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

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Outline for today: a transition for research ethics??

• Era or “paradigm” #1: “The distinctions paradigm”:
  – Research and care must be treated differently
  – Ethics and oversight should be based on whether activity meets regulatory definition of research

• Era or “paradigm” #2: “The learning healthcare system paradigm”
  – Research and care must be integrated
  – Ethics and oversight should be based on whether there are moral concerns
“The Distinctions paradigm”

- 1960s-1970s: research scandals revealed
- 1974: Federal regulations passed for research
  - 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 using distinction for policy about what needs ethical oversight should be sustained

- We believe there are practical, conceptual, and moral problems in relying on distinction...
Practical, conceptual, and moral problems with this paradigm

- **Practical problems**: complete confusion!
- **Conceptual problems**: assumptions are not accurate
- **Moral problems**:
  - Overprotection (of low risk research)
  - Underprotection (from unsafe or unproven care)
Moving forward: assumptions

• Integrating learning into healthcare is ethically good
  – Should continuously learn from care provided
  – Should better evaluate what does/doesn’t work
  – Goal: to increase quality, value, fairness, efficiency of healthcare, systems, institutions

• Such “learning” must proceed ethically
  – Patients’ rights and interests must be respected and protected
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
6. Clinicians and HC institutions should conduct continuous learning activities
7. Patients and families should contribute to the common purpose of improving the quality and value of clinical care
Obligation 1: Respect Patients

• How does learning activity impact patients’ rights, respectful treatment, and dignity?
  – Not every decision is of equal moral relevance to patients
  – Duties of respect go well beyond autonomous decision making by patients
Obligation 2: Respect Clinical Judgment

• How does activity impact a clinician’s ability to use his/her own judgment?
  – Clinicians’ judgments advance patients’ medical interests and autonomy 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, conflicted, or less than fully informed
• How will learning activity impact net clinical benefit to patients, compared to benefit from “ordinary care”?
  – General obligation to promote the welfare interests of patients toward the best clinical outcome
  – Compare with “ordinary” care absent learning
Obligation 4: Avoid Imposing Nonclinical Risks and Burdens

• What other nonclinical risks and burdens do patients experience?
  – How do these compare to those likely from “ordinary care” outside of activity?
Obligation 5: Address Unjust Inequalities

• Will learning activity exacerbate unjust inequalities? Decrease them?
  – Can activity be structured 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, institutions, payors, have obligation to conduct and contribute to learning activities…
  - …that advance the quality, fairness, and economic viability of the healthcare system
  - They are uniquely situated to contribute such data
  - Relevant to their responsibilities to provide high quality care
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 the enterprise of “learning”
  – 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
  – **Does not mean** patients must participate in all learning activities!!
  – Activities that might adversely impact rights and interests (obligations 1-4) will require consent/oversight
Implementation

• Part 1: Ethics-relevant policies must be in place in a Learning Healthcare system
  • Transparency to patients (about ongoing “learning”)
  • Engagement
    • patients help decide which studies need consent and further protections
  • Accountability

• Part 2: Evaluation (triage) of types of learning activities for what needs review/consent
Part II: Evaluation (triage) of types of learning activities

- Category #1
  - No additional risk/burden; No change to clinical care; good protections; [records review; some systems level; observational]
  - No consent required; no prospective oversight required?
  - Random audits to ensure meeting criteria

- Category #2:
  - Low risk/burden; no reason to think patients object or prefer one arm (approach) over another; e.g., comparison two similar treatment approaches;
  - prospective oversight but streamlined or no consent

- Category #3:
  - More Risk and/or burden; meaningful difference to patients among approaches;
  - prospective oversight and prospective patient consent
Thank You!!!
Reactions?
Criticism?