Public Workshop of the Committee on Clinical Trials During the 2014–2015 Ebola Outbreak
Fourth Committee Meeting
August 15–16, 2016
Bella Casa Hotel
2nd Street Sinkor Tubman Blvd
Monrovia, Liberia
August 15, 2016

Day ONE

SETTING RESEARCH PRIORITIES DURING EMERGENCY INFECTIOUS DISEASE EVENTS

Day One Meeting Objective:
- Explore lessons learned from the 2014–2015 Ebola outbreak to best prioritize, design and implement clinical research during public health emergencies

8:30a.m. Meeting Registration
9:00a.m. Welcome by Committee Co-Chairs
Gerald Keusch, Committee Co-Chair
Keith McAdam, Committee Co-Chair

Welcome and Perspectives from the Ministries of Health
- Discuss the top lessons learned from the Ebola outbreak. How can research best be incorporated into national response efforts in the event of future outbreaks?

Co-Moderators: Janice Cooper, Carter Center Liberia
M. Bailor Barrie, Wellbody Alliance

Speakers: (10 minutes prepared remarks each, followed by Q&A)
- Hon. Zulianatu Cooper, Deputy Minister of Health and Sanitation II, Ministry of Health and Sanitation of the Republic of Sierra Leone

10:00a.m. BREAK
Panel 1: Prioritizing Research in Outbreak Response

- Describe national capacity over time to respond to the outbreak. What were the key challenges and lessons learned?
- Discuss the process by which research proposals were prioritized.
- Discuss how the numerous and varied institutional pressures influenced decision-making priorities.
- Consider how to facilitate the incorporation of clinical trials in the public health and care response during future emergency infectious disease events.

Co-Moderators: Janice Cooper, Carter Center Liberia
M. Bailor Barrie, Wellbody Alliance

Panelists: (10 minutes prepared remarks each):
- Tolbert Nyenswah, Legal & Senior Public Health Specialist, Deputy Minister Health for Disease Surveillance and Epidemic Control, Liberia
- Alie Wurie, Case Management Lead, National Emergency Response, Ministry of Health & Sanitation, Republic of Sierra Leone
- Alpha Mahmoud Barry, Public Health Specialist, Researcher, University of Gammal, Conakry, Guinea

Respondents: (5 minutes each, reaction to panelists)
- Moses Massaquoi, National Case Manager, Ebola Response, Ministry of Health/IMS; Country Director, Clinton Health Access Initiative (CHAI); Chair, Sub-Regional Consortium on Ebola Virus Vaccine and Therapeutic Trials in Guinea, Liberia and Sierra Leone
- Vuyu Kanda Golakai, Professor, College of Health & Life Sciences, University of Liberia

Moderated Discussion with Committee and Participants

LUNCH
Panel 2: Perspectives from the Research and Training Community

- Discuss lessons learned from the international research partnerships during the Ebola outbreak. How would you apply those lessons to future research collaborations?
- Examine the research capacity that was acquired by the national researchers as a result of the international research partnerships.
- Discuss the process by which research proposals for therapeutic and vaccine candidates were prioritized for clinical trials. How can this process be improved?
- Describe challenges with designing and implementing scientifically and ethically robust vaccine and therapeutic trials during the Ebola outbreak.
- Explore new ideas and innovative approaches for accelerating future clinical trials in emergency contexts; identify pragmatic methods for building community support, speeding data collection, and assessing the safety, efficacy, and effectiveness of therapeutics and vaccines.

Moderator: Fred Wabwire Mangen, Makerere University – Uganda

Panelists: (10 minutes prepared remarks each)

- Mandy Kader Konde, Professor and Chair, Department of Public Health, University of Conakry; Chairman Guinea Ebola Research Commission; Executive Director, Center of Research on Diseases (CEFORPAG) – Guinea Ring Vaccine
- Mohamed Samai, PI STRIVE vaccine study; Acting Provost of College of Medicine and Allied Health Sciences (COMAHS); Deputy Director for Research, Ministry of Health and Sanitation, Freetown, Sierra Leone – STRIVE Vaccine Trial
- Stephen B. Kennedy, Co-PI, PREVAIL & Coordinator, EVD Research, Incident Management System (IMS), Liberia – PREVAIL Trials

Respondents: (5 minutes each, reaction to panelists)

- Abdoul Habib Beavogui, Director, National Center for Training and Research in Rural Health (CNFRSR) “Jean SENECAL “of Maferinyah, Republic of Guinea – JIKI (favipiravir)
- Bartholomew Wilson, Social Mobilization, Communication and Community Engagement (SMC) Lead of the Partnership for Research on Ebola Virus in Liberia – PREVAIL Trials

Moderated Discussion with Committee and Participants

2:45p.m.  BREAK
Panel 3: Perspectives from Regulatory Authorities

- Describe the mandate of your agency and role in research, development, and procurement of therapeutic and vaccine products.
- Discuss the lessons learned and practical challenges encountered during the Ebola outbreak.
- Identify key capacity building needs to improve local regulatory capabilities; consider the availability of resources and regulatory protocols to enable the rapid review of investigational medical products.

Moderator: Susan Ellenberg, University of Pennsylvania

Panelists: (10 minutes prepared remarks each)

- Beno Yakubu Nyam, Chief Regulatory Officer, Clinical Trial Unit, Drug Evaluation and Research Directorate, National Agency for Food and Drug Administration and Control (NAFDAC)
- Onome Thomas Abiri, Head of Pharmacovigilance and Clinical Trial Department, Pharmacy Board of Sierra Leone, Ministry of Health and Sanitation
- David Sumo, Managing Director, Liberian Medicines Health Products Regulatory Authority (LMHRA)

Moderated Discussion with Committee and Participants
Panel 4: Perspectives from the Ethics Review Board (ERB)

• Describe the procedures for review of research proposals during the Ebola outbreak. Discuss lessons learned, practical challenges encountered, and identify approaches for more efficient reviews in the future.
• Discuss the role of the ERB in helping shape the clinical trial design decisions and in negotiating terms of the trial.
• In the event of a future outbreak, discuss any best practices to achieve community understanding of key trial design components (such as randomization) if they are determined to be required for valid trial results.

Moderator: Olayemi Omotade, University of Ibadan

Panelists: (10 minutes prepared remarks each)

• Hector Morgan, Professor, Department of Microbiology, College of Medicine and Allied Health Sciences, University of Sierra Leone; Director, Research Ethics Committee, Freetown, Sierra Leone
• Fatorma K. Bolay, Director, Liberia Institute of Biomedical Research (LIBR); Chairperson, Liberia Institute for Biomedical Research Ethics Committee
• Nnah Djenab Sylla, Secretary General, National Ethics Committee on Health Research, Guinea
• Gloria Mason, Coordinator, National Research Ethics Board (NREB), Liberia

Moderated Discussion with Committee and Participants

5:30p.m. ADJOURN

6:15p.m. Wine reception at the Bella Casa restaurant ‘Suave’ followed by dinner in the large meeting hall

• Hosted by the National Academy of Medicine’s independent commission for a Global Health Risk Framework
• Remarks by Dr. Oyewale Tomori, President, Nigerian Academy of Science
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Day TWO

ENGAGING COMMUNITIES IN RESEARCH DESIGN AND IMPLEMENTATION DURING OUTBREAKS

Day Two Meeting Objective:

- Explore lessons learned from the 2014–15 Ebola outbreak to best engage communities in the design and implementation of clinical research during future outbreaks.
- Discuss opportunities for community involvement in planning activities to better prepare and build local research capacity for future epidemics.

8:30a.m.  Meeting Registration

9:00a.m.  Welcome by Committee Co-Chairs

Gerald Keusch, Committee Co-Chair
Keith McAdam, Committee Co-Chair

Panel 5: Community Mobilizer’s Perspectives

- Explore challenges and lessons learned during the Ebola outbreak to overcome fear, rumors, and stigma in the community; consider key groups to engage to ensure effective and far-reaching community engagement.
- Identify best practices for community engagement during a future outbreak and explore methods to gauge individual and community comprehension, acceptance, and adherence to key messages, such as those conveyed during the communication of vaccine or therapeutic trials.

Moderator: Charles Wells, Sanofi
Panelists: (10 minutes prepared remarks each)

- **Reverend John Barclay Sumo**, Director, National Health Promotion Division; Chair, Social Mobilization Pillar, Ministry of Health
- **Mohammad Bailor Jalloh**, Chief Executive Officer, Focus1000
- **Alpha Mahmoud Barry**, Public Health Specialist, Researcher, University of Gammal, Conakry, Guinea
- **Musa Sangarie**, Program Manager, BBC Media Action Sierra Leone

*Moderated Discussion with Committee and Participants*

10:30a.m. BREAK

10:45a.m. Panel 6: Patient and Clinician Perspectives

- Discuss your experiences during the Ebola outbreak; consider the clinical care provided in ETUs and explore lessons learned to overcome fear, rumors, and stigma in the community.
- Discuss the role of research during the Ebola outbreak and explore how research should be done during a future outbreak, both during the crisis and once the crisis has passed. How can researchers best address survivors' concerns?
- In the event of a future outbreak, examine your community’s understanding of and expectations from clinical care and clinical trials.

*Moderator: David Peters*, Johns Hopkins University

Panelists: (10 minutes prepared remarks each)

- **Achille Diona Guemou**, Chairman, Ebola Association Network; Physician with Association pour la Réinsertion des Personnes Guéries et Affectées d'Ebola en Guinée (Association for Rehabilitation of Persons Affected and Cured of Ebola in Guinea)
- **Abdul Karim Bah**, National Coordinator, Sierra Leone Association of Ebola Survivors (S.L.A E.S)
- **Patrick Faley**, Survivor’s Consultant – PREVAIL Research Program; Former President, National Ebola Survivors Network Liberia

*Moderated Discussion with Committee and Participants*

12:15p.m. LUNCH
1:15p.m.  Panel 7: Perspectives from Civil Society
- Discuss lessons learned and greatest challenges during the Ebola outbreak, and explore the engagement of civil society in the Ebola clinical trials.
- In the event of a future outbreak, discuss how civil society can best be involved in outbreak response and clinical research.

**Moderator:** Abdel G. Babiker, Medical Research Council Clinical Trials Unit at UCL

**Panelists:** *(10 minutes prepared remarks each)*
- **Ambassador Juli Endee**, Culture Ambassador of the Republic of Liberia, traditional Queen; UNICEF Goodwill Ambassador for Children in Liberia; Executive Director of the Liberia Crusaders for Peace
- **Abdoulaye Touré**, Associate Professor of Epidemiology, Conakry University
- **Chief Zanzan Kawa**, Chairman of the Council of Chiefs, Liberia

*Moderated Discussion with Committee and Participants*

2:30p.m.  BREAK

2:45p.m.  Breakout groups with facilitated discussion
- Further explore strategies to engage communities in advance of and during outbreaks so that future research is designed to meet the communities’ needs.

3:45p.m.  Reconvene in plenary session
- Recap breakout group discussions
4:15p.m.  
**Panel 8: Building Local Research Capacity to Meet Community Needs**

- Explore planning activities during the inter-epidemic period to better prepare for and improve the execution of clinical trials during future infectious disease public health emergencies.
- Identify collaborative opportunities to achieve long-term ethical and scientific gains from clinical trials conducted during emerging infectious disease events.

**Panelists and Group Leads:** *(10 minutes prepared remarks followed by breakout groups with facilitated discussion)*

**Moderator:** Roger Lewis, Harbor-University of California at Los Angeles Medical Center

**Panelists:** *(10 minutes prepared remarks each)*

- Oyewale Tomori, President, Nigerian Academy of Science
- Mosoka Fallah, Ebola Emergency-Response Program Manager, Action Contre la Faim (ACF) – Liberia

**Moderated Discussion with Committee and Participants**

5:15p.m.  
**Open Comment Period and Workshop Wrap-Up**

- Members of the public are invited provide comments geared toward the topics covered in the panel discussions over the course of the two days.

5:30p.m.  
ADJOURN