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Ethics, oversight, CER, and learning health care systems: Where are we, and Where might we go?

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Organization of my comments today:

- What are ethics challenges in CER projects now?
- What are empirical questions that can inform the ethics of CER?
- What else is ethically important that we are not thinking enough about?
  - (Or at least what is not sufficiently part of the conversation)?

What are the ethics challenges in CER now?

- Should CER studies ever be classified as **minimal risk?**
- What type of **consent/disclosure** is appropriate for different types of studies?
- What are the **Costs to patients** of the studied, randomized treatments compared to their usual care?

Minimal Risk

- General agreement that studies comparing standard, approved treatments **pose lower risks** than studies of experimental treatments
- Also general agreement that, even if they are comparing "standard" or usual care approaches, **not all CER studies are comparable in risk**
- Anecdotally, many (most??) IRBs believe **studies of clinical interventions must be classified** as greater than minimal risk

So how could policy help here?

- **Policy must clarify:**
  - Is the risk of a CER study the risks of the treatments or approaches themselves?
  - Or is it the risk the study poses *above and beyond* the risk of clinical care the patient would otherwise have likely received?
- Such risks might include:
  - Risks of additional procedures, tests
  - Risks of randomization (which brings us to..)

What Consent/disclosure is acceptable

- For studies…
  - That randomize patients to different treatments or approaches?
  - For cluster randomized studies of different patient-level treatments/approaches
  - For systems level interventions (e.g., nurse ratios, computer reminders, hand sanitizers)
- Is streamlined consent acceptable for studies with fewer risks?

So how could policy help here?

- Criteria relevant to what types of consent are allowable in different contexts. E.g.,
- How similar or dissimilar are two approaches
  - In clinical risk?
  - In how patients experience them (even if "clinically equivalent")?
- Comparison of 2 inhalers or 2 BP meds vs. comparison of surgery to PT

Policy guidance that would be helpful regarding consent/disclosure

- Whether to treat cluster randomized differently from individually randomized
  - And if so, does this affect when cluster-randomized designs could be used? (could CRTs be used for surgery vs. PT??)
- Whether to treat systems or care process studies differently from patient-level?
  - Patients never involved in nurse ratio decisions or types of reminders given

When (perhaps) should patients have a say?

- In a context where the different treatment options are different in meaningful ways,
- And where good physicians would agree patients **in clinical care** *should* be told about alternatives (even if in they are not always told in practice)
- Consent here appropriately allows patients to decide themselves about tradeoffs meaningful to *them* --even if tradeoffs are reasonable or balanced in a more general sense– while also explaining need for research

What are (financial) costs to patients of being in a CER studies?

- Study randomizes patients to one of two treatments or approaches
- One has higher copay, or is not in their insurance formulary
- Relevant not only during the study, but potentially long term if tx is for chronic condition and assigned drug works (but they might have done well with the other [covered] medicine, too)

Costs to patients and CER studies

- Studies must anticipate this:
  - Can/should studies pay for additional copays?
  - Can this be done at pharmacy level rather than patient level?
- What happens after the study is over??

Ethically relevant empirical questions: Empirical Question #1:

- Many questions about streamlined consent:
  - Understanding of oral vs. written fact sheet?
  - *What Meaning* do patients attach to different types of consent/disclosures
    - *Is there* an implication to spending more vs. less time on the consent procedure?
    - *Is* how patients interpret this accurate/appropriate (i.e., to how much they "should" worry or think about it, beyond usual clinical care)

Empirical Question #2:

- Are patients' views about what consent/disclosure options they find acceptable affected by context or framing:
  - Emphasizing that QI goes on without their consent and why
  - Emphasizing that almost all types of research use written (lengthy) informed consent forms and why some think CER is or is not different
  - With goal of presenting neutrally, with pros/cons, etc.
- Relevance of trust in institution?

Empirical Question #3:

- How else can we demonstrate respect to patients in addition to consent/disclosure?
  - Involvement of (more) patients in how decisions like these are made about recruitment, consent
  - More transparency about ongoing studies (easier in self-contained [learning] healthcare system)
  - More accountability about what really will happen afterwards
  - More accountability to really change care afterwards
- And does demonstrating respect in other ways affect how patients think about consent requirements?

Empirical question #4:

- Is care better or worse when patients are in CER compared to if they are not?
  - Can some studies include a 3rd "usual care" arm that is used to evaluate effect of being in the study? With NO study interaction– simply a truly usual care comparison to the CER study
  - Or "case control" study of those in study vs. those not in study? (similar to SUPPORT study analysis?)

What do we need to think more about?

- Get more health systems administrators at the table
- (Especially because we need to consider-) How can we be more accountable for findings being implemented after studies are over
  - When clinically appropriate to do so
  - At least where studies are conducted

Relevance, ethically, of this accountability

- A key rationale for streamlining is the urgent need to answer clinical (or systems level) care questions better and faster (need to include more practices, more patients, get studies done quickly)
  - But this is based on an implicit promise that care for patients like them will improve from the findings
  - What have we put in place to secure that?

Relevance of health care administrators being at the table (two-way need?)

- They have the authority to implement
  - Need to be include them in conversation about WHICH types results or interventions might realistically be implementable and why (helps us target agenda)
  - Reasons why QI has been treated differently than research– implicit ethical commitment to implementation

Who else is at the table?

- Need to face, acknowledge, confront- potential difference in priorities of care between researchers and health care administrators??
- Need to be in SAME discussions about vision of the health care system–
  - Our own conversations about learning healthcare systems often miss those who run healthcare systems…
- Short of learning healthcare system, create more partnerships for learning and what they involve, clinically and ethically