Section B

Methods of Randomization
The Randomized Trial

- We want to assign a group of subjects to one of two groups—Treatment A or Treatment B
  - How can we do this in a random manner?
The Randomized Trial

- Random assignment
  - Flip a coin
  - “Heads”—Tx A
  - “Tails”—Tx B

- Roll a six-sided die (from a pair of dice)
  - Even number—Tx A
  - Odd number—Tx B

- Table of random numbers
  - Practical statistics for medical research, Altman, table B13

- Computer generated random numbers
  - STATA
“Almost” Random Assignment

- Alphabetical
  - Tx A = patients with last name A–M
  - Tx B = patients with last name N–Z

- Telephone number/social security number
  - Tx A = last digit odd
  - Tx B = last digit even

- Sequential
  - Tx A = morning patients
  - Tx B = afternoon patients

- There are potential problems in the “almost random” assignment scheme—thoughts?
Simple Randomization (Flip a Coin)

- Randomize individuals to one of two treatments
  - If $n$ is big, works great

- Randomize individuals to one of two treatments
  - If $n$ is small there may be imbalance with respect to . . .
    - Sample sizes
    - Other variables
Potential Problems with Simple Randomization

- Unequal sample sizes

- If the study has a very small sample size, there is no guarantee that the two groups will have equal sample size using simple randomization

- Bad luck
  - Extremely unbalanced sample sizes

- Bad luck (worst case scenario)
  - All Tx A
  - None Tx B
Example of Block Size of Four

- Blocked randomization
  - Suppose we want to randomize a small number of patients to two groups
  - AABB
  - ABAB
  - ABBA
  - BABA
  - BAAB
  - BBAA
Example of Block Size of Four

- Roll a die (#1-6) to determine pattern
  - Each pattern has same probability of being chosen (one in six)

- Guarantees balance after every four patients
Example of Block Size of Four

- Example—suppose 12 subjects total
  - Roll die: you roll a “3”
  - “3” corresponds to ABBA

- Assignments for first four subjects
  - Subject # 1: group A
  - Subject # 2: group B
  - Subject # 3: group B
  - Subject # 4: group A
Blocked Randomization

- Altman, p. 87
  - You can have blocks of any size
Potential Problem with Simple Randomization

- Imbalance on a key variable
  - If study is very small, no guarantee groups are “comparable”
  - Solution—stratify
  - Suppose you are worried about differential age distributions in each group assigned
  - Stratify on age, then you do block randomization
  - Younger: ABBA  BABA
  - Older    : BBAA  ABAB