Research Minute

Research Bias

Sandra Burge, Ph.D.

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The purpose of research design is to systematically answer a question while controlling bias and ruling out alternative explanations. *What is research bias? It is anything that produces systematic (but unexpected) variation in a research finding.* Every study design has bias. Even the "gold standard," a randomized controlled trial, tightly defines who is eligible for the study, limiting generalizability to broader populations. On the other hand, pragmatic clinical trials with more diverse samples are subject to confounding variables or alternative explanations of the study outcomes. Your job is to choose the best design for your research question, and reduce bias as much as possible.

Bias in Study Design

<u>Alternative explanations</u>. Something else, unmeasured, may be affecting your outcomes.

<u>Confounding variable</u>. This variable is correlated with both predictor and outcome, affecting how they are correlated to each other.

<u>History</u>. Stuff happens outside of your control that affects your study.

<u>Maturation bias</u>. Subjects change, with or without your study.

<u>Testing bias</u>. When you test your subjects more than one time, they 'get better' at the test.

<u>Subjects' bias</u>. Subjects have their own opinion about how the research will affect them.

Bias Affecting Generalizability

<u>Sample selection</u>. A sample should represent a larger population. If it does not, generalizability is limited.

<u>Attrition</u>. People who drop out of a study are probably systematically different than the ones who stay in.

Unique setting. If you draw a sample from a unique setting, they are likely to be systematically different from others; this will limit generalizability.

Note—we in San Antonio have a large Hispanic population, which is unique across the country. Our generalizability to other regions is limited.

Bias in Measurement

<u>Subject error</u>. Subject responds in an inaccurate or inconsistent way.

Instrument error. Calibration is off, or the wrong instrument is used.

Observer error. The observer records data inaccurately or inconsistently.

<u>Investigator bias</u>. The investigator's opinion about the study outcome affects measurement.

<u>Inconsistency in treatments</u>. Interventions should be delivered in a consistent way, or the researcher won't know what caused the outcome.

Bias Affecting Statistical Conclusions

Low statistical power. This is a Type II error, caused by a too-small sample size or too-small group differences.

<u>Violated assumption of statistical</u> <u>tests</u>. Consult your statistician; some tests are not appropriate for your data.

Fishing. When the primary hypothesis is not met, a researcher may look for *any* significant results. Such results can happen randomly; use caution in interpreting their importance.

Random heterogeneity of subjects. Even with random selection, one can draw a sample and control group that are dissimilar in important ways, affecting findings.

<u>Regression toward the mean.</u> Most measurements hug the middle. Extreme values in time 1 may become more moderate in time 2.



How to Control Bias

<u>Careful Sampling</u>. Use randomization when you can, choose a largeenough sample, and do persistent follow up with longitudinal studies.

<u>Comparison Groups</u>. To avoid History and Maturation Bias, also test comparison groups who will endure the same history and mature the same way as your treatment group.

<u>Minimize fishing.</u> State a hypothesis at the beginning, and test it at the end. It's OK to do a little fishing; it is useful for generating a new hypothesis for your next study.

<u>Blinding</u>. Blind subjects and clinicians to treatments.

<u>**Be consistent**</u>—in how you measure concepts, and how you deliver interventions.

Account for alternative causes. If you think an additional cause might affect your findings, measure it and include it as part of your study. Or, exclude subjects who have that condition/cause.