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Quality Improvement Oversight or Research? A Harmonized Oversight Process

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May 5, 2008

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Overview

- Background
- SickKids QI Review Process
- Results Thus Far
- Lessons Learned
- Next Steps

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Research & QI - Similarities

- Systematic
- Guided by data
- Varying degrees of complexity and methodological/statistical rigor
- Produces “generalizable” knowledge

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Research & QI - Differences

Research

- Distinct and separate from care delivery
- Participation is optional
- Independent review

QI

- Expected part of healthcare
- Implemented in the care delivery context in which it is carried out
- Participation not completely optional
- Frequently no review mechanism

Research & QI – "Grey Zone"

- **Designed** to be generalized
- Whether outcomes or processes are the targets
- Risk of harm to participants
- [Intent to publish]

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QI Oversight Goals - 2005

- Protect QI participants from harm
- Help distinguish QI from Research
- Improve organizational awareness of QI projects across the hospital
- Improve effectiveness of QI projects
- Ensure no additional barriers to QI
- Integrate with REB process

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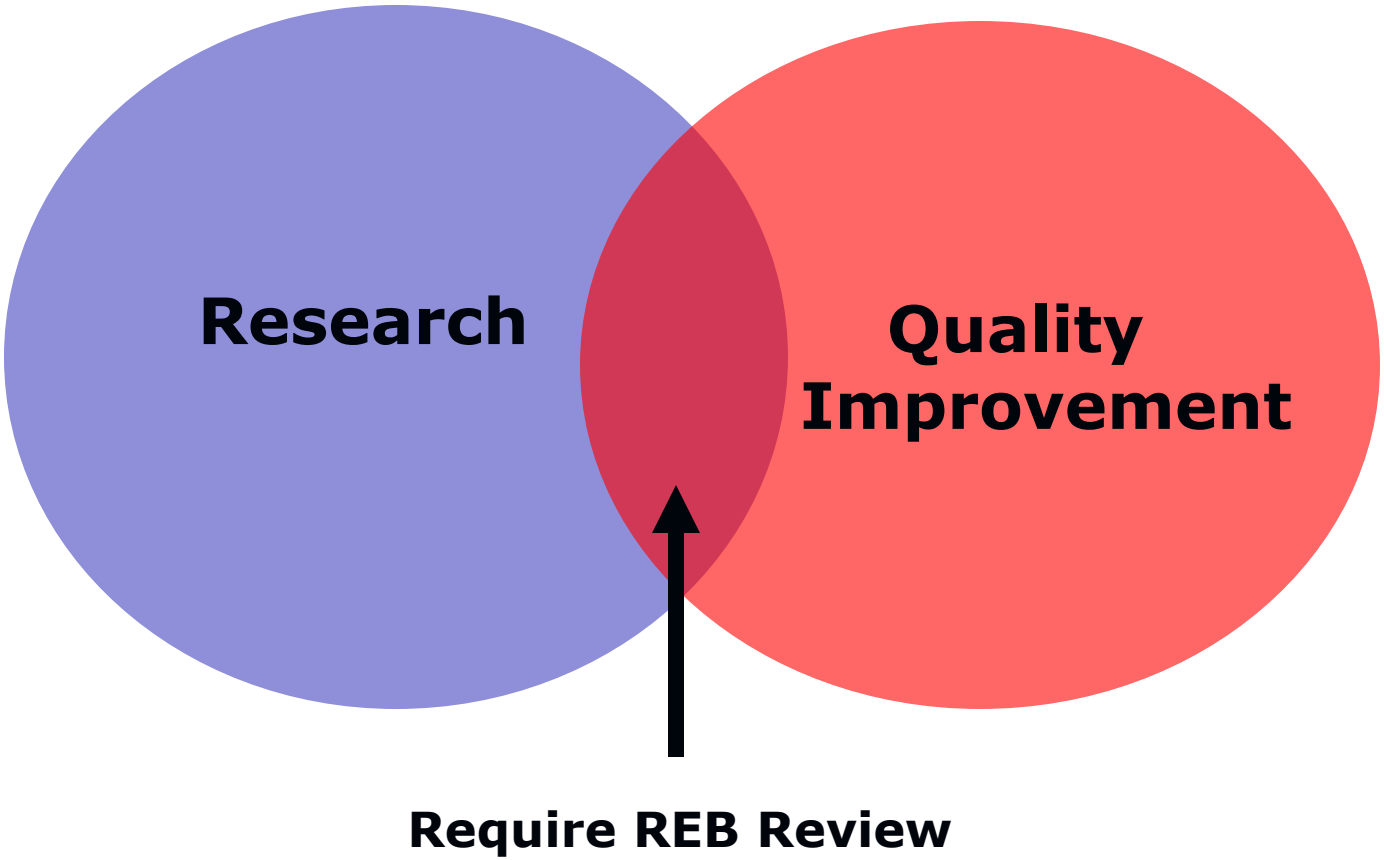
Grey Zone



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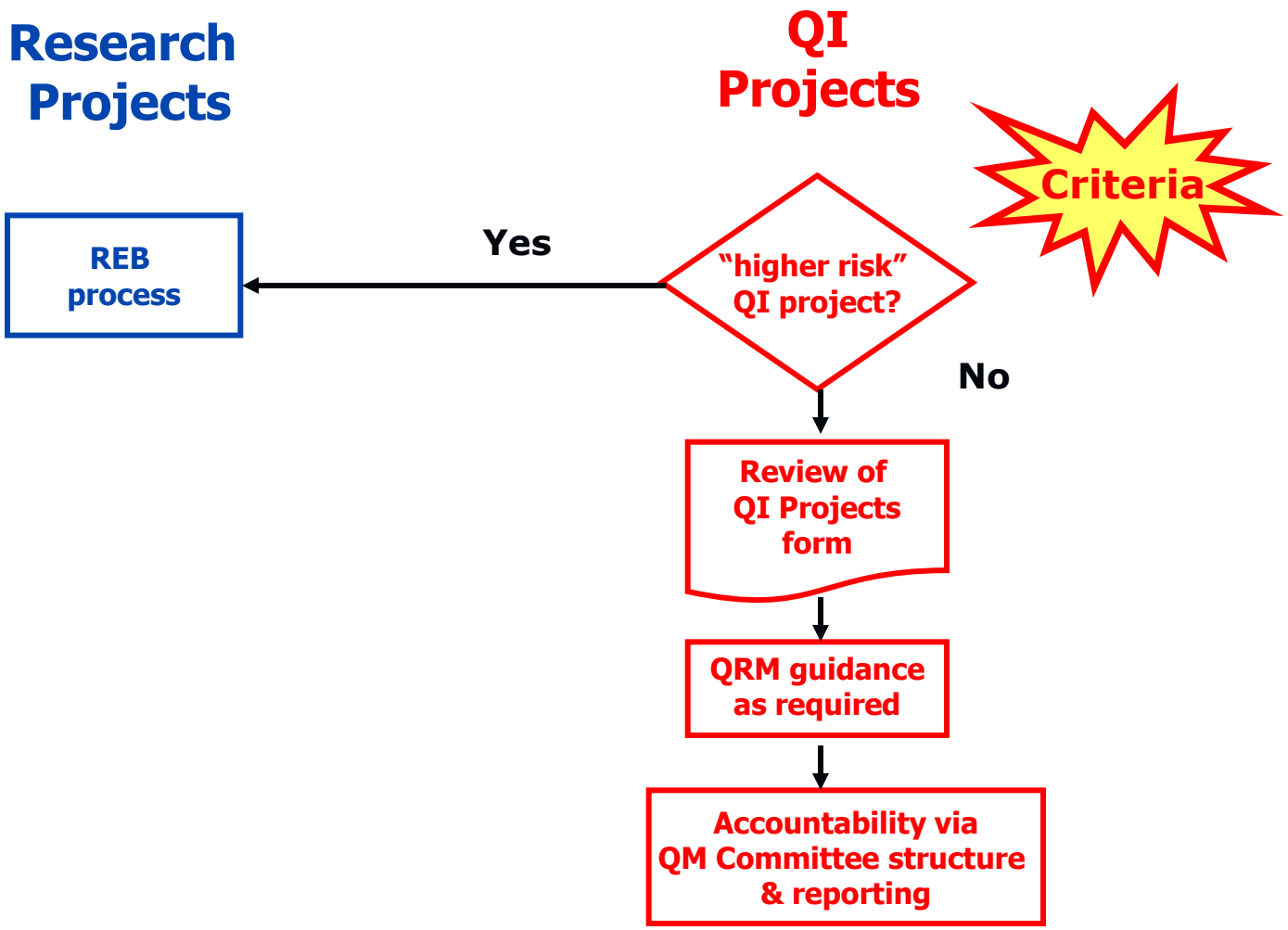
Process



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Criteria for REB Review

Not so magic

- The **primary** audience of the QI project is the external scientific community
- The QI project involves interventions that are untested or different than the current standard of care
- The QI project could pose risks to the participant
- The QI project involves additional burdens which are beyond what would be considered reasonable and outside what is required for the normal delivery of care

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Hospital-Wide Document

Welcome | Marie Pinard - All Documents | Marie Pinard - Calendar | Policies & Procedures - Approve... | Quality Improvement Projects

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Hospital-wide Administration
Policy, Procedure & Guideline

Valid only on date printed: 2007-01-30 14:59. Discard immediately after use!

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Quality Improvement Projects

Document | Approvers

Issuing Department:	Quality & Risk Management	**Category:**	Quality & Risk Management
Issuing Authority:	Polly Stevens	**Sub-Category:**	Quality Management
Section Name:	Quality Management	**Publication Status:**	Approved
Content Reviewer:	Marie Pinard	**Last Modified:**	2006-11-09 19:18
Additional Editors:	Marie Pinard, Polly Stevens	**Additional Readers:**	Melvin Freedman, Margo Farren, Ronald Laxer, Jennifer Pepper, Maggie Campbell, Kim Streitenberger, Cheryl Jackson, Alastair Hodinott
Written By:	Marie Pinard - Quality & Risk Management	**Review Committee Name:**	Quality & Utilization Steering Committee

1.0 Introduction

Quality Improvement (QI) activities are an essential and integral part of delivering health care.[1,2,5] It is acknowledged that the benefits of participating in QI projects should be balanced against the potential risks of harm to patients, families, staff and the hospital. The purpose of this document is to encourage and facilitate QI activities at The Hospital for Sick Children (SickKids), while improving their effectiveness and mitigating any potential harm to the participants. A secondary purpose of this document is to help clarify the distinction between

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QI Projects Review Form

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Review of Quality Improvement Projects

This form must be completed for all "lower risk" QI projects*. Submit completed forms to the Quality & Risk Management Department via email, internal mail or in person.

Note: Cells will expand to fit text Attachments included: Yes ☐ No ☐

a) Cluster / Department: Hospital-wide QI project Y ☐ N ☐
b) QI project contact name: Phone:
c) Supervisor/Director sponsoring or involved with QI project:
d) Why are you undertaking this QI project (background)? What is the change intended to achieve?
e) Brief description of QI project (alternatively other documents that contain this information may be submitted):
f) List of key stakeholders involved with QI project (who will be affected?):
g) How will the QI project be evaluated? What type of data will you be collecting? Please attach any data collection tools developed (including surveys).
h) Will you be interacting directly with humans (patients, families, staff, and community partners) to evaluate the QI project? i.e. using surveys, collecting data, conducting focus groups or performing tests directly with participants and specifically related to your QI project? Yes ☐ No ☐
i) Will you be testing or conducting a pilot of your improvement? Yes ☐ No ☐
j) What is the timeline for your QI project? Approximate start date: Approximate end date: Ongoing activity ☐
k) How will the results of the QI project be disseminated?

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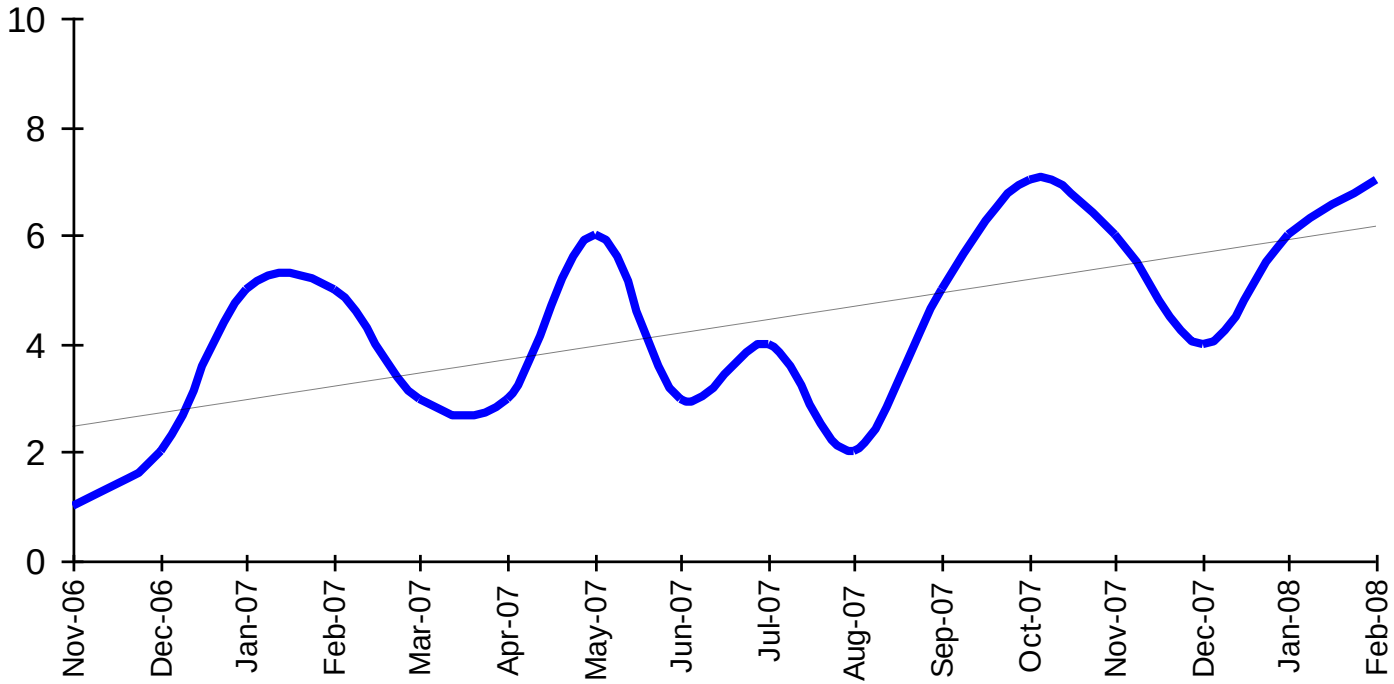
QI Project Review Process

- Completed forms submitted to Quality & Risk Management
- Each project reviewed by two Quality Analysts
- Questions and concerns are discussed with the Chair of the REB as they arise
- Response within 10 business days
- Individuals are asked to report final results of project to QRM

QI Projects Submitted



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Results – As of Feb08

71 submissions

- 3 approved
- 58 approved with recommendations
- 4 requested to resubmit
- 4 referred to REB
- 2 other

293 recommendations

- Average 4.1 per submission (range 0-14)
- Privacy & data security
- data collection tools
- project aim, endorsement and timing

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Observations Thus Far

- Earlier consultation with QRM staff
- Staff still want to discuss project prior to submission
- Anecdotally, the form is easy to complete
- Publication as research criteria is entrenched (but lessening)

Observations Thus Far

- Increasing complexity of projects submitted
- Increasing number of interdisciplinary projects
- Increasing project “addendums”
- More “overlap” projects

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Lessons Learned & Next Steps

- Include QI publications guidelines
- Improvements to form & process
  - Template and electronic option
  - Database
  - Streamline response process
- Assess workload for QRM
- Involve local QM Leaders in reviews
- Continue to monitor the landscape

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Lessons Learned & Next Steps

- Complete evaluation
  - Review QM quarterly reports
  - Follow up with projects submitted
  - User feedback
- Refine criteria and/or language used
  - Move from “risk” to “overlap”
  - Shrink grey area?
  - Address project “evolution”
- Integrate privacy & data security
- Integrate Clinical Innovations process

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Thank You

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Additional Slides

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Background & Definitions

What is the Difference?

- Research
- Quality Improvement

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Research

- Involves a systematic investigation to establish facts, principles or **generalizable** knowledge
- Uses scientific methods and standardized protocols
- May involve human subjects through their physical participation and/or through collection or use of personal health information and tissues

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Quality Improvement (QI)

- Covers a broad range of activities
- Primary purpose is to monitor, evaluate or improve the quality of health care delivered
- Change in operational context in which they are carried out
- Usually involve small tests of change for which rapid feedback is examined for trends prior to broader implementation in the local or organizational setting

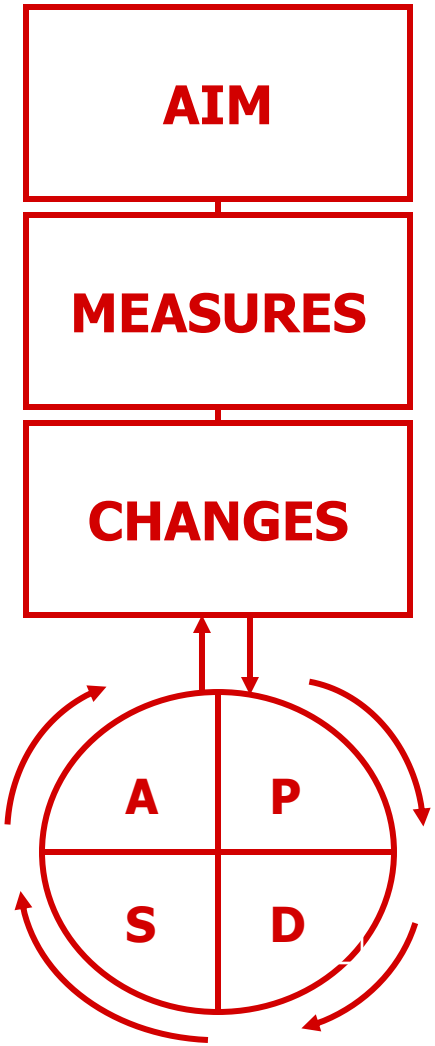
The Improvement Model

Objectives

Methods

Results

Conclusions



What are we trying to accomplish?

How will we know we have made an improvement?

What changes can we make that will result in improvement?

Plan

Do

Study

Act

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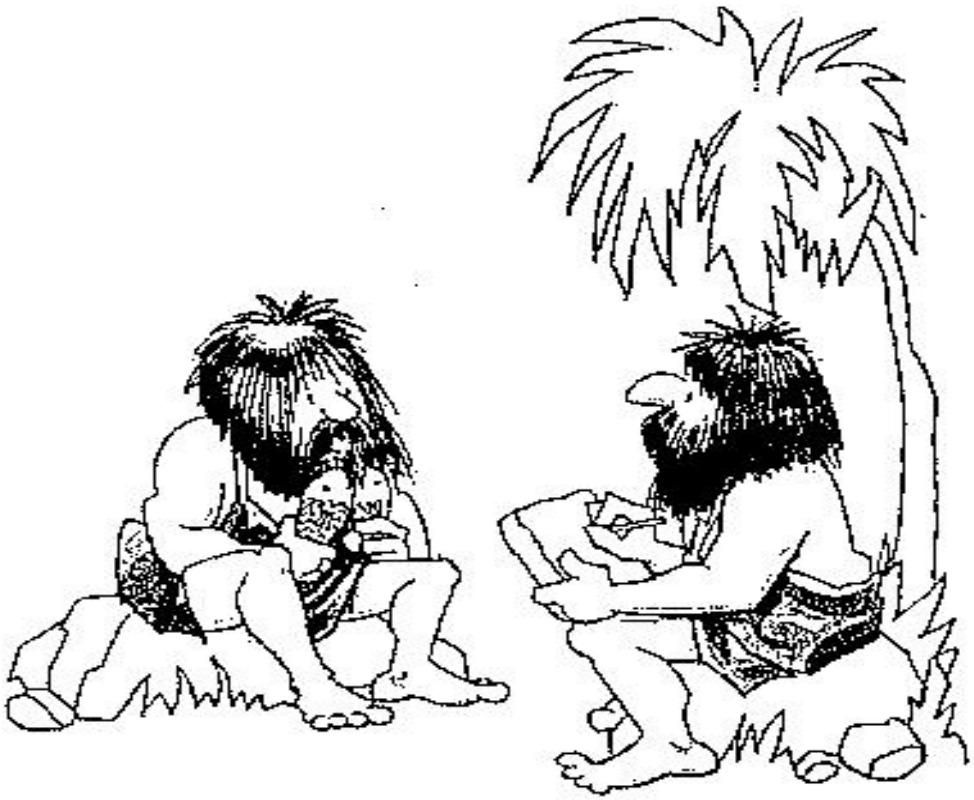
"Negative results on the fish… Let's try rubbing two sticks together."



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The Continuum of Change in Healthcare

Clinical Practice

- Adaptation, innovation
- At the individual patient level

Quality Improvement

- Systematic experiential learning
- Operational context
- Rapid feedback of trends that shapes changes

Clinical Research

- Distinct from clinical care
- Designed to contribute to scientific knowledge

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Making a Case for QI Oversight

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Why Distinguish?

- Oversight
- Research has a comprehensive and well-established oversight mechanism

- Research Ethics Board (REB)

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Why Now?

- The lines between research & QI are becoming increasing "blurred"
- Greater rigor, dissemination of QI efforts
- Healthcare reform
- Quality Management requirements (accreditation, academic affiliations etc.)
- Patient Safety movement
- QI methodologies and approaches borrowed from other industries
- Publicized cases

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Is There Risk of Harm With QI?

- Over burdening QI participants
  - Over-surveying
  - Excessive time
  - Stress
- Poorly designed or executed QI projects
- Privacy and confidentiality issues
- Potential consent issues
- Other

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Ethical Requirements

Research	QI
▪Social or scientific value	▪QI project is of benefit & justify resources/risks
▪Scientific validity	▪QI project uses sound principles/methodology
▪Fair subject selection	▪Fair distribution of burdens of QI project

(Adapted from references 5 & 6)

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Ethical Requirements (cont'd)

- Favourable risk/benefit ratio
- QI participants are not subject to undue risks
- Informed consent
- Permission of participants when appropriate
- Respect for participants
- Privacy and confidentiality principles are maintained
- Independent review
- Appropriate ethical review and supervision

(Adapted from references 5 & 6)

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Oversight for QI

What kind of oversight is needed?

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REB Oversight of QI?

Yes

- Resource intensive
- Intimidating process
- Somewhat counter intuitive to QI
- Roadblocks to QI
- Beyond REB mandate?

No

- Potential harm to participants
- Potential for wasted efforts and therefore hospital resources

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Literature & Landscape on this topic

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What Are Others Doing?

- Increasing attention in the literature
- Moving beyond the Quality field
- Varying opinions, focusing largely on differentiating between QI and research

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Tri-Counsel Statement

"Quality assurance studies, performance reviews or testing within normal educational requirements should also **not** be subject to REB review."

Article 1.1 (d)

SickKids REB (before Nov06)

REB FAQ

"If we anticipate **publishing** the results of changes in our delivery of clinical care i.e., program improvements, do we need REB approval?
- Yes"

REB Expedited Review Criteria

"The study involves non-invasive product testing, Phase IV drug or medical device testing, or **quality assurance activities and publication is planned**."

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Literature & Landscape

- National Committee on Quality Assurance (US, 2004)
- National Health & Medical Research Council (Australia, 2003)
- Alberta Research Ethic Community Consensus Initiative (2005)
- Hastings Center Special Report (US, 2006)
- Johns Hopkins case (2008) – Office for Human Research Protection

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Publication as Criteria

"Publication is not a definitive feature of research. There is research done that is never published and there's lots of publications out there that have nothing to do with research."

Dr. M. Carome, Office for Human Research Protection – Secretary's Advisory Committee on Human Research Protection, 2004

"The intention to publish does not by itself determine the primary purpose of a project."

Alberta Research Ethics Community Consensus Initiative, 2005

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Extra Notes

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QI Oversight Working Group

- Marie Pinard, Quality & Risk Management
- Dr. Melvin Freedman, Chair, Research Ethics Board
- Polly Stevens, Director, Quality & Risk Management
- Dr. Ronald Laxer, Vice-President, Education and Quality
- Margo Farren, Manager, Research Ethics Board

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Project Plan

- Establish Working Group
- Review of Literature / Benchmarking
- Develop Project Principles & Framework
- Develop QI Project Review Process
- Determine Criteria Requiring REB Review
- Develop QI Projects Policy & Procedure and QI Form
- Obtain Approval of QI Projects Policy & Procedure
- Pilot QI Oversight Process
- Implement QI Oversight Process
- Evaluate QI Oversight Process

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