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Publication Bias

Publication bias can result from the selective publication of manuscripts based on the direction and magnitude of results. In particular, research with statistically significant positive results is more likely to be submitted for publication, to be published, and to be published more quickly than research with negative or nonsignificant results. Consequently, published studies on a particular topic might not be representative of all valid studies conducted on the topic, leading to distortion of the scientific record. Other sources of publication bias include multiple publication of results, and selective reporting of results within a published study.

Publication bias tends to be greater in clinical research than in public health research, and in observational studies as opposed to randomized studies. Nevertheless, publication bias has been demonstrated across all of these types of research. One area where a variety of publication biases has been documented is pharmaceutical industry studies of new drug applications.

The primary causes of publication bias are commonly assumed to be editorial decision making, together with authors' reluctance to submit research with null or negative results—sometimes referred to as the file drawer problem. While research has supported the latter explanation, studies of publication bias in editorial decision making have yielded mixed findings. Another common source of publication bias is within-study selective reporting among multiple outcomes, exposures, subgroup analyses, and other multiplicities. Although this cause has until recently been largely ignored, it is likely to cause even greater bias in the literature than does selective publication.

Publication bias presents a serious threat to the validity of systematic reviews and meta-analyses. Undetected publication bias not only can lead to misleading conclusions, but at the same time can give the impression of unfounded precision of results. A screening method for publication bias in meta-analysis involves correlating observed effect sizes with study design features that are potential risk factors for selective-publication, such as sample size. A funnel plot provides an informal graphical method where effect sizes are plotted against sample sizes, while the null hypothesis of no publication bias can be tested using rank correlation approaches such as Kendall's tau or Spearman's rho. Detecting within-study selective reporting presents a greater challenge, unless access is available to a study's original protocol and complete results of all analyses performed.

Several imperfect strategies exist for reducing or adjusting for publication bias. *Sampling methods* involve tracking down unpublished manuscripts, sometimes referred to as the grey literature, as well as broader systemic solutions such as requiring prospective registration and public release of complete trial protocols. *Analytic methods*, applicable primarily to selective publication situations, include the file drawer adjustment strategy. This involves estimating the number of zero-effect studies needed to eliminate significant findings in a meta-analysis. More

complex analytic approaches employing weighted distribution theory also are available. All analytic methods require important assumptions, which in many situations can be questionable. Analytic methods are less applicable for within-study selective reporting situations, where the solution must be found in authors' complete reporting and straightforward interpretation of results. Perhaps most importantly, consumers of research reports, meta-analyses, and systematic reviews are cautioned to be constructively skeptical in appraising results and conclusions.

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See also Evidence-Based Medicine; Meta-analysis; Peer Review Process

Further Readings

- Chan, A. W., Hrobjartsson, A., Haahr, M. T., Gotzsche, P. C., & Altman, D. G. (2004). Empirical evidence for selective reporting of outcomes in randomized trials - Comparison of protocols to published articles. *Journal of the American Medical Association*, *291*, 2457–2465.
- Easterbrook, P. J., Berlin, J. A., Gopalan, R., & Matthews, D. R. (1991). Publication bias in clinical research. *Lancet*, *337*, 867–872.
- Melander, H., Ahlqvist-Rastad, J., Meijer, G., & Beermann, B. (2003). Evidence b(i)ased medicine: Selective reporting from studies sponsored by pharmaceutical industry. *BMJ*, *326*, 1171–1173.
- Phillips, C. V. (2004). Publication bias in situ. *BMC Medical Research Methodology*, *4*(20).
- Thornton, A., & Lee, P. (2000). Publication bias in meta-analysis: its causes and consequences. *Journal of Clinical Epidemiology*, *53*, 207–216.