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A New Ethical Framework for the Learning Healthcare System: The Hopkins Model

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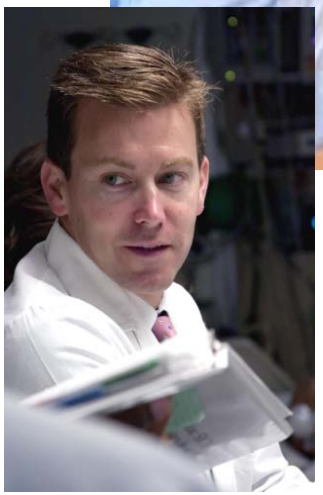


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Research Ethics in U.S.

- 1960s-1970s research scandals
- 1974: Federal regulations passed for research
  - Strong emphasis on protection
  - Required IRB review/informed consent
- **Regulations relied on being able to distinguish clinical research from clinical care, because…**
  - Research now required ethical oversight
  - Clinical care did not

Criteria used to distinguish research from therapy in regulations and literature

- **Conceptual distinctions:**
  - **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 more risk and clinical uncertainty**
    - Practice: Treatments given only when benefits outweigh risks
  - **Research: Poses burdens from activities not necessary for good care**
    - Practice- all clinical interventions contribute to good 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

- We believe there are **practical, conceptual, and moral problems** in relying on distinction

Moral problems with current approach

- Our oversight system is designed to ensure ethical protection for patients who need it
- Yet, Underprotection of some patients
  - From risk and uncertainty in clinical care
  - Medical errors, care/procedures never evaluated
  - Diffusion of technology for indications never evaluated
- Overprotection of some patients
  - Extraordinary oversight apparatus for very low risk activity
  - Routine collection of records
  - Comparisons of approved, widely used therapies

Goals of an Ethical Framework for learning healthcare system

- To increase the likelihood (ethical good) that continuous learning occurs;

- To ensure that this learning proceeds in an ethically acceptable fashion (rights and interests are appropriately protected)

To what does framework apply?

- Activities with targeted objective of learning
  - How to improve the quality, value, fairness, or efficiency of healthcare, systems, institutions;

- **AND** that involve delivery or healthcare services or use of individual health Information

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 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 or less than fully informed

Obligation 3: Provide Each Patient Seeking Care Optimal Clinical Care

- **How will learning activity impact net clinical benefit to patients, compared to benefit from "ordinary care" without learning activity?**
  - General obligation to promote the welfare interests of patients toward the best clinical outcome

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 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
  - 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 policies that must be in place in a Learning Healthcare system
- Part 2: Evaluation (triage) of types of learning activities

Part I: Ethics policies that must be in place in a Learning Healthcare system

- **Wide disclosure (at enrollment, newsletters, etc.)**
  - That HC system is committed to continuous learning in order to improve care
  - That confidentiality will be protected
  - Listing available of all learning activities
  - Key findings will be disseminated
  - Key findings will be used to improve care (and then disseminate examples!)

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

Part II: Evaluation (triage) of types of learning activities

- Category #1
  - No additional risk/burden; No change to clinical care; good protections; [records review]
  - No consent required; no prospective oversight required? Random audits to ensure meeting criteria
- Category #2:
  - Low risk/burden; no reason to think patients object to research or prefer one arm (approach) over another; e.g., comparison two similar treatment approaches; prospective oversight but modified authorization/no consent (?)
- Category #3:
  - Risk/burden; meaningful difference among approaches; prospective oversight and prospective patient consent

Thank You!!!

Reactions?

Criticism?