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Ethics for a learning health care system: The "Common Purpose" Framework

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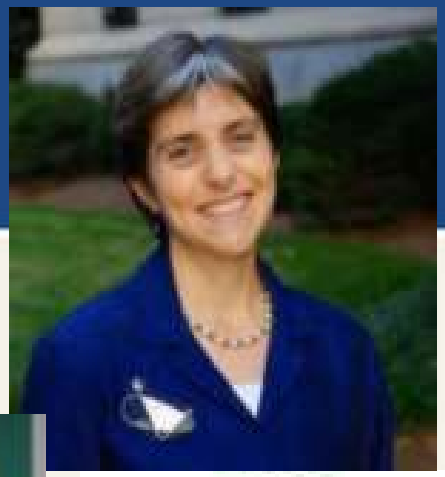


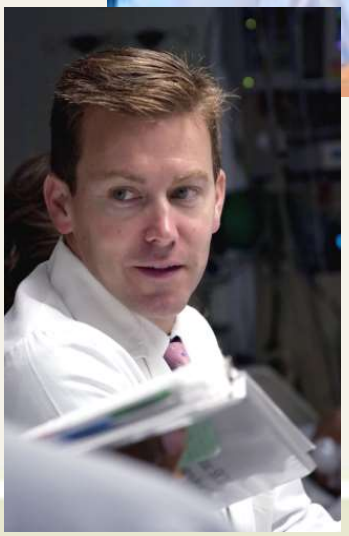


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Outline for talk

- Traditional approach to ethical oversight for research?
- What are problems with this approach, **particularly as care and research/ systematic data collection are increasingly integrated?**
- Possible ethics framework for an integrated, learning healthcare system

"Distinctions paradigm"– how to distinguish research from clinical care?

- **Regulatory (conceptual) definition:**
  - **Research: intent to produce generalizable knowledge**
    - Practice: intent to help patient at hand
  - **Research: Systematic collection of data**
    - Practice: no systematic data collection
- **Claims from literature:**
  - **Research: Poses risk; uncertainty about clinical benefit**
    - Practice: Treatments given only when benefits outweigh risks
  - **Research: Poses burdens from activities not necessary for good care**
    - Practice- all interventions contribute to good care management
  - **Research: Protocols determine the care patients receive**
    - Practice: physician-patient autonomy to decide

Practical, conceptual, and moral problems with this paradigm

- **Conceptual problems**: assumptions are not accurate
  - We "generalize" from practice, quality improvement
  - We collect data systematically in practice
  - Many preventable harms in practice; much research (e.g., some CER) very low risk
  - Care includes burdens (extra visits, duplicate tests) not needed for providing high quality care
- **Practical problems**: complete confusion! What needs IRB review??
  - What is QI? What is research?
  - OHRP investigations related to disagreements…

Moral problems with current approach

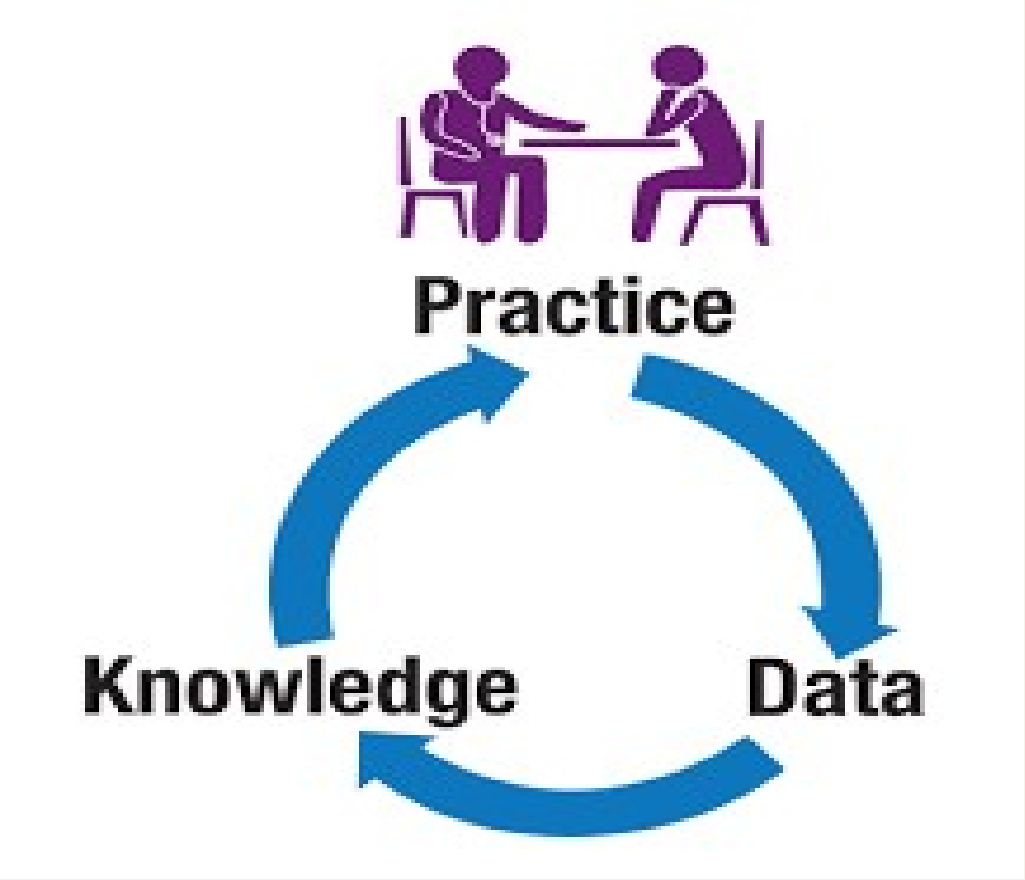
- Overprotection of some patients
  - Extraordinary oversight apparatus for many low risk research activities
- Underprotection of some patients
  - So much medical care has no evidence behind it
  - At least as much random variation in care as in research

Stated differently:

- Current system examines risks and uncertainties to patients only when we're doing research
- But what about the threats to patients' interests by creating barriers to learning, when patients enter **a U.S. health care system that spends $700 billion to $1 trillion on care with no evidence, in error, or that's unnecessary?**

What if care and learning were systematically *integrated*?

Learning Health Care System



Goals of an Ethical Framework for learning healthcare system

- To justify, ethically, why this system is important

- To ensure that ongoing learning proceeds in an ethically acceptable fashion
  - Participants' rights, health, and interests must be appropriately protected, both…
    - When we provide care
    - When we learn systematically from that care

Ethics Framework for the Learning Healthcare System

Learning Health care systems should:

1. Respect the rights and dignity of patients/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

***to the extent that learning activities compromise obligations 1-4, then more oversight and patient authorization needed**

(Builds on Faden, R.R., Kass, N.E., Goodman S.N., Pronovost, P., Tunis, S., Beauchamp, T.L. "An Ethics Framework for a Learning Health Care System", Hastings Center Report, 2013. 43(1): S16-27.)

Ethics Framework for the Learning Healthcare System

Health care providers and institutions should:

6. Participate in (some) continuous learning activities
7. Put systems in place to implement what was learned

Patients/families should:

8. Participate in (some) continuous learning activities

Obligation 1: Respect Patients

- **How does learning activity impact patients' rights, respectful treatment, and dignity (compared with usual care)?**
  - Not all decisions equally relevant to patients
    - Value preferences at stake in the activity?
  - Duties of respect go beyond autonomous patient decision making. How else to show respect?
    - Is system *transparent* about commitment to continuous learning? Are examples posted and described publicly?
    - Engagement of patients in decision making?

Obligation 2: Respect Clinicians' Judgment

- **How does activity impact a clinician's ability to use his/her own judgment (compared to usual clinical care)?**
  - Clinicians' judgments advance patients' medical, welfare, and autonomy (value) interests
  - 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 Optimal Clinical Care

- **How will learning activity impact net clinical benefit to patients, compared to usual clinical care?**
  - General obligation to promote the welfare interests of patients toward the best clinical outcome
  - Does “learning” make the care any riskier for patients? Likely for patients to be worse off? Or is it the same?

Obligation 4: Avoid Imposing Nonclinical Risks and Burdens

- **What nonclinical risks and burdens do patients experience, compared with usual care?**
  - Any additional burdens for patients because the "learning activity" is happening?

Obligation 5: Address Unjust Inequalities

- **Will learning activity exacerbate unjust inequalities? Decrease them?**
  - What is the topic of the learning activity?
  - Might results increase or decrease existing inequalities (in health/health care)?
  - Can activity be structured to better *advance* the goal of reducing unjust inequalities in healthcare?

Obligation 6: Health care providers and institutions should engage in continuous learning

- **Healthcare professionals, institutions, payors**, have obligation to conduct and contribute to [at least some] learning activities that advance quality, fairness, and viability of HC system
  - Thereby contributing to the common purpose of improving the quality and value of health care
  - They are uniquely situated to execute such activities
  - They are uniquely situated to contribute such data
  - Relevant to responsibilities to provide high quality care
  - **[And by-product; may increase likelihood of future implementation of what is learned]**

Obligation 7: Accountability: Health care institutions should put systems in place to implement what was learned

- Health care systems must fulfill promises to patients that learning was built into care *in order to* improve future care
- Asking patients and providers to automatically participate in certain activities can be justified, ethically, only if care ultimately changes
- People with authority to implement changes should be part of team designing, implementing, or giving "go-ahead" to new learning activities

Obligation 8: Patients should contribute to ongoing learning -1

- Patients have an obligation to participate in [at least certain] learning activities
  - Derived from moral norm of common purpose-- a common interest in having a high quality, just, and economically viable healthcare system
  - Derived from obligations of reciprocity

Obligation 8: Patients should contribute to ongoing learning -2

- Does **not mean** patients must participate in all learning activities
- Degree to which the learning activity adversely impacts patients' rights, burdens, preferences, and/or clinical well-being (compared to usual care) (obligations 1-4) must be assessed;
- Activities that might adversely impact rights and interests (obligations 1-4) will require more oversight, disclosure, and voluntary consent

Implementation- What should system have in place?

- **Transparency** about ongoing learning and protections
- **Engagement** with clinicians and patients about learning, which activities, implemented how?
- **Accountability:** what is learned is implemented (and transparency about that)
- **Triage process:** Need process to evaluate degree to which proposed activities (or classes of activities) affect respectfulness, choice, burden, riskiness of care and clinician judgment

Thank You!!!

Reactions?

Criticism?