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Day 2

Introduction to Research

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Topics Covered Today

- Ethical Conduct of Research
- Study Design

Review of Tuesday

- Research area
 - Broad topic for research
- Research question
 - Specific question that will be answered by your research project
- Specific aims
 - Three to five
 - Exactly how you will answer the research question

Ethics in research

- **Tuskegee syphilis study (1932-1972)**
- **Nazi hypothermia trials**
- **HeLa cells (Henrietta Lacks) in use since 1951 – immortal cervical cancer cells – major contribution to polio eradication**



Image by [Jrtayloriv](#)

Ethics

- **The Ethical Conduct of Research includes:**
 - **Consideration for the rights of participants**
 - **Being aware of what is appropriate in a given context**
 - **Informed consent**
 - **Keeping an eye on unintended consequences**

St. Paul's Millennium Medical College Institutional Review Board

- **Institutional Review Board**
 - A committee formally designated to approve, monitor and review biomedical and behavioral research involving humans
 - Aim to protect the rights and welfare of the research subjects

Ethics Boards

- **Ethics Boards**
 - **Where are they applicable? What do they do?**
 - Review research protocol, instruments, recruitment materials
 - Approve data collection, management, storage plans
 - Oversee deviations from protocol
 - Track adverse events

Ethical approval is critical

**You cannot
publish your findings
without review
and approval
by an ethics board!**

IRB Application

- Cover letter
- Application form
- Research protocol
- Participant information leaflet
- Summary of protocol
- Data capturing sheets
- Permission from study site
- CV of PI

Other things to include

- Inclusion criteria
- Exclusion criteria
- Expected number of participants
- Proposed start / end date / length of study
- Funding

Study Design Considerations

- **Many taxonomies r.e. study design**
 - 1) **Descriptive Studies**
 - 2) **Relational Studies**
 - 3) **Causal Studies**

Study Design Considerations

- **Just as many taxonomies with regard to methods**
 - 1) **Experimental vs. non-experimental**
 - 2) **Control group vs. no control group**
 - 3) **Retrospective vs. prospective**
 - 4) **Animal vs. human**

Study design considerations

- **Data collection taxonomies**
 - 1) **Quantitative vs. qualitative**
 - 2) **Primary vs. secondary**
 - 3) **Biometric / clinical vs. self-reported**

For Your Research...

- **Choice of study design reflects:**
 - **Goal of the study**
 - Description, exploring relationships, establishing causality
 - **Context**
 - Remote rural clinic w/o medical records vs. high tech hospital

A few specifics...

- **Experimental research**
- **Survey research**
- **Secondary data analysis**
- **Retrospective study**
- **Evaluation research**

Experimental Research

- **Need control over context**
- **One group gets an intervention, drug, treatment, etc. while another doesn't**
- **Best results when done well, perhaps among the hardest to do well**

Experimental Research

- ***Manipulation*** of an independent variable.
- An attempt is made to hold all other variables except the dependent variable constant - ***control***.
- Effect is observed of the manipulation of the independent variable on the dependent variable - ***observation***.

Experimental Research

- *Internal Validity*
- *External Validity*

One-shot experimental case study

- Aim
 - To attempt to explain a consequent by an antecedent
- X.....O
- The least reliable of all experimental approaches

One Group Pretest-Posttest

- Aim:
 - To evaluate the influence of a variable
- O.....X.....O
- An approach that provides a measure of change

Static Group Comparison

- Aim
 - To determine the influence of a variable on one group but not another group
- X.....O
.....O
- Weakness lies in to examination of pre-experimental equivalence of groups

Nonrandomized Control Group Pretest-Posttest

- Aim
 - To investigate a situation in which random selection and assignment is not possible
- O.....X.....O
O.....O
- One of the most widely used quasi experiment designs. Comparing pretest results will indicate degree of equivalency

Time Series

- Aim
 - To determine the influence of a variable introduced only after a series of initial observations and only where one group is available
- O...O...O...X...O...O

Control Group Time Series

- Aim
 - To bolster the above design by adding a control group

- O....O....O....X....O....O
O....O....O.....O....O

- Very strong study design if two groups are similar

Randomized Control Trial

- Aim
 - To determine the effect of an intervention
- R O.....X.....O
R O.....O
- When done well, this is the gold standard of experimental research

Survey Research

- **Two kinds of surveys**
 - Interviews
 - Questionnaires
- **Types of surveys**
 - Cross-sectional vs. longitudinal or cohort
 - Qualitative vs. quantitative

Survey Research

- **Potential challenges:**
 - **Poorly worded questions = poor quality data**
 - **Poorly chosen sample = non-representative data**
 - **Missing data = non-representative data**
 - **Self-report doesn't always match reality**
 - **Language issues**

Survey Research

- Benefits of survey research
 - Relatively inexpensive
 - Describe a large population
 - Many questions

Secondary Data Analysis

- **Uses existing data sets to ask and answer research questions**
- **Data collected by a person or organization other than the users of the data**

Secondary Data Analysis

- **Strengths of Secondary Data Analysis**
 - Unobtrusive
 - Fast & inexpensive
 - Avoid data collection problems
 - Provide basis for comparison

Secondary Data Analysis

- **Potential challenges:**
 - Limits what you can look at
 - Data quality may be suspect
 - Public access data means you are not the only one analyzing it

Secondary Data Analysis

- Evaluation of Data Sources
 - Purpose of the study
 - Sponsor/collector of the data
 - Mode of data collection
 - Sampling procedures
 - Consistency of data with other sources
 - Documentation
 - Number of observations

Retrospective Studies

- Looking backward to collect data
- Most common example: Chart Reviews
 - Pulling data on patients from their medical records
- Potential challenges:
 - Quality, accuracy, availability of medical records / retrospective data
 - Missing data

Case-Control Study

- Used if a condition is rare
- After data is collected, go back and match cases with demographically similar controls
- Used to determine risk factors of developing a particular condition

Evaluation Research

- Also called “Operations Research”
- Determining if a program is effective, what parts are working, which parts are not
- Potential Challenges
 - Availability of baseline data
 - Dealing with differential participation of those for whom the program works
 - Availability of process data
 - Resistance to negative findings

Key Take-Home Points

- Find something that interests you
- Think creatively about what's not being studied
- Think creatively about different ways to study it

From here...

- Putting it all together
 - Developing a research question
 - Writing a protocol
 - Submitting an IRB

Questions?

- Thank you!