

Breakout Session Descriptions

• **Advanced Statistical Process Control (SPC) in QI Research**: This session is designed for participants who have developed and used control charts in their QI work or research and who feel comfortable with the basic theory and use of charts such as P- charts, U-charts, and X-bar and S-charts. PARTICIPATION IN THE MORNING INTRODUCTION SESSION WILL NOT PREPARE YOU ADEQUATELY FOR THIS SESSION. We will discuss advanced topics including control charts for special situations (e.g. g- charts for rare events), and common dilemmas in the use of control charts in healthcare, such as violations of underlying assumptions. This session will include a small group case study exercise. There will be ample time for questions and answers. This highly rated session will again be led by QI research experts **Maria T. Britto, MD, MPH**, Professor of Pediatrics in the Division of Adolescent Medicine at Cincinnati Children's Hospital Medical Center and **Terri Byczkowski, PhD, MBA**, Assoc. Professor in the Division of Emergency Medicine at Cincinnati Children's Hospital Medical Center (CCHMC).

• **Anatomy of a Quality Measure**: Developing valid and reliable quality metrics that are feasible to implement in multiple settings is critical to the conduct of rigorous QI intervention evaluation research. This session will provide an introduction to methods for developing valid, feasible quality indicators and the application of these metrics to QI evaluation research. The session will cover common pitfalls in quality measure development and how to avoid them. Participants will have the opportunity to evaluate a set of quality metrics and make suggestions for how they might be improved. They will also have the opportunity to develop de-novo quality metrics to evaluate the care provided for various clinical scenarios. This popular workshop on methods for developing valid and reliable quality metrics that are useful in various contexts will be led by **Rita Mangione-Smith, MD, MPH**, Professor and Chief, Division of General Pediatrics and Hospital Medicine at the University of Washington and a national leader in the field.

• **Bridging Classical Statistics and QI Research**: Both classical statistics and the methods of data display and analysis used for quality improvement seek to distinguish the real effects of interventions from random variation. In this session, we will develop an understanding of the statistical underpinnings of the "rules" for detecting non-random variation in run charts, control charts, and other quality improvement tools. Using case studies, we will also consider how researchers can complement QI analytical methods with more classical biostatistics to obtain a more complete picture of the effects of QI interventions. Using tools from multiple paradigms to assess evidence of intervention impact may be particularly appropriate for publication in medical journals. This session will be led by **Jonathan Finkelstein, MD, MPH**, and **Terri Byczkowski, PhD, MBA**, Assoc. Professor in the Division of Emergency Medicine at Cincinnati Children's Hospital Medical Center (CCHMC).

• **Choosing the Right Methods to Design and Evaluate Improvement Projects to Yield Credible Results**: Performing rigorous, publishable QI research in complex health care settings requires careful selection of the methodological approach best suited to the problem being addressed and the context in which the research is to be conducted. This session will

provide guidance on using logic models, conceptual models, and driver diagrams to frame the study design and establish the measurement plan. The importance of considering how the project will be evaluated when choosing its design will be emphasized. Various quasi-experimental and dynamic study designs, including Bayesian adaptive cluster randomized trials, step wedge and factorial designs, and mixed-methods approaches, will be compared and contrasted. In particular, the hazards of fixed-protocol designs that do not allow for real-time learning will be stressed. Examples of QI studies that were published in first-line peer review journals will be discussed to justify the presenter's optimistic view of the career path for QI investigators. This session is led by **Donald Goldman, MD**, Chief Medical and Scientific Officer, Institute for Healthcare Improvement (IHI).

- **Cluster Randomized Trials (CRTs) in QI Research:** Cluster randomized trials (CRTs) can offer unparalleled opportunities to demonstrate causal effects of QI and health systems interventions, but also present unique challenges in both design and implementation. This workshop will provide an overview of common methodological, statistical, and logistical issues with cluster randomized trials, and hands on experience in 1) evaluating the "fit" of CRTs for a given intervention and context, and 2) designing a CRT in small groups in response to real world pediatric QI cases from both inpatient and outpatient settings. Participants will have the opportunity to explore how CRT designs could be useful in their own QI work and settings, and to problem-solve some of the likely hurdles involved. This session is led by **Michelle M. Garrison, PhD**, Assoc. Research Professor in the Department of Pediatrics at the University of Washington.

- **Context in Quality Improvement Research:** This session will focus on understanding organizational and other contextual factors in implementation efforts. Real world examples will be used in a series of interactive exercises to help learners apply the session's content to their own settings and projects. Classic clinical intervention research is concerned with testing cause-effect relationships in specific experimental instances where context is either irrelevant or its effects are minimized in the design of the study. However, when introducing and testing delivery system interventions designed to improve health care quality and safety, context cannot be ignored. Interventions designed to improve quality are typically complex, sociotechnical interventions whose targets are health care systems, organizations, or groups of providers. As such, these interventions are sensitive to the context in which they are implemented and studies of their effectiveness must include an examination of context, particularly when others are interested in replicating such interventions in their own setting. This session will (1) briefly describe the important role of context in QI interventions; (2) identify some theoretical models and particular methods that can help guide researchers in addressing context in their QI research; and (3) include practical exercises on designing QI research studies to explicitly address the role of context. This session will be led by **Evaline Alessandrini, M.D., M.S.C.E.**, Professor of Pediatrics, University of Cincinnati College of Medicine and Assoc. Chair of Outcomes and Process Improvement, Department of Pediatrics, Cincinnati Children's Hospital Medical Center and **Heather Kaplan, M.D., M.S.C.E.**, Assistant Professor, University of Cincinnati Department of Pediatrics and Attending Neonatologist, Neonatology and Pulmonary Biology, Cincinnati Children's Hospital Medical Center.

• **Creating and Measuring Value in Pediatric Care:** This workshop will build on lessons from the Pediatric Research in Inpatient Settings network and Primary Children's Hospital. It will focus on the network's approach to quality improvement, including creating a national agenda, work on specific conditions and processes of care and how quality improvement occurs at Primary Children's hospital – which is part of the larger health care delivery system of Intermountain Healthcare. This session will be led by **Dr. Raj Srivastava, MD, MPH**, Assistant Vice President of Research, Intermountain Healthcare and Professor of Pediatrics, University of Utah, and, and **Dr. Christopher G. Maloney MD, PhD**, Chief Medical Officer, Primary Children's Hospital, Division Chief of the Division of Inpatient Medicine and Professor of Pediatrics, University of Utah.

• **Developing a Portfolio in Safety Research: Methods and Considerations:** While there are Works in Progress Sessions, this is a Works "You Want to Put" In Progress Session. Patient safety research offers the opportunity to integrate sophisticated conceptual thinking with health services and social science research methods to save lives. Through a mix of didactic and interactive learning this session will provide a survey of the methods for establishing a portfolio of patient safety this interactive session will help attendees develop an understanding of how a research portfolio on a single safety topic can involve a spectrum of goals and methods. Using a specific example, attendees will also develop an understanding of how safety research relates to other topics in the research enterprise and to quality improvement research specifically. Patient safety research findings can change care at institutional, regional and national levels. Matching methods to research questions, institutional needs and identified opportunities will be discussed. This session will focus on patient safety research involving a spectrum of goals and methods. It will be led by **Michael Rinke, MD, PhD**, Medical Director of Pediatric Quality at the Children's Hospital at Montefiore and an Asst. Professor of Pediatrics at Albert Einstein College of Medicine.

• **The Fundamentals of Quality-Improvement: How to Do QI Evaluation – Part 1 and Part 2:** This introductory course is appropriate for those participating in or planning quality improvement / patient safety projects, but who have little to modest experience or training in QI science. There are no course prerequisites. This course will include a survey of common overarching QI methodologies (e.g. lean engineering, the model for improvement, process control), specific QI strategies (e.g. standardization, error-proofing, checklists, iterative PDSAs), issues around quality measures (e.g. outcome measures, process measures, balancing measures), and a very brief introduction into a couple of broad but related concepts (e.g. scoping, high reliability organizations, safety culture). Small groups will take example quality/safety problems, explore possible QI approaches, plan interventions, and interpret mock data. Participants will be encouraged to see how particular problems may suggest very fitting QI approaches, just as a particular QI approach may suggest very fitting analytic methods (covered by many of the other break-out sessions). This session will be led by **Matthew Niedner, MD**, Director of Quality and Safety at the Pediatric Intensive Care Unit (PICU) at CS Mott Children's Hospital, University of Michigan, and co-chair of several multicenter QI collaboratives.

• **Interrupted Time Series:** Interrupted Time Series (ITS) analysis is the strongest quasi-experimental design for evaluating natural experiments. This session focuses on the use of ITS

to measure changes in population outcomes associated with program implementation or policy changes. Topics will include: when to use an ITS design, strengths and weaknesses of the approach, pitfalls to avoid, and implementation of the approach in SAS. Participants will also review and critique examples of published pediatric re-search using ITS. This will be led by **Robert Penfold, PhD**, Assoc. Investigator at the Group Health Research Institute (GHRI).

• **Introduction to Qualitative and Mixed Methods in Implementation and QI Research:**

Numbers alone may not tell the full story regarding the successes and challenges of an intervention or program being implemented. This session will provide an overview of qualitative and mixed methods research. Participants will review the epistemological foundations and relative strengths of qualitative vs. quantitative approaches, explore some common approaches to qualitative research methods, and become conversant with strategies for integrating quantitative and qualitative data. Using real life case examples, participants will explore how qualitative and/or mixed methods can enhance implementation and QI research, and assess which approaches might be most appropriate for specific QI research questions. The session will be led jointly by **Clarissa Hsu, PhD**, an anthropologist and Senior Research Assoc. at Group Health Research Institute, and **Sarah Ronis, MD, MPH**, Asst. Professor of Pediatrics at Case Western Reserve and Rainbow Babies & Children's Hospital.

• **Introduction to Statistical Process Control (SPC):** This session will cover the fundamentals of statistical process control (SPC) in QI Research. We will briefly discuss the concept of variation followed by an overview of the principles of SPC and selecting the right control chart. This will be followed by small group exercises regarding selection of SPC charts for different study designs and data types. Ample time will be allowed for questions and answers. This session is designed for those with basic knowledge of SPC. For those who are completely unfamiliar with SPC, there will be suggested reading to complete prior to the course so that you will be prepared to participate. This session will be led by QI research expert **Maria T. Britto, MD, MPH**, Professor of Pediatrics in the Division of Adolescent Medicine at Cincinnati Children's Hospital Medical Center.

• **Navigating the IRB for QI and Implementation Science Projects:** Using a case-based approach, this session addresses important questions about IRB review for QI and implementation science research. The session will be led by **Dr. Finkelstein, Judith S. Shaw, EdD, MPH, RN**, Executive Director of the Vermont Child Health Improvement Program (VCHIP) and Professor of Pediatrics at the University of Vermont College of Medicine, and **Daniel Hyman, MD**, Chief Quality Officer at Colorado Children's Hospital.

• **Publishing QI Research: What you Need to Know:** The act of writing can inform a quality improvement project's design and execution. This interactive, practical session will focus on strategies for organizing and writing about quality improvement. Participants will be introduced to the concept of a key driver diagram - an important tool used to display the theory for improvement in a project – and will have an opportunity to create a diagram based on their own work or from examples provided. The second part of the session will be an introduction to the Standards for Quality Improvement Reporting Excellence (SQUIRE) 2.0 Guidelines. We will review specific examples of SQUIRE elements in current healthcare improvement literature.

Participants will then have an opportunity to employ writing techniques that are applicable for scholarly improvement writing. At the close of the session we will review top-tier and second-tier journals that are currently publishing work about quality improvement. It will be led by **Lori Rutman, MD, MPH**, Asst. Professor of Pediatrics at the University of Washington and member of the national collaborative responsible for developing Standards for Quality Improvement Reporting Excellence (SQUIRE) 2.0 Guidelines. Participants will have an opportunity to employ writing techniques effective for scholarly reporting of QI and implementation science.

• **Techniques for Assessing the Impact of System Interventions and Other Innovations on Disparities. QI Interventions and Health Care Disparities:** What every implementer needs to know: Health care disparities remain pervasive, in spite of growing efforts to address them through research, policy, and QI, and many well-intentioned interventions may either maintain or inadvertently worsen existing disparities, or create new ones. In this interactive session, we will discuss the mechanisms by which that can happen and techniques for evaluating the impact of an intervention on disparities. Through small-group exercises using example cases and participants' own projects (ongoing or planned), we will explore the ways in which the underlying process or system, the intervention itself, or the context can contribute to improving, maintaining or worsening disparities, and how to optimally design interventions and evaluations with that in mind. If the group is interested, we can also discuss issues in evaluation design for interventions explicitly aimed at reducing disparities, including study design, comparator group selection, and resource constraints. This session will be relevant for anyone conducting QI interventions or QI research who does not wish to contribute to disparities, as well as those who are explicitly interested in reducing them. It will be led by experienced health disparities researchers, **Casey Lion, MD, MPH**, Asst. Professor of Pediatrics at University of Washington.

• **Works in Progress Session:** This session will allow presenters to share their works in progress. This will be an opportunity for those currently engaged in a quality-improvement project to share their successes and challenges and to get advice about how to improve their work. This session will cover all aspects of a rigorous quality improvement project, including study design, human subjects protection, site recruitment, implementation, project management, data collection, data analysis, manuscript writing, and planning for future activities. This will be also be an opportunity for the group as a whole to learn from one another in a dynamic learning environment. This session will be led by **Alex R. Kemper, MD, MPH, MS**, Professor of Pediatrics at Duke University, Assoc. Chief for Research, Division of Children's Primary Care at Duke, and Assoc. Editor of *Pediatrics*. He will be accompanied by **Jonathan Finkelstein, MD, MPH**, Donald M. Berwick Chair in Pediatric Quality and Outcomes at Boston Children's Hospital, and Professor of Pediatrics and Population Medicine, Harvard Medical School, **Lawrence Kleinman, MD, MPH**, and **Lori Rutman, MD, MPH**, Asst. Professor of Pediatrics at the University of Washington.