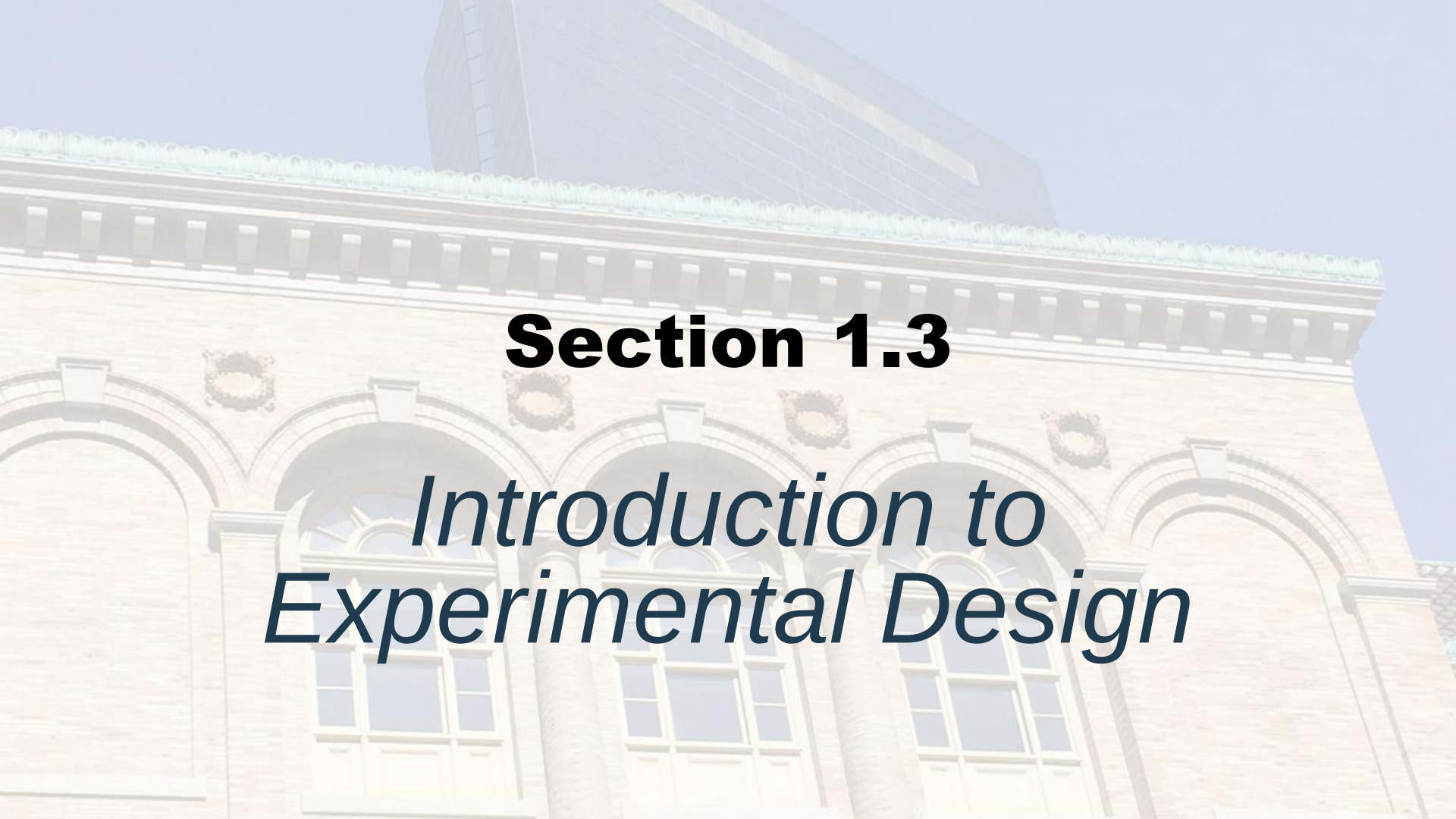


Section 1.3

Introduction to Experimental Design

Learning Objectives

At the end of this lecture, the student should be able to:

- State the steps of conducting a statistical study.
- Select one step of developing a statistical study, and state the reason for this step.
- Name one common mistake that can introduce bias into a survey, and give an example.
- Explain what a lurking variable is, and give an example.
- Define what a completely randomized experiment is.

Introduction

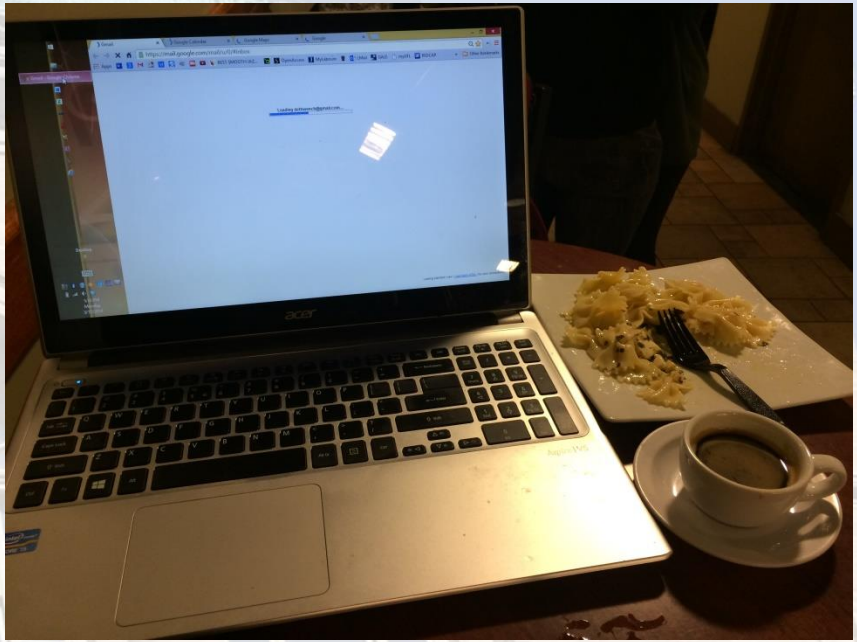
- Steps to Conducting Statistical Study
- Basic Terms & Definitions
- Avoiding Bias in Survey Design
- Topics in Randomization

Basic Terms & Definitions

Terms you Need to Know

This Section

- Review the steps to conducting a statistical study
- Define vocabulary terms
- Examples provided from healthcare



Basic Guidelines for Planning a Statistical Study

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Hypothesis & Variables

- *Hypothesis:* Air pollution causes asthma in children who live in urban settings
- *Individuals:* Children in urban settings
- *Variables:* Air pollution and asthma

A person whom goes by the name Imagere

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Sampling, Ethics & Data Collection

Photo courtesy of US Army Africa.

- Either collect data or use existing dataset
  - Can use a government dataset for population measures

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Photo courtesy of US Army Africa.

- Either collect data or use existing dataset
  - Can use a government dataset for population measures
- Can collect data from a sample for estimates
  - Need to choose sampling approach
  - Will need consent if legally found to be “human research”
  - May need consent from parents to collect data about children

Sampling, Ethics & Data Collection

IRB

Photo courtesy of US Army Africa.

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Census vs. Sample

In a census, measurements or observations from the entire population are used.

Photo courtesy of Che/Wikimedia Commons

In a sample, measurements or observations from *part* of the population are used.

Photo courtesy of Sandstein/Wikimedia Commons

Experiment vs. Observational Study

Experiment

- A *treatment or intervention* is deliberately assigned to the individuals
- The *purpose is to study the possible effect of the treatment or intervention* on the variables measured

Photo courtesy of US Marines.

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Observational Study

- Observations and measurements of individuals are taken
- However, *no treatment or intervention is assigned* by the researcher

Examples of Experiment vs. Observational Study

Experiment (with OS)

Women's Health Initiative

Examples of Experiment vs. Observational Study

Experiment (with OS)

Women's Health Initiative

Observational Study (OS)

Nurses Health Study

Replication

- Studies must be done rigorously enough to be replicated.
- Replicating the results of observational studies and experiments is necessary for science to progress.

Photo courtesy of Neils B.

Review

- Several steps need to be followed in order when conducting a statistical study.
- It is necessary to determine the type of study, and make other study-related decisions.

Avoiding Bias in Survey Design

Important Concepts

Bias

- Surveys can provide a lot of useful information
- However, it is important that all aspects of survey design and administration minimize “bias”
- Several considerations should be made

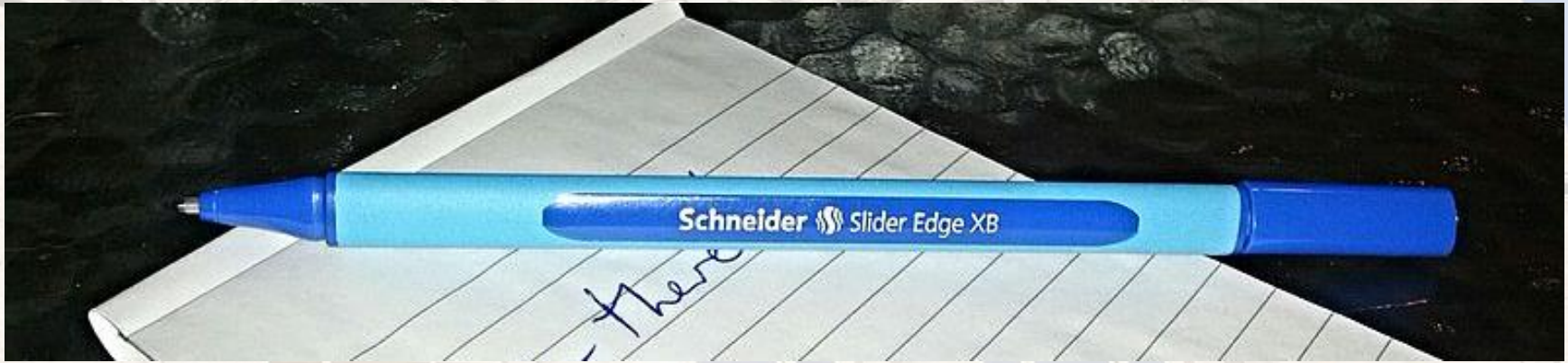

Photo by Revital9

Non-response & Voluntary Response

- If many people refuse your survey, the people who do complete it are likely to have a biased opinion.
- There may be a reason they do not complete your survey that has to do with how they feel about your survey topic.

Photo by Shay of Belfast, Northern Ireland.

Truthfulness of Response

- Respondents may lie on purpose
  - If asked a question that is too personal
  - If asked a question too hard to think about

Truthfulness of Response

- Respondents may lie on purpose
  - If asked a question that is too personal
  - If asked a question too hard to think about
- Respondents may lie inadvertently
  - May not remember if asking about something that happened a long time ago
  - May have “recall bias” influenced by events that have happened since original event

Hidden Bias

- Question wording may induce a certain response.
  - How long have you been using Software A?
- Order of questions and other wording may induce a certain response.
  - Do you agree with Obamacare?
  - *More people have health insurance than ever before.* Do you agree with Obamacare?
- Scales of questions may not accurately measure responses
  - Do your feelings always fit on a scale of 1 to 5?

Interviewer Influence

- This is important with in-person and phone surveys
- Best to have interviewer from same population as research participant
- All verbal and non-verbal influences matter

Photo by UK Department for International Development.

Vague Wording

- Avoid vague terms used in a survey.
  - Instead of asking if a person waited “a long time” in the waiting room, ask the number of minutes.
- If you must use vague terms, include grounding language.
  - Where 10 is extremely important, and 1 is not at all important, how important is having a controllable lifestyle to you in your future career? A controllable lifestyle is defined as one that allows the physician to control the number of hours devoted to practicing his/her specialty.

Lurking Variable

- “Lurk” means to sneak around behind the scenes
- A “lurking variable” is a variable that is associated with a condition, but may not cause that condition.
- For example, we know that having more education increases income. However, people of the same education level do not all make the same income.
- Lurking variables are sex and race. In the US, according to the Department of Labor, these variables can decrease a person’s income at the same level of education.

Lurking Variables Cause Confounding

- Current studies show that why women and African Americans make less money on the whole is not explained by *fewer of them working, or fewer of them getting degrees.*
- Early studies were *confounded by these lurking variables.*

Photo of Jackie Lacey, Los Angeles County District Attorney, by Neon Tommy..

Final Note on Bias

- Survey results are important for improving healthcare and the progression of science.
- It is important to pay special attention to avoiding bias in the design and conduct of surveys.

Topics in Randomization

Definitions & Terms

Randomization

- Steps in a completely randomized experiment
- Placebo and placebo effect
- Blocked randomization
- Blinding

Why Randomize?

- Randomization is used to assign individuals to treatment groups.
- This helps prevent bias in selecting members for each group.
  - It distributes “lurking variables” evenly

Image courtesy of Svjo.

A Completely Randomized Experiment

Recruit sample

A Completely Randomized Experiment

Recruit sample → Measure confounders, outcome

A Completely Randomized Experiment

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Image courtesy of Wirelizard.

A Completely Randomized Experiment

Recruit sample → Measure confounders, outcome → 

Group A
Treatment

Group B
Placebo

Image courtesy of Wirelizard.

A Completely Randomized Experiment

Recruit sample → Measure confounders, outcome →  → Group A Treatment / Group B Placebo → Measure confounders, outcome

Image courtesy of Wirelizard.

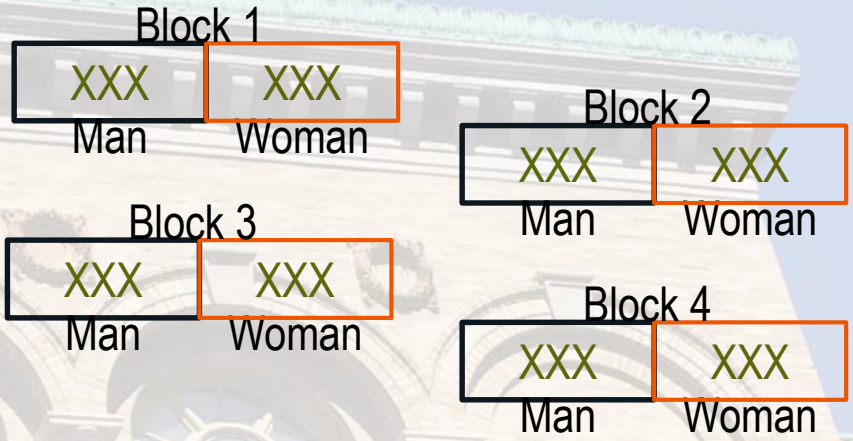
Placebo & Placebo Effect

- Placebo effect occurs when there is no treatment, but participant assumes s/he is receiving treatment and responds favorably.
- The placebo is given to a control group, which receives the placebo (or attention control if treatment is not a drug).
- Used as a control or comparison group.

Image courtesy of the National Institutes of Health

Blocked Randomization

- If you want men and women equal in two randomized groups, create “blocks” with two slots – one for a man, and one for a woman.



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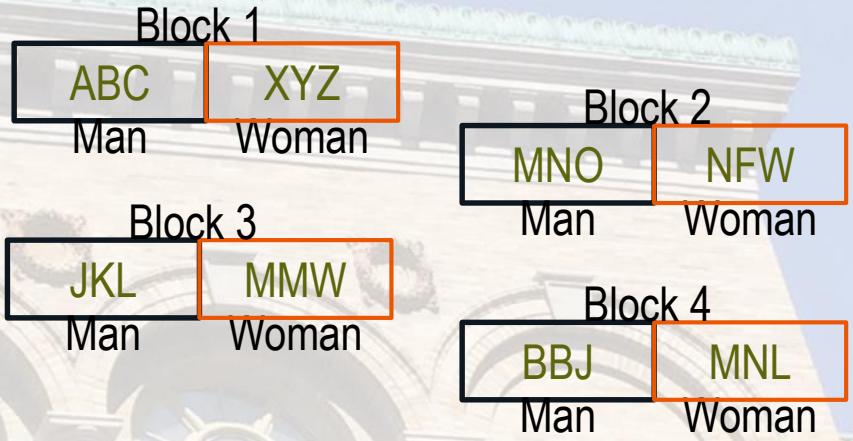

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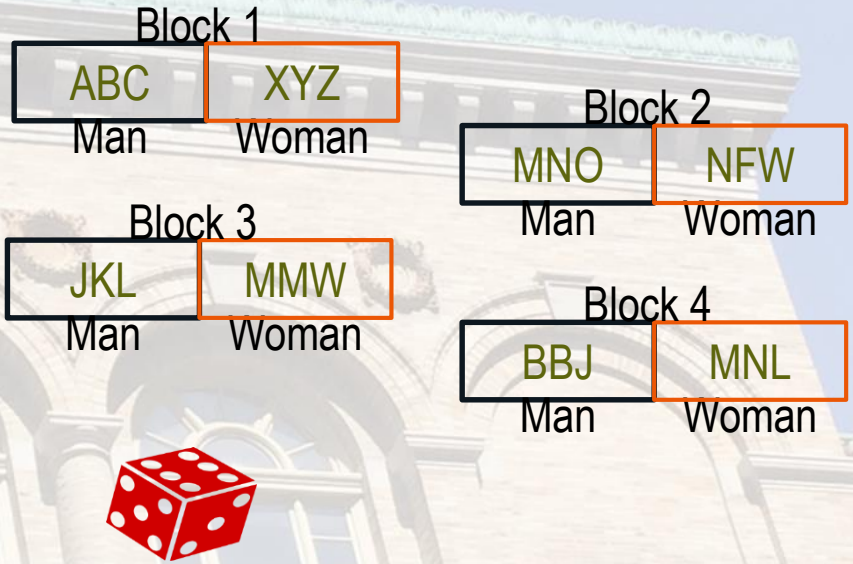
- Then, randomize the blocks. You will get a paired couples in each group!



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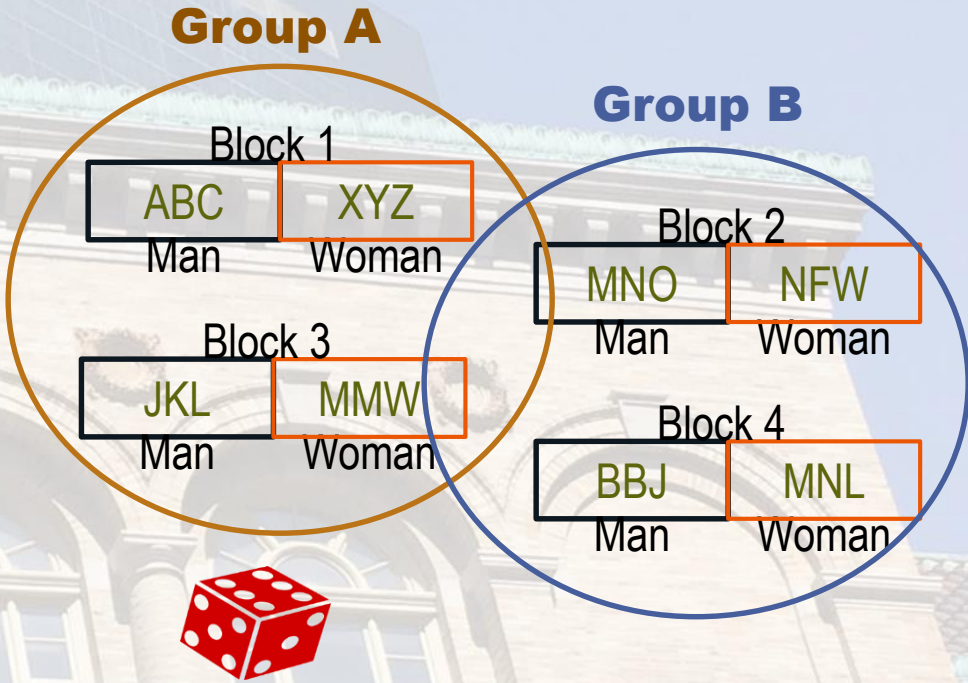

Blinding

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  - *Example:* A participant is blinded to treatment or placebo.

Image courtesy of U.S. Marines

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  - *Example:* A participant is blinded to treatment or placebo.
  - *Example:* A study radiologist may be blinded to treatment group when looking at images during study procedures.
- Double-blind means study staff and participant do not know treatment assignment.

Image courtesy of U.S. Marines

Randomization & Bias

Photograph by US Navy

- Randomization is used to reduce bias in an experiment.
- Blocked randomization can even out groups.
- Blinding further prevents bias
- The placebo effect is necessary to take into account.

Conclusion

- Steps to Conducting Statistical Study
- Basic Terms & Definitions
- Avoiding Bias in Survey Design
- Topics in Randomization

Photo by photosteve101