The Research Process

- Find a Research Idea
- Convert Idea into Hypothesis
- Identify Participants
- Define Variables, Choose Measures
- Select a Research Design
- Conduct the Study
- Analyze the Data
- Report the Results
- Refine or Reformulate Your Idea

Steps of the Research Process
Protocol Components

- Research Topic & Question
- Background/ Literature Review
- Research Objectives
- Hypotheses
- Study Designs
- Independent & Dependent Variables
- Subject Selection/Inclusion & Exclusion Criteria
- Study Implementation & Keys to Success
- Data Management & Statistical Analysis
- References

*Additional components required for clinical drug trials*
Study Design
Study Design

- Guides interpretation of study results
- Can be quantitative, qualitative, or mixed methods
- Approach may depend on feasibility

- Various types of designs
  - Retrospective
  - Prospective
  - Observational
  - Interventional
  - Longitudinal
Cohort Study

- Type of observational design
  - Participants are treated as a group
  - Share something in common (i.e. disease, injury, prescribed medication)
  - Cohort group compared to control over period of time

* Example: Evaluating the longitudinal impact of warfarin on drug-drug interactions or drug-disease interactions.
Cohort Study

Advantages
• Provides clarity of sequence of events
• Aids incidence calculation
• Can study rare exposures (e.g. Agent Orange)
• Examine multiple effects of a single exposure
• Avoid selection bias

Limitations
• May be difficult to follow subjects longitudinally
• Expensive & time consuming
• Not optimal for rare diseases
Cross-Sectional Study

- Type of observational design
  - Observational study at a point in time
  - Data collected from a population subset and is analyzed

* Example:
  Effect of childhood trauma on cognitive functioning as adults
Cross-Sectional Study

Advantages
• Less time-consuming
• Inexpensive
• Can examine prevalence of exposure and outcomes

Limitations
• Lacks element of time- just a snapshot
Case-Control Study

- Type of observational design
  - Retrospectively investigates whether or not frequency of exposure is associated with a particular outcome
  - Cases are compared to those with little or no exposure

*Example:
  Exposure to second hand tobacco smoke to asthma in children
Case-Control Study

Advantages

• Inexpensive
• Less time-consuming than cohort design
• Efficient for studying rare outcomes

Limitations

• Subject to recall bias
• Not optimal for rare exposures
• Difficult to establish timing of exposure and outcome
Crossover Study

- Type of interventional design
  - Two treatments given consecutively to participants
  - Each group serves as their own control

* Example:
  Evaluating the effects of glucose and sucrose on mood
Crossover Study

Advantages
• Minimizes influence of confounding variables
• Statistically efficient
• Requires fewer subjects

Limitations
• May not always be feasible or ethical
• Can have “order effects”: order of administration of treatment may affect outcomes
• “Carry-over” between treatments can confound treatment effects
Randomized Control

• Type of interventional design
  - People allocated at random to intervention or control groups (standard of care/placebo)
  - Considered the gold standard of clinical trial designs

* Example
  Drug trials with study drug vs. placebo
Randomized Control

Advantages

• Can investigate cause-effect relationships with minimum bias and confounding variables
• Easier to generalize your findings
• Controls for selection bias
• Crossover design can be used

Limitations

• Expensive and time consuming
• Follow up can be difficult to complete with patients
Independent & Dependent Variables
Independent & Dependent Variables

- What factors will be measured

- **Independent Variable**
  - Stable and unaffected by other variables measured
  - Predictor variable

- **Dependent Variable**
  - Depends on other factors that are measured
  - Expected to change
  - Outcome variable
Exercise

• **Opioid doses and acute care utilization outcomes for adults with sickle cell disease: ED versus acute care unit**

• **Independent Variable:**
  – SCD Pain-related care received at Emergency Department or Acute Care Unit

• **Dependent Variable(s):**
  – Dosage of opioids
  – Pain ratings
  – Hospital admission rates
  – Length of stay
Subject Selection & Inclusion/Exclusion Criteria
Subject Selection

• Define the target population
  - Determine population of interest
  - Identify patients best suited for the research question

• Determine Sample Size
  - Consider number of subjects needed
  - Is this number achievable?
  - Specify the inclusion/exclusion criteria

• Items to consider
  - Cost per patient
  - Controlling for random error
  - Generalizability to the population of interest
  - Clarity and realism of inclusion & exclusion criteria
Study Population: Sampling

- Who is your target population?
- How many participants are needed?
- What sampling method will you use?
- How can you maximize the representation of your sample?
Sampling Strategies

Your sampling strategy is crucial in ensuring you have adequate representation of the entire study population.

**Probability Sampling**
- Simple random sampling
- Systemic sampling
- Stratified sampling
- Cluster sampling
- Multistage sampling

**Nonprobability Sampling**
- Quota sampling
- Convenience sampling
- Purposive sampling
- Snowball sampling

[Additional information on sampling strategies](#)
How many subjects do I need?

• **Quantitative Data: Power Analysis**
  – Plan for estimating study scope
  – Aids in determining sample size required to show an effect of a given size with a specified degree of confidence (i.e. 95% CI)
  – Determines the number of participants needed to help generalize study findings
  – Probability of finding an effect that is really there
  – Basis for testing the statistical significance of findings

• **Qualitative Data: Data/Theoretical Saturation**
  – Goal: depth of data, not a specific number of subjects
  – Saturation: when incoming data becomes repetitive and contains no new information
Inclusion & Exclusion Criteria

**Inclusion criteria** - attributes or characteristics of subjects that are necessary for study participation.

- BMI between 18-40
- Current tobacco use

**Exclusion criteria** - attributes or characteristics that exclude the subject from study participation

- Presents with chronic pain
- 1000 mg Tylenol daily for 1 year
- Positive urine drug screen
- Cancer treatment in past 5 yrs
- Uncontrolled HTN
- IM of Haldol in past 60 d yrs
Evaluating Eligibility Criteria

- Subjects must have hypertension.
  - Too vague, needs quantifiable parameters

- Subjects who have a major medical condition will be excluded from the study.
  - Too general, it is better to specify a list of excluded conditions within a specific time frame (five years)

- Subjects aged 18-64 will be included in the study.
  - Good, clear, and precise
Practice-based Study Implementation & Keys to Success
Study Implementation

- Planning is key
- Develop logistical processes
- Recruit site(s) and determine physician and staff roles
- Regulatory processes, Research Advisory Committees, IRBs
- Form development
  - Recruitment materials
  - Enrollment and other tracking logs
  - Data collection templates
  - Develop interview/focus group guides
- Data storage platform
- Site level training
Keys to Success

• Acknowledge clinic time constraints
• Develop processes with minimal workflow disruption
• Flexible protocol to achieve project goals
• Engaging entire clinic in the study concept
• Creating collaborative professional relationships
Data Management & Analysis
Quantitative Research

• **Quantifiable data:**
  Based on quantities obtained using an objective measurement process
  - Surveys with closed-ended questions
  - Lab results

• **Benefits:**
  - Data can be collected and analyzed quickly
  - Can generalize to population
  - Reliable
  - Repeatable
Common Statistical Tests

(Handout)

• Correlational
  – Pearson correlation
  – Spearman correlation
  – Chi-square

• Comparison of Means
  – Paired T-test
  – Independent T-test
  – ANOVA

• Regression
  – Linear or Logistic
  – Simple regression
  – Multiple regression

• Non-parametric
  – Wilcoxon rank-sum test
  – Wilcoxon sign-rank test
  – Sign test
Statistical Tests Example

- **Opioid doses and acute care utilization outcomes for adults with sickle cell disease: ED versus acute care unit**

- **Descriptive statistics**
  - Mean; standard deviation, count, frequency

- **Fisher’s Tests & ANOVA**
  - Compare demographics of patients visiting ED; ACU; Both

- **Regression**
  - Compare patient outcomes between ED and ACU
Qualitative Research

- Descriptive in nature

Data Collection:
- Interviews
- Focus groups
- Ethnography
- Open ended questions on surveys, etc.

Benefits:
- Depth of data
- Focuses on key issues of participants from their perspective
- Investigate sensitive and complex topics
Qualitative Analysis

• Qualitative research generates large amounts of text data
  – Just one transcript can generate easily generate 20 pages of text
• Analysis is labor intensive and time consuming
• Goal is to extrapolate meaning from subjects’ words
  – Emic perspective: represents the subjects’ views and perspectives, not the researchers’
  – Grounded theory: building theories that are grounded in/based on the data
Qualitative Analysis

- Analysis Steps
  - Document (e.g., field notes, transcripts of recorded interviews)
  - Define concepts and categories
  - Code data
  - Explore relationships, themes
- Analytical software: 2 most common
  - Atlas.ti
  - Nvivo
Group Activity

You want to conduct a study comparing patients taking antihypertensive medications after a stroke and identify subsequent ER visits and hospital admissions for recurrent stroke. How might you address the following key questions for the study design?

*Please reference handout: “Small Group Exercise for Workshop Research Design 2”*
Thank you!

Questions & Discussion