RAISE Community Workshop Series Workshop 7
April 6, 2023

Speakers

Michele Jonsson-Funk, PhD
Associate Professor, Department of Epidemiology
Director, Center of Pharmacoepidemiology
UNC Gillings School of Global Public Health

Dr. Jonsson-Funk's research takes place at the intersection of pharmacoepidemiology, methods for estimating valid treatment effects in observational data, and women's health research. Her ongoing research studies use data from Medicare, IBM Watson Health Analytics' Marketscan data, and the Carolina Data Warehouse for Health (CDW-H) – an electronic medical record warehouse that brings together rich clinical and administrative data on over 2 million patients seen across the spectrum of care by providers in the UNC Health Care System. More recently, she has led efforts at UNC to link complementary data (e.g. Medicare claims with the UNC CDW-H).

Her methods research has assessed the performance of propensity scores and doubly robust estimators. In her current R01, she is evaluating alternative methods for identifying treatment effect heterogeneity – specifically sex differences in the safety and effectiveness of cardioprotective medications. Dr. Jonsson-Funk has contributed to research on reducing measurement error in studies using claims data, methods for generalizing treatment effects from clinical trials to real world populations and improving control of confounding by frailty. In collaboration with clinical colleagues and graduate students in epidemiology, she has addressed a range of important topics related to women's health including treatment of pelvic floor disorders, effects of medication use during pregnancy, health outcomes after sterilization, and effects of diabetes medications on breast and endometrial cancer risk.

Kamaria Kaalund
Policy Analyst for Health Equity
Duke-Margolis Health Policy Center

Kamaria Kaalund is the Policy Analyst for Health Equity at Duke-Margolis. In this role, Kamaria supports health equity research projects, policy analysis, and educational initiatives. Her research interests include community-focused health policy approaches to reduce health inequities and the intersections between neuroscience, environmental health, and policy.

She is a 2020 graduate of Wellesley College where she earned a bachelor's degree in Neuroscience and Anthropology. During her time at Wellesley, she

worked with the: Early Childhood Cognition Lab at MIT on an online child development research platform; at the Computational Cognitive Development Lab at Rutgers University as a summer intern; and then within Wellesley's Centers for Women National SEED Project to support its goals of creating conversational communities that drive personal, organizational, and societal change toward greater equity and diversity.

Aaron Kamauu, MD, MS, MPH
Managing Director
Ikaika Health LLC

Dr. Kamauu (MD, MS Biomedical Informatics, MPH, University of Utah School of Medicine) is an industry-leading advisor in the Real-World Data (RWD) space, specifically focusing on leveraging real-world healthcare data to support a variety of clinical research, informatics, clinical trials, drug development, and market access activities. Aaron's experience spans the drug development and value access spectrum as well as big Pharma, biotech, big CRO and entrepreneurship in the space.

Dr. Kamauu is a member of leading medical societies where he has presented innovative research in clinical research informatics, public health informatics, and radiology/imaging informatics. Dr. Kamauu brings a unique combination of clinical, biomedical informatics, drug development, and public health training and experience, resulting in the application of innovative biomedical informatics methodologies to support projects based on individual patient care as well as population-based observations.

Anne-Marie Meyer, PhD
Adjunct Associate Professor at the Department of Epidemiology
University of North Carolina Gillings School of Public Health

Dr. Meyer is an Adjunct Associate Professor at the University of North Carolina at Chapel Hill in the Department of Epidemiology. She has over 20 years' experience combining epidemiology and health informatics to tackle important problems in public health, health policy, cancer outcomes and personalized healthcare. Dr. Meyer has engaged in many interdisciplinary collaborations to measure disparities in care, untangle the multi-factorial influences that impact patients, and design interventions to improve outcomes for patients. She has spent time in both academia and industry as a Director of Real-World Evidence at Quintiles and Sr. Principal Data Scientist at Roche Personalized Health Care. Dr. Meyer has a passion for innovating large, real-world data (RWD), and observational data for health research. As a faculty member at UNC Chapel Hill, she led the development of a data platform at the Lineberger Cancer Center, which includes over 6 million patients and linkages between the cancer registry, multiple payers, epidemiologic cohorts, medical records, census, and other ecological data sources. Her work focuses

on developing novel methods for organizing, managing, and using RWD to make the data more systematic and accessible for all stakeholders.

Andrea Thoumi, MPP, MSc
Faculty Director, Health Equity Education
Duke-Margolis Health Policy Center

Andrea Thoumi, MPP, MSc, is the Health Equity Policy Fellow, Core Faculty Member, and Faculty Director, Health Equity Education at Duke-Margolis. In this capacity, she advances the Center's aim to enhance policy analysis, research, and education in health equity. Andrea combines expertise in health policy, health financing, health equity, and community health. Her research interests include mitigating systemic inequities that Latinx communities experience through health policies. She is also an instructor on Bass Connections courses and a research collaborator with LATIN-19, RADx-UP, and Women-Inspired Strategies for Healthcare. She previously served as Research Director, Global Health at Duke-Margolis. She is the recipient of Academy Health's Disparities Interest Group Early-Stage Distinguished Investigator Award (2021) for her leadership, mentorship, and research and recipient of the Duke Presidential Award (2020) for exceptional service to the Duke community as a LATIN-19 team member.

Previously, she oversaw Duke-Margolis's global health portfolio spanning value-based care, universal health coverage, primary health care, reproductive health, and innovations to increase access to health services. Prior to joining Duke-Margolis, she was a Research Associate at the Brookings Institution and Senior Analyst at PwC. She has consulted for the Institute for Healthcare Improvement, Pan American Health Organization/World Health Organization, and the World Bank. She is published in American Journal of Managed Care, Annals of Global Health, BMJ Global Health, Brookings Future Development, Health Affairs, Health Research Policy and Systems, Journal of Oncology Practice, and Vaccine. She holds a master's degree in Health Policy, Planning, and Financing from the London School of Economics and London School of Hygiene and Tropical Medicine, a master's degree in Public Policy from the McCourt School of Public Policy, Georgetown University, and a bachelor's degree in Community Health and International Relations from Tufts University.

RAISE FDA & FDA Foundation Team

RDML Richardae Araojo, PharmD, MS
Associate Commissioner for Minority Health, Director
Office of Minority Health and Health Equity, U.S. Food and Drug Administration

Rear Admiral Richardae Araojo, PharmD, MS, serves as the Associate Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity at the U.S. Food and Drug Administration (FDA). In this role, RDML Araojo provides leadership, oversight, and direction on minority health and health disparity matters for the Agency. RDML Araojo previously served as the Director of the Office of Medical Policy Initiatives in FDA's Center for Drug Evaluation and Research (CDER), where she led a variety of broad-based medical and clinical policy initiatives to improve the science and efficiency of clinical trials and enhance professional and patient labeling. RDML Araojo joined FDA in 2003, where she held several positions in CDER. RDML Araojo received her doctoral degree in Pharmacy from Virginia Commonwealth University, completed a Pharmacy Practice Residency at University of Maryland, and earned a master's degree in Pharmacy Regulation and Policy from the University of Florida.

Carla Rodriguez-Watson, PhD, MPH
Director of Research
Reagan-Udall Foundation for the FDA

Carla Rodriguez-Watson, PhD, MPH, is the Director of Research for the Reagan-Udall Foundation for the FDA. Dr Rodriguez-Watson is focused on continuously developing and enhancing a portfolio of work that leverages real-world data and experiences to inform and conduct clinical and post-market drug safety and effectiveness studies. Projects include those focused on developing and advancing frameworks and tools to systematically describe data sources and methods for use in pre and post-market studies of product safety and effectiveness; as well as the the Innovation in Medical Evidence, Development and Surveillance (IMEDS) Program – where such tools can be leveraged. IMEDS leverages a distributed network and tools developed by the FDA's Sentinel initiative to design and execute post-market drug safety studies in a network of 9 healthcare systems representing over 111 M persons. Dr. Rodriguez-Watson brings her extensive background in public health surveillannce and health outcomes research to this work. She earned her doctoral degree in Epidemiology from the University of Washington School of Public Health, her master's degree in Public Health from Columbia University Mailman School of Public Health, and her bachelor's degree from Rutgers University.

Susan C. Winckler, RPh, Esq.
CEO

Reagan-Udall Foundation for the FDA

Susan C. Winckler, RPh, Esq., is CEO of the Reagan-Udall Foundation for the FDA, the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post, she served as President of Leavitt Partners Solutions, a healthcare strategy firm founded by Gov. Michael O. Leavitt, former Secretary of the U.S. Department of Health and Human Services. Winckler directly advised C-suite executives of a wide range of organizations on public policy and regulation, business strategy, investments, and other major business matters.

As Chief of Staff for the U.S. Food and Drug Administration (2007-2009), she managed the Commissioner's Office, served both Republican and Democratic commissioners as their senior-most staff adviser, analyzed complex policy challenges and represented FDA with myriad government entities and external stakeholders. Her earlier career service included more than a decade at the American Pharmacists Association in a series of positions of increasing responsibility.