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

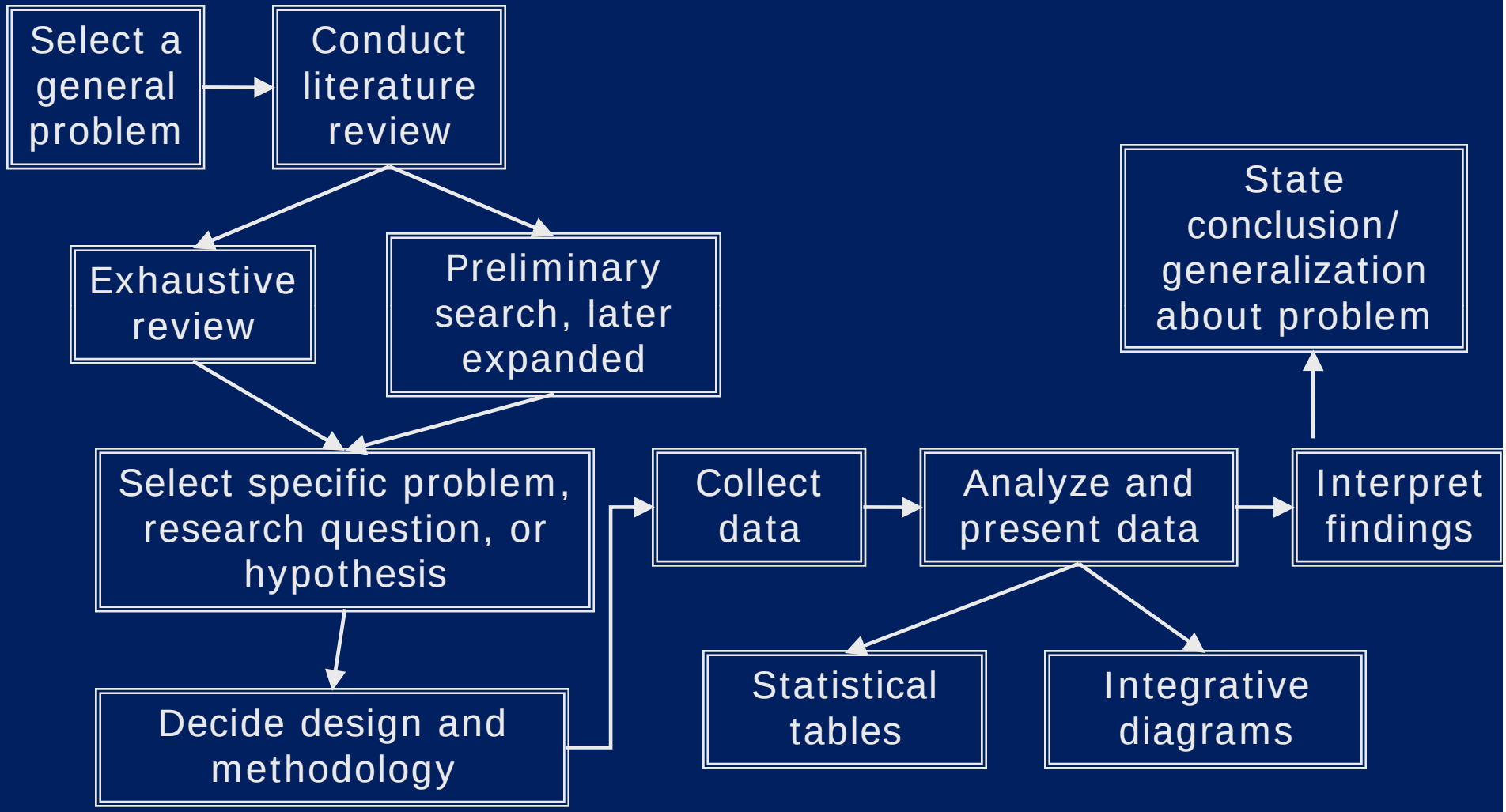
SCIENCE

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

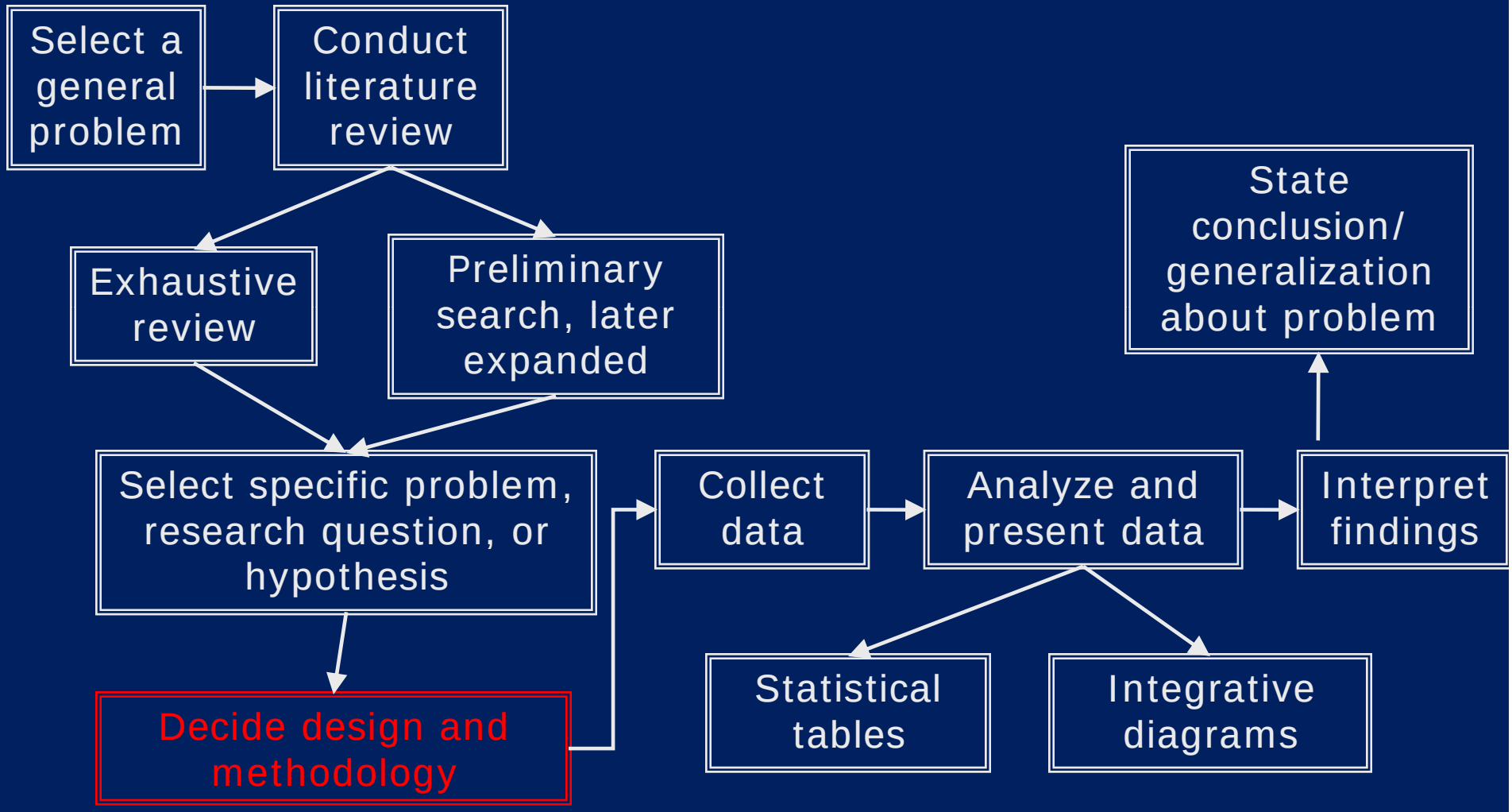
Research design

- 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

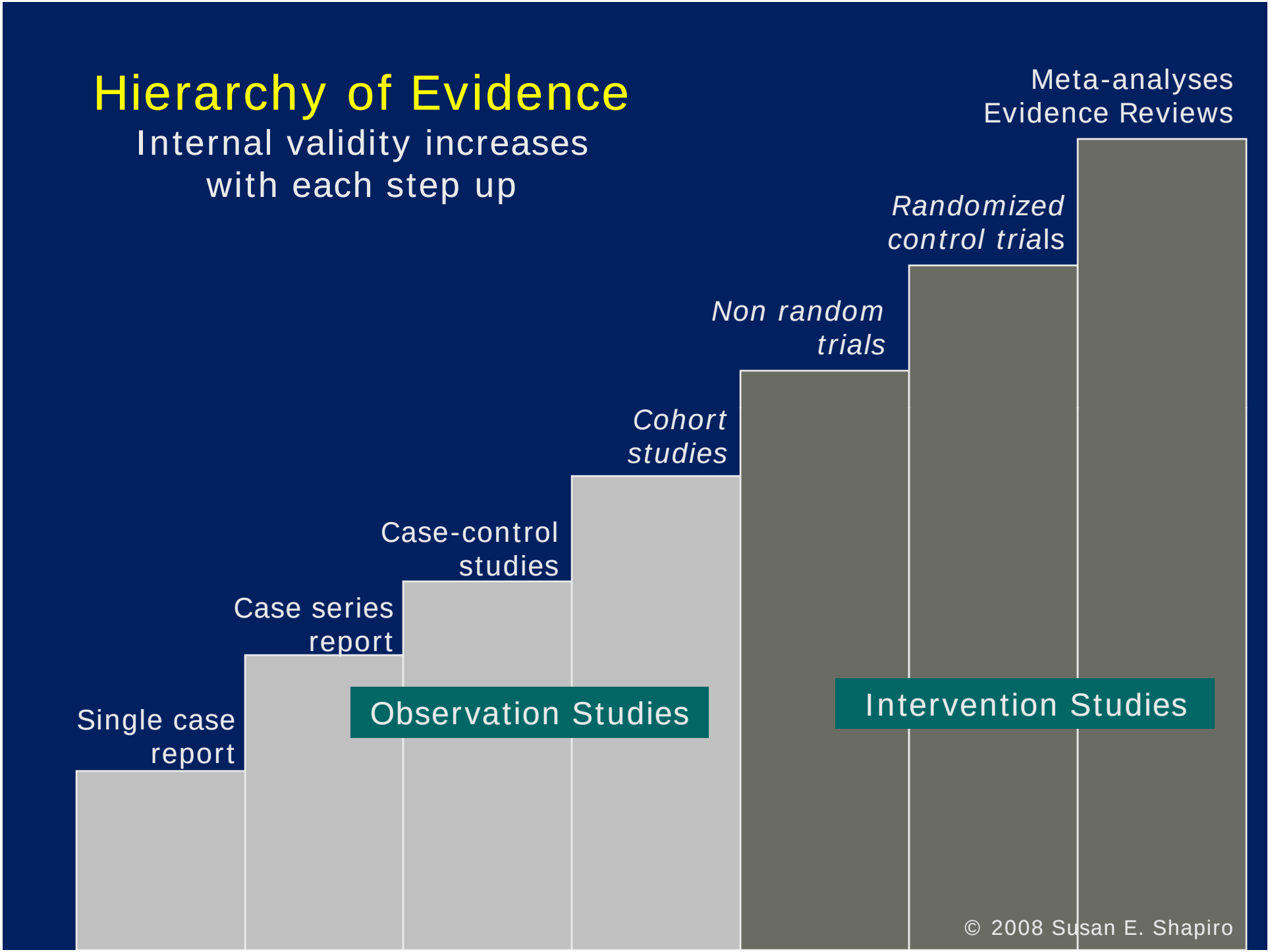
- Bias
  - Anything that could distort the results of the study, reducing the likelihood that the findings are “true.”
  - Different kinds of bias can reduce internal or external validity

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
- Data readily obtained
- Subject to bias:

Selection	*How subjects selected or assigned to groups*
Measurement	*How outcomes measured*
Performance	*How subjects exposed to factor of interest*
Attrition	*How participants lost (dropout, non-response, withdrawal, protocol deviators), creating groups unequal in regard to exposure &/or outcome*

DESCRIPTIVE STUDIES

- Measure and report on:
  - Selected subject characteristics
  - Relationships between characteristics

Case Report/Case Series
Survey Designs
Case Control
Cohort

Case Report/Case Series

- Identify and describe an unusual patient care situation

- Retrospective or prospective
  - Includes patient presentation, interventions, outcomes
  - Identifies patterns; raises awareness

- Example: Pyelonephritis and urosepsis in pregnancy

Case Report/Case Series

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 & external validity
  - Sample
  - Non-random assignment / selection bias

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)

Survey Research

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 (dropouts)

Survey Research

Internal Validity

- Reliability of measurement
  - Response biases in surveys and questionnaires
    - e.g., Selective recall, social acquiescence
  - Reporting errors in data sets - Uploading results

External Validity

- Sampling biases
- Return rates
  70% gold standard
  (difficult to obtain)

Case Control & Cohort

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

Case Control Study

Usually retrospective

Depends on presence/absence of outcome

Example:

1. Identify patients who fell during hospital stay, versus those who did not (controls)

2. Analyze groups for presence of predictors that explain fall risk
   - *Age*
   - *Mobility problems (balance, weakness)*
   - *Confusion/delirium*
   - *Medications*
   - *Urgency*

Cohort Study

Usually prospective

Cohort depends on presence/absence of predictor

Example:

1. Identify cohort of patients at risk for HAPU
   Hospitalized patients >65
2. Follow cohort to see who develops HAPU
3. Analyze for influence of + or – of predictors

Case Control & Cohort Studies

Strengths

- Useful when outcome of interest is rare, or takes a long time to develop
- Useful for initial studies
  - Case control & cross-sectional studies generally require small samples and are relatively inexpensive

Limitations

- Exposures not manipulated
- *Does NOT establish causality* – Only levels of risk and association between risk and outcome

Case Control & Cohort Studies

Internal Validity

- Reliability of measures for predictor & outcome variables
  - e.g., Inter-rater reliability
- Quality of recorded data on exposures & outcomes

External Validity

- Defining cases & controls
  - Careful selection criteria
- Exhausting all possible predictors

Design & Methods for Getting Started

- Descriptive studies
- Chart review & other measurements
  - 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

References

- Craig, J.V. & Smyth, R.L. (2007). *The Evidence-based Practice Manual for Nurses*. Churchill Livingstone, Edinburgh
- Guyatt, G., Gutterman, D., Baumann, M. H., Addrizzo-Harris, D., Hylek, E. M., Phillips, B., et al. (2006). Grading strength of recommendations and quality of evidence in clinical guidelines. *Chest,* 129, 174-181.
- Guyatt, G., Vist, G., Falck-Ytter, Y., Kunz, R., Magrini, N., & Schunemann, H. (2006). An emerging consensus on grading recommendations? *ACP Journal Club,* 144, A8-A9.

References

- Flew, A. (1979) A Dictionary of Philosophy (rev. 2nd Ed.) . New York: St. Martins Press
- Pedhazur, E.J. and Schmelkin, L. P. (1991). *Measurement, Design, and Analysis: An Integrated Approach*. Lawrence Erlbaum Associates, New Jersey
- Polit, D. F., & Hungler, B. P. (1999). *Nursing research: Principles and methods* (Sixth ed.). Philadelphia: Lippincott.
- Valanis, B. (1999)*Epidemiology in Health Care*. Stamford, CT: Appleton & Lange