Oversight on the borderline: Quality Improvement and Pragmatic Research

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I have no conflicts of interest to disclose.
This presentation is based on the work of the QI and Pragmatic Trials Workgroup of the NIH Collaboratory/ PCORnet Ethics and Regulatory Task Force

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A (very) brief history of human subjects oversight

• 1974 National Research Act creates the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research

• 1979 Belmont Report Released
  – “statement of basic ethical principles and guidelines to assist in resolving research problems”
  – Respect for Persons
  – Beneficence
  – Justice
Federal definitions

- **Research** - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

- **Human Subject** - a living individual about whom an investigator conducting research obtains:
  - data through intervention or interaction with the individual, or
  - identifiable private information
Current oversight through implementation of the “Common Rule”

- Assessment of Risks and Benefits
  - Nature and scope, systematic assessment
- Selection of Subjects
- Elements of Informed Consent
  - Information, comprehension, voluntariness
- All under the Office of Human Research Protection, 45 CFR Part 46, part A, (the Common Rule)
- Special protections for children
Contrast with “Healthcare Operations”...
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- Routine Healthcare operations do not require oversight as human subjects research, but are regulated in many other ways by local, state, federal, and professional bodies.
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- Quality improvement activities are considered part of routine operations.
Current concern that the oversight regime requires updating
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- Current research oversight system has generally worked well in:
  - Protecting patients from potential harm in research, particularly trials of experimental treatments
  - Maintaining voluntariness of participation (autonomy)
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  – Pragmatic research about existing clinical alternatives
  – QI related research
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• Major revision of the Common Rule now underway...
What do we mean by Pragmatic Research, QI, and QI Research??
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• QI Research: creation of generalizable knowledge about methods for measuring and improving health care quality, or that utilize quality improvement tools and strategies in study design or intervention.
Relation of QI and QI research
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Relation of QI and QI research

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Relation of QI and QI research

**Research**

Pragmatic Research on Clinical Alternatives (diagnostic, therapeutic, care delivery) → Knowledge of best alternatives in particular patients or setting → Accepted Clinical Standards
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- Implementation and spread using QI (and other methods)
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QI and Research: where do we draw the line
QI and Research: where do we draw the line

• When does “learning from data” become “seeking generalizable knowledge”?
QI and Research: where do we draw the line

- When does “learning from data” become “seeking generalizable knowledge”?
- When does “measurement” become “systematic collection”?
QI and Research: where do we draw the line

- When does “learning from data” become “seeking generalizable knowledge”?
- When does “measurement” become “systematic collection”?
- How do we think about “routine operations” in a Learning Health System with “best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience”? (IOM Roundtable on Value and Science-driven Health Care)
What’s special about QI research?

• We are studying “meta” issues compared to direct biological/clinical effect (though the interventions may have biological effects)
• Potential harms generally different in both magnitude and type.
• Interventions often at the system level
• Interventions could typically be implemented within current care, often without measurement to assess whether they worked.
• How care is mediated by clinician-patient relationship and health systems structures
Ethical Issues in a learning health care system: Hastings Center Report 2013

- Lines between system learning and research.
- Role of the IRB or other oversight.
- Issues of consent in system level tests of change.
- Ensuring patient privacy in a digital, learning system
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The research-treatment dichotomy

• Kass and Faden\(^1\) question core tenets of the distinction:
  – Generalizable knowledge as the criterion for ethical oversight
    • “In a learning health care environment, practice is a continuous source of data for the production of generalizable knowledge, and the knowledge that is produced is used to continuously change and improve practice.”
  – “Systematic data collection” is now part of practice
  – Research may or may not present less clinical benefit or increased burden/risk

\(^1\)Kass NE et al. Hastings Center Report 2013
A risk-based framework?

- Working group of the IOM Roundtable on Value and Science Driven Health Care proposes a framework of oversight based primarily on risk.

<table>
<thead>
<tr>
<th>Operations</th>
<th>Information-only</th>
<th>Minimal</th>
<th>Greater</th>
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<tr>
<td>institutional oversight</td>
<td>institutional oversight no IRB oversight no consent needed</td>
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<td>other operations</td>
<td>IRB oversight consent requirement determined by IRB HIPPAA research standards</td>
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\(^1\)Selker H et al. The Common rule and continuous improvement. IOM 2012
QI and Pragmatic Trials Workgroup of the NIH Collaboratory PCORnet Ethics and Regulatory Task Force

• Multi-stakeholder perspective
  – Researcher
  – Clinician
  – Legal/Ethics
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- Overarching premise: all activities related to health care must occur in a framework of oversight that addresses ethical principles.

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Two questions addressed by the workgroup:

• What QI activities should have explicit ethical oversight in order to help ensure adherence to fundamental ethical principles of health care?
• Are there special considerations in the oversight of pragmatic QI research activities that optimally protect patients and other participants yet allow for rapid system learning?
Attaching names is challenging...
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- Differentiation of activities for appropriate oversight
  - Routine QI
  - Non-Routine QI
  - QI Research
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• Who decides which category applies?
• Who provides ethical oversight?
Criteria for consideration of projects (no bright line test)

- Purpose
- Sponsorship and leadership
- Locus of control of intervention/clinical decisions
- Ability of individuals to opt out
- Data analysis/monitoring
- Dissemination plan
- Expected application of findings
- Accountability and regulatory issues
- Stakeholder engagement
Routine QI

- A Children’s Hospital identified that 35% of the time patients with asthma were discharged with a written asthma treatment plan that included all 7 elements as required by The Joint Commission
  - A multidisciplinary team convened to define set roles, responsibilities for improving this process
  - Data was collected monthly and reported to team and oversight committee
  - PDSA cycles run to test different strategies for improvement
  - The team was interested in presenting their work at various regional and national meetings

Courtesy D. Hyman, MD
Routine QI: oversight by clinical program leadership

- Are interventions to promote standard or established care?
- Does the project further the goals of the clinical leadership and team?
- Are there additional risks to patients because the project is underway?
- Are data collection burdens consistent with what is expected in routine care and organizational improvement?
- Are there additional privacy concerns?
Intent to publish as a criterion? No.

• The Office for Human Research Protections (OHRP), states “intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research.”

• Other health systems may learn from QI approaches, even if the project has not answered a specific research question.

• However, such dissemination must be described as a QI activity, and not make claims of new knowledge generation using typical standards of clinical or health services research.

Non-routine QI
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• Each participating program chooses which interventions to implement in rapid cycle tests of change (PDSA cycles).
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• All agree to track and share outcomes measures (deidentified) with all other sites.

• There is intent to share (through publication of a “quality report”) what works best in specific settings.
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  - Include QI experts, clinicians, system leaders
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• IRB’s may take on this role but may not have the expertise in all areas.
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- A design in which patients are randomized (by day of week) to receive the “improvement”?
QI Research Example

• Improving Chronic Disease Management with Pieces (ICD-Pieces) trial

www.nihcollaboratory.org/demonstration-projects/Pages/ICD-Pieces.aspx
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- Tests a novel technology that leverages data from EHR’s to identify patients with chronic kidney disease, diabetes, and hypertension, and provides clinician support to monitor therapies and measure outcomes.

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• Tests a novel technology that leverages data from EHR’s to identify patients with chronic kidney disease, diabetes, and hypertension, and provides clinician support to monitor therapies and measure outcomes.
• Research question: does incorporating new IT facilitate collaborative care.

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Oversight: IRB

• Tests system level change.
• Designed to provide generalizable knowledge about average effect, across many contexts.
• Robust number of participants and measurement strategy designed to determine results with certainty typical of health services research.
• Funded as research.
Our conclusions

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• 1. Health care organizations should have systematic, transparent processes for designing activities as QI or research and determining what independent evaluation each will receive.
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• 2. Health care organizations should have formal and explicit oversight of Non-QI activities.

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• 1. Health care organizations should have systematic, transparent processes for designating activities as QI or research and determining what independent evaluation each will receive.

• 2. Health care organizations should have formal and explicit oversight of QI activities.

• 3. QI-related research should be reviewed by an IRB; for such review to be effective, IRB’s should develop particular expertise in assessing QI studies.

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• 3. QI-related research should be reviewed by an IRB; for such review to be effective, IRB’s should develop particular expertise in assessing QI studies.

• 4. Stakeholder engagement should be included in the review of QI and QI-related research proposals and implementation.
We live in the real world: current guidance from OHRP

- QI does not need IRB review. Research does. QI includes:
  - Implementing a practice to improve the quality of care
  - Collecting patient or provider data regarding implementation for “clinical, practical, or administrative uses.”

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- Human subjects research definition per HHS applies to pragmatic trials as well
- Minimal risk research can receive expedited review (not exemption).

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Notice of Proposed Rule Making (NPRM) to Modernize the Common Rule (9/8/15)

• By HHS and 15 federal agencies
• Followed an Advanced Notice of Proposed Rule
  – Exclusions for activities that are not research, are low risk, or covered by other protections
  – New process for exemption without IRB review
  – Requirement for a single IRB for multi-center studies
  – Extend scope to cover all clinical trials (regardless of funding source) at any institution that receives federal funding
New exclusion for QI activities: we may have a problem

- The exclusion for QI 101(b)(1)(iv) currently states:
  101(b)(1)(iv) “Quality assurance or improvement activities involving the implementation of an accepted practice to improve the delivery or quality of care or services (including, but not limited to, education, training, and changing procedures related to care or services) if the purposes are limited to altering the utilization of the accepted practice and collecting data or biospecimens to evaluate the effects on the utilization of the practice.”
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• Awaiting the revision of the Common Rule...

• (Spoiler alert: it won’t solve all of the issues.)
The floor is open...