Formulating Research Questions and Designing Studies

Research Series Session I

January 4, 2017

CARILION CLINIC

Course Objectives

- Design a research question or problem
- Differentiate between the different types of research
- Formulate what methodology is used to solve a research question or problem
- Describe the Research Process: Data Collection and Analysis
- Identify the uses of Research

What is the Definition of Research?

1: careful or diligent search

***2*: studious inquiry or examination; *especially* : investigation or experimentation aimed at the discovery and interpretation of facts, revision of accepted theories or laws in the light of new facts, or practical application of such new or revised theories or laws**

***3*: the collecting of information about a particular subject**

Merriam-Webster

What is the Definition of Research?

- The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions

Oxford Dictionary

Types of Research

- Pure
  - Abstract and general; concerned with generating new theory, e.g., $E=mc^2$
- Experimental
  - Manipulation of one variable and its effect on another in a controlled environment, e.g., psychology experiments
- Clinical
  - Clinical setting where strict control over variables is difficult, e.g., drug trials
- Applied
  - Designed to answer a practical question; industry R&D
- Descriptive
  - Describing a group or situation to gain knowledge that may be applied to other groups, e.g., surveys
- Laboratory
  - Performed under tightly controlled surrounding, e.g., basic science research

Empirical Approach

- Knowledge based on observations
  - Why
    - Establishes need for study
    - Often hypothesis driven: What results are expected
  - Whom
    - Entire population (entire hospital)
    - Sample (one floor of hospital)
      - Need to establish that this will not introduce bias
  - How
    - Selection of measures: objective tests, interviews, direct observations
      - Data generation
  - When
    - Validity and Reliability

Experimental versus Nonexperimental Studies

- Experimental
  - Treatments are given for the research purpose
    - Simple experiment with two groups
      - Treatment group: Experimental group
      - No treatment group: Control group
  - If the participants for the two groups were randomly selected, the experiment is called a true experiment

Not all Experiments are True Experiments

- A psychiatrist identified100 clinically depressed clients who volunteered to take a new drug under her direction. She also identified 100 non-volunteers with the same diagnosis and similar demographics to serve as controls. The study was conducted to investigate the effectiveness of the new drug in treating depression.

True experiment or not?

Nonexperimental Studies

- No treatment given
- Participants are observed or recorded
  - Survey or poll
    - Interviewed, questioned or observed as they exist without experimental intervention

Important Note:

The act of measurement is usually not considered to be a treatment; moreover, researchers strive to measure in such a way that the act of measurement does not affect or change the outcome

Experimental versus Causal-Comparative Studies

- In general, when researchers want to investigate cause and effect relationships, they prefer experimental over nonexperimental studies

However, lets consider the following:

The effect of smoking 1 pack of cigarettes per day for 15 years on your health compared to a non-smoking control group

Experiment or Nonexperiment Study

Why?

Factors that rule out an Experimental Study

- Physical
- Ethical
- Legal
- Financial
- Time frame

Nonexperimental Study Design

- Compare a group of individuals with lung cancer to a control group without lung cancer exhibiting similar demographics
  - Socioeconomic status
- Examine differences with regard to lifestyle characteristics including smoking history
- If you can demonstrate that the two groups who exhibit similar demographics can be differentiated by smoking then you could conclude that smoking may be the possible cause of lung cancer

This nonexperimental study is known as a casual-comparative or ex post facto study

Potential issues with interpretation

- Not randomized
- Rural versus urban environment (smog)
- Stress, e.g., stress may be the cause of cancer and causes individuals to smoke excessively
- Many causal-comparative studies (over 100) have been performed linking smoking and health. Interestingly, many were disputed because they were not true experiments

Additional types of Nonexperimental Research

- Survey or poll
  - Collect data from a sample population to make inferences on the population
- Census
  - Entire population
- Case study
  - Generally one participant
- Longitudinal research
  - Measure over a period of time
- Correlational research
  - Degree of relationship among two or more variables

Research Study Definitions

- Quantitative
  - The use of applied mathematics to assist in research process (clinical trial to assess efficiacy)
- Qualitative
  - The nonnumerical examination and interpretation of observations for the purpose of describing and explaining the phenomena that those observations reflect (Community-based Participatory Research) *Healthy Roanoke Valley*
- Quasi-experimental
  - Research designs that have the characteristics of experimental design but lack randomization

Research Study Definitions

- Variable
  - An observable characteristic of an object or event that can be described according to some well-defined classification or measurement scheme
    - Independent variable
      - A phenomenon that is manipulated by the researcher and is predicted to have an effect on another phenomenon. The independent variable is presumed to **cause** or determine a dependent variable
    - Dependent variable
      - A phenomenon that is affected by the researcher's manipulation of an independent variable

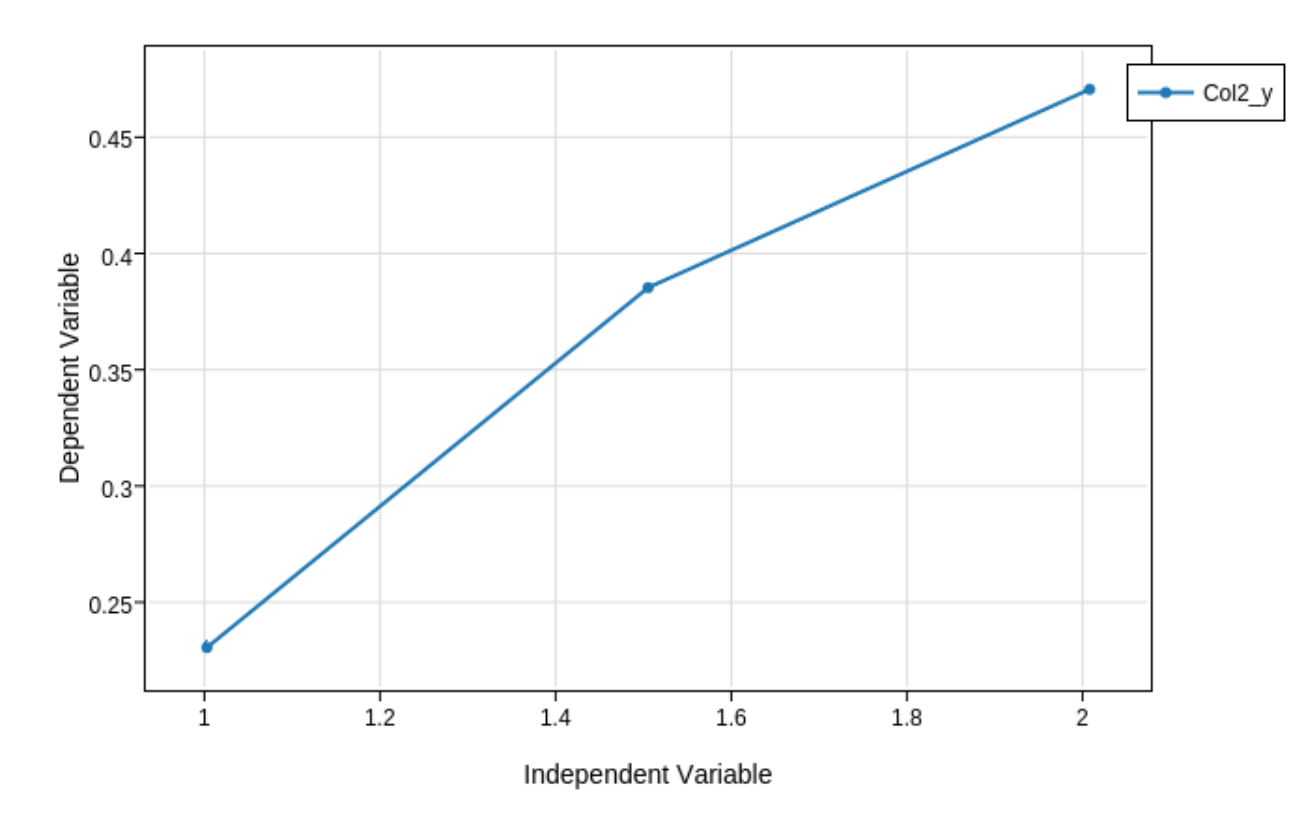
Independent and Dependent Variables

- Independent Variable
  - Experimental study: stimulus or event, e.g., drug, placebo
  - Nonexperiment study: observation
- Dependent Variable
  - Experimental study: Response
  - Nonexperiment study: Outcome

Studies may have multiple independent variables that impact the dependent variable

Independent versus Dependent Variable Graph

(response, effect)



(date, time, length, dose)

Null Hypothesis (to be discussed)

- A statement that statistical differences or relationships have occurred for no reason other than the laws of chance operating in an unrestricted manner. The null hypothesis is sometimes stated instead of or in addition to the hypothesis. It is a form of the hypothesis stated in a negative manner.

Research Hypothesis, Purpose, Question

- A prediction of an outcome of a study
  - Directional hypothesis

It is hypothesized that patients with a BMI < 25 will have a better surgical recovery than patients with a BMI > 25

  - Non directional hypothesis

It is hypothesized that there is a difference in surgical recovery of patients as a function of BMI

- Research Purpose

Investigation of BMI status and patient surgical recovery

- Research Question

Does BMI status effect patient surgical recovery

The Research Project (Considerations)

- Are there institutional requirements that must be met before you begin your training
  - Approval by the IRB
  - Research Education Modules
  - Collaborative Institutional Training Initiative
- How much time are you planning for your study
- Costs

The Research Project (Considerations)

- Key personnel identified to carry out project
  - Co-principal investigator
  - Statistician
  - Collaborators
  - Reviewers
  - Consultant
  - Advisor
  - Laboratory assistant
  - Research coordinator

The Research Project (Identification)

- Origin of Research Topics
  - Work environment
  - Personal interest
  - Prior studies (journal article or report)
  - Mentor or preceptor or teacher interest
  - Literature review
  - Studies by others
  - Graduation requirement
  - List five research problems; rank by degree of interest (most interesting = 5; least interesting =1)

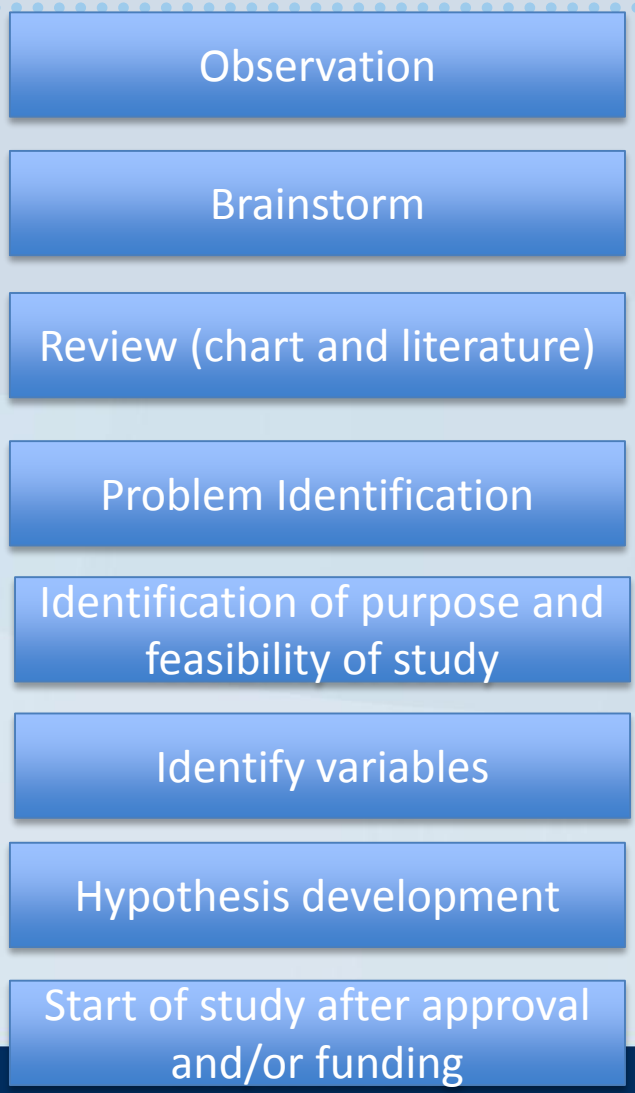
Work Environment Research Project

- Hospital Acquired Conditions (HAC)
  - Catheter-associated Urinary Tract Infections (CAUTI)
  - Significance
    - Patient care
    - CMS penalty
    - Reputation
  - What can be done
  - What is known
  - What information or data needs to be gathered

Catheter-associated Urinary Tract Infections (CAUTI)

- Research Question
  - Are there procedural differences between infected and noninfected patients
- Null hypothesis
  - There are no procedural differences between infected and noninfected patients
- Directional hypothesis
  - There are procedural differences between infected and noninfected patients

Research Problem Development Work Plan



Introduction to Research and Medical Literature, 3rd edition Blessing and Forister; Jones and Bartlett

Research Problem Method Development

- Will your study be a quantitative or qualitative study?
- Describe your subjects and sample population
- How will samples be drawn or assigned (inclusion/exclusion criteria)
- Describe the design of study you will perform (protocol)
- What are your treatment and/or measurement instruments
- Identify the independent and dependent variables

Research Problem Method Development

- Identify how you will apply controls to your study
- Identify any possible problems with obtaining a sample or carrying out your interventions
- How will you keep records of your samples, procedures, statistical analysis
- Will you need to do a pilot study
- How will you determine reliability and validity
- Can you identify any problems with your methods to include possible limitations, biases and threats to validity

Research Problem Data Analysis

- What statistical analyses will you use
  - Descriptive statistics (organization of data)
  - Inferential statistics (what is the data telling me)
- Correlate your choice of analyses with the type of data that is produced
- How will you carry out the analyses
- What will your alpha and p levels be
- Who is your “expert’ for statistical analysis
- Can you identify any problems with your planned analysis, including limitations of tests

Choosing a Statistical Test 101

- Continuous data are unlimited values that are equally spaced along a continuum, e.g., blood glucose levels, weeks, years (numbers)
  - Interval
  - Ratio
- Ordinal data are values that have some sort of order but no defined spacing between categories, e.g., approximate time of day when you take medications, Likert scales
- Nominal data are categorical designations, e.g., age, marital status, gender, race

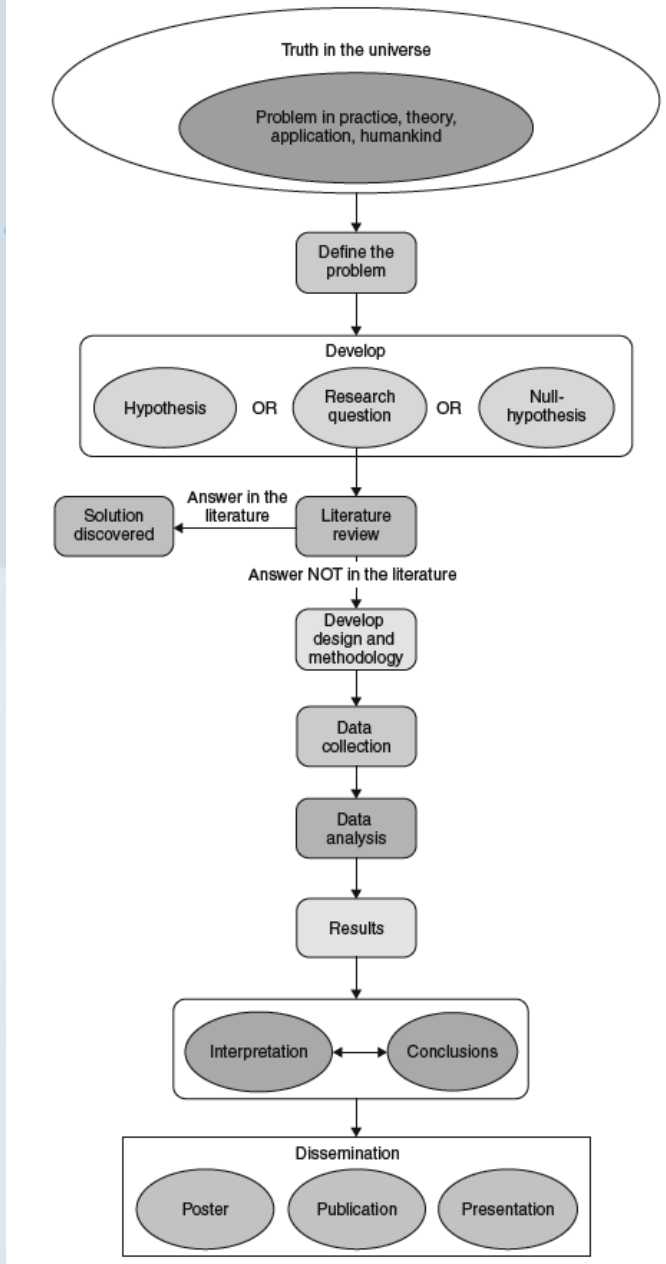
Choosing a Statistical Test 101

- Parametric analysis is performed on continuous data
  - t-test, ANOVA, Regression
- Non-parametric analysis on ordinal and nominal data
  - Kruskal-Wallis test
  - Spearman rho
  - Wilcoxon Ranked Sum Test

Research Problem Results and Discussion

- How will you report your results
- Will you use tables, graphs, illustrations
- What are the results from similar studies

- Limitations
- Biases
- Threats to validity
- Significance of your results or can I publish this work!



Scientific Process Summary

Questions