

STUDY DESIGN Part I

(Cross-sectional, Cohort, Case-Control)

Clinical Research Workshop

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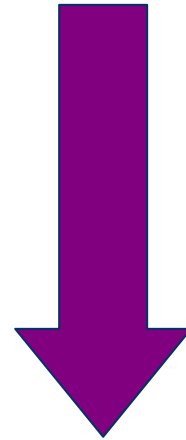
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Study Designs

Strength of Evidence

- ◆ Observational
- ◆ Correlational
- ◆ Quasi-Experiment
- ◆ True Experiment



Weaker

Stronger

Classification of Structures

- ◆ Observational/Correlational ⇒ Cohort
Cross-Sectional
- ◆ Quasi-Experiment ⇒ Case-Control
Multiple-Cohort
- ◆ True Experiment ⇒ Clinical Trial
Time-Series
Cross-Over

Prevalence vs. Incidence

Prevalence =

$$\frac{\text{Number who currently have characteristic}}{\text{Number currently at risk}}$$

Incidence (1 year) =

$$\frac{\text{Number who exhibit characteristic within 1 year}}{\text{Number at risk within 1 year}}$$

Cross-Sectional Example (Observational)

In patients referred for antinuclear antibody testing, what is the prevalence of anti-ribonucleoprotein (anti-RNP)?

Ref: Bridges AJ, Anderson JD, McKay J, Wang G, Johnson J, Sharp GC: Antinuclear Antibody Testing in a Referral Laboratory. Laboratory Medicine 24(6):345-349, 1993.

Cross-Sectional Example (Correlational)

Is self-efficacy associated with level of physical activity in persons with fibromyalgia?

Ref: Buckelew SP, Murray SE, Hewett JE, Johnson JC, Huyser B: Self-Efficacy, Pain, and Physical Activity Among Fibromyalgia Subjects. Arthritis Care and Research 8(1):43-50, 1995.



Cross-Sectional Procedure

1. Select sample from population.
2. Measure all variables at the same time.



Cross-sectional Strengths



Cross-sectional Strengths



- ◆ Short duration
- ◆ Relatively inexpensive
- ◆ Estimate prevalence



Cross-Sectional Weaknesses



Cross-Sectional Weaknesses



- ◆ No sequence to events
- ◆ Not feasible for rare events
- ◆ Cannot estimate incidence or relative risk



Cohort

Timing of Measurements

- ◆ Prospective – Measure variables currently and in the future
- ◆ Retrospective – Measure variables in the past up to current time

Prospective Cohort Example

In persons with rheumatoid arthritis, can total active joint count predict psychological disability 6 months later?

Ref: Schoenfeld-Smith K, Petroski GF, Hewett JE, Johnson JC, Wright GE, Smarr KL, Walker SE, Parker JC: A Biopsychosocial Model of Disability in Rheumatoid Arthritis. Arthritis Care and Research 9(5):368-375, 1996.



Prospective Cohort Procedure

1. Select sample from population.
2. Measure predictor variables and confounding variables currently.
3. Measure outcome variables in the future.



Prospective Cohort

Strengths

- ◆ Sequence to events
- ◆ Estimate incidence and relative risk
- ◆ More control over selection of subjects
- ◆ More control over measurements
- ◆ Avoid bias in measuring predictor/
confounding variables



Prospective Cohort Weaknesses





Prospective Cohort Weaknesses

- ◆ Large sample sizes needed
- ◆ Less feasible for rare outcomes
- ◆ More expensive
- ◆ Longer duration



Retrospective Cohort Procedure

1. Identify sample.
2. Collect data on predictor variables and confounding variables from past.
3. Measure outcome variables currently (or more recently than predictor variables).



Retrospective Cohort Strengths





Retrospective Cohort Strengths

- ◆ Sequence to events
- ◆ Estimate incidence and relative risk
- ◆ Less expensive
- ◆ Shorter duration



Retrospective Cohort Weaknesses





Retrospective Cohort

Weaknesses

- ◆ Large sample sizes
- ◆ Less feasible for rare outcomes
- ◆ Less control over selection of subjects
- ◆ Less control over measurements

Multiple-Cohort Example

Following implementation of a workplace smoking ban, do employees have a higher rate of quitting smoking than employees of workplaces with no ban on smoking?

Ref: Longo DR, Brownson RC, Johnson JC, Hewett JE, Kruse RL, Novotny TE, Logan RA: Hospital Smoking Bans and Employee Smoking Behavior: Results of a National Survey. JAMA 275(16):1252-1257, 1996.



Multiple-Cohort Procedure

1. Select sample from each population.
(Predictor variable is “cohort membership”.)
2. Measure outcome variable.



Multiple-Cohort Strengths and Weaknesses

Unique Strengths:

- ◆ Feasible to study different or rare exposures.
- ◆ Cohort from census data is population-based and less expensive.

Unique Weaknesses:

- ◆ Confounding can be inflated.



Case-Control Example

Is conviction for a felony predictive of future traumatic brain injury?

Ref: Unpublished.

Case-Control Procedure

1. Select sample of cases.
2. Select sample of controls
(Outcome variable is membership in either case or control sample.)
3. Measure predictor variables from past.



Case-Control Selecting Controls



- ◆ Controls from same facility as cases.
- ◆ Matched controls.
- ◆ Population-based controls.
- ◆ Multiple control groups.



Case-Control Strengths





Case-Control Strengths



- ◆ Useful for rare conditions
- ◆ Short duration
- ◆ Less expensive
- ◆ Smaller sample size
- ◆ Estimate odds ratio (relative risk)



Case-Control Weaknesses





Case-Control Weaknesses

- ◆ Bias and confounding
- ◆ No sequence of events
- ◆ Survivor bias
- ◆ Only one outcome variable
- ◆ Cannot estimate prevalence or incidence