

CEPI

CEPI NEW VACCINES FOR A SAFER WORLD

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Senior Medical Officer

October 19, 2016



Norwegian Ministry
of Foreign Affairs

BILL & MELINDA
GATES *foundation*



WORLD
ECONOMIC
FORUM



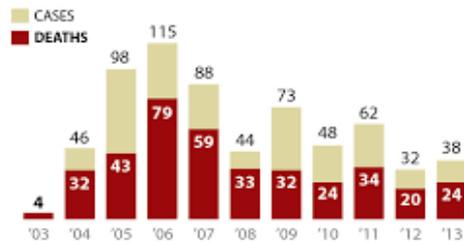
DEPARTMENT OF BIOTECHNOLOGY
Ministry of Science & Technology

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.

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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, DPhil, Sophie Delaunay, MDPH, Prof Eric Goosby, MD, Prof Leung, MD, J Stephen Morrison, Benjamin Hawkins, PhD, LSHTM
Published Online: 22 November 2015

NATIONAL ACADEMY OF MEDICINE

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Global Health Risk Framework

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

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The NEW ENGLAND JOURNAL of MEDICINE

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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/NEJMp1506620

Comments open through July 29, 2015

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

CEPI - January - June



**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 and constituted
Business Plan presented to stakeholders**

CEPI - July - September



Core Group and Leadership Group Teleconferences



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

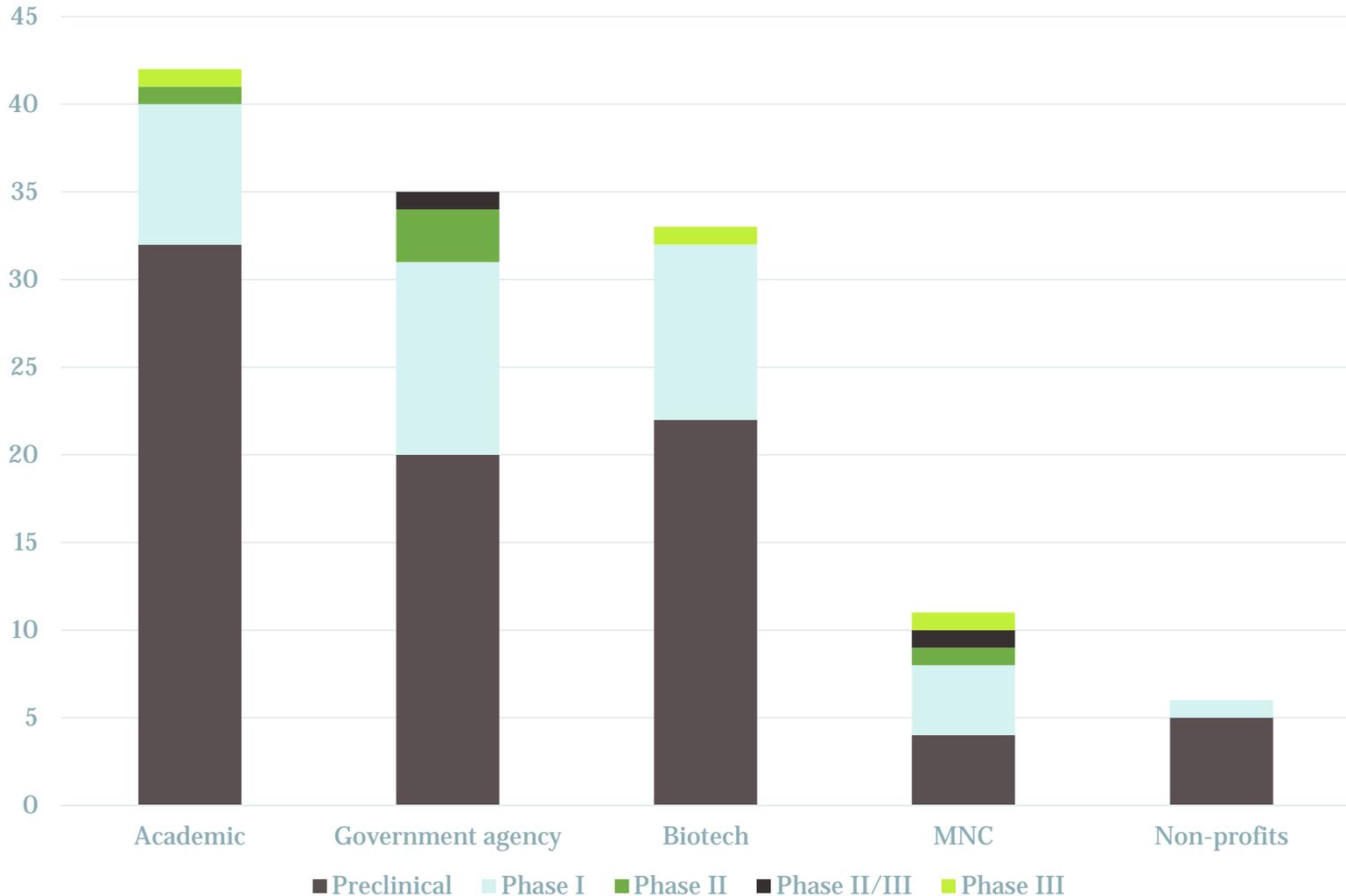
Clinical & regulatory pathways are not easily adaptable to epidemic contexts

4

Incentives are lacking to motivate greater industry engagement

Vaccine pipelines

FIGURE: VACCINE PIPELINES FOR PRIORITY PATHOGENS INCLUDED IN THE WHO R&D BLUEPRINT LIST AS AT MID- 2016



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

Vision

*Vaccines contributing
to preventing outbreaks
from becoming
humanitarian crises*

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

Strategic objectives

1

Preparedness

2

Response speed

3

Market predictability

4

Equity

CEPI's Two Roles



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

Approach

Gap-filling role

1. **Advance new vaccines** through late preclinical studies to proof of concept and safety in humans, and
2. Develop **platforms** that can be rapidly deployed against known and unknown pathogens.

CEPI's operating principles

1

Equitable access

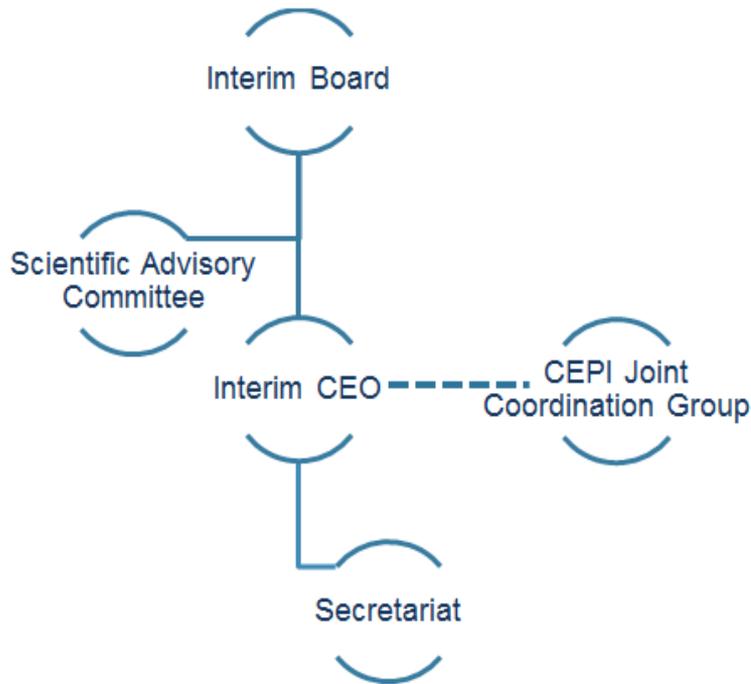
2

Cost coverage

3

Shared benefits

Organizational Setup: Startup Phase



- Founding Partners are the Gates Foundation, Wellcome Trust, Department of Biotechnology of India, Government of Norway, and World Economic Forum
- Independent legal entity; 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
- The permanent organizational structure and governance will be made by the CEPI Interim Board prior to launch
- 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 LSHTM

Jane Halton

Permanent Secretary
Department of Finance, Australia

Tore Godal

Special Adviser on Global Health
MFA, Norway

Christopher Whitty

Chief Scientific Adviser
Department of Health, UK

Kesetebirhan Admasu

Minister of Health, Ethiopia

Jeremy Farrar

Director, Wellcome Trust

Trevor Mundel

President Global Health
Division
The Bill & Melinda Gates
Foundation

Adar Poonawalla

CEO and Executive Director
Serum Institute of India

Nima Farzan

President and CEO
PAXVAX INC.

Julie Gerberding

Executive Vice President
Merck

Moncef Slaoui

Chairman of vaccines
GSK

Joanne Liu

International President
Medecins sans Frontieres

Victor Dzau

President of the Institute of
Medicine
National Academy of
Sciences

Arnaud Bernaert

Head of Global Health and
Healthcare Industries
World Economic Forum

Ruxandra Draghia-Akli

Deputy director-general of
DG RTD, EC

Eduardo de Azeredo

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

Yah Zolia

Deputy Minister of Health and
Social Welfare, Liberia

Observers

Marie-Paule Kieny

Assistant Director-General
World Health Organization

Mark Feinberg (Chair of SAC)

President & Chief Executive
Officer, IAVI

Peggy Hamburg (Chair of JCG)

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

Chery 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

Jesse Goodman
Georgetown University

Kathleen Neuzil
University of Maryland

James Robinson
James Robinson Biologics
Consulting

Maharaj Kishan Bhan
JIPMER

Peter Smith
London School of Hygiene and
Tropical Medicine

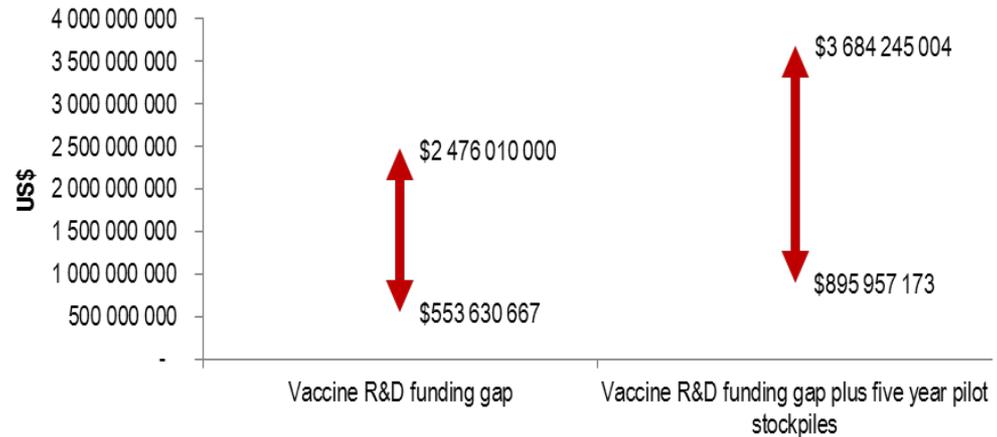
Rick Bright
Biomedical Advanced Research
and Development Authority
(BARDA)

Stanley Plotkin
VaxConsult

Subhash Kapre
Inventprise

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.

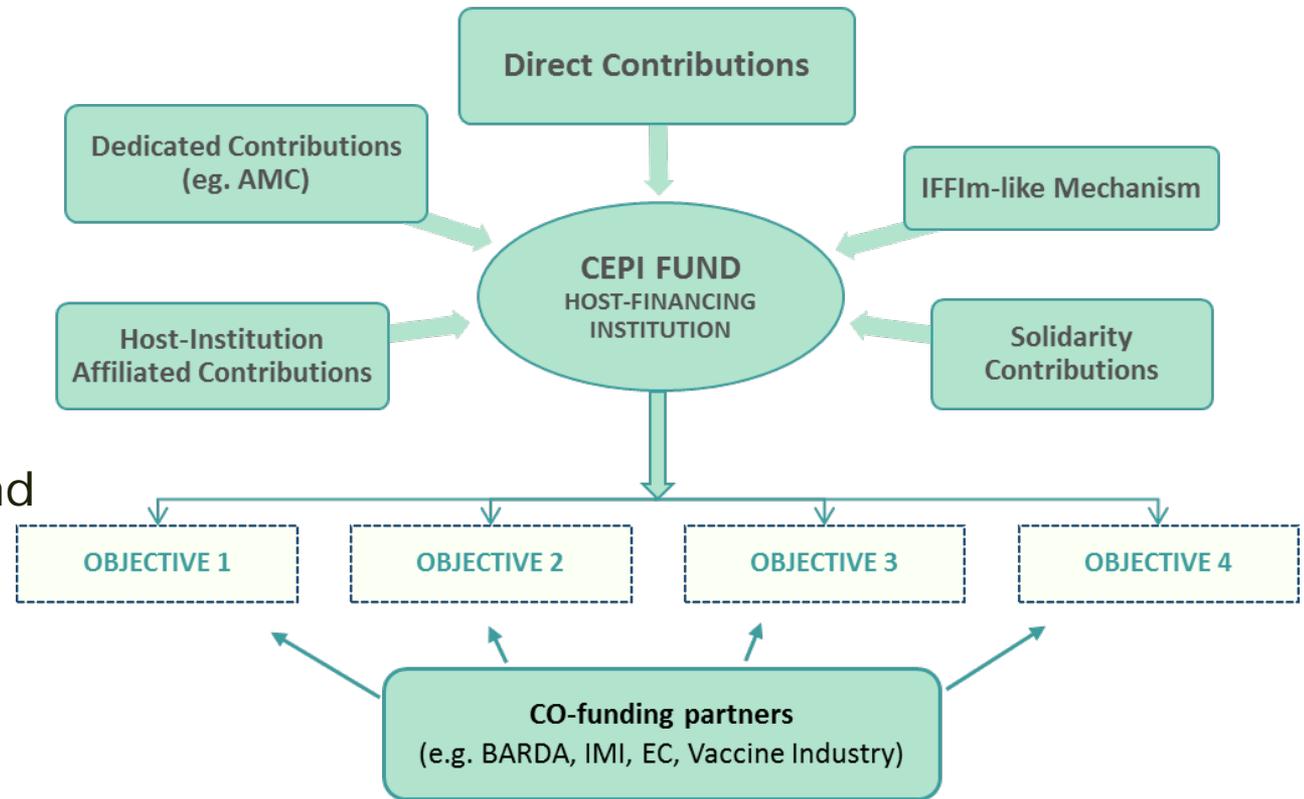
* Details on cost estimates and assumptions are available upon request.

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



CEPI Partnership Models

VACCINE INDUSTRY

- **Aligned contributions** from industry and other R&D partners, including staff support, access to IP, and use of vaccine production lines that will significantly reduce CEPI's overall costs and production timelines.

INTERNATIONAL DONORS

- **Direct donor contributions** through multi-year grants and innovative financing mechanisms like IFFIm, which will complement indirect support through alignment on domestic R&D investments and regulatory policies.

DEVELOPING COUNTRIES

- **CEPI's Solidarity Fund** will channel tiered, equitable contributions from affected countries that will benefit from CEPI's 'insurance policy' against future pandemics emergencies. Solidarity Fund partners will also contribute and benefit through advance coordination on clinical trial arrangements.

Next steps

→ Oct → Nov → Dec → Jan 2017

Launch Partnership



Scientific Advisory Committee Meeting, 20 and 21 October



Joint Coordination Group Meeting, 18 November 2016



Secure initial commitments of CEPI participation and contribution

2nd Interim Board Meeting in India 16 December 2016



Lead funders to launch CEPI and call for additional participation at the Annual Meeting at Davos, January 2017