Quantitative Research Design:
Fitting the Method to the Question

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Objectives

- Describe how research designs differ depending on the questions being asked.
- Identify concepts of bias, threats to validity, strengths, and limitations as related to observational designs
- Identify concepts of bias, threats to validity, strengths, and limitations as related to experimental designs

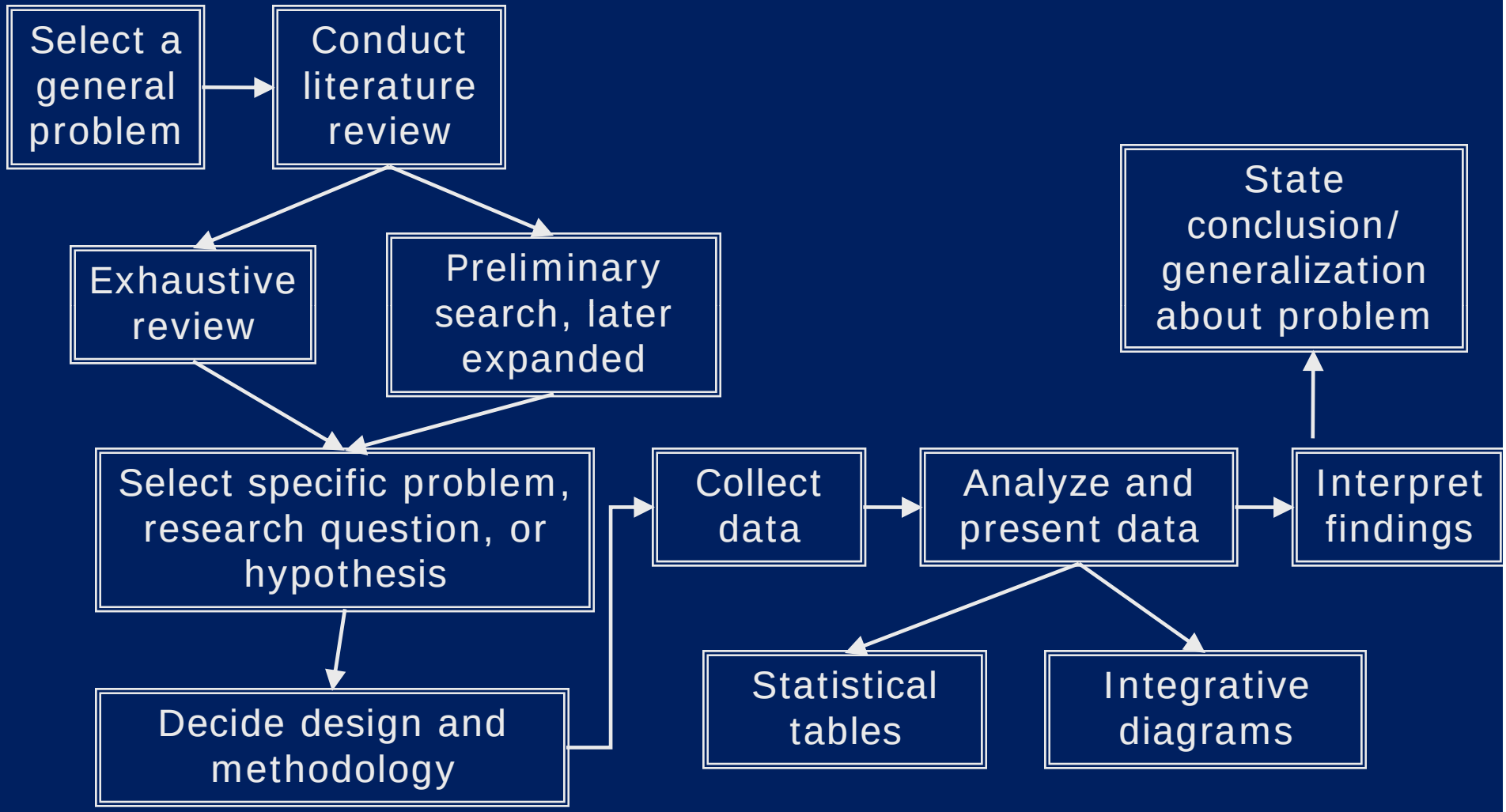
SCIENCE

- Basic aim of SCIENCE is to explain natural phenomena with *generalizable knowing*
  - Identify / Understand
  - Describe
  - Explain
  - Predict
  - Control

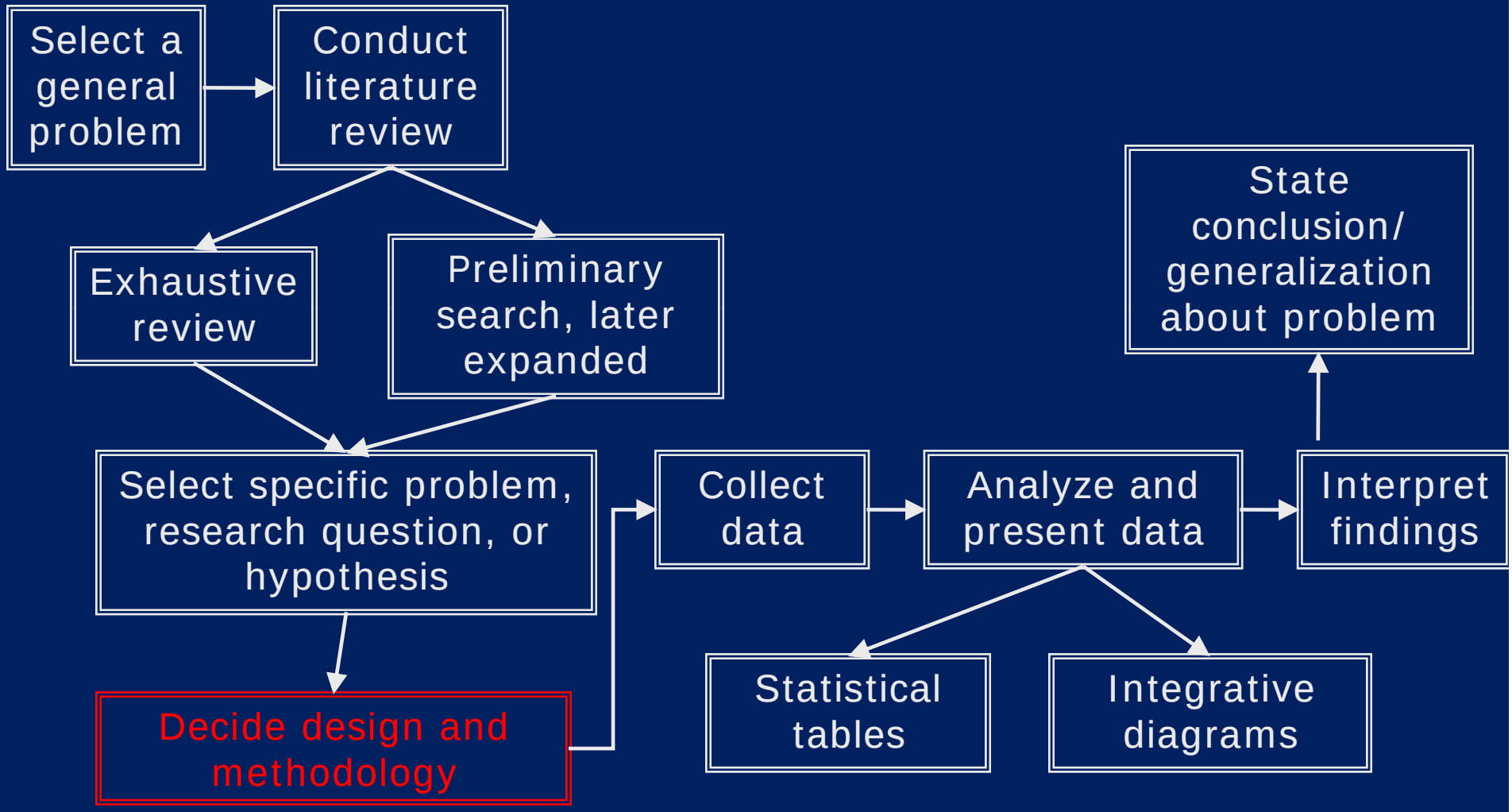
Research design

- Research design is an attempt limit variability and minimize complexity
  - Control
- Well-designed research increases chances that findings are real
  - Generalizable
- Well-designed research takes time, planning, and resources
  - and well-designed human science research takes even more of all

Research Process



Research Process



Key concepts in measurement

- Reliability
  - consistency; the likelihood that you'll see the same results from subject-subject, or within the same subject over time.
  - Reduce error variance
- Validity
  - the degree to which the investigator is measuring/describing the intended phenomenon

Key concepts in design

- Internal validity
  - the likelihood that the results obtained in a study are due to the treatment, and not to some other factor. Good research designs = strong internal validity
- External validity
  - Aspects of design that make it more likely the results from one study can be applied to a different sample in a different setting. Similar to generalizability.

Key concepts

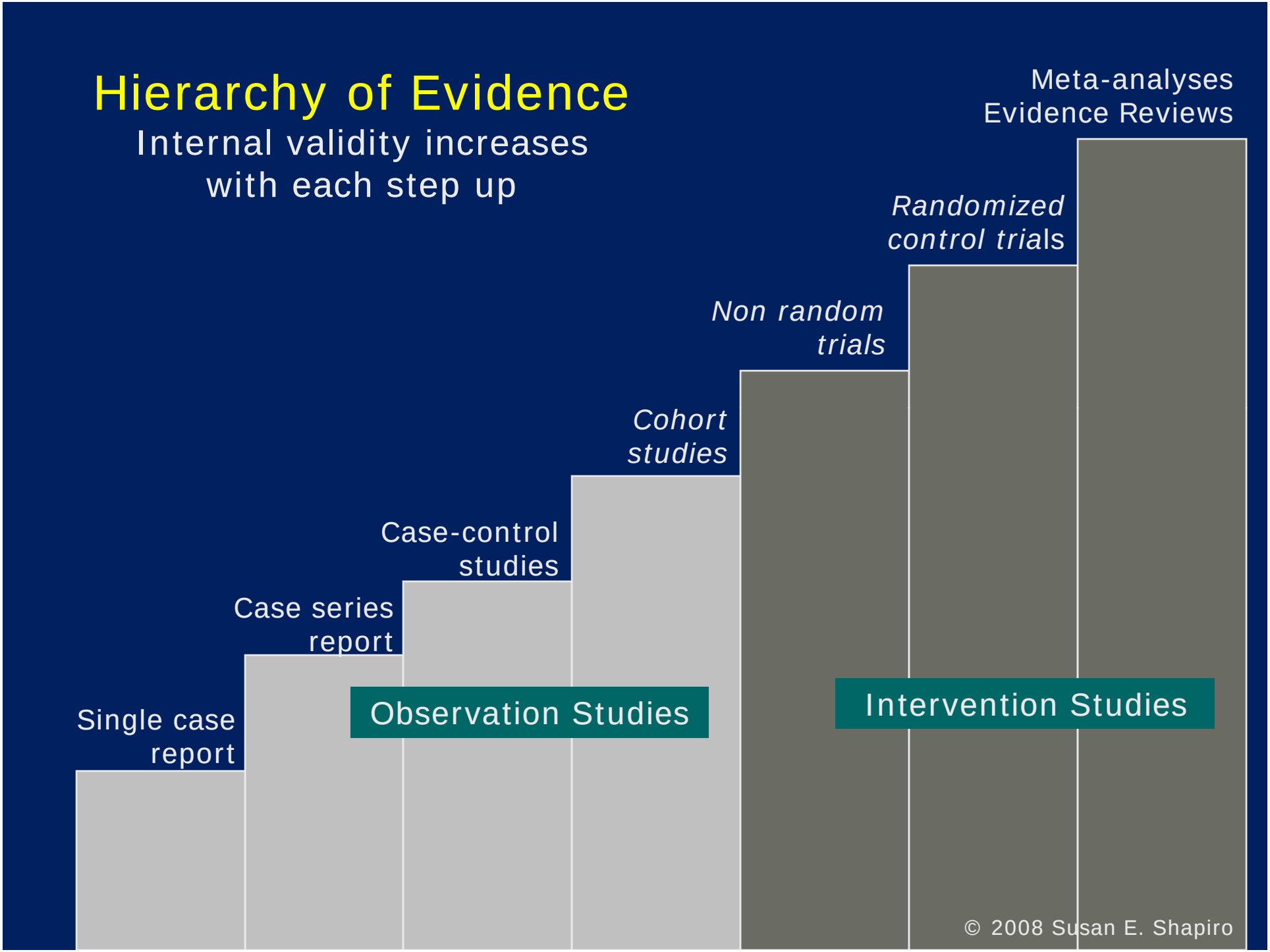
- Bias
  - Anything that could distort the results of the study, reducing the likelihood that the findings are “true.”
  - Different kinds of bias can reduce internal or external validity

Research designs

- Task of the investigator is to maximize internal and external validity
  - To the extent possible, eliminate or account for possible sources of bias
  - Lack of internal validity=lack of confidence in the result
  - Strength of the evidence
- Choice of design is contingent upon
  - Study question
  - Ethics and pragmatics

Hierarchy of Evidence

Internal validity increases
with each step up



What do levels indicate?

- Increasing probability that results reflect some objective reality
  - Limit investigator-induced bias in measuring intervention or outcome
  - Reduce threats to internal validity

Generation of practice knowledge

- Exploratory — Qualitative
- Descriptive — Correlational, regression, time series, path model
- Quasi-experimental
- Experimental
- Clinical trials — Meta-analysis
- Evaluation research — Efficacy, utility, cost-benefit, feasibility
- Utilization in practice — Practice dissemination

Design dichotomies

- Qualitative vs. quantitative
- Descriptive vs. analytical
- Experimental/ quasi-experimental vs. non-experimental
- Hypothesis-generating vs. hypothesis testing
- Cross-sectional vs. longitudinal
- Retrospective vs. prospective
- Observational vs interventional

Design to match question being asked

Nursing research designs

- Observational: Identify, describe and explain characteristics of
  - Nurses
  - Patients
  - Processes
- Experimental
  - Evaluate interventions (predict / control)
  - Establish causation (predict / control)

Observational Designs:
Identify, Describe, Explain

- Identify subjects
- Observe & record characteristics
- Readily obtained
- Subject to bias

I. **Descriptive Study**

- Measure and report on selected characteristics
- Measure and report on relationships between characteristics

Case Report/Case Series

- Identify and describe an unusual patient care situation
- Retrospective or prospective
  - Includes patient presentation, interventions, outcomes
  - Identify patterns; raise awareness

Strengths & Limitations

- Strengths
  - Relatively inexpensive to design and analyze
  - Describes phenomena as they naturally occur
  - Initial step in understanding phenomena
- Limitations
  - No causation can be inferred
  - Minimal control over threats to internal and external validity
    - Sample
    - Non-random assignment / selection bias

II. Survey Research

- Describe or explain almost anything!!!
  - Nurse satisfaction surveys
  - Behavioral health risk surveys

- Survey results can be used as measures of predictor or outcome variables

- Cross-sectional vs. longitudinal

  One moment in time vs. series of observations over time

Strengths & Limitations

- Strengths
  - Flexible
  - Broad in scope: can survey for anything
- Limitations
  - Data: Superficial; self-report
  - Information on how survey developed is important
  - Repeated measures – Testing effects; attrition

Validity

- Internal validity
  - Reliability of measurement
    - Response biases in surveys and questionnaires
    - Reporting errors in data sets- Uploading results
- Threats to external validity
  - Sampling biases
  - Return rates

III. Case Control & Cohort Studies

- Look at relationships between predictors (independent variables) and outcomes (dependent variables)
- Intervention/exposure is independent variable
- +/- outcome is dependent variable

Case Control Study

Usually retrospective

Depends on presence or absence of outcome

Example:
- Identify patients with HAPU
- Identify controls (without HAPU)
- Analyze groups for presence of predictors that explain HAPU (ex. use of special bed mattress, nutritional status)

Cohort Study

Usually prospective

Cohort depends on presence or absence of predictor

Example:

- Identify group (cohort) of patients at risk for HAPU for given time period - Hospitalized patients >65
- Follow to see who develops HAPU
- Analyze for influence of predictors

Strengths & Limitations

- Strengths
  - Useful when outcome of interest is rare, or takes a long time to develop
  - Useful for initial studies
    - Case control and cross-sectional studies require relatively small samples and are relatively inexpensive
- Limitations
  - Exposures not manipulated
  - Does NOT establish causality, only levels of risk and association between risk and outcome.

Validity

- Internal validity
  - Reliability of measures of predictor and outcome variables, e.g. inter-rater
  - Quality of recorded data – exposures and outcomes
- External validity
  - Defining cases and controls
  - Exhausting all possible predictors

Design & methods for getting started

- Descriptive studies
- Chart review
  - Need precise variable definition
  - Inter-rater reliability
  - Data limited by what was recorded
- What about this...
  - Discovering something you weren't looking for

Experimental Designs

- Identify subjects
- Place in common context
- Intervene
- Observe effects of intervention
- Hard to do well
- Answer narrow question definitively

Pre- & post-test intervention trial

- May or may not involve control group
  - Participants rarely randomized
- Prominence in nursing studies
  - Example: most studies involving educational interventions
  - More likely to estimate effectiveness than efficacy

Randomized clinical trials

- Gold standard to predict or control
  - Participants randomized to intervention or control
  - All parties blinded (participant, investigator, analyst)
  - Presence of control group – similar in every way except for intervention

Quasi-Experimental Design

- When it is not possible to meet the gold standard to predict or control
  - Participants randomized to intervention or control
  - All parties blinded (participant, investigator, analyst)
  - Presence of control group – similar in every way except for intervention

Strengths and limitations

- Strengths
  - Least opportunity for bias
  - Greatest likelihood that outcomes are caused by intervention
- Limitations
  - Dependent on integrity of investigator for randomization
  - Fidelity to intervention critical
  - Measures efficacy; may not translate directly to “real world.”

Internal and external validity

- Internal validity
  - Extent to which investigator is blinded
  - Integrity of control
  - Effective randomization re: hypothesized covariates
- External validity
  - Sampling biases
  - Generalizability limited by complexity of intervention and sample selection

Criteria for causation

- Preponderance of the evidence
- Need reasonable explanation for relationships
- Need consistency across time and populations
- Caution: the basic science may change!

Design & methods for getting started

- ‘Quick’ intervention
  - Time for intervention to work
  - Completeness of intervention
  - Influences external to research project

Criteria of (good) Research Design

- Answer the research question
- Does the design test the hypotheses?
- Research question / hypotheses need to be consistent with research design
- Caution: lack of congruence

Criteria of (good) Research Design

- Control extraneous independent variables
- Does the design adequately control independent variables?
- Solution: RANDOMIZE
  - Select participants at random
  - Assign participants to groups at random
  - Assign experimental treatments to groups at random

Criteria of (good) Research Design

- Generalizability
- Can we generalize the results of a study to other participants, other groups, and other conditions?
  - Basic research (add knowledge to field of study)
  - Applied research (generalizabilty is primary concern)

Two sources of research weakness

- Intrinsically poor designs
  - Inability to manipulate independent variables
  - Lack of power to randomize
  - Risk of improper interpretation
- Good designs, poorly executed

Research and design

- Research is basic work of science
- Careful design helps reduce bias
  - Improves internal and external validity
- Contributes to the scientific basis for nursing practice

Research design

- There is no perfect design!
- The choice of design depends on the question and pragmatics of the project
- The investigator's responsibilities are to:
  - Conduct the study ethically
  - Report results honestly
  - Identify limitations to study, both design and conduct

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