CEPI
NEW VACCINES FOR A SAFER WORLD

Frederik Kristensen, MD, MBA/MPH
Senior Medical Officer
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The challenge of epidemics
Calls for global action

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.
CEPI - January - June

High Level Meeting Davos 21 January

Task Team Meeting, Oslo 6-7 April

Task Team Teleconferences

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

Academic | Government agency | Biotech | MNC | Non-profits
--- | --- | --- | --- | ---
Preclinical | Phase I | Phase II | Phase II/III | Phase III

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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 bottleneck in epidemic events. Major vaccine manufacturers can drive pipelines forward
New partnership models needed

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

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

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

CEPI’s role as a coordinator involves significant focus by others.

CEPI’s role as a funder also involves significant focus by others.

## Phase

<table>
<thead>
<tr>
<th>Phase</th>
<th>1 Discovery</th>
<th>2 Development/Licensure</th>
<th>3 Manufacturing</th>
<th>4 Delivery/Stockpiling</th>
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<tbody>
<tr>
<td><strong>Current Stakeholders</strong></td>
<td>• Academia • Governments • WT/NIH • GLOPID-R • Industry • Regulators • Biotech</td>
<td>• Industry • National Governments • Regulators • Bill and Melinda Gates Foundation • BARDA/DTRA etc. • WHO • Biotech • PDPs</td>
<td>• Industry • BARDA • CMOs • Regulators • National Governments • WHO • GHIF</td>
<td>• GAVI • UNICEF • PAHO • National Governments • WHO • Industry • Pandemic Emergency Facility (World Bank) • WHO Contingency Fund</td>
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**CEPI**

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14
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

Kesetebrhan 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

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

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