Settling (Only) for the Best: Shaping Excellence in ICU

Quality Improvement: Ethical Imperatives and Ethical Implications

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The Ethics of Using Quality Improvement Methods in Health Care

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Hastings Center Leadership Convention Definition:

- systematic, data-guided activities to bring about immediate improvements in healthcare delivery
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• **intrinsic part of normal healthcare operations**
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- intrinsic part of normal healthcare operations
- both clinicians and patients have ethical responsibility to participate
- most QI activities are not ‘human subjects research’ and need modified professional & ethical oversight
Professional Ethical Obligations

• Professional societies require
  – practice competence
  – competence to improve their own practice

• We have a professional ethical responsibility to serve patients by improving quality of care

• …..as long as professional risk is minimal and confidentiality is ensured
Patient Ethical Obligations

• Patients declining to participate in this normal part of healthcare operations constrain the efforts of the healthcare system to improve itself and jeopardize public benefits sought by QI.

• Responsibility does not pivot only on whether patients derive benefit or harm, but on societal benefit or ‘public good’.

• …as long as patient risk is minimal and confidentiality is ensured.
Patient Ethical Obligations

- Patients declining to participate in this normal part of healthcare operations constrain the efforts of the healthcare system to improve itself and jeopardize public benefits sought by QI.

Especially in a publically funded healthcare system, so care can be monitored & improved for the benefit of all…

- …as long as patient risk is minimal and confidentiality is ensured.
QI Studies
That Neither Help
QI Observational Studies that Neither Benefit Nor Harm Index Patients

- Registries
- Audits
- Utilization reviews
- Observational studies (non-interventional)

.....whether retrospective or prospective
Favouring Informed Consent
For QI Observational Studies

- Respect for persons
- Patient autonomy
- Minimize chance of harm
  - Overzealous application of intervention
    (wrong patients, too early, too late, too long)
  - Inattention to other interventions
  - Privacy violation
Favouring Waived Consent For QI Observational Studies

• No to minimal risk
• Need representative, unbiased data
• Consent often impractical
• Results benefit future patients
• Obligation (especially in universal healthcare system)
• Consent still needed for interventions (e.g., interviews, blood work)
Written informed consent and selection bias in observational studies using medical records: systematic review

Michelle E Kho, registered physical therapist and PhD student, Mark Duffett, clinical pharmacist and assistant professor, Donald J Willison, associate professor, Deborah J Cook, practising intensivist, clinical trialist, and professor, Melissa C Brouwers, associate professor, provincial director

**Objective:** to determine whether mandatory informed consent introduces selection bias in observational studies using medical record data

**Methods:** systematic review of prospective observational studies reporting characteristics of participants & non-participants approached for informed consent to use their medical records
Results: consent rate 67% for use of medical record data among 161,604 persons

Significant differences between participants and non-participants (e.g., age, sex, SES, health status, outcome, etc) in 17 studies

Inconsistent magnitude & direction of effect

Impact of authorization bias is problematic and unpredictable
• **Objective:** to examine the impact of attempts to obtain informed consent on participation rates and patient characteristics in Canadian Stroke Registry

• **Purpose of Registry:** to monitor and improve the quality of stroke care in Canada
• **Methods:** from 20 hospitals, encrypted, password-protected de-identified data were electronically submitted to the Institutes for Clinical Evaluative Sciences in Toronto.
• Results:

• Consent frequently not obtained (early death or discharge, patient not present when visited, patient or family declined)

Phase 1: June 2001-Feb 2002 participation rate 39.3%
Interim: decreased data collection
Phase 2: June 2002-Dec 2002 participation rate 50.6%
Figure 2. In-Hospital Mortality Rates among Patients Who Participated or Did Not Participate in Phase 2 of the Registry of the Canadian Stroke Network, According to Hospital.
Conclusions:
Informed consent for a stroke registry led to
- low participation rates
- invalid data
- waste (one third of research coordinator’s time and $500,000 from CIHR spent on attempting consent)
- underscored need for waiver of informed consent for minimal risk QI studies
QI Studies
Designed to Improve
Which Strategies Improve Care?

- checklists
- guidelines, protocols, bundles
- opinion leaders
- education
- reminders
- audit and feedback
- multiply redundant approaches
- layered approach
- customized approach
- network membership
- teaching clinicians quality improvement
- pay for performance
An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU

Peter Pronovost, M.D., Ph.D., Dale Needham, M.D., Ph.D., Sean Berenholtz, M.D., David Sinopoli, M.P.H., M.B.A., Haitao Chu, M.D., Ph.D., Sara Cosgrove, M.D., Bryan Sexton, Ph.D., Robert Hyzy, M.D., Robert Walsh, M.D., Gary Roth, M.D., Joseph Bander, M.D., John Kepros, M.D., and Christine Goeschel, R.N., M.P.A.

- Central line cart in 103 ICUs with a checklist for
  - Handwashing
  - Full barrier precautions
  - Chlorhexidine
  - Avoiding femoral site
  - Removing catheter as soon as possible
The Keystone Project Saga
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• Funded by AHRQ, sponsored by the Michigan Health & Hospital Association

• Johns Hopkins exempted it from federal regulations governing human subjects research
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- One year post publication in Dec 2007
  - Office of Human Research Protections terminated any further data collection on the grounds of no informed consent from patients
Harming through Protection?
Mary Ann Baily, Ph.D.

• “You know you are in the presence of dysfunctional regulations when people cannot tell what they are supposed to do!”

• Is it appropriate to ask patients & families whether they would like to opt out of hospital efforts to ensure the use of proven precautions against deadly infections?
The Keystone Project Saga

**Human subjects research**

- Risks variable
- Not participating induces ‘usual risk’
- Patient informed consent usually possible
- Goal is to create generalizable knowledge to inform future optimal care
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Human subjects research
– Risks variable
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Quality Improvement
– Risks zero to minimal
– Risks of not participating are substantial
– Patient informed consent nearly impossible
– Goal is to ensure patients receive optimal care
The Common Rule Permits Waiver of Informed Consent If

- Research involves no more than minimal risk to patients
- Waiver will not adversely affect rights & welfare of the subjects
- Research could not be practically conducted without waived consent
- When appropriate, participants will receive pertinent information about the research
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QI Studies
Multicentre, cluster-randomized clinical trial of algorithms for critical-care enteral and parenteral therapy (ACCEPT)


11 community + 3 teaching hospitals randomly allocated to education, reminders, detailing vs usual approach to nutrition
A Multifaceted Intervention for Quality Improvement in a Network of Intensive Care Units
A Cluster Randomized Trial

Damon C. Scales, MD, PhD
Katie Dainty, MSc, PhD
Brigette Hales, MSc
Ruxandra Pinto, PhD
Robert A. Fowler, MDCM, MS
Neill K. J. Adhikari, MDCM, MSc
Merrick Zwarenstein, MBBCch, PhD

- Education
  - Videoconferences
  - EB bibliographies & summaries
  - Local opinion leaders
- Reminders
  - Posters, pocket cards
  - Preprinted orders, checklists
- Audit and feedback
  - Daily audit
  - Monthly performance reports
Change over time

Difference between groups

### Semi-recumbency
- Ratio of ORs: 3.12 (95% CI, 0.79-12.41); P = .11
- Control: 497, 563, 610, 569
- Intervention: 297, 222, 335, 260

### CRBSI
- Ratio of ORs: 17.55 (95% CI, 4.72-65.26); P < .001
- Control: 42, 37, 40, 29
- Intervention: 30, 29, 39, 34

### DVT prophylaxis
- Ratio of ORs: 2.49 (95% CI, 0.80-7.70); P = .11
- Control: 231, 193, 221, 184
- Intervention: 194, 218, 214, 202
Consent Requirement Causing Bias in Cluster RCTs
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- Consider cRCT to test a KT strategy to encourage uptake of a practice guideline
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- Characteristics of persons with different propensities to consent are in intervention and control arm → selection bias.
Consent Requirement Causing Bias in Cluster RCTs

- Consider cRCT to test a KT strategy to encourage uptake of a practice guideline.
- Characteristics of persons with different propensities to consent are in intervention and control arm → selection bias.
- Control group changes behaviour in accord with guideline, attenuating effect of KT strategy → response bias.
When is informed consent required in cluster randomized trials in health research?

Andrew D McRae¹,²,³*, Charles Weijer¹,³,⁴, Ariella Binik³, Jeremy M Grimshaw³,⁵,⁶, Robert Boruch⁷, Jamie C Brehaut⁵,⁸, Allan Donner¹,³,⁹, Martin P Eccles¹⁰, Raphael Saginur¹¹, Angela White³ and Monica Taljaard³,⁵,⁸
• Research could not be practically conducted without waived consent
  – large group size, not possible to approach persons at time of randomization, cost too great, logistically infeasible

• Or bias would result
  – selection bias, response bias
Different, But The Same Bottom Line

• **Research**
  • History of abuse
  • Researcher & patient interests may conflict
  • Variable risk

• Consent usual
  • Validity optimal with full participation

• **Quality Improvement**
  • No ethical scandals
  • Interests generally align with patient interests
  • Usually presents lower risk than standard care
  • Consent not mandatory
  • Validity optimal with full participation
Summary
Summary

• We know that
  – Privacy legislation requiring consent can bias QI studies
  – Ethical principles, guidelines and professional documents support a waiver of informed consent for QI studies using medical record data and studies implementing best practices based on strong evidence

• I believe that
  – QI is integral, not optional
  – Individually and collectively, we have a moral responsibility to improve patient care
  – It is unethical to undertake invalid research
Thank You