

Ethical Challenges of a Changing Research Paradigm

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The shifting ethical paradigm: Outline for today

- **Paradigm #1:** “The distinctions paradigm”
 - Ethical requirements of this paradigm
 - Problems with the distinctions paradigm
- **Patient engagement:**
 - The importance of what we want
 - The (potential) paradox of what we want
- **Paradigm #2:** “The learning healthcare system paradigm”
 - Ethical requirements for this paradigm?
 - Maybe the paradox is not so great?

“The Distinctions paradigm”

- 1960s-1970s: research scandals become known to American public
- 1974: Federal regulations passed for research
 - Required IRB review
 - Required informed consent
- **Regulations relied on being able to distinguish clinical research from clinical care**
 - Research must have ethical oversight
 - Clinical care need not have ethical oversight

“Distinctions paradigm”– how to distinguish research from clinical care?

- **Regulatory 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

Problems with this paradigm?

- **Practical problems:** complete confusion!
- **Conceptual problems:** assumptions are not accurate
 - We generalize from practice, quality improvement
 - We collect data systematically in practice
 - Many errors/risks in practice; yet research increasingly designed to compare effective treatments
 - Practice includes unnecessary or duplicate tests and treatments (unnecessary burdens)
- **Moral problems:**
 - Overprotection (of low risk research)
 - Underprotection (from unsafe or unproven care)

Patient engagement

- Importance of what we want from patient engagement
 - In clinical care: “Shared decision making”
 - In research: As a sign of respect, disclosure and discussion that research is happening

Paradoxes related to patient engagement

- Paradox #1—
 - **Health Affairs**: “Shared decision making” must rely on doctors and patients using “best available evidence”
 - **but we have so little evidence for most clinical decisions—** *in part from* hurdles of ethics oversight and privacy concerns
- Paradox #2—
 - **Health departments, CDC, all hospitals routinely collect data (that is useful to us as patients!!), but we never give permission**
 - Cancer rates, obesity rates among different populations
 - Rates of infections, falls, medication errors in hospitals and impact of related interventions

Paradigm #2: The learning healthcare system paradigm

- Care and learning deliberately integrated
- Assumption that high quality care and learning depend on each other
- Research with experimental drugs is separate
- Much (integrated) learning to discover
 - What are the outcomes of different treatment choices?
 - What are the outcomes of different care approaches?

Ethical requirements of LHCS

- Respect the rights and dignity of patients
- Respect clinician judgments
- Provide optimal clinical care to patients
- Avoid imposing nonclinical burdens and risks
- Address health inequalities
- Participate in the learning process (clinicians)
- Participate in the learning process (patients)

Maybe the paradox is not so great??

- Patients clamoring for better evidence/data
 - Focus group with patient advocates reveal desperate interest in more data/evidence
 - Books, videos, websites advocating contributing data for better treatments and better decisions
- Patients in “trust relationships” more willing to share data
- Many possible strategies for engaging, disclosing, discussing with patients about learning in HC
 - its responsibilities and benefits??
 - What engagement/authorization acceptable?
- PCORI project to gather some preliminary data