SESSION PROPOSAL 25

BAD BUGS IN TOUGH PLACES – DEVELOPING CAPACITY TO OBTAIN COMPELLING EVIDENCE IN CHALLENGING ENVIRONMENTS

Tyler A Bonnett, Frederick National Laboratory for Cancer Research, Clinical Monitoring Research Program Directorate

Description of Session:

Generating compelling evidence for some of the world's baddest bugs necessitates resources and infrastructure often difficult to achieve in regions where some of these pathogens reside. As a result, vulnerable populations continue to suffer from under-researched, debilitating diseases, many of which have no approved treatments. These diseases are worthy of further study based solely on the large populations who currently take on their burden. But incidence in remote locations does not mean the rest of the world will be insulated from their effects. A changing climate and increasingly mobile populations could lead to global spread. To lessen health disparities across the globe, and perhaps to prevent the next pandemic, we must commit to developing research capacity to study bad bugs locally, in a way that develops regional capacity and that ultimately informs local and global public health policy.

This 90-minute session will describe strategies for building sustainable research capacity to collaboratively design and conduct randomized clinical trials in especially challenging settings. We focus on the Pamoja Tulinde Maisha (Swahili for "Together, Save Lives") collaboration between the National Institute of Biomedical Research (INRB), Democratic Republic of the Congo, and the National Institute of Allergy and Infectious Diseases (NIAID), United States. The speakers will describe lessons learned from their efforts to develop research capacity in Africa to study Ebola virus disease, monkeypox virus disease and malaria.

Talk 1 (15 minutes) – Two decades of establishing collaborative research partnerships in Africa

Dr. Cliff Lane, NIAID Deputy Director for Clinical Research and Special Projects, will give a brief overview of establishing collaborative research partnerships via government-to-government agreements, highlight key challenges, and describe the importance of these centers for the future of global infectious disease research.

Talk 2 (15 minutes) – Setting up collaborative research capacity in the Democratic Republic of the Congo

Dr. Placide Mbala, Chief of Epidemiology for INRB, will discuss the process of establishing a multilateral partnership to create a Clinical Research Center in the Democratic Republic of the Congo.

Talk 3 (15 minutes) – Challenges in the field

Drawing on his history studying and treating Ebola and malaria in Democratic Republic of the Congo, Dr Nsengi Ntamabyaliro will discuss in-country challenges that arise from conducting research in remote settings, including local and regional infrastructure, cultural aspects, and economic conditions, all of which must be addressed by the study teams to ensure a well-conducted trial.

Talk 4 (15 minutes) – Design of a randomized controlled trial for monkeypox virus disease treatments in the Democratic Republic of the Congo

Dr. Olivier Tshiani, Medical Affairs Scientist with the NIAID Clinical Trials Research Section, will describe the development of a randomized controlled trial protocol for treatment of monkeypox virus disease. Monkeypox virus is a relatively rare and under-studied virus (related to smallpox virus) that is an emerging threat with increasing incidence in the Democratic Republic of the Congo and other countries in Africa, with spillover cases that occurred in the United Kingdom and the United States in 2021.

Discussant (15 minutes) - Collaborative clinical research as a tool for capacity building in resource limited settings

Dr Seydou Doumbia, Director of the University Clinical Research Center in Bamako, Mali, will synthesize the main

points from each speaker, provide context from the perspective of the director of another government-to-government research collaboration, and highlight issues for broader discussion.

Q&A (approximately 15 minutes)

The session will conclude with approximately 20 minutes devoted to a panel style question-and-answer session with the speakers and discussant.

Contributors:

H Clifford Lane, MD, Division of Clinical Research, National Institute of Allergy and Infectious Diseases
Placide Mbala, MD PhD, National Institute of Biomedical Research
Nsengi Ntamabyaliro, MD, University of Kinshasa
Olivier Tshiani, MD , 1. Clinical Monitoring Research Program Directorate, Frederick National Laboratory for Cancer Research and 2. National Institute of Biomedical Research, Democratic Republic of the Congo
Seydou Doumbia, MD PhD, University Clinical Research Center