

Ethics for a learning
healthcare system—
***A presentation for
the NIH
collaboratory in two
parts***

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March 18, 2013

Two-part presentation: February 27 and March 18

Part 1: February 27, 2013:

“The Research-Treatment Distinction: A Problematic Approach for Determining Which Activities Should Have Ethical Oversight”

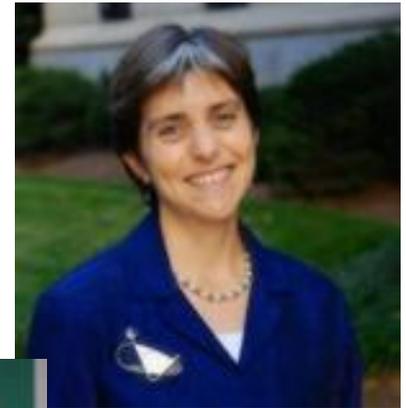
Part 2: March 18, 2013:

“An Ethics Framework for a Learning Health Care System: A Departure from Traditional Research Ethics and Clinical Ethics”

Project Team

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**Funding from the National
Center for Research
Resources, NIH: grant
RC1RR028876**



Ethical Justification for Learning Healthcare System

Continuous learning about the effectiveness and value of healthcare interventions is necessary to the securing of three foundational societal goals

- Just healthcare
- Quality healthcare
- Economic well-being

Goal of Ethics Framework for Learning Healthcare Systems

1. To support the transformation to a learning healthcare system
2. To help ensure that learning activities carried out within such a system are conducted in an ethically acceptable fashion

Scope of Learning Healthcare Systems Ethics Framework

- Applies to any activity that
 - Involves the delivery of healthcare services or the use of individual health information ***and***
 - Has a targeted objective of learning how to improve the quality, value, justness, or efficiency of healthcare systems, institutions and modalities through which healthcare services are delivered

All such activities are ***learning activities***

Ethics Framework for the Learning Healthcare System

1. Respect the rights and dignity of patients and families
2. Respect the judgment of clinicians
3. Provide each patient optimal clinical care
4. Avoid imposing non-clinical risks and burdens
5. Address unjust health inequalities
6. Conduct continuous learning activities (clinicians and health care institutions)
7. Contribute to the common purpose of improving the quality and value of clinical care (patients and families)

Obligation 2: Respect Clinical Judgment

- Assess the impact of a learning activity on clinical judgment
 - Clinicians' judgments advance the medical interests of patients and the autonomy interests of patients
 - Importance of this obligation is not equally stringent in all circumstances
 - Tension exists between honoring this obligation and evidence that clinicians' judgments can be biased or less than fully informed

Obligation 3: Provide Each Patient Seeking Care Optimal Clinical Care

- Assess expected net clinical benefit to patients receiving care as part of the learning activity compared to the net clinical benefit to patients receiving ordinary clinical care, not part of a learning activity
 - General obligation to promote the welfare interests of patients toward the best clinical outcome

Obligation 5: Address Unjust Inequalities

- Assess the likelihood that the learning activity will exacerbate unjust inequalities;
- Determine whether it is possible to structure the activity to advance the goal of reducing unjust inequalities in healthcare

Obligation 6: Conduct Continuous Learning Activities that Improve the Quality of Clinical Care

- Healthcare professionals, and officials of healthcare institutions, have obligations to conduct and contribute to learning activities that advance the quality, fairness, and economic viability of the healthcare system
 - Obligation is rooted in the role-specific opportunities of healthcare professionals to achieve such learning
 - Each activity should be assessed to determine the level of expected contribution

Obligation 7: Contribute to the Common Purpose of Improving the Quality and Value of Clinical Care and Healthcare Systems

- Patients have an obligation to participate in (at least some types of) learning activities
 - Obligation is derived both from the moral norm of common purpose, rooted in our common interest in having a high quality, just, and economically viable healthcare system, and from obligations of reciprocity
 - Does not mean that patients have an obligation to participate in all learning activities, especially those that might adversely impact their rights and interests (obligations 1-4)

LHS Ethics Framework:

How is this different from existing codes of research and medical ethics?

- Sets moral presumption in favor of learning
 - Health professionals/institutions have affirmative obligation to participate in learning
 - Patients have affirmative obligation to contribute to that learning
- Includes obligation to address problems of unjust inequalities in healthcare
- Ensures learning activities governed by shared ethical norms and oversight processes emphasizing
 - Patients must receive high quality care
 - Procedures be integrated in ways demonstrating respect

Implementation

- Part 1: Certain ethical requirements exist throughout and characterize the system
- Part 2: Evaluation (triage) of some types of learning activities

Implementation Part 1: Universal ethics requirements and policies for a Learning Healthcare system

- **Wide disclosure, transparency, and dissemination that HC system is committed to learning**
 - At enrollment, in waiting rooms, in newsletters
 - All ongoing learning activities on website
 - New or interesting activities highlighted in newsletters, posters
 - All findings available; certain findings that changed care delivery highlighted in newsletters, posters, etc.

What key messages to disclose?

- **System is committed to continuous learning**
 - Learning is integrated into all care delivery
 - Learning is ethical imperative to ability to deliver high quality care
- **System committed to protecting patients' rights and interests**
 - Confidentiality protections
 - Quality of care never knowingly compromised
 - All activities first evaluated with ethics framework
 - Any activity that might meaningfully change care or how it is delivered will always include explicit informed consent requirements

Implementation Part 2: Evaluation of Learning Activities

- HC systems develop policies for which types of activities can go forward without additional ethical oversight, once required protective policies are in place
 - Random audits for accountability (really meet criteria)
 - These will proceed without written informed consent
- HC Systems identify a person/persons to triage **other types of** learning activities to other oversight processes (which may include patients and families as well as HC professionals)
 - Some more “expedited” oversight
 - Others to IRB or IRB-like entity
 - Triage to determine which do or do not require written IC

- Thanks!!
- Questions??