Data Ethics

Example

In the 1990s a clinical trial was performed where researchers were determining the benefits of a new treatment to combat Parkinson’s Disease (PD). This treatment involved the injection of fetal tissue into the brain of PD patients. Before treatment could be administered, 2 holes (each the size of a quarter) were cut into the skull of the patients to gain access to the brain area.

Design a completely randomized design for this clinical trial. Be sure to include an appropriate control group.

Terminology

Important terms of this chapter:

- An institutional review board reviews all aspects of the experiment to ensure the methodology is not only sound but also ethical.
- Every subject in the study should offer his/her informed consent.
- The subject’s data should be kept confidential (which is different from anonymous).
Example: Tuskegee Syphilis Study ... (see example in textbook)

- In the 1930s syphilis was common among black men in the rural south.

- In 1932, the Public Heath Service recruited 399 poor black sharecroppers with syphilis and 201 others without the disease.

- Purpose: Observe how syphilis progressed when no treatment was given.

- In 1943, penicillin became available to treat syphilis. By 1947, this was the drug of choice for treating syphilis.

  - The 399 with syphilis were NOT allowed to be treated.

  - The PHS prevented treatment for these subjects until word leaked out and forced an end to the study in 1972.

  - Subjects in this experiment had no opportunity to provide informed consent.

Example: Domestic Violence ... (see example in textbook)

- Usual practice was to remove offender and order him/her to stay out of the household overnight.

- However, victims rarely pressed charges so the police were reluctant to make arrests.

- Can we show that arrest will reduce future offenses? Police tried an experiment:

  - Police arrive at the home where DV is reported

  - If the facts permit an arrest but do not require it, the police randomly determine if the offender should be arrested.

  - Subjects in this experiment had no opportunity to provide informed consent.
Washington (CNN) -- The United States apologized Friday for a 1946-1948 research study in which people in Guatemala were intentionally infected with sexually transmitted diseases.

A statement by Secretary of State Hillary Clinton and Secretary of Health and Human Services Secretary Kathleen Sebelius called the action "reprehensible."

"We deeply regret that it happened, and we apologize to all the individuals who were affected by such abhorrent research practices," the joint statement said. "The conduct exhibited during the study does not represent the values of the United States, or our commitment to human dignity and great respect for the people of Guatemala."

President Barack Obama called his Guatemalan counterpart Friday "offering profound apologies and asking pardon for the deeds of the 1940s," President Alvaro Colom told CNN en Espanol in a telephone interview from Guatemala City.

"Though it happened 64 years ago, it really is a profound violation of human rights," said Colom, who said the report took him by surprise.

Clinton called him on Thursday, he said. "She too offered her apologies," he said, adding that she told him she was ashamed the United States had been involved in the matter.

Asked whether Guatemala was planning to take legal action, Colom said, "That's part of the work of the commission."

"We reject these types of actions, obviously," said Guatemala presidential spokesman Ronaldo Robles. "We know that this took place some time ago, but this is unacceptable and we recognize the apology from Secretary Clinton."

The scientific investigation, called the U.S. Public Health Service Sexually Transmitted Disease Inoculation Study of 1946-1948, aimed at determining the effectiveness of penicillin in treating or preventing syphilis after subjects were exposed to the disease. Gonorrhea and chancres were also studied. Penicillin was a relatively new drug at the time.

The tests were carried out on female commercial sex workers, prisoners in the national penitentiary, patients in the national mental hospital and soldiers. According to the study, more than 1,600 people were infected: 696 with syphilis, 772 with gonorrhea and 142 with chancres.

The study came to light recently when Wellesley College researcher Susan Reverby found the archived but unpublished notes from the project as she was researching a similar study that was conducted between 1932 and 1972 in Tuskegee, Alabama. That study included nearly 400 poor African-American men with preexisting syphilis whose disease was allowed to progress without treatment. Researchers did not infect the subjects, but they did not tell them they had the disease either.

The Tuskegee study was done under the direction of Dr. John C. Cutler, a U.S. Public Health Service medical officer who died in 2003.

"I was doing what historians do," said Reverby, a professor of the history of ideas and women and gender issues, who has written a book on the Tuskegee study. She went to the University of Pittsburgh, where Cutler had taught, and searched through an archive of his papers.
Class Activity

In your assigned groups, discuss the ethical issues raised in three of the questions at the end of this chapter. I will then ask each group to report on its discussion to the rest of the class.

**Group 1:** 7.1 Minimal risk, 7.10 Not really anonymous, 7.18 A right to know?

**Group 2:** 7.2 Institutional review board, 7.11 Human biological materials, 7.19 Telling government

**Group 3:** 7.8, 7.12 Equal treatment, 7.20 Charging for data?

**Group 4:** 7.4 Informed consent, 7.13 Sham surgery, 7.21 Surveys of youth

**Group 5:** 7.5 Is consent needed?, 7.14 AIDS clinical trials, 7.22 Deceiving subjects

**Group 6:** 7.6 Students as subjects, 7.15 AIDS trials in Africa, 7.23 Tempting subjects

**Group 7:** 7.7 HIV infection?, 7.17 Opinion polls, 7.24 Decency and public money