Preparing for the inevitable: the R&D Blueprint

With more frequent travel, globalized trade and greater interconnectedness between countries, infectious disease outbreaks of international concern are becoming as inevitable as they remain unpredictable.
Problem statement: Ebola R&D response

Funding available

1st Vaccine Phase 1 trial
1st Drug trial
1st Convalescent Plasma trial
1st Vaccine Efficacy trial
Phase3 Ring Trial

Research Response in West Africa
“...welcomed the development of a **Blueprint** — in consultation with Member States and relevant stakeholders— for **accelerating research and development** in epidemics where there are no, or insufficient, preventive, and curative solutions”
Two key and complementary objectives for the Blueprint

- Better R&D preparedness for diseases that might lead to epidemics
  - Portfolio of promising experimental medical technologies with results available from Phase 1 safety trials in man

- Better readiness to promptly conduct R&D during an emergency
  - Mechanisms to improve global coordination
Three main approaches designed to identify key actions required to achieve the objectives

- Coordination and establishing an enabling environment
- Accelerating R&D processes
- Developing new norms and standards tailored to the epidemic context
First Blueprint early deliverables
The initial list of disease priorities needing urgent R&D attention comprises: Crimean Congo haemorrhagic fever, Ebola virus disease and Marburg, Lassa fever, MERS and SARS coronavirus diseases, Nipah and Rift Valley fever. Chikungunya, severe fever with thrombocytopenia syndrome, and Zika designated as "serious". The list will be reviewed annually or when new diseases emerge.
Public consultation on ideas for potential platforms to support development and production of health technologies for priority infectious diseases with epidemic potential

The epidemic of Ebola in West Africa showed that the world is unable to develop effective interventions in a timely manner for control of severe emerging infectious diseases using current approaches to vaccine, drug and diagnostics development.

The World Health Organization (WHO) is inviting submission of structured ideas on how to improve R&D readiness for priority infectious disease threats. Specifically, propositions are requested for flexible development and production platform technologies.

Submission of platform ideas by Friday 5 February 2016, 17:00 Geneva time.

Read more...
Development of R&D Roadmaps for priority pathogens

Roadmaps as a Vehicle for Addressing Large-Scale Public Health Challenges
Governance and coordination
In the event of a public health emergency (as defined by public health officials), information with immediate implications for public health should be disseminated without concern that this will preclude subsequent consideration for publication in a journal.

An exception to this principle may occur when information that has immediate implications for public health needs to be disseminated, but when possible, early distribution of findings before publication should be discussed with and agreed upon by the editor in advance.

Sharing with public media, government agencies, or manufacturers the scientific information described in a paper or a letter to the editor that has been accepted but not yet published violates the policies of many journals. Such reporting may be warranted when the paper or letter describes major therapeutic advances; reportable diseases; or...
Monitoring and evaluation Framework

In the event of an Emergency

W31: Mechanisms to prioritize pathogens for research and product development
W32: Gap analysis and identification of research priorities for the priority diseases
W33: Organization, coordination, and strengthening of capacities
W34: Assessment of preparedness level and impact of interventions
W35: Funding options for preparedness and emergency responses

Prepared work needed to develop new technologies, e.g. stage 1 clinical trials conducted

Mechanisms established to collaborate over response to MERS and other prioritized pathogens

A system for funding R&D exists characterized by higher levels of funding and more coordination

WHA

Public health emergencies due to prioritized pathogens can be preempted

Responses to public health emergencies caused by prioritized pathogens are faster and more effective

Monitoring and evaluation of response to outbreak

Procedures in place to rapidly evaluate new technologies in emergency while maintaining ethical standards

Stakeholders have the capacity needed to respond to the outbreak in a way that is appropriate and rapid

Coordinated funding needed for effective R&D of technology needed to control the outbreak

Plan and system in place for the transition from preparedness to action in the event of an outbreak

ASSUMPTION. WHO coordinates blueprint work-streams effectively with good communication between work streams

R&D road maps for other pathogens

R&D platforms established and functioning

The technologies (see footnote 2) that are needed to diagnose, treat and prevent diseases caused by prioritized pathogens are more available.

The world is unable to develop effective interventions in a timely manner for control of some infectious diseases using current approaches particularly when they (i) are sporadic or unpredictable; (ii) occur largely in low and middle income countries; and (iii) are new diseases

The Problem
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.
Options for strengthening information-sharing on diagnostic, preventive and therapeutic products and for enhancing WHO’s capacity to facilitate access to these products, including the establishment of a global database, starting with haemorrhagic fevers

Report by the Secretariat

BACKGROUND

1. In resolution EBSS3.R1, adopted in January 2015 by the Executive Board at its special session on the Ebola emergency,¹ the Director-General was requested to provide to the Executive Board at its
R&D Blueprint response to Zika

- 1 Feb 2016: PHEIC declared for microcephaly and neurological disorders
- 4 Feb: 1st R&D Blueprint meeting on Zika
- Feb - March:
  - Mapping of Zika product pipeline
  - 7-9 March: Global consultation to discuss accelerated product development and evaluation
  - Target Product Profiles (TPPs) for Diagnostics & Vaccine under development
  - Dx developers invited to submit their products to the WHO EUAL procedure
  - Work underway to prepare reference standards underway
New technologies are not sufficient for disease control and response

• Control and response to severe emerging diseases like Zika demands more than innovative products
• Requires systems for surveillance and detection of unusual events
• Requires systems to deliver antenatal care, access to hospitals able to manage neurological complications, access to services for long-term impacts, e.g., disability, etc.
NEXT TIME???

Efficacy testing

1st Phase 1 trial

1st Drug trial
1st Convalescent Plasma trial

1st Dx-PCR

1st Vaccine Efficacy trial

Phase3 Ring Trial

1st Dx-RDT

Funding available

# of Ebola cases

Jan-14  Feb  Mar  Apr  May  Jun  Jul  Aug  Sep  Oct  Nov  Dec

0  500  1000  1500  2000  2500  3000  3500  4000

OEM-CEWG, 2-4 May 2016

World Health Organization