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Ethics for a learning healthcare system—
A presentation for the NIH collaboratory in two parts

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Two-part presentation February 27 and March 18

- **Part 1: February 27, 2013:**
  - "The Research-Treatment Distinction: *A Problematic Approach for Determining Which Activities Should Have Ethical Oversight*"

- **Part 2: March 18, 2013:**
  - "An Ethics Framework for a Learning Health Care System: *A Departure from Traditional Research Ethics and Clinical Ethics*"

Project team

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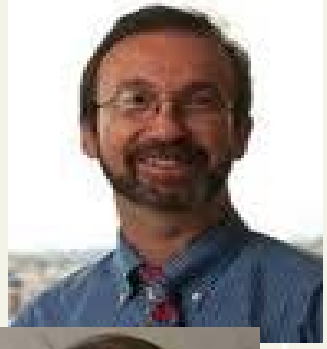
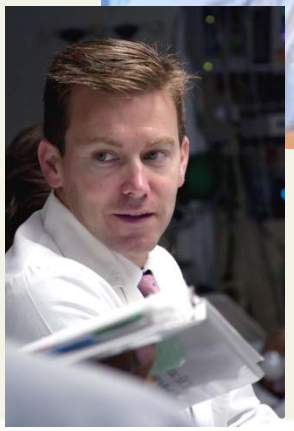


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Research Ethics in U.S.

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

Growing scholarship on research Ethics

- Scholarship emphasized that research and treatment are conceptually distinct and must be separated
  - E.g., "**Sound ethical thinking**" about research **depends on "a basic distinction between research and therapy**" (Miller/Brody)

- Much literature focused on HOW and WHY clinical research was different from clinical care

Criteria used to distinguish research from therapy

- **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

Our claim: The distinction does not work

- We challenge the view that this distinction, and associated classification scheme, should be sustained

- We believe there are **practical, conceptual, and moral problems** with continuing this distinction and relying on its implications

Practical problems with distinction

- Complete confusion!
  - E.g., Michigan checklist study
- Conscientious IRBs and professionals don't know if many activities are research or practice
  - Similar activities provided with different oversight
  - Significant amount of time figuring it out

Focus group: How IRB decides of project requires IRB review

- "I think [the IRB's] focus was really on 'Are you planning on publishing or do you think you might consider publishing in the future?'"

Focus group with QI professionals-

- "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."

Conceptual concerns with current paradigm: intent to produce generalizable knowledge

- **Claim: Research can be defined by its intent to produce generalizable knowledge**
- But, quality improvement activities are undertaken to "generalize" what is learned to future patients
- Learning is increasingly an explicit goal of practice arrangements
- To say that research and practice can be separated in these arrangements misses the point
  - The delivery of high quality care *depends on learning being integrated* and constantly fed back to improve care

Conceptual concerns: systematic collection of data

- **Claim: Research is defined by the systematic collection of data**
- But, hospitals are required to collect systematic data to be accredited
- Private companies collect clinical data systematically to modify insurance coverage, for safety surveillance and for provider performance
- New electronic health record systems (e.g., VistA) facilitate systematic analysis of data to learn and to change care protocols.

Research poses risk; uncertainty about clinical benefit

- **Claim: Research offers less prospect of benefit and greater chance of risk**
- And yet systematic reviews suggest patients no worse in clinical trials than in care
- And in care, more than 50% of clinical interventions have never been tested
- Numerous interventions diffuse into care without evaluation; many later found useless or harmful
- Millions harmed through medical error

Research poses additional burdens not necessary for good care

- **Claim: research poses additional burdens (tests, surveys) unrelated to good clinical management**
- Yet clinical care includes multiple unnecessary and repeated visits, tests, and medications
- And much (pragmatic and CER) research involves no extra testing or data collection beyond usual care

In research, clinical care assigned by protocol

- **Claim: therapies assigned by protocol making care in research less personalized**
- And yet
  - Geographic data suggest practice variation not generally based on patient preferences
  - outcomes are no worse in research
  - Many clinical research designs are flexible to change if needed or desired
  - Much clinical practice is dictated by protocol from health system and/or payor and/or pharmacy

Moral problems with current approach

- Current system of ethical protection results in underprotection of some patients
  - At least 50% of clinical practice gives patients interventions not properly evaluated for efficacy
- Overprotection of other patients
  - Huge oversight apparatus for many low risk activities
  - Significant oversight for activities that do not alter care
  - Misplaced moral concern

Going forward?

- Alternative framework needed
  - To encourage the moral good of learning, and to honor patients' interests in having good evidence
  - To protect patients from undue risks, exploitation, and compromises to important rights