

WHO Ebola Research and Development Summit Geneva, 11-12 May 2015

Executive summary

Purpose of meeting

The meeting was held to develop a clearer understanding of the interests and constraints for countries, partners, and funders, in regard to building collaborations to accelerate access to novel interventions in emergency situations. The aim was to analyze the lessons learned from the R&D response to the 2014-2015 West African Ebola crisis. The intent was to apply such lessons to the eventual creation of a *Blueprint for Research and Development Procedures in the Context of Global Public Health Threats*.

Key outcomes

Among lessons learned were that R&D protocols, priorities for choosing research topics, and approved standards of care should be set in advance to ensure that as much time is gained as possible prior to an emergency; that research data, including negative results, should be openly shared in a timely and transparent manner; and that a practical funding strategy should be developed to spur pharmaceutical research and subsequent manufacture of drugs and vaccines to prepare for diseases such as Ebola, which strike poor populations in developing regions. It was also recognized that health systems should be strengthened to address future serious disease outbreaks; and that research and development activities must include not only product development for diagnostics, therapeutics and vaccines but also address such matters as protective equipment, surveillance methods, and the training of research workers down to the local level.

Broad-based collaborative research arrangements were forged in the heat of the Ebola crisis. These resulted in teamwork among the health departments of the Ebola-affected countries, foreign national health agencies, international health organizations, regional institutions, academia, pharmaceutical firms, and non-governmental organizations. There was a conviction that, although these arrangements must be improved, the model set by these collaborations should be built on, fine-tuned, and used as the foundation for future R&D responses to global crises.

Among the next steps called for by the summit were efforts reduce the time between the declaration of an emergency and the initiation of efficacy trials to four months (or less); to identify the most efficient designs of efficacy trials that can be applied under emergency settings; to identify how the development of medical technology can be accelerated for epidemic-prone diseases of concern; and to identify how significant improvements can be made in infectious disease surveillance, including through better point-of-care diagnostic tests. In addition, a mechanism for prioritizing epidemic-prone

diseases was called for, based on the seriousness of their potential threats, so that gaps in R&D -- such as those relating to the underlying scientific understanding of the pathogen, design of diagnostics, treatments, and vaccines -- can be identified and addressed before crises occur.

Proposals to improve future R&D responses

Key concepts raised at the summit to improve future responses included:

- Establishing target product profiles (TPPs), and global R&D roadmaps, for priority novel interventions.
- Protocols, review mechanisms, reference preparations for assays, approved standards of care, and related arrangements for carrying out clinical trials and other research activities should as much as possible be set up and agreed to in advance. Such arrangements should be stringent and of the highest possible standard, but also allow for flexibility based on the circumstances of an outbreak.
- A specific learning, based on the realities of the West African Ebola outbreak, was to incorporate plans in product development pathways for how development can be continued and concluded for products that show promise, but cannot be fully evaluated because the number of cases declines before clinical trial endpoints are reached.
- Data generated by clinical trials and other research during public-health emergencies, including negative results, should be openly shared, and where possible should be comparable. A body of knowledge based on data sharing during outbreaks would enable effective choices, effective use of funding, and appropriate prioritization of candidate products. It was suggested that a framework or platform be developed, with a code of conduct for how data are to be generated and the conditions under which they are to be shared.
- R&D decisions during -- and in preparation for -- outbreaks should include consideration of whether existing vaccines or medications for other diseases can be repurposed. Research into whether existing products are effective may result in treatments that are more rapidly available than research into potential new treatments.
- There is a need for new R&D funding models to support the development of products where the market is non-existent, unknown, or unreliable. The participation of major pharmaceutical firms -- particularly in relation to their manufacturing capacities and expertise -- is critical, and while they don't necessarily require profits to help produce and deploy treatments for serious health threats in poor countries, they need dependable financial support for the costs of production and to make up for the losses that come from diverting resources from other projects. Issues of product liability and intellectual property rights should also be resolved ahead of time.

- Where advisable and feasible, astutely located stockpiles should be established of effective treatments derived from research. That will help with rapid response to future disease outbreaks.
- Countries affected by serious public health threats – and those at risk of them – should be enabled to participate in R&D efforts and build their capacities for research. Those enduring extensive public suffering during outbreaks are likely to consider that they “own” the results of research carried out on their territories, and own the biological samples taken for research use. At a minimum such countries want their own health and academic personnel to work in collaboration with experts who come to carry out research, and they want to learn from the process.
- A broad range of R&D capacity-building is needed in developing countries afflicted by or at risk of serious infectious disease outbreaks. This includes establishing BSL 3 or 4 laboratories, and it may include establishing national biobanks or a regional biobank. It requires training not only research workers but of health staff extending down to the local level on such matters as the use of protective equipment, the proper taking of samples, and appropriate data recording and sharing.
- R&D must encompass far more than vaccines and drugs. It should be extended, among other things, to personal protective equipment; diagnostics; communication with communities to prepare the way for research (taking into account socio-cultural attitudes); and disease surveillance.
- Several collaborative fora or systems already in existence at the time of the 2014-2015 EVD crisis helped save time and proved useful for starting and coordinating R&D. Among them were the African Vaccine Regulatory Forum (AVAREF), which had been in place for 10 years as a mechanism for the fast-track review of clinical trial applications of candidate vaccines; the European Mobile Laboratory Project, established in 2012, that enabled mobile laboratories to be deployed and made operational in Guinea two days after they had been requested in connection with the Ebola crisis; the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R), established in 2013, with the purpose of bringing together research funders and coordinating their response to epidemics at the global level had, in July 2014, mobilized 24.4 million Euros for five research projects to address EVD; the International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC), established in 2011 to facilitate rapid assessment of potential interventions and drugs, had set-up research studies in the field. A gap analysis of these, and the novel partnerships created in response to the EVD crisis, would facilitate future coordination of stakeholders conducting R&D in the context of global public health threats.
- Research should not detract attention or resources from the delivery of existing approaches already proved to be effective. It was pointed out at the summit that basic, well-delivered intensive care – improved over time as front-line health workers fortified their skills – was what had saved lives during the West

African Ebola outbreak. Similarly, the epidemic ultimately was contained by the careful tracing of cases and contacts.

Next steps

A Blueprint for Research and Development Procedures in the Context of Global Public Health Threats will be prepared by the WHO Secretariat for presentation at the 69th World Health Assembly, in May 2016. A summary was submitted as input to the High Level Panel on Global Response to Health Crises convened by the UN Secretary General to strengthen national and international systems to prevent and manage future health crises, taking into account lessons learned from the response to the outbreak of Ebola virus disease.