PHIL 226
Biomedical Ethics
Week 7

Exercise 2: Oct. 25

Exam 2: Nov. 1

This week: Human Experimentation

No electronics

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Human Experiments

- Goals
  - Determine causes of diseases.
  - Determine effective treatments for diseases.
- Effective clinical trials: Evidence-based medicine
  - Randomized: Divide people randomly into conditions.
  - Double blind: Neither the participants (subjects) nor the researchers know what condition each participant is in.
  - Placebo controlled: Include a condition in which people are given a non-treatment.

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Competence

- A person is competent to make medical decisions if he or she:
  - Understands the different options available.
  - Understands the consequences of different options.
  - Can compare the consequences in order to choose the best option.
- Examples of incompetent people: young, disabled, mentally ill, unconscious, demented.

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Notorious Cases

- Tuskegee syphilis experiment, 1932-1972
- Nazi medical experiments
- Brainwashing at McGill
- The Nancy Olivieri controversy
- David Healy

Nature Reviews | Drug Discovery

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Ethical Issues

1. Should research be approved by Research Ethics Boards (REB)?
2. Does research require informed consent by the subjects? What degree of information is necessary?
3. How can the risks to subjects be balanced against the potential benefits for later patients?
4. Is it ethical to use placebos, especially when standard therapies are available?
5. Should medical research be funded by industry?
6. Medical ghostwriting

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Discussion question

- What kind of consent is required before people participate in medical experiments?

Ethical Conduct of Research: Principles

1. Respect for persons: autonomy, protect those with diminished autonomy
2. Concern for welfare: quality of life, avoidance of harm
3. Justice: fairness and equality

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1. Does the proposed research jeopardize the safety of participants and/or researchers?
2. Are the risks to the participants justified by the potential benefits of the research?
3. Is there a process that ensures that participants give consent?
4. Do the researchers have any conflicts of interest?
5. Do incentives of the study make participants vulnerable to harm?
6. Are there threats to privacy and confidentiality?
7. Does dissemination of results put participants at risk?
8. Are vulnerable individuals included in the study? If so, how are they protected?
9. Are relevant individuals or groups being excluded from the study?

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Placebo Trials

- Placebos are used to determine whether a treatment is biologically effective.
- Problem 1: Deception vs. informed consent.
- Problem 2: Availability of standard therapies.

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University-Industry Relationships

- Problems
  - Researchers may have conflicts of interest, becoming motivated to get results that support those who fund them.
  - Universities may have conflicts of interest, not supporting ethical researchers.
- Possible Solutions
  - Have researchers disclose all sources of funding.
  - Schafer: Ban all industry funding of university research.
  - Moderate: ensure more oversight.

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Consent Problems with Neonates

- Efficacy of new treatments needs to be evaluated.
- Newborns cannot give consent.
- Time is very limited with neonatal problems.
- Parents are distressed and have difficulty giving informed consent.
- Specific antenatal consent is unattainable.
- Solution? Presume consent then allow parents to opt out.

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Dementia

- Kinds of dementia: senile (vascular, Alzheimer's), Huntington's.
- Dementia involves loss of insight, intellect, and judgment.
- Should patient's be informed that they have Huntington's?
- How directive should physicians be?

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