Research Skills

Module 7
Sources of Bias
Internal and external validity

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Bias versus Quality

Bias is not the same a quality. A research study can be conducted to the highest standards of methodological practice (have high quality) but still have a bias.

Source: Higgins, Julian P. T. and Altman, Douglas G. in Higgins, Julian P. T. and Green, S. (eds). Cochrane Handbook for Systematic Reviews of Interventions, Chapter 8.2.2. 'Risk of bias' and 'quality.' Available from: https://books.google.com.au/books?isbn=1119964792

What is bias?

"Bias is defined as any tendency which prevents unprejudiced consideration of a question[6]. In research, bias occurs when "systematic error [is] introduced into sampling or testing by selecting or encouraging one outcome or answer over others" [7]. Bias can occur at any phase of research, including study design or data collection, as well as in the process of data analysis and publication.

Bias is not a dichotomous variable. Interpretation of bias cannot be limited to a simple inquisition: is bias present or not? Instead, reviewers of the literature must consider the degree to which bias was prevented by proper study design and implementation. As some degree of bias is nearly always present in a published study, readers must also consider how bias might influence a study's conclusions[8]. " (Pannucci & Wilkins, 2010, p 1.)

Pannucci, CJ and Wilkins, EG. Identifying and Avoiding Bias in Research. Plast Reconstr Surg. 2010 Aug; 126(2): 619–625. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2917255/#R6

6. Dictionary.com; http://dictionary.reference.com/browse/bias.
7. Merriam-Webster.com; http://www.merriam-webster.com/dictionary/bias.
8. Gerhard T. Bias: Considerations for research practice. Am. J. Health. Syst. Pharm. 2008;65:2159–2168. [PubMed]

What is bias?

*A bias is a **systematic error**, or deviation from the truth, in results or inferences*. Biases can operate in either direction: different biases can lead to underestimation or overestimation of the true value.

Biases can vary in magnitude: some are small (and trivial compared with the observed effect) and some are substantial (so that an apparent finding may be entirely due to bias). Even a particular source of bias may vary in direction: bias due to a particular design flaw (e.g. lack of allocation concealment) may lead to underestimation of an effect in one study but overestimation in another study.

It is important to assess risk of bias in all studies irrespective of the anticipated variability in either the results or the validity of the studies.

Bias should not be confused with imprecision. Bias refers to systematic error, meaning that multiple replications of the same study would reach the wrong answer on average.

Imprecision refers to random error, meaning that multiple replications of the same study will produce different effect estimates because of sampling variation even if they would give the right answer on average. The results of smaller studies are subject to greater sampling variation and hence are less precise. Imprecision is reflected in the confidence interval around the intervention effect estimate from each study and in the weight given to the results of each study in a meta-analysis. More precise results are given more weight.

Source: Higgins, Julian P. T. and Altman, Douglas G. in Cochrane Handbook for Systematic Reviews of Interventions, Chapter 8.2.1 ‘Bias’ and ‘risk of bias’. Available from:
http://handbook.cochrane.org/chapter_8/8_2_1_bias_and_risk_of_bias.htm

Bias (Systematic Error) and Random Error

Error is defined as the difference between the true value of a measurement and the recorded value of a measurement. Error can be described as **random** or **systematic**.

Random error is also known as variability, random variation, or 'noise in the system'. The heterogeneity (diversity) in the human population can five rise to relatively large random variance. Random error *has no preferred direction*, so we expect that averaging over a large number of observations will yield a net effect of zero. The estimate may be imprecise, but not inaccurate. The impact of random error, imprecision, can be minimized with large sample sizes. **Random error corresponds to imprecision.**

Systematic error or bias refers to deviations that are not due to chance alone. The simplest example occurs with a measuring device that is improperly calibrated so that it consistently overestimates (or underestimates) the measurements by X units. Bias, *has a net direction and magnitude* so that averaging over a large number of observations does not eliminate its effect. In fact, bias can be large enough to invalidate any conclusions. Increasing the sample size does not usually help. In human studies, bias can be subtle and difficult to detect. Even the suspicion of bias can render judgment that a study is invalid. Thus, the design of a study needs to focus on removing known biases.
Bias corresponds to inaccuracy.

Source: Eberly College of Science (Pennsylvania State University). Stat505, Lesson 4: Bias and Random Error. Available from: https://onlinecourses.science.psu.edu/stat509/node/26

Bias due to Measurement Error

A poor measurement process can also lead to bias. In survey research, the measurement process includes the environment in which the survey is conducted, the way that questions are asked, and the state of the survey respondent.

Response bias refers to the bias that results from problems in the measurement process. Some examples of response bias are given below.

Leading questions. The wording of the question may be loaded in some way to unduly favour one response over another. For example, a satisfaction survey may ask the respondent to indicate where she is satisfied, dissatisfied, or very dissatisfied. By giving the respondent one response option to express satisfaction and two response options to express dissatisfaction, this survey question is biased toward getting a dissatisfied response.

Social desirability. Most people like to present themselves in a favourable light, so they will be reluctant to admit to unsavoury attitudes or illegal activities in a survey, particularly if survey results are not confidential. Instead, their responses may be biased toward what they believe is socially desirable.

Source: Statistics and Probability Dictionary. Selection Bias in Survey Sampling. Available fromhttp://stattrek.com/survey-research/survey-bias.aspx

Selection Bias (Bias Due to Unrepresentative Samples)

In survey sampling, the bias that results from an unrepresentative sample is called **selection bias**. Some common examples of selection bias are described below.

Under-coverage. Under-coverage occurs when some members of the population are inadequately represented in the sample. A classic example of under-coverage is the *Literary Digest* voter survey, which predicted that Alfred Landon would beat Franklin Roosevelt in the 1936 presidential election. The survey sample suffered from under-coverage of low-income voters, who tended to be Democrats. Under-coverage is often a problem with convenience samples .

Voluntary response bias. Voluntary response bias occurs when sample members are self-selected volunteers, as in voluntary samples . An example would be call-in radio shows that solicit audience participation in surveys on controversial topics (abortion, affirmative action, gun control, etc.). The resulting sample tends to over-represent individuals who have strong opinions.

Nonresponse bias. Sometimes, individuals chosen for the sample are unwilling or unable to participate in the survey. This can be a big problem with mail surveys, where the response rate can be very low.

Random sampling is a procedure for sampling from a population in which (a) the selection of a sample unit is based on chance and (b) every element of the population has a known, non-zero probability of being selected. Random sampling helps produce representative samples by eliminating voluntary response bias and guarding against under-coverage bias. All probability sampling methods rely on random sampling.

Source: Statistics and Probability Dictionary. Selection Bias. Available from http://stattrek.com/statistics/dictionary.aspx?definition=selection%20bias

Sampling Error and Survey Bias

A survey produces a sample statistic, which is used to estimate a population parameter. If you repeated a survey many times, using different samples each time, you might get a different sample statistic with each replication. And each of the different sample statistics would be an estimate for the *same* population parameter. If the statistic is unbiased, the average of all the statistics from all possible samples will equal the true population parameter; even though any individual statistic may differ from the population parameter. The variability among statistics from different samples is called **sampling error**.

Increasing the sample size tends to reduce the sampling error; that is, it makes the sample statistic less variable. However, increasing sample size does not affect survey bias. A large sample size cannot correct for the methodological problems (under-coverage, nonresponse bias, etc.) that produce survey bias.

Source: Statistics and Probability Dictionary. Selection Bias in Survey Sampling. Available fromhttp://stattrek.com/survey-research/survey-bias.aspx

Statistical Biases

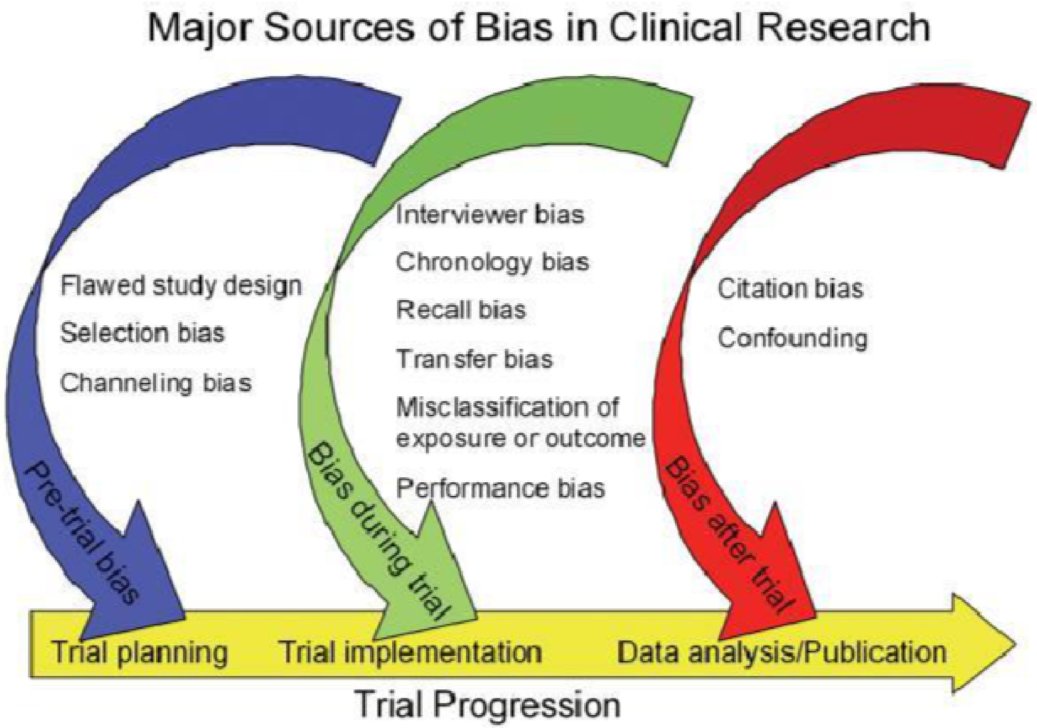
For a point estimator, statistical bias is defined as the difference between the parameter to be estimated and the mathematical expectation of the estimator.

Statistical bias can result from methods of analysis or estimation.

For example, if the statistical analysis does not account for important prognostic factors (variables that are known to affect the outcome variable), then it is possible that the estimated treatment effects will be biased. Fortunately, many statistical biases can be corrected, whereas design flaws lead to biases that cannot be corrected.

Source: Eberly College of Science (Pennsylvania State University). Stat505, Lesson 4.3 - Statistical Biases. Available from: https://onlinecourses.science.psu.edu/stat509/node/29

Table 1 provides a summary of different types of bias, when they occur, and how they might be avoided.



Pannucci, CJ and Wilkins, EG. Identifying and Avoiding Bias in Research. Plast Reconstr Surg. 2010 Aug; 126(2): 619–625. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2917255/#R6

Respondent bias in interview and questionnaire based research (qualitative research)

1. **Acquiescence bias**: This bias occurs when a respondent demonstrates a tendency to agree with and be positive about whatever the moderator presents. In other words, they think every idea is a good one and can see themselves liking, buying and acting upon every situation that is proposed. To avoid it, researchers must replace questions that imply there is a right answer with those that focus on the respondent's true point of view. (Sarniak, 2015.)

2. **Social desirability bias**: This bias involves respondents answering questions in a way that they think will lead to being accepted and liked. Researchers can minimize this bias by phrasing questions to show it's okay to answer in a way that is not socially desirable, or by asking about what a third-party thinks, feels and how they will behave. (Sarniak, 2015.)

3. **Habituation**: In cases of habituation bias, respondents provide the same answers to questions that are worded in similar ways. Moderators must keep the engagement conversational and continue to vary question wording to minimize habituation. (Sarniak, 2015.)

4. **Sponsor bias**: When respondents know – or suspect – the sponsor of the research, their feelings and opinions about that sponsor may bias their answers. (Sarniak, 2015.)

Adapted from: Sarniak R. 9 types of research bias and how to avoid them. Quirk's Marketing Research Review. August 2015. Article ID: 20150825-2. Available from: http://www.quirks.com/articles/9-types-of-research-bias-and-how-to-avoid-them

<u>Researcher</u> bias in interview and questionnaire based research (qualitative research)

1. **Confirmation bias**: This bias occurs when a researcher forms a hypothesis or belief and uses respondents' information to confirm that belief. This takes place in-the-moment as researchers' judge and weight responses that confirm their hypotheses as relevant and reliable, while dismissing evidence that doesn't support a hypothesis. Confirmation bias then extends into analysis, with researchers tending to remember points that support their hypothesis and points that disprove other hypotheses. To minimize confirmation bias, researchers must continually re-evaluate impressions of respondents and challenge pre-existing assumptions and hypotheses. (Sarniak, 2015.)

2. **Culture bias**: Assumptions about motivations and influences that are based on our cultural lens (on the spectrum of ethnocentricity or cultural relativity) create the culture bias. Ethnocentrism is judging another culture solely by the values and standards of one's own culture. To minimize culture bias, researchers must show unconditional positive regard and being aware of their own cultural assumptions. (Sarniak, 2015.)

3. **Question-order bias**: One question can influence answers to subsequent questions, creating question-order bias. Respondents are primed by the words and ideas presented in questions that impact their thoughts, feelings and attitudes on subsequent questions. While question-order bias is sometimes unavoidable, asking general questions before specific, unaided before aided and positive before negative will minimize bias. (Sarniak, 2015.)

Adapted from: Sarniak R. 9 types of research bias and how to avoid them. Quirk's Marketing Research Review. August 2015. Article ID: 20150825-2. Available from: http://www.quirks.com/articles/9-types-of-research-bias-and-how-to-avoid-them

Researcher bias in interview and questionnaire based research (qualitative research)

4. **Leading questions and wording bias**: Elaborating on a respondent's answer puts words in their mouth and, while leading questions and wording aren't types of bias themselves, they lead to bias or are a result of bias. Researchers do this because they are trying to confirm a hypothesis, build rapport or overestimate their understanding of the respondent. To minimize this bias, ask questions that use the respondents' language and inquire about the implications of a respondent's thoughts and reactions. Avoid summarizing what the respondents said in your own words and do not take what they said further. (Sarniak, 2015.)

5. **The halo effect**: Moderators and respondents have a tendency to see something or someone in a certain light because of a single, positive attribute. Researchers should address all questions about one brand before asking for feedback on a second brand, as when respondents are required to switch back and forth rating two brands, they are likely to project their opinion on one attribute to their opinion of the brand as a whole. (Sarniak, 2015.)

Adapted from: Sarniak R. 9 types of research bias and how to avoid them. Quirk's Marketing Research Review. August 2015. Article ID: 20150825-2. Available from: http://www.quirks.com/articles/9-types-of-research-bias-and-how-to-avoid-them

Types of bias

1. **Bias in concepts**: Lack of clarity about the concepts that are to be used in the proposed research. This gives an opportunity to the investigators to use subjective interpretation that can vary from person to person. Sometimes the logic used can be faulty and sometimes the premise itself of the logic can be incorrect.

2. **Definition bias**: The study subjects should be sharply defined so that there is no room for ambiguity. Blurred definition gives room to the assessor to use subjective interpretation that can affect the validity of the study.

3. **Bias in design**: This bias occurs when the case group and control group are not properly matched, and the confounding factors are not properly accounted for at the time of analysis.

4. **Bias in selection of subjects**: This occurs when the subjects included in the study are not truly representative of the target population. This can happen either because the sampling was not random, or because sample size is too small to represent the entire spectrum of subjects in the target population. Studies on volunteers always have this kind of bias.

5. **Instruction bias**: When unclear or no instructions are prepared, the investigators use discretion and this can vary from person to person, and from time to time.

6. **Bias due to confounder**: Failure to take proper care of the confounders so that any difference or association cannot be fully ascribed to the antecedent factors under study.

Source: Indrayan, A. VARIETIES OF BIAS TO GUARD AGAINST. MedicalBiostatistics.com. Available from: http://www.medicalbiostatistics.com/Types%20of%20bias.pdf

Types of bias

7. **Interviewer bias**: Interviewer bias occurs when one is able to elicit better response from one kind of respondent relative to another.

8. **Observer bias**: This bias occurs when the observer unwittingly (or even intentionally) exercises more care about one type of responses or measurements such as those supporting a particular hypothesis than those opposing this hypothesis.

9. **Instrument bias**: This bias occurs when the measuring instrument is not properly calibrated. A scale may be biased to give a higher reading than actual, or lower than actual.

10. **Hawthorne effect**: If a subject knows that he is being observed or being investigated, their behaviour and response can change.

11. **Recall bias**: There are two types of recall bias. One type of recall bias arises from better recall by respondents of recent events than those events occurring a long time ago. The second type of recall bias occurs because emotionally/psychologically significant events are easier to recall than events of lesser significance or non-significant events.

12. **Response bias**: If the subjects/respondents are able to exchange notes, the response to questions might alter, in some cases might even be uniform. Response bias also comes under information bias.

Source: Indrayan, A. VARIETIES OF BIAS TO GUARD AGAINST. MedicalBiostatistics.com. Available from: http://www.medicalbiostatistics.com/Types%20of%20bias.pdf

Types of bias

13. **Repeat testing bias**: In a pre-test-post-test situation, the subjects/respondents tend to remember some of the previous questions and they may remove previous errors in post-test, and thus do better. Observer may also acquire expertise second or third time to elicit correct response. Conversely fatigue may set in repeat testing that could alter the response.

14. **Digit preference**: It is well known that almost all of us have special love for digits 0 and 5. Measurements are more frequently recorded ending with these digits. A person of age 69 or 71 is very likely to report his age 70 years. Another manifestation of digit preference is in forming intervals for quantitative data.

15. **Bias due to nonresponse**: Some individuals selected as participants may refuse to cooperate/participate from the beginning or may drop-out of the study. Non-respondents make two types of effects on the responses. First, they are generally different from those who respond, and their exclusion can lead to biased result. Second,
Non-response reduces the sample size that can decrease the power of the study to detect differences or associations.

16. **Attrition bias**: Differential non-response in various groups. The pattern of non-response can differ from one group to the other.

Source: Indrayan, A. VARIETIES OF BIAS TO GUARD AGAINST. MedicalBiostatistics.com. Available from: http://www.medicalbiostatistics.com/Types%20of%20bias.pdf

Types of bias

17. **Bias in handling outliers**: No objective rule is available to label a value as outlier except a guideline that the value must be far away from the mainstream values. If the duration from HIV infection to development of AIDS is mostly between 6 and 10 years, some researchers would call 16 years as outlier and exclude it on the suspicion of being wrong reporting, and some would include in their calculation. Some would not exclude any outlier, however different it might be. Thus the results would vary.

18. **Recording bias**: Two types of errors can occur in recording. One bias arises due to inability to properly decipher the notes on participant sheets. Second is due to carelessness of the investigator such as number reversals and incorrect recording of values and responses when the dependence is on memory that can fail to recall the correct response/code/value.

19. **Bias in analysis**: This bias can be of two types. First is the gearing of analysis to support a particular hypothesis. For example, while comparing pre- and post- values such as blood iron level before and after weekly supplementation of iron, the increase may be small that will not be detected by comparison of means. But it may be detected when evaluated as proportion of subjects with level <10 mg/dl before and after supplementation. The second can arise due to differential P-values. When P = 0.055, one researcher can straight refuse to say that it is significant at 0.05 level and the other can say that it is marginally significant. Some researchers may change the level of significance from 5 percent to 10 percent if the result is to their liking.

Source: Indrayan, A. VARIETIES OF BIAS TO GUARD AGAINST. MedicalBiostatistics.com. Available from: http://www.medicalbiostatistics.com/Types%20of%20bias.pdf

Types of bias

20. **Bias due to lack of power**: Statistical tests are almost invariably used to check the significance of differences or associations. The power of these tests to detect difference or association depends to a large extent on the number of subjects included in the study (the sample size). If the study is conducted on small sample, even a big difference cannot be detected, leading to a false negative conclusion. When conducted on an appropriate number of subjects, the conclusion can change.

21. **Interpretation bias**: This bias is the tendency among some research workers to interpret the results in favour of a particular hypothesis ignoring the opposite evidence. This can be intentional or unintentional.

22. **Reporting bias**: Researchers are human beings. Some can create a report such that it gives the anticipated result yet still is based on the evidence. It is easy to suppress the contradictory evidence by not talking about it.

23. **Bias in presentation of results**: Scale for a graph can be chosen to depict a small change look like a big change, or vice-versa. The second is that the researcher may merely state the inconvenient findings that contradict the main conclusion but does not highlight them in the same way as the favourable findings.

24. **Publication bias**: Many journals are much too keen to publish reports that give a positive result regarding efficacy of a new regimen, compared to the negative trials that did not find any difference. If a 'vote count' is done on the basis of the published reports, positive results would hugely outscore the negative results, although the fact may be just the reverse.

Source: Indrayan, A. VARIETIES OF BIAS TO GUARD AGAINST. MedicalBiostatistics.com. Available from: http://www.medicalbiostatistics.com/Types%20of%20bias.pdf

Box: Steps for minimising bias

Following steps can be suggested to minimise bias in the results. All steps do not apply to all the situations. Adopt the ones that apply to your setup.

- Develop an unbiased scientific temperament by realising that you are in the occupation of relentless search for truth.
- Specify the problem to the minutest detail.
- Assess the validity of the identified target population, and the groups to be included in the study in the context of objectives and the methodology.
- Assess the validity of antecedents and outcomes for providing correct answer to your questions. Beware of epistemic uncertainties arising from limitation of knowledge.
- Evaluate the reliability and validity of the measurements required to assess the antecedents and outcomes, as also of the other tools you plan to deploy.
- Carry out a pilot study and pretest the tools. Make changes as needed.
- Identify all possible confounding factors and other sources of bias, and develop an appropriate design that can take care of most of these biases if not all.
- Choose a representative sample, preferably by random method.
- Choose an adequate size of sample in each group.
- Train yourself and coworkers in making correct assessments.
- Use matching, blinding, masking, and random allocation as needed.
- Monitor each stage of research, including periodic check of the data.
- Minimise nonresponse and partial response.
- Double check the data and cleanse it of errors in recording, entries, etc.
- Analyse the data with proper statistical methods. Use standardised or adjusted rates where needed, do the stratified analysis, or use mathematical models such as regression to take care of biases that could not be ruled out by design.
- Interpret the results in an objective manner based on evidence.
- Report only the evidence based the results – enthusiastically but dispassionately.
- Exercise extreme care in drafting the report and keep comments or opinions separate from the results.

Source: Indrayan, A. VARIETIES OF BIAS TO GUARD AGAINST. MedicalBiostatistics.com. Available from: http://www.medicalbiostatistics.com/Types%20of%20bias.pdf

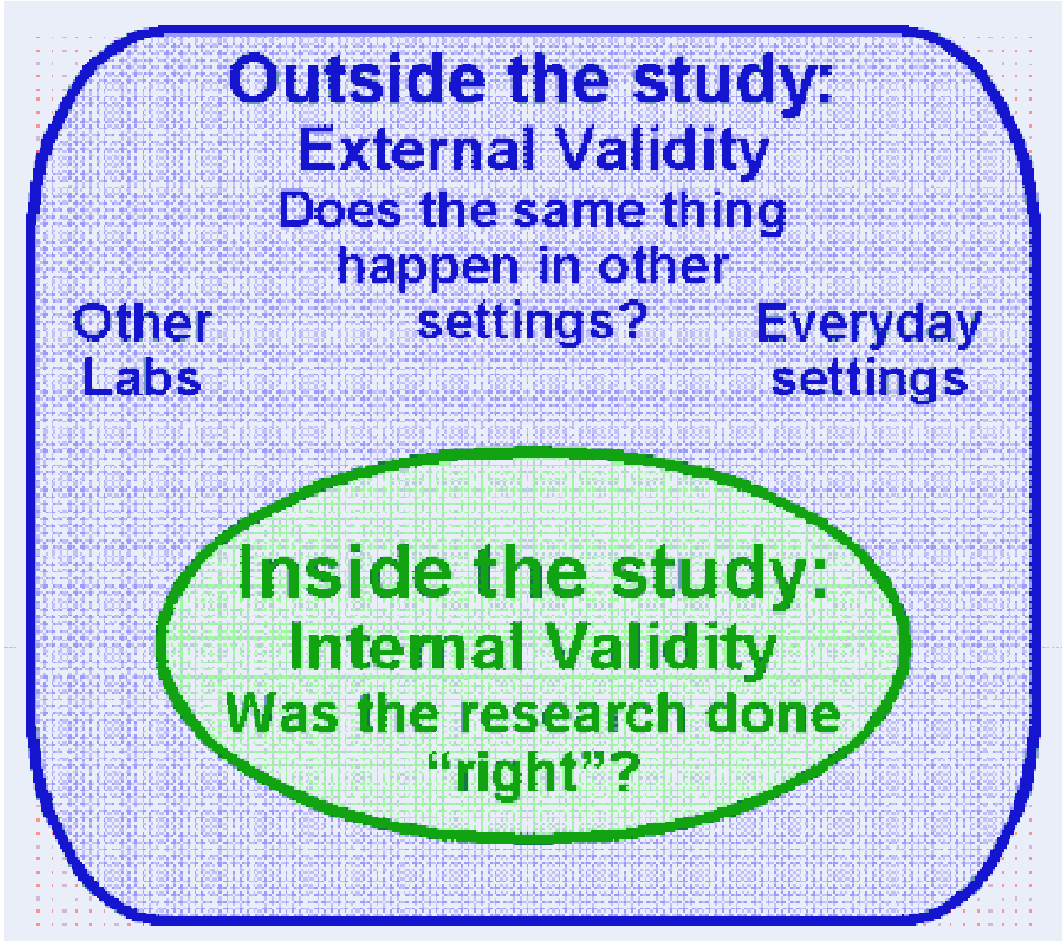
Validity

The validity of a study may be considered to have two dimensions. The first dimension is whether the study is asking an appropriate research question. This is often described as 'external validity', and its assessment depends on the purpose for which the study is to be used. External validity is closely connected with the generalizability or applicability of a study's findings.

The second dimension of a study's validity relates to whether it answers its research question 'correctly', that is, in a manner free from bias. This is often described as 'internal validity', and it is this aspect of validity that we address in this chapter. As most Cochrane reviews focus on randomized trials, we concentrate on how to appraise the validity of this type of study.

Assessments of internal validity are frequently referred to as 'assessments of methodological quality' or 'quality assessment'.

Source: Higgins, Julian P. T. and Altman, Douglas G. in Higgins, Julian P. T. And Green S. (eds). Cochrane Handbook for Systematic Reviews of Interventions, Chapter 8.1 Introduction. Available from: https://books.google.com.au/books?isbn=1119964792



Source: www.indiana.edu