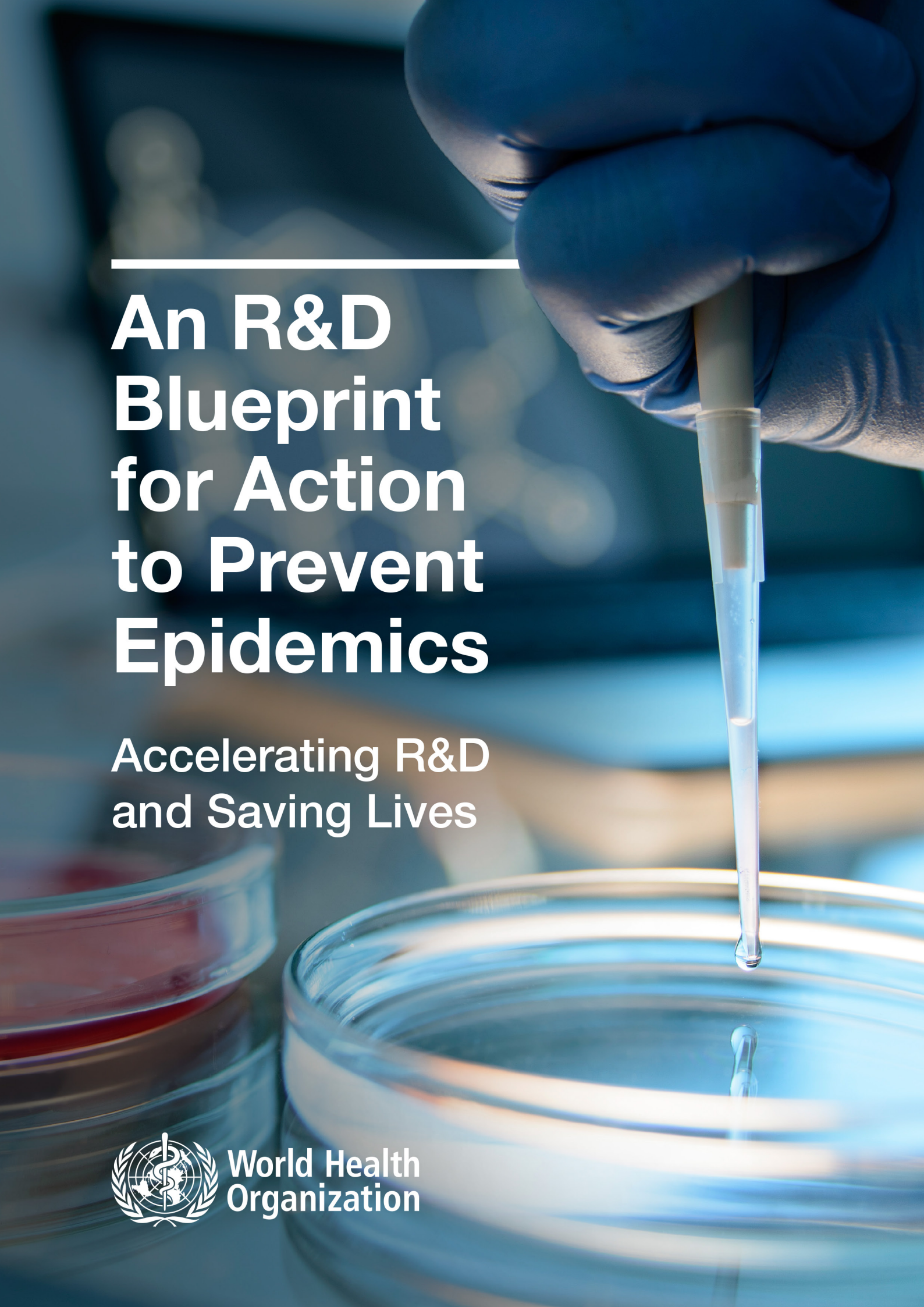




An R&D Blueprint for Action to Prevent Epidemics

Accelerating R&D
and Saving Lives



World Health
Organization

Ebola broke out of its rural seclusion and into West African cities in a matter of weeks.

The Middle East Respiratory Syndrome (MERS) virus spread to 26 countries in three years and is still on the move.

SARS travelled by plane across hemispheres to cause hundreds of deaths and cost billions of dollars in just six months.

CREATING A GLOBAL STRATEGY FOR Epidemic Preparedness

With more frequent travel, globalised trade and greater interconnectedness between countries, infectious disease outbreaks of international concern are becoming inevitable, and they remain unpredictable. When faced with diseases for which there are few or no medical countermeasures, massive chaos and loss of life can ensue.

The World Health Organization (WHO) is spearheading a global movement to avert full-blown epidemics by making Research and Development

(R&D) outbreak-ready. Together, we can spot emerging epidemics and stop them before they spiral out of control. We can save lives.

While conventional surveillance, contact tracing and containment measures remain cornerstones of a health emergency response, better understanding of highly infectious pathogens, and a repertoire of effective health technologies could be the key to pre-empting full-blown epidemics, and limiting their human, social and economic losses.

The Ebola epidemic taught us that we can move faster to try to curb the spread of disease. By acting together based on a coordinated plan, we can accelerate the development of the vaccines, drugs, diagnostics and delivery systems needed to short-circuit emerging health threats.



“ It is essential that we collaborate to build the capacity to rapidly evaluate investigational drugs and vaccines that meet the highest scientific and ethical standards, protect patients’ welfare, and generate actionable results.

– Dr Luciana BORIO, Food and Drug Administration, USA ”

An R&D Blueprint

FOR ACTION TO PREVENT EPIDEMICS

At the request of its 194 Member States in May 2015, the World Health Organization (WHO) has convened a broad coalition of experts to develop an R&D Blueprint for Action to Prevent Epidemics.

The R&D Blueprint will present options to reduce the time lag between the identification of a nascent outbreak and approval of the most advanced products that can be used to save lives and stop larger crises.

The R&D Blueprint will map the knowledge already

accrued through efforts of research and development stakeholders, as well as remaining gaps. It will identify the main activities needed to promote strategic research in advance of and during outbreaks. As we saw with Ebola, we can compress R&D timelines from a decade or longer, to less than a single year.

WHO expert teams, an international scientific advisory board, and partners engaged through global forums are collaborating to formulate this novel R&D model. Already,

several consultations have been held among public health agencies, industry, researchers, social scientists and governments. They have identified major bottlenecks to international collaboration; agreed upon basic data-sharing principles; and explored innovative clinical trial models.

Intensive work will be carried out over the next 10 months to ensure an R&D preparedness plan is ready by the time the next unpredictable outbreak hits.

Learning from Ebola

TO PREPARE FOR THE NEXT EPIDEMIC: ACCELERATED R&D

When the Ebola outbreak in West Africa erupted in the spring of 2014, the medical community was ill-prepared to cope. There were no vaccines, few diagnostics, no drugs for treatment, and few medical teams and trained responders. With no public education in place, fear raced ahead of the virus.

As the crisis quickly deepened, the international community responded with urgency. Over a period of 10 months, WHO-facilitated collaborations achieved unprecedented results:



“ To save lives we need to accelerate the development of drugs, vaccines and diagnostics in response to epidemics of emerging pathogens.

– Pr Lucille BLUMBERG,
National Institute for Communicable Diseases, South Africa **”**



The testing of multiple vaccines, leading to at least one that appears to be safe and effective against Ebola;



Release of 13 diagnostic tools that can detect Ebola virus in a matter of hours rather than days, and 24 testing laboratories;



Accelerated development of novel therapies and testing of existing drugs.

“ If we are to take the lessons from Ebola to heart, we need to improve how we develop the full range of R&D tools to detect, treat and control these diseases, as well as to determine what new threats are inevitably lurking around the corner.

– Dr Jeremy FARRAR, Wellcome Trust, UK ”

As convener, WHO enabled complex communication among many partners and facilitated the simultaneous testing of different vaccines, drugs and diagnostics. Emergency WHO review assured the quality of these new medical tools, and enabled those that were approved to quickly reach people suffering from Ebola.

Gaps in R&D Practice

It is clear today that there is insufficient research on epidemic-prone diseases and gaps in R&D practice. During the Ebola epidemic, there was a need for the following:

- Platforms that expedite vaccine clinical trials, drug testing and data sharing;
- A broader R&D scope that encompassed, for example, better understanding of the disease, animal models and personal protective equipment;
- Community engagement plans from the outset; and
- Funding sources that could be quickly activated.

Even as WHO and its partners continue to learn from Ebola, we are applying these lessons to the R&D Blueprint so that next time, we can be better prepared.

We should never again experience a crisis like the West Africa Ebola epidemic.

Five Work Streams

TO MAP OUR LINE OF DEFENCE

The R&D Blueprint builds on the efforts of international partners and communities through five work streams:

01

Prioritise Global Infectious Disease Threats

Identify the top global disease threats on which to focus initial R&D efforts;

Develop a review process to reassess priorities in light of changing circumstances; and

Plan for the transition from preparedness to action in the event of an outbreak.

02

Identify Research Priorities

Create a prototype R&D roadmap for MERS, identifying the basic and applied research, and health technologies needed to contain this emerging threat;

Based on this prototype, develop roadmaps for all priority diseases and for cross-cutting issues such as regulatory science and social science research; and

Agree on standard procedures to rapidly evaluate new health technologies in emergencies while maintaining the highest scientific and ethical standards.

“ We should never again experience a crisis like the West Africa Ebola Epidemic. The world needs a more dynamic approach to R&D for life-saving drugs, vaccines and diagnostics.

– Dr Mimi DARKO, Food and Drugs Authority, Ghana ”



03 Global Coordination & Expansion of Capacity

Develop organisational frameworks for the coordination of national and international actors and inclusion of scientists in low- and middle-income countries as equal partners;

Build the capability to conduct clinical trials for vaccines and therapeutics against emerging disease threats in low- and middle-income countries; and

Agree on the open sharing of data, the fair sharing of biological samples for research, and manufacturing plans for new health products.

04 Continuous Assessment

Develop a plan to evaluate the impact of the R&D Blueprint and continuously improve the Blueprint;

Create a high-level checklist to monitor preparedness and impact, using MERS as an example; and

Conduct the first assessment of the presence of supportive conditions for R&D in 2017, and evaluate the impact of the R&D Blueprint when the next outbreak occurs.

05 Mobilise Funding

Explore funding models for R&D preparedness and response.

The WHO team has developed a comprehensive work schedule that includes a series of expert consultations and aggressive deadlines for deliverables related to each of the five work streams, with the final Blueprint due to the 69th World Health Assembly in May 2016.

“ Our ability to stand up to new global disease threats is crucial to achieving the Sustainable Development Goals. As we saw with Ebola, an uncontained epidemic can wipe out decades of progress in health and economic development. We cannot afford to let that happen.

– Dr John-Arne ROTTINGEN, Norwegian Institute of Public Health, Norway ”



The Ebola R&D response awakens hope. There are many diseases with the potential to trigger chaos and human suffering, but we have learned how to jumpstart research and development to stem the tide of suffering from these diseases. Please join the global effort to develop an R&D Blueprint for Action to Prevent Epidemics.



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WHO's Assistant Director General for Health Systems and Innovation leads overall development of the R&D Blueprint, and a Scientific Advisory Group reviews and guides the work carried out by five teams, each devoted to one work stream. In addition, WHO is convening a series of global consultations to address specific aspects of the R&D agenda.