

Leveraging Real-World Evidence to Assess Benefits and Risks of GLP-1–Based Therapies



**May 7–8, 2025
(Virtual Only)**



Workshop Co-Chairs

David Arterburn, M.D., M.P.H.

Lesley Curtis, Ph.D.

Darren Toh, Sc.D.

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Susan Yanovski, M.D.

Workshop Co-Chairs

David Arterburn, M.D., M.P.H., Kaiser Permanente Washington Health Research Institute

General Internist, Senior Investigator, and Manager, Investigative Sciences



David Arterburn, MD, MPH is a general internist, senior investigator, and manager in the Investigative Sciences Division at the Kaiser Permanente Washington Health Research Institute, and he is an Affiliate Professor with the University of Washington's Department of Medicine. His research focuses on the long-term health and economic outcomes of obesity treatment as well as implementation and evaluation of shared decision-making tools. He previously chaired the NIH Symposium on the Long-Term Outcomes of Bariatric Surgery, the Adult Obesity Measurement Advisory Panel for NCQA, and the Health Services Research Section of The Obesity Society.

Lesley Curtis, Ph.D., Duke University School of Medicine

Chair and Professor, Departments of Population Health Sciences and Medicine



Lesley H. Curtis is the Chair and Professor in the Departments of Population Health Sciences and Medicine at the Duke School of Medicine. As a health services researcher, Dr. Curtis specializes in utilizing health care and Medicare claims data for both health services and clinical outcomes research. She also plays a leading role in national efforts to improve data quality. Additionally, Dr. Curtis has served as a senior policy advisor at the Food and Drug Administration (FDA) for one year, supporting the Agency's efforts in evidence generation initiatives. She is the co-principal investigator of the NIH Pragmatic Trials Collaboratory, which aims to enhance the national capacity for large-scale research studies integrated into health care delivery. Dr. Curtis earned her Bachelor of Arts in Economics from Washington University. She also holds a Master of Science in Public Policy Analysis and a Ph.D. in Health

Services Research and Policy, both from the University of Rochester.

Darren Toh, Sc.D., Harvard Medical School and Harvard Pilgrim Health Care Institute
DPM Endowed Professor, Department of Population Medicine



Darren Toh, ScD is DPM Endowed Professor in the Department of Population Medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute. He is a pharmacoepidemiologist with an interest in the comparative safety and effectiveness research of medical products. His research focuses on 1) assessing the risks and benefits of medical products using electronic data collected as part of routine healthcare delivery, and 2) developing and applying privacy-protecting analytic methods to conduct multi-center studies in distributed data networks. Dr. Toh is Principal Investigator of the Operations Center of the FDA-funded Sentinel System, a congressionally mandated national medical product safety surveillance program. He is also Principal Investigator of projects funded by the National Institutes of Health, the Agency for Healthcare Research and Quality, the Patient-Centered Outcomes

Research Institute, and the Food and Drug Administration. Dr. Toh received his pharmacy training at the National Taiwan University and his doctoral degree in Epidemiology from the Harvard School of Public Health.

Workshop Faculty

Marie Bradley, Ph.D., Food and Drug Administration
Senior Advisor, Office of Medical Policy, Center for Drug Evaluation and Research



Dr. Marie Bradley is a Senior Advisor on the Real-World Evidence Analytics team in the Office of Medical Policy, Center for Drug Evaluation and Research (CDER), FDA. Her responsibilities related to real-world evidence (RWE) include serving as program lead for the FDA Advancing Real World Evidence Program and lead for a portfolio of externally conducted RWE demonstration projects, evaluating real-world evidence protocols, participating in internal Agency processes, interacting with external stakeholders, and contributing to guidance development. She is a pharmacoepidemiologist and a pharmacist with over 15 years of experience working in regulatory, government, and academic sectors in US and the UK, including 11 years at the FDA. Dr. Bradley has a PhD in Pharmacoepidemiology and a Masters in Pharmacy degree from Queen's University Belfast as well as a Masters in

Public Health degree from London School of Hygiene and Tropical Medicine.

David D'Alessio, M.D., Duke University School of Medicine
Professor and Director of the Division of Endocrinology



Dr. D'Alessio is Professor of Medicine at the Duke University School of Medicine and Director of the Division of Endocrinology. He practices endocrinology at Duke Hospital and the Durham VA Medical Center. His primary research interest is in the regulation of glucose tolerance and food intake by gut hormones, and abnormalities in these processes that lead to type 2 diabetes. Work in his lab is directed at the interplay between endocrine, paracrine and neural signals to control insulin secretion. His primary focus has been proglucagon peptides, particularly glucagon and GLP-1 and their roles in physiology and pharmacology. As the science underlying GLP-1 has generated considerable drug development, Dr. D'Alessio has taken an active role in clinical trials testing the effects of new compounds to lower blood glucose, cause weight loss and reduce the risk of vascular disease. He and his colleagues receive

research funding from the NIH as well as industry and foundational sources. He is Editor-in-Chief at the journal *Diabetes*, serves as the VA representative to the NIH NIDDK Council and has contributed to expert panels writing guidelines for diabetes care.

Noelia Duchovny, Ph.D., Congressional Budget Office
Health Economist



Noelia Duchovny is a health economist at the Congressional Budget Office with more than 20 years of experience conducting research in health policy. One of her areas of expertise is on policies related to population health—in the areas of obesity, smoking, opioids, hepatitis c, prevention, and climate, for example—and their impact on the federal budget. In addition, she has worked on issues related to long-term care and supports and spillover effects resulting from expansions of Medicaid. Before joining the Congressional Budget office, she completed a post-doctoral fellowship at Yale’s University School of Public Health with a research focus on Medicaid and tobacco policies. Noelia received her Ph.D. in Economics from the University of Maryland at College Park.

Serena Guo, M.D., Ph.D., University of Florida
Assistant Professor, Department of Pharmaceutical Outcomes and Policy



Dr. Serena Guo is an Assistant Professor in the Department of Pharmaceutical Outcomes and Policy at the University of Florida. Her research focuses on pharmacoepidemiology and pharmacoinformatics. She aims to advance precision therapeutics and promote health equity by utilizing large real-world data, such as electronic health records and insurance claims, alongside advanced analytics, including AI and machine learning. Her work involves assessing the heterogeneous treatment effects and developing intelligent social risk management tools for integration into clinical care. She has authored over 115 peer-reviewed manuscripts, with publications in esteemed journals like *Annals of Internal Medicine*, *Nature Communications*, and *JAMA Neurology*. Her research and collaborations have attracted funding from organizations such as the NIH, Veterans Affairs, CDC, FDA, and the

PhRMA Foundation.

Miguel Hernan, M.D, M.P.H., Sc.M., Dr.P.H., Harvard T.H. Chan School of Public Health

Professor of Biostatistics and Epidemiology and Director, CAUSALab



Miguel Hernán is the Director of CAUSALab, the Kolokotronis Professor of Biostatistics and Epidemiology at the Harvard T.H. Chan School of Public Health, and faculty at the Harvard-MIT Division of Health Sciences and Technology. He 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 research methodology worldwide. Miguel teaches causal inference methods to generate and analyze data for health policy and clinical decision making. At Harvard, he has mentored dozens of trainees. His free online course *Causal Diagrams* and book *Causal Inference: What If*, co-authored with James Robins, are widely used for the training of researchers.

David Hines, Metro Nashville Public Schools

Executive Director of Employee Benefits



David's career started at Blue Cross Blue Shield of Tennessee in claim's management. He went on to serve as the Director of Operations for the State of Tennessee Employee Health Plans; Benefit Manager for Nissan Motor Manufacturing; benefits consultant; Insurance Director for Rutherford County, TN and now as Executive Director of Benefits for Metro Nashville Public Schools (MNPS). While at MNPS he established a network of primary care clinics to serve their employees, retirees and their dependents. In 2017, he opened MNPS' first integrated health and wellness facility, combining primary care, behavioral health, health coaching, fitness, physical therapy, chiropractic, acupuncture and pharmacy. His current work extends to creating greater access to specialty care through clinic-based telehealth and the development and expansion of value-based care, including adoption of bundled payment programs for medical services

ranging from maternity care to medical and surgical weight loss. David serves on the boards of HealthcareTN, the State and Local Government Benefit Association and the National Association of Worksite Health Centers.

Esti Iturralde, Ph.D., Kaiser Permanente Northern California
Clinical Psychologist and Investigator, Division of Research



Esti Iturralde, PhD is a clinical psychologist and investigator with the Kaiser Permanente Northern California (KPNC) Division of Research. She received her doctorate from the University of Southern California and completed training at the VA Northern California Health Care System and the Stanford University School of Medicine in behavioral medicine and diabetes management. As a health system-embedded researcher in KPNC, she uses quantitative and qualitative methods to study ways to personalize and integrate care for people with mental illness to improve both mental health and chronic disease prevention. Her K23 career development award focuses on preventing diabetes among people with schizophrenia and bipolar spectrum illness -- a population that suffers higher rates of these conditions compared to peers without serious mental illness. This project seeks to increase evidence-based prevention care through the use of machine-learning prediction algorithms that rely on clinical data, as well as shared decision-making and collaborative care to bridge across primary and mental health care. Her work uses electronic health record data from Kaiser Permanente and other (both private and public) health care systems to understand barriers to good health for people with mental illness and to evaluate novel care models seeking to overcome these barriers.

Ania Jastreboff, M.D., Ph.D., Yale School of Medicine
Associate Professor of Medicine and Pediatrics



Ania M. Jastreboff, MD, PhD is an Associate Professor in Medicine and Pediatrics at Yale School of Medicine. Dr. Jastreboff is a clinically active physician-scientist and international thought leader in the scientific development and clinical application of novel anti-obesity pharmacotherapeutics revolutionizing obesity treatment. As founding director of the Yale Obesity Research Center (Y-Weight), she is leading and shaping pivotal landmark studies of dual- and triple-receptor hormone agonists and NIH-funded studies investigating the physiology of obesity. She has served as lead investigator and author for trials investigating novel nutrient-stimulated hormone (NuSH)-based therapies for obesity including dual hormone receptor agonist, tirzepatide, a GIP/GLP-1 receptor agonist (Jastreboff, *et al.*, *NEJM*, 2022 & *NEJM*, 2024) and triple hormone receptor agonist retatrutide, a GIP/GLP-1/Glucagon receptor agonist (Jastreboff, *et al.*, *NEJM*, 2023). Trained in both adult endocrinology and pediatric endocrinology, she serves on the Board of Governance for The Obesity Society, as a director on the American Board of Obesity Medicine, developing Obesity Clinical Practice Guidelines, and as co-director of the Yale Center for Weight Management, where she sees patients and teach trainees. She is a highly sought after speaker, teaching internationally, nationally, and locally. She is also a compassionate advocate for patients with obesity, from grass-roots patient groups to interviews with Ms. Oprah Winfrey.

Kristina Lewis, Wake Forest University School of Medicine
Associate Professor, Division of Public Health Sciences



Kristina Lewis is an Associate Professor in the Division of Public Health Sciences at Wake Forest University School of Medicine. Dr. Lewis' clinical practice is at the Atrium Health Wake Forest Baptist Weight Management Center and she serves on the Board of Directors for the American Board of Obesity Medicine. She co-directs Wake Forest CTSI's Workforce Development Program and the Digital Communications Core resource for scientists who wish to leverage the electronic health record and digital tools such as text messaging in their research. In 2024, she was named an inaugural Dean's Research Scholar within the School of Medicine by Dean Ebony Boulware. Her research focuses on identifying scalable and translatable methods of preventing and treating obesity and she has a particular interest in leveraging real-world datasets such as electronic health records and insurance claims to examine health care use patterns. Dr. Lewis earned her BS in Biology from Duke

University, then completed her MD and MPH in Epidemiology at Tulane University, an Internal Medicine residency at the Massachusetts General Hospital, and a fellowship in General Internal Medicine at Harvard Medical School, during which she also earned a Master of Science in Health Policy and Management at the Harvard School of Public Health.

Jennifer Lund, M.S.P.H., Ph.D., University of North Carolina at Chapel Hill
Professor of Epidemiology, Gillings School of Global Public Health



Jennifer Lund, MSPH, PhD, FISPE is Professor of Epidemiology at the University of North Carolina at Chapel Hill (UNC) Gillings School of Global Public Health and the Director of Data Strategy and Education with the UNC Lineberger's Cancer Information and Population Health Resource (CIPHR). Dr. Lund conducts pharmacoepidemiologic and health services research, with applications in cancer, aging, and the environment. The overall objective of her work is to generate robust evidence on the delivery and effectiveness of healthcare interventions that will improve decisions made by policymakers, providers, and patients and their families. Dr. Lund's research program draws upon clinical trials, large healthcare databases, publicly available surveys, and environmental data, along with advanced epidemiologic methods to evaluate: (1) the delivery of high-quality care, (2) the effectiveness and safety of treatment, and (3) the role of

environmental exposures on treatment access, adherence, and outcomes. She is a Fellow of the International Society for Pharmacoepidemiology (FISPE) and an Associate Editor for *Pharmacoepidemiology and Drug Safety*, as well as an Editorial Board member for *Epidemiology* and the *Journal of Geriatric Oncology*.

Matthew Maciejewski, Ph.D., Duke University School of Medicine
Professor, Department of Population Health Sciences



Matt Maciejewski, PhD is a Professor in the Department of Population Health Sciences. He is also a Senior Research Career Scientist in the Center of Innovation to Accelerate Discovery and Practice Transformation at the Durham VA Medical Center. Matt also holds Adjunct Professor appointments in the Schools of Public Health and Pharmacy at the University of North Carolina at Chapel Hill. He has received funding from NIDDK, NIDA, CMS, AHRQ, VA HSR, and the RWJ Foundation to conduct evaluation of long-term clinical and economic outcomes of surgical interventions, behavioral interventions and Medicare program/policy changes on patients with obesity or cardiometabolic conditions. Matt has evaluated a range of long-term clinical and economic outcomes following bariatric surgery in VA and Kaiser Permanente populations, and has an ongoing NIDDK-funded R01 to evaluate access to GLP-1s. He is interested in methods for addressing

unobserved confounding in observational studies, conducted the first-ever population-based implementation of value-based insurance design (VBID) and led the first-ever linkage of lab results and Medicare FFS claims. He has published over 325 papers in peer-reviewed journals such as JAMA, JAMA Internal Medicine, JAMA Surgery, Annals of Internal Medicine, Health Economics, Medical Care, and Health Services Research. Previously, he was a Statistical Editor at *JAMA* and is now a Senior Associate Editor at Health Services Research. He received his PhD in *Health Services Research* in 1998 from the University of Minnesota.

Rozalina McCoy, M.D., M.S., University of Maryland School of Medicine
Associate Professor of Medicine and Director of Precision Medicine and Population Health



Dr. Rozalina McCoy is Associate Professor of Medicine and Director of Precision Medicine and Population Health in the University of Maryland School of Medicine. She serves as the Associate Division Chief for Clinical Research in the Division of Endocrinology, Diabetes, and Nutrition and directs an interdisciplinary Center for Population Health in the University of Maryland Institute for Health Computing. Dr. McCoy's research program, funded by the NIH, PCORI, and the American Diabetes Association leverages real-world data to improve the quality, accessibility, and sustainability of diabetes care on both the individual and population levels. In particular, she is currently leading NIDDK and PCORI funded studies using national claims data to compare the effectiveness and safety of second-line diabetes medications in adults with type 2 diabetes at moderate risk for cardiovascular disease, and to compare metabolic surgery, GLP-1 receptor agonists, and SGLT2 inhibitors in adults with type 2 diabetes and obesity. She is an

active member of the American Diabetes Association, where she co-chairs the Professional Practice Committee.

Kathleen McTigue, M.D., M.P.H., University of Pittsburgh School of Medicine
Professor of Medicine and Vice-Chief for Real-World Evidence



Kathleen McTigue, MD MPH, is a Professor of Medicine and Vice-Chief for Real-World Evidence for the Department of Medicine of the University of Pittsburgh's School of Medicine. She is the inaugural Director of the Trilogue Center for Real-World Evidence. Dr. McTigue serves as current Chair of the PCORnet Steering Committee and has been the Contact Principal Investigator for the PaTH Clinical Research Network since 2015. She is a general internist whose research focuses on obesity and cardiovascular prevention. Dr. McTigue has led multiple observational and interventional studies focused on obesity and weight-related health implications. This work includes a role as contact PI for the Bariatric Surgery Impact on Cancer Screening (BASICS) and co-PI for the PCORnet Bariatric (PBS), which both leverage PCORnet data. In addition, Dr. McTigue focuses on developing and evaluating approaches to support partnering with patients and other

shareholders throughout the research process.

Kimberly Narain, M.D., Ph.D., M.P.H., David Geffen UCLA, School of Medicine
Primary Care Physician, Obesity Medicine Specialist, Researcher



Dr. Kimberly Narain is a primary care physician, obesity medicine specialist and researcher in the Division of General Internal Medicine & Health Services Research at the David Geffen UCLA, School of Medicine. She is also the Director of Health Services and Health Optimization Research for the Iris Cantor-UCLA Women's Health Center. She uses advanced quantitative and qualitative methods to identify structural factors (health insurance benefit, healthcare delivery system, socioeconomic policy and work structure design) underlying racial, ethnic and socioeconomic differences in the prevalence and treatment of obesity and obesity-related diseases (Type 2 diabetes and cardiovascular disease). She endeavors to use her expertise to provide evidence regarding the most promising strategies to stem the tide of the obesity epidemic.

Dr. Narain received dual B.S. degrees in Microbiology and African-American studies from UCLA and an M.D. from Morehouse School of Medicine. She completed her residency in Primary Care Internal Medicine at UCSF. Following residency, she completed a California Endowment Health Policy Fellowship at Harvard Medical School. After leaving Harvard, she completed a Robert Wood Johnson Clinical Scholar Fellowship at UCLA. Upon completion of this fellowship, Dr. Narain stayed on at UCLA as a Specialty Training Advanced Research Fellow in the Department of General Internal Medicine & Health Services Research and earned a Ph.D. in Health Services from the UCLA Fielding School of Public Health. Prior to joining the UCLA faculty, Dr. Narain was a post-doctoral fellow in the West Los Angeles VA Center for the Study of Healthcare Innovation, Implementation & Policy.

Anand Parekh, M.D., M.P.H., Bipartisan Policy Center (BPC)
Chief Medical Advisor



Dr. Anand Parekh is Chief Medical Advisor at the Bipartisan Policy Center (BPC) where he provides clinical and public health expertise across the organization. Prior to joining BPC, he completed a decade of service at the U.S. Department of Health and Human Services (HHS). As a HHS Deputy Assistant Secretary for Health from 2008 to 2015, he developed and implemented national initiatives focused on prevention, wellness, and care management. Briefly in 2007, he was delegated the authorities of the HHS Assistant Secretary for Health overseeing ten health program offices and the U.S. Public Health Service Commissioned Corps. Parekh is a board-certified internal medicine physician, a fellow of the American College of Physicians, an adjunct professor of health management and policy at the University of Michigan School of Public Health, and an adjunct associate professor of

medicine at Johns Hopkins University. He is the incoming chair of the Roundtable on Obesity Solutions at the National Academies of Sciences, Engineering and Medicine, where he previously served as a member of its Board on Population Health and Public Health Practice. His book *Prevention First: Policymaking for a Healthier America* (second edition) was released in October 2024 and argues that prevention must be our nation's top health policy priority.

Asheley Skinner, Ph.D., Duke University School of Medicine
Professor in Population Health Sciences



Asheley Cockrell Skinner, PhD, is a health services researcher and Professor of Population Health Sciences at Duke University. Her work focuses on improving population health, with an emphasis on addressing childhood obesity through data-driven, evidence-based strategies. A recognized expert in pediatric obesity, she contributed to the American Academy of Pediatrics Clinical Practice Guidelines for its treatment, shaping national standards for care. Dr. Skinner's research integrates innovative methods to address health disparities, particularly among vulnerable populations, and her extensive publication record reflects her commitment to advancing implementation science. She also serves as Vice Chair for Education in Population Health Sciences at Duke, where she leads graduate education initiatives, mentors students and faculty, and fosters interdisciplinary collaboration.

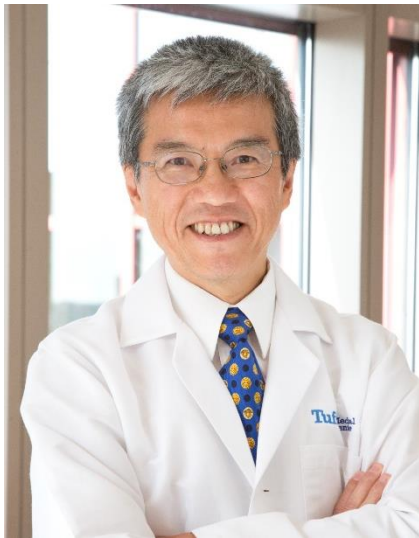
Christina Wee, M.D., M.P.H., *Annals of Internal Medicine*
Senior Deputy Editor



Christina C. Wee, MD, MPH, FACP, FTOS is Senior Deputy Editor at *Annals of Internal Medicine* and Vice President of the *Annals* Division of the American College of Physicians. She also serves as Secretary for the International Committee of Medical Journal Editors (ICMJE) and helps lead ACP's Advancing Equitable Obesity Care Initiative. Prior to joining *Annals* in 2019, Dr. Wee was a clinician-investigator and Associate Section Chief for Research in the Division of General Medicine at Beth Israel Deaconess Medical Center. She was also Associate Professor of Medicine at Harvard Medical School (where she maintains a faculty appointment) and Co-Program Director of the Harvard-wide General Medicine Research Fellowship Program. A nationally recognized researcher and mentor, Dr. Wee has been funded by numerous foundation and NIH R01 grants to study the interplay of race, obesity, weight

stigma, healthcare of persons with obesity, and patient preferences on weight treatment and health outcomes. She was among the first to identify persons with obesity as a disenfranchised group within the healthcare system and to bring this issue to national attention. She published a seminal paper in *Annals of Internal Medicine* in 2000 demonstrating that women with obesity were less likely to receive cancer screening than thinner women despite their higher risk. She subsequently published a series of high-profile studies in *JAMA* suggesting that clinicians nationally were not addressing obesity with their patients despite its epidemic rise. Dr. Wee's research also demonstrated that health disparities and healthcare cost associated with obesity varied by race and ethnicity and that many primary care patients with obesity placed greater value on achieving substantial weight loss than achieving "perfect health." An outstanding investigator and mentor known for her methodologic rigor, Dr. Wee was inducted into the American Society for Clinical Investigation in 2012 and is the recipient of several regional and national awards, including a NIH K24 Mentorship Award and the 2011 Midcareer Research and Mentorship Award from the Society of General Internal Medicine.

John B. Wong, M.D., Tufts Medical Center
Vice Chair for Academic Affairs and Chief, Division of Clinical Decision Making



Dr Wong received his B.S. in biology with honors from Haverford College and his M.D. from University of Chicago. He completed an internal medicine residency, medical informatics fellowship, and medical chief residency at Tufts Medical Center. He is currently vice chair for Academic Affairs, chief of the Division of Clinical Decision Making, and primary care internist at Tufts Medical Center, and a vice chair for the US Preventive Services Task Force. Dr. Wong's research focuses on the application of decision analysis to help patients, health professionals, and policymakers make informed decisions when choosing among alternative tests, treatments, or health policies, thereby promoting rational evidence-based efficient and effective patient-centered care. His research includes decision analysis, technology assessment, guideline development, appropriate use criteria, evidence synthesis, and shared decision making.

Davene Wright, Ph.D., Harvard Pilgrim Health Care Institute
Associate Professor, Department of Population Medicine



Davene R. Wright, PhD is an Associate Professor in the Department of Population Medicine, a partnership between the Harvard Pilgrim Health Care Institute and Harvard Medical School. At Harvard, she serves as the Associate Director of the Division of Child Health Research and Policy and is core faculty in the Harvard PhD Program in Health Policy, the Harvard-Wide Pediatric Health Services Research Fellowship, and the Harvard T.H. Chan School of Public Health Center for Health Decision Sciences. Dr. Wright is a decision scientist with experience in health policy, health services research, health economics and outcomes research (economic evaluation and simulation modeling), and preference elicitation (discrete choice experiments and best-worst scaling). Her research focuses on designing and promoting evidence-based policies and scalable care strategies to improve the management of chronic diseases like obesity and diabetes, particularly for pediatric populations.