

Clinical Trials During the 2014-2015 Ebola Outbreak

Committee

Gerald T. Keusch

Co-Chair

Dr. Keusch is a graduate of Columbia College and Harvard Medical School. He has been involved in academic medicine for his entire career, currently as Professor of Medicine and International Health at Boston University where he serves as an Associate Director of the National Emerging Infectious Diseases Laboratory. Prior to this he was Chief of the Division of Geographic Medicine and Infectious Diseases at Tufts Medical Center in Boston from 1979-1998, and Associate Director for International Research and Director of the Fogarty International Center at the U.S. National Institutes of Health from 1998 to 2004. Dr Keusch is a fellow of the Infectious Diseases Society of America, and an elected member of the American Society for Clinical Investigation, the Association of American Physicians, and the National Academy of Medicine, where he has served on the Board on Global Health, the Forum on Microbial Threats, and Co-Chaired an IOM/NRC report, "Sustaining Global Surveillance and Response to Emerging Zoonotic Diseases", released in September 2009. His research experience spans both laboratory and clinical field research on infectious diseases in Latin America, Africa and Asia. He has been a member of multiple committees for the Tropical Diseases Research Program at WHO, and served on a review committee for the Wellcome Trust on Global Clinical Trials.

Keith McAdam

Co-Chair

Dr. Keith McAdam is the founding director of the Infectious Diseases Institute (IDI) (2004-7) at Makerere University. He is emeritus professor of clinical tropical medicine at the London School of Hygiene and Tropical Medicine, a position he held from 1985 to 2004. From 1994 to 2003, Dr. McAdam was seconded to West Africa to serve as director of the UK Medical Research Council Laboratories in the Republic of The Gambia. Dr. McAdam grew up in Uganda, where his father, Sir Ian McAdam, was Professor of Surgery at Makerere. He did his schooling in Kenya and went on to study medicine at Cambridge University and the Middlesex Hospital in London. After training in internal medicine in London, he spent three years at the Institute of Medical Research in Papua New Guinea working on leprosy, malaria, and filariasis as causes of secondary amyloidosis. Two years, from 1975 to 1977, Dr. McAdam developed his laboratory and clinical research focus on inflammation, acute phase proteins, and cytokines, at the Immunology Branch of the National Cancer Institute in Bethesda, Maryland, and continued this focus over the next seven years in Boston as a clinical scientist in the Department of Medicine at Tufts New England Medical Center. Professor McAdam was medical advisor to the UK Parliamentary Select Committee on AIDS in 1987 and a member of the Nuffield Council on Bioethics working party that produced an authoritative publication *The Ethics of Healthcare Related Research in Developing Countries*. He has been associate international director at the Royal College of Physicians in London and is currently their special advisor on East Central and Southern Africa. He has just rotated off the International Board of the African Medical and Research Foundation (AMREF) and is currently on the Board of Trustees of the charity BBC Media Action.

Abdel Babiker

Member

Professor Abdel Babiker completed a PhD in mathematical analysis at the University of London. In the 1980s he worked on a number of cancer trials at the Institute of Cancer Research (ICR) and with the Imperial Cancer Research Fund.

He joined the MRC HIV Clinical Trials Centre (HIV CTC) as Deputy Head in 1992 and was directly responsible for overseeing all statistical aspects of the Centre's research programme. When the HIV CTC became part of the MRC Clinical Trials Unit in 1998, he was appointed Head of the HIV Group. HIV research has expanded greatly since 1998, through wider national and international collaborations addressing key questions in treatment and prevention of HIV and has impacted on international guidelines for the treatment of HIV.

Mohamed B. Barrie

Member

Dr. Mohamed Bailor Barrie grew up in poverty in rural Sierra Leone. After finishing secondary school, he received one of two scholarships in the country to study medicine at the College of Medicine and Allied Health Sciences in Freetown, Sierra Leone. Dr. Barrie trained in general medicine, building his skills in all areas of medicine. The civil war in Sierra Leone forced him to suspend his studies and, after one year as a refugee in neighboring Guinea, he graduated with his degree in medicine in 2004. After obtaining his degree Dr. Barrie worked as a medical officer at a rural nonprofit hospital and was one of four physicians in his graduating class to continue to practice medicine in Sierra Leone. He has also acted as a consultant for UNICEF and World Health Organization. In 2006 Dr. Barrie co-founded and became the executive and medical director of Wellbody Alliance, a nonprofit healthcare organization based in Kono District, Sierra Leone. His current role is as chief strategic officer. Dr. Barrie is the recipient of the 2013 Grace Humanitarian Award from Thomas Jefferson University. For 2013-2015, Dr. Barrie was awarded a prestigious Fulbright Fellowship to study global health delivery at Harvard University.

Janice Cooper

Member

Dr. Janice L. Cooper is the country lead for the Liberia Mental Health Initiative. She oversees a national training, policy, and support program to expand capacity for mental health services delivery. She also is responsible for interacting with national and international colleagues and partners of the program. A native Liberian and health services researcher specializing in children's mental health, Dr. Cooper has worked in the private, public, and nonprofit sectors in the United States and Liberia. Prior to joining The Carter Center in 2010, Dr. Cooper was the interim director of the National Center for Children in Poverty as well as an assistant clinical professor in health policy and management at Columbia University's Mailman School of Public Health. From 2005-2009, she also served as the Center's director of child health and mental health, receiving the distinguished Calderone Prize for Junior Faculty in 2007. Dr. Cooper received her Ph.D. in health policy from Harvard University. She was a 2001 fellow in medical ethics at Harvard Medical School and a 1999 Archibald Bush Foundation Leadership Fellow. She holds additional undergraduate and graduate degrees from the University of Essex in Colchester, England, and Columbia and Harvard universities in the United States.

Sheila Davis

Member

Dr. Sheila Davis is the Chief of the Ebola Response and Chief Nursing Officer at Partners In Health (PIH) where she led the Ebola response efforts in West Africa for PIH in Sierra Leone and Liberia. At peak of the effort, PIH was operating in collaboration with the Ministries of Health at over 20 facilities for screening and treatment of Ebola. Currently she is leading the effort to transition from Ebola response to health system strengthening in Liberia and Sierra Leone as part of PIH's long term commitment to both countries. Sheila has been a nursing leader in the in the field of HIV/AIDS since its emergence in the mid-1980's and served on the National Board of the Association of Nurses AIDS Care (ANAC). She entered the global health arena in 1999 when she began working for Partners AIDS Research Center as part of Massachusetts General Hospital on community outreach and HIV treatment efforts. Partnering with global nursing colleagues, she co-founded a small NGO that worked in South Africa and Boston from 2004-2010 on health projects including a rural village nurse clinic and urban vulnerable children feeding program.

Dr. Davis received her BSN from Northeastern University in 1988, her Masters in Nursing as an Adult Nurse Practitioner from the MGH Institute of Health Professions in 1997, and her Doctorate in Nursing Practice with a concentration in global health in 2008 also from the MGH Institute of Health Professions. Sheila was a faculty member at the School of Nursing at the MGH Institute of Health Professions for 4 years and an Adult Nurse Practitioner at MGH Infectious Diseases outpatient practice for over 15 years. She is currently adjunct faculty at the University of California San Francisco School of Nursing.

Inducted as a Fellow into the American Academy of Nursing in 2008, Dr. Davis is a frequent national speaker on global health, clinical topics including Ebola, HIV/AIDS, and role of nursing in human rights. In 2009, she was inducted as one of the inaugural class of 12 Carl Wilken's Fellows working on anti-genocide global efforts as part of the Genocide Intervention Network. Dr. Davis has published in number of domestic and global journals and is on the editorial board of the Health and Human Rights: An International Journal. She was part of the 2012 cohort of the Robert Wood Johnson Executive Nurse Fellowship, a three year fellowship that prepares 20 national nursing leaders to contribute to the national health care strategy.

Kathryn M. Edwards

Member

Kathryn M. Edwards, MD, the Sarah H. Sell and Cornelius Vanderbilt Professor of Pediatrics, has had an extensive experience in leading NIH-funded multicenter initiatives and in designing, conducting, and analyzing pivotal Phase I, II, and III clinical studies on vaccines and therapeutics. She initially focused her efforts on conducting studies of Haemophilus influenzae, type b capsular polysaccharide protein conjugate vaccines in infants. In 1985, she received NIH-funding to conduct a comparative influenza efficacy trial of live attenuated and inactivated influenza vaccines in 3000 children and adults each year for five years. In 1990, she coordinated the NIH-funded Multicenter Acellular Pertussis Trial comparing acellular pertussis vaccines and whole cell pertussis vaccines. In the late 1990s, she conducted additional studies on bacterial vaccines when she studied pneumococcal conjugate vaccines in young infants and determined their role in preventing colonization and disease.

In 1998, Dr. Edwards was awarded a contract from the Centers for Disease Control and Prevention (CDC) to conduct active population-based surveillance to monitor the impact of newly licensed vaccines. She has also led the CDC-funded Center for Immunization Safety Assessment (CISA). In 2012 Dr. Edwards conducted comprehensive pneumonia surveillance studies in over 2000 adults and children admitted to Vanderbilt. Dr. Edwards has served on many CDC, NIH, WHO, and IDSA committees. In 2008 she was elected to the Institute of Medicine of the National Academy of Sciences. She also recently served as chief of a DSMB for Ebola trials in Mali.

Susan S. Ellenberg

Member

Susan Ellenberg joined the biostatistics faculty at the University of Pennsylvania as Professor of Biostatistics in the fall of 2004. She also has a secondary appointment in the Department of Medical Ethics and Health Policy. Dr. Ellenberg directs the Biostatistics Core for the Penn Center for AIDS Research, and is also collaborating on projects in pulmonary research, breast cancer, anesthesiology, endocrinology and HIV. Prior to arriving at Penn, Dr. Ellenberg held leadership positions at the National Institutes of Health and the Food and Drug Administration. Her areas of research have included surrogate endpoints for treatment effects in clinical trials, operational issues for data monitoring committees, clinical trial designs, adverse event monitoring, vaccine safety and special issues in cancer and AIDS trials. Dr. Ellenberg is a Fellow of the American Statistical Association, the Society for Clinical Trials and the American Association for the Advancement of Science, and is an elected member of the International Statistical Institute. She has served as President of the Eastern North American Region (ENAR) of the International Biometric Society, and of the Society for Clinical Trials, and as Chair of the Board of Trustees of the National Institute of Statistical Sciences. She is an Associate Editor of Clinical Trials and the Journal of the National Cancer Institute. Her book, Data Monitoring Committees in Clinical Trials: A Practical Perspective, co-authored with Drs. Thomas Fleming and David DeMets, was named Wiley Europe Statistics Book of the Year for 2002.

Roger J. Lewis

Member

Dr. Lewis received his PhD in Biophysics and MD from Stanford University. He is a Professor at the David Geffen School of Medicine at UCLA and Chair of the Department of Emergency Medicine at Harbor-UCLA Medical Center. Dr. Lewis's expertise centers on adaptive and Bayesian clinical trials, including platform trials; translational, clinical, health services and outcomes research; interim data analysis; data monitoring committees; and informed consent in emergency research studies.

In 2009, Dr. Lewis was elected to membership in the National Academy of Medicine (formerly the Institute of Medicine). He is a Past President of the Society for Academic Emergency Medicine (SAEM), currently a member of the Board of Directors for the Society for Clinical Trials, and the Senior Medical Scientist at Berry Consultants, LLC, a group that specializes in adaptive clinical trials.

Dr. Lewis has served as a grant reviewer for the Agency for Healthcare Research and Quality (AHRQ), the Canadian Institutes of Health Research (CIHR), the Centers for Disease Control and Prevention (CDC), the National Cancer Institute of France, the National Institutes of Health (NIH), the Patient Centered Outcomes Research Institute (PCORI) and foundations. He is also a member of the Medicare Evidence Development & Coverage Advisory Committee of the Centers for Medicare & Medicaid Services. Dr. Lewis serves as the chair of data and safety monitoring boards (DSMB) for both federally-funded and industry-sponsored clinical trials, including international trials. He is a research methodology reviewer for JAMA and an editor of the JAMA series entitled "JAMA Guides to Statistics and Methods." He has served as a content reviewer for many other peer reviewed journals. He has authored or coauthored over 200 original research publications, reviews, editorials, and chapters.

Alex London

Member

Alex John London is Professor of Philosophy and Director of The Center for Ethics and Policy at Carnegie Mellon University. Professor London is an elected Fellow of the Hastings Center and recipient of the Distinguished Service Award from the American Society of Bioethics and Humanities (ASBH).

Professor London's research focuses on foundational ethical issues in human-subjects research, issues of social justice in the trans-national context, and on methodological issues in theoretical and applied ethics. His papers have appeared in *Mind*, *Science*, *The Lancet*, *PLoS Medicine*, *Statistics In Medicine*, *The Hastings Center Report*, and numerous other journals and collections. He is co-editor of *Ethical Issues in Modern Medicine*, one of the most widely used textbooks in medical ethics.

In 2012 he joined the Working Group on the Revision of the CIOMS 2002 International Ethical Guidelines for Biomedical Research Involving Human Subjects and in 2011 he was appointed to the Steering Committee on Forensic Science Programs for the International Commission on Missing Persons (ICMP). Since 2007 he has served as a member of the Ethics Working Group of the HIV Prevention Trials Network. He has testified before the Presidential Commission for the Study of Bioethical Issues and has been commissioned to write papers for the Centers for Disease Control and Prevention (CDC) and the Institute of Medicine (IOM). He has served as an ethics expert in consultations with numerous national and international organizations including the U.S. National Institutes of Health, the World Health Organization, the World Medical Association and the World Bank.

Jens Lundgren

Member

Jens Lundgren is Professor of Viral Diseases and a practicing infectious disease specialist. He founded, and heads, the Centre for Health and Infectious Disease Research and PERSIMUNE (Centre of Excellence for Personalised Medicine of Infectious Complications in Immune Deficiency) at the department of infectious diseases (CHIP/PERSIMUNE), based at the Copenhagen University Hospital (Rigshospitalet), University of Copenhagen. Jens Lundgren is a member of the Executive Committee of the NIH/NIAID funded INSIGHT network (International Network for Strategic Initiatives in Global HIV Trials), chairs its scientific steering committee and is Co-PI for the START study. He is Co-editor-in-chief of the "HIV Medicine" journal, Chair of the Steering Committee for the "D:A:D study"; founder and current member of the steering committee for the EuroSIDA study; founder and current member of the steering committee of the "HIV In Europe" initiative focused on early testing and care for HIV+ persons across Europe, and chairs the EACS non-infectious co-morbidity guidelines panel, and was awarded the EACS Award for Excellence in HIV Medicine in 2015. He is member of American Society of Clinical Investigation (ASCI) and Association of American Physicians (AAP), and honorary life-long member of IAPAC. His list of publications in scientific literature is extensive, and he has mentored several younger colleagues in their research development.

Michelle M. Mello

Member

Michelle Mello is Professor of Health Research and Policy at Stanford University School of Medicine and Professor of Law at Stanford Law School. She holds doctoral degrees in law and health policy, and conducts research on issues at the intersection of health policy, law, and bioethics. Mello's scholarship includes work on ethical issues arising in industry-sponsored clinical trials; legal and ethical barriers to clinical trial data sharing; legal concerns as a hindrance to clinical volunteerism during the Ebola epidemic; and a range of legal and ethical issues in pharmaceutical regulation and human subjects research. For 7 years, she served as Chair of the institutional review board at the Harvard School of Public Health, which is responsible for oversight of numerous clinical trials in African countries.

Olayemi Omotade

Member

Olayemi Omotade is a Professor of Paediatrics and Child Health and the Director of the Institute of Child Health, College of Medicine, University of Ibadan. He is a Consultant Paediatrician to the University College Hospital, Ibadan Nigeria. As part of his residency training in Paediatrics at the University College Hospital, he was on attachment to the University Hospital of Wales, Cardiff where he was trained as a clinical geneticist.

At the Institute of Child Health, his research interests spans Community/Preventive Paediatrics and while combining this with his clinical genetics, he has been able to carry out research on infectious and communicable diseases. He has been involved in Program planning and monitoring with international Organizations including WHO, UNICEF and UNDP both at the country and international levels.

Through a Fogarty Fellowship (2001-2) he was able to undertake a course of study leading to the award of a Master of Arts at the Case Western Reserve University Cleveland, Ohio during which he was instrumental to the drawing up of the initial works for Nigeria's National Ethical Guidelines. He was for some time a member of the National Ethics Review Board for Nigeria as well as for the Joint IRC University of Ibadan/University College Hospital. He has over eighty publications in international and regional journals and he is a member of many professional associations including the Paediatrics Association of Nigeria, American Society for Bioethics and Humanities, Member, Puebla Group of Networks Collaborating on Health Research for Development, Member, Clinical Genetics Society of Great Britain and International Association for Tropical Paediatrics to mention a few. He is the foundation Director for Centre for HIV-AIDS Intervention, Nigeria (CEHAIN). He has also coordinated several studies for the Nigerian Academy of Sciences and he has been a reviewer for several bodies and journals including reviewing some chapters of two books for the Institute of Medicine (IOM) February 2015.

He is also a member of the Task Force MIM/TDR/WHO. Member, Scientific Review Committee for the European & Developing Countries Clinical Trials Partnership (EDCTP) for the EDCTP Senior Fellowships Training Awards 2005 and Member of WHO/MIM/TRD Task Force on Malaria Research Capability Strengthening in Africa (WHO/TDR Steering Committee) 2003 - 2011. Dr. Omotade is also a member of several Expert Technical groups including WHO Expert Technical group on IPTi. Member, International Advisory Board, Institute for Research on Unlimited Love, Altruism Compassion Service, Case Western Reserve University, Cleveland, Ohio, USA Fogarty Fellowship for Bioethics at the Case Western Reserve University Cleveland Ohio 2001

He has been on the University College hospital Board of Management 2010 -2015 and he is member of the National Child Health Technical Working Group 2015 - to date. He has been the Chairman of the College of Medicine, University of Ibadan Post graduate Committee since 2010 - to date.

David Peters

Member

David H. Peters, MD, MPH, DrPH, is Professor and Chair of the Department of International Health at Johns Hopkins Bloomberg School of Public Health. He is a specialist in international health systems who has worked as a researcher, policy advisor, educator, bureaucrat, manager, and clinician in a number of developing countries over the last two decades. He previously worked as a Senior Public Health Specialist at the World Bank, and as the Director of the Health Systems Program at Johns Hopkins. He is Research Director for the Future Health Systems research consortium, which is working to improve access, affordability and quality of health services for the poor, with field sites in five countries in Africa and Asia. He pioneered the development of Sector Wide Approaches (SWAps) in health, and created the first national Balanced Scorecard to assess and manage health services (in Afghanistan). He is currently leading a program to strengthen public health systems in Liberia in the wake of the Ebola epidemic. He has written seven books and over 100 scientific articles, mostly focusing on health systems in low and middle-income countries. His teaching and research focus on the performance of health systems, implementation research methods, poverty and health systems, innovations in organization, technology, and financing of health systems, the role of the private sector, human resource management, and ways to use donor assistance to strengthen local capacity in low-income countries.

Fred Wabwire-Mangen

Member

Dr. Fred Wabwire-Mangen was trained in Human Medicine at Makerere University, in Tropical Medicine at Liverpool University and in Immunology and Infectious Diseases and Infectious Disease Epidemiology at Johns Hopkins University where he obtained a PhD in 1994. He is an Associate Professor of Epidemiology and Public Health at the Makerere University School of Public Health, where he teaches infectious disease epidemiology, intervention trials, and health services research. He is also has a secondary appointment as a senior research scientist and executive chair at the Makerere University Walter Reed Project (MUWRP). MUWRP is one of the few projects that is conducting Ebola and Marburg vaccine trials in Uganda. Dr Wabwire-Mangen has over 25 years of conducting research on emerging and re-emerging diseases of public health importance in Uganda including malaria, STIs, HIV/AIDS, influenza and other emerging viral infections. He also has demonstrated experience leading and managing multi-disciplinary research teams. He served as a co-investigator on a cluster randomized trial on STD control for AIDS prevention and an individual randomized controlled trial on male circumcision for HIV prevention while working at the Rakai Health Sciences Project between 1994 and 2008, and as co-investigator of a Phase I and a Phase II-a HIV vaccine trial at MUWRP. As Principal Investigator of the Surveillance of Influenza Viruses among Human and Non-Human Hosts in Uganda study and the GEIS-funded Antimicrobial Resistance Surveillance in Uganda study, Dr Wabwire-Mangen leads a team of medical doctors, laboratorians, epidemiologists, veterinarians, ornithologists and other scientists. Dr Wabwire-Mangen has published widely on public health issues and has over 150 journal publications in peer reviewed journals.

Charles D. Wells

Member

Charles D. Wells, MD, currently serves as Head of Development and Associate Vice President for the Infectious Diseases Therapeutic Unit at Sanofi based in Bridgewater, NJ, having joined the organization in September 2015. Prior to joining Sanofi he served as the Senior Medical Director for the tuberculosis products development group at Otsuka Pharmaceuticals in Rockville, MD. He joined Otsuka in May 2007 to provide the medical and clinical leadership for developing Otsuka's anti-tuberculosis compound, delamanid, which was successfully registered as Delyba® in 2014 in the E.U., Japan and Korea for treatment of multidrug resistant (MDR)- tuberculosis (TB). In his role at Otsuka he oversaw the clinical development program for delamanid, including clinical operations charged with conducting the global clinical trials in 14 countries across 5 continents, and served on the regulatory submission team responsible for the product's registration. Additionally, he led the publication strategy for reporting results from the clinical development trials for delamanid and led the data submission process to the World Health Organization required for development of interim global guidelines for the use of delamanid in MDR-TB treatment.

Prior to joining Otsuka, he served as Chief of the International Research and Programs Branch of the Division of Tuberculosis Elimination at the U.S. Centers for Disease Control and Prevention (CDC) during 2000-2007. The branch he led at CDC conducted extensive epidemiologic, clinical, and diagnostics research on TB which fed supportive data into evolving global policy and provided direct technical assistance internationally for implementation and scale up of public health programs for control of TB, HIV-associated TB, and MDR-TB in sub-Saharan Africa, Southeast and South Asia, Eastern Europe, as well as South America. During this time he also served as CDC's lead representative on the Strategic Advisory Group for the STOP-TB Department at the World Health Organization (WHO) and also the United States Agency for International Development (USAID)-supported TB Coalition for Technical Assistance. Additionally, he served as a technical expert on disease control program reviews in numerous countries for WHO, USAID, and the President's Emergency Plan for AIDS Relief (PEPFAR).

Early in his career, he began work in clinical development serving as a research associate at Burroughs Wellcome and Glaxo in Research Triangle Park, NC, in the late 1980's and as an associate medical director at PathoGenesis Corporation in Seattle, WA, in the late 1990's working on clinical development for anti-infectives, including new drugs for TB.

He is a native of North Carolina and attended North Carolina State University where he received a Bachelor of Science in Chemical Engineering in 1987. He then completed his medical studies at the University of North Carolina at Chapel Hill in 1992 and his post-graduate medical training in internal medicine and infectious diseases at Emory University and the CDC in Atlanta during 1992-1998.