PaTH TO HEALTH
diabetes
JUST-IN-TIME
DATA ANALYSIS TRAINING
PART: 2

FALL 2018
Recap Part 1 Training

• Natural experiments observe what is occurring in real world (researchers can not control for conditions).

• Comparative Effectiveness Research (CER) compares two or more health interventions (i.e. treatments, policies) to determine benefits/harm to key stakeholders.

• Our PaTH to Health: Diabetes study is both a natural experiment and CER!

• Data errors and missing data present challenges during data analysis phase.
Part 2 Learning Objectives

- To understand the importance of statistical tests in explaining study data.
- To become familiar with some statistical language, such as p values and null hypotheses.
- To be able to state some outcomes we are examining in our study.
Statistical Tests

• Mathematical tools used to analyze data collected in a research study.
  – There are many of them!

• Often times a research study involves 2 or more groups – a statistical test can help compare/contrast the groups.

Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2996580/
• **Variable:** A value that can change. In research, this is your study data that will help you answer your research question.

• **Control:** This can be a group that does not receive a treatment (i.e. placebo group) OR it can be a way to make any “extra” variables constant during a study so they do not affect your outcome.

• **Bias:** Over or under-estimate effects in overall population based on what you found in your study.
Potential Confounders

• Some statistical tests can control for variables.
  – Separate out the effects of other study factors from the main variable of interest.

• A confounding variable is an “extra” variable that you didn’t account for:
  – Can suggest there is relationship when in fact there isn’t
  – Can introduce bias

• In our study, we need to control for obesity counseling happening at different times; frequency of visits; not everyone has counseling

Source: https://www.statisticshowto.datasciencecentral.com/experimental-design/confounding-variable/
Why Run Statistics?

• When we conduct research, we collect information (data) to help answer important questions.

• We select/recruit/enroll a sample of a population to study.

• Statistical methods are used to help us draw conclusions about the sample population.

  – If there is a statistical relationship in a sample, is it caused by chance or is there a true relationship in the population?
In our study, we are looking at if obesity counseling improves weight/diabetes outcomes for patients with or at risk of type 2 diabetes BUT we are only able to look at a sample of this population.

- If weight and/or diabetes are improved in patients who underwent obesity counseling, would these same results occur for patients outside of our study sample? How did policy impact this?
Which Statistical Tests To Use?

• Deciding which statistical test(s) to use occurs **BEFORE THE STUDY BEGINS.**
  – We decided our statistical plan in the project proposal.
• This ensures that the study results do not influence the test selection.
• Decision is based on the research question you are hoping to answer, the format of study data, and the study design.
Study Statistical Plan

• **Descriptive Statistics:**
  – To describe the variables of each study cohort (diabetes, at-risk)
  – Examples include: patient demographics, receiving obesity counseling, controlled diabetes, weight loss

• **Subgroup Analyses:**
  – We will examine the benefits of policy changes for different subgroups
  – Examples include: patient characteristics, patients with vs. without insurance, provider characteristics, rural vs. urban areas
Null Hypothesis

• Every study has a null hypothesis, which means:
  – There are NO SIGNIFICANT DIFFERENCES between study groups.
  – Any observed differences are due to research errors, not true differences.

• A statistical test is always a test on your null hypothesis. One of 2 results are found:
  – You either Reject or Fail to Reject the Null Hypothesis.

Source: https://www.cbgs.k12.va.us/cbgs-document/research/Stats%20For%20Dummies.pdf
Scenario

• For example, in a clinical trial to investigate whether a diabetes medication works better than a placebo, the test variable is lowered A1c values.
  – The null hypothesis is: “There is no difference in A1c values between the active treatment and placebo groups”.
  – The study hypothesis is: “The treatment group will have lower A1c.”

• As a researcher, you are testing your hypothesis that your treatment works.
A Statistician Responds to a Marriage Proposal

I Reject the Null Hypothesis.

Will you marry me?

Huh? What does that mean?

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from the book Statistics from A to Z — Confusing Concepts Clarified.
P Value

• Data collected from two groups has 2 different means (averages):
  • Samples really have different means OR
  • Difference that is observed is a coincidence
    • *No way to confirm either of these possibilities*

• We calculate the Chances (known as “$P$” value in statistics for probability) of observing a difference between sample means in an experiment.

• P value ranges from zero to one.
  – Closer to 0, difference found between two samples is real.
  – Closer to 1, difference likely caused by chance.

Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2996580/
## Differences Between Study Groups

<table>
<thead>
<tr>
<th>Treatment Group A1c Values (%)</th>
<th>Placebo Group A1c Values (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.5</td>
<td>8.4</td>
</tr>
<tr>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>3</td>
<td>7.5</td>
</tr>
<tr>
<td>4.7</td>
<td>6.5</td>
</tr>
<tr>
<td>2</td>
<td>9.5</td>
</tr>
<tr>
<td>2.5</td>
<td>8</td>
</tr>
<tr>
<td><strong>MEAN A1c</strong></td>
<td><strong>MEAN A1c</strong></td>
</tr>
<tr>
<td>3.45</td>
<td>8.2</td>
</tr>
</tbody>
</table>
Reject Null Hypothesis?

Let’s say that the p value was less than 0.01 ($p<0.01$)
– What does this tell us about the data?

1). The differences in A1c values between the treatment and placebo study groups are likely due to a random sampling

OR

2). The differences in A1c values are likely REAL – treatment group has lower A1c values likely due to treatment.
Sample Size

• Sample size is the amount of data you have in each study group (i.e. participants, health values).

• The larger the sample size, the higher the statistical power.

• The higher the statistical power, the more likely it is that your study results could also be found in the overall population (generalizable).
Interrupted Time Series

- Time series are continuous observations of a population taken at set intervals over time.
- Interrupted time series (ITS) analysis can help us understand if health interventions implemented at a clearly defined point in time are actually helping people.
- For our study, we are looking at the uptake of obesity counseling coverage before and after this benefit was implemented.

Source: https://academic.oup.com/ije/article/46/1/348/2622842
Timeline for Policy Changes

- **Maryland**
  - ACA: Expansion of Medicaid

- **Pennsylvania**
  - ACA: Expansion of Medicaid

- **Utah**
  - Unchanged

**National Changes**

- **2009**: ACA: Signed into law
- **2011**: CMS: Coverage for intensive behavioral therapy for obesity
- **2013**: ACA: Coverage of and removal of cost-sharing for preventive services

**Proposed Study Period**
(2009-2019)
Individual vs. Population Effects

• Our primary study analysis is focused on individual-level outcomes.
  – Does a patient have better A1c or weight outcomes after attending obesity counseling?

• Through the electronic health record data (EHR), we can also examine diabetes outcomes at a community and clinical level.
  – I.e., Look at rural vs. urban effects, the number of patients with controlled diabetes in each county can be obtained through the EHR data.
The goal of research is to answer the study’s research question. Statistical tests can be used to help us understand study data.

Sometimes study results are not what we anticipated or hypothesized. This is still important knowledge.

When we analyze study data, it’s important to control for any extra variables that could affect the outcome of our study.
Questions