

Review of Relevant Literature Regarding Adverse Events Associated with Vaccines

Committee

George J. Isham

Chair

George Isham, M.D. M.S., (Chair) is a senior fellow at the HealthPartners Institute and a senior advisor for the Alliance of Community Health Plans. Previously, he was HealthPartners' medical director and chief health officer, responsible for improving health and quality of care. He served as a member of the Centers for Disease Control and Prevention's Task Force on Community Preventive Services, the Agency for Healthcare Research and Quality's United States Preventive Services Task Force, was a founding co-chair of the National Committee for Quality Assurance's committee on performance measurement and was founding co-chair of the National Quality Forum's Measurement Application Partnership. Dr. Isham is an elected member of the National Academy of Medicine (NAM). He has an M.D. from the University of Illinois at Chicago and an M.S. in preventive medicine and administrative medicine from the University of Wisconsin-Madison.

Anne R. Bass

Member

Anne Bass, M.D., is Professor of Clinical Medicine at Weill Cornell Medicine and a practicing rheumatologist at the Hospital for Special Surgery (HSS) and New York Presbyterian Hospital (Cornell). She served as the principal investigator for the "2022 American College of Rheumatology (ACR) Guideline for Vaccinations in Patients with Rheumatic and Musculoskeletal Diseases (RMD)" and prior to that was a member of the core group for the "ACR Guidance for COVID-19 Vaccination in patients with RMD". Dr. Bass has served the ACR as chair of the Committee on Training and Workforce Issues and as a member of the Board of Directors. Her clinical research focuses on autoimmune side effects of immune checkpoint inhibitor cancer therapy, particularly inflammatory arthritis. She did her undergraduate training at Harvard and earned her M.D. and did her residency at Columbia, followed by a rheumatology fellowship at NYU.

Alicia Christy

Member

Alicia Christy, M.D., was the Deputy Director of Reproductive Health, Veterans Health Administration. She served as obstetrics and gynecology department chair and Consultant to the Army Surgeon General. She was a clinical researcher at the National Institute of Health (NIH) where her research focused primarily on the areas of contraception, treatment of leiomyoma, and health disparities. She has been involved in evidence review for two Department of Veterans Affairs (VA) and Department of Defense clinical practice guidelines. She was the co-editor of Contraception and Reproductive Medicine. She held the rank of professor at the Uniformed Services University, and adjunct professor at Howard University. Dr. Christy has received the NIH Award of Merit, multiple research awards, the NIH Collaborator Award, a Humanism in Medicine Award, an Excellence in Teaching Award, and a Mentor of the Year Award. Dr. Christy was the chair of the American Society of Reproductive Medicine Health Disparities Special Interest Group, and the VA liaison to an American College of Obstetricians and Gynecologists committee. Dr. Christy received her undergraduate degree from Princeton University, is an Alpha Omega Alpha graduate of Northwestern University School of Medicine, and received a master's degree in Health Science and Clinical Research from Duke University School of Medicine.

DeLisa Fairweather

Member

DeLisa Fairweather, Ph.D., is a Professor of Medicine, Director of Translational Research in the Department of Cardiovascular Medicine and Co-Director of Research for the Ehlers-Danlos syndrome (EDS) Clinic at Mayo Clinic in Jacksonville, Florida, USA. In addition to an interest in myocarditis, dilated cardiomyopathy, and heart failure, Dr. Fairweather conducts research and publishes about how sex differences in inflammation caused by environmental exposures such as viruses lead to chronic inflammatory diseases like autoimmune diseases, cardiovascular disease, cancer, and lung disease. She was a co-investigator and leader of the Mayo-led FDA-funded Expanded Access Program (EAP) that provided convalescent plasma to patients with COVID-19 during the first year of the pandemic. She studies the implications of mRNA technology for inflammatory diseases, including myocarditis and pericarditis. She was a standing member of the Atherosclerosis and Inflammation of the Cardiovascular System Study Section at NIH for 6 years, and she serves on the Medical Advisory Board for the Myocarditis Foundation. She obtained her Ph.D. at the University of Western Australia in microbiology and immunology and conducted a postdoctoral fellowship at Johns Hopkins University.

James S. Floyd

Member

James Floyd, M.D., M.S., is a physician at Harborview Medical Center, an associate professor of medicine (general internal medicine) and adjunct associate professor of epidemiology at the University of Washington, and an affiliate investigator at Kaiser Permanente Washington Health Research Institute. He has expertise in cardiovascular epidemiology and drug safety, including postmarket surveillance using electronic health data, and is an active investigator in several National Heart, Lung, and Blood Institute (NHLBI)-funded prospective cohort studies and international research consortia. In 2019 he acted as a consultant for Shionogi. Dr. Floyd earned his M.D. from Duke University. He completed a T32 Fellowship in cardiovascular epidemiology at the University of Washington Cardiovascular Health Research Unit, where he is the codirector.

Eric Hegedus

Member

Eric J. Hegedus, Ph.D., D.P.T., M.H.Sc., is a Professor at Tufts University School of Medicine and Director of the Tufts Doctor of Physical Therapy (DPT) program. Prior to this he was a Professor at High Point University where he developed their Doctor of Physical Therapy program, and an Associate Professor at Duke University. He has over 30 years of clinical experience and has taught in the U.S. and abroad. Dr. Hegedus answers clinical questions in the orthopaedic and sports prevention, diagnosis, and rehabilitation realm and translates the findings to clinical practice. He is on the ADx Health Scientific Advisory Board and he has been a member of the American Physical Therapy Association (APTA) since 1991. He received its James A. Gould Teaching Award, a national award given annually to the single most deserving teaching professor of musculoskeletal physical therapy. Dr. Hegedus earned a Ph.D. from the University of Ulster, a D.P.T. from Slippery Rock University, and a M.H.Sc. from Duke University.

Chandy John

Member

Chandy John, M.D., M.S., holds the Ryan White Endowed Chair in Pediatric Infectious Diseases and is director of the Ryan White Center for Pediatric Infectious Diseases and Global Health at Indiana University. Dr. John's research investigates why children die from severe malaria and why children who survive severe malaria develop problems with thinking and learning. Dr. John also studies ways to prevent malaria and other infections in children with sickle cell disease and he has studied the epidemiology and immunology of COVID-19 in children. Dr. John is co-chair of the Thrasher Research Fund Scientific Advisory Committee, a member of Fogarty International Center Advisory Board, a member of the American Academy of Pediatrics Committee on Infectious Diseases, and a member of the CDC Advisory Committee on Immunization Practices Polio Working Group. Dr. John received the Bailey K. Ashford Medal from the American Society of Tropical Medicine and Hygiene (ASTMH) in 2011 and served as president of ASTMH in 2019. He received his medical degree and completed residency in internal medicine and pediatrics at the University of Michigan and completed fellowship training in pediatric infectious diseases at Case Western Reserve University.

John Edward (Jed) Kuhn

Member

John E. (Jed) Kuhn, M.D., M.S., is the Kenneth D. Schermerhorn Professor in the Department of Orthopaedic Surgery in Vanderbilt University Medical Center. He serves as the Director of the Sports Medicine and Shoulder Surgery Division. Dr. Kuhn is the founder of the Multicenter Orthopaedic Outcomes Network Shoulder Group- a multicenter research collaboration designed to study conditions about the shoulder. He is currently the President Elect for the American Shoulder and Elbow Surgeons and is the Deputy Editor in Chief for the Journal of Shoulder and Elbow Surgery. He earned his M.D. and was a resident in Orthopaedic Surgery at the University of Michigan, then was a Fellow in Sports Medicine and Shoulder Surgery at the Steadman Hawkins Clinic in Vail, Colorado. He returned to serve as faculty at the University of Michigan for 8 years. Dr. Kuhn started at Vanderbilt University in 2003 to build the Division in Sports Medicine and Shoulder Surgery.

Evan Mayo-Wilson

Member

Evan Mayo-Wilson, Ph.D., M.P.A., is an Associate Professor of Epidemiology at the UNC Gillings School of Global Public Health. His research aims to improve public health, and to advance methods for conducting health and behavioral research. He focuses on: (1) evaluating the effectiveness of pharmacological and behavioral interventions; (2) improving methods for clinical trials and systematic reviews; and (3) developing methods and interventions to increase research transparency and openness. Dr. Mayo-Wilson serves on several editorial boards, including as Associate Editor for Systematic Reviews for the American Journal of Public Health. He has contributed to several reporting guidelines, and to guidance for increasing transparency and openness. Dr. Mayo-Wilson completed his D.Phil. (PhD) in the Department of Social Policy and Intervention at University of Oxford. He also has master's degrees in public administration (M.P.A., University of Pennsylvania) and evidence-based intervention (M.Sc., University of Oxford).

Thomas L. Ortel

Member

Thomas Ortel, M.D., Ph.D., the chief of hematology and a professor of medicine and pathology at Duke University, is nationally and internationally recognized for his clinical and research expertise in hemostatic and thrombotic disorders. His primary interests focus on rare antibody-mediated thrombotic disorders, including antiphospholipid antibody syndrome and heparin-induced thrombocytopenia, and developing and managing novel antithrombotic therapies. His experience conducting prospective, randomized, multicenter clinical trials and interest in rare thrombotic disorders resulted in becoming the study chair for the NHLBI-sponsored Accelerating COVID-19 Therapeutic Interventions and Vaccines Post-Hospital Thrombosis Prevention Study, investigating the use of extended thromboprophylaxis to prevent thromboembolic complications. Dr. Ortel has been the site principal investigator at Duke University for studies funded by Takeda Pharmaceutical Company on treatment of patients with congenital and acquired thrombotic thrombocytopenic purpura since 2020, and, previously, a study on acquired hemophilia, during which he also received compensation for a steering committee meeting. As of December 2023, he is serving as a consultant to Takeda on the steering committee for the phase 3 study using recombinant ADAMTS13 in patients with acquired thrombotic thrombocytopenic purpura. In 2023 he reviewed the results of a clinical trial for a drug to treat hemophilia, for which he was compensated by Sanofi. During the past year, he collaborated with colleagues at CDC on the Clinical Immunization Safety Assessment Project related to the development of TTS after COVID-19 vaccination. He completed a combined M.D./Ph.D. program at Indiana University in 1985, followed by internship and residency training in internal medicine and fellowship training in hematology and medical oncology, both at Duke University.

Nicholas Reed

Member

Nicholas S. Reed, Au.D., is an Assistant Professor in the Department of Epidemiology at Johns Hopkins Bloomberg School of Public Health with a joint appointment in the Department of Otolaryngology-Head and Neck Surgery (Audiology) at Johns Hopkins School of Medicine. He is the director of the Audiology Core at the Johns Hopkins Cochlear Center for Hearing and Public Health, where he oversees the integration and management of hearing measures into multiple large epidemiologic cohort studies and clinical trials. His research focuses on the association of hearing loss among older adults and healthy aging outcomes including cognitive decline and health resource utilization, the impact of hearing intervention on health outcomes, and novel models of hearing care delivery. He was awarded the Early Career Research Award in 2021 from the American Auditory Society. Dr. Reed received his clinical doctorate in audiology from Towson University and completed his audiology clinical fellowship at Georgetown University Hospital. He previously served on the National Academies committee on Evaluating Hearing Loss for Individuals with Cochlear Implants.

Andy S. Stergachis

Member

Andy Stergachis, Ph.D., B.Pharm., is Professor of Pharmacy and Global Health and Director of the Global Medicines Program, and Associate Dean for Research, Graduate Studies and New Initiatives, School of Pharmacy, University of Washington (UW). He is Director of the UW Biomedical Regulatory Affairs Program. He holds adjunct faculty appointments in the UW Departments of: Health Metrics & Evaluation; Epidemiology; and Health Systems & Population Health. He is an author of publications in areas such as pharmacovigilance, pharmacoepidemiology, pharmaceutical services and clinical epidemiology. He has developed and evaluated novel approaches for safety surveillance of essential medicines and vaccines. A licensed pharmacist, he served as Editor-in-Chief of the Journal of the American Pharmacists Association for 6 years until 2019. Dr. Stergachis also served as a special government employee at the Food and Drug Administration on matters of drug safety and risk management. He currently serves as a member of the Coalition for Epidemic Preparedness Innovations (CEPI) Maternal Immunization Working Group (formerly via COVAX) and serves on the executive board of the CEPI-funded Safety Platform for Emergency Vaccines (SPEAC). Dr. Stergachis is an elected member of the National Academy of Medicine (NAM), Fellow of the American Pharmacists Association, and Fellow of the International Society for Pharmacoepidemiology. He received a Ph.D. in Social and Administrative Pharmacy from University of Minnesota.

Michel Toledano

Member

Michel Toledano, M.D., is Assistant Professor of Neurology at Mayo Clinic in Rochester, MN where he currently serves as the Medical Director for the inpatient neurology services. He completed his neurology residency at the Mayo Clinic where he subsequently pursued a fellowship in Multiple Sclerosis. He then undertook a fellowship in neuroinfectious diseases at Chelsea and Westminster Hospital in London, UK. His research interests include improving care delivery models for hospitalized neurology patients and optimizing diagnostic test utilization, especially for patients presenting with encephalitis and other infectious or neuroinflammatory syndromes. Dr. Toledano earned his M.D. from Ben-Gurion University of the Negev.

Robert B. Wallace

Member

Robert Wallace, M.D., M.Sc., is an Emeritus Professor of Epidemiology and Internal Medicine at the University of Iowa (UI) College of Public Health. He was trained in General Internal Medicine and is board-certified in preventive medicine. After his residency he worked at the Centers for Disease Control and Prevention, where he specialized in the epidemiology and control of several communicable and vaccine preventable diseases, including measles, mumps and rubella, smallpox and some agents more common in tropical countries. Additionally, he worked on the infectious causes of chronic illnesses, such as some cancers. During his long career at the U. of Iowa, he did research on the prevention and control of several chronic illnesses of older people, such as cardiovascular disease, cancer and other disabling conditions, including Alzheimer's disease and other neurodegenerative conditions. He is an elected member of the National Academy of Medicine (NAM) and received the NAM's Walsh McDermott Medal in recognition for his distinguished service, having participated in more than twenty NASEM consensus committees. Dr. Wallace has an M.D. from Northwestern University in Illinois and a M.Sc. from State University of New York at Buffalo.

Ousseny Zerbo

Member

Ousseny Zerbo, Ph.D., is a Research Scientist II at the Vaccine Study Center at Kaiser Permanente Northern California, Division of Research. He is an epidemiologist with expertise in infectious diseases, neurodevelopmental disorders (autism), and vaccine safety and effectiveness, including safety and effectiveness of COVID-19 vaccines. He is the principal investigator on two NIH-funded projects to investigate the effectiveness of influenza vaccination, COVID-19 vaccination during pregnancy, and infant risk of influenza and COVID-19. He collaborates with other vaccine researchers in the Vaccine Safety Datalink project. Dr. Zerbo holds a Ph.D. in Epidemiology from the University of California Davis and a B.S. in Biological Sciences from the Universite de Ouagadougou.