Epidemiology

Ethics in Epidemiology
Part B

Importance of research regulation
- The Tuskegee film shows the importance of protecting research subjects and how we have failed in the past in doing this.
- There are other cases of questionable research activities.
  - Willowbrook School 1950s, director of research intentionally infected residents with hepatitis A.
  - Milgram experiment told research participants they were shocking other people.
  - Tea room trade, researcher stationed himself in public restrooms, not identifying himself as a researcher.

Belmont Report
- 1979 The Belmont report was enacted.
- Summarized basic ethical principles of research
  - Respect for persons (autonomy)
  - Beneficence
  - Justice
- These guide all human subjects research conducted today.

The Common Rule
- Passed in 1991
- Requirements for assuring compliance with regulations by research institutions.
- Requirements for obtaining informed consent
- Requirement for IRB membership
- Additional protections for vulnerable populations including pregnant women, children, and prisoners.

Ongoing issues
- Many new challenges to ethical research
  - Impact of DNA testing
  - Using the internet to conduct surveys

Ethical Principles in Epidemiology
- Ethics refers to the norms for conduct that distinguish between acceptable and unacceptable behavior
- Two general frameworks
  - Deontological – Set of clear rules which indicates that a given behavior is always right or always wrong
  - Situational – The end justifies the means, ethics of a behavior depends on the end result
### Ethical rule

- People should not kill other people
  - War
  - Abortion when the mother’s life is at risk
  - Abortion at other times
  - Assisted suicide
  - Providing high doses of pain medicine to terminally ill

### Four principles of medical ethics

- Beneficence (do good)
- Non-maleficence (do no harm)
- Respect for autonomy (people’s ability to make their own decisions)
- Justice (providing equal benefits for all)

### Beneficence

- Doctors and researchers should act in the best interest of their patients
  - If one knows for sure that a treatment is beneficial then it is not ethical to withhold it
  - But there have been medical treatments we thought were beneficial that on later study turned out not to be.
    - High rates of tonsillectomies

### Non-maleficence

- Doctors and researchers should not do harm to their patients
  - Concept that benefits must outway the risks
  - Determine the risks to the patient
    - Physical
    - Psychological
    - Loss of confidentiality

### Respect for autonomy

- People give informed consent
- People have the right to make their own decisions
  - Need sufficient information

### Justice

- People should equally benefit from research
  - Situations where those in clinical trials do not benefit from the results as they cannot afford medications being tested
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<thead>
<tr>
<th>USF</th>
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<tbody>
<tr>
<td>- <a href="http://www.research.usf.edu/CS/irb.htm">http://www.research.usf.edu/CS/irb.htm</a></td>
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<tr>
<td>- IRB meets monthly to review research</td>
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<td>- Investigators need to submit protocols to the IRB before starting a study and every year until it ends</td>
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<td>- Investigators need training in how to protect human subjects</td>
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<table>
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<th>Group discussion on ethics</th>
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<td>- Read the case assigned to your group</td>
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<td>- Answer the questions and also consider how your decision meet the goals of</td>
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