Preparedness for the inevitable: overcoming obstacles to a timely and effective R&D response

The WHO Blueprint Team
Context of the Blueprint

WHO Executive Board¹ (January 2015)

WHO Summit on Ebola R&D (May 2015)

World Health Assembly (May 2015)

¹Special Session on Ebola, 25 January, 2015
“….welcomed the development of a Blueprint—in consultation with Member States and relevant stakeholders—for accelerating research and development in epidemics or other health emergency situations where there are no, or insufficient, preventive, and curative solutions, taking into account other relevant work-streams within WHO”
Objectives

Preempt development of public health emergencies:

- Implement roadmap for R&D preparedness,
- Enable prompt roll-out of emergency R&D plan during outbreaks of highly infectious pathogens
Key milestones

September 2015:
Submit summary to the UNSG High Level Panel on Global Response to Health Crises

May 2016:
Blueprint endorsed by WHA
Five workstreams

1. Mechanism to prioritize pathogens for research and product development

2. R&D preparedness: gap analysis and identification of research priorities for the priority diseases
   - MERS Roadmap

3. Organization of stakeholders and strengthening of capacities

4. M&E of preparedness level and of interventions

5. Funding options for preparedness and emergency response
Blueprint activities and functions

R&D Blueprint

- Mechanism to prioritize pathogens for research and product development
- R&D preparedness: gap analysis and identification of research priorities
- Organization, coordination of stakeholders and strengthening of capacities
- Assessment of preparedness & impact of interventions
- Funding options for preparedness and emergency response

Legal and regulatory affairs; Ethics
Organization of blueprint secretariat

Lead: Marie-Paule Kieny
Coordinator: Bernadette Murgue

Work-stream leaders:
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WS-2: David Wood

MERS R&D Roadmap: Vasee Moorthy
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1. Biobanking: 6-7 August 2015; Freetown
2. Data sharing: 1-2 September; Geneva
3. Pre-clinical models: October; Washington DC
4. Clinical trial design: October; Welcome Trust
5. Funding models & governance: 29-30 October; Oslo
6. Biobanking: November; Geneva
Blue print – Work streams

- Select pathogens
- Prioritize research
- Assess preparedness
- Explore funding options
- Coordinate and enhance capacity
1. Mechanism to prioritize pathogens for research and product development

**Determination of R&D priorities – pathogens**

- develop criteria and review process to assess
  - severe emerging epidemic-prone diseases with potential to cause a public health emergency
  - new pathogens which may emerge

**Criteria will consider risks and available tools**

**Define a mechanism to trigger and initiate an urgent research response during a public health emergency**
2. R&D preparedness: gap analysis and identification of research priorities

Identify and facilitate the "background" research required for preparedness for future events

- must be performed in the inter-epidemic period
- focus on basic research, proof-of-principle studies, preclinical and early phase clinical studies, behavioral research
- identify technologies with broad potential applications
- develop strategies for use of existing and innovative health technologies
- promote regulatory science to develop adapted regulatory pathways

Technical outputs will include, e.g.:
- Target product profiles,
- Reference standards and preparations,
- Regulatory specifications
Pathogen-specific case study of a fully developed R&D roadmap

This will:

Articulate strategic goals for preparedness efforts

Development of point of care diagnostics

Pre-positioning of candidate preventives and/or therapeutics for use in emergency

Express agreed priority activities for initiation during 2016 in areas of research, product development, and key capacities to achieve above objectives

- Strengthened assays, and preclinical models
- Validation of platform technologies for vaccine

Identify potential partners to implement the roadmap

Case study: MERS CoV?
3. Organization, coordination of stakeholders and strengthening of capacities

Investigate stakeholder engagement-plan and governance-structure to promote collaboration with national and International actors:

- How to ensure national leadership and ownership?
- International coordination? Who should convene?

Reach consensus on various frameworks for collaboration

- Data sharing, Biobanking, Standard MTAs, agreements for clinical trial consortia, agreements with manufacturer, ToRs for national research oversight committees, management of intellectual property, clinical trials protocols, etc.

Prioritize research capacity strengthening investments to facilitate engagement of LMICs

Identify networks and centres to engage in future work
map current and potential resources and sites encourage further networking connections

Develop guidance on good practices for community engagement
4. Assessment of preparedness and impact of interventions

Develop procedures to evaluate and monitor:

- level of preparedness (enabling environment)
- impact of interventions on next emergency

Identify key evaluation parameters e.g. inclusiveness, effectiveness, impact, sustainability.
5. Funding options for preparedness and emergency response

Explore options for R&D preparedness funding e.g.

- Pooled resources in R&D fund(s), e.g. the "CEWG voluntary fund" managed by TDR
- Joint planning with individual implementation by different entities
- GLOPID model
- Financing of product R&D hubs (e.g. GSK proposal for vaccines)
- Options for better coordination of existing funds
- Innovative financing models

What financing for R&D during an emergency e.g.

- Earmarked contribution from WHO contingency funds, from new World Bank finance facility