RECOMMENDATIONS

RECOMMENDATION 1

Support the development of sustainable health systems and research capacities—Inter-epidemic

To better prepare low-income countries to both respond to future outbreaks and conduct foundational research, during the inter-epidemic period (as covered in IHR 2005), major research funders and sponsors (e.g., NIH and comparable public and private research funders) and development agencies (e.g., USAID and comparable public and private development funders) should collaborate with WHO and regional centers of excellence to:

(1) Assist in monitoring and evaluating the development of national and regional core capacities under IHR 2005.
(2) Provide financial and technical assistance to the extent possible or establish a financing mechanism, to help build sustainable core capacities at the intersection of health systems and research (e.g., diagnostics, surveillance and basic epidemiology).

RECOMMENDATION 2-A

Develop memoranda of understanding to facilitate data collection and sharing—Inter-epidemic

Research funders, sponsors, national governments, and humanitarian organizations should work together with WHO to develop memoranda of understanding during the inter-epidemic period to improve capacity to collect and share clinical data, with all necessary provisions to protect the privacy of individuals and anonymize data for epidemiological research.

RECOMMENDATION 2-B

Provide resources to enable data collection and sharing—Epidemic

At the start of an outbreak, developed countries, research funders and sponsors should work together with national and international health care providers responding to an outbreak, to provide the additional resources and personnel needed to enable systematic data collection on routine care practices and outcomes. Data collection should begin as soon as possible, and data should be shared and coordinated in a central database to advance an understanding of the natural history of the disease and of the best practices for standard of care. This information should also be used to inform protocols for clinical trials.

RECOMMENDATION 3

Facilitate capacity for rapid ethics reviews and legal agreements—Inter-epidemic

Major research sponsors should work with key stakeholders in low- and middle-income countries to:

- Build relationships between local ethics boards and entities that could provide surge capacity for ethics review in the event of an emergency situation. Such efforts would include strengthening networks of ethics boards in a region or connecting local and outside ethics boards, agencies, or experts. Memoranda of understanding setting forth who will provide what services and how decisions will be made should be executed in the inter-epidemic period.
- Establish banks of experts in negotiation of clinical trial and material transfer agreements, and other essential components of collaboration, who are willing to offer pro bono advice and support to counterparts in countries affected by outbreaks.
- Develop template clinical trial agreements reflecting shared understandings about key issues such as data sharing, post-trial access to interventions, storage and analysis of bio-specimens and investments to build local capacity.

RECOMMENDATION 4

Ensure that capacity-strengthening efforts benefit the local population—Epidemic

When the health care services of a population need to be enhanced or augmented in order to support the conduct of research, development organizations (e.g., USAID), international bodies, and other stakeholders should partner with national governments to ensure that capacity-strengthening efforts are not limited to services that solely benefit study participants.

RECOMMENDATION 5

Enable the incorporation of research into national health systems—Inter-epidemic

National governments should strengthen and incorporate research systems into their emergency preparedness and response systems for epidemic infectious diseases. The multilateral institutions (WHO and The World Bank Group), and regional and international development agencies, and foundations working in global health, should support national efforts by providing expertise and financing.

RECOMMENDATION 6-A

Prioritize community engagement in research and response—Epidemic

International and national research institutions, public health agencies, and humanitarian organizations responding to an outbreak should engage communities in the research and response by:

a) Identifying social science experts in community engagement and communications to lead their efforts to effectively engage and connect with communities affected by the epidemic.
b) Consulting with key community representatives from the outset of an outbreak to identify a range of local leaders who can participate in planning research and response efforts, help to map community assets, articulate how to infuse cultural and historical context into presentations, and identify gaps and risks in developing public health measures and designing research protocols. Consultations should be continued throughout the implementation phase by relevant actors to provide information as the outbreak evolves, provide feedback about progress and results, and inform and recommend changes to strategies based on feedback from the community.
c) Coordinating within and across sectors, with national authorities and with each other to ensure alignment of social mobilization and communication activities with the overall response and research strategies, and that there is sufficient support and training to local leaders and organizations to engage communities in research and response.

RECOMMENDATION 6-B

Fund training and research into community engagement and communication for research and response—Inter-epidemic

WHO, international research institutions, governments, public health agencies, and humanitarian organizations should actively collaborate together to fund training and research for developing frameworks, networks, strategies and action plans for community engagement and communication on public health and research that could inform and be mobilized during an epidemic.

RECOMMENDATION 7-A

Coordinate international efforts in research and development for infectious disease pathogens—Inter-epidemic

An international coalition of stakeholders (ICS) with representation from governments, foundations, academic institutions and researchers, pharmaceutical companies, humanitarian organizations, and WHO (such as the Coalition for Epidemic Preparedness Innovations) should work on the following planning activities to better prepare for and improve the execution of clinical trials conducted during infectious disease events:

(1) Advise on and invest in priority pathogens to target for research and development, and promote a process to ensure that, whenever possible, interventions should be brought through Phase 1 or Phase 2 trials prior to an outbreak.
(2) Develop generic clinical trial design templates for likely outbreak scenarios. The reasoning and rationale behind the designs and the situations in which each would be best utilized should be discussed with representatives of ethics review boards, major humanitarian organizations, and at-risk local communities to promote buy-in from stakeholders in advance of an outbreak.
(3) Develop a list of key experts in clinical research from different agencies and organizations who could be rapidly seconded to the coalition of stakeholders and deployed anywhere in the world when an outbreak is first identified.

RECOMMENDATION 7-B

Establish and implement a cooperative international clinical research agenda—Epidemic

In the event of an emerging epidemic the international coalition of stakeholders (ICS) in Recommendation 7a should designate an independent multi-stakeholder rapid research response workgroup (R3W) with expertise in the pathogen of concern, R&D of investigational interventions, clinical trial design, and ethics and regulatory review, and including representatives from the affected communities, to:

(1) Rapidly appraise and prioritize a limited set of vaccine and therapeutic products with the most promising preclinical and clinical data for clinical trials.
(2) Select a portfolio of trial designs that are best suited to the investigational agent(s) and the manifestation of the epidemic.
    a) The trial designs used should lead to interpretable safety and efficacy data in the most reliable and fastest way.
    b) Randomized trials are the preferable approach, and unless there are compelling reasons not to do so, every effort should be made to implement randomized trial designs.
(3) Monitor and evaluate clinical trials conducted during an outbreak to enhance transparency and accountability.