

## Coalition for Epidemic Preparedness Innovations

### Newsletter 13 October 2017

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#### Address from our CEO



As I write an epidemic of pneumonic plague is spreading throughout Madagascar. Cases have been recorded in twenty districts across ten regions of the country. At least 385 persons have been infected since August and of these at least 42 have died. Untreated pneumonic plague is associated with a mortality rate of nearly 100% and is transmissible from person to person, differentiating it from the bubonic and septicemic forms of the disease, which are spread mainly by infected fleas. The index case, a 31-year-old man who died in August, brought the disease to Madagascar's densely populated capital, Antananarivo, where it has continued to spread. Fortunately, *Yersinia pestis*, the causative agent of plague, is susceptible to many antibiotics and, if diagnosed quickly, easy to treat.

To help control the epidemic, WHO has released 1.2 million doses of antibiotics, enough to treat several thousand cases and provide prophylaxis to 100,000 more, and \$1.5 million in emergency funding. As further steps to hasten disease control, schools across the country have been closed and mass gatherings banned.

Plague is one of the ancient scourges of mankind. Scientists have long suspected *Y. pestis* to be a possible cause of the Plague of Justinian, which ravaged the Eastern Mediterranean for several hundred years beginning in 541-542 CE, and the Black Death of the 14<sup>th</sup> century, but this etiology wasn't proved scientifically until DNA analysis of human skeletons excavated from widely distributed plague pits demonstrated amplification of genetic material specific to *Y. pestis* (1,2). Phylogenetic analysis of the retrieved specimens also provided crucial clues as to how plague spread through medieval populations.

In 2015, the Danish evolutionary geneticist Eske Willerslev and colleagues recovered plague in human teeth from Asia and Europe dating from 2800 to 5000 years ago and considerably enhanced our understanding of plague's ancient epidemiology (3). They showed that *Y. pestis* was endemic in human populations in Eurasia at least 3000 years before any historical recordings of pandemics and only gradually acquired genetic changes leading to increased virulence and enhanced transmissibility. In particular, they describe the late emergence, sometime prior to 951 BCE of the *ymt* gene, which encodes a phospholipase that protects *Y. pestis* inside the flea gut, enabling the bacteria to use the flea as a vector, and the emergence subsequent to 951 BCE of a point mutation in the *pla* gene that is essential for the development of bubonic plague.

This fascinating scientific detective work is important because it helps us understand (and put a timestamp on) the emergence of pathogenicity in a bacterium of great historical significance. The implication of such work is that with time and greater understanding of the genetic and cultural milieux facilitating disease transmission, we might gain the ability not only to describe but to predict threats before they are upon us.

*Richard Hatchett, CEPI CEO*

1) Haensch S, et al. PLoS Pathogens 2010 Oct 7;6(10):e1001134. doi: 10.1371/journal.ppat.1001134

2) Harbeck M, et al. PLoS Pathogens 2013;9(5):e1003349. doi: 10.1371/journal.ppat.1003349. Epub 2013 May 2.

3) Rasmussen S, et al. Cell 2015;163:571-582.

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## Unicef Vaccine Industry Days

CEPI was invited by UNICEF to participate at UNICEF's Vaccine Industry Consultation 5 and 6 October in Copenhagen. The key focus on the first day was Regulatory Systems Strengthening and Karianne Johansen presented work from CEPI's Regulatory Working group and participated in the panel discussion. As CEPI will fund vaccines until end of Phase 2b and provide stockpile for clinical trials during outbreak, our regulatory challenges are somewhat different from current vaccines procured by UNICEF. Stockpiling was on the agenda the second day, and also in this area it is clear that CEPI vaccines will differ from currently stockpiled vaccines by the fact that our vaccines will not be licenced by National or Regional Regulatory Authorities and prequalified by WHO. In a side event, Åge Nærdal presented CEPI and where we are with our Calls for Proposals. The meeting was an excellent opportunity to meet many industry representatives and make them aware of the role of CEPI. We are grateful to UNICEF for inviting us and look forward to future collaboration.

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## Global Grand Challenges Meeting

The Gates Foundation held their major annual Grand Challenges meeting in Washington from October 2-4. Richard and CEPI participated in Tuesday's plenary session titled "Innovation Ecosystems for Global Health & Pandemic Preparedness". On the plenary panel moderated by Trevor Mundel (President, Global Health Division, Bill & Melinda Gates Foundation), Richard joined Dr Penny Heaton (CEO, Bill and Melinda Gates Medical Research Institute), Dr John Nkengasong (Director, Africa Centres for Disease Control and Prevention), and Dr Camilla Stoltenberg (Director General, Norwegian Institute of Public Health), for a discussion which asked "pandemic preparedness – are we making progress?"

Panellists discussed the multiple connected endeavours which are needed to prepare for and respond to pandemics – including great science, research and development, in-country expertise, regulatory work, public health, manufacturing and a sustained commitment to implementation and innovation. In discussion Richard stressed the central importance of developing vaccines as part of preparedness and response, and panellists suggested that the birth of CEPI was a hugely positive step forwards.

In considering whether the world is ready to respond to a major epidemic – "the big one" – panellists discussed recent experiences of Ebola and Zika and lessons learned, and reflected that the timelines for developing vaccines needs to be dramatically reduced, and that global collaboration is critical.

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## International Vaccines Task Force

On October 5th CEPI and the World Bank co-hosted the introductory teleconference of the International Vaccines Task Force (IVTF). The IVTF has been set up to help strengthen R&D capacity and preparedness in low income countries, building on the lessons learned and the work of existing R&D capacity-building initiatives (such as the EDCTP and WHO R&D Blueprint), and the central importance of this issue for CEPI's success. Through its work, the IVTF will propose ways in which national governments and development partners can effectively and sustainably establish and finance vaccine research and development capacity at the national level.

The final deliverable will be a report that lays out focused and actionable recommendations on building clinical research capacity around vaccine development, initially focused on the WHO R&D Blueprint diseases, and other integral capacities that impact vaccine development, such as laboratories which can be utilized for both public health functions and vaccine clinical research. The task force is co-chaired by Marie-Paule Kieny and Richard Sezibera and will deliver its report to CEPI and the World Bank in time for presentation at the World Health Assembly and other forums such as the G20.

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## Road Map for MERS-CoV

CEPI-representatives participated in a global technical meeting on MERS-CoV; organized by WHO, FAO (UN's Food and Agriculture Organization) and OIE (World Organisation for Animal Health) in Geneva from September 25-27. The latest research on MERS-CoV was presented, gaps identified and agreement achieved for cross-sectorial collaboration. The WHO had in advance provided participants with a document summarizing priority actions for MERS-CoV control was prepared and an agreement was reached on a research agenda with an updated road map for a global and coordinated effort for handling of the MERS-CoV threat.

Of the more than 130 invited participants, a high number came from countries where there have been sporadic cases or outbreaks of MERS-CoV disease (e.g. Saudi Arabia and South-Korea). The meeting covered both epidemiology, disease aspects, diagnostics, therapeutics and vaccines for MERS-CoV. A particular issue raised was the issue of vaccines for camels versus humans, with a consensus reached that both were needed. Another gap highlighted was the need for standardized assays, reference materials and sharing of sera and data.

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## Job openings at CEPI

The positions as Program Manager and Contract Manager are still open. If you are interested in joining the CEPI team in London and have appropriate qualifications for either of these roles, please check out the job descriptions on the CEPI website. Follow CEPI on LinkedIn for further job openings.

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## Pipeline Survey

CEPI has launched a vaccine R&D pipeline and cost tracking survey to inform vaccine preparedness efforts against non-commercial epidemic disease threats. If you have something to report and are interested in sharing this information with us, please fill in our survey template which you can download here. Through the information provided in this survey CEPI will be in a better position to identify gaps and plan investments in the development and manufacturing of vaccines against priority epidemic infectious diseases. This is relevant both for targeted Calls for Proposals as well as CEPI's overall strategic plan for responding to the newly emerging/unexpected pathogen outbreaks. The survey is open until 10 November 2017. In case of questions, contact [Pipeline@cepi.net](mailto:Pipeline@cepi.net).

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## World Vaccine Congress

Richard attended the industry-focused World Vaccine Congress in Barcelona and spoke in the opening plenary discussion "Creating a new strategy: how does the current global outbreak response system need to change". Joining him in the discussion were Dr. Marie-Paule Kieny, former Assistant Director General of the World Health Organization, and Dr. Helen Rees, the Chair and Executive Director of the Wits Reproductive Health and HIV Institute and also a member of CEPI's Scientific Advisory Committee. Richard provided an update on CEPI's activities, framing these in the context of the WHO R&D Blueprint for Action to Prevent Epidemics and ongoing efforts to harmonize international regulatory frameworks for emergency vaccines.

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## Upcoming Meetings

- 15-17 October: **World Health Summit 2017**, Berlin, Germany
  - 26 October: **Prix Galien Forum**, New York, USA
  - 31 October - 2 November: **2nd OIE Global Conference on Biological Threat Reduction**, Ottawa, Canada
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