The Evidence Base for Lyme Infection-Associated Chronic Illnesses Treatment

Committee

Kent E. Kester

Chair

Dr. Kent Kester is currently the Executive Director of Vaccine Research and Development at the Coalition for Epidemic Preparedness Innovations (CEPI). During 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 with a major emphasis on emerging infectious diseases, 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. More recently, he served as the head of translational medicine and biomarkers at Sanofi Pasteur. Dr. Kester holds an undergraduate degree from Bucknell University and an M.D. from Jefferson Medical College Currently a member of 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 Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), 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 the 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. 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.

John A. Branda

Member

John A. Branda, M.D., is an Associate Professor of Pathology at Harvard Medical School and an Associate Pathologist at Massachusetts General Hospital. He specializes in Medical Microbiology and has broad expertise in infectious disease diagnostic testing methods. His primary academic focus has been the development of improved diagnostic tests for Lyme disease and other tick-borne infections. He was co-recipient of the 2015 Bay Area Lyme Foundation Emerging Leader Award and a 2022 Phase 1 LymeX Diagnostics Prize through the Lyme Innovation Accelerator (administered independently in a public-private partnership between the US Department of Health and Human Services and the Steven & Alexandra Cohen Foundation). Prior to 2020, he received research funding support from the Lyme Disease Biobank Foundation, the Fairbairn Family Lyme Research Initiative at Harvard Medical School, as well as from diagnostic companies for the detection of acute Lyme disease. Dr. Branda is currently a principal investigator for the Pfizer-Valneva vaccine trial for Lyme disease. He received his medical degree in 2000 from Harvard Medical School, after which he completed a Clinical Pathology residency and a Medical Microbiology fellowship at Massachusetts General Hospital. Dr. Branda is a co-inventor on a patent pending for a serologic diagnostic assay to detect Borrelia burgdorferi sensu lato complex. He previously served on the scientific advisory board of DiaSorin (2019), Roche Diagnostics (2019), FlightPath Biosciences (2023), and Tarsus Pharmaceuticals (2023) and received compensation for these services. He is also a coauthor on the 2020 IDSA/AAN/ACR Lyme disease treatment and diagnosis guidelines and was a member of the Federal Tick-borne Disease Working Group.

Betty A. Diamond

Member

Betty A. Diamond, M.D., is the Director of the Institute of Molecular Medicine in the Feinberg Institute for Medical Research at Northwell Health. Her research has focused on the induction and pathogenicity of autoantibodies in systemic lupus erythematosus (SLE), especially in the brain. Most recently, she has become interested in the anti-inflammatory effects of the immune protein C1q. In recent years, she has also become involved in clinical trials in SLE and has led several clinical trials of novel therapeutics. Dr. Diamond currently receives compensation as a consultant for biotech companies that are developing CAR-T cell therapies, including iCell Gene Therapeutics, Atara Biotherapeutics, Adicet Bio, and Sail Biomedicines. She also serves as an editor for eLife and Frontiers journals. Dr. Diamond is a member of both the National Academy of Medicine and the National Academy of Sciences and previously served on the National Academies committee on Examining the Working Definition for Long COVID and the committee on the Diagnostic Criteria for Myalgic Encephalomyelitis / Chronic Fatigue Syndrome. She is a past president of the American Association of Immunologists and has received the Distinguished Investigator Award and the Presidential Gold Medal from the American College of Rheumatology. She received her M.D. from Harvard Medical School, performed a residency in Internal Medicine at Columbia Presbyterian Medical Center, and then trained in immunology at the Albert Einstein College of Medicine.

Jesse L. Goodman

Member

Jesse L. Goodman, M.D., M.P.H., is Professor of Medicine at Georgetown University and Director of the Center on Medical Product Access, Safety and Stewardship which focuses on science and policy to address public health needs. He is an Attending Physician in Infectious Diseases at Georgetown University, Washington DC Veterans Administration, and Walter Reed Medical Centers. He was previously Chief Scientist of the U.S. FDA, serving in the government's senior leadership for the 2009 influenza pandemic and other public health responses. Prior to that, he served as Senior Advisor to the FDA Commissioner where he co-chaired the U.S. Task Force to Combat Antimicrobial Resistance, before going on to direct FDA's Center for Biologics Evaluation and Research. Previously he was a Professor of Medicine and Chief of Infectious Diseases at the University of Minnesota, where his laboratory isolated Anaplasma phagocytophilum, the cause of human granulocytic anaplasmosis, and studied Lyme disease, including dissemination of the organism in early disease and persistent infection as the primary cause of arthritis. Dr. Goodman currently serves as member of the board of directors and recently completed his term as chair of the science committee at GlaxoSmithKline, for which he receives compensation. He also currently serves as a scientific advisory board member at Intellia and Adaptive Phage Therapeutics, both with compensation. He received his M.D. from the Albert Einstein College of Medicine and his M.P.H. from the University of Minnesota. He has served on advisory committees at the CDC, NIH, DoD, CEPI, and WHO and as past president and board member of the US Pharmacopeia. He is a member of the National Academy of Medicine and was previously a member of the Forum on Microbial Threats.

Miguel Hernán

Member

Miguel Hernán, M.D., Dr.P.H., M.P.H., is the Kolokotrones Professor of Biostatistics and Epidemiology and Director of CAUSALab at the Harvard T.H. Chan School of Public Health. He uses health data and causal inference methods to learn what works. Miguel and his collaborators repurpose real world data into evidence for the prevention and treatment of infectious diseases, cancer, cardiovascular disease, and mental illness. This work has contributed to shape health policy and research methodology worldwide. Miguel has received several awards, including the Rousseeuw Prize for Statistics, the Rothman Epidemiology Prize, and a MERIT award from the U.S. National Institutes of Health. Miguel has also received research funding from the National Institutes of Health, the Veteran Administration, Patient Centered Outcome Research Institute (PCORI), and the Department of Defense. He is a Fellow of the American Association for the Advancement of Science and the American Statistical Association, and Associate Editor of Annals of Internal Medicine. He has served on multiple committees of the U.S. National Academies. Miguel received an M.D. from the Universidad Autónoma de Madrid and an M.P.H., Dr.P.H., and M.S. from Harvard University.

Adrian F. Hernandez

Member

Adrian F. Hernandez, M.D., M.H.S., is the Vice Dean of Duke School of Medicine and Executive Director of the Duke Clinical Research Institute (DCRI). He is a cardiologist who aims to improve health by accelerating clinical evidence through outcomes research, clinical trials, comparative effectiveness, and health policy. He has led multiple large-scale patient-centered research programs, registries, and clinical trials across multiple health conditions including the NIH's Health System Collaboratory and PCORI-funded PCORnet®, and is involved in the NIH Researching COVID to Enhance Recovery initiative. He has served as the steering committee chair or principal investigator on multiple studies and has authored over 800 publications. Dr. Hernandez received his medical degree from the University of Texas-Southwestern at Dallas and completed his residency in internal medicine at the University of California San Francisco School of Medicine, before completing a fellowship in cardiology at Duke University. He is an elected member of the American Society for Clinical Investigation, the Association of American Physicians, and serves on the board of directors of the Reagan-Udall Foundation. Dr. Hernandez frequently consults with and receives research support from pharmaceutical companies, none of which have active portfolios in the treatment or diagnosis of Lyme disease.

Nicole M.E. Malachowski

Member

Nicole Malachowski, COL, USAF (ret.), M.A., a 2019 National Women's Hall of Fame inductee and recent Presidential appointee, Colonel Nicole M. E. Malachowski (USAF, Ret.) has over 21 years of experience as an officer, leader, and fighter pilot in the United States Air Force. Upon her commission into the military, she was competitively selected to fly combat aircraft and embarked on an adventure among the first group of women to fly modern fighter jets. Nicole served as a mission ready fighter pilot in three operational F-15E squadrons and accumulated over 2,300 flight hours, including 188 hours in combat. She has had the honor of commanding a fighter squadron, flying as a USAF Thunderbird pilot, serving as a White House Fellow, and as an advisor to the First Lady of the United States. Nicole has forged a successful path through immense cultural changes in the military as well as significant adversity in her personal life. Following her medical retirement from the Air Force due to the severe impacts of late-stage tick-borne illness, Nicole reinvented herself as a highly successful entrepreneur, professional speaker, and leadership consultant. Nicole is a sought-after keynote speaker and shares her experience with Lyme disease to inspire resilience and reinvention with many companies, such as Endo Pharmaceuticals. Nicole served on the Tick-Borne Diseases Panel for the Department of Defense Congressionally Directed Medical Research Program and as a subcommittee member of the Federal Tick-Borne Diseases Working Group. She continues to hold volunteer positions as an ambassador with the Bay Area Lyme Foundation, patient advocate speaker with the Center for Lyme Action, and as a mentor and ambassador in the Wounded Warriors program. Nicole currently serves on the advisory board of Invisible International and as a board member of the LivLyme Foundation. She has previously volunteered as an advisory board member at the Dean Center for Tick Borne Illness. Nicole has been honored with the IMPACT Award by the White House Fellow Foundation. She’s been happily married to her husband Paul, an Air Force veteran, for over 22 years. When not hurriedly chasing their thirteen-year-old twins around, she finds immense meaning in traveling and advocating for those impacted by tick-borne illnesses.

Cherie L. Marvel

Member

Cherie Lynn Marvel, Ph.D., is a cognitive neuroscientist and Associate Professor of Neurology at the Johns Hopkins University School of Medicine. She uses brain imaging methods (e.g., MRI) to examine brain function in healthy and clinical populations. Her research in Lyme disease applies MRI methods to characterize brain changes in people with acute Lyme and post-treatment Lyme disease and relate these changes to cognition, mood, and clinical outcomes. Dr. Marvel has served as President of the International Society of Behavioural Neuroscience since 2021 and served as Chair of the NIH study section “NIH Fellowships: Learning and Memory, Language, Communication, and Related Neurosciences (F01B)” from 2022-2023. She is funded by the National Institutes of Health, Department of Defense, and private foundations to support her research in Lyme disease. Dr. Marvel obtained her Ph.D. in Neuroscience from Georgetown University. She completed a fellowship in Clinical Neuroscience at the University of Iowa and then completed a second fellowship in Cognitive Neuroscience at Johns Hopkins University.

Debjani Mukherjee

Member

Debjani Mukherjee, Ph.D., M.A., is an associate professor of medical ethics in clinical medicine and clinical rehabilitation medicine at Weill Cornell Medicine and senior clinical ethicist at New York Presbyterian/Weill Cornell Medical Center. Dr. Mukherjee is a clinical/community psychologist and clinical ethicist with expertise in disability and rehabilitation ethics. She was invited to help start the first Center for Clinical Ethics in Paris France and was awarded a Fulbright Scholarship to India to study long-term adjustment to brain injury. In 2023, she was elected a Hastings Center Fellow. Her scholarly interests are in the ethical dilemmas posed by neurological impairments, the emotional impact of medical decisions, the practice of clinical ethics consultation, and ethical concerns in rehabilitation medicine. Dr. Mukherjee received her bachelor's degree in psychology from Cornell University and her M.A. and Ph.D. in Clinical/Community Psychology from the University of Illinois at Urbana-Champaign. She then completed two years of postdoctoral fellowship at the Maclean Center for Clinical Medical Ethics at the University of Chicago. Before joining the faculty of Weill Cornell Medicine in 2020, she was the Director of the Donnelley Ethics Program at the Shirley Ryan AbilityLab and faculty at Northwestern University Feinberg School of Medicine.

Lise E. Nigrovic

Member

Lise E. Nigrovic, M.D., M.P.H., is a Professor of Pediatrics at Harvard Medical School and practices as a pediatric emergency physician at Boston Children's Hospital. She serves as the Boston Children's Hospital principal investigator for the NCATS supported Harvard Catalyst program. Dr. Nigrovic is the founding chair of the Pedi Lyme Net research network, the only multicenter pediatric Lyme disease clinical research network, with more than 5,000 adults and children undergoing evaluation for Lyme disease enrolled to collect clinical phenotype and matched biosamples. With support from the NIAID, she is leading a 21-center study to compare short and long-term outcomes for children with Lyme meningitis by antibiotic treatment regimen. Dr. Nigrovic previously served as a consultant with Adaptive Biotechnologies and as an advisory board member with Tarsus Pharmaceutical and received compensation for these services in assisting with the development of diagnostic tests, preventatives, and prophylaxis. She currently serves on the clinical research advisory committee at Global Lyme Alliance. Her current research support includes funding from the National Institutes of Health, the Department of Defense, and Global Lyme Alliance. Dr. Nigrovic has also received funding in the past from the Global Lyme Alliance, the Bay Area Lyme Foundation, the Milton Foundation, Fairbairn Family Lyme Research Initiative at Harvard Medical School. Of her more than 200 peer-reviewed publications, 50 are related to Lyme disease and other tick-borne infections in children. Dr. Nigrovic received her M.D. from Harvard Medical School and her M.P.H. from the Harvard School of Public Health. In recognition of her expertise, Dr. Nigrovic was selected as an inaugural member of the Federal Tick-Borne Illness Working Group as well as a working group member of IDSA/AAN/ACR Lyme disease clinical guideline panel.

Simone A. Seward

Member

Simone A. Seward, Dr.P.H., M.P.H., is currently an Assistant Professor in Public Health & Preventive Medicine at Upstate Medical University in Syracuse, NY. As an educator, community health advocate, and mixed methods researcher, Dr. Seward has developed strategic approaches that center on social justice and racial equity. Using community engagement as a vehicle for systemic change, Dr. Seward builds interdisciplinary, collaborative partnerships that are sensitive to diverse perspectives and population needs. With over 15 years of extensive training and diverse practice-based experiences at the federal, state, and local levels and in academia, Dr. Seward ensures that community health interventions and programs include the voices and lived experiences of the target community. As a dedicated researcher and advocate specializing in maternal and child health disparities, Dr. Seward has devoted her career to understanding and addressing the unique challenges facing Black mothers and infants. Her research and scholarly area of interest focuses on examining the root causes of racial disparities in maternal and infant health outcomes, including the impact of systemic racism as a contributing factor to healthcare disparities. Dr. Seward obtained a Master of Public Health degree from Boston University School of Public Health, followed by a Doctor of Public Health degree from the University at Albany School of Public Health. Dr. Seward has received numerous awards for her work and leadership, including the Faculty Gold Standard Award, Upstate President Award for Community Service Team, and Faculty and Staff Association for Diversity Award. In addition, Dr. Seward is a scholar of the Public Health Leadership Institute of Florida (PHLIF), the SUNY SAIL Leadership Institute, and a former Presidential Health Disparities Fellow of the Center for the Elimination of Minority Health Disparities at the University at Albany. Dr. Seward also has several professional affiliations where she donates her time. She currently serves as Vice-Chair of the board of directors for the Central New York Lyme and Tickborne Disease Alliance and a member of the Blueprint 15 board of directors, the Onondaga County Health Advisory Council whose responsibilities include Lyme disease reporting as well as a member of the Community Action Network (CAN) for the Syracuse Healthy Start initiative. She was also previously a Public Health Fellow for Onondaga County focusing on maternal and child health.

Robert P. Smith

Member

Robert “Rob” Pease Smith, M.D., M.P.H., is an infectious disease physician who currently directs research studies into the ecology, epidemiology, and clinical recognition of tick-borne diseases at the MaineHealth Institute for Research. His team at the Vector-borne Disease Laboratory there includes scientists with training in medical entomology, biostatistics/mathematical modeling, vector ecology, and clinical research. Current projects include tick-borne disease surveillance/epidemiology, strategies for vector control, phylogenetics and ecology of Powassan virus, and novel diagnostic approaches for early Lyme disease. He is a member of the Division of Infectious Diseases at Maine Medical Center, and served as Director of the Division of Infectious Diseases there from 2014-2022. Rob has been a regional leader in professional and public outreach regarding the recognition and treatment of tick-borne diseases and often gives talks and publishes on Lyme disease. He also served since its inception in 1992, until 2022, as the Director of an interdisciplinary specialty clinic at Maine Medical Center focused on the care of persons with HIV and other viral infections. Dr. Smith has received research support from the National Institutes of Health, including two SBIR awards, from the CDC, and from the State of Maine Department of Health and Human Services related to Lyme disease research. Dr. Smith also served as co-investigator as part of the Pfizer-Valneva vaccine trial research site at MaineHealth.Dr. Smith received his medical degree from Johns Hopkins University School of Medicine and is a Professor of Medicine at Tufts University School of Medicine. He has widely published on served on numerous federal panels and work groups related to tick-borne diseases, the Federal Tick-borne Disease Working Group (2018), and was an invited reviewer of the (then) Institute of Medicine 2011 Report on “Critical Needs and Gaps in Understanding, Amelioration and Prevention of Lyme disease and Other Tick-borne Infections.” He is a Fellow of the American College of Physicians and of the Infectious Disease Society of America.

Qing Mei Wang

Member

Qing-Mei Wang, M.D., Ph.D., is a physician-scientist and physiatrist at Spaulding Rehabilitation Hospital, the teaching affiliate of Harvard Medical School. She is an assistant professor in the Department of Physical Medicine and Rehabilitation at Harvard Medical School. She is also the director of the Stroke Biological Recovery Laboratory and conducts translational research in neuro-rehabilitation. She has been providing rehabilitation care to patients with Post-Treatment Lyme Disease Syndrome (PTLDS) since 2020. This devastating disease and the lack of effective treatment led her to conduct clinical studies using non-invasive vagal nerve stimulation technology. The results from her study suggest that transcutaneous auricular vagal nerve stimulation may improve neurocognitive impairment in PTLDS. This study may provide a novel approach to treat PTLDS. She is the receiver of the Rehabilitation Medicine Scientist Training Program (K12) and NIH K08 awards. Dr. Wang obtained Ph.D. and M.D. at the University of Medicine and Dentistry of New Jersey and completed residency training in Physical Medicine and Rehabilitation at Mount Sinai Medical Center in New York. She is a member of the American Association of Physiatrists.

Susan J. Wong

Member

Susan J. Wong, Ph.D., M.Sc., was the Director of Diagnostic Immunology at the Wadsworth Center (New York State Department of Health, NYSDOH) for 26 years before retiring in 2020. While at the Wadsworth Center, Dr. Wong set up the first tests for Anaplama phagocytophilum and Babesia microti serology for NY state. She has evaluated microsphere immunoassays using recombinant proteins of Borrelia, Babesia, and Anaplasma for multiplex serology of tickborne infections; established microsphere immunoassays to detect Powassan virus, deer tick virus, and tick-borne encephalitis virus; and applied microsphere immunoassays to differentiate flavivirus infections (West Nile, St. Louis encephalitis, Zika, and dengue). Dr. Wong earned a Bachelor of Science in Molecular Biology from the University of Wisconsin and then went on to receive a Master of Science in Biochemistry from the University of New Hampshire and a Ph.D. in Biochemistry from the University of Saskatchewan. Dr. Wong has been honored with the Wadsworth Center Recognition Award in 1999, the NYSDOH Commissioner's Recognition Award for response to the West Nile Virus and SARS, and the Thomas Nakano Commendation from the CDC and U.S. Public Health Service (USPHS), and a nominee for the Charles Shepard Science Award from the CDC and USPHS. Dr. Wong also has experience working globally, serving as a consultant to the Ethiopian Health and Nutrition Research Institute in Addis Ababa through the Association of Public Health Laboratories, and worked as a consultant to the Iraq Science Engagement Program in Baghdad, Iraq with the Civilian Research and Development Foundation.

Julie Liao

Staff Officer

Dr. Julie Liao is a Senior Program Officer with the Board on Global Health of the National Academies of Sciences, Engineering, and Medicine where she directs the Forum on Microbial Threats. In 2023, the Forum on Microbial Threats co-convened a public workshop, Toward a Common Research Agenda for Infection-Associated Chronic Illnesses that highlighted current research progress and opportunities for coordination between these chronic conditions including myalgic encephalomyelitis (chronic fatigue syndrome), Long COVID, and Lyme disease. Before joining the National Academies in 2020, she was involved in pre-clinical vaccine development research in the biotechnology industry. She received a Ph.D. in molecular science and microbiology from Binghamton University and completed postdoctoral training at Boston Children's Hospital.

Andrew March

Staff Officer

Andrew March is a Program Officer with the Board on Health Sciences Policy of the National Academies of Sciences, Engineering, and Medicine. Most recently, he served as the co-director for the consensus study, Developing a Framework to Address Legal, Ethical, Regulatory, and Policy Issues for Research Specific to Pregnant and Lactating Persons. He has contributed to consensus studies on diverse topics in health policy, including medical product supply chains, dementia care interventions, and the safety and effectiveness of compounded drug preparations. Before joining the National Academies in 2018, he conducted research on the intersection of maternal and occupational health at the Center for Research in Occupational Health in Barcelona, and worked in the Department of Clinical Epidemiology and Public Health at the Hospital de la Santa Creu i Sant Pau. Andrew obtained his M.P.H. at the Universitat Pompeu Fabra and his B.S. degree in Biology and Spanish from Roanoke College.