

Appropriate Oversight of QI Activities: An Ethical Issue

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Background

Uncertainty about the relationship between data-guided quality improvement activities and the federal regulations for the protection of human research subjects

Example:

Pronovost ICU infection control work

Hastings Center/AHRQ Project:

“The Ethics of Using QI Methods to Improve Health Care Quality & Safety,”
Hastings Center Report Special Report,
36:4, July-August, 2006, S1-S40.

Special Report and book of background papers available for free download at:
www.thehastingscenter.org

Questions

- What is QI and what is its role in health care?
- What ethical requirements should QI activities meet?
- What institutional arrangements are needed to ensure that QI activities are conducted ethically?

What is QI?

- Systematic data-guided activities
- Designed to bring about immediate improvements in health care delivery
- In particular settings
- Through a wide variety of methods.

QI can look like:

- A type of practical problem-solving
- An evidence-based management style
- The application of a theory-driven science of how to bring about organizational change

Related Categories

- Clinical & Managerial Practice
- QI
- Research

QI vs. Clinical & Managerial Practice

- Clinical & managerial practice includes innovation and adaptation.
- QI is DATA-GUIDED C & M innovation and adaptation.
- QI is an integral part of normal health care operations.

QI is not completely optional for health care professionals, organizations, and patients.

What is Research?

(Federal Definition)

- A systematic investigation
- Including research development, testing and evaluation
- Designed to develop or contribute to generalizable knowledge

QI vs. Research

- QI is closely linked to the implementation of change in the setting in which it occurs, whereas research is a distinct enterprise.
- Participation in research is optional, whereas participation in QI is not completely optional.

QI vs. Research

- QI can produce knowledge that is useful to others.
- The intent to publish does not distinguish QI from research.

Ethical Requirements for QI

See table from:

Lynn, J., M.A. Baily, M. Bottrell, etal. "The Ethics of Using Quality Improvement Methods in Health Care," *Annals of Internal Medicine* 2007;146 (9):666-673.

Significant Differences in Ethical Requirements for QI

- Informed consent
- Independent review

Informed Consent for Patient Participants in QI

- Background consent to inclusion in minimal risk QI activities as part of consent to treatment
- Informed consent to inclusion in specific QI activity that represents more than minimal risk
- Patient risk is measured relative to risk in standard health care
- Confidentiality is protected

Informed Consent for Health Worker Participants in QI

- Informed consent to inclusion in specific QI activity that represents more than minimal risk to worker BUT
- Worker risk is measured relative to risk in usual work situation and DOES NOT INCLUDE risk that QI will show the worker to be incompetent or unnecessary

Independent Review

There must be accountability for the ethical conduct of QI, but the IRB process is not the right approach.

Problems with IRB Review of QI

- IRB process has high transactions costs.
- IRB process does not fit the structure of many QI activities.
- Ethical principles must be interpreted in the light of both the activity's characteristics and the environment in which it is carried out.
- Requiring IRB review creates a disincentive for systematic monitoring and evaluation of change.

Conclusion

NO:

Export QI to IRB-based system for protection of human subjects of research.

YES:

Import protection of human participants in QI into a transformed accountability system for clinical care.

Needed to Ensure Ethical Conduct of QI

- Guidance on ethical requirements
- Accountability structure
 - Internal (within orgs)
 - External (across orgs)

Tough Questions

- What ethical oversight is appropriate for activities that are BOTH QI and Human Subjects Research?
- How do we determine which activities fall into this overlap category?

Internal QI Accountability Categories

- Professional responsibility for QI
- Local management review and supervision of QI
- QI-IRB review and supervision of QI/Human Subjects Research overlap activities

Policy Options

- Reinterpret regulations
- Change regulations
- Pass new legislation
- Act to facilitate QI work within current regulatory framework

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