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Preparing for the inevitable

With more frequent travel, globalised 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 and
WHO has the mandate and the capacity to coordinate and encourage a preparedness strategy.

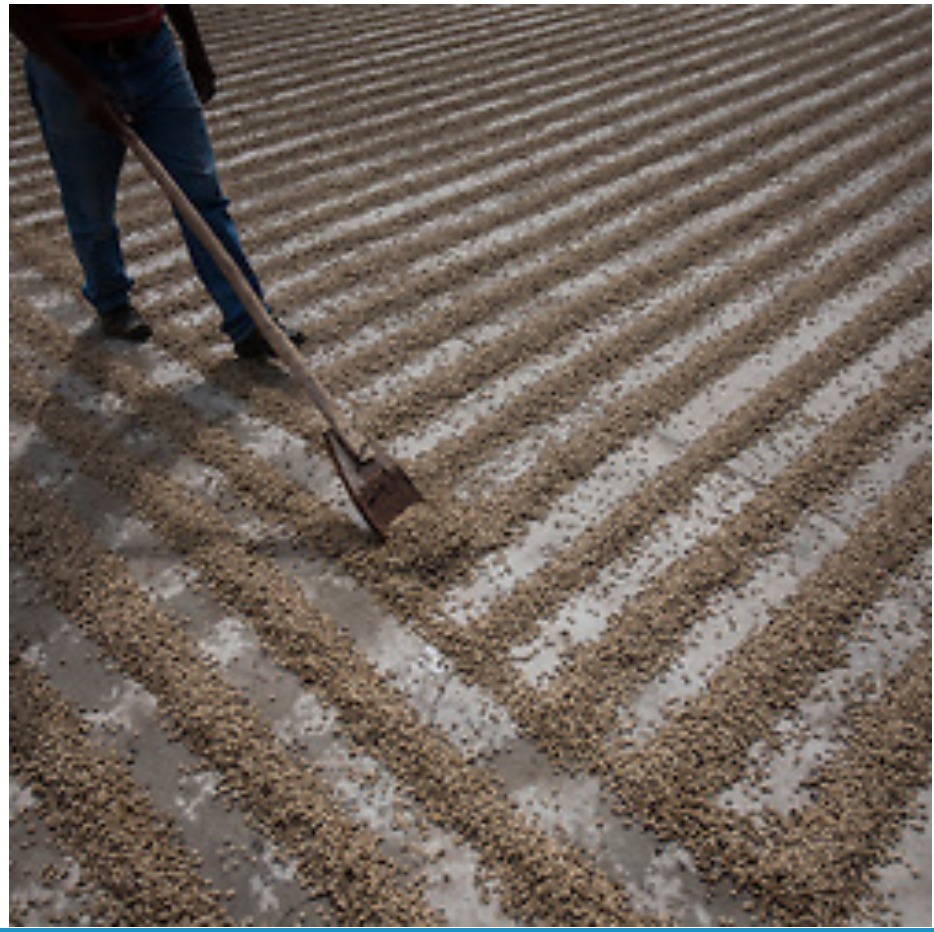
A blueprint for research and development: a paradigm shift

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 generate safety data from Phase 1 studies in man 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

The R&D Blueprint aims to map existing knowledge and good practices, identify gaps and establish a roadmap for R&D preparedness, through 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

Key objectives
during future public health emergencies due to highly infectious pathogens

to develop and implement a roadmap for R&D preparedness, and

to enable roll-out of an emergency R&D plan as early and as efficiently as possible

WHO and international partners are poised to address the challenge of developing and implementing the R&D blueprint

R&D can and must be accelerated.

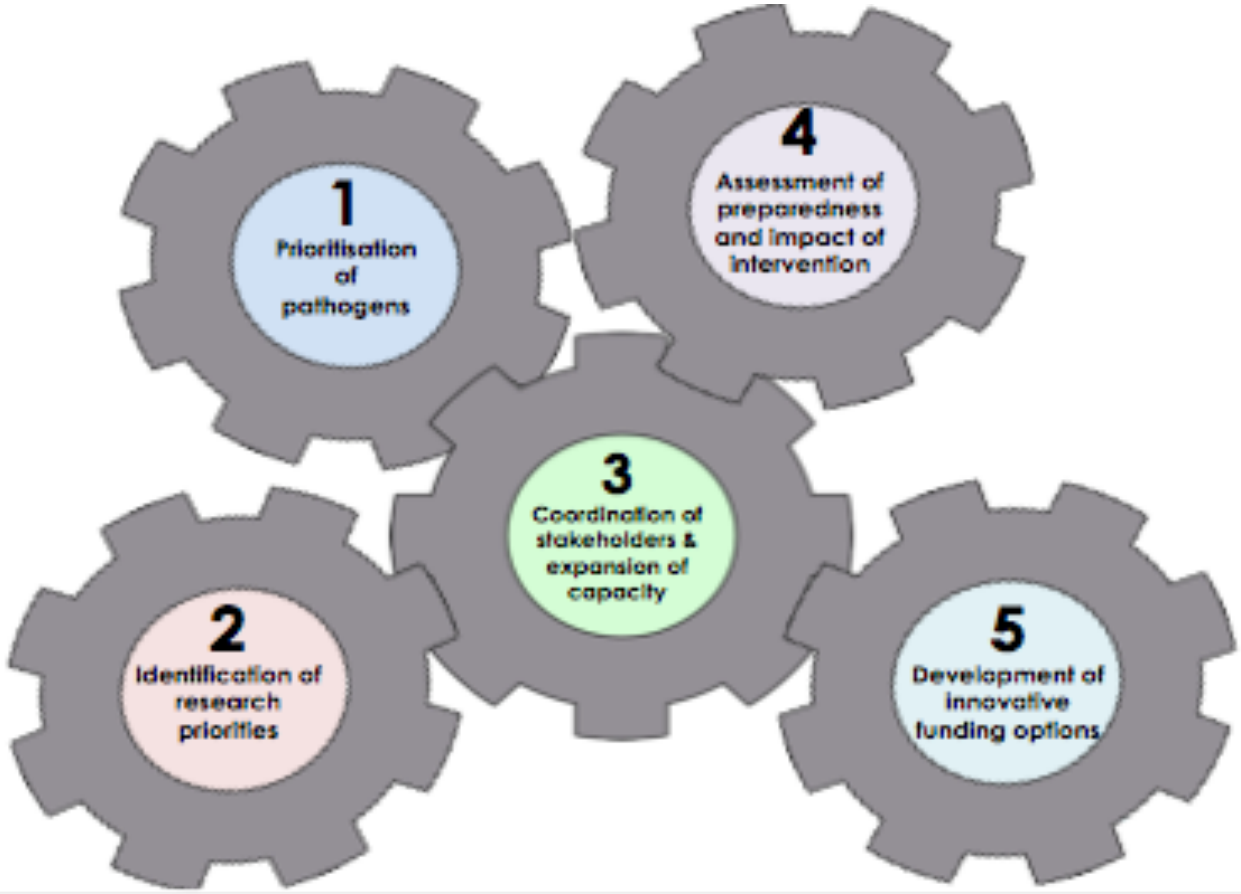
The research gaps must be anticipated and addressed before the epidemic occurs

Global experts and stakeholders have begun to contribute to outline the blueprint

An outline of the blueprint already exists

Five work-streams

designed to identify key actions required to achieve the objectives



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.

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 organising 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.