RAISE Community Workshop Series Workshop 11
June 15, 2023

Speakers

Louis Cabanilla, MSc
Director of Corporate Data and Analytics
Point32 Health

Louis Cabanilla has a healthcare analytics career that spans payor, provider, pharma, and policy. Over the past six years with Point32Health, Louis designed and implemented analytic solutions to drive Population Health and Health Equity initiatives. Through collaboration with academic collaborations at the Harvard Pilgrim Health Care Institute the Enterprise Segmentation and Stratification tool was developed to identify unmet needs in populations, to create algorithms to match members to interventions, to drive processes to measure program effectiveness, and to build predictive models. Most recently, Louis led the development of a composite Social Inequality Index for all Point32Health members leveraging geospatial analytics which has enabled the company to pinpoint actions for their Health Equity initiatives. Louis is passionate about analytics and how it can be leveraged to unlock equity in healthcare. He has a special interest in addressing health literacy in marginalized communities to improve preventative care. Louis received an MSc in Health Economics from Erasmus University (Rotterdam, The Netherlands), and a bachelor's degree in Economics from the University of Colorado at Boulder.

Alecia Clary, PhD, MSW
Founder and CEO, Evidence to Practice
Co-Investigator, RAISE

Dr. Alecia Clary is the founder and CEO of Evidence to Practice, a consulting and advisory services firm that provides clients expert research, policy, and operations support to accelerate the adoption of health care innovations. She also serves as a co-investigator on the RAISE project and leading the development of the RAISE roadmap and the RAISE program evaluation. She is a health services researcher and implementation scientist by trade. Prior to founding Evidence to Practice, Dr. Clary served as the Associate Director of Research for the Reagan-Udall Foundation for the FDA. She held previous roles as a research scientist at Avalere Health, where she designed and conducted studies focused on using real-world evidence to evaluate and improve healthcare quality, and as both a research analyst and health science specialist at the Durham VAMC. Dr. Clary earned a doctoral degree from the Gillings School of Global Public Health at UNC Chapel Hill, a master's degree from the UNC School of Social Work, and a bachelor's degree in Sociology from UNC Chapel Hill.

Rachele Hendricks-Sturrup, DHSc, MSc, MA
Research Director of Real-World Evidence (RWE)
Duke-Margolis Center for Health Policy

Dr. Rachele Hendricks-Sturrup is the Research Director of Real-World Evidence (RWE) at the Duke-Margolis Center for Health Policy in Washington, DC, strategically leading and managing the Center's RWE Collaborative. As an engagement expert, researcher, bioethicist, and policy practitioner, her work centers on addressing implementation and ethical, legal, and social implications issues at the intersection of health policy and innovation. She also partners with Duke University faculty, scholars, students, and external health experts to advance the Center's biomedical innovation work. She is presently adjunct faculty at rural Ohio University, teaching graduate courses in the Department of Interdisciplinary Health Science's Health Policy Certificate program, and has taught graduate courses within the Masters of Health Care Innovation program at the University of Pennsylvania's Perelman School of Medicine. Prior to joining Duke-Margolis, Dr. Hendricks-Sturrup was Health Policy Counsel and Lead at the Future of Privacy Forum (FPF), leading the organization's health and genetic data initiatives and workgroup. Prior to FPF, she served in several administrative and scientific roles at various industry, health care, and academic institutions. To date, she has published several commentaries and original research papers in high-quality, peer-reviewed journals. Dr. Hendricks-Sturrup is also an accomplished health and science journalist, having completed a comparative effectiveness research fellowship with the Association of Health Care Journalists in 2017. Dr. Hendricks-Sturrup received her bachelor's degree in Biology from Chicago State University, her master's degree in Pharmacology and Toxicology from Michigan State University, her master's in Legal Studies from the University of Illinois, and her doctoral degree in Health Science from Nova Southeastern University. She completed a predoctoral internship with the National Health Service in London, UK, and postdoctoral research training within the Department of Population Medicine at Harvard Pilgrim Health Care Institute and Harvard Medical School.

Allen Hsiao MD, FAAP, FAMIA
Professor of Pediatrics (Emergency Medicine) and Chief Health Information Officer
Yale School of Medicine & Yale New Haven Health

Dr. Allen Hsiao is Professor of Pediatrics and of Emergency Medicine at the Yale School of Medicine and serves as the Chief Health Information Officer (CHIO) for the Yale School of Medicine and Yale New Haven Health System. He received his BA in Biomedical Ethics and MD from Brown University, then completed residency training in Pediatrics at Yale before completing fellowships and board certifications in Pediatric Emergency Medicine and Medical Informatics. He has served on numerous medical informatics-related committees for the Hospital and University, as well as nationally for groups such as the American Academy of Pediatrics, Health Information Management Systems Society, and the National Association of

Children's Hospitals and Related Institutions. As the CHIO, Dr. Hsiao leads the medical informatics and data and analytics teams for the School and System, including an experienced group of physician informaticians and the Joint Data and Analytics Team (JDAT). He and the informaticians are responsible for medical leadership of the electronic health record system (EHR) and supporting information technology systems to provide the functionality, clinical decision support, and innovation needed to deliver the best healthcare possible. His Joint Data and Analytics Team includes the database administrators, data architects, and a team of over 50 analysts that provide the reporting and analytics for the System and the School, supporting operational, clinical, and research reporting and data needs and is led by a talented Chief Data & Analytics Officer. Current priorities for Allen and team include supporting COVID-19 informatics needs, predictive analytics, strategies to address growing physician burnout, patient engagement, population health, and supporting genomic medicine.

Lenel James, MBA
FHL7, Business Lead – Health Information Exchange & Innovation
Market Solutions, Blue Cross Blue Shield Association

Lenel James is the Business Lead for Health Information Exchange and Innovation at the Blue Cross and Blue Shield Association (BCBSA), in the Health Information Technology department. He has been with the Association for 20 years and has been the Health Level Seven (HL7) voting representative for 19 years. At BCBSA, Mr. James has been engaged with various initiatives and roles. He was the planning and execution lead for the BCBSA HIPAA Conference He has held various leadership, management and senior analyst positions which have built upon experience with Health IT standards, information technology & strategy consulting, project management, business development/marketing, training, healthcare, and systems implementations. Mr. James has led a wide variety of payer/provider/vendor-focused projects toward successful productive outcomes that advanced health data interoperability through pilots and standards development. As part of his more than 35 years of experience in clinical information systems and information technology strategic planning, Mr. James also spent five years as the acting director of Clinical Systems for the IT Department of the third largest public hospital in the United States—giving him both a health system and payer perspective on the challenges of the health care industry. James was a member of the Executive Committee of the Great Lakes Regional Health Equity Council (RHEC). The RHEC was part of an HHS (Health and Human Services) Office of Minority Health initiative, the National Program for Action to End Healthcare Disparities, where Lenel co-chaired the Social Determinates of Health Committee. He also co-founded and co-chaired the Cross-RHEC Community Health Worker Coalition—representing four regions across over 25 states.

Bradley Malin, PhD
Accenture Professor of Biomedical Informatics, Biostatistics, and Computer Science
Vice Chair for Research Affairs Department of Biomedical Informatics
Affiliated Faculty, Center for Biomedical Ethics & Society
Vanderbilt University Medical Center

Dr. Bradley Malin is the Accenture Professor of Biomedical Informatics, Biostatistics, and Computer Science, as well as Vice Chair for Research Affairs in the Department of Biomedical Informatics. His research is funded through grants from the National Science Foundation (NSF), National Institutes of Health (NIH), and Patient Centered Outcomes Research Institute (PCORI). His research is on the development of technologies to enable artificial intelligence and machine learning (AI/ML) in the context of organizational, political, and health information architectures. He has made specific contributions in several areas, including distributed data processing methods for medical record linkage and predictive modeling, intelligent auditing technologies to protect electronic medical records from misuse in the context of primary care, and algorithms to formally anonymize patient information disseminated for secondary research purposes. His investigations on the empirical risks to health information re-identification have been cited by the Federal Trade Commission in the Federal Register and certain privacy enhancing technologies he developed have been featured in popular media outlets and blogs, including Nature News, Scientific American, and Wired magazine. Dr. Malin completed his education at Carnegie Mellon University, where he received a bachelor's in biological sciences, a master's in machine learning, a master's in public policy and management, and a doctorate in computer science (with a focus on databases and software systems).

Krystal Tsosie, PhD, MPH, MA
Indigenous Geneticist-Bioethicist
Assistant Professor
School of Life Sciences, Arizona State University

Dr. Krystal Tsosie (Diné/Navajo Nation) is an Indigenous geneticist-bioethicist and Assistant Professor in the School of Life Sciences at Arizona State University. As an advocate for Indigenous genomic data sovereignty, she co-founded the first US Indigenous-led biobank, a 501c3 nonprofit research institution called the Native BioData Consortium. Her research can be encapsulated in two main foci: Indigenous population genetics and bioethics. In particular, she focuses on bioethical engagement of Indigenous communities in genomics and data science to build trust. As a whole, her interest is in integrating genomic and data approaches to assess Indigenous variation contributing to health inequities. She began her research career at the laboratory bench, where she developed and patented a combined targeted ultrasound imaging and chemotherapeutic drug delivery device for treating early metastases in cancer. Upon seeing the disparities in emerging genomics technologies, she switched fields to genetic epidemiology, public health, and bioethics. Her first master's degree in Bioethics at Arizona State University focused on the cultural implications of

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REAL-WORLD ACCELERATOR TO IMPROVE THE STANDARD OF COLLECTION
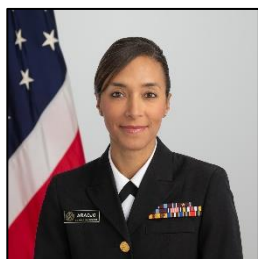AND CURATION OF RACE AND ETHNICITY DATA IN HEALTHCARE

genetics in Native American communities. She added biostatistical knowledge and computational programming in large genomics datasets earning her second master's degree in Public Health (genetic epidemiology) at Vanderbilt University, where she studied disparities in uterine fibroids in African American women. She has co-led an ongoing longitudinal genetics study in a North Dakota Tribal community. This project serves as one of few examples of community-based participatory research involving genetics in an Indigenous tribal nation. Her research and educational endeavors have received increasing national and international media attention as scientists worldwide are understanding the importance of equitable, community-based engagement models and the importance of Indigenous genomic data sovereignty. Her work has been covered by popular media outlets including PBS NOVA, The Washington Post, NPR, New York Times, The Atlantic, Forbes, and Boston Globe. She currently serves on the Government Policy and Advocacy Committee for the American Society of Human Genetics and the National Academy of Medicine Announces Committee on Emerging Science, Technology, and Innovation. She is a current Global Chair in ENRICH (Equity for Indigenous Research and Innovation Coordinating Hub), which focuses on enhancing Indigenous rights to develop, control, and govern Indigenous data and supports participation in STEM and in digitally-enabled futures.

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

Dr. Carla Rodriguez-Watson 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 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.