

Introduction to the Ethics of Research on Human Subjects

Ethics: Bioethics (Fall 2014)

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WHAT IS CLINICAL EQUIPOISE?

- When standard treatment for a condition is A, but a clinical investigator wants to test B on human subjects, he/she needs to be in a state of “**genuine uncertainty**” regarding the “comparative merits” of A vs. B for the relevant patient population.

WHY DOES EQUIPOISE MATTER, ETHICALLY?

- Condition for **all** clinical trials
- Truthfully conveying purposes, intents of study
- Sufficient disclosure of what the investigator believes...?
- Scientific merit of study enough to subject people to risks
- “A clinician is not merely obliged to treat a patient on the basis of the information that he or she currently has, but is also required to discover information that would be relevant to treatment decisions” (Freedman 514)

“THEORETICAL EQUIPOISE”

- Irrelevant, misleading, inaccurate...
- Disrupted when investigator has *slightest inclination* toward A over B or vice versa.



Bias, hunch,
attentiveness to
only some
evidence, personal
concerns →
Preference for A/B

CLINICAL EQUIPOISE

- **Persists**
 - “there is current or imminent conflict in the clinical community over what treatments preferred for patients in a defined population” (Freedman 516)
- **Disrupted**
 - No open-minded, reasonable, and competent clinician would be without a strong and clear preference for one treatment over other, *given the available evidence*

FOR CONSIDERATION

- If clinical equipoise is truly disrupted, do you believe that it is unethical for an investigator nonetheless to *offer* participation in the trial?
- Are there any instances where you think that clinical equipoise is not ethically mandated of a study?
- Freedman states that the “ethics of medical practice grants no ethical or normative meaning to a treatment preference, however powerful, that is based on a hunch or on anything less than evidence publicly presented and convincing to the clinical community” (517)
 - Are there lingering moral concerns about an investigator’s sense of integrity?

DISCUSSION GROUPS

**Research scenarios and ethical red flags
handout**

Questions? Comments?
