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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
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

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
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
Data collection taxonomies

1) Quantitative vs. qualitative
2) Primary vs. secondary
3) Biometric / clinical vs. self-reported
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
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
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
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
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!