Hartford Hospital Research Program Research Methods Lecture Series Part I :

Research Design, Sampling and Measurement

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Yes! We're going to talk about research methods!

OVERVIEW:

- October: Basic concepts of research design
- November: Concepts of inferential statistics
- December: Choosing the right statistic Part I
- January: Choosing the right statistic Part II
- February: Meta analysis and clinical trials
- March: Grant-writing

Presenters:

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Today's presentation

- Characteristics of systematic design
- Developing background/significance
- Experimental and non-experimental approaches
- Common study designs
- Sampling methods
- Levels of measurement

Going beyond statistics… looking at concepts of research design

- Statistics offers tools and techniques to organize, summarize, analyze and interpret data
- Crucial element of research design
- Can be element of protocol that is most challenging
- **Statistics are of limited use unless they are part of good design**

Everyone has done ‘research’ as part of their everyday lives

- Wanted to know how, what or why something happens
- Gathered information to learn more
- Asked others or observed what is happening
- And then made conclusions based on the information collected

Systematic research requires:

- Clear definition of research questions and target population
- Systematic gathering of information
- Use of diverse, representative sources
- Accurate, unbiased interpretation of information

If these criteria are not met, the validity of the conclusions will be compromised

Formal research requires a clear statement of aims and objectives:

- Define the study objective (what)
  - Simply descriptive – e.g. prevalence
  - Relational – how two or more variables interact
  - Causal – hypothesis testing – determining whether one or more variables causes or affects one or more outcome variables
- Identify the target population (who)

Background and significance: The foundation of any study

- Determine current state of knowledge (what has been done)
- Use multiple data bases (Medline, Ovid, etc.) and search strategies to ensure comprehensiveness
- Review past work critically
- Build on past research: The inverted triangle
  - What questions are left unanswered?
  - Do you want to replicate and extend current body of knowledge?
  - Do you want to correct methodological errors?
  - How is your study going to add to/refine what is known?

Required elements of research protocol (and most research manuscripts)

Hypotheses	The research purpose Areas of exploration Hypotheses (both primary and secondary), specific aims.
Literature review	Relevant background Discuss the differences from currently published research Discuss areas of specific importance your research will provide
Research design & Sampling	Discuss structure of the experiment Is it retrospective or prospective? Randomized? How many samples involved?
Enrollment Criteria	Inclusion and exclusion criteria
Methods of Data collection	Study timeline and procedures Variables and outcomes to be collected
Data analysis	Power and statistics Ensure there are sufficient numbers of subjects enrolled to obtain a definitive answer to the hypotheses.
Benefit/Significance	Significance to the hospital mission & patients

Research design: Basic decisions

Design needs to fit the research question or aim

- Descriptive or Explanatory
- Retrospective or Prospective
- Cross sectional or Longitudinal
- Experimental or Quasi-Experimental

Other Considerations:

- Ethics (protection of research subjects)
- Resources

Retrospective vs. prospective

Retrospective

- Outcome established at start of study; look backwards to examine predictors, possible exposures
- Design: Case control studies
- Method: Data base extraction or chart reviews

Most commonly used design for "quick studies"

Retrospective vs. prospective

Prospective

- Explore the development of clinical outcomes
- Cross Sectional
  - –one moment in time;
  - –often looks at differences among groups of people
- Longitudinal
  - –Cohort studies
  - –Intervention studies
  - –Focus on change over time

NEXT:

Experimental &
quasi-experimental designs

Sampling

Levels of measurement

Reliability and validity

Experimental designs

- Experimental Designs
  - A *treatment* is deliberately imposed on a group of participants in the interest of observing the response.
  - Subjects randomly assigned to two or more comparison groups

Quasi-experimental designs

- Quasi-Experimental Designs

  - Non-randomized comparison groups

  - Case-control study – e.g. to better understand the etiological factors of a disease

    - A study that compares 2 group of people:
      - those with the disease (cases) and
      - a very similar group of people who do not have the disease (controls)

  - Historical controls

    - all patients coming in receive a new treatment and the outcomes are compared at 2 time points

Quasi-experimental designs contd...

- Quasi-Experimental Designs
  - Repeated Measures
    - Measurements made on same subjects under different conditions.
  - Cross over
    - Participants are randomly assigned to a specific treatment order. Some receive treatment A first, followed by treatment B. Others receive B first and A next.

Choosing the study sample

- **Population** – all persons within a category about whom the researcher wishes to explain; define inclusion and exclusion criteria
- **Sample** -- a subset of those people from whom it is feasible to gather data.
  - Random, stratified, or non random
  - Sample size

Results can be generalized from a sample to the population only if the sample is representative

Results can only be generalized to a specified population

Choosing appropriate measures

- Need to operationalize each concept, i.e. determine how it will be measured
  - Clear clinical outcomes: such as mortality, re-admission, etc. (but are they clear or also need to be defined?)
  - Other outcomes measures: Are standard or previously used measures available?
- Measures must be reliable
- Measures must be valid

Levels of measurement

- Nominal
  - categorical data, order of the categories is arbitrary
  - Example: race/ethnicity; 1=White, 2=Hispanic, and so on.
- Ordinal
  - sequence, values represent categories with some intrinsic ranking
  - example, levels of service satisfaction
- Interval
  - ordered, constant scale, but no natural zero
  - e.g., temp., 0° is relative temperature
- Ratio
  - ordered, constant scale, has a real zero e.g., height, weight, age, length

Reliability

- The degree to which an instrument or measure is consistent over time and across methods of gathering.
- Types of reliability
    - Test-retest reliability
    - Inter-rater reliability
    - Internal consistency

Validity

- Internal Validity: Does instrument measure what it is intended to measure?
- External Validity: Are findings in the sample generalizable to the population?

If at all possible, want to use measures that have already been empirically shown to be reliable and valid

- Questions or comments?