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
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

1. Select a general problem
2. Conduct literature review
   - Exhaustive review
   - Preliminary search, later expanded
3. Select specific problem, research question, or hypothesis
4. Decide design and methodology
   - Collect data
5. Analyze and present data
6. Interpret findings
   - State conclusion/generalization about problem
   - Statistical tables
   - Integrative diagrams
Research Process

Select a general problem → Conduct literature review

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Collect data → Analyze and present data

- Statistical tables
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State conclusion/generalization about problem → Interpret findings
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

- Single case report
- Case series report
- Case-control studies
- Cohort studies
- Non random trials
- Randomized control trials
- Intervention Studies

Meta-analyses Evidence Reviews

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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 (generalizability 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


References

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