Preview of This Week's Lab

The Problem

- Clinical depression is a recurrent illness requiring treatment and often hospitalization.
- Nearly 50% of people who have an episode of major clinical depression will have a recurrence within 2-3 years.
- Preventing recurrence of depression would alleviate individual pain and suffering, and save society many thousands of dollars per patient in medical expenses and lost wages due to an inability to work.

A Randomized Controlled Clinical Trial

• During the 1980's the National Institutes of Health (NIH) sponsored a clinical trial to **evaluate two drugs to prevent the recurrence of depression** in patients who have had at least one previous episode of the illness (Prien et al., *Archives of General Psychiatry*, 1984).

Design of the Study

- The study was **multi-centered**. There were 5 medical clinics across the country that participated in this trial. Using many clinics enables the investigators to enroll many more patients into the study and allows for a diversity of patients to participate.
- There were 3 **treatment** groups. Patients received either *Imipramine* (Imip), *Lithium* (Li), or a *Placebo* (Pl). Imip and Li are active drugs.
- Patients were **randomized** to one of the 3 treatment groups, using a random device (like rolling a 3 sided die).
- Patients were followed from 2-4 years to see whether or not they had a recurrence of depression. If they did not have a recurrence within this time frame, then their treatment was considered a *Success*. If they did have a recurrence, it was considered a *Failure*.
- The study was **double-blinded**.
- A number of additional background variables were measured for each patient.

Variables Measured in the Study

The variables in the data set are:

- HOSPT: Which hospital: 1, 2, 3, 5 or 6.
- TREAT: 0=Lithium; 1=Imipramine; 2=Placebo.
- OUTCOME: 0=Success 1=Failure (recurrence of depression).
- TIME: number of weeks until a recurrence (if OUT-COME=1) or until study ended (if OUTCOME=0).
- GAS: a measure of social functioning from 0-100. Low scores are bad.
- ACUTET: How many days the patient was depressed before the start of the study.
- AGE: Age in years.
- GENDER: 1=Female 2=Male.

The Main Questions

- (I) Which of the drugs (if either) was more successful in preventing the recurrence of depression relative to the placebo?
- (II) Which of the drugs (if either) delayed the recurrence of depression longer relative to the placebo?