I.2 Observational Studies

1. Introduction

- subjects assign themselves to the different groups being compared
- investigators watch for results

- examples:
  - smokers vs. nonsmokers, relative to heart attacks, lung cancer, etc
  - issue of confounding:
    - by gender
      - men smoke more than women and are more prone to heart attack anyway
    - by age
      - older people have different smoking habits and are more at risk for lung cancer
      - resolution: control for confounding variables
  - compare within similar groups
  - issue of vested interest: tobacco companies want to sell cigarettes
2. The Clofibrate Trial, 1980

- "Coronary Drug Project"
- randomized, controlled, double-blind
- goal: evaluate five drugs for prevention of heart attacks
- subjects: middle-aged men with heart trouble
- random assignment: 8391 subjects
- 5552 drug groups: drugs (capsules) and 2739 control groups: placebo (lactose) (identical capsules)
- timeline: 5 years
- one drug: clofibrate
  - did not same liver: 20% death rate for clofibrate gp.
  - 21% for control gp.
  - proposed explanation: many subjects in clofibrate group did not take their medicine

- Investigation of this hypothesis:
  "adherers" = those who took > 80% of their prescribed medicine.

  "non-adherers" = the others

  Results: Clofibrate Adherers: 4708 15.2%
  Clofibrate Nonadherers: 353 2.5%

  Suggests evidence in favor of clofibrate.

  But look at same for placebo: Adherers: 1813 15.2%
  Nonadherers: 882 28.2%

- Concluding: 1. Clofibrate has no effect
  2. Adherence does, however. Adherers are more concerned with their health and take better care of themselves in general.
3. More Examples

- Pellagra

- Cervical cancer and circumcision

- Ultrasound and low birthweight

- The Samaritans and suicide

4. Sex Bias in Graduate Admissions (Berkeley, 1973)

- Overall: 44% admission for men, 35% for women

- By majors, however: some favored men, some women

  fewer applied to easier majors  more applied to harder major

- Simpson's paradox

  Rates by subgroups can compare in reverse pattern for the combined group

5. Confounding

- A difference between treatment and control groups that is other than the treatment and affects the response