World Health Organization

MEETING REPORT

WHO Ebola Research and Development Summit

11-12 May 2015

WHO/EVD/Meet/HIS/15.3

WHO Ebola Research and Development Summit

Executive summary

Purpose of meeting

The summit was held to develop an understanding of the interests and constraints for countries, partners, and funders in building collaborations to accelerate research and development for, and access to, novel interventions during infectious disease outbreaks representing public-health emergencies. The intent was to analyze the lessons learned from the R&D response to the 2014-2015 West African Ebola crisis and contribute to the creation of a *Blueprint for Research and Development Preparedness in the Context of Global Public Health Infectious Threats*.

Key outcomes

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 and research agencies, international health organizations, regional institutions, academia, pharmaceutical firms, and non-governmental organizations. There was general consensus that, though 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 emergencies linked to infectious diseases.

Among lessons learned from the R&D response to the 2014-2015 crisis were that R&D protocols, priorities for research, 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 countries. It also was 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, communication with communities to prepare the way for research (taking into account socio-cultural attitudes), and the training of research workers down to the local level.

Among the next steps called for by the summit were efforts to 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 to cope with serious diseases of epidemic potential; 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 and the design of diagnostics, treatments, and vaccines -- can be identified and addressed before crises occur.

Proposals to improve future R&D responses

Numerous suggestions were centered on advanced preparation. These included establishing target product profiles (TPPs) and global R&D roadmaps for priority novel interventions. They also included the creation of a priori protocols, review mechanisms, reference preparations for assays, approved standards of care, and related arrangements for carrying out clinical trials and other research activities. It was stressed that 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 lesson cited from the West African Ebola crisis was that research arrangements during future emergencies should incorporate plans for how R&D can be continued and concluded for products that show promise but cannot be fully evaluated because the number of cases has declined before clinical trial endpoints are reached.

Participants stressed that data generated by clinical trials and other research during future 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 more effective choices, effective use of funding, and appropriate prioritization of candidate products.

There were calls for R&D decisions during -- and in preparation for -- outbreaks to include consideration of whether existing 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. Similarly, it was noted that research should not detract attention or resources from the delivery of other 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 saved lives during the 2014-2015 Ebola outbreak. Similarly, the epidemic ultimately was contained by the traditional tracing of cases and contacts.

Meeting participants said new R&D funding models should be established 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 also should be resolved ahead of time.

One pharmaceutical company, GSK, proposed that manufacturers are asked to provide, for the public good, technological platforms that have the potential to be used for products to address specified global health threats. Such projects should be under the control of a supranational board hosted, for example, by WHO.

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.

It was stated that countries affected by serious public health threats – and those at risk of them – should be enabled to participate in R&D efforts and to build their capacities for research. At a minimum the health and academic personnel of these countries should work in collaboration with experts who come to carry out research so that they can learn from the process. Such ambitions indicate that 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 even 4) laboratories and may include establishing national biobanks or a regional biobank. It requires training not only research workers but 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.

It was recommended that a gap analysis be performed of several collaborative fora or systems already in existence at the time of the 2014-2015 EVD crisis, as these arrangements helped to save time and proved useful for starting and coordinating R&D. Analyzing how they worked – and how such cooperation could be improved -- could ease future coordination of stakeholders conducting R&D in the context of global public health threats.

Next steps

A *Blueprint for Research and Development Preparedness in the Context of Global Public Infectious Health Threats* will be prepared by the WHO Secretariat for presentation at the 69th World Health Assembly, in May 2016. A summary will be 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.

Annex 1

Narrative of discussions held at the Summit

The specific mandate for the 11-12 May Summit stemmed from a resolution[1] adopted during a 25 January 2015 WHO Executive Board special session on the 2014-2015 Ebola crisis. The scope of the two-day meeting, given the developments since that time, was expanded to a focus on developing concepts for an anticipated *Blueprint for R&D Preparedness in the Context of Global Public Infectious Health Threats*.

Attending the summit were representatives of international and regional health and research organizations; officials of the national health systems of numerous countries, including those which had responded to the Ebola outbreak; and representatives of manufacturers involved in developing products for the Ebola response (see Annex 2 for the list of participants).

The Director-General of WHO and the organization's Assistant Director-General for Emergencies (who is serving as DG Special Representative for the Ebola Response), summarized the current status of the outbreak and pointed to the painfully won instructive potential of the experience.

The epidemic had infected 26 000 as of 11 May 2015, and more than 11 000 had died. By early May, the disease was confined to a few sites on the coasts of Guinea and Sierra Leone as a result of aggressive case finding in the forested area from which the outbreak had spread, and as a result of house-to-house searches in urban areas.

Four candidate vaccines currently were being tested in hopes of preventing a future epidemic, and a number of other possible treatments, including the use of convalescent plasma, were under study. The traditional R&D model, which had not delivered any vaccines, drugs or diagnostics before the current epidemic broke-out, would need to be adapted.

Health officials of Guinea, Liberia, and Sierra Leone – the three countries most heavily affected by the outbreak – cited a number of shared concerns, including a need for extensive basic improvements to their health systems. Such progress required expanding infrastructure, including laboratories. In addition, better equipment and training should extend to the local level, where illnesses with epidemic potential are best identified, the alarm sounded, and responses mounted quickly. The representatives also said that greater attention should be paid to social-cultural beliefs and practices, as these can accelerate epidemics – as they did during the Ebola crisis -- and can hinder research. And they stressed that their national and regional capacities to carry out research and development must be strengthened. Collaborative and open R&D arrangements should be set up on their territories, with the results widely and equitably shared.

Lessons learned

A session of the summit was devoted to "main lessons learned on R&D during the 2014-2015 Ebola outbreak in West Africa," and a number of examples were cited by summit participants.

One positive outcome from the epidemic was that innovative R&D partnerships formed under the stress of the crisis were surprisingly fruitful and should be studied, adjusted, and made more efficient for use during future health emergencies. These collaborations between governments, small and large companies, and academia sped up the development of drugs from two to three years to eight months. Partnerships also were rapidly formed between governments, industry, and non-governmental organizations (NGOs) to fund such developments. The result was that at the time of the summit, several vaccines were in phase III

[1] The resolution "requests the Director-General to ensure the sustainability of the working groups on therapeutic drugs and vaccine clinical trial designs while they are needed, to ensure continued progress in the development of quality, safe, effective, and affordable vaccines and treatments, while emphasizing the importance of completing WHO's work on emergency regulatory mechanisms and procedures ensuring patient safety, committing the results of this work to the most affected countries in West Africa as a first priority, with an accompanying distribution and financing plan, to be communicated to Member States as soon as it is ready;
requests the Director-General to evaluate the current status of the epidemic and to disseminate information as to the most critical research studies to complete; and requests the Director-General in consultation with technical experts and Member States' regulatory agencies to develop guidance on the value and limitations of the data obtained from the clinical trials, giving particular attention to ethics, quality, efficacy, and safety." http//apps.who.int/gb/ebwha/pdf_files/EBSS3_R1-en.pdf?ua=1

clinical trials; trials of convalescent plasma and small molecule drugs were under way; and four diagnostic tests were already listed for emergency use.

Among difficulties from which lessons could be drawn were that negative results from R&D during the Ebola crisis often were not shared. That was the case, for example, for some diagnostic assays and for some in vitro drug screening assays. It was pointed out that sharing negative results saves time and helps research to proceed more efficiently. It has been proposed that WHO set up a database of negative results.

In addition, it was noted that the variety of novel government-industry-academic-NGO partnerships and varied R&D projects carried out under varying protocols compounded the difficulties faced by local decision makers as they undertook the task of reviewing and approving studies during the EVD epidemic.

Questions that came up during the 2014-2015 crisis indicate that issues of liability and intellectual property should be resolved ahead of time; manufacturing capacity should be arranged; and advance agreement should be reached on funding the manufacture of novel interventions.

Based on the limited product pipeline when the Ebola crisis struck, it was noted that a practical incentive strategy should be developed to spur research and subsequent manufacture of diagnostics, drugs and vaccines to prepare for diseases such as Ebola, which strike poor populations in developing regions. It was not acceptable that human clinical trials of vaccines for EVD began approximately 40 years after the first Ebola outbreak. Among the apparent reasons for the delay was that there was little chance that such a vaccine would be profitable. Any incentive mechanism would have to address sustainability of the R&D effort, as humanitarian funding to create a market for such novel interventions would likely dry up once an outbreak ended.

It was noted that one lesson that might be drawn from the West African crisis is that emphasis on R&D, potential vaccines, and potential drugs should not deflect attention and resources from the provision of basic intensive care during future epidemics. Almost all lives saved during the 2014-2015 outbreak were accomplished through intensive care provided by health workers applying hard-won practical skills under difficult conditions.

At times during the crisis, there was intense competition and a lack of coordination between the clinical trials carried out, which suggests that frameworks and procedures should be set in advance to reduce confusion and improve efficiency.

Similarly, more attention is needed so that appropriate records are kept, permissions obtained, and plans made to follow up on survivors in the wake of such outbreaks, to ensure that maximum new information is obtained from such cases.

Difficulties encountered by several R&D projects under way as the number of West African Ebola patients dwindled indicate that during future public health emergencies there should be planning that takes into account the fact that trials can be hindered by declining numbers of patients as outbreaks are brought under control. Having pre-approved research topics and protocols in place may help with quicker initiation of research.

R&D during the 2014-2015 crisis also was hindered by lack of access to key clinical data on drugs used outside of formal clinical trials; and by lack of an integrated approach to rapid data assessment from trials themselves. The latter affected the use of the data as a basis for prioritizing further research. Planning could rectify such difficulties during future emergencies.

One lesson learned from experience in West Africa is that R&D is urgently needed on the personal protective equipment (PPE) worn by health workers during crises such as the 2014-2015 outbreak. Optimal technical specifications for protective suits had yet not been defined when the epidemic struck. The material provided was of variable quality, was often unnecessarily complicated to use, and the components were not always compatible. In some cases even the colors of the protective suits had cultural significance which limited their acceptability. In addition, most of the PPE available had been designed for use in industry, not in health care settings, nor was it appropriate for the tropics, where there are high temperatures and high humidity.

Various problems encountered during epidemic indicate that the design of emergency treatment centres and related facilities also would benefit from R&D.

Additional lessons learned were cited at other points during the summit. Among them were that research is urgently needed into cultural, social, and religious, and other factors in countries and regions where Ebola outbreaks and other potential serious disease outbreaks may occur. Where these factors may conflict with treatment, or may limit community acceptance of research, appropriate steps should be designed in advance to address opinions or attitudes, or to adjust R&D so that it is more acceptable but still effective. There should be deepened understanding of effective community engagement practices to enable prompt initiation of research during future serious disease outbreaks.

Experience during the West African crisis showed that where there is local suspicion of or resistance to R&D during outbreaks, it can in many cases be overcome by tactfully educating and persuading community leaders, such as village elders, imams, and traditional healers, so that they can advocate for participation in trials and perhaps can set an example by participating themselves. Communication, advocacy, and community engagement are best carried out when a research question is conceived and the research is designed, rather than when a study is under way.

During health emergencies, priority should be given to the quick establishment of clinical case databases. Lack of sufficient health staff to provide clinical care during the height of the Ebola outbreak delayed the establishment of such a database.

A major lesson appears to be the importance of strengthening health systems in Ebola-affected countries and in other less-developed countries that may be the sites of serious future disease outbreaks. An investment of US$ 3 billion could have significantly bolstered the health systems of the three Ebola-affected countries before the 2014-2015 crisis, a representative of the Ministry of Health of Guinea said. It was stated that these health systems had inadequate infrastructure and equipment, gaps in coverage, and a lack of communication facilities left their populations especially vulnerable to the outbreak.

Sensitivities encountered over which patients have received new or innovative Ebola treatments indicates that careful consideration and advance planning should be given to the matter of who will receive a new vaccine or vaccines when the deployment stage is reached. A representative of Guinea noted that the country is expecting wide vaccination programmes and that Guinea's National Pharmaceutical Regulatory Committee has requested that, if a vaccine proves to be effective, it be made available to the entire population. By contrast, indications are that much more limited vaccinations may take place in Ebola-affected countries. One scenario envisions vaccination of health workers, front-line workers, burial teams, contact tracers, community caregivers, the contacts of persons infected, and "ring vaccination" around contacts.

It became clear at the Summit that broad-based, altruistic teamwork that in many cases bridged pre-existing barriers in research and development was an encouraging outcome of the response to the crisis.

Summit participants said several collaborative fora or systems already in existence at the time of the 2014-2015 epidemic helped save time and proved useful for starting and coordinating R&D. Among them:

The African Vaccine Regulatory Forum (AVAREF) had been in place for 10 years as a mechanism for the fast-track development of candidate vaccines. It brought together regulators and ethics committees from the participating countries with sponsors' representatives and clinical trial teams from sites, and was supported by stringent regulatory agencies, including the European Medicines Agency, Health Canada, Swiss Medic, and the U.S. Food and Drug Administration (FDA). With the onset of the crisis, AVAREF conducted three Ebola vaccine reviews, coordinated by WHO, based on protocols and supporting documents sent to countries for independent review. The advice of a technical expert committee was sought for most reviews. A 60-day review time was achieved. It was suggested that the overall approach could be applied to future emergency and non-emergency situations involving research applications with "multicentre design."

The establishment of the European Mobile Laboratory Project in 2012 enabled mobile laboratories contained in modules designed in Canada 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) was established in 2013 with the purpose of bringing together research funders and coordinating their responses to epidemics at the global level. The EVD epidemic subsequently showed that such a platform was needed to enable funders to identify the best research solutions and to channel the necessary funds rapidly, as research and innovation were needed at the outset of crises to develop essential diagnostics, vaccines, and therapeutics. In July 2014, the Collaboration had mobilized 24.4 million Euros for five research projects to address EVD. In November 2014, a call had been launched for 215 million Euros for research projects that were coordinated to avoid duplication. In May 2015, a meeting of member countries analyzed problems encountered by researchers and funders during the EVD outbreak and proposed ways to address those problems in the future.

The International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC) was established in 2011 to allow rapid assessment of potential interventions and drugs. ISARIC supported discussions on products to be used during the 2014-2015 epidemic, on the endpoints of clinical trials, and on study sites.

The Vesicular Stomatitis Virus Ebola Consortium (VEBCON) was established to accelerate development of an Ebola vaccine – rVSV-ZEBOV -- for which GMP-grade material was available and for which high efficacy in non-human primate challenge models had been demonstrated. The Consortium worked with national and international agencies, pharmaceutical companies, funding organizations, regulatory authorities, and ethics committees. Four research sites were established in Europe and Africa, with centralized data management and independent oversight.

In the midst of the crisis, laboratories were using diagnostic tests of unknown quality or safety, many of which had not been proved effective in the field. Development of an *i*n vitro diagnostic test usually took from two to five years or more. On this occasion, international collaboration was sought in support of the WHO emergency use assessment and listing (EUAL) for in vitro diagnostics, and expertise in dossier requirements was obtained to speed up the process. International support was obtained for laboratory and field evaluations by African Union laboratories and by the Bernhard Nocht Institute in Germany. A clinical performance study subsequently was performed in Sierra Leone.

A representative of the Bill and Melinda Gates Foundation reported that with the emergence of the Ebola crisis, the Foundation mobilized up to US$ 75 million in extrabudgetary funds for collaborative work by UNICEF, the International Federation of the Red Cross, and the Ebola-affected countries, with US$42 million targeted at R&D for products that were effective in non-human primates. The Foundation also seconded more than 100 staff members for collaborative response to the epidemic, with many working with WHO or with the UN Mission for Ebola Emergency Response (UNMEER).

Following the arrival in Lagos, Nigeria, of an EVD case from Liberia, a Global Emerging Pathogens Treatment Consortium was formed in collaboration with Gates Foundation with an initial focus on convalescent plasma. Subsequently a network of African scientists was created which now had 70 members and was growing rapidly. This network had enlisted the involvement of over 10 000 EVD survivors who were being followed up for post-EVD syndromes.

A Partnership for Research on Ebola Vaccines in Liberia (PREVAIL) was created and based on collaboration between the University of Liberia, the Liberian and U.S. health departments, and other participants extending down to the community level, where infrastructure was ensured at study sites through community fora and study volunteers. On the basis of this experience it was stressed that Government ownership was critical to ensure sustainability of any platform for preparation and implementation of an integrated clinical research response.

A “Team B” was established in November 2014 by the U.S.-based Center for Infectious Disease Research to review issues related to the development and delivery of Ebola vaccines. The team included 26 experts involved in one or more areas of vaccine work, including eight senior African scientists. Numerous teleconferences and document reviews were conducted through January 2015. Reports on target product profiles (TPPs) were issued in January 2015, and recommendations for accelerating the development of vaccines were issued in February 2015. Working groups were set up on such matters as R&D, manufacture, safety, and determination of vaccine efficacy.

Among collaborative responses initiated within WHO, a Product Development for Vaccines Advisory Committee (PDVAC), consisting of 13 experts, was established in April 2014 to provide strategic advice on vaccines in phase 2 of clinical evaluation or earlier. Among other activities, PDVAC has worked in cooperation with the WHO Strategic Advisory Group of Experts (SAGE) on Immunization, which has been in existence since 1999.

The role of industry

The extent and character of the participation of the pharmaceutical industry in response to future developing-world disease outbreaks was discussed at length at the summit. Representatives of a number of companies spoke. Key issues raised were practical considerations of how an Ebola vaccine or vaccines, once approved, will be manufactured, funded, and distributed in currently affected countries.

It was stated that companies lose millions of dollars when they halt research on one product to concentrate on an emerging disease such as EVD. It was further noted that while firms' research expertise is important, their capacity in subsequent phases is critical; they alone have the expertise and the facilities for carrying out mass production. Production of vaccines and other medications for diseases such as Ebola, which will not turn a profit, mean halting the manufacture of other products that are profitable. In such cases, the issue is not just arranging for some return for the production-related costs but a need for planning – decisions will need to be made based on types of vaccines (monovalent or multivalent), on the amounts to be produced, and on the size of stockpiles of medications to be established in case of future crises. Pharmaceutical representatives said it is far from clear how many Ebola vaccines now in development will be produced at scale, or how funding issues will play out for candidate vaccines that prove not to be effective.

It was pointed out that pharmaceutical manufacturers not only have incurred costs, but have to make decisions about scaling up production even as the incidence of the disease has fallen. It was unclear at the time of the summit whether data on efficacy of vaccines even would be sufficient for a WHO recommendation on production.

On the greater issue of future crises, one pharmaceutical official suggested that the four largest vaccine producers pool their resources and technology in an independent industrial group to be governed by an independent body. A list of priority pathogens for which vaccines are needed can be drawn up, with an annual budget of about US$ 45 million**.** How this would be funded would have to be determined, but such an approach could prove capable of developing two to three vaccines per year.

Various opinions were expressed that basic research funding should come from governments; that financial commitments and incentives are necessary to attract involvement from more pharmaceutical firms; that the aim of firms in such situations is to make a process viable and efficient, not necessarily to make a profit; and that additional proposals should be worked up to pool resources to develop vaccines against new lethal viruses.

Improving the planning and execution of research activities before and after crisis

Proposals were outlined at the summit for agreeing a priori on the characteristics of products to be developed as a matter of priority, so that there is better preparation for future global public health threats. Such work could include establishing target product profiles (TPPs), global R&D roadmaps, and trial designs for vaccine evaluation in cooperation with the WHO Product Development for Vaccines Advisory Committee. Also discussed were efforts to develop consensus on generic approaches, innovative methods, and protocols, so that these are available and can be promptly reviewed and endorsed when outbreaks happen.

The WHO Strategic Advisory Group of Experts' (SAGE) draft framework for formulating recommendations for the deployment of Ebola vaccines was presented. Discussion followed on how, in general, the transition can be improved from research to broad delivery of successful treatments. A more specific concern, based on the realities of the West African Ebola outbreak, was how development can be continued and concluded for products now being researched that have shown promise against Ebola, but cannot be fully evaluated because the number of EVD cases has declined.

A number of concepts emerged from the two-day meeting, and these may be incorporated into the anticipated *Blueprint for Research and Development Preparedness in the Context of Global Public Health Infectious Threats*

Among the concepts raised at the summit is that R&D must encompass far more than vaccines and drugs. It should be extended, among other many other things, to personal protective equipment and to communication with communities to prepare the way for research, taking into account socio-cultural attitudes.

A concept clearly important to developing countries affected by serious public health threats – and those at risk of them – is that they should participate in R&D efforts and so build their capacities for research. Countries 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 representative of Guinea reported that the country's National Regulatory Committee had emphasized that each Ebola study should include capacity-building and should involve national bodies. WHO's Assistant Director-General for Health Systems and Innovation said there was unanimity that countries should lead research, with regional groupings, and that WHO should function as a facilitator.

Hence, 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 of 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. Capacity-building in terms of regional institutions is also of great importance.

Preparations for future crises should keep in mind the basic concept that surveillance is critical. Initially, symptoms during the Ebola outbreak were attributed to several other possible causes. That indicates the importance of syndromic surveillance, and it highlights the need for point-of-care diagnostic tests. Additional R&D for diagnostics should be considered a priority.

A basic principal for improving readiness is that of effective advance preparation. Protocols, review mechanisms, standards 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.

Concepts of across-the-board cooperation – built on those which proved their value during the 2014-2015 Ebola epidemic – should include the open sharing of data, including negative results, generated by clinical trials and other research during public-health emergencies in developing countries. Where possible, such data should be comparable. Lack of sharing resulted in duplication of effort and wasted research in West Africa. In addition, the Ebola experience showed that isolated, uncoordinated research initiatives are more likely to fail. The better approach appears to be to build a body of knowledge based on data sharing during outbreaks to 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.

Summit participants said it should be an operating principle in the future that R&D decisions during -- and in preparation for -- outbreaks should include consideration of whether existing vaccines or medications for other diseases can be repurposed. Unusually rapid R&D efforts during the 2014-2015 crisis still did not result in effective new treatments in time for their employment during the epidemic. Research into whether existing products are effective may result in treatments that are more rapidly available than research into potential new treatments.

A concept that should be explored is how to establish new R&D funding models to support the development of products where the market is non-existent, unknown, or unreliable. The participation of 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.

One aspect of advance planning is that where advisable and feasible, astutely located stockpiles should be established of effective treatments derived from research. That will help with rapid responses to future disease outbreaks.

An additional concept is that strategies should be designed and approved in advance for how vaccines should be deployed in response to disease outbreaks such as the recent Ebola crisis, taking into account public sensitivities and wishes for equal treatment.

Next steps

The WHO Assistant Director-General for Health Systems and Innovation indicated that the proposal for a *Blueprint for Research and Development Preparedness in the Context of Global Public Health Infectious Threats* will be prepared by the WHO Secretariat for presentation at the 69th World Health Assembly, in May 2016. A summary of this meeting, and the Blueprint concept, also will be 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.

Based on inputs from the R&D summit, the Blueprint should include both generic elements and specific elements for specific diseases. Generic elements should include rapid detection, strengthening of surveillance, interoperable point-of-care diagnostic tests, and improved personal protective equipment. In addition, a mechanism for prioritizing diseases should be established so that R&D gaps can be identified, such as those relating to correlates, diagnostics, treatments, and vaccines

Among the structural elements required to support future R&D efforts for epidemic-prone diseases are a platform for pre-clinical evaluation; a clinical trials network; capacity-building for ethical approval of clinical trials and capacity-building for developing-country regulatory agencies. Also needed will be adaptable clinical protocol packages, frameworks for rapid data-sharing, and procedures to facilitate sample storage. With regard to funding, a “proactive” system should be set up that can become operational during an outbreak.

In other discussion it was noted that if capacity is built to conduct studies with common protocols, personnel thus trained also can use their skills to work in other clinical trial networks, such as for malaria; that there should be a master plan for processes and mechanisms related to all pathogens that have caused or may cause global health crises; and that there should be an agreement on maximizing collaboration during outbreaks because competition, although useful, is not appropriate in an emergency.

Also called for were steps to ensure supply-chain security, transparency in R&D operations, and adequate bio-containment for risk-4 agents.

Annex 2

Agenda of summit

Rapporteur: Elisabeth Heseltine

Monday 11 May 2015

8:00-9:00 **Registration**

Session 1: Introduction
Chair: ***John Mackenzie (Curtin University, Australia)***

9:00-9:15 Welcome: Margaret Chan, Director-General, World Health Organization (WHO)
Objectives of meeting, expected outcomes: Marie-Paule Kieny, Assistant-Director General, Health Systems and Innovation (WHO)

9:15-9:35 **Keynote lecture:** The Ebola response/getting to zero (20 min), Bruce Aylward (WHO)

9:35-10:15 **Country perspectives on R&D during the Ebola epidemic** (10 min each)

- Wiltshire Johnson (Pharmacy Board, Sierra Leone)
- Stephen Kennedy (Ministry of Health, Liberia)
- Mandy Kader Konde (CEFORPAG, Guinea)

Discussion (10 min)

10:15-10:45 ***Coffee break***

SESSION 2: Main lessons learnt on R&D in the 2014-15 EVD outbreak in West Africa. Main challenges, and factors that facilitated implementation of research activities in the affected countries
Chair: ***Nicole Lurie (HHS/ASPR, USA)***

10:45-11:30 **What were the known facts, pipelines and major challenges to Ebola R&D when the international emergency was declared in August 2014, and what has been achieved since then?**

This presentation and discussion will identify crucial knowledge gaps at the start of the outbreak, e.g., in immunopathogenesis, appropriate animal models, use of in vitro data, natural history of disease ; and map out the current (May 2015) achievements in filling these gaps.

Peter Jahrling (NIH/NIAID, USA): Addressing knowledge gaps in countering Ebola Virus Disease (20 min)

Panel discussion (25 min) moderated by Peter Jahrling:
Sina Bavari (USAMRIID, USA), Inger Damon (CDC, USA), Stephan Günther (BNI, Germany), Mandy Kader Konde (CEFORPAG, Guinea), Janusz Paweska (NICD, South Africa)

11:30-12:00 Robin Robinson (BARDA, USA): Developing an integrated R&D agenda: prioritizing, developing and funding considerations (30 min)

12:00-12:10 Discussion (10 min)

12:10-13:00 ***Lunch break*** (50 min)

13:00-13:40 What are the decisive actions that helped to advance R&D? (10 min each)

From Recommendations to Actions: Lessons learnt in Ethics from the Ebola R&D, Aissatou Toure (Institut Pasteur, Senegal)

The role of the Scientific and Technical Advisory Committee (STAC-EE) in prioritising experimental interventions, Fred Hayden (University of Virginia, USA)

The VEBCON consortium for vaccine evaluation, Maxime Agnandji (CRM, Gabon)

Consultation on innovative Personal Protection Equipment (PPE), Adriana Velasquez-Berumen (WHO)

13:40-14:10 Round table (30 min) moderated by Robin Robinson: What processes should be in place to facilitate prioritising interventions and the R&D agenda in the future.
May Chu (OSTP/EOP, USA), Russ Coleman (DoD, USA), Jean-François Delfraissy (INSERM, France), Steve Landry (BMGF, USA), Samba Sow (CVD, Mali)

Session 3: National and International Coordination of R&D activities, sharing of results and implementation of networks and collaborations
Chair: Janusz Paweska (NICD, South Africa)

14:10-14:55 How were regulatory coordination efforts and timelines adjusted to expedite R&D?

AVAREF-facilitated joint reviews of clinical trial applications (15 min), Mimi Darko (FDA, Ghana)

Short presentations (5 min each):

Assisted review of Phase 3 trial protocol, Kabiné Souaré (Ministry of Health, Guinea)

International Collaborative Efforts Supporting the WHO Emergency Use Assessment and Listing (EUAL) of Diagnostics Procedure, Robyn Meurant (WHO)

Preparation of standards reagents, Philip Minor (NIBSC, UK)

Discussion (15 min)

14:55-15:30 Data sharing and access to early information on epidemiology and results of clinical trials.

Introduction (10 min): Piero Olliaro (WHO/TDR)

Panel discussion (25 min) moderated by Piero Olliaro:
Amadou Sall (Inst Pasteur, Senegal), Philippa Easterbrook (WHO), Bronwyn MacInnis (Broad Inst, USA), Calum Semple (LSTM, UK)

15:30-16:00 ***Coffee break***

16:00-16:30 Country level and international level coordination. Technology-specific and general coordination

Panel discussion (30 min) moderated by Brian Greenwood (LSHTM, UK):
Nyankoye Haba (NBTS, Guinea), Wiltshire Johnson, (Pharmacy Board Sierra Leone), Libby Higgs (NIH/NIAID, USA), Line Matthiessen (EC), Marie-Paule Kieny (WHO)

16:30-17:50 Establishing, sustaining and using networks/platforms for effective R&D responses to global public health threats

The experience of the European Mobile Lab network, Stephan Günther (BNI, Germany) (15 min)

The 'Global Research Collaboration for Infectious Disease Preparedness' (GloPID-R), and the new European Commission's Emergency research funding mechanism, Line Matthiessen (EU) (20 min)

Coordinated platform for evaluation of therapeutics, Peter Horby (Oxford University, UK) (15 min)

Panel discussion (30 min) moderated by John Mackenzie (Curtin University, Australia): Akin Abayomi (African Voices Conference), Rob Fowler (SHSC, USA), Johan van Griensven (ITM-Antwerp, Belgium), Adam Levine (Brown University, USA), Lucy Ward (DoD, USA)

17:50-18:15 General Discussion and wrap-up of Day 1

Tuesday 12 May

SESSION 4: Improving the planning and execution of research activities before and after global public health threats.
Chair: David Kaslow (PATH, USA)

The time available between public health threats provides an opportunity to convene scientists and other relevant stakeholders to involve them in the development of innovative approaches that address a broad range of R&D questions in the context of global public health threats. Critical activities might include the establishment of research platforms/networks for the coordinated conduct and requirements of studies, identifying sources and mechanisms for the coordinated and rapid funding of research, and agreeing on coordinated central mechanisms that can provide timely reviews of studies, and ethical and regulatory guidance, among others tasks.

9:00-9.35 **Agreeing *a priori* on the characteristics of priority products for development** (5 min each)

The experience of Team B, Mike Osterholm (University of Minnesota, USA)

Setting Target Product Profiles (TPPs) for vaccines against diseases of epidemic potential through the WHO PDVAC, David Kaslow (PATH, USA)

The experience of setting up TPPs for *in vitro* diagnostics, Manica Balasegaram (MSF, Switzerland)

Discussion (20 min)

9:35-10:30 **Developing consensus on generic approaches, innovative methods and protocols so that these are available and promptly reviewed and endorsed when outbreaks happen**

Perspectives *(discussion on clinical trial designs including prior approval of protocols*):

Trudie Lang (Oxford University, UK): How do we design trials in disease outbreaks that enable a rapid answer within the realities on the ground? (10 min)

Libby Higgs (NIH/NIAID, USA): An innovative adaptive trial design to assess efficacy and safety of investigational therapeutics during infectious disease outbreaks: the MCM RCT (10 min)

Gail Carson (ISARIC): Accelerating access to R&D results to inform the response to outbreaks (10 min)

General discussion (25 min) moderated by David Kaslow (PATH, USA)

10:30-11:00 ***Coffee break***

11:00-11:20 **Keynote address: Preparing and integrating communication, advocacy and community engagement efforts required to mount an effective R&D response,** Cheikh Niang (Diop University, Senegal) (20 min)

SESSION 5: Integrating R&D efforts into broader public health response measures in future outbreaks/public health threats
Chair: Helen Rees* (*University Witwatersrand, South Africa)

Vaccine research preparedness and research implementation in the context of an on-going epidemic. How do we prepare the future, what have we learnt for current experiences? What are the gaps, how do we undertake research in the middle of the immediate need for a lifesaving response to an outbreak?

11:20-11:30 **Framing and expediting recommendations,** Helen Rees, co-chair of SAGE Working Group on Ebola vaccines (10 min)

11:30-11:40 Integrating investments into Ebola vaccines procurement, preparedness; and deployment and into immunization programme recovery and strengthening, Seth Berkley (GAVI) (10 min)

11:40-13:15 Improving the transition from research to access for successful interventions

Outlining the key components, contributions and challenges to collaborative vaccine deployment plans, Jean-Marie Okwo-Bele (WHO), on behalf of countries and partners (10 min)

Panel discussion (30 min) on "Potential roadmap and blueprint for transitioning vaccines from development to deployment in the context of an Ebola or other emerging disease outbreak", moderated by Helen Rees:
Gregory Glenn (Novavax, USA), Swati Gupta (Merck Sharp & Dohme, USA), Adam MacNeil (CDC, USA), Eric Midboe (DoD, USA), Doreen Mulenga (UNICEF), Moncef Slaoui (GSK, Belgium), Camille Soumah (EPI Guinea), Paul Stoffels (J&J, USA)

Completing the development pathway for products that have shown promise during the 2014 Ebola virus outbreak, but could not be fully evaluated due to the diminishing number of EVD cases

13:15-14:00 ***Lunch break***

14:00-14:40 Introduction to key regulatory issues, Luciana Borio (FDA, USA) and Enrica Altieri (EMA) (15 min)

Discussion (40 min) moderated by Margareth Sigonda (NEPAD):
Enrica Alteri (EMA), Luciana Borio (FDA, USA), Gregory Glenn (Novavax), Swati Gupta (Merck), Wiltshire Johnson (Pharm Board, Sierra Leone), Michael Pfleiderer (PEI, Germany), Moncef Slaoui (GSK), Matthias Stahl (WHO), Paul Stoffels (J&J)

14:40-15:10 **New R&D funding models to support the development of products where the market is inexistent, unknown or unreliable.**

Panel discussion (30 min) moderated by John-Arne Rottingen (NIPH, Norway):
Gregory Glenn (Novavax, USA), Swati Gupta (Merck Sharp & Dohme, USA), Bernard Pécoul (DNDi, Switzerland), Robin Robinson (BARDA, USA), Margareth Sigonda (NEPAD), Moncef Slaoui (GSK, Belgium), Paul Stoffels (J&J, USA), Angela Wittelsberger (IMI, EC)

15:10-15:40 ***Coffee break***

SESSION 6: Bringing it all together: setting up a process for identifying, agreeing and implementing a blueprint for R&D preparedness in the context of global public health threats
Chair: Mike Levine (Univ Maryland, USA)

15:40-16:00 **Keynote address (20 min)** (Mike Levine)

16:00-17:00 General discussion and Next Steps

Annex 3

List of participants

Prof. Akin Abayomi

Professor of Haematology, University of Stellenbosch, South Africa

Dr Selidji Agnandji

Co-Director, Centre de Recherches Médicales de Lambaréné, Gabon

Dr Umberto Alessandro

Director, MRC Laboratories The Gambia,, Gambia

Dr Enrica Alteri

Head, Division Human Medicine Evaluation, European Medicines Agency, London, UK

Dr Annick Antierens

Manager, Investigational Experimental Ebola Products, Medical Department, MSF, Geneva, Switzerland

Dr Oumou Bah-Sow

Chef du service de Pneumophtisiologie, Présidente du Comité National d'Ethique pour la Recherche en Santé, Hopital National Ignace Deen, Conakry, Guinea

Dr Manica Balasegaram

Executive Director, Access Campaign, MSF, Geneva, Switzerland

Dr Sina Bavari

Science Director, US Army Medical Research Institute of Infectious Diseases, Ft. Detrick, MD, USA

Dr Elizabeth Bell

Director, National Center for Emerging and Zoonotic Diseases, Centers for Disease Control and Prevention, Atlanta, GA, USA

Dr Seth Berkley

Chief Executive Officer, GAVI - The Vaccine Alliance, Geneva, Switzerland

Dr Luciana Borio

Acting Chief Scientist, Food and Drug Administration (FDA), Washington, DC, USA

Dr Miles Brennan

Director of Regulatory Affairs, MAPP Biopharmaceutical, Inc., San Diego, CA, USA

Dr Miles Carroll

Deputy Director, Head of Research, Public Health England, Salisbury, UK

Dr Gail Carson

Clinical Coordinator & Consultant in Infectious Diseases, Centre for Tropical Medicine, University of Oxford (ISARIC), UK

Dr Dominique Charron

Director, Agriculture and Environment, International Development Research Centre (IDRC), Ottawa, Canada

Dr Fadima Cheick

Center for Vaccine Development (CVD), Bamako, Mali

Dr May Chu

Assistant Director for Public Health, Office of Science and Technology Policy, Executive Office of the President, Washington, DC, USA

Dr Arlene Chua

Diagnostics Advisor, MSF, Geneva, Switzerland

Mr Jacob Cohn

Vice President, Governmental Relations, Bavarian Nordic, Kvistgaard, Denmark

Col/Dr Russell Coleman

Joint Project Manager, Medical Countermeasure Systems, US Department of Defense, Washington, DC, USA

Mrs Emer Cooke

Head of International Affairs, European Medicines Agency, London, UK

Dr Christine Dahlke

I. Medizinische Klinik und Poliklinik. Infektiologie: Emerging Infection, Universitätsklinikum Hamburg Eppendorf, Hamburg, Germany

Dr Inger Damon

Director, Division of High Consequence Pathogens and Pathology, NCEZID/DHCPP, Centers for Disease Control (CDC), Atlanta, GA, USA

Dr Mimi Darko

Head, Safety Monitoring & Clinical Trials Division, Food and Drugs Authority (FDA), Accra, Ghana

Prof. Jean-François Delfraissy

Director, ANRS, Paris, France

Dr Enria Delia

Director, Instituto Nacional de Enfermedades Virales Humanas (Inevh), Pergamino, Argentina

Dr Emmet Dennis

President, University of Liberia, Monrovia, Liberia

Dr Alpha Amadou Diallo

Chef Service Recherche, Bureau de Stratégie et Développement, Ministère de la Santé, Conakry, Guinea

Dr Fatoumata Diallo

Center for Vaccine Development (CVD), Bamako, Mali

Prof. Xiaoping Dong

Deputy Director, National Institute for Viral Disease Control and Prevention, China CDC, Beijing, People's Republic of China

Dr Ousmane Doumbia

Secrétaire Général du Ministère de la Santé et de l'Hygiène Publique, Bamako, Mali

Dr Monica Eimunjeze

Director, Registration & Regulatory Affairs, National Agency for Food and Drug Administration and Control (NAFDAC), Lagos, Nigeria

Dr Eleanor Fish

Senior Scientist & Professor, Immunology, University Health Network & University of Toronto, Canada

Dr Rob Fowler

Sunnybrook Health Sciences Centre, Toronto, Canada

Dr Gregory Glenn

Senior Vice President of Research and Development, Novavax Inc., Gaithersburg, MD, USA

Dr Tore Godal

Special Adviser, Section for Global Initiatives, Norwegian Ministry of Foreign Affairs, Oslo, Norway

Mr Dimitris Gouglas

Adviser, Department of International Public Health, Norwegian Ministry of Foreign Affairs, Oslo, Norway

Dr Rebecca Grais

Director, Research, EPICENTRE/MSF, Paris, France

Dr Brian Greenwood

Professor, Faculty of Infectious & Tropical Diseases, London School of Hygiene & Tropical Medicine, London, UK

Prof. Stephan Guenther

Head of Department, Virology, Bernhard-Nocht-Institute for Tropical Medicine, Hamburg, Germany

Dr Swati Gupta

Executive Director, Office of Public Health and Science, Merck & Co., Inc., West Point, PA, USA

Mr Nyankoye Haba

Director General, Centre National de transfusion Sanguine (CNTS) de Conakry, Ministère de la Santé, Conakry, Guinea

Prof. Scott Halperin

Director, Canadian Center for Vaccinology, Dalehousie University, Halifax, Canada

Prof. Frederick Hayden

Stuart S. Richardson Professor of Clinical Virology and Professor of Medicine, University of Virginia School of Medicine, Charlottesville, VA, USA

Dr Miriam Henkens

International Medical Coordinator, MSF, Brussels, Belgium

Dr Elizabeth Higgs

Global Health Advisor, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Rockville, MD, USA

Prof. Adrian Hill

Director, Jenner Institute, University of Oxford, UK

Prof. Peter Horby

Senior Clinical Research Fellow, Centre for Tropical Medicine and Global Health, University of Oxford, UK

Ms Anne Hradsky

Advocacy Coordinator, Global Health R&D, DSW, Brussels, Belgium

Dr Giuseppe Ippolito

Scientific Director, National Institute for Infectious Diseases Lazzaro Spallanzani, Rome, Italy

Dr Michael Jacobs

Chief of Infections Diseases, Royal Free London NHS Foundation Trust, London, UK

Dr Peter Jahrling

Director, Integrated Research Facility (IRF), Division of Clinical Research (DCR), National Institute of Allergy and Infectious Diseases (NIAID), NIH, Frederick, MS, USA

Dr Markieu Janneh-Kiara

Director of Pharmaceutical Services, Ministry of Health & Social Welfare, Banjul, Gambia

Dr Lloyd Jeffs

Principal Investigator, TKM-Ebola Program, Tekmira Pharmaceuticals, Burnaby, Canada

Mr Wiltshire Johnson

Registrar/CEO , Pharmacy Board of Sierra Leone, Ministry of Health, Freetown, Sierra Leone

Dr Franca Jones

Acting Principal Director, Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense, Department of Defense, Washington, DC, USA

Dr David Kaslow

Vice President, Product Development and Introduction, PATH, Seattle, WA, USA

Dr Konstantin Keller

Head of Department, Blood, Tissues and Cells, Vaccines, Blood, Sera, Allergens, Federal Ministry of Health, Bonn, Germany

Dr Stephen Kennedy

Coordinator, EVD Research, Incident Manager System (IMS) and Research Scientist, Pacific Institute for Research and Evaluation (PIRE), Monrovia, Liberia

Prof. Oleg Kiselev

Director, Research Institute of Influenza, Saint-Petersburg, Russian Federation

Dr Hiroshi Kitaguchi

Director, General Manager, Department of Business Development, Toyama Chemical Co., Ltd., Tokyo, Japan

Ms Maria Klimathianaki

Project Officer, Fighting Infectious Diseases and Global Epidemics, DG Research and Innovation, European Commission, Brussels, Belgium

Prof. Mandy Kader Konde

Chairman, Guinea Ebola Research Commission, Cellule de Coordination Ebola, Ministère de la Santé, Conakry, Guinea

Prof. Peter Kremsner

Director, Institute of Tropical Medicine, University of Tübingen, Germany

Prof. Sanjeev Krishna

Professor of Molecular Parasitology and Medicine, Institute for Infection and Immunity, St George's University of London, UK

Dr Steve Landry

Vaccine Program Manager, Bill & Melinda Gates Foundation, Seattle, USA

Prof. Trudie Lang

Global Health Network, Nuffield Department of Medicine, Medical Sciences Division, University of Oxford, UK

Dr Regine Lehnert

Consultant, Bad Honnef, Germany

Dr Betrand Lepine

President, FabEntech, Lyon, France

Dr Eric Leroy

Directeur Général, Centre International de Recherches Médicales de Franceville, Gabon

Dr Adam Levine

Primary Investigator, Ebola Research Team, Technical Unit, International Medical Corps, Boston, USA

Dr Mike Levine

Director, Center for Vaccine Development, University of Maryland School of Medicine, Baltimore, USA

Dr Chris Lewis

Health Adviser, Research and Evidence Division, Department for International Development (DFID), London, UK

Dr Bronwyn MacInnis

Associate Director, Infectious Disease Program, Broad Institute and Harvard School of Public Health, Cambridge, MA, USA

Prof. John Mackenzie

Research Associate and Professor of Tropical Infectious Diseases, Curtin University, Melbourne, Australia

Dr Adam Macneil

Epidemiologist, Global Immunization Division, Centers for Disease Control and Prevention (CDC), Atlanta, GA, USA

Prof. Saibou Maiga

Member, Comité National d'Ethique pour la Santé et les Sciences de la Vie (CNESS), Bamako, Mali

Mr Jacques-François Martin

Président du conseil de surveillance, FabEntech, Lyon, France

Dr Line Matthiessen

Head of Unit, Fighting Infectious Diseases and Global Epidemics, DG Research and Innovation, European Commission, Brussels, Belgium

Dr Gisele Mbuyi

National Surveillance Officer, Department of Diseases Control, Kinshasa, Democratic Republic of Congo

LTC/Dr Eric Midboe

Joint Product Manager, BioDefense Therapeutics, Department of Defense, Fort Belvoir, VA, USA

Dr Philip Minor

Deputy Director, Head of Virology, National Institute for Biological Standards and Control (NIBSC), Potters Bar, UK

Dr Oliver Morgan

Chief Science Officer, CDC Sierra Leone, Centers for Disease Control and Prevention (CDC), Atlanta, GA, USA

Dr Doreen Mulenga

Deputy Director, Supply Programme, United Nations Children's Fund (UNICEF), Nordhavn, Norway

Ms Aurelia Nguyen

Director, Policy and Market Shaping, Policy & Performance, GAVI - The Vaccine Alliance, Geneva, Switzerland

Dr Cheik Ibrahima Niang

Professor of Sociology, Cheikh Anta Diop University, Dakar, Senegal

Dr Wissedi Sio Njoh

Director of Operations for the Phase II/III EVD Clinical Study, Pacific Institute for Research and Evaluation (PIRE), Monrovia, Liberia

Dr Dieudonné Nkoghe

Chef d'Unité, Centre International de Recherches Médicales de Franceville, Gabon

Dr Gunnstein Norheim

Scientist, Division of Infectious Disease Control, Norwegian Institute of Public Health, Oslo, Norway

Dr Mike Osterholm

Director, Center for Infectious Disease Research and Policy (CIDRAP), University of Minnesota, Minneapolis, MN, USA

Prof. Janusz Paweska

Head, Center for Emerging and Zoonotic Diseases, National Institute for Communicable Diseases, Sandringham-Johannesburg, South Africa

Dr Bernard Pécoul

Executive Director, DNDI, Geneva, Switzerland

Mr Michel Perron

Vice-President of External Affairs and Business Development, Canadian Institutes of Health Research, Ottawa, Canada

Dr Elizabeth Petzold

Project Lead, Duke Clinical Research Institute, Duke University, Durham NC, USA

Dr Olivier Peyrrouset

Medical Affairs, FabEntech, Lyon, France

Dr Micheal Pfleiderer

Head, Section of Viral Vaccines, Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Langen, Germany

Mr Julien Potet

NTD Policy Advisor, Access Campaign, MSF, Paris, France

Dr Engelhardt Rainer

Assistant Deputy Minister and Chief Science Officer, Office of the Chief Science Officer, Public Health Agency of Canada, Ottawa, Canada

Dr Helen Rees

Task Force on Immunization co-chair , Executive Director, Wits Reproductive Health & HIV Institute, University of Witwatersrand, South Africa

Dr Jim Richards

Director and Strategic Advisor, National Research Council Canada, Ottawa, Canada

Dr Robin Robinson

Director, Biomedical Advanced Research Development Authority (BARDA), US Department of Health and Human Services (HHS), Washington DC, USA

Prof. John-Arne Rottingen

Director, Division of Infectious Disease Control, Norwegian Institute of Public Health, Oslo, Norway

Dr Tomoya Saito

Chief Senior Researcher, Department of Health Crisis Management, National Institute of Public Health, Ministry of Health, Labor and Welfare, Wako, Japan

Dr Amadou Sall

Institut Pasteur de Dakar, Senegal

Dr Michael Selgelid

Director, Centre for Human Bioethics, Monash University, Melbourne, Australia

Dr Calum Semple

London School of Hygiene and Tropical Medicine, London, UK

Dr Micaela Serafini

Medical Director, MSF, Geneva, Switzerland

Joe Sgherza

Senior VP, Global Operations, ClinicalRM, Hinckley, OH, USA

Dr Margareth Sigonda

Pharmaceutical Coordinator, Human Development - NEPAD Science, Technology and Innovation Hub, Pretoria, South Africa

Dr Lucky Slamet

Technical Consultant, National Agency of Drug and Food Control, Jakarta, Indonesia

Dr Moncef Slaoui

Chairman, GSK Vaccines, King of Prussia, VA, USA

Dr Kabiné Souaré

Director, Direction nationale de la Pharmacie et des Laboratoires, Ministère de la Santé, Conakry, Guinea

Dr Camille Tafsir Soumah

EPI Manager, Ministry of Health, Conakry, Guinea

Prof. Samba Sow

Director General, Center for Vaccine Development-Mali (CVD-Mali), Bamako, Mali

Dr Christina Spiropoulou

Team Lead, Molecular Pathogenesis and Therapeutics, Viral Special Pathogens Branch, Centers for Disease Control and Prevention, (CDC), Atlanta, GA, USA

Dr Armand Sprecher

Public Health Specialist, MSF, Brussels, Belgium

Dr Paul Stoffels

Chief Scientific Officer, Johnson & Johnson, New Brunswick, NJ, USA

Mrs Oulématou Telly

Social Worker, Center for Vaccine Development (CVD-Mali), Bamako, Mali

Mrs Victoria Tifft

CEO, Clinical Research Management, ClinicalRM, Hinckley, OH, USA

Dr Mame Aissatou Toure

Head of Immunology Department, Pasteur Institute, Dakar, Senegal, Senegal

Mr Laurent Vacher

Responsable R&D et Business Development Manager, Lyon, France

Prof. Johan Van Griensven

Head of Unit of HIV and Neglected Tropical Diseases, Institute of Tropical Medicine, Antwerpen, Belgium

Dr Geert Vanden Bossche

Ebola Program Manager, Vaccine Implementation, GAVI - The Vaccine Alliance, Geneva, Switzerland

Dr Shiyong Wang

Senior Health Specialist, GHDNR (Health Practice), World Bank, Washington, DC, USA

Dr Lucy Ward

Senior Scientist, JPM-MCS/JVAP, US Dept of Army, Washington, DC, USA

Dr Conall Watson

Senior Registrar in Public Health, Infectious Disease Epidemiology, London School of Hygiene & Tropical Medicine, London, UK

Dr Angela Wittelsberger

Scientific Officer, Innovative Medicines Initiative (IMI), Brussels, Belgium

Mr Aminu Yakubu

Desk Officer, Health Planning, Research and Statistics, National Health Research Ethics Committee, Federal Ministry of Health, Abuja, Nigeria

Mr Koichi Yamada

Executive Vice President, FUJIFILM Corporation, Pharmaceutical Products Division, Boston, Japan

Dr Yazdan Yazdanpanah

Service des Maladies Infectieuses et tropicales, Hopital Bichat Claude Bernard, , FRANCE

Dr Larry Zeitlin

President, Mapp Biopharmaceutical, Inc., San Diego, CA, USA

Mrs Jennifer Zimmerer

Senior Program Manager, ClinicalRM, Hinckley, OH, USA

Observers

Mr Martin Enserink

Contributing News Editor, Science Magazine, USA

WHO Secretariat

Dr Dicky Akanmori

Technical Officer, AF/RIN - Routine Immunization and New Vaccines, (IVE/RIN), WHO/AFRO, Brazzaville, Democratic Republic of Congo

Dr Bruce Aylward

Assistant Director-General, Polio and Emergencies (PEC) / Special Representative for the Ebola Response, WHO/HQ, Geneva, Switzerland

Ms Daniela Bagozzi

Senior Information Management Officer, Essential Medicines and Health Products, (EMP) / Ebola R&D Communications, WHO/HQ, Geneva, Switzerland

Dr Martin Friede

Lead, Technology Transfer Initiative (EMP/PHI/TTI) / Lead, Drugs, Ebola R&D, WHO/HQ, Geneva, Switzerland

Dr Ana Maria Henao-Restrepo

Medical Officer, Immunization, Vaccines and Biologicals (IVB) / Lead Vaccines Phase 3 and Initial Deployment, Ebola R&D, WHO/HQ, Geneva, Switzerland

Dr Marie-Paule Kieny

Assistant Director-General, Health Systems and Innovation/Lead, Ebola R&D, Geneva, Switzerland

Dr André Loua

Regional Adviser, AF/BLT Blood Safety, Laboratories and Health Technology, (HSS/BLT), WHO/AFRO, Brazzaville, Democratic Republic of Congo

Dr Vasee Moorthy

Technical Officer, Initiative for Vaccine Research (IVB/IVR) / Lead, Vaccines Phase 1 and 2, Ebola R&D, WHO/HQ, Geneva, Switzerland

Dr Jean-Marie Okwo-Bele

Director, Immunization, Vaccines and Biologicals (IVB), WHO/HQ, Geneva, Switzerland

Dr Marie-Pierre Preziosi

Medical Officer, Initiative for Vaccine Research (IVB/IVR) / Lead, Preparation for Large Scale Vaccine Introduction, Ebola R&D, WHO/HQ, Geneva, Switzerland

Dr Cathy Roth

Technical Adviser, Office of the Assistant Director-General, Health Systems and Innovation (HIA) / Lead, Research Priorities, Data Synthesis and Ethics, Ebola R&D, WHO/HQ, Geneva, Switzerland

Dr Mathias Stahl

Medical Officer, Prequalification Team (EMP/RHT/PQT) / Lead, Regulation, Ebola R&D, WHO/HQ, Geneva, Switzerland

Dr David Wood

Coordinator, Technology, Standards and Norms (EMP/RHT/TSN) / Lead, Blood Products and Diagnostics, Ebola R&D, WHO/HQ, Geneva, Switzerland