

Research Study Designs

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Key Topics

- Definition of 5 common study designs
 - Advantages, disadvantages
- Examples from journals we read

Terms

- Exposure (factor that we think is influencing the person's health)
- Outcome (the specific health event that we are studying)
- Retrospective vs. prospective (timing of data collection relative to health event)

1. Case Report/Series

- Def: Published report with documentation of a limited number of new patient observations
- Advantages
 - Easy article for practicing physicians
- Disadvantages
 - No comparison group
 - Cannot make any conclusions

2. Cross-Sectional Study

- Def: Study at one point in time that compares “what % of people with outcome have characteristic X”
- Advantages
 - Relatively easy to do
 - Often can use existing data
 - Can be good for generating ideas for future studies
- Disadvantages
 - Cannot make any conclusions on causation
 - Exposure may not be related to outcome

3. Case-Control Study

- Def: Study that identifies people who have the outcome, and then assesses if the exposure is more/less common in those with the outcome; always retrospective
- Advantages
 - Efficient design (few people needed)
 - Sometimes this is the best you can do
 - Good for rare outcomes or latent exposures
 - Can make strong conclusion with good design and enough people
- Disadvantages
 - Always at risk for unmeasured confounding or faulty logic that yields erroneous results
 - Can be hard to identify best control group

4. Cohort Study

- Def: Study that identifies people with the exposure and people without the exposure, and then watches “over time” to see who develops the outcome; can be retrospective or prospective
- Advantages
 - Ensures correct time sequence (exposure, then outcome)
 - Direct measurement of risk
 - Very do-able for pregnancy research
- Disadvantages
 - May take years and much money to do this right
 - What to do when exposure status changes over time?
 - Potential bias from loss to follow-up

5. Clinical Trial

- Def: Study that creates the exposure and placebo non-exposure and watches over time to see who develops the outcome; always prospective
- Advantages
 - Gold standard of scientific rigor since the exposure and outcome assessments are controlled by the investigator
- Disadvantages
 - Loss to follow-up and non-compliance can bias results
 - Trial conditions \neq real world
 - Potential ethical issues for exposed or non-exposed
 - Expense

Bottomline as an Epidemiologist

Better to conduct a well-designed, well-conceived study that cannot make a definitive causal statement (like a great case-control study) than to conduct a clinical trial that is flawed and poorly designed.

In other words, the study design category cannot compensate for flawed hypotheses and flawed patient selection.

Easy study design to identify?

- Case-series
- Clinical trial

Two Key Questions to Ask in Separating C-C-C Study Designs

- Are patients selected based on the exposure or the outcome?
- Is there a comparison group?

Design Features of C-C-C Studies

Study Design Category	Patients selected by...	Comparison group?
Cross-sectional		No
Case-control	Outcome	Yes
Cohort	Exposure	Yes

Key Questions to Ask in Determining Study Design

- What is the exposure?
- What is the outcome?
- Are patients selected based on the exposure or the outcome?
- Is there a comparison group?
- Does the exposure measurement predate the outcome measurement?
- Is this an experiment (vs. observation)?