The Common Rule and Continuous Improvement in Healthcare

A Learning Health System Perspective

Based on October 2011 IOM Discussion Paper by
Harry Selker, MD, MSPH *(Tufts Clinical and Translational Science Institute and Tufts Medical Center);* **Claudia Grossmann, PhD** *(Institute of Medicine);* **Alyce Adams, PhD** *(Kaiser Permanente);* **Donald Goldmann, MD** *(Institute for Healthcare Improvement);* **Christopher Dezii, RN MBA, CPHQ** *(Bristol-Myers Squibb);* **Gregg Meyer, MD, MSc** *(Partners HealthCare);* **Veronique Roger, MD** *(Mayo Clinic);* **Lucy Savitz, PhD, MBA** *(Intermountain Healthcare); and* **Richard Platt, MD, MS** *(Harvard Pilgrim Health Care Institute and Harvard Medical School)*

Responding to the Needs of a Changing Healthcare Environment

- It is the responsibility of all healthcare organizations to ensure continuous improvement of their care

- Research and quality improvement are often thought of as distinct, but they both draw on scientific methods and require rigorous planning, evaluation, and learning processes

- What distinguishes continuous improvement and human subject research that requires institutional review board (IRB) oversight?

- We propose criteria based on 1) risk to patients, and 2) operational relevance to improving quality, safety, and outcomes

Evaluation of Care in a Learning Health System

In a learning health system, for continuous improvement, the creation of generalizable new knowledge is a necessary routine aspect of healthcare, including:

- Use and exchange of routinely collected protected healthcare information for purposes other than direct patient care
- Analysis of administrative databases
- Surveys related to quality and effectiveness of care
- Systematic variation of care within a healthcare system or patient population
- Coordination of any of these activities among multiple providers or organizations
- Dissemination of learning through implementation, publication, and other means

Regulatory Environment for Continuous Improvement of Clinical Effectiveness

Federal regulations cited in regard to clinical effectiveness and quality assessment include:

- For IRB scientific and ethical review of projects, application of the *Common Rule* to ensure that human subjects are informed about, and protected from, research related risks
- For IRB protection of health information security and privacy, application of the *Health Insurance Portability and Accountability Act* (HIPAA) in addition to institutional HIPAA requirements for handling of patients' private information

Issues at the Interface of Continuous Clinical Improvement and Regulatory Requirements

- A basic tenet of a learning health system is that normal expected operations include measurement, comparison, evaluation, systematic introduction of accepted therapies, sharing of experience and information, implementation of results in practice, and coordination of these activities among organizations

- Ambiguity around whether continuous improvement is seen as human subject research has hampered this work

- Human subject research regulatory mechanisms and review processes are time consuming, expensive, and may contribute to the abandonment of important initiatives

Issues at the Interface of Continuous Clinical Improvement and Regulatory Requirements

- *Inconsistent and unpredictable application of IRB and HIPAA standards* to healthcare research impede evaluation and research, leads to biased sampling, invalid conclusions, and impairs multi-center studies in which different centers' IRBs come to different conclusions about the same study

- Criteria used to designate a project as quality assessment rather than research, such as whether intended to generate generalizable knowledge or a publication, *do not relate to the level of risk posed to human subjects*, the intended focus of regulatory requirements

Precepts for Application of Regulatory Requirement to Continuous Improvement

- If a study confers *minimal risk* (i.e., risk no greater than typical of usual care) and is a *routine and appropriate activity of the healthcare system*, it should *not be classified as human subject research* covered by the Common Rule and special research HIPAA oversight

- When this applies, evaluations and trials of interventions of accepted therapies should be excluded from regulation and oversight as research

- Evaluations that confer *greater than minimal risk* must use standard protections of human research subjects, including IRB review and approval

Precepts for Application of Regulatory Requirement to Continuous Improvement

- The current requirement of IRB review of studies limited to personal information from electronic health records should be ended except when there is actual risk to a patient

- Even if IRB review is not required for rigorous continuous improvement activities, healthcare institutions still bear responsibility as for usual clinical care and for handling of private health information in accordance with HIPAA

Change Needed in Oversight and Regulation for Clinical Quality Improvement

- We propose a framework for oversight and regulation that should provide important protections for patients and study participants and should reduce the uncertainty that currently hampers quality improvement and clinical effectiveness assessment

- The distinction as to whether quality improvement is "research" is counterproductive, as continuous improvement using the best available methods and resources should be part of a learning health system's core operations, which should not be encumbered simply because of using state-of-the-art methods, patient information, or interventions

Change Needed in Oversight and Regulation for Clinical Quality Improvement

We recommend quality improvement *oversight focus* on:

- Protecting patients from risk beyond that incurred through regular care
- Ensuring that health systems and providers meet their moral responsibilities to assess and improve care
- Lessening the burdens of oversight so that care evaluation and improvement is not impeded
- Assigning oversight responsibilities appropriately

Risk Based Oversight Framework for Human Subject Research and Healthcare Evaluation

• We endorse use of a risk-based framework, with oversight commensurate to the level of risk imposed by the study, as per the three risk categories proposed by Emanuel and Menikoff:

1. studies limited to the *collection of information*, without a study intervention
2. studies of an intervention, but only of *minimal risk* ("encountered in daily life or during the performance of routine physical or psychological examinations or tests")
3. studies of an intervention of *more than minimal risk*

Risk Based Oversight Framework for Human Subject Research and Healthcare Evaluation

Category 1: Studies limited to the *collection of information*, without a study intervention

- Quality and effectiveness assessments that only pose risk to patients related to misuse or release of health information *should not require oversight as research*

- Oversight should be done *as part of clinical operations*, not by the IRB

- HIPAA regulations regarding the use of data for *standard healthcare operations* should apply

Risk Based Oversight Framework for Human Subject Research and Healthcare Evaluation

Category 2: studies of an intervention, but of *minimal risk*

- If risk to patients does not exceed that of usual care, i.e., is minimal, and the intervention is part of accepted customary care, *IRB oversight is not warranted*

- Assuming measurement and analysis do not confer additional risk, assessment of accepted care is not itself more risky than receiving care without assessment

Risk Based Oversight Framework for Human Subject Research and Healthcare Evaluation

Category 2: studies of an intervention, but of *minimal risk*

Example: Systematically comparing, including by random allocation, two alternative accepted treatments (e.g., statins), collecting information to compare outcomes -- for which responsibilities of healthcare organizations would be to:

1) designate such activities as having operational importance
2) oversee such activities as part of its care responsibilities
3) assume responsibility for the project's conduct

NB: IRB oversight *is* warranted if *not an operational focus* or involving a *new intervention*, even if intended to support a continuous improvement goal

Risk Based Oversight Framework for Human Subject Research and Healthcare Evaluation

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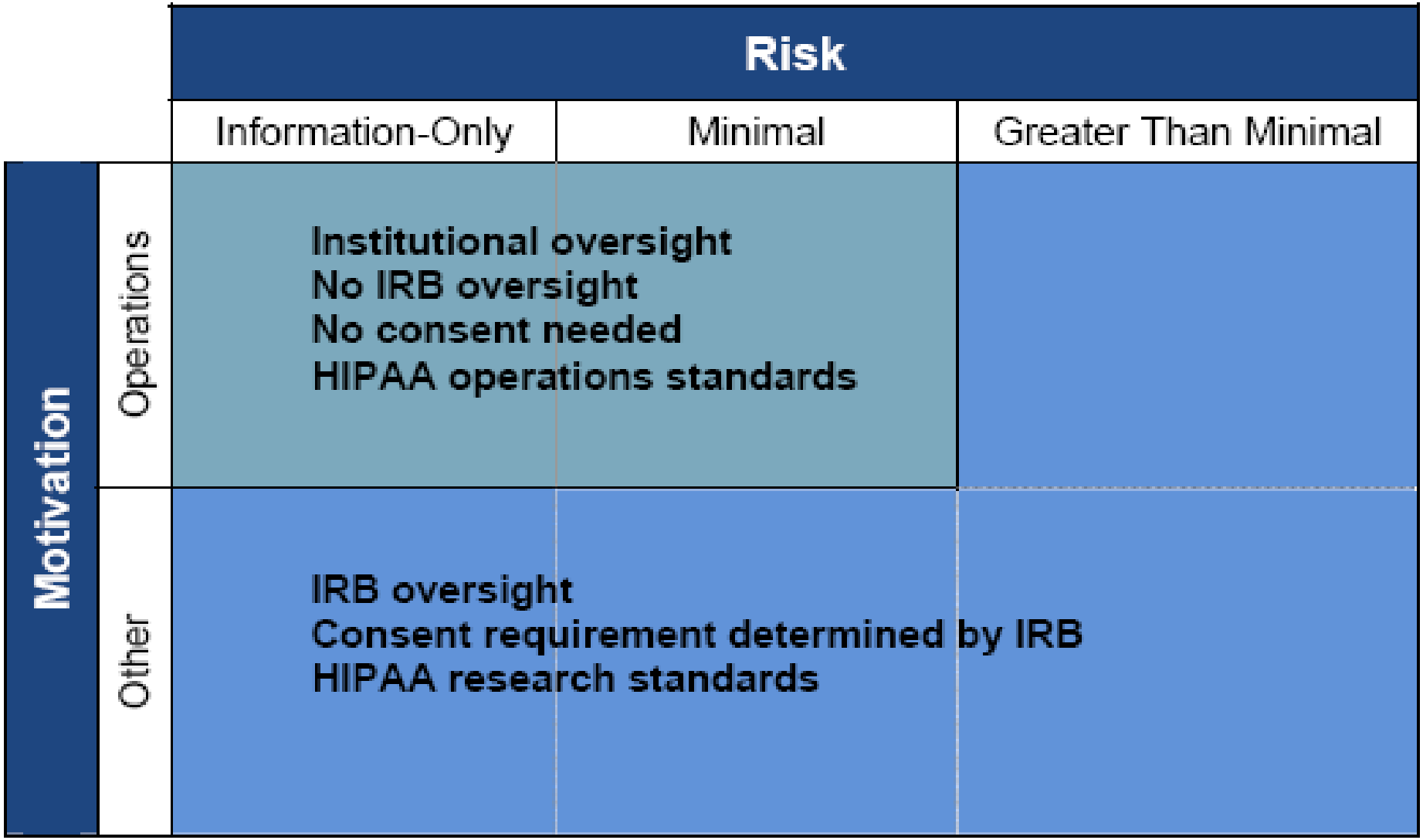
Category 3: Studies of interventions of *more than minimal risk*

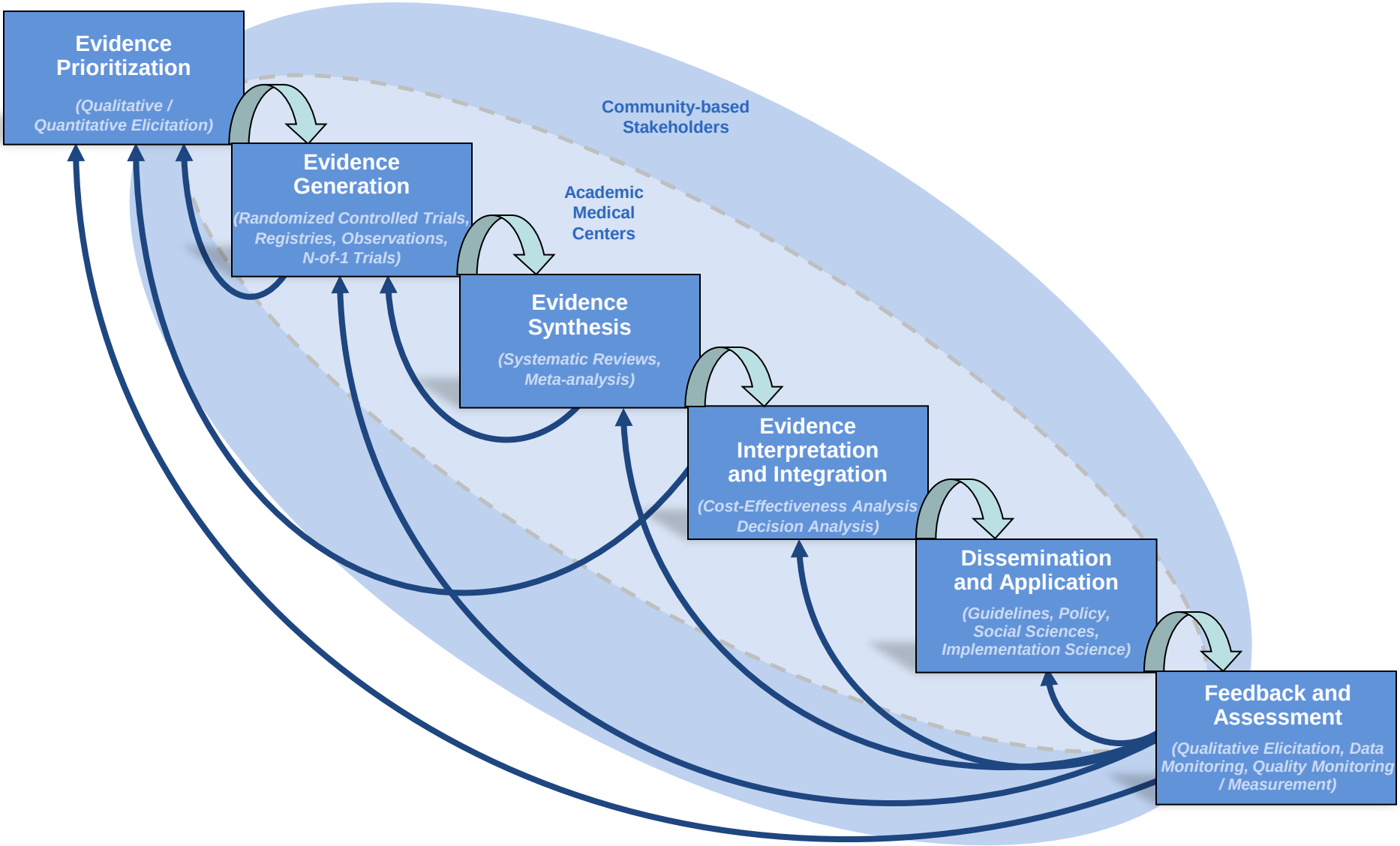
- Studying an intervention of greater than minimal risk requires full IRB oversight

- Redirecting operational improvement studies to alternative oversight will allow overburdened IRBs to dedicate more of their time and resources to reviewing these studies that pose the greatest risk and are not part of routine operations

Oversight of Continuous Improvement Efforts in a Learning Health System



Translational Spectrum of Comparative Effectiveness Research at Tufts CTSI



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The Common Rule and Continuous Improvement in Healthcare: Summary

- Continuous assessment and improvement, as part of the obligation of a learning organization, is a social good that should be facilitated, not impaired

- Participation in these investigations should be considered a normal part of giving and receiving care

- Implicit in a patient's consent to care should be consent to improve and participate in quality and effectiveness assessments limited to the information-only and no-more-than-minimal risk categories

The Common Rule and Continuous Improvement in Healthcare: Summary

- Health care organizations bear responsibility for overseeing the safe and effective delivery of care, and this includes identifying and disseminating knowledge about best treatments and practices

- If part of this responsibility, unless evaluating other than an accepted practice, or posing more than minimal risk, these activities should not require the processes required for human subject research under the Common Rule

- Realigning responsibilities this way will reinforce understanding that quality, safety, and effectiveness assessments, along with care innovation, are core for a learning health system

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