Fast-tracking vaccines for epidemic diseases: an update from CEPI

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First traces of a mysterious disease
Plague of Cyprian

Started in Ethiopia before 250 CE and spread through Egypt, reaching Alexandria by 249 and Rome in 251, causing a pandemic lasting 20 years.

At its peak, 5000 a day died in Rome. Its geographic scope was vast; it is attested everywhere we have sources.

St. Cyprian, the Bishop of Carthage, left the most detailed account we have, saying he believed the kingdom of God to be at hand.
Plague in the 21st Century

- 2348 suspected cases (82 HCW), 202 deaths (November 22)
- 55% of cases in Antananarivo and Toamasina
- 16 of 22 regions reporting cases
- Schools and universities closed, mass gatherings banned; travel advisories
- South Africa, Mauritius, Seychelles, Tanzania, La Reunion, Mozambique, Kenya, Ethiopia and Comoros placed on high alert
Lassa outbreak in Nigeria

- From 1st Jan to 4th March 2018
  - Total reported suspected cases 1121
  - 353 confirmed cases
  - 8 probable cases
  - 86 deaths (78 lab confirmed, 8 probable)
  - 16 Health care workers
  - CFR: 23.8%
  - Cases reported in 18 states
  - Ondo, Edo and Ebonyi most affected

- Response being led by Nigeria CDC
- WHO requested to coordinate proposition for research response
- CEPI willing to support where it can, focussing on laying groundwork for future vaccine development including harmonisation of clinical data collection, diagnostics, biobanking
Global impact of epidemics

Spanish Flu
- 50 million deaths
- GDP loss: Gross domestic product (GDP) loss of 3% in Australia, 15% in Canada, 17% in the UK, and 11% in the USA

SARS
- 774 deaths
- GDP loss: Gross domestic product (GDP) loss of US $52.2 billion

Zika
- 20 deaths, birth defects
- GDP loss: Expected loss of US $3.5 billion in the Latin American and Caribbean region

Ebola: global impact
- over 11,000 Deaths
- £2.8 billion Estimated negative economic impact (2014-2016)

Ebola: Economic impact
Sierra Leone Impact of Ebola on GDP (%)

Ebola: impact on health Systems
- Most maternal and child health indicators significantly declined during Ebola outbreak
- Malaria morbidity and mortality in Ebola-affected countries caused by decreased health-care capacity

Source: Yama et al, 2017: Financing of international collective action for epidemic and pandemic preparedness
A global challenge

- Epidemics affect us all – they can target anyone at any time and they don’t respect borders or nations
- They are one of our world’s greatest challenges
  - Dense cities, easy travel and ecological change mean they spread faster and further than ever before
  - Huge direct and indirect economic impact
  - Containment is challenging and can take months, at a cost of hundreds or thousands of lives
- Vaccines can protect us – and we can do more to have them ready in time

We’ve sent people into space and created incredible gravity defying structures; we’ve connected the world in ways preceding generations never imagined; but we have yet to outsmart epidemics.
Delivering vaccines during outbreaks

- WHO High level meeting: 23 Oct
- Ring design decided: 5 Nov
- Vaccine choice: 5 Feb
- Vaccination initiated: 23 Mar
- Preliminary results: 31 Jul
- Interim analysis: 20 Jul
- Extension to Sierra Leone: 1 Sept
- WHO Consultation on Ebola Vaccines: 29-30 Sept
- Protocols/Financing: 5 months
CEPI Launched at Davos 2017

CEPI
Coalition for Epidemic Preparedness Innovations

Preliminary Business Plan
2017-2021
CEPI...

- We are a coalition of public, private, philanthropic and civil society organisations
- We stimulate, finance and coordinate vaccine development for EIDs
- We identify priority threats and drive needed development when market forces fail
- We will build capabilities for rapid response to unknown threats
- We will move vaccine candidates through late preclinical studies to proof of concept and safety in humans before epidemics begin

New vaccines for a safer world

[www.cepi.net](http://www.cepi.net)
Strategic objectives...

1. Preparedness
2. Response speed
3. Market predictability
4. Equity
# CEPI’s roles: funder and facilitator

## CEPI role as a facilitator

|-------|-------------|--------------------------|-----------------|------------------------|
| Current stakeholders | ▪ Academia  
▪ Governments  
▪ WT/NIH  
▪ EC/IMI  
▪ GLOPID-R  
▪ Industry  
▪ Regulators  
▪ Biotech | ▪ Industry  
▪ Governments  
▪ Regulators  
▪ WT/NIH  
▪ EC/IMI  
▪ Bill and Melinda Gates Foundation  
▪ BARDA/DTRA etc.  
▪ WHO  
▪ Biotech  
▪ PDPs | ▪ Industry  
▪ BARDA  
▪ CMOs  
▪ Regulators  
▪ Governments  
▪ WHO  
▪ GHIF | ▪ GAVI  
▪ UNICEF  
▪ PAHO  
▪ Governments  
▪ WHO  
▪ Industry  
▪ Pandemic Emergency Facility (World Bank)  
▪ WHO Contingency Fund |

Significant focus by others

**New vaccines for a safer world**

[www.cepi.net](http://www.cepi.net)
CEPI’s initial target diseases

Starting point: List of priority pathogens defined by the WHO R&D Blueprint
CEPI’s Scientific Advisory Committee chose three initial diseases based on expected

Public health impact  |  Risk of an outbreak occurring  |  Feasibility of vaccine development
Camel densities in areas with evidence of MERS COV infection

- Camelids density ind / 100 km² (source: WAHID)
- Color codes:
  - 0-15: Low density
  - 15-50: MERS-CoV negative results in camels
  - 50-135: MERS-CoV positive results in camels
  - 135-400: Our study
  - 400-1,000: High density


Confirmed global cases of MERS COV 2012-2017

http://www.who.int/emergencies/mers-cov/en/
Disease burden

- Endemic, annual outbreaks
- Estimated 300,000 cases/year
- CFR in hospitalized patients is 15-20% but can reach as high as 50% during epidemics

Key countries

- Nigeria
- Sierra Leone
- Liberia
- Ivory Coast

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4501400/
Nipah

Disease burden
- Annual outbreaks in Bangladesh/India
- Up to 80% Case fatality rate
- Human-human transmission and via intermediate hosts (pigs)

Key countries
- Bangladesh
- India
- Malaysia

http://www.who.int/csr/disease/nipah/en
First partnership agreement signed March 5

• Novel proprietary platform to develop vaccines against Lassa Fever and MERS

• Up to $37.5 million

• Lassa vaccine recently demonstrated protection in non-human primates and could enter phase 1 clinical trials by late 2018/early 2019.

• The agreement provides funding for Themis’ development of the Lassa vaccine over five years and supports the completion of the preclinical package for the MERS vaccine
Call for proposals 2 – Platform technologies

• CEPI will support the development of vaccine platform technologies that can be rapidly deployed against known and newly emerging pathogens, to limit or prevent future outbreaks of known or new diseases

• Projects must demonstrate
  ➢ Safety and immunogenicity
  ➢ Validation of the platform using 3 pathogens:
    – 2 with known correlates of protection & validated animal model
    – 1 from the WHO priority pathogen list

• Manufacturing performance characteristics
  ➢ 16 weeks for development of vaccine for a new pathogen (up to phase I)
  ➢ 6 weeks to clinical benefit after 1st dose
  ➢ 8 weeks to produce 100,000 doses after go-decision
Fast-tracking vaccine development: CEPI’s JCG

Joint Coordination Group

• A team of external stakeholders that focus on identifying and working through potential hurdles that might arise in the end-to-end vaccine development process
• Pays special attention to issues arising around the delivery of, and access to the specific candidates supported by CEPI with the intention that these solutions will help others facing similar issues.
• Includes partners outside of CEPI that have vested interests in the successful development and delivery of CEPI-funded vaccines

Composition
Chair: Peggy Hamburg
Permanent Members: IFRC, WHO, EMA, FDA, NIBSC, GAVI, MSF, UNICEF, AVAREF, Wellcome
Concluding thoughts

• CEPI is committed to acting quickly, boldly, and to change the system for vaccine development

• CEPI has begun to build a vaccine development portfolio which it will proactively manage

• CEPI is looking to partner with those who can speed up the development of vaccines.

• Vaccine development is a complex, high risk business, with recent high profile set backs: Zika, Dengue, bringing an Ebola vaccine to license