4th Annual
Advancing Quality Improvement
Science for Children’s
Healthcare Research

APA Conference for Pediatric
Quality Improvement Methods,
Research and Evaluation

May 2, 2014
Hyatt Regency
Vancouver, British Columbia, Canada

Meeting is Jointly-Sponsored by

wwwacademicpedsorg
This unique meeting will focus on state-of-the-art methods for pediatric healthcare quality improvement (QI) research and bring together leaders and innovators in pediatric QI research.

Topics to be addressed include:

- The Anatomy of a Quality Measure
- Advanced Application of Interrupted Time Series Analysis
- Bridging Classical Biostatistical Methods & QI Research
- Cluster Randomized Controlled Trials
- NEW! Context in Quality-Improvement Research
- NEW! Estimating the Value of QI: Organizational Perspectives on the Cost per Unit of Improved Quality
- NEW! The Fundamentals of Quality-Improvement: How to Do QI
- NEW! To IRB or not to IRB, That is the Question
- Interrupted Time Series
- NEW! Quality Improvement Works in Progress
- Regression Risk Analysis
- Stepped Wedge Designs
- Statistical Process Control in QI Research
- NEW! Survey of Quality-Improvement Intervention Research Methods

The meeting will discuss challenges of using these methods and develop an agenda for further improving and applying QI research methodologies, as well as integrating evidence-based quality improvement strategies into front-line QI efforts such as maintenance of certification.

Who Should Attend?
Individuals with interest and/or experience in how to conduct, evaluate, apply, or interpret quality improvement research.

Objectives:
1. Implement appropriate state-of-the-art QI research methodologies in future QI work;
2. Describe limitations of current methodologies and methods to address these limitations;
3. Identify and name 3 new local, regional and national resources, contacts and collaborators for future QI research activities;
4. Describe in detail at least one method for evaluating the effectiveness of a quality improvement intervention.

Cancellation Policy
We reserve the right to cancel any sessions due to lack of enrollment or other factors. In the event of a cancellation, registered participants will be notified by e-mail and will have the option to choose an available alternative or receive a refund.

Cancellation Fees
All registration cancellations by participants must be received in writing.

A $50 administration fee will be assessed for all cancellation requests received by April 14, 2014. Cancellations received after April 14, 2014 will not be eligible for a refund. All reimbursements will be processed following the meeting.
Accreditation
This activity has been planned and implemented in accordance with the Essential Areas and Pol-
icies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint
sponsorship of the Icahn School of Medicine at Mount Sinai and the Academic Pediatric Asso-
ciation. The Icahn School of Medicine at Mount Sinai is accredited by the Accreditation Council
for Continuing Medical Education to provide continuing medical education for physicians.

Credit Designation
The Icahn School of Medicine at Mount Sinai designates this live activity for a maximum of 6.75
AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with
the extent of their participation in the activity.

Verification of Attendance
Verification of attendance will be provided to all professionals.

Special needs
The Icahn School of Medicine at Mount Sinai is in full compliance with provisions of the Ameri-
cans with Disabilities Act (ADA) and is accessible for individuals with special needs. If you would
like to attend this conference and require any special needs or accommodations please contact
Allison Hartle at the APA office at 703-556-9222 or Allison@academicpeds.org.

Faculty Disclosure
It is the policy of the Icahn School of Medicine at Mount Sinai to ensure objectivity, balance,
independence, transparency, and scientific rigor in all CME-sponsored educational activities. All
faculty participating in the planning or implementation of a sponsored activity are expected to
disclose to the audience any relevant financial relationships and to assist in resolving any con-
flict of interest that may arise from the relationship. Presenters must also make a meaningful
disclosure to the audience of their discussions of unlabeled or unapproved drugs or devices.
This information will be available as part of the course materials.

Acknowledgement
Funding for this conference was made possible in part by grant 1R13 HS023045-01 from the
Agency for Healthcare Research and Quality (AHRQ).¹

¹Funding for this conference was made possible [in part] by grant number 1R13 HS023045-01 from the Agency for
Healthcare Research and Quality (AHRQ). The views expressed in written conference materials or publications and
by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human
Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S.
Government.
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<td>8:00-8:30 am</td>
<td>Continental Breakfast/Networking</td>
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<tr>
<td>8:30-8:40 am</td>
<td>Welcome &amp; Conference Overview</td>
<td>Jon Finkelstein, MD, MPH</td>
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<td>8:45-9:30 am</td>
<td>Keynote: The Future of Quality Improvement Research</td>
<td>Virginia Moyer, MD, MPH</td>
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<td>9:45-11:45 am</td>
<td>Breakout Session 1 – Choose 1</td>
<td>Session Leader(s)</td>
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<tr>
<td>TRACK 1</td>
<td>The Anatomy of a Quality Measure: Key Issues to Consider when</td>
<td>Rita Mangione-Smith, MD, MPH</td>
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<td>Developing Quality Metrics for QI Evaluation Research</td>
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<td>The Fundamentals of Quality-Improvement: How to Do QI</td>
<td>Matthew Niedner, MD</td>
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<td>Interrupted Time Series</td>
<td>Robert Penfold, PhD</td>
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<td>Introduction to Statistical Process Control</td>
<td>Maria Britto, MD, MPH</td>
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<td>Quality Improvement Works-in-Progress</td>
<td>Alex Kemper, MD, MP, MS</td>
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<td>12:00-1:15 pm</td>
<td>Networking Lunch and Discussion of Posters with Authors and</td>
<td>Jon Finkelstein, MD, MPH, Judy Shaw, EdD, MPH, RN</td>
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<td>1:30-3:30 pm</td>
<td>Breakout Session 2 – Choose 1</td>
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<td>TRACK 1</td>
<td>Estimating the Value of QI: Organizational Perspectives on the</td>
<td>David Grossman, MD, MPH</td>
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<td>Cost per Unit of Improved Quality</td>
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<td>To IRB or not to IRB, That is the Question</td>
<td>Jon Finkelstein, MD, MPH, Daniel Hyman, MD</td>
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<td>Qualitative Methods for Quality Improvement Research</td>
<td>Clarissa Hsu, PhD</td>
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<td>TRACK 2</td>
<td>Advanced Application of Interrupted Time Series Analysis</td>
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<td>Context in Quality-Improvement Research</td>
<td>Denise Dougherty, PhD, Heather Kaplan, MD</td>
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<td>Regression Risk Analysis</td>
<td>Nathan Carroll, MHA, Lawrence Kleinman, MD, MPH</td>
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<td>Statistical Process Control in QI Research</td>
<td>Maria Britto, MD, MPH, Terri Byczkowski, PhD, MBA</td>
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<td>3:30-3:45</td>
<td>Coffee Break and Networking</td>
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<td>3:45-4:30 pm</td>
<td>Closing Plenary</td>
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<td>Quality Improvement versus Quality Improvement Research: Academic</td>
<td>Moderator: Lawrence Kleinman, MD, MPH</td>
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<td>Work on the Borderline</td>
<td>Donald Goldman, MD</td>
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<td>Alex Kemper, MD, MPH</td>
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<td>Rita Mangione-Smith, MD, MPH</td>
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<td>James Stout, MD, MPH</td>
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Track 1 sessions are for QI Researchers with less experience and will be taught at an introductory level.

Track 2 sessions are for more advanced QI researchers and a basic knowledge of the topic is assumed. Attending an introductory version of a session on a given topic will not be adequate preparation for attending the advanced version of the session.

Track 1 Breakout Sessions

The Anatomy of a Quality Measure: Key Issues to Consider when Developing Quality Metrics for QI Evaluation Research (Track 1)
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.

Estimating the Value of QI: Organizational Perspectives on the Cost per Unit of Improved Quality (Track 1)
David Grossman, MD, MPH
Quality leaders are often challenged by administrative colleagues to provide a sound business case for quality improvement. With an ever growing scrutiny of health care spending and focus on value based care, the importance of establishing a sound ‘business case’ for investments in care improvement has become paramount. This session will review some of the key organizational and external drivers that propel quality improvement initiatives from the perspective of delivery systems, health plans and purchasers. In breakout groups, we will also develop sample “business cases” for quality improvement initiatives using a template and then use group feedback to critique and discuss the presentations.

The Fundamentals of Quality-Improvement: How to do QI (Track 1)
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 over-arching QI methodologies (eg, lean engineering, the model for improvement, process control), specific QI strategies (eg, standardization, error-proofing, checklists, iterative PDSAs), issues around quality measures (eg, outcome measures, process measures, balancing measures), and a very brief introduction into a couple of broad but related concepts (eg, 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).

Interrupted Time Series (Track 1)
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 re-search using ITS.
**Session Descriptions**

**4th Annual Advancing Quality Improvement Science for Children’s Healthcare Research**

**Introduction to Statistical Process Control (Track 1)**  
*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.

**To IRB or not to IRB, That is the Question (Track 1)**  
*Jon Finkelstein, MD, MPH and Daniel Hyman, MD*

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.

**Qualitative Methods for Quality Improvement Research (Track 1)**  
*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.

**Quality Improvement Works-in-Progress (Track 1)**  
*Alex Kemper, MD, MPH, MS*

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.
Track 2 Breakout Sessions

Advanced Application of Interrupted Time Series Analysis (Track 2)
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).

Bridging Classical Biostatistical Methods & QI Research (Track 2)
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.

Cluster Randomized Controlled Trials (Track 2)
Michelle Garrison, PhD
Cluster randomized trials (CRTs) can be a rigorous study design for testing interventions in pediatric quality improvement research, and are especially useful when intervention delivery and outcomes are at different levels -- for example, patients, provider panels, clinics, or hospitals. We will learn what situations call for a CRT, how CRTs are designed, what pitfalls to watch out for, and practice solving these issues with real life cases.

Context in Quality-Improvement Research (Track 2)
Heather Kaplan, MD and Denise Dougherty, PhD
When introducing and testing interventions designed to improve health care quality and safety, context cannot be ignored. 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 using an ongoing mixed methods process evaluation of a QI intervention study as an informative example.

Regression Risk Analysis (Track 2)
Nathan Carroll, MHA and Lawrence Kleinman, MD, MPH
This advanced session (for researchers comfortable with performing logistic regression analysis) will focus on how to estimate adjusted risk ratios and risk differences when reporting results from logit, probit, and related ordered and multivariate models. These methods avoid commonly known (but sometimes underappreciated) problems associated with interpreting adjusted odds ratios. In addition, we will explain how to perform such analyses in data that incorporates complex survey design, including sampling weights, clustered observations, and stratification, as may be encountered in both national surveys and in clinical QI research. Participants will analyze data sets interactively (if they bring laptops with Stata 12.0 or SAS 9.3 or higher). While intended as a practical session, a brief overview of the theory will be presented.
**Statistical Process Control in QI Research (Track 2)**

*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.

**Stepped Wedge Designs (Track 2)**

*James Hughes, PhD*

Stepped wedge trials, also known as rollout trials, delayed implementation trials or partial crossover trials, are characterized by the sequential rollout of an intervention to participants (often in clusters such as cities or clinics) over time. The design is often used to evaluate the “real-world” effect of an intervention during the implementation of an intervention that has been shown to be effective in smaller scale, controlled studies. This session will begin by introducing the stepped wedge design and issues related to the design and analysis of stepped wedge trials. Participants will then break into groups where they will either (i) discuss the strengths and weaknesses of a stepped wedge design for a particular scenario (several scenarios will be presented) and/or (ii) analyze data from a stepped wedge trial (laptop with Stata version 12 or R with lmer and gee packages required). Participants are assumed to be familiar with regression methods and the basics of trial design.

**Survey of Quality-Improvement Intervention Research Methods (Track 2)**

*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.
Name: ___________________________  Degree(s): ___________________________

Check All that Apply:
☐ Published QI Investigator  ☐ Funded QI Investigator  ☐ QI Implementer
☐ Planning to publish  ☐ Not planning to publish
☐ Not sure about publishing results  ☐ No QI to date but interested in QI research
☐ Other (please explain): ___________________________

Program/Institution: ___________________________

Academic Rank: ___________________________  Department: ___________________________

Address: ___________________________

City: ___________________________  State/Province: ___________________________

Zip/Postal Code: ___________________________  Phone: ___________________________

Email: ___________________________

What do you hope to gain by attending this meeting? ___________________________

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BREAKOUT SESSION SELECTION: Number your Breakout Session choices 1 through 8 for the morning and afternoon sessions. Use each number or placement may be randomized.

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<th>Breakout Session 2- 1:30-3:30 PM</th>
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<td>1. Advanced Application of Interrupted Time Series-Analysis (Track 1)</td>
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<td>2. Bridging Classical Biostatistical Methods &amp; QI Research (Track 2)</td>
<td>2. Context in Quality-Improvement Research (Track 1)</td>
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<td>3. Cluster Randomized Controlled Trials (Track 2)</td>
<td>Full 3. Estimating the Value of QI: Organizational Perspectives on the Cost per Unit of Improved Quality (Track 1)</td>
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<td>4. The Fundamentals of Quality-Improvement: How to do QI! (Track 1) repeated at 1:30 pm</td>
<td>4. The Fundamentals of Quality-Improvement: How to do QI! (Track 1) repeated at 9:45 am</td>
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<td>9. Survey of Quality-Improvement Intervention Research Methods (Track 2)</td>
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