Building Resilience Against Outbreaks & Pandemics

Research to identify sustainable solutions

The 3rd Global Research and Innovation Forum
Building Resilience Against Outbreaks & Pandemics

Epidemics, pandemics and how research can help to control them

Ana Maria Henao-Restrepo MD MSc
Lead WHO R&D Blueprint for Epidemics
WHO Health Emergencies Department
The Constitution of WHO states that one of WHO’s key roles is to promote, conduct, and coordinate research in the field of health.

In May 2015, the 68th World Health Assembly welcomed the development of an R&D Blueprint for Epidemics, in consultation with Member States and relevant stakeholders, for accelerating research and development (R&D) in epidemics or health emergency situations where there are no, or insufficient, preventive and therapeutic medical countermeasures.
Today, we stand at a crossroads in shaping global resilience, preparedness, and response strategies for the next major epidemic or pandemic.

It is critical that we assimilate the lessons learned from the pandemic and harness the wealth of research knowledge, platforms and collaborative frameworks forged during the COVID-19 crisis to help protect the world from future threats.
Coordinating and accelerating global research must promote universal values

Regarding a collaborative effort to ensure access to MCMs, some have emphasized the importance of speed and sometimes cost in responding to future pandemics.

It is equally important to take a broader view that recognizes the primary importance of quality, equity in availability, and trust in the products’ safety and efficacy.
Sometimes dreams become reality...

News of Ebola vaccine reaches a rural village in Liberia in 2015

Local photographer Alphanso Appleton #thankyouscience
In 2014-16, an unprecedented and collaborative WHO-led effort built on a number of candidate Ebola vaccines that could enter clinical trials

A series of international consultations and activities were led by WHO as a contribution to the unprecedented global efforts to develop and assess an Ebola vaccine.

Panel discussion on ethical considerations for use of unregistered interventions for Ebola virus disease

Summary of the panel discussion
8 August 2014 | Departmental news (Reading time less than a minute 214 words)

The recent treatment of two health workers infected with the Ebola virus with experimental medicine has raised questions about whether medicine that has not been tested and shown to be safe in people should be used in the outbreak, and, given the extremely limited amount of medicine available, if it is used, who should receive it.

A number of interventions have been through the laboratory and animal study phases of development. It is likely that first in man studies will be conducted over the next 2-4 months. It is also likely that the number of doses available for further study and deployment from end 2014 onwards will remain insufficient to meet demand.

On Monday, August 11, WHO is convening a panel discussion of medical ethicists, scientific experts and lay people from affected countries to assess the role of experimental therapies in the Ebola outbreak response.

Issues to be considered include:

- Whether it is ethical to use unregistered interventions with unknown adverse effects for possible treatment or prophylaxis. If it is, what criteria and conditions need to be satisfied before they can be used?

Ebolavirus — An Urgent International Priority

Raju Kamathpathy, M.D., Napo Mara Hemas, Remmyo, M.D., Patricia Font, M.D., Ph.D., David Wood, Ph.D., Christoph De, Ph.D., and Vincent Masienda, M.D., Ph.D.

The Ebola epidemic in West Africa continues to grow, the World Health Organization (WHO) convenes an urgent meeting on September 20 and 21 to assess the efforts under way to reduce deaths and prevent new cases and effective Ebola vaccines as soon as possible. The WHO committee, public health officials, and representatives from industry and regulatory bodies who gathered in Geneva discussed two vaccine candidates at length: one is at the stage of Phase II trials, from Chiron Biologicals (CHIR) and the U.S. National Institutes of Allergy and Infectious Diseases (NIAID, and FVH:009-043444; HIV), from Novartis Vaccines and the Public Health Agency of Canada; several other vaccine candidates are at earlier, preliminary stages in the development pipeline. While 1 million of the SIV vaccine began in the United States and the United Kingdom, and researchers plan to begin enrollment in Phase II trials of 3000 each, rollout plans for development in 2015 are constrained due to the small number of volunteers who will receive the vaccine at two different sites (0.5 mg and 1 mg). The WHO panel will be convened to discuss the current state of the development of Ebola vaccines and the challenges associated with their use.

Emergency use listing procedure

Version: 8 August 2012

Overview

The World Health Organization (WHO) developed the Emergency Use Assessment and Listing (EUAs) mechanism in response to the 2013–2014 Ebola virus Disease (EVD) outbreak. The EUA, a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostic (IVD) for use primarily under public health emergencies of international concern (PHEIC). Only a few other public health emergencies are appropriate.

Two submissions for Ebola vaccines were received but none were listed. No therapeutic products that were in development were submitted during the 2014-15 Ebola outbreak. Twenty-five applications for EUAs were received for Ebola vaccines of which ten were listed. Also, three out of thirty applications received for other public health emergencies were listed.
WHO consulted widely and immediately fostered interactions

With the international scientific, ethics, regulatory, vaccine development, public health partners, industry, and funders' communities. WHO participated in consortia to facilitate Ebola vaccine assessments. WHO also fostered key activities to ensure the optimal policy and deployment of Ebola vaccines.
On a path to accelerate access to Ebola vaccines: The WHO's research and development efforts during the 2014–2016 Ebola epidemic in West Africa

Ana Maria Henao-Restrepo, Marie-Pierre Preziosi, David Wood, Vasee Moorthy, Marie Paule Kiény, the WHO Ebola Research, Development Team
A novel trial design with **the country in the driving seat** and 26 global institutions collaborating.
Since 2016 all STUDIES STARTED PROMPTLY

✓ Previously agreed prioritization of candidate vaccines
✓ Phase 1 (and 2 data)
✓ Funded investigational vaccines already in vials (internationally transferable)
✓ Previously established trial platforms
✓ Previously agreed simple protocol

Previously agreed:
✓ LEGAL collaboration, ✓ Insurance and ✓ Liability frameworks
✓ Previously agreed funding
Expanded Access with rVSV ZEBOV GP (unlicensed doses), for outbreaks reported between 2016 - 2022

12 EVD (Zaire) outbreaks and 3,721 EVD confirmed cases reported

Over 350,000 people at risk vaccinated (contacts and contacts of contacts) including >100,000 HCWs/FLWs

Informed consent for all and individual data collection from 250,000
New strategic components steering future global research agenda

Countries begin negotiations on global agreement to protect world from future pandemic emergencies

WHO to identify pathogens that could cause future outbreaks and pandemics
Core activities of the WHO R&D Blueprint for Epidemics toward a robust and coordinated global research response to emerging disease threats

- Viral and Bacterial families prioritization
- R&D Roadmaps and Target Product Profiles (TPPs) for each prioritized viral and bacterial family
- Pipeline monitoring and prioritization for evaluation.
- Research in the context of outbreaks and pandemics
- Promotion of building capacities to conduct clinical trials and research in accordance with international standards.

Figure 1 shows progress on the delivery of key activities within the R&D Blueprint up to May 2023.
Global collaborative research approach to prevent and tackle outbreaks, epidemics and pandemics

- Vaccines and therapeutics
- Epidemiology
- Health intelligence and surveillance
- Virus natural history, transmission and diagnostics
- Human-animal-environment interface

Research in the interepidemic period

- Public health and social measures (PHSM)
- Infection prevention and control (IPC)

Research integrated in the outbreak response

- Vaccines and therapeutics
- Clinical management

Enabling research

- Tackling Infodemics
- Trust
- Good participatory practice (GPP-EP)
- Community-centred readiness and response
- Regulatory science
- Biological standardization
- Ethics
Many countries across the globe participated in WHO-coordinated research activities between May 22 and May 2023. Activities have been diverse and include a range of countries that took part in large global clinical trials to test vaccines and treatments for COVID-19.
Research undertaken before an epidemic is critical – with one key focus being the global prioritization, detection and monitoring of new or existing pathogen threats.

Research in the interepidemic period

Vital vaccines and therapeutics research in the interepidemic period
Human-animal-environment interface
Epidemiology
Health emergency intelligence and surveillance
During a disease outbreak, different plans and strategies across all the research areas are rapidly enacted.

A core focus of this phase is delivering major clinical trials of promising vaccines and treatments quickly and robustly.

Research integrated in the outbreak response

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Vital vaccines and therapeutics research in the outbreak response
At the heart of the global response against deadly outbreaks

Clinical management
Optimizing clinical management of COVID-19 patients and clinical care in large-scale health emergencies

Infection prevention and control (IPC)
Readiness and response research and innovation (RI) for public health emergencies

Public health and social measures (PHSM)
Providing global evidence on the effectiveness and impact of PHSM for emergency preparedness and response
The delivery of effective medical countermeasures and wider policies to combat a disease outbreak is underpinned by a wide range of research areas. They all coordinate and work together enabling the global research effort before and during an outbreak.

Enabling research

Regulatory science
Biological standardization
Ethics
Community-centred readiness and response
Tackling infodemics
WHO Initiative on Trust and Pandemic Preparedness
Good participatory practice (GPP-EP)
Regulatory science
Regulatory systems are integral to the public health response: working together to accelerate equitable access to vital medical products

Biological standardization
Helping increase access to life-saving vaccines, treatments and diagnostics

Ethics
Prioritizing pivotal ethics work before and during pandemics and outbreaks

Community-centred readiness and response
Data driving action
WHO Initiative on Trust and Pandemic Preparedness

Good participatory practice for clinical trials of new or re-emerging pathogens (GPP-EP)
Evidence-driven community engagement in clinical trials

Building on the global research response to the pandemic to combat the next one
On behalf of thousands of colleagues across the three levels of WHO, we would like to thank the over 50,000 researchers and Ministries of Health officials who have joined our efforts; the funders who have facilitated critical research; and the thousands of volunteers who have generously contributed to the studies worldwide.
The current challenges of Research and innovation is a problem that can be solved. 

Let’s solve it together.