An R&D Blueprint for Action to Prevent Epidemics

Accelerating R&D and Saving Lives

Update 2017

World Health Organization

Zika virus cases have been reported in 67 territories since 2015.

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

R&D Preparedness and Response

With more frequent travel, globalized 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 coalition 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 human, social and economic losses.

The Ebola epidemic taught us that we can and must advance the development of new medical products to detect, prevent and treat infectious diseases with epidemic potential. By acting together based on a coordinated plan, we can accelerate the development of vaccines, drugs, diagnostics, vector control tools and delivery systems needed to control emerging health threats. We can also increase our knowledge of how best to engage with affected communities.

> It is a priority to support expansion of capacity to implement adequate study designs and to develop guidance and tools to facilitate collaboration and efficient decision-making in case of an outbreak.
>
> – Dr Marco CAVALERI, European Medicines Agency, UK

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 network of experts to develop an R&D Blueprint for Action to Prevent Epidemics.

The R&D Blueprint has made important strides forward since then. It has constructed a preparedness plan 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 is mapping the knowledge already accrued through efforts of research and development stakeholders, as well as the remaining gaps. It has identified 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.

A Scientific Advisory Group reviews and guides the work carried out by the WHO expert teams. In addition, WHO is convening a series of global consultations to address specific aspects of the R&D agenda. The Blueprint also works with partners such as the Coalition for Epidemic Preparedness Innovations (CEPI) and the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R). Several tools have been developed and a priority list of pathogens has been created to focus pre-outbreak R&D.

Intensive work is being carried out to ensure an R&D preparedness plan for action is in place to tackle the next unpredictable outbreak.

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:

Testing of several vaccine candidates, resulting in at least one shown to be safe and effective against Ebola;

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

Emergency testing of existing and 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, United Kingdom

As convener, WHO enabled complex communication among many partners and facilitated the simultaneous testing of different vaccines, drugs and diagnostics.

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.

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

– Professor Lucille BLUMBERG,
National Institute for Communicable Diseases, South Africa

PREPAREDNESS

THREE APPROACHES TO MAP OUR LINE OF DEFENCE

The R&D Blueprint builds on the efforts of international partners and communities through three approaches:

01

Improving Coordination & Fostering an Enabling Environment

Build an effective coordination framework;

Outline innovative transparent and aligned funding processes; and

Encourage effective communication among stakeholders.

02

Accelerating R&D Processes

Assess epidemic threats & define priority pathogens;

Develop R&D roadmaps to accelerate evaluation of diagnostics, therapeutics & vaccines; and

Outline appropriate regulatory & ethical pathways.

03

Developing New Norms & Standards Tailored to the Epidemic Context

Support expansion of capacity to implement adequate study designs;

Develop guidance & tools to frame collaborations and exchanges; and

Anticipate evidence needed to inform regulatory review and policy development.

WHO/Sean Hawkey

RESPONSE PLAN

In the event of an outbreak, Blueprint activities will shift from R&D preparedness to an emergency R&D response plan

WHO coordination and planning mechanism to facilitate the implementation of an effective product and non-product research response;

Mobilization of external stakeholders.

The WHO team has developed a comprehensive work schedule that includes the creation of tools and aggressive deadlines for deliverables related to each of the three approaches.

Zika

A TESTING GROUND FOR THE R&D BLUEPRINT

The sudden emergence of the Zika Virus outbreak in the Americas, and its link to microcephaly and neurological disorders, provided an opportunity for the testing of the Blueprint in a real life setting. Initial activities included the development of landscapes on existing research and product development for the disease and a consultation with world experts to identify knowledge gaps and agree on a plan for accelerating product development.

WHO

WHO prioritized R&D activities for diagnostics, vaccines and vector control measures. In April, WHO published target product profiles (TPPs) for Zika virus diagnostic tests, outlining the desired features for these assays to facilitate development and manufacture. A TPP for vaccines aimed at protecting against Zika virus infection and associated congenital syndrome was published in July 2016.

The Emergency Use Assessment and Listing (EUAL) procedure established during the Ebola outbreak to accelerate quality assessments of new products was opened to candidate Zika in vitro diagnostics in early February. To date, two Zika diagnostics have been listed for procurement by UN agencies.

"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

The Ebola R&D response awakened 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.

“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, The Research Council of Norway


"THANK
YOU
SCIENCE!"

WHO/HIS/HIA/17.5

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