

February 16-17, 2016

Kingsgate Marriott Conference Center at the University of Cincinnati, Cincinnati, Ohio

Patient-Centered Outcomes Research and Comparative Effectiveness Workshop

A 2-day workshop for researchers

The workshop is structured into didactic sessions focusing on methods, and breakout groups during which participants will be asked to present research ideas they are working on to get feedback from course faculty and participants.

Study design

- Adaptive Bayesian Trial Design
- Pragmatic Clinical Trials
- Observational, Quasi-Experimental Study Designs and Stepped Wedge Designs

Data analysis

- Overview of PCORI Methodology Report
- Heterogeneity of Treatment Effects
- Propensity Scores
- Instrumental Variables

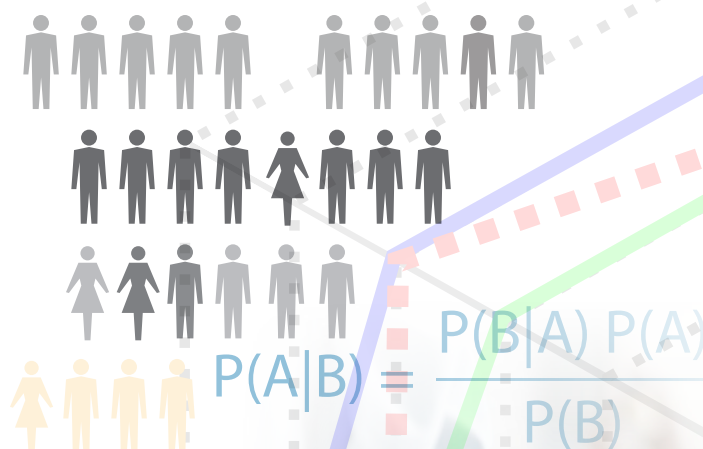
Patient engagement

- Shared Decision-Making
- Tools for Engaging Patients in Research

“Tales From The Trenches”

Speakers will be those who have successfully obtained funding in PCOR/CER discussing what was critical to their success, what they learned from prior unsuccessful attempts, and other insights they feel would be helpful for getting CER/PCOR research funded.

Small group breakout sessions



WORKSHOP ORGANIZERS:

University of Cincinnati • Cincinnati Children's Hospital Medical Center • University of Iowa

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February 16, 2016

Data Analysis & Reporting Standards

Time	Event	Lecturer	Room
8:00-8:30am	Continental Breakfast		Amphitheater 1
8:30-9:00am	Introductions & Overview	Mark H. Eckman, MD Christopher J. Lindsell, PhD	Amphitheater 1
Methods for Alternate Study Designs:			
9:10-9:50am	Adaptive & Bayesian Trial Design	Christopher S. Coffey, PhD	Amphitheater 1
9:50-10:00am	Break		
10:00-10:40am	Pragmatic Clinical Trials	Gary Rosenthal, MD	Amphitheater 1
10:40-10:50am	Break		
10:50-11:40am	Observational, Quasi-Experimental Study Designs, Stepped Wedge Designs	Elizabeth (Betsy) Chrischilles, PhD	Amphitheater 1
11:40-1:00pm	Lunch		Caminetto Restaurant
Data Analysis:			
1:00-1:15pm	Overview from PCORI Methodology Report	Lilliam Ambroggio, PhD Maurizio Macaluso, MD, DrPH Rhonda Szczesniak, PhD, MS	Amphitheater 1
1:15-1:45pm	Propensity Scores	Mary Sarrazin, PhD	Amphitheater 1
1:45-1:55pm	Break		
1:55-2:25pm	Heterogeneity of Treatment Effects	Bin Huang, PhD	Amphitheater 1
2:25-2:35pm	Break		
2:35-3:05pm	Instrumental Variables	Rhonda Szczesniak, PhD, MS	Amphitheater 1
Breakout Sessions - Specific Aims and Research Questions:			
3:15-4:15pm	Breakout Sessions		Breakout rooms: Amphitheater 1 Mount Lookout Mount Echo
4:15-4:30pm	Break		
4:30-5:30pm	Breakout Sessions		*Rooms listed above
5:30-6:00pm	Break		
6:00-8:00pm	Dinner		Mount Auburn Room

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Time	Event	Lecturer	Room
7:30-7:45am	Continental Breakfast		Amphitheater 1
7:45-8:00am	Introductions & Overview	Mark H. Eckman, MD Christopher J. Lindsell, PhD	Amphitheater 1
Tales From the Trenches:			
8:00-8:30am	Hospital to Home Outcomes (H ₂ O) Study	Jeffrey (Jeff) M. Simmons, MD, MSc	Amphitheater 1
8:30-9:00am	The MOBILITY Study: A Journey into Patient-Centered and Patient -Reported Research	Melissa DelBello, MD, MS	Amphitheater 1
9:00-9:30am	Developing a Competitive PCORI Proposal to Evaluate Post-Trauma Interventions for Injured Children	Marizen Ramirez, PhD	Amphitheater 1
9:30-9:40am	Break		
Patient Engagement:			
9:40-10:20am	Shared Decision Making	Mark H. Eckman, MD Lori E. Crosby, PsyD	Amphitheater 1
10:20-11:00am	Tools for Engaging Patients in Research	Donna S. Martsolf, PhD, RN, CNS, FAAN	Amphitheater 1
11:00-12:30pm	Lunch		Caminetto Restaurant
Breakout Sessions:			
12:30-1:35pm	Breakout Sessions <u>Topic Areas:</u> Study Design Data Analysis Patient Engagement	Seong-Yi Baik, PhD, RN Lilliam Ambroggio, PhD Christopher S. Coffey, PhD Christopher J. Lindsell, PhD Maurizio Macaluso, MD, DrPH Gary Rosenthal, MD Rhonda Szczesniak, PhD, MS Joel Tsevat, MD, MPH Melissa DelBello, MD, MS Marizen Ramirez, PhD Donna S. Martsolf, PhD, RN, CNS, FAAN Karen Bankston, RN, PhD	Breakout rooms: Amphitheater 1 Breakout room 113 Breakout room 115 Breakout room 117 Breakout room 119
1:35-1:45pm	Break		
1:45-2:50pm	Breakout Sessions	*Lecturers listed above	* Rooms listed above
2:50-3:00pm	Wrap Up and Goodbyes	Mark H. Eckman, MD Christopher J. Lindsell, PhD	Amphitheater 1

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UC Health

Workshop Lecturers:

Lilliam Ambroggio, PhD, has a long-term research goal to improve outcomes for children with common, serious infections by developing methods to improve diagnostic accuracy and implementing these methods into clinical practice. Her previous work has focused on observational, comparative effectiveness and quality improvement studies investigating antibiotic resistance, empiric antibiotic choice, and imaging modality in the management of pneumonia in children. She is an Assistant Professor in the Divisions of Hospital Medicine and Biostatistics and Epidemiology at Cincinnati Children's Hospital Medical Center.

Seong-Yi Baik, PhD, RN, is an Associate Professor, tenured in the UC College of Nursing. Dr. Baik, with her multidisciplinary team, has been involved in health services and patient outcomes research in depression care and depression comorbidities. Building upon her NIH funded research on depression care in primary care, her recent RCT research is to investigate the effect of depression comorbidities on patient outcomes. The long-term goal of her research focuses on designing and implementing quality interventions for depression care in primary care settings, while empowering the patients with depression comorbidities.

Elizabeth (Betsy) Chrischilles, PhD, leads the Research Expertise and Methods component and co-directs Biostatistics, Epidemiology and Research Design in the University of Iowa Institute for Clinical and Translational Science where she is responsible for comparative effectiveness and medical product safety research leadership. Betsy's research involves evaluating the pharmacoepidemiology and comparative effectiveness of medical products and care management systems. Betsy is an investigator in the PCORNet Greater Plains Collaborative Clinical Data Research Network, developing and validating electronic algorithms and phenotypes exposures, covariates and outcomes using the network's i2b2 warehouse.

Christopher S. Coffey, PhD, is a Professor of Biostatistics and Director of Clinical Trials Statistical and Data Management Center in the University of Iowa College of Public Health. He is the principal investigator of the Data Coordinating Center for Network of

Excellence in Neuroscience Clinical Trials); the Data Coordinating Center for the Childhood and Adolescent Migraine Prevention study; and the Statistics Core for the Parkinson's Progression Markers Initiative. Chris is a Fellow of the Society for Clinical Trials, currently sits on the Board of Directors for the SCT, and serves on data and safety monitoring boards.

Lori Crosby, PsyD is a Professor in the Division of Behavioral Medicine and Clinical Psychology, Co-Director of Innovations in Community Research, and faculty for the Adherence Center & Center for Innovation in Chronic Disease Care at Cincinnati Children's Hospital Medical Center. She has a passion for and expertise in community and patient engagement and is the Principal Investigator for a project funded by the AHRQ Center for Education, Research and Therapeutics Center to develop and implement an intervention to facilitate shared decision-making in pediatric sickle cell disease.

Melissa DelBello, MD, MS is a Professor of Psychiatry and Pediatrics and Dr. Stanley and Mickey Kaplan Chair of Psychiatry and Behavioral Neurosciences at the University of Cincinnati College of Medicine (UCCOM). Dr. DelBello received her medical degree from the University of Rochester, completed residencies at the UCCOM and Payne Whitney Psychiatric Clinic of the New York Hospital-Cornell Medical Center, and completed a fellowship in Child and Adolescent Psychiatry at Cincinnati Children's Hospital Medical Center. She also obtained a master's degree in Epidemiology and Biostatistics from UCCOM. Dr. DelBello has co-authored over 250 articles, and has served as principal or co-investigator of NIH, PCORI, foundation, and pharmaceutical research grants.

Mark Eckman, MD, has followed his passion as a general internist and a decision scientist, first as a member of the Division of Clinical Decision Making at the New England Medical Center (1984-1999) and more recently as Director of the Division of General Internal Medicine and the Center for Clinical Effectiveness at the University of Cincinnati Medical Center. As a researcher and clinician, this environment has supported his interests in applying a variety of methodological approaches in real world clinical settings.

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Bin Huang, PhD is a Professor of Biostatistics at Cincinnati Children's Hospital Medical Center, with 16 years of experiences in the design and analyses of pediatric research studies in disciplines such as adolescent medicine, rheumatology, health disparity, sports medicine, and preventive medicine. His method interest is in statistics causal inference. Currently, he is leading a PCORI funded method development addressing the needs for robust, efficient and general causal inference method that can be used in evaluating routine clinical treatment strategies that involves time-varying adaptive treatment, using EHR and PCORnet data.

Christopher J. Lindsell, PhD, joined the University of Cincinnati in 2001, since then he has focused on clinical research in the acute care setting. He has published over 220 papers covering topics including health systems and services, stroke epidemiology, risk stratification in sepsis, biomarkers in diabetes, and best practices for building clinical research in academic health centers. He is currently Professor and Vice Chair for Research in Emergency Medicine, Associate Dean for Clinical Research in the University of Cincinnati College of Medicine and VP of Research for UC Health.

Maurizio Macaluso, MD, DrPH, is Director of the Division of Biostatistics and Epidemiology, Cincinnati Children's Hospital Medical Center, and of the Biostatistics, Epidemiology and Research Design Core of the Center for Clinical and Translational Science and Training. He has 35 years of experience in epidemiologic research methods; surveillance systems; cancer epidemiology; occupational epidemiology; sexual and reproductive health. He has led numerous research projects sponsored by the federal government and nongovernmental organizations and has held leadership positions in academia and at the CDC. He has extensive teaching experience and has mentored graduate students, post-doctoral fellows and junior faculty.

Donna S. Martsof, PhD, RN, CNS, FAAN, is Professor and Associate Dean for Research and Translation at the University of Cincinnati College of Nursing. She received undergraduate and advanced-practice psychiatric nursing degrees from the University of Michigan and the University of Pennsylvania, and a PhD from the University of Pittsburgh. Her research focuses on interpersonal violence (teen dating violence, sexual violence, childhood maltreatment) across the lifespan.

She has been funded by the National Institutes of Health and the Centers for Disease Control and is a Fulbright Scholar and a Fellow of the American Academy of Nursing.

Marizen Ramirez, PhD, is an Associate Professor of Occupational and Environmental Health in the University of Iowa College of Public Health. In 2014 she was awarded \$1.7 million by the PCORI for a study entitled "Evaluation of Parent-Based Interventions to Support Children after Traumatic Injury". The study compares two parent-based approaches to help injured children recover emotionally and socially. Researchers will identify 300 children ages 10-17 admitted to the University of Iowa Children's Hospital or Blank Children's Hospital in Des Moines because of injury.

Gary Rosenthal, MD, is Director of the University of Iowa Institute for Clinical and Translational Science. His research centers around three related themes: interdisciplinary interventions to implement evidence-based practices; identification of variations in healthcare delivery and gaps in quality; and development of novel approaches for measuring comorbidity and severity of illness. Gary is PI of a large CMS award to improve transitional care of rural Iowans and as site PI of a PCORnet award to build capacity for conducting pragmatic trials.

Mary Sarrazin, PhD, is an investigator and research scientist in Internal Medicine, at the University of Iowa. Mary is an expert in the management and analysis of large health care databases and is experienced in research project administration. She has coordinated several studies involving secondary analyses of large clinical and administrative databases with Dr. Rosenthal and other investigators. Mary is interested in gender differences in health service utilization and in quantifying the magnitude of risk in VA populations that are not captured in current healthcare databases.

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UCC Health.

Jeffrey M. Simmons, MD, MSc, Associate Division Director for Quality, Division of Pediatric Hospital Medicine and Associate Safety Officer, James Anderson Center for Quality and Transformation, has practiced as a pediatric hospitalist for 11 years. During the past decade of transformation at Cincinnati Children's Hospital Medical Center, Dr. Simmons has been a frontline leader for many key transformations including family-centered rounds, rapid adoption of evidence-based practice, population health for children with asthma, and improved inpatient patient safety through improved situation awareness.

Rhonda Szczesniak, PhD, MS is an Associate Professor at Cincinnati Children's Hospital Medical Center in the Division of Biostatistics & Epidemiology (DBE); she holds a joint appointment in Department of Pediatrics at the University of Cincinnati. Her statistical research areas are causal inference and functional data analysis methods for large-scale data with epidemiologic applications to chronic diseases and disorders. Her current applications emphasize computational statistics methods for real-time medical monitoring of patients with cystic fibrosis lung disease. She has successfully collaborated on and initiated over 20 extramurally funded research projects.

Joel Tsevat, MD, MPH is a general internist and University of Cincinnati Professor of Medicine; Associate Dean for Clinical and Translational Research; Co-Director, Center for Clinical and Translational Science and Training; Chair, VISN 10 Research Sub-Council for VISN 10; and Director, Cincinnati VAMC R&D Committee. A past-president of the Society for Medical Decision Making, Dr. Tsevat's expertise is in health-related quality of life, in particular health status vs. utility assessment; HIV/AIDS outcomes research; spirituality/religion; cost-effectiveness analysis; and decision analysis. He has served on the PCORI Pilot Grant Program Review Study Section.