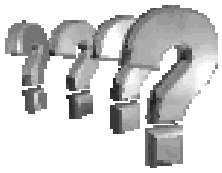
M6728

Research Designs



Goals

- Match appropriate research designs to the study purpose and questions
- Differentiate between experimental and non-experimental studies
- Discuss epidemiologic designs
- Evaluate designs of studies in literature
- Identify types of study validity and potential threats to validity

Depression Scores

Baseline	Old Drug	New Drug
23.9	12.8	13.4
26.0	13.4	13.0
28.1	20.3	19.4

Depression scores again

Baseline	Old Drug	New Drug	Placebo
23.9	12.8	13.4	14.8
26.0	13.4	13.0	13.9
28.1	20.3	19.4	18.9

What is an experiment?

- Manipulation: investigator intervenes or changes something
- Control: a comparison group without the intervention
- Randomization: each subject has an equal chance of receiving the intervention

Example: Antiseptic Handwashing and Infections

- Hypothesis: There is no difference in nosocomial infection rates among patients receiving care from staff who use an antiseptic soap or a non-antimicrobial soap.

The experimental elements….

- Manipulation: type of soap
- How and what to compare?
- What to randomize?
  - Individual subjects to one soap or another?
  - Order of soap?
  - Clinical units?

Quasi-Experimental Designs

An intervention, but no randomization

Pre-Post Test Control Group

0 X 0

0 0 0

Repeated Treatment

Subjects act as their own controls

0 X 0 X 0 X 0 X

Crossover Design

Same subjects, different interventions

0 Xa 0 Xb 0 Xa 0 Xb

Crossover Study Examples

- Subjects:Insulin-dependent diabetics
- Treatment: Insulin injection into arm, leg, abdomen
- Outcome: Insulin absorption, glucose levels

- Subjects: Non-coffee drinkers
- Treatment: Caffeine or placebo
- Outcome: Plasma renin, catecholamine, cardiovascular function

Post-test Only Control Group

X º 0
- º 0

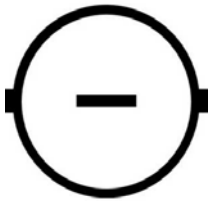
One Group Pretest-Posttest

0➔X➔0

Post-test Only

Non equivalent groups

X ➔ 0
- ➔ 0



Pros

Experiment

- More controls
- More internal validity
- Fewer rival hypotheses

Quasi-Experiment

- More practical
- More feasible
- More generalizable

Why not always an experiment?

- Can't manipulate certain variables (sex, age, race, profession)
- Unethical (e.g. can't have a control group with no handwashing)
- Impractical or undesirable (insufficient time, resources, cooperation, inability to randomize)

Non-Experimental Designs

No intervention

Sometimes in Health services research it is called a "natural experiment"

ICUWC

Classifying Non-Experimental Designs

- By time: retrospective, cross-sectional, prospective
- By method: survey, observational, historical, case study, qualitative
- By purpose: description, correlation, prediction, evaluation, methodologic

Descriptive Research by Timing

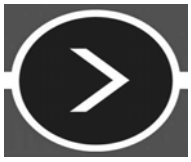
Retrospective: Effect⇨Cause
Prospective: Cause⇨Effect

Retrospective (case-control)

- Start with an event (e.g. a disease) and look back to see what factors may have caused the event or disease
- Frequency of factor is compared among those who are diseased (cases) and those who are similar but don't have the disease (controls)
- RR (measured by odds ratio) must be higher in cases than controls

Use a retrospective approach when…

- The suspected cause (disease) is rare;
- Exposure is common among diseased;
- An event has already occurred (e.g. an outbreak investigation)



Case-Control Pros and Cons

- Relatively quick, easy, economical
- Difficult to make causal inferences (e.g. Which came first--the exposure or disease?)
- Finding appropriate controls may be difficult

Sources of Cases and Controls

Cases

- All cases diagnosed in a community
- All cases in a single hospital
- All cases from one or more hospitals

Controls

- Sample of gen. pop. in same community
- Pts. from same hospital without the disease
- Persons resident in same block or neighborhood as cases

Prospective (cohort) Studies

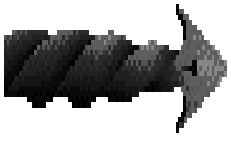
- Start with a condition (e.g. exposure) and look forward
- Frequency of the outcome (e.g. a disease) is compared between those with and without the exposure
- RR must be higher in those exposed

Use A Prospective Approach When….

- Suspected exposure (cause) is not common, but effect (disease) of interest is frequent among those exposed;
- Time between exposure and disease is short;
- Attrition can be minimized
- Investigator has a long life expectancy

Cohort Study Pros and Cons

- Better able to establish causality;
- Expensive, time consuming, difficult to maintain follow up;
- Selection of non-exposed comparison group difficult



What's your choice? An association between….

- Smoking and peptic ulcer disease?
- Radiation exposure and breast cancer?
- Cholesterol and heart disease?
- Home health care and patient's functional status?
- Hepatitis and needle-sticks?

Survey Research

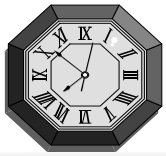
Data gathered from a portion of a population to examine characteristics, opinion, intentions

(e.g. census, vital statistics)

Pros and Cons of Surveys

- Flexible, allows access to many subjects;
- Data may be superficial;
- Low return rate

Historical Research



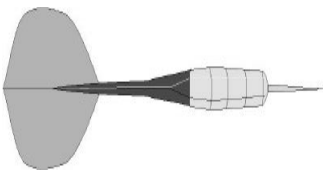
Systematic collection and critical evaluation of past data

Types of Historical Data

- Primary sources: original documents, first hand information, witnesses
- Second sources: textbooks, references

One-shot Case

X + 0



To evaluate historical data:

- External criticism: are data authentic and genuine?
- Internal criticism: is the content of the data accurate (i.e. was the writer unbiased) and worthwhile?

Methodological Research

To develop and test tools or techniques

Study validity…

- Measures the accuracy of a claim
- So important (the crux of a study's value), but so difficult to assess

Questions to Ask (in EBP is this study valid?)

- Is there a relationship between the variables (*statistical conclusion validity*)?
- Is it plausible that the relationship is causal (*internal validity*)?
- If there appears to be a causal relationship, are the cause-and-effect constructs measured accurately (*construct validity*)?

Internal Validity

Extent to which the relationship detected found is truth

Threat to Internal Validity

- HISTORY

An event not related to the planned study but occurring at the same time that affects study results

Statistical Conclusion Validity

Whether conclusions about relationships and differences drawn from analyses are an accurate reflection of reality (i.e., did not occur by chance)

Threat to Internal Validity

- MATURATION

Changes among subjects (e.g. growing older, wiser, more experienced) during the study in ways that affect the study results

Threats to Internal Validity

- TESTING

Effect being measured is due to previous testing

- INSTRUMENTATION

Effect due to measurement instrument rather than treatment (e.g. more experienced observers, change in instrument)

Threats to Internal Validity

- MORTALITY/DROPOUT

Those who drop out of a study differ from those who stay in, or drop out occurs differentially in experimental and control groups

Questions to Ask (In EBP, is this study applicable?)

- How generalizable is this relationship to other settings, times, persons (*external validity*)?

External Validity

Extent to which findings can be generalized beyond the sample

Threats to External Validity

- Hawthorne or novelty effects
- Interaction of treatment and history, setting or selection
- Investigator effects
- Measurement effects