## Purpose of Class

Change the way you **think** about data

- How they are **collected**
- How they are **analyzed**

***More*** emphasis on critical thinking, concepts, ideas
***Less*** emphasis on formulas and math

"Statistical thinking will one day be as necessary for efficient citizenship as the ability to read and write."
- H.G. Wells (c. 1905).

# COMMENTS ON *STATISTICS*

"The only *great* introductory statistics text."—John Hartigan
Professor of Statistics, Yale University

"This is the best introduction to the ideas of statistics. It is friendly, clear, and correct. The examples are real. The book is deep without being technical."
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Professor of Mathematics, Indiana University, Bloomington

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## Chapter 1: Controlled Experiments

How should we design an experiment to evaluate a new drug or therapy for a medical condition?

Method of comparison:

- Treatment group
- Control group

} differ **only** with respect to treatment

Compare the two groups and conclude that any differences are due to the treatment.

7 a

## Chapter 1: Controlled Experiments

If the two groups differ with respect to something ***other*** than the treatment, we say there is a ***confounding factor***.

E.g. if the treatment group is healthier than the control group before the study starts, "initial health" is a confounding factor.

Example.

Do caffeine pills (200 mg) make you a better test-taker? Design an experiment to help you answer this question by using all 260 Stat 1040 students who will take the first midterm on the 12$^{th}$ of February. (10 points)

## Polio Vaccine (1954)

## NFIP Study Design

(*National Foundation for Infantile Paralysis*)

Vaccinate all children in grade 2 whose parents consent.

Use grade 1 and grade 3 as controls.

Is the NFIP study design a controlled experiment?

Is the NFIP study design a “good” experiment? Why or why not?

## Another Study Design

All students in grades 1-3 were asked to participate in a study in which they might or might not get the vaccine.

Students whose parents agreed were randomly assigned to the Vaccine and Control groups.

Students in the control group were given a placebo so the study was blind.

The investigators who evaluated the students did not know who was in the vaccine group and who was in the control group, so the study was double-blind.

# Definitions

**Controls**: subjects who get no treatment, or the standard treatment.

**Controlled Experiment:** investigators get to assign subjects to the treatment or control group.

**Randomized Experiment:** subjects are assigned to the treatment and control groups using a chance procedure, such as coin tossing.

**Blind:** subjects do not know if they are getting the treatment or the placebo.

**Placebo**: resembles the treatment but lacks the active ingredient.

**Double Blind:** neither the subjects, nor those who interact with them, know who is getting the treatment or the placebo.

## Ideal Study

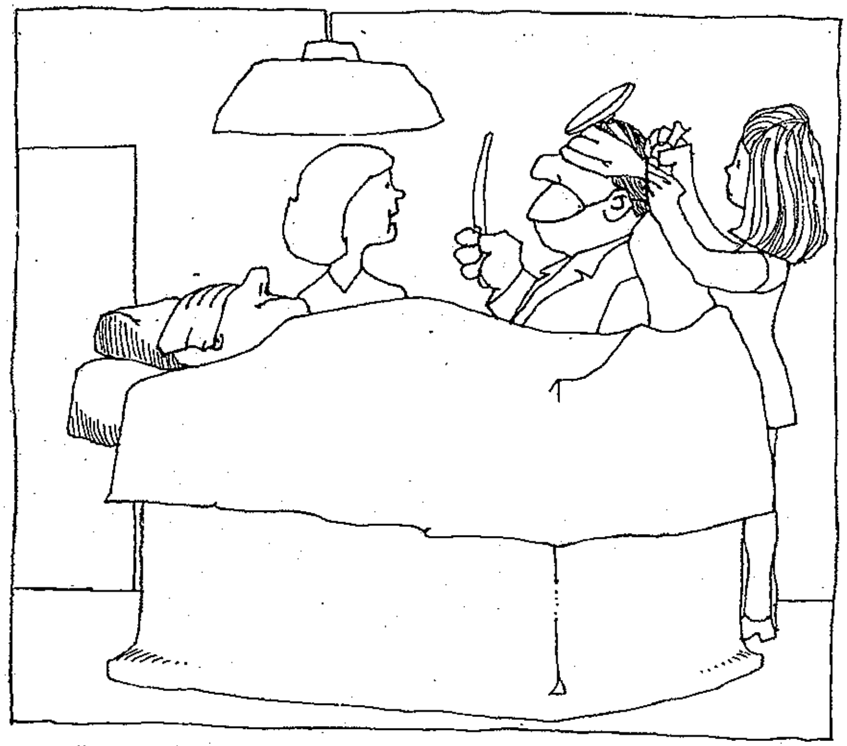
### Randomized, controlled, double-blind

- Reduces or eliminates confounding factors.
- Reduces or eliminates psychosomatic effects.
- Reduces or eliminates effects of personal bias.

BUT

- Good placebos are hard to find.
- Can't always randomize.
- Controls are not always ethical.
- Treatments are not always ethical. E.g., smoking studies.

Vitamin C
Caffeine pills



*"Dr. Burns, are you sure this is what the statisticians call a double blind experiment?"*

## Salk Vaccine Trial Results

*The randomized, controlled double-blind experiment*

| | *Size* | *Rate* |
|---|---|---|
| Treatment | 200,000 | 28 |
| Control | 200,000 | 71 |
| No Consent | 350,000 | 46 |

*The NFIP Study*

| | *Size* | *Rate* |
|---|---|---|
| Grade 2 (Vaccine) | 225,000 | 25 |
| Grades 1 & 3 (Control) | 725,000 | 54 |
| Grade 2 (No Consent) | 125,000 | 44 |

## The Portacaval Shunt

### A treatment for cirrhosis of the liver

| | *Degree of Enthusiasm* | | |
|---|---|---|---|
| *Design* | *Marked* | *Moderate* | *None* |
| No controls | 24 | 7 | 1 |
| Controls, but not randomized | 10 | 3 | 2 |
| Randomized controlled | 0 | 1 | 3 |

## 5-year Survival Rates

*For coronary bypass patients*

Randomized controlled studies versus historical controls

| | Randomized | Historical |
|---|---|---|
| Surgery | 87.6% | 90.9% |
| Controls | 83.2% | 71.1% |