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Outcome Measures, Variables and Data Collection

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Objectives

- A few more words about study design…
- Discuss aspects of measurements of outcome and data collection

Study Design

Experimental Group	Control Group

Experimental Group

- the investigational drug

- the "test" treatment or intervention

Control Group

- standard of care; active control

- "gold standard" therapy

- comparator group

To placebo or to not placebo

- what question are you trying to answer?
- ethical issues

Study Design

- Placebo control
  - no standard or accepted treatment or controversy surrounding validity of standard treatment
  - "add on" or "supplemental" therapy
  - "no better than placebo"
- Ethics
  - cardiovascular dz, infectious disease, cancer, diabetes

Variables, Variables, Variables

- Your study design has to have a *primary* outcome that can be <u>measured</u>
  - patients will feel better
  - to test whether the drug is effective
  - keep your aims and hypothesis in mind
- Perception vs. measurement
- For example, "effectiveness" of a health program or intervention
  - morbidity, mortality, utilization, incidences of illnesses, costs, quality of life

End Point Variable(s)

- Describe the variable(s) you will use as your primary end point
  - e.g., change in blood pressure
- Describe HOW you will measure your primary end point
- Think about what type of data will you generate
  - nominal
  - ordinal
  - interval scale
  - ratio scale
- READ THIS!
  - Understanding Statistics: An approach for the clinician

Nominal Data

- Enables the classification of individuals, objects or responses based on a common property or characteristic (these are categorical data)
  - gender
  - Democrat or Republican
  - religion (e.g., Christian, Muslim, Hindu)
  - ethnicity (e.g., white, black, Hispanic)

Ordinal Data

- Ranks data based on a scale
  - income (above average, average, below average)
  - attitude- Likert scale (strongly agree, agree, neutral, disagree, strongly disagree)
    - symptom severity
    - "subjective" or "perception" end points
    - when using a "referenced" or validated tool include it in your proposal as an appendix

Kumar, R. Chapter 5: Identifying Variables. In: Research Methodology, 2nd Edition.
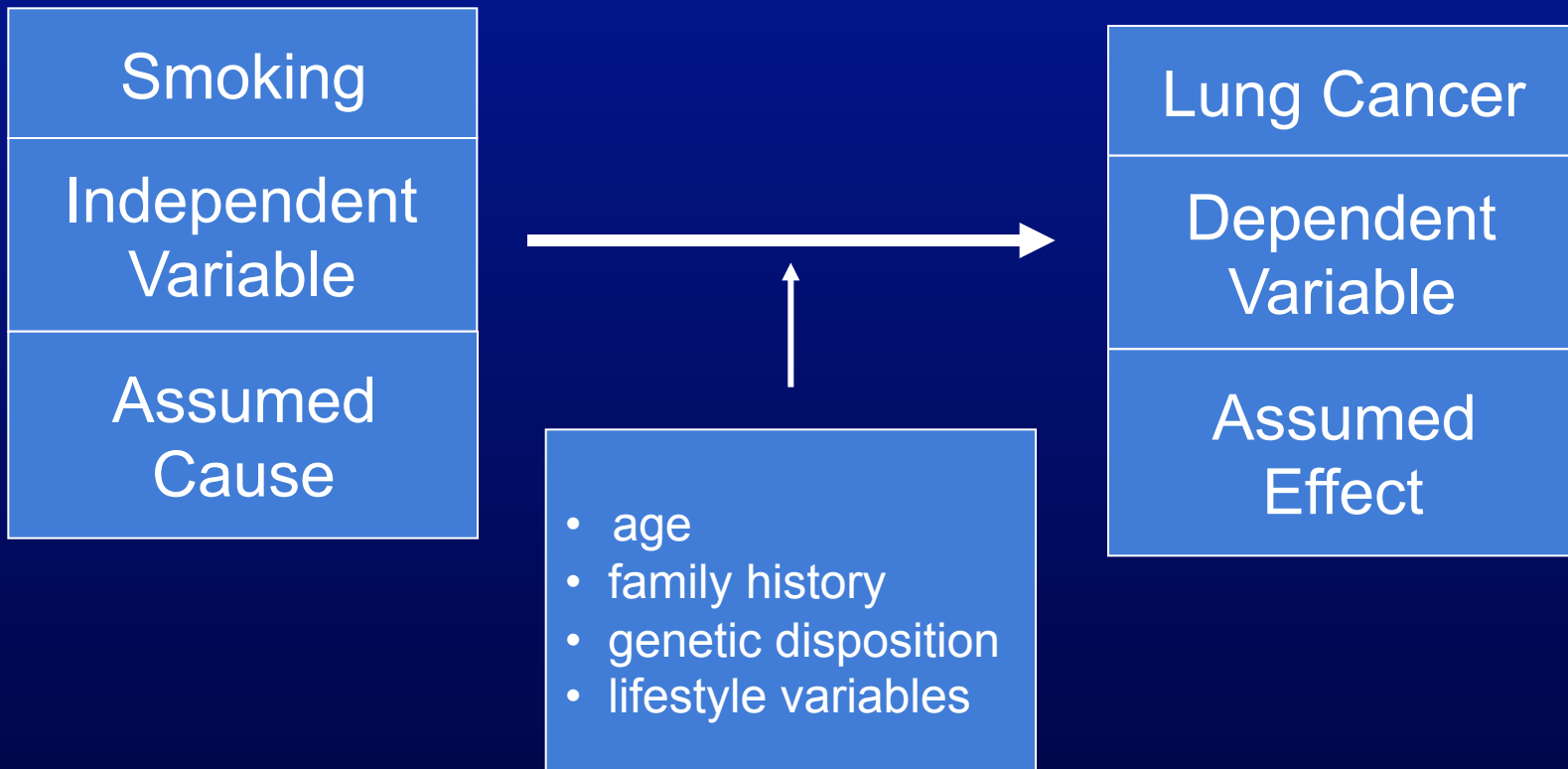
Interval Scale

- Has a unit of measure with an arbitrary starting point and ending point
  – temperature
  – blood pressure
  – cholesterol

Ratio Scale

- Numerical data
  - discrete- how many cars to you have?
  - continuous- how tall are you?
  - can have a "zero" point
  - height, weight, age

Controlling for Confounding Variables

Smoking
Independent Variable
Assumed Cause

→

Lung Cancer
Dependent Variable
Assumed Effect

- age
- family history
- genetic disposition
- lifestyle variables

Confounding Variables

- Methods for controlling for confounding variables
  - randomization
  - age or gender matching
  - identification and measurements of known confounding variables (e.g., secondary end points)
  - unanticipated
- Timing and frequency of data collection

Data Collection

- The study's primary end point
  - define it
    - it should be very clear from reading your proposal what your study's primary end point is
  - describe when and how you'll collect it in relationship to your intervention

Develop Your Study Design

- should effectively test your hypothesis and should be detailed enough so that the variables that will be measured and how data will be collected are apparent

- the study population should be described and inclusion/exclusion criteria presented (if applicable)

- the test groups (e.g., treatment and placebo) should be mentioned

- the study's primary end point (variable) should be clearly stated

- THESE ELEMENTS NEED TO BE CLEAR!

- READ! articles posted in "other resources"

- RUBRIC, RUBRIC, RUBRIC!

Statistical Plan

- Your study design will direct the development of your statistical plan
  - the TYPE of data (e.g., ordinal) your study will generate will direct your statistical plan
  - Dr. Michael Dorsch will give the lecture on developing a statistical plan (2/24/11)
  - Assignment #3: study design, statistical plan, human subjects/vertebrate animals change in due date
    - now 3/14/11
    - updated schedule posted

University of Michigan

Additional Source Information

for more information see: http://open.umich.edu/wiki/CitationPolicy

Slide 5: Kathleen A. Stringer

Slide 9: Kumar, R. Chapter 5: Identifying Variables. In: Research Methodology, 2nd Edition.

Slide10: Kumar, R. Chapter 5: Identifying Variables. In: Research Methodology, 2nd Edition.

Slide 11: Kumar, R. Chapter 5: Identifying Variables. In: Research Methodology, 2nd Edition.

Slide 13: Kathleen A. Stringer

Slide 18: University of Michigan, http://www.umich.edu/