QUALITY IMPROVEMENT

Critical appraisal of QI literature

Dr. Jennifer Twiss MSc, MD FRCPC
Disclosure

• I declare no personal or financial conflict of interest in this presentation

• There will be no discussion of unlicensed drugs or therapies during this presentation
Objectives

• The value of QI research in the practice of evidenced based medicine
• Appreciate the common difficulties of QI research
• Use of current frameworks to assess the quality of published QI research
• Review study designs that lead to high quality QI research
PollEV

• Please sign into POLLEV with your cellphones

• Text JENNIFERTWIS625 to 37607 once to join
What is Quality Improvement?

• QUALITY IMPROVEMENT IN HEALTH CARE
• Together, making care better: supporting and promoting substantial and sustainable positive improvements in care
  – It’s looking for opportunities for improvement, implementing evidence based medicine practices, trying new approaches, and adopting them if they work.
• Systematic, data-guided activities designed to bring about immediate improvements in health delivery in particular settings
• Improving the quality of care of patients is a fundamental obligation of health care providers
  – The QI process involves evaluating and learning from experience
Model for Improvement

<table>
<thead>
<tr>
<th>Human Subjects Research</th>
<th>Quality Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>develop or contribute to generalizable knowledge</td>
</tr>
<tr>
<td></td>
<td>implement knowledge, assess a process or program as judged by accepted standards</td>
</tr>
<tr>
<td>Starting Point</td>
<td>independent of routine care and intended to answer a question or test a hypothesis</td>
</tr>
<tr>
<td></td>
<td>integral to ongoing management system for delivering health care</td>
</tr>
<tr>
<td>Design</td>
<td>follows a rigid protocol that remains unchanged throughout the research</td>
</tr>
<tr>
<td></td>
<td>adaptive, iterative design</td>
</tr>
<tr>
<td>Benefits</td>
<td>might or might not benefit current subjects; intended to benefit future patients</td>
</tr>
<tr>
<td></td>
<td>directly benefits a process, system or program; might or might not benefit patients</td>
</tr>
<tr>
<td>Risks</td>
<td>may put subjects at risk</td>
</tr>
<tr>
<td></td>
<td>does not increase risk to patients</td>
</tr>
<tr>
<td>Participant Obligation</td>
<td>no obligation of individuals to participate</td>
</tr>
<tr>
<td></td>
<td>responsibility to participate as component of care</td>
</tr>
<tr>
<td>Endpoint</td>
<td>Answer a research question</td>
</tr>
<tr>
<td></td>
<td>improve a program, process or system</td>
</tr>
<tr>
<td>Analysis</td>
<td>Statistically prove or disprove hypothesis</td>
</tr>
<tr>
<td></td>
<td>compare program, process or system to standards</td>
</tr>
<tr>
<td>Adoption of Results</td>
<td>little urgency to disseminate results quickly</td>
</tr>
<tr>
<td></td>
<td>results rapidly adopted into local care delivery</td>
</tr>
<tr>
<td>Publication/Presentation</td>
<td>investigator obliged to share results</td>
</tr>
<tr>
<td></td>
<td>QI practitioners encouraged to share systematic reporting of insights</td>
</tr>
</tbody>
</table>

Table adapted from: [https://irb.research.chop.edu/quality-improvement-vs-research](https://irb.research.chop.edu/quality-improvement-vs-research)
Quality Improvement is Different

• Focus on studying
  – How to implement best practices in different contexts
  – Application of therapies known to work in different populations
  – How proven therapies function in an uncontrolled environment
Quality Improvement is Different

- Iterative design
  - The implementation strategy changes over time based on the outcome of small tests of change
  - Multiple changes occur to look at effect on one ultimate outcome

Figure 1  Learning from the PDSA cycle to improve our understanding of the barriers for reduction in the incidence of cold stress in ELBW infants.

Quality Improvement is Different

• Innovation
  – Adaptation to a changing complex environment
  – Change and adaptation conducted using data and structure

Table 2  Characteristics of five knowledge systems involved in improvement

<table>
<thead>
<tr>
<th>Knowledge system</th>
<th>Illustrative features</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Generalisable scientific evidence</td>
<td>Controls and limits context as a variable; tests hypotheses</td>
</tr>
<tr>
<td>2. Particular context awareness</td>
<td>Characterises the particular physical, social and cultural identity of local care settings (e.g., their processes, habits and traditions)</td>
</tr>
<tr>
<td>3. Performance measurement</td>
<td>Assesses the effect of changes by using study methods that preserve time as a variable, use balanced measures (range of perspectives, dimensions), analyse for patterns</td>
</tr>
<tr>
<td>4. Plans for change</td>
<td>Describes the variety of methods available for connecting evidence to particular contexts</td>
</tr>
<tr>
<td>5. Execution of planned changes</td>
<td>Provides insight into the strategic, operational and human resource realities of particular settings (drivers) that will make changes happen</td>
</tr>
</tbody>
</table>

Figure 2  Formula illustrating the way in which knowledge systems combine to produce improvement.

Batalden PB, Davidoff F.  Qual Saf Health Care 2007;16:2-3
Quality Control

Customer

Standard
Efficiency
Reliability
Process

Criteria
SATISFACTION
CHECK
GUARANTEE
Quality Improvement Research

• Study of the net benefit of existing therapies in different environments and populations
  – Change behavior
  – Implementation of accepted clinical practices
  – Changes in the delivery of health care
  – Practical problem solving
  – Innovation and adaptation
Features of Quality Improvement Research

• Description of the motivation for change
• Rationale

“Over recent decades there has been a significant reduction in the congenital heart disease mortality rate. As a result, increasing emphasis has been placed on reducing morbidity and identifying markers of care delivery such as hospital LOS and incidence of hospital readmission. The paediatric cardiac population is at particular risk for in-hospital deterioration and subsequent readmission to the cardiac intensive care unit (CICU).”

Features of Quality Improvement Research

• Description of the motivation for change
  – Hospital readmission to pediatric CICU associated with mortality

• Assumptions
  – Prevention of readmissions
    • No data looking at preventing readmission
  – Higher rate of readmissions
    • Internal data demonstrate there are readmissions, not high no benchmark data
  – Standardized transfer of care
    • Not existing
  – Standardized monitoring based on risk
    • Not existing

Features of Quality Improvement Research

• Description of the motivation for change

• Hypothesis 1
  – Subtle clinical changes occur and go unrecognized due to lack of patient specific monitoring leading to more urgent and complex interventions

• Hypothesis 2
  – Complicance with standardized care process based on risk or condition would reduce in hospital readmissions back to the CICU within 48 hours of transfer

Features of Quality Improvement Research

• Description of the context
• Physical

“Hutzel Women’s Hospital is an urban, academic women’s hospital with a 55-bed level 3 inborn NICU and special care nursery along with a high-risk maternal-fetal medicine service. There are about 5500 deliveries each year. The delivery areas are connected to the NICU by an enclosed bridge, which takes 1–3 min to traverse. Delivery of a pre-mature neonate (<32 weeks’ gestational age) is attended by a neonatal fellow, a nurse practitioner, a respiratory therapist, and two residents. A neonatology attending physician attends deliveries of infants at <32 weeks’ gestation during the day shifts, and a neonatal nurse attends some deliveries anticipated to need extensive resuscitation.”
Features of Quality Improvement Research

• Description of the context

• Cultural

“Our organisation has a mature quality improvement infrastructure within our Center for Health Systems Excellence. Hospital faculty and staff are trained in improvement science via multiple course offerings.”

Features of Quality Improvement Research

• Description of the context
• Resources

“Quality improvement consultants and data analysts provide assistance for many improvement projects.”

Features of Quality Improvement Research

- Data collection to drive the improvement efforts
- Systematic
  - One pretest and two post test measurements (3 and 12 months)
  - 3 ICUs received training and compared with a matched control unit
  - Education delivered to all groups of staff
  - Using an evaluation framework
  - Mixed method design using questionnaires, observations and patient outcome data

QI Pitfalls

• Generalizability
  – Context dependent
  – Less able to produce consistent results
Have you ever read a QI paper and tried to implement a similar process in your own practice?
QI Research Pitfalls

• Complex
  – Multiple interventions
  – Multiple time periods
  – May require financial backing and personnel
Difficulties in QI Research

• High risk of bias
  – Factors such as environment, resource influence results
  – Difficult to identify all factors that may have contributed to published effect
Difficulties in QI Research

• Heterogeneous approach
  – Qualitative and quantitative data
  – Mixed method studies
  – Design methods not always rigorously followed
EVALUATING QI LITERATURE

TOOLS
Determining Quality of a QI Study

• Interventions should consider current standards of care or evidence based practice recommendations
• QI work is subject to biases and confounders
  – Applicability to your context
  – Changes in practice over time (drift/creep)
  – Variation in trends of patient outcomes over time
• Follow up period has to be long enough
  – Sustainability plans are important to describe
• All outcomes need to be identified
  – Unintended consequences
  – Resource utilization
  – Cost
SQUIRE 2.0

• Standards for Quality Improvement Reporting Excellence
• Created to guide quality of QI studies
• Provide a framework for reporting QI studies
  – Usually applicable to system level change to improve quality safety and value of healcare
  – Published standard directing written framework of QI work
• May be adapted to suit different methodologies
• A general guide to writing up QI work

SQUIRE 2.0

• TITLE AND ABSTRACT

• Title: Indicate that the manuscript concerns an initiative to improve healthcare

• Abstract:
  – Provide adequate information to aid in searching and indexing
  – Summarize all key information from various sections of the text using a structured summary
    • Eg. Background, local problem, methods, interventions, results and conclusions

SQUIRE 2.0

• INTRODUCTION: WHY DID YOU START?
  - Problem description:
    – Nature and significance of the problem
  - Available knowledge:
    – Summary of what is currently known about the problem including relevant previous studies
  - Rationale:
    – Informal or formal frameworks, models, concepts and or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention, and reasons why the intervention was expected to work
  - Specific aims:
    – Purpose of the project and of this report

SQUIRE 2.0

• METHODS: WHAT DID YOU DO?
• Context:
  – Contextual elements considered important at the outset of introducing the interventions
• Interventions:
  – Description of the intervention in sufficient detail that others could reproduce it
  – Specifics of the team involved in the work
• Study of the Interventions:
  – Approach chosen for assessing the impact of the intervention
  – Approach used to establish whether the observed outcomes were due to to the intervention

SQUIRE 2.0

- **METHODS: WHAT DID YOU DO?**
  - Measures:
    - Measures chosen for studying processes and outcomes of the interventions including rationale for choosing them, their operational definitions and their validity and reliability
    - Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency and cost
    - Methods employed for assessing completeness and accuracy of data
  - Analysis:
    - Qualitative and quantitative methods used to draw inferences from the data
    - Methods for understanding variation within the data, including the effects of time as a variable
  - Ethical considerations:
    - Ethical aspects of implementing and studying the intervention and how they were addressed, including but not limited to formal ethics review and potential conflict of interest

• **RESULTS: WHAT DID YOU FIND?**

• Results:
  – Initial steps of the intervention and their evolution over time, including modifications made to the intervention during the project
  – Details of the process measures and outcome
  – Contextual elements that interacted with the intervention
  – Observed associations between outcomes, interventions and relevant contextual elements
  – Unintended consequences such as unexpected benefits, problems, failures or costs associated with the intervention
  – Details about missing data

SQUIRE 2.0

• DISCUSSION: WHAT DOES IT MEAN?
• Summary:
  – Key findings, including relevance to the rationale and specific aims
  – Particular strengths about the project
• Interpretation:
  – Nature of the association between the interventions and the outcomes
  – Comparison of the results with findings from other publications
  – Impact of the project on people and systems
  – Reasons for any differences between observed and anticipated outcomes, including the influence of context
  – Costs and strategic trade-offs, including opportunity costs

SQUIRE 2.0

• **DISCUSSION: WHAT DOES IT MEAN?**
  • Limitations:
    – Limits to the generalizability of the work
    – Factors that might have limited internal validity such as confounding, bias or imprecision in the design, methods, measurement, or analysis
    – Efforts made to minimize and adjust for limitations
  • Conclusions:
    – Usefulness of the work
    – Sustainability
    – Potential for spread to other contexts
    – Implications for practice and for further study in the field
    – Suggested next steps

• **OTHER INFORMATION**

• **Funding:**
  – Sources of funding that supported the work. Role if any of the funding organization in the design, implementation, interpretation and reporting

SQUIRE 2.0

• Allows for
  – Transparency
  – Description of the entire process
  – Accuracy of reporting
  – Reporting of the ‘doing’ and ‘studying’ of QI work

• Does not address
  – How to assess quality of evidence provided in the article
Users’ Guide for an Article Assessing Quality Improvement

• Insight into how to assess the quality of the article
• Emphasizes specific problematic features of QI articles
  – STUDY DESIGN
  – BIASES
    • Confounders, cluster effects, time trend effects
    • Generalizability and spread
    • Sustainability
    • Benefits, hassles, costs
  – DATA
    • Data quality, definitions, rigorous measurement
    • Size, precision and effect of the results
    • Outcomes and balancing measures

Fan et al.  JAMA 2010;304(20):2279-2287
Box 1. Users’ Guide for an Article Assessing Quality Improvement (QI)

Are the results valid?
Did intervention and control groups start with the same prognosis?
Were patients randomized? *If not, did the investigators use an alternative design that minimizes the risk of bias?*
Was randomization concealed?
Were patients in the study groups similar with respect to known prognostic factors?
If the QI intervention primarily targeted clinicians, was the clinician or the clinician group the unit of analysis?
Was data quality acceptable?
Was prognostic balance maintained as the study progressed?
To what extent was the study blinded?
Aside from the experimental intervention(s), were the groups treated equally?
Was the initial prognostic balance maintained at the completion of the study?
Was follow-up complete?
Were patients analyzed in the groups to which they were randomized or allocated? *a*
Was the trial stopped early?
What were the results?
How large was the treatment effect?
How precise was the estimate of the treatment effect?
How can I apply the results?
If the QI study focused on a process of care, what was the quality of evidence that the process improves patient-important outcomes?
Was follow-up sufficiently long?
Is the QI intervention exportable to my site?
Were all patient-important outcomes considered?
Are the likely benefits worth the potential hassles, harms, and costs?

*a* Points in italics represent guides specific to QI studies.
QI Designs That Work

• Stepped Wedge design
  – Sequential roll out of intervention study units (phases) over defined periods of time
  – Random and sequential crossover of clusters from control to intervention
  – All patients receive the intervention over time
  – Can randomize the order of interventions

• Step
  – Data and outcomes measure at the point where the patient enters the intervention

• Wedge
  – Observed differences in outcome in control vs intervention, then can say the change is attributable to the intervention
Stepped Wedge Design

• With individual recruitment and without concealment of allocation (blinding)
  – At risk of selection bias
  – Effect of the intervention might be confounded with temporal trends
• Each cluster contributes both exposed and unexposed data and therefore can act as its own control
• Time is associated with potential for changes in practice and new evidence so should be adjusted for in the analysis
• Rising tide effect
  – Prompting of the intervention or sentiment towards overall improvement may impact the effect side

Hemming K et al. BMJ 2015;350:h391
Fig 1 Schematic illustration of the conventional parallel cluster study (with variations) and the stepped wedge study.

K Hemming et al. BMJ 2015;350:bmj.h391
QI Designs That Work

• Interrupted time series design
  – Quasi-experimental design
  – Evaluates longitudinal effects of interventions through regression modelling

• Determines whether the intervention’s effect is present beyond the underlying trend
  – Well thought out/defined timelines for interventions

• Multiple measurements before and after
  – Allows a determination of regular variation and trends

• Intervention can be stopped and started multiple times or singularly

Kontopantelis E et al. BMJ 2015;350:h2750
Figure 1 Interrupted time series study design showing the 48-month timeline of the study, divided into pre-intervention, intervention, and post-intervention stage.
QI Designs That Work

• Controlled Before-After studies, uncontrolled Before-After studies
• Prospective design
• Specific data collected and outcomes measured before intervention and again after implementation
• Differences can be assumed to be related to the intervention
  – Difficult to identify appropriate control group
  – Subject to confounders that may not be measured or understood
  – Unable to confirm relationship as causal

Fan et al. JAMA 2010;304(20):2279-2287
Biases

• Cluster effect
  – Consideration for effect of environment or location of practice that influences the outcome
  – Improved when able to compare effects in different locations or types of practices

• Common biases
  – Attrition bias
    • Loss to follow up
  – Allocation bias
    • Unclear allocation of patients to intervention
  – Selective outcome reporting
    • Important outcomes omitted from results
  – Contamination
    • Crossover, adoption of the practice over time
Data Quality

• Units of analysis
  – Process and outcome measures
  – Clearly defined, rationale

• Collection as part of the QI study
  – Rigorous methods of data collection
  – Review of data collection
  – Training for data collection and abstraction

• Reporting of missing data
  – Should report sensitivity analyses if missing data proportion is large

• Balancing measures
  – Unintended consequences
  – Effects on other aspects of care

Fan et al.  JAMA 2010;304(20):2279-2287
Data Quality

• Follow up
• Critical in the setting of QI interventions
• Determines the sustainability of the intervention and the potential applicability in other settings
Data Quality Example

• A communication tool to improve situational awareness and promote proactive care is implemented in a Neonatal ICU
• Carried out over a study period of 6 months, and followed up again 3 months after the active intervention
• It demonstrates a decrease in need for ‘rescue’ therapies such as saline boluses and inotropes during the active study period
• The authors publish in a report that their intervention was a success and this approach should be adopted by NICUs as a standard of care
What do you think of the length of time that the authors chose to monitor the success of the intervention?

<table>
<thead>
<tr>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Too short</td>
</tr>
<tr>
<td>Just right, they demonstrated success, so no need to continue monitoring</td>
</tr>
<tr>
<td>Too long</td>
</tr>
<tr>
<td>Unsure</td>
</tr>
</tbody>
</table>
Generalizability

• When evaluating QI research for your own practice, must consider the context

• Aspects of context include
  – Physical aspects → circumstances, environment, equipment, skill, location
  – Cultural → motivation, training, appetite for change, providers, leadership, organizational climate
  – Resources → financial, stakeholder buy in

• The article should reveal an understanding of
  – Why, When and Where the QI methods used worked most effectively
  – Assumptions around the nature of the intervention as applicable to the context they were used
Other QI Research Evaluation Tools

• MUSIQ
  – Model for Understanding Success in Quality
• Conceptual model that can be applied to QI research to identify factors that lead to success in QI research.
• Can be used
  – Proactively in designing QI studies
  – Systematic way to describe and evaluate the contextual factors impacting on a project’s success
  – To guide the collection and analysis of data
• Identified 25 contextual factors that influence the success of QI research

Other QI Research Evaluation Tools

• Promoting Action on Research Implementation in Health Services (PARIHS)
  – Proposes that certain contextual elements are required in the successful implementation of evidence based practice improvements

• Theoretical framework suggests that implementation of research into practice is a function of
  – Nature of the Evidence (E)
  – Context/Environment into which it is implemented (C)
  – Nature of how the process is Facilitated (F)

• These elements should be described in high quality QI studies to demonstrate the rigor required of successful QI research

Kitson A et al. Quality in Health Care 1998;7:149-158
Figure 1  Linear implementation models.
Additional Considerations

• Interpretation of the data should include
  – Impact of the change on the intended outcome
  – Comment on the mechanism by which the intervention facilitated the change
  – Impact upon the system itself
  – Cost evaluation (financial, workforce)
  – Factors limiting validity and other limitations
  – Assessment of usefulness, and other applications of the work
  – Sustainability
  – Future implications
Summary

• Published research in the field of QI in healthcare should be subject to rigorous frameworks to ensure accurate and comprehensive reporting of findings
  – Users’ guides to the medical literature How to use an article about quality improvement
  – Squire 2.0

• Implementation of findings from QI research should take into account
  – The original context in which the implementation occurred
  – Cultural factors
  – Study Design
  – Data Quality
  – Risk of bias
THANK YOU