Breakout Session 1:

Interrupted Time Series
Robert Penfold, PhD
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 research using ITS.

Anatomy of a Quality Measure
Rita Mangione-Smith, MD, MPH
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.

The Fundamentals of Quality-Improvement: How to do QI – Part I
Matthew Niedner, MD
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).

Bridging Classical Statistics and QI Research
Terri Byczkowski, PhD, MBA and Jon Finkelstein, MD, MPH
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.

**Introduction to Statistical Process Control (SPC)**  
*Maria Britto, MD, MPH*

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.

**Introduction to Qualitative Methods in QI Research**  
*Clarissa Hsu, PhD*

There is increasing recognition of the value of integrating qualitative methods into QI research. This session will provide an introduction to qualitative research methods including a brief discussion of underlying epistemological foundations of qualitative methods and an overview of common methods used in qualitative data collection and analysis. Participants will have the opportunity to explore how qualitative methods can be used to enhance QI research and assess which data collection and analysis strategies might be most appropriate for specific QI research questions and/or projects.

**Breakout Session 2:**

**Interrupted Time Series Analysis**  
*Robert Penfold, PhD*

This session includes advanced topics including: selecting control populations, designing and evaluating sequential interventions, use of multiple assignment variables, difference-in-differences analysis, accounting for selection bias and population attrition, and population stratification. Participants will work in groups to design evaluation strategies for real-world policies and interventions. This advanced session assumes participants are familiar with introductory time series analysis and some Masters level biostatistical training (e.g., autocorrelation, logistic regression).

**Works-in-Progress - Session 1**  
*Jonathan Finkelstein, MD, MPH, Alex Kemper, MD, MPH, MS, Lawrence Kleinman, MD, MPH*

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.

The Fundamentals of Quality-Improvement: How to do QI – Part II
Matthew Niedner, MD
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).

Survey of Quality Improvement Research Methods
Donald Goldmann, MD
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.

Advanced Statistical Process Control (SPC)
Maria Britto, MD, MPH and Terri Byczkowski, PhD, MBA
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 and autocorrelated data. This session will include a small group case study exercise. There will be ample time for questions and answers.
Introduction to Qualitative Methods in QI Research
Clarissa Hsu, PhD
There is increasing recognition of the value of integrating qualitative methods into QI research. This session will provide an introduction to qualitative research methods including a brief discussion of underlying epistemological foundations of qualitative methods and an overview of common methods used in qualitative data collection and analysis. Participants will have the opportunity to explore how qualitative methods can be used to enhance QI research and assess which data collection and analysis strategies might be most appropriate for specific QI research questions and/or projects.

Breakout Session 3:

Anatomy of a Quality Measure
Rita Mangione-Smith, MD, MPH
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.

To IRB or not to IRB, That is the Question
Jonathan Finkelstein, MD, MPH
In this interactive session, participants will explore the tensions between federal requirements for review of research by Institutional Review Boards and the need for organizations to engage in continuous improvement efforts that may be worthy of publication and/or otherwise meet criteria that some would consider research. Participants are encouraged to bring with them for discussion their own project proposals and the existing policies and practices at their own institutions with respect to what requires review by their IRB. The faculty will share their experiences with alternative, simplified review processes for QI projects and discuss evolving national standards in this area.

Developing a Portfolio in Safety Research: Methods and Considerations
Michael Rinke, MD, PhD
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.
**Funding Opportunities for Pediatric QI Research**  
*David Chambers, PhD, NIH, Steve Clauser, MD, PCORI, Kamila Mistry, PhD, AHRQ*

External funding is almost always a prerequisite for conducting QI intervention research that involves multiple entities. It is also needed for foundational and methodological research in QI. This session will feature very brief overviews of funding opportunities from representatives of 3 key entities interested in QI and related research: Agency for Healthcare Research and Quality, National Institutes of Health, and the Patient Centered Outcomes Research Institute. Then, the panel will react to questions from a member of the APA Quality Improvement Research Conference faculty who is a funded investigator, and the audience. Finally, individuals will have the opportunity to meet with the funder representatives in small groups.

**How to Obtain Risk Ratios and Risk Differences from Logistic Regression: An introduction to Regression Risk Analysis for SAS and STATA**  
*Lawrence Kleinman, MD, MPH; Nathaniel Carroll, PhD*

This session is for researchers who are comfortable using logistic regression and would like to enhance the reporting of their results. The shortcomings of reporting odds ratios are important and well-described. Regression risk analysis represents a straightforward method for obtaining valid estimates of adjusted risk ratios and adjusted risk differences from your typical logistic regression models. The method also works for probit and related ordered and multivariate models. We will explain how to perform such analyses both in un-weighted data, and in data that incorporates complex survey design, including sampling weights, clustered observations, and stratification, as are often encountered in national surveys and in clinical QI research. Participants will analyze data sets interactively individually and in small groups (please bring laptops with Stata 12.0 or SAS 9.3 or higher if you have them). This will be primarily an interactive hands-on session. In addition to working on practical applications, we will distribute SAS and Stata programs/macros to download, and offer a brief overview that links the practices we show to the underlying theory.

**Works in Progress - Session 2**  
*Donald Goldmann, MD, Alex Kemper, MD, MPH, MS, Lori Rutman, MD, MPH*

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 also be an opportunity for the group as a whole to learn from one another in a dynamic learning environment.