the safe and effective vaccines we need aren't being developed quickly enough. The risks and costs of development, always significant, are especially great for epidemic diseases. Outbreaks come and go, and hit poor countries the hardest, straining already fragile health systems. Trials are particularly complex to conduct, and market potential is often limited. When a vaccine is developed, complex regulations and laws that vary from country to country can delay getting vaccines to people who desperately need them.

Ebola demonstrated that epidemic vaccines *can* be developed swiftly, even in extremely challenging conditions. Trials that normally take years were done within months. But this achievement was possible only because viable candidates were already in the pipeline, and the gravity of the crisis forged ad-hoc partnerships between the private, public and philanthropic sectors, who each took on unusual, unsustainable and unrepeatable risks. And even this unprecedented speed was too slow. Candidate vaccines had not been tested for safety in advance, delaying efficacy trials. By the time anybody in West Africa could be vaccinated, the epidemic was waning, and many people who might have been protected had died.

Even this limited success will be difficult to replicate. The vaccine pipeline is weak for most epidemic threats, and developers are unlikely to take on similar risks a second time around. We need a system that will advance vaccine candidates as far as possible before epidemics emerge, and then run efficacy trials immediately when they do.

CEPI – the Coalition for Epidemic Preparedness Innovations – will provide that new system. It will tackle the barriers to epidemic vaccine development, advancing safe, effective and affordable vaccines that can help to contain outbreaks at the earliest possible stage. It will give us the joint global insurance policy we need, helping the populations most at risk and making us all safer.

## A Global Mandate

Ebola exposed the need for a global mechanism to coordinate research and development for health technologies (diagnostics, vaccines and medicines) against epidemic threats. Discussions began in March 2015 with an expert meeting in Berlin, convened by Chancellor Merkel as part of G7 discussions and chaired by Bill Gates. Four high level expert assessments of the Ebola response then reached a common conclusion that the current system is broken.<sup>1</sup>

In response to this clear mandate, stakeholders from international organisations, governments, the pharmaceutical industry, public and philanthropic R&D funders, academia, NGOs and civil society groups agreed at the 2016 World Economic Forum Annual Meeting in Davos to explore new ways to drive vaccine innovation for priority public health threats, in alignment with the WHO R&D Blueprint for action to prevent epidemics. This initiative is CEPI – the Coalition for Epidemic Preparedness Innovations. The coalition was officially launched in Davos January 2017.

## Vision

Vaccines contributing to preventing outbreaks of emerging infectious disease from becoming humanitarian crises.

## Approach

CEPI will build a new system to advance the development of safe, effective and affordable vaccines, ensuring that price is not a barrier to access for populations most at need. This will offer the world an insurance policy against the growing threat from emerging infectious diseases. CEPI will be a partnership of public, private, philanthropic and civil organisations to stimulate, finance and co-ordinate vaccine development against priority threats, particularly when development is unlikely to occur through market incentives alone.

CEPI will pursue a proactive (“just-in-case”) and accelerated (“just-in-time”) vaccine development strategy for epidemic threats by:

- Moving vaccine candidates through late preclinical studies to proof of concept and safety in humans before epidemics begin, so that larger effectiveness trials can begin swiftly in an outbreak and small stockpiles are ready for potential emergency use;
- Building technical platforms and institutional capacities that can be rapidly deployed against new and unknown pathogens.

<sup>1</sup> WHO Ebola Interim Assessment Panel, Harvard-LSHTM Independent Panel, US National Academy of Medicine and the UN Secretary General's High Level Panel

## Governance

CEPI is in start-up phase until the end of 2017. During this period, an Interim Secretariat provided by the Government of Norway is coordinating CEPI activity with close support from the Government of India, Wellcome Trust, the Bill & Melinda Gates Foundation, and the World Economic Forum.

Richard Hatchett was appointed Chief Executive Officer of CEPI in February 2017. The Interim Board, with representatives from founding partners, industry, governments and non-governmental organisations, is chaired by K. Vijay Raghavan, Secretary of the Department of Biotechnology of India, and with Peter Piot, Director of the London School of Hygiene and Tropical Medicine, as vice-chair.

A Scientific Advisory Committee serves as advisor to the Inter-

im Board and the Secretariat on pathogen priorities and selection of programmes and projects. A Joint Coordination Group will integrate vaccine development efforts with affiliated CEPI partners and stakeholders to ensure regulatory approval and access to populations in need. CEPI Partners Forum provides a model for early collaboration and expression of support.

CEPI is actively seeking partnerships with governments, potential funders, industry partners, regulators, and civil society organisations with an interest in building a proactive and accelerated approach to vaccine development and delivery.

**For further information, please contact the Interim Secretariat via [info@cepi.net](mailto:info@cepi.net).**

## Initial target diseases

CEPI has chosen for its first call for proposals the three diseases MERS, Lassa and Nipah taking as its starting point the WHO's list of priority pathogens against which medical countermeasures are urgently needed. CEPI's Scientific Advisory Committee chose the three diseases based on a set of criteria including the public health impact, the risk of an outbreak occurring and the feasibility of vaccine development, based on current knowledge, tools and pipeline candidates.

## Investors

CEPI has an initial investment of US \$540m from the governments of Germany, Japan and Norway, plus the Bill&Melinda Gates Foundation and the Wellcome Trust. In addition the European Commission plans to co-fund with EUR 250m. India will as one of CEPI's founders announce its investments later this year.

## Next Steps

- Formalize Interim governance and plan for permanent arrangements
- Explore the CEPI concept with G7 and G20 countries and with UN member states
- Broaden advocacy and secure additional funding

## Key Dates

- **10-11 May, 2017** - Third Scientific Advisory Committee meeting (London, UK)
- **11-12 July, 2017** - Board retreat and fourth interim Board meeting (Berlin, Germany)
- **23-24 August, 2017** - Fourth Scientific Advisory Committee meeting (Oslo, Norway)

## Board Members

K. Vijay Raghavan (Chair)	Department of Biotechnology, India	Julie Gerberding	Merck
Peter Piot (Vice Chair)	London School of Hygiene and Tropical Medicine	Line Matthiessen	European Commission
Adar Poonawalla	Serum Institute of India	Luc Debruyne	GlaxoSmithKline
Arnaud Bernart	World Economic Forum	Nima Farzan	PaxVax Inc.
Christopher Whitty	Department of Health, UK	Tore Godal	Ministry of Foreign Affairs, Norway
Eduardo de Azeredo Costa	Center for International Affairs in Health, Fiocruz	Trevor Mundel	Bill & Melinda Gates Foundation
Jane Halton	University of Canberra	Victor Dzau	National Academy of Sciences
Jeffrey Mphahlele	South African Medical Research Council	Yah Zolia	Ministry of Health and Social Welfare, Liberia
Jeremy Farrar	Wellcome Trust	Yifru Berhan	Ministry of Health, Ethiopia
Joachim Klein	Federal Ministry of Education & Research, Germany	Yusuke Fukuda	Ministry of Health, Labor and Welfare, Japan
Joanne Liu	Medecins sans Frontieres		

## Observers

Mark Feinberg (Chair, Scientific Advisory Committee)	International AIDS Vaccine Initiative
Margaret Hamburg (Chair, Joint Coordination Group)	National Academy of Sciences
Peter Salama	World Health Organization
Richard Hatchett	CEO of CEPI
George Korch	Department of Health and Human Services

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