Accelerating the Development & Uptake of Rapid Diagnostics to Address Antibiotic Resistance - A Workshop

Committee

Kent E. Kester

Co-Chair

Kent E. Kester (CO-CHAIR), MD is currently Vice President, Translational Medicine, at IAVI. He was previously Vice President and Head, Translational Science and Biomarkers at Sanofi Pasteur, the vaccine business unit of the Sanofi Group. Prior to this, in the context of a 24-year career in the US Army, he worked extensively in clinical vaccine development and led multiple research platforms at the Walter Reed Army Institute of Research, the U.S. Department of Defense's largest and most diverse biomedical research laboratory an institution he later led as its Commander. His final military assignment was as the Associate Dean for Clinical Research in the School of Medicine at the Uniformed Services University of the Health Sciences (USUHS). During his military service, Dr. Kester was appointed as the lead policy advisor to the US Army Surgeon General in both Infectious Diseases and in Medical Research & Development. In these capacities, he worked extensively in the interagency environment and developed a variety of Army and DoD medical policies related to infectious diseases.

Dr. Kester holds an undergraduate degree from Bucknell University and an M.D. from the Sidney Kimmel Medical College, Thomas Jefferson University, completing his internship and residency in internal medicine at the University of Maryland and a research fellowship in infectious diseases at the Walter Reed Army Medical Center. Currently a member of the US Government Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), the Department of Veterans Affairs Health Services Research & Development Service Merit Review Board, the National Academy Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats, and the CEPI Scientific Advisory Committee, he previously chaired the Steering Committee of the NIAID/USUHS Infectious Disease Clinical Research Program, and has served as a member of the FDA Vaccines & Related Biologics Products Advisory Committee (VRBPAC), the NIAID Advisory Council, and the CDC Office of Infectious Diseases Board of Scientific Counselors. He is a Vice Chair of the National Academy of Medicine Forum on Microbial Threats. Board-certified in both internal medicine and infectious diseases, Dr. Kester holds faculty appointments at USUHS and the University of Maryland; and is a fellow of the American College of Physicians, the Royal College of Physicians of Edinburgh, the Infectious Disease Society of America, and the American Society of Tropical Medicine and Hygiene where is also serves as the Society's Secretary-Treasurer. He is a member of the clinical faculty at the University of Maryland Shock Trauma Center in Baltimore and the Wilkes-Barre VA Medical Center in Wilkes-Barre, PA.

Betsy W. Trainor

Co-Chair

Betsy W. Trainor brings over a decade of experience in the diagnostics industry, focused mainly on the validation and implementation of infectious disease diagnostics. Betsy has a background in clinical and behavioral research that started during her undergraduate studies at Cornell University. Betsy's work initially focused on HIV in Africa and then on infectious diseases, globally, including HCV, TB, and Ebola. In addition to leading diagnostic validation studies, she has led the commercialization of diagnostic product lines and a variety of global partnerships on behalf of both private and public entities. She has supported the development of global guidelines and negotiated deals with large donor organizations as well as private entities. Betsy has recently led business development efforts at multiple innovative diagnostic companies, including Daktari Diagnostics and Aldatu Biosciences, in addition to leading product validation and implementation efforts at the Foundation for Innovative New Diagnostics (FIND) and the World Health Organization (WHO). Betsy is looking forward to putting her experience to good use in supporting the CARB-X mission.

John Billington

Member

John Billington, JD, MPH is Head of Health Security and Infectious Diseases Policy and Advocacy in the global corporate government affairs department of GSK. In this role, he is responsible for the company's policy and advocacy strategy for infectious diseases at the enterprise level, with a focus on pandemic preparedness and antimicrobial resistance (AMR). Prior to this role, John was director of science policy for the global vaccines business and director of U.S. vaccines policy before that. Before joining GSK, John was director of health policy at the Infectious Diseases Society of America (IDSA). At IDSA, John served as lead subject matter expert on vaccines, antibiotics, and medical countermeasures policy. He also launched and coordinated the U.S. Stakeholder Forum on Antimicrobial Resistance (S-FAR), a national stakeholder partnership to advance U.S. and global policies and practices in response to AMR. Earlier in his career, John was a manager in the health reform practice at Avalere Health, a health policy advisory firm. He was also a legislative fellow for health policy in the office of U.S. Senator Sherrod Brown of Ohio. John received his Juris Doctor and Masters of Public Health from the Ohio State University in Columbus, Ohio. He received his undergraduate degree from Colgate University in Hamilton, New York. He is originally from Cleveland, Ohio and lives in Washington, DC with his wife Eleanor, daughter Frances, and son Sam.

Carey-Ann Burnham

Member

Carey-Ann Burnham, PhD, D(ABMM), FIDSA, F(AMM) is currently Chief Clinical Officer, Pattern Bioscience, and Professor of Pathology & Immunology, Washington University in St. Louis School of Medicine. She was previously Professor of Pathology & Immunology, Pediatrics, Molecular Microbiology, and Medicine at Washington University in St. Louis School of Medicine and Vice Chair for Faculty Mentoring & Advancement in Pathology & Immunology. In addition, for 11 years she served as Medical Director of the system clinical microbiology laboratory at Barnes-Jewish Hospital in St. Louis, and the program director for the Medical and Public Health Microbiology Fellowship at Washington University. At Washington University, her research program focused on the development of new diagnostics for infectious diseases, antimicrobial resistance, and transmission and epidemiology of antimicrobial resistant microorganisms. Burnham is actively involved in several editorial roles, including serving as an editor for the Journal of Clinical Microbiology, Clinical Microbiology Newsletter, and Clinical Microbiology Procedures Handbook, 5th ed. Burnham has held leadership roles in professional societies, including the American Society for Microbiology, Clinical and Laboratory Standards Institute, the American Academy of Microbiology, and the Academy of Clinical Laboratory Physicians and Scientists. In 2020, Burnham received the prestigious American Society for Microbiology Award for Research and Leadership in Microbiology, and Burnham has published more than 200 articles in the area of diagnostic and clinical microbiology.

Paul Eder

Member

Paul Eder, PhD is a Senior Scientific Officer and leads the Concept Acceleration Program for Diagnostics in the Division of Microbiology and Infectious Diseases (DMID) at NIAID. Previously he served for eight years as a Senior Medical Diagnostics Advisor at the Biomedical Advanced Research and Development Authority (BARDA) inside the US DHHS. For seven years prior he served as the Director of Assay Development at Qiagen, where he used a Bill and Melinda Gates Foundation grant to create the first WHO pre-qualified HPV screening test for utility in resource-limited communities worldwide. For that he won the Qiagen Sydney Brenner R&D Award for outstanding accomplishment in global R&D. He completed postdoctoral fellowships in nuclear tRNA transport at the Howard Hughes Medical Institute at the University of Pennsylvania and in catalytic RNA with Nobel laureate Sidney Altman at the Department of Biology at Yale University. His Ph.D. is in biochemistry from the University of Iowa. He holds ten issued patents and has authored 25 publications and reviews.

Deborah Hung

Member

Deborah Hung, M.D., works at the interface of chemical biology, genomics, and bacterial pathogenesis to establish new paradigms for an antibiotic based on the essential biology required for a pathogen to cause disease within the host. Using her training as a synthetic chemist, bacterial geneticist, and clinical physician, she explores approaches to disrupting the pathogen-host interaction. Dr. Hung is a physician-scientist at the Broad Institute of MIT and Harvard, the Department of Molecular Biology at the Massachusetts General Hospital, and the Department of Genetics at Harvard Medical School, and is the Co-Director of the Infectious Disease and Microbiome Program at the Broad Institute. She is an attending physician at the Brigham and Women's Hospital in Boston in infectious diseases and critical care

Amanda Jezek

Member

Amanda Jezek is currently the Senior Vice President for Public Policy and Government Relations at the Infectious Diseases Society of America (IDSA), which represents over 12,000 ID physicians and scientists. Amanda oversees IDSA's public policy and government relations department, with responsibility for policy development and advocacy on IDSA priority issues, including antimicrobial resistance, the infectious diseases workforce, pandemic preparedness and response, immunizations, federal funding, and other issues relating to public health and biomedical research. Amanda has been with IDSA since 2011, previously serving as IDSA's Government Relations Director. Prior to joining IDSA, Amanda was the Deputy Director for Federal Affairs at the March of Dimes Foundation. In this capacity, Amanda led the March of Dimes' policy development and lobbying efforts on all issues related to access to healthcare for women of childbearing age, infants, and children, including the Foundation's work on the Affordable Care Act. Amanda also lobbied for Mental Health America, and worked as a legislative assistant and press secretary for U.S. Representative Grace Napolitano (D-CA). Amanda holds a B.A. in Political Science from Dartmouth College.

Robin Patel

Member

Robin Patel, MD(CM), D(ABMM), FIDSA, FACP, F(AAM) graduated from Princeton University with a BA in Chemistry and from McGill University with an MD. She completed a residency in Internal Medicine and fellowships in Infectious Diseases and Microbiology at Mayo Clinic. She is the Elizabeth P. and Robert E. Allen Professor of Individualized Medicine, Professor of Medicine, Professor of Microbiology, Director of the Infectious Diseases Research Laboratory, and Co-Director of the Clinical Bacteriology Laboratory at Mayo Clinic. Dr. Patel is a Fellow of American Academy of Microbiology, Past President of the American Society for Microbiology, an associate editor for Clinical Infectious Diseases, and course director for the Mayo Clinic Alix School of Medicine microbiology course. She is also the Laboratory Center Director for the NIH's Antibacterial Resistance Leadership Group. Her research focuses on clinical bacteriology diagnostic testing, antimicrobial resistance, and microbial biofilms.

Ribhi Shawar

Member

Ribhi Shawar, PhD currently serves as the branch chief at the Division of Microbiology in the Office of In vitro Diagnostic and Radiological Health (OIR) at the Center for Devices and Radiological Health (CDRH) at FDA where he specializes in the area of antimicrobial susceptibility testing and detection of resistance. Dr. Shawar has a Ph.D. in Medical Microbiology and an M.Sc. in Medical Parasitology. He is a certified diplomate by the American Board of Medical Microbiology (ABMM) for 25 years and was recently elected as a Fellow of the American Academy of Microbiology (F-AAM). Dr. Shawar is a recognized clinical microbiologist with diverse experience in hospital settings, diagnostic and pharmaceutical microbiology and anti-infective drug development with strong knowledge in regulatory aspects both in antimicrobial drug products and infectious disease diagnostics. Dr. Shawar has authored multiple publications in peer reviewed journals, served or currently serves as advisor to several CLSI Sub-committees and is the recipient of multiple awards including GSK Gold Award and most recently FDA's Outstanding Service Award for his pioneering role in the creation of the FDA-CDC AR Isolate Bank. He served for two terms as Chair of the ABMM Standards and Examinations Committee (Parasitology) and as member of the editorial board of the Journal of Clinical Microbiology. Prior to joining FDA, Dr. Shawar served in multiple roles at various institutions including Baylor College of Medicine, VA Medical Center in Houston, PathoGenesis Corporation, Chiron (Novartis) in Seattle, and GlaxoSmithKline in Philadelphia.

Susan Van Meter

Member

Susan Van Meter is Executive Director of AdvaMedDx. AdvaMedDx represents manufacturers of in vitro diagnostic (IVD) tests and technologies. AdvaMedDx member company innovations allow early detection of disease, facilitate evidence-based medicine, improve patient health and health care, and enable personalized medicine, while often lowering overall health care costs. AdvaMedDx is the only advocacy organization exclusively addressing policy issues facing diagnostics manufacturers in the U.S. and around the world. AdvaMedDx operates as a division of AdvaMed, the Advanced Medical Technology Association. AdvaMed is the world's largest medical technology association, with over 400 member companies that develop medical devices, diagnostic tools, and health information systems. Prior to joining AdvaMedDx in 2018, Ms. Van Meter was Senior Vice President at the Healthcare Association of New York State (HANYS), focused on hospital and health system policy, payment, quality and health information technology priorities. Prior to joining HANYS she served in the Center for Medicare and Medicare Services (CMS) Office of Legislation. Ms. Van Meter holds undergraduate and graduate degrees from Villanova University and Boston University, respectively.