

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

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Outline for talk

- What has been approach to ethical oversight for research, and how did we get there?
- What are the problems with this approach?
- What might an ethics framework for an integrated, learning healthcare system look like?

How did we get to where we are with U.S. federal regs? – “The Distinctions paradigm”

- 1960s-1970s: research scandals
- 1974: U.S. federal regulations passed
 - Strong emphasis on protections
 - Required IRB review/informed consent
- **Regulations relied on being able to distinguish clinical research from clinical care**
 - Research now required ethical oversight
 - Clinical care did not



“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

Our claim: The distinction does not work

- **We challenge the view** that this distinction – **and the policy implications of using it-** should be sustained
 - *Maybe this definition shouldn't be the basis of what gets ethical oversight, and what does not?*
- We believe there are **conceptual, practical, and moral problems** in relying on distinction

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 avoidable risks and harms in practice; much research (e.g., some CER) very low risk
 - Care also has unnecessary burdens (extra visits, duplicate tests)
- **Practical problems:** complete confusion! What needs IRB review??
 - What is QI? What is research?
 - OHRP investigations related to disagreements...

“Grey zone” examples described in Focus Groups

“We introduced an electronic medical records system... for medication ordering so we want to study that. So...we're going to look at medication errors after we implement our ...system and compare it...with our historic data....”

We're not the only ones using this system, and -- well, there could be a risk. You're certainly not getting consent. You're not randomizing people. You're just implementing a system that is going to apply to everybody here... We'd like to publish it and make it widely known.”

“Grey zone” examples described in Focus Groups

- “We've been involved in a couple of [QI] projects that go into...implementation of research, and... you're beginning with some practice that apparently has good evidence, ... And we'll ...try to understand the barriers to adoption of best practice, and in doing so, I presume we're disrupting current practice, bad as it might be, and the question is, is that really research?”

How do institutions navigate?

- “Our Patient Safety Group is funded out of a medical care budget at [institution]. The [institution has] a separate research budget, so we never have to call anything **we** do research. So we never call it research. We have, like, research centers, but we call them ‘Centers of Inquiry’. If we send out a form for people to fill out, we call it a questionnaire, not a survey because a survey has a certain feel of epidemiology to it. A questionnaire doesn't, you know.”

Moral problems with current approach

- Our oversight system is in place to ensure ethical protection for patients who need it; does current approach do that appropriately?



YOU DON'T THINK YOU'RE JUST A TAD OVERPROTECTIVE?

Current approach *overprotects* some patients and *underprotects* others

- Overprotection of some patients

- Extraordinary oversight apparatus for many low risk activities
- E.g., routine (observational) collection of records
- E.g., Comparisons of approved, widely used therapies

- Underprotection of some patients

- From risk and uncertainty in clinical care
- So much medical care never evaluated
- Interventions used where never evaluated



Stated differently:

- Current system examines risks to patients only when we say we're doing research
- But in a U.S. health care system where we spend \$700 billion to \$1 trillion on care given **either in error or unnecessarily--**
 - Are we also considering threats to patients' interests continue by creating barriers to learning?
- Should the balance be shifted a bit?

What might the ethics of a more *integrated system* look like?



Goals of an Ethical Framework for learning healthcare system

- To increase the likelihood that continuous learning occurs;
 - Learning what works in healthcare and what doesn't is an ethical good
- To ensure that this learning proceeds in an ethically acceptable fashion
 - Participants' rights, health, and interests must be appropriately protected both when we provide care, and when we learn



To what does framework apply?

- Institutions who deliver care and also are engaged in systematically learning...
 - ...to improve the quality, value, fairness, or efficiency of healthcare, systems, institutions;
 - Where learning activities involve care delivery, health system organization, and/or use of individual health Information
 - “Data only” or with human interaction;
 - traditionally labeled “clinical research”, “systems research”, “quality improvement”, etc.

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 only be justified, ethically, if care changes based on what is learned
- 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?