

CEPI

# CEPI NEW VACCINES FOR A SAFER WORLD

Coalition for Epidemic Preparedness Innovations



Norwegian Ministry  
of Foreign Affairs

BILL & MELINDA  
GATES *foundation*



WORLD  
ECONOMIC  
FORUM



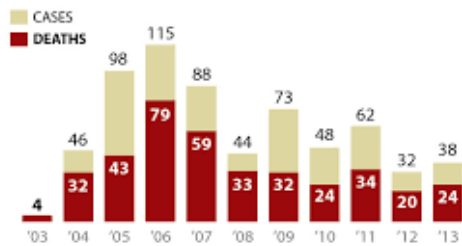
DEPARTMENT OF BIOTECHNOLOGY  
Ministry of Science & Technology

# The challenge of epidemics



## H5N1 AVIAN FLU CASES

Annual confirmed human cases for avian influenza A(H5N1) and deaths reported to the World Health Organization as of Dec. 10, 2013:



SOURCE: WORLD HEALTH ORGANIZATION

THE CANADIAN PRESS



# Calls for global action

ADVANCE UNEDITED COPY

## Protecting Humanity from Future Health Crises

Report of the  
High-level Panel on the Global Response to Health Crises

25 January 2016

## Report of the Ebola Interim Assessment Panel



## AN R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS PLAN OF ACTION MAY 2016



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 and other relevant actors. The consultation was jointly organized by WHO and the Norwegian Institute of Public Health and hosted by the Norwegian Institute of Public Health.

## THE LANCET

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Health Policy

Will Ebola change the game? Ten essential reforms before the next pandemic. The report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola

Dr Suerie Moon, PhD, DPHI, Sophie Delaunay, MDPH, Prof Eric Goosby, MD, Prof Leung, MD, J Stephen Morris, Benjamin Hawkins, PhD, LSHTM  
Published Online: 22 November 2015

## NATIONAL ACADEMY OF MEDICINE

ABOUT THE NAM PROGRAMS INITIATIVES PERSPECTIVES NEWS SUPPORT MEMBER RESOURCES

## Global Health Risk Framework

*The Neglected Dimension of Global Security: A Framework to Counter Infectious Disease Crises*

Download the Report



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## Perspective

### Establishing a Global Vaccine-Development Fund

Stanley A. Plotkin, M.D., Adel A.F. Mahmoud, M.D., Ph.D., and Jeremy Farrar, M.D., Ph.D.  
N Engl J Med 2015; 373:297-300 | July 23, 2015 | DOI: 10.1056/NEJMp1506020

Comments open through July 29, 2015

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Article References Citing Articles (8) Comments (2) Metrics

# CEPI – January – November 2016



**High Level Meeting  
Davos  
21 January**



**Task Team Meeting  
Oslo  
6-7 April**



**Task Team Tele-conferences**



**Leadership Group Meeting  
Washington DC  
17 May**



**Interim CEO appointed  
Interim board constituted  
Business Plan presented to stakeholders**



**Core Group and Leadership Group Tele-conferences**



**First CEPI interim board meeting  
London,  
31 August**



**CEPI soft launch  
Media coverage**



**G7 Health ministers' side event,  
Kobe,  
10 September**



**UNGA side event on health emergencies,  
NY,  
19 September**

# Challenges

1

The pipeline is weak for most emerging infectious diseases characterized by lack of market incentives

2

Unilateral, uncoordinated government efforts to fund R&D preparedness are inefficient and unsustainable in addressing global epidemic risks

3

Clinical & regulatory pathways are not easily adaptable to epidemic contexts

4

Incentives are lacking to motivate greater industry engagement

# Opportunities

1

The Ebola momentum: **vaccines are feasible** despite a risky development pathway

2

The Ebola momentum: it is **possible to advance the clinical development** of safe and effective vaccines against EIDs in an emergency

3

**R&D actors supporting EID vaccine pipelines:** government health research agencies, academic research institutions, biotechs, multinational vaccine manufacturers, and non-profits

4

Manufacturing capability and capacity for vaccines has always been a critical bottle-neck in epidemic events. **Major vaccine manufacturers can drive pipelines forward**

# New partnership models needed

## SUSTAIN- ABLE

**Sustainable partnership models for product development** (vaccines, diagnostics, therapeutics) to contain outbreaks of emerging infectious diseases

## GAP FILLING

**Partnership models that fill in the gaps**

- Need for coordinated and proactive R&D and increased funding
- Stronger advanced development and manufacturing capabilities
- Clear and predictable regulatory procedures and improved regulatory coordination

## END-TO- END

**Comprehensive policy ecosystem required with a collective end-to-end vision**

- Ebola response reviews/panels suggest lack of mechanisms to unite funders, developers, regulators
- Effective coordination will require dedicated mechanisms and resources, as well as end-to-end coordination of R&D and access

# The CEPI response

**Rationalize  
&  
accelerate**

**Rationalize** and **accelerate** research and development responses to new outbreaks



**Coordinate**

**Coordinate** resources across industry, academia, governments, philanthropies, and NGOs



**Prioritize  
& facilitate**

**Prioritize** vaccine targets and platform technology and **facilitate** the advanced development of vaccines for emerging infectious diseases

# Mission

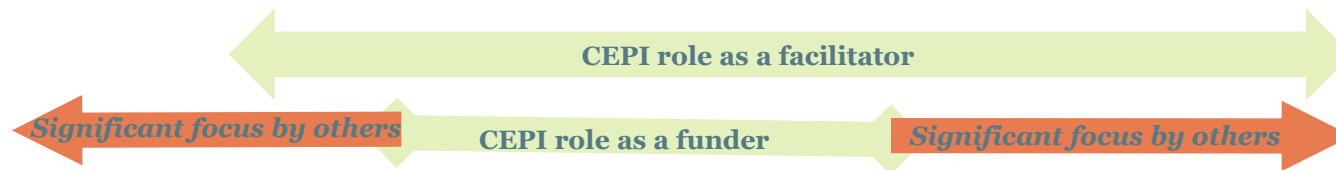
To ***prioritize, stimulate, finance and co-ordinate*** vaccine development against emerging infections with epidemic potential, especially in cases where market incentives alone do not achieve this

# Timely vaccine development – objectives for efficient global R&D preparedness

## 1. *“Just in Case” – Preparedness*

Advance **vaccine candidates** through late preclinical studies to proof of concept and safety in humans during non-epidemic periods

# CEPI's Gap-Filling Role



Phase	1 Discovery	2 Development/Licensure	3 Manufacturing	4 Delivery/Stockpiling
<b>Current Stakeholders</b>	<ul style="list-style-type: none"> <li>Academia</li> <li>Governments</li> <li>WT/NIH</li> <li>GLOPID-R</li> <li>Industry</li> <li>Regulators</li> <li>Biotech</li> <li>IMI / EC</li> </ul>	<ul style="list-style-type: none"> <li>Industry</li> <li>National Governments</li> <li>Regulators</li> <li>Bill and Melinda Gates Foundation</li> <li>BARDA/DTRA etc.</li> <li>WHO</li> <li>Biotech</li> <li>PDPs</li> <li>IMI / EC</li> </ul>	<ul style="list-style-type: none"> <li>Industry</li> <li>BARDA</li> <li>CMOs</li> <li>Regulators</li> <li>National Governments</li> <li>WHO</li> <li>GHIF</li> </ul>	<ul style="list-style-type: none"> <li>GAVI</li> <li>UNICEF</li> <li>PAHO</li> <li>National Governments</li> <li>WHO</li> <li>Industry</li> <li>Pandemic Emergency Facility (World Bank)</li> <li>WHO Contingency Fund</li> </ul>

- Adhering to equitable access principles of affordable pricing and availability of vaccines by priority populations in emergencies
- Securing industry participation through predictable pathways and risk/benefit sharing arrangements and handling of liability through indemnification
- Supporting data sharing and sample sharing mechanisms, and long-term development of regional capabilities for epidemic vaccine preparedness

# CEPI's operating principles

1

Equitable access

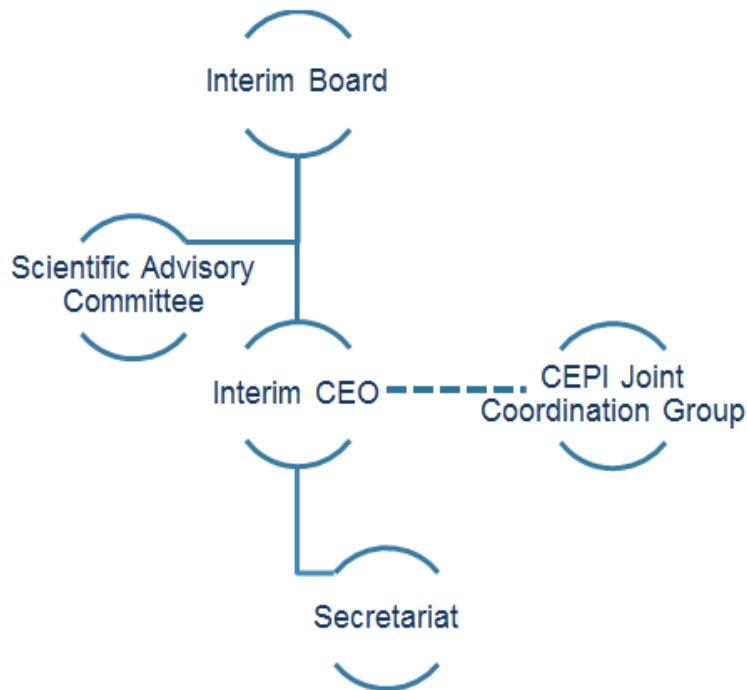
2

Cost coverage  
(Delinkage)

3

Shared benefits  
(Partial delinkage)

# Organizational Setup: Startup Phase



- Founding Partners include the Gates Foundation, Wellcome Trust, Department of Biotechnology of India, Government of Norway, and World Economic Forum
- Independent legal entity, existing as an international non-profit association under Norwegian law
- Interim Secretariat is hosted by the Norwegian Institute of Public Health under a service agreement
- Flexible arrangement, can transition into other institutional and governance arrangements
- Decisions about its permanent organizational structure and governance made by the CEPI Interim Board during the interim phase
- SAC advises on scientific matters and JCG coordinates CEPI's activities with other stakeholders

# CEPI Interim Board

## **K. Vijay Raghavan (Chair)**

Secretary, Department of Biotechnology  
Ministry of Science and Technology, India

## **Peter Piot (Vice Chair)**

Director of the London School of  
Hygiene and Tropical Medicine

## **Adar Poonawalla**

CEO and Executive Director  
Serum Institute of India

## **Arnaud Bernaert**

Head of Global Health and Healthcare  
Industries, World Economic Forum

## **Christopher Whitty**

Chief Scientific Adviser  
Department of Health, UK

## **Eduardo de Azeredo Costa**

Technical Advisor, Center for International  
Affairs in Health, Fiocruz, Brazil

## **Glenda Gray**

President & CEO  
South African Medical Research Council

## **Jane Halton**

Adjunct Professor  
University of Canberra

## **Jeremy Farrar**

Director  
Wellcome Trust

## **Joachim Klein**

Deputy Head of Division Health  
Research Federal Ministry of Education  
and Research, Germany

## **Joanne Liu**

International President  
Medecins sans Frontieres

## **Julie Gerberding**

Executive Vice President  
Merck

## **Moncef Slaoui**

Chairman of vaccines  
GSK

## **Nima Farzan**

President and CEO  
PAXVAX INC.

## **Ruxandra Draghia-Akli**

Deputy director-general of DG RTD  
European Commission

## **Tore Godal**

Special Adviser on Global Health  
Ministry of Foreign Affairs, Norway

## **Trevor Mundel**

President Global Health Division  
The Bill & Melinda Gates Foundation

## **Victor Dzau**

President of the Institute of Medicine  
National Academy of Sciences

## **Yah Zolia**

Deputy Minister of Health and Social  
Welfare, Liberia

## **Yifru Berhan**

Minister of Health  
Ethiopia

## **Yusuke Fukuda**

Assistant Minister for Technical  
Affairs and Global Health, Ministry of  
Health, Labor and Welfare, Japan

## **Observers**

### **Marie-Paule Kieny**

Assistant Director-General  
World Health Organization

### **Mark Feinberg**

President & Chief Executive Officer  
IAVI

### **Peggy Hamburg**

Foreign Secretary of the Institute of  
Medicine  
National Academy of Sciences

### **John-Arne Røttingen**

Interim CEPI CEO

### **Nicole Lurie**

Assistant Secretary,  
Department of HHS, US  
(serving in a liaison position)

# CEPI interim SAC

**Mark Feinberg (Chair)**  
International AIDS Vaccine  
Initiative

**Alan D. Barrett**  
University of Texas Medical  
Branch

**Amadou Sall**  
Institute Pasteur Dakar

**Bernard Fanget**  
Abivax, Neovacs

**Cherry Gagandeep Kang**  
Christian Medical College Vellore

**Connie Schmaljohn**  
University of Maryland

**Daniel Brasseur**  
European Commission

**David Kaslow**  
PATH/CIVA

**David Wood**  
World Health Organization

**George Fu Gao**  
Chinese Center for Disease Control  
and Prevention

**Gunnstein Norheim**  
Norwegian Institute of Public Health

**Heinrich Feldman**  
NIH National Institute of Allergy and  
Infectious Diseases

**Helen Rees**  
Wits Reproductive Health and HIV  
Institute

**James Robinson**  
James Robinson Biologics  
Consulting

**Jean-Francois Delfraissy**  
ANRS/INSERM

**Jesse Goodman**  
Georgetown University

**Kathleen Neuzil**  
University of Maryland

**Kenji Shibuya**  
Department of Global Health  
Policy, University of Tokyo

**Maharaj Kishan Bhan**  
JIPMER

**Penny Heaton**  
Bill & Melinda Gates Foundation

**Peter Smith**  
London School of Hygiene and  
Tropical Medicine

**Rick Bright**  
Biomedical Advanced Research  
and Development Authority

**Stanley Plotkin**  
VaxConsult

**Subhash Kapre**  
Inventprise

## Non-voting members

**Ali Allouèche**  
Takeda

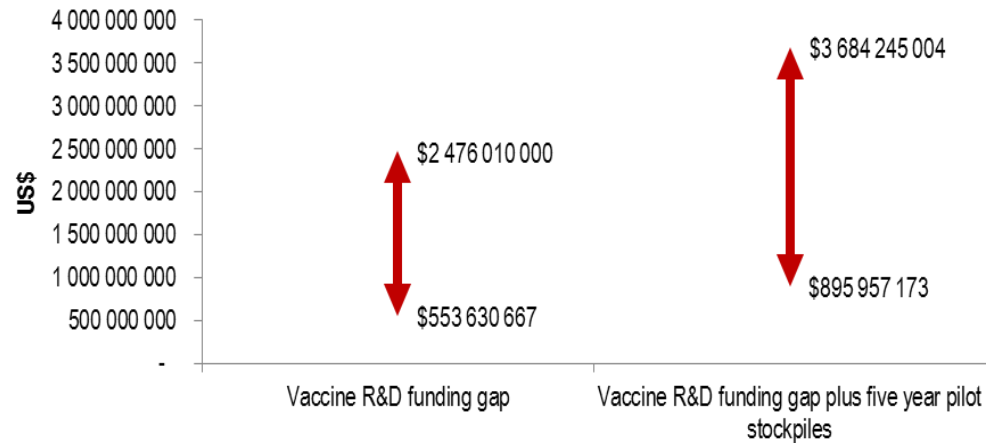
**Jean Lang**  
Sanofi Pasteur

**Johan Van Hoof**  
Johnson & Johnson

**Kathrin Jansen**  
Pfizer

# CEPI's Funding Needs

Preliminary cost-modeling estimates\*  
5-year costs for advancement of **10 WHO Blueprint EID vaccine candidates** to the end of clinical phase IIa development at between **US\$600M and US\$3.7B**, depending on the complexity of the technology used, pilot manufacturing requirements and other manufacturing cost variants, and stockpiling needs.



CEPI is seeking multi-year donor contributions to an **initial investment pool of US\$1B** (2017-21) to advance **late-stage development of 4 to 6 vaccine candidates** against 2 to 3 priority EIDs to the end of clinical phase II development, and save countless lives and billions of dollars.

\* Details on cost estimates and assumptions are available upon request.

# CEPI Financing Model

CEPI will use a multi-source financing model to satisfy its core resource needs.

## Four financing principles

1. Broad-based
2. Long term, predictable
3. Complementary and new financial resources
4. Fit-for-purpose funding

