

Study Design - 2

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Key Terms

- **Sampling**
- **Bias**
- **Confounding**
- **Power, beta error**

Assessing Methodological Quality

- Note the study design and whether it was appropriate for the question.
- Who was the study population? Do they represent the general population?
- Was the study well designed?
- Was systematic bias avoided?
- Was the study large enough and long enough? (What was the power?)

Review of Study Designs

■ Primary studies

– Descriptive/Observational Studies

- Case report (and Case series)

- Prevalence Survey (aka cross-sectional study)

– Analytic Studies

- Case-control study (retrospective)

- Cohort study (prospective or retrospective)

– Experimental/Interventional Studies

- Clinical trials (randomized controlled trials)

■ Secondary Studies

– Systematic Review

- Meta-analysis

Sampling

- Who was studied? Are they representative of the target population?
 - *Target population*: that group to which we would like to generalize the findings.
- Was the study population a convenience sample or random sample?
 - *Convenience sample*: those who agree to participate
- Were certain people excluded?
 - Exclusions based on age and co-morbidities may result in greater differences between the study group and the target population.

Bias - Anything that produces a systematic error in the research findings and threatens the validity of the study

- Bias may be due to *selection* of study participants
 - Volunteer effect
 - Healthy worker effect
 - Non-response effect
- Bias may be due to the treatment or study *procedures* performed
 - Attention bias
 - Therapeutic effect
 - Non-compliance effect
- Bias may be due to *measurement* and data collection
 - Recall bias
 - Insensitive measures
 - Diagnostic suspicion
 - Unblinded assessment bias
- Bias may be due to methods of *data analysis*
 - Efficacy analysis vs. *Intent to treat*
 - Sub-group analyses
- Some study designs are more prone to bias than others:
 - Randomized controlled trials vs. non-randomized controlled trials
 - Cohort studies vs. case control studies

Confounding

- Confounding occurs when the effects of several variables cannot be distinguished. It may not be possible to determine if the observed effect is due to the variable in question or some other *confounding* variable.
- Multivariate analysis (logistic regression) may allow you to separate confounding variables from true predictors of effect.

Power

- It is defined as the likelihood of detecting a specified difference between two groups if it truly exists.
- The power of a study should be determined prior to the actual conduct of the trial. Two pieces of information are needed:
 - What is considered a clinically significant effect?
 - The mean and standard deviation of the outcome variable.
- When a clinical trial has negative results (findings were not statistically significant), the study may not have had adequate power to detect the desired effect. It may be erroneous to conclude that the intervention has no efficacy. If a study had 80% power then there is a 20% chance that you won't find a significant relationship even if that relationship exists (20% chance of beta error).



Summary

- Ask the right question
- Search for the right articles
- Note appropriateness of the study design
- Is the study valid? - look at the methods
 - Sampling
 - Source bias
 - Possible confounding variables
 - Adequate power
- What are the results and are they significant