

Ph 458 Evidence and Policy

WEEK 5: Clinical Trials and “Equipoise”: How Ethical and Epistemic Issues become interlinked

Reading and Study questions

1. Reading:

- (a) Wikipedia entry on ‘clinical equipoise’ http://en.wikipedia.org/wiki/Clinical_equipoise
- (b) John Worrall ‘Evidence and Ethics in Medicine’ *Perspectives in Biology and Medicine*, 2008
- (c) Lecture Slides

- A. Make sure you are clear about the ECMO case study – particularly the methodologies involved in the various clinical trials on the treatment.
- B. Discuss the claim that (i) the ethics of performing a trial at all, (ii) the ethics of using a stopping rule in a trial and (iii) the ethics of particular methods of gaining “informed consent” may all look very different depending on your views about the strength of evidence delivered by trials involving particular methodologies.

2. Reading:

Emmanuel, E.J. et al “What makes a clinical trial ethical?” *JAMA*, 2000, 283(20), 2701-2711
<http://jama.jamanetwork.com/article.aspx?articleid=192740>

Presentation: outline and critically evaluate the claims presented about ‘informed consent’ in this paper.

3. Reading:

Miller, FG and Brody H “A Critique of Clinical Equipoise: Therapeutic Misconception in the Ethics of Clinical Trials” *The Hastings Center Report*, 2003, 33(3), 19-28

<http://onlinelibrary.wiley.com/doi/10.2307/3528434/full>

Presentation: Why do Miller and Brody think that it is a mistake to bring the considerations that would be ethically appropriate in the therapeutic realm into the realm of clinical research? Is their argument convincing?