Case Study 3: Dressings

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Recap of Problem

- Compare new dressing for minor operations to a standard dressing.
  - Two sites will be selected on each subject and wounds simulated at each site.
    - New dressing at one site and standard dressing at the other
- Measurements will be made on several responses such as pain, level of infection, speed of healing, and others on a 1(worst) to 5(best) scale.
  - Repeated at 7 days, 14 days, and 42 days after surgery.
  - Standard dressing heals wounds in 42 days

Questions for Client

- What they want to do?
- Where sites are selected and how?
  - Same area or similar body part?
  - Randomize which body part is selected if different patients have different body parts selected
  - Area selected could affect healing time.
- Site effects of dressing?
  - Could be a random effect.
- Who is being selected?
  - Will prior medical history be accounted for?
  - Age of people could matter.
- What does the scale mean?
  - The scale 1 (worst) to 5 (best) measures many different responses
  - What does each number correspond to?
  - How to use the scale to measure pain?
    - Different pain tolerances

Advice on Experiment

- Depending on which body parts are selected, randomize which wound gets which dressing.

- It might actually be easier to select areas that are similar.
  - Either in the same general area
  - Or use symmetry of the human body

Number of Patients

- What is their budget?
  - Maybe the dressing is expensive
  - Take into account people may drop out
  - Demographics of people
    - Age
    - Prior medical conditions
- We could calculate the size of the sample based on perceived effects and the desired power

How to Analyze

- Could use a table to compare means of measured quantities and test for differences on each of the three different days between Standard and New Dressings for a body part selected.

  ◦ For example we could find the New has a higher pain score on day 7, but a lower pain score on day14 and 42.

Days	7	14	42
Standard	2.9	3.4	4.6
New	1.2	3.8	5

How to Analyze

- Could use a Time Series model if the client wants to see a change in the measurement taken over time

  ◦ Could include random effects
    • Random Intercepts
    • Random Slopes

  ◦ Could include both time variant and time invariant covariates
    • Maybe medical history could change during the study and biological sex remain the same