A Blueprint for research & development

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Preparing for the inevitable
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
Leveraging lessons learnt for an effective R&D preparedness strategy

Current, market-driven models of medical R&D do not cater for the application of new or improved technologies for diseases that are sporadic or unpredictable.

The international community needs to invest to improve our ability to respond to new threats and prepare itself with a novel R&D paradigm to address future epidemics.

WHO has the mandate and the capacity to coordinate and encourage a preparedness strategy.
Two Key and complementary objectives

to develop and implement a roadmap for R&D preparedness for priority pathogens, and
to enable roll-out of an emergency R&D response as early and as efficiently as possible
A Blueprint for research and development: a paradigm shift - 1

It aims to reduce the time lag between the declaration of an international public health emergency and the availability of effective medical technologies that can be used to save lives and avert crisis.

The Blueprint will encourage research to produce diagnostic tools and to generate safety data from Phase 1 studies in man (vaccines and treatments) for the most promising experimental products for priority infectious diseases before the outset of an outbreak.
A Blueprint for research and development: a paradigm shift - 2

The R&D Blueprint also aims to map existing knowledge and good practices, identify gaps and establish an enabling environment in affected countries.
How will the Blueprint be developed?

Driven by scientific knowledge

An inclusive process with a clear mandate and defined milestones

Building on the efforts of others

A collaborative effort with Member States and other relevant stakeholders
Five work-streams

designed to identify key actions required to achieve the objectives

1. Prioritisation of pathogens
2. Identification of research priorities
3. Coordination of stakeholders & expansion of capacity
4. Assessment of preparedness and impact of intervention
5. Development of innovative funding options
What concrete benefits are expected from the implementation of the R&D Blueprint?

Better R&D preparedness for diseases which might lead to epidemics

- Identification of the 5 (to 10) top priority diseases
- Mapping of pipelines for medical technologies
- List of optimal attributes for medical technologies (Target Product Profiles)
- Diagnostic tools to identify emerging outbreaks due to top priority diseases
- Innovative approaches to leverage industry’s expertise (through R&D and production platforms)
- Mechanisms to improve global coordination
- A portfolio of promising experimental medical technologies (e.g. treatments and vaccines) for the top priority diseases, with results available from Phase 1 safety trials in man
What concrete benefits are expected from the implementation of the R&D Blueprint?

Better readiness to promptly conduct R&D during an emergency

- Mechanisms to improve global coordination
- Identification of pathways to produce, procure, deliver and use priority health technologies during an emergency
- Better and stronger ethical and regulatory capacity in low- and middle-income countries
- Mapped and strengthened networks of clinical trial centres and experts – both in the North and the South
- A toolbox of generic protocols and agreements
- Solutions for liability and indemnification challenges for manufacturers
- Options to take into consideration the Nagoya Protocol obligations with a view to facilitate sharing of samples and accelerating detection of infectious threats

Oslo Workstream 5 consultation | October 2015
Initial milestones achieved

May 11-12, 2015 - Ebola R&D Summit: held at WHO brought together many of the key actors in the Ebola R&D response to identify main bottlenecks encountered.

August 6-7, 2015 - Consultation on Biobanking: held in Sierra Leone, to discuss best practices for the storage and research of bio-samples collected during outbreaks. Agreement was reached that these should be 'global public goods' for the purposes of medical research.

A meeting on data and results sharing, held in Geneva on 1-2 September 2015, achieved broad consensus from international researchers, funders and sciences journal editors that the timely sharing of information on epidemiological data and research carried out during emergencies must be a cornerstone of the blueprint.
WHO is organizing a series of consultation to address some of the already identified challenges.

- **20-23 October, 2015**
  A meeting on preclinical models for novel vaccines

- **20 October, 2015**
  A consultation on clinical trials' design aiming to document experiences, with the Wellcome Trust.

- **29-30 October, 2015**
  A consultation on funding mechanisms for R&D that can be leveraged for the R&D blueprint, with the

- **May, 2016**
  The R&D blueprint will be presented to the World Health Assembly for consideration by WHO Member States

In the coming months, WHO will continue to support R&D efforts on Ebola to bring in new evidence and conclusions, which will in turn inform the development of the R&D blueprint.