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

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

Practice

Knowledge

Data
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

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

- 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?