The Existence of Publication Bias and Risk Factors for Its Occurrence

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Publication bias is the tendency on the parts of investigators, reviewers, and editors to submit or accept manuscripts for publication based on the direction or strength of the study findings. Much of what has been learned about publication bias comes from the social sciences, less from the field of medicine. In medicine, three studies have provided direct evidence for this bias. Prevention of publication bias is important both from the scientific perspective (complete dissemination of knowledge) and from the perspective of those who combine results from a number of similar studies (meta-analysis). If treatment decisions are based on the published literature, then the literature must include all available data that is of acceptable quality. Currently, obtaining information regarding all studies undertaken in a given field is difficult, even impossible. Registration of clinical trials, and perhaps other types of studies, is the direction in which the scientific community should move.

(*JAMA*. 1990;263:1385-1389)

The human intellect . . . is more moved and excited by affirmatives than by negatives.

Francis Bacon, 1621

EVER SINCE about 1450, the standard method of imparting information and of acquiring knowledge has been use of the written word. Even before Gutenberg's printing press, the benefits of writing things down was recognized (Moses did not rely on oral tradition to interpret and pass on the Ten Commandments correctly). The value of the written tradition is manifold: it preserves, as in the recording of historical information about families or communities; it provides a basis for common understanding, as in lawmaking; and it provides the vehicle by which we share information deemed to be important, as in reporting the news of the day or the latest scientific findings.

In artistic endeavors, reinterpretation of the written word, such as in translations, is acceptable, even welcome. In other areas, the inherent ambiguities of language lead to a constant struggle to decipher the meaning or intent of the written word. The US Constitution is a case in point. Science depends on clear, accurate, and precise wording in the descriptions of work performed and results obtained. It is imperative that there be only one possible interpretation of what is written.

Moreover, to advance, science depends on complete reporting, both in terms of what experiments or studies were conducted and in terms of how an experiment or study was conducted. Practically, it is not possible or even desirable that every experiment or every element of an experiment be reported. Yet, there seem to be no established standards by which an investigator decides what is worth reporting: the decision to report one's findings and the manner in which they are reported are a matter of judgment.

The question of how and when study results are reported is of interest because of potential selection bias: given a set of characteristics about a study—design, operation, and outcome—could one predict the likelihood of publication? If one could, then that on which our "knowledge" is based, the published literature, is a biased representation of knowledge as a whole.

If the characteristics that determine publication are related to study quality, then the selection bias incurred by studying only the published literature is acceptable, even desirable. If, on the other hand, the direction of study results or the statistical significance of the results is the reason for differential publication, the bias in terms of the information available to the scientific community may be considerable. The bias that is created when publication of study results is based on the direction or significance of the findings is called *publication bias*. This term seems to have been used first in the published scientific literature by Smith[1] in 1980.

Even if publication bias exists, is it worth worrying about? In a scholarly sense, it is certainly worth worrying about. If one believes that judgments about medical treatment should be made using all good, available evidence, then one should insist that all evidence be made available. In reality, however, medical decisions, to date, have mainly been guided by the individual clinician's training and personal experience. Recently, there has been a change in the way decisions have been made. The rise of consensus conferences, decision analysis, expert systems, using clinical trials as a basis for policy, and meta-analysis has propelled decisions regarding medical treatment toward a more scientific approach.

PUBLICATION BIAS

Historical Aspects

There seem to be no formal guidelines in science as to when study results should or should not be published. The decision as to what to include in a publication and whether to publish is largely personal, although dictated by the fashion of the times to a certain extent. When Robert Boyle, the chemist, published his experiments on air in 1680, he was credited with being the first to report the details of his experiments and the precautions necessary for their replication. This work ushered in a new type of report—one that described difficulties and errors. Thus, in the 1600s, 1700s, and early 1800s, the usual scientific report described not only the "positive" findings but also the "negative" or "nil" results.

Concerned about publication practices in the physical and life sciences, Boyle lamented in 1661 that scientists did not write up single results but felt compelled to refrain from publishing un-

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til they had a "system" worked out that they deemed worthy of formal presentation: "But the worst inconvenience of all is yet to be mentioned, and that is, That whilst this vanity of thinking men obliged to write either systems or nothing is in request, many excellent notions or experiments are, by sober and modest men, suppressed . . . ."[2] Apparently, the notion of going to press only if one has something "big" to present is not modern at all.

By the mid-1800s, the style of scientific writing was in the process of changing to the terse, rather technical approach with which we are familiar. Limitations of time (as science began to move quite rapidly), journal space, the development of groups of scientists working together and forging a written document together, the response to peer review, and economic dependence on a system that rewarded quick success were all factors that led to a change in scientific writing and publishing. The change in style that has taken place over the years is not inherently bad. The problem is whether the increased brevity has resulted in lost information and whether it represents biased reporting.

Evidence for Publication Bias

Perhaps as a result of the difficulties of designing studies to address the problem, more has been written to complain about publication bias than to report results of studies undertaken to evaluate it. Most research on publication bias has been done in the psychology and education fields.[3-10]

Sterling[3] was probably the first to emphasize that the tendency to publish positive results and reject negative findings is a serious problem. He reviewed all articles published in four journals during 1 year (1955 or 1956) and found that 97% of the articles that used tests of significance rejected the null hypothesis. Others in the social and behavioral sciences have found similar evidence for publication bias.[4-9]

Two experimental studies have been done in this area (*New York Times*. September 27, 1988)[10]; both found that when all other variables were held constant, reviewers were highly influenced by the direction and strength of the study results. The study by Mahoney[10] is particularly illustrative of where biases may exist in the reviewing process. Seventy-five referees for one journal were randomly assigned to receive one of five similar manuscripts. All manuscripts were identical in the "Introduction" and "Methods" sections but varied in either the "Results" or "Discussion" sections. One group of referees received a manuscript that described positive results, another received a manuscript that described negative results. A third group was asked to evaluate a manuscript on the basis of the "Methods" section and relevance alone; no data were provided. The fourth and fifth groups received manuscripts with "mixed" results, with either a positive or negative "Discussion" section. The referees used a scale of 0 to 6 (low to high) to rate the manuscripts for five items: relevance, methods, data presentation, scientific contribution, and publication merit. The referees' ratings are presented in Table 1. Although studies with positive and negative results had identical "Methods" sections, referees rated the negative results lower in the quality of methods, as they did studies with mixed results. Data presentation, scientific contribution, and publication merit scores were also scored lower when results were negative or mixed. Negative studies received significantly lower scores for publication merit as well.

Table 1.—Manuscript Ratings for Same Manuscript With Varying Presentations of Results or Discussion[10]

Presentation	No. of Referees	Mean Ratings: Methods	Data Presentation	Scientific Contribution	Publication Merit
Positive results	12	4.2	4.3	4.3	3.2
Negative results	14	2.4	2.6	2.4	1.8
Methods only	14	3.4	. . .	4.5	3.4
Mixed results, Positive discussion	13	2.5	1.3	1.6	0.5
Mixed results, negative discussion	14	2.7	2.0	1.7	1.4

Table 2.—Studies of Publication Bias in Medicine

Source, y	Subject	Index Source	Follow-up Method	Results
Simes, 1986[17]	Cancer trials	Cancer trials register	Publications and register	Published trials show increased efficacy of combined treatment
Dickersin et al, 1987[18]	Randomized, controlled trials	File of randomized, controlled trials	Questionnaire	Published trials favor test treatment more often
Sommer, 1987[19]	Menstrual cycle research	Society membership	Questionnaire	Published studies more often statistically significant
Chalmers et al, 1989[24]	Perinatal trials	ODPT* abstracts	ODPT full reports	Strength of results in abstract not associated with full publication

*ODPT indicates Oxford Database of Perinatal Trials.

Little has been done to investigate the possibility of publication bias in the medical area.[11] Despite the dearth of empirical evidence, it has been accepted as fact, rather than as a hypothesized problem in need of further study. Disregarding the absence of good data, prominent investigators have written articles in medical journals where they have referred to publication bias as if it is known to exist and its etiology well understood. "Investigators are more strongly motivated to offer positive results for publication rather than null results. Many journal editors select papers for publication on this very basis, some of them expecting to see P values less than 0.05. Published clinical trials are inevitably a positively biased selection."[12]

Information regarding publishing practices is not easily obtained or readily available; it is likely that this is the reason so little research has been done. One approach is to survey investigators regarding their habits and experience. The problems with this method are illustrated by a study by Hetherington et al[13] in which a one-page questionnaire requesting information regarding unpublished perinatal trials was sent to approximately 42 000 obstetricians and pediatricians around the world. Of the 395 unpublished trials reported to the investigators, only 18 were completed more than 2 years before the survey. The rest were either ongoing (252) or had ceased recruitment within 2 years of completion (125) and, thus, were considered to be within the period needed for results to reach publication. Hetherington et al concluded that it is not possible to estimate the size of publication bias by attempting to identify unpublished trials retrospectively.

What data from the medical field support the notion that publication is related to the direction and strength of study findings? Indirect evidence for publication bias has been provided by several studies.[14-16] Chalmers reviewed 23 publications that provided fatality rates for serum hepatitis and found that reported rates ranged from 0.3% to 62%. The higher rates were associated with studies that had smaller numbers of patients. The authors suggested that these results may indicate an increased tendency on the part of the investigators to report unusual findings.

Direct evidence for publication bias in the medical area is shown in Table 2. Simes[17] compared results of published trials and results of trials registered with the International Cancer Research Data Bank. Trials were chosen for the therapeutic situations: (1) initial alkylating agents vs combination chemotherapy for the treatment of advanced ovarian cancer and (2) alkylating agents or prednisone vs combination chemotherapy for the treatment of multiple myeloma. All trials were registered or published before October 1983. The pooled results of the published trials of treatments for ovarian cancer demonstrated a statistically significant benefit of the combination therapy, while the pooled results of the registered trials, which included some published and some unpublished trials, did not show a significant survival advantage. Similarly, a statistically significant survival advantage was seen for combination therapy in the published trials of treatment for myeloma, with a reduced, although still statistically significant, advantage in the registered trials.

Additional evidence has come from a survey of 318 authors of published trials who were asked whether they had participated in any unpublished trials[18] (Table 3). The 156 respondents reported 271 unpublished and 1041 published trials. Completed unpublished trials favored the test therapy 14% of the time, compared with 55% of the published trials. The major reasons the authors gave for not publishing were results not favoring the test treatment and lack of interest (Table 4). It appears from the data that nonpublication resulted primarily from a failure to write up trial results rather than decisions on the part of referees or editors.

Sommer[19] surveyed all 140 members of the Society for Menstrual Cycle Research and identified 73 published and 28 unpublished studies (response rate was 67%). Thirty percent of 73 published studies, 38% of 42 reports in the publication pipeline, and 29% of the 28 unpublished studies had statistically

Table 3.—Results of Published Randomized, Controlled Trials (RCTs) vs Results of Completed Unpublished RCTs[18]*

Trend or Statistical Significance	Published RCTs†		Completed Unpublished RCTs†	
	No.	% of Total With Trend Specified	No.	% of Total With Trend Specified
Favors new therapy ($P<.05$)	423	55.1	26	14.6
Trend favors new therapy	123	16.0	40	22.5
No difference between therapies	170	22.2	79	44.4
Trend favors control or standard therapy	25	3.3	23	12.9
Favors control or standard therapy ($P<.05$)	26	3.4	10	5.6
Total No. of RCTs With Trend Specified	**767**	**100.0**	**178**	**100.0**
No. of RCTs with trend of results not specified	274	...	26	...
Total No. of RCTs	**1041**	...	**204‡**	...

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†χ^2 (4 *df*) = 111.09; $P<.001$.
‡Does not include 34 completed, unpublished trials by one author.

Table 4.—Randomized, Controlled Trial (RCT) Status and Reasons for Not Publishing Completed RCTs[18]*

RCT Status	RCT Stopped	RCT Completed but Article Not Submitted	RCT Completed and Article Submitted	Response Blank	Total No. (%)
Article intended, in progress, or in peer review	0	15	10	...	**25** (12)
Results negative	16	35	7	...	**58** (28)
Lack of interest	6	16	2	...	**24** (12)
Sample size problems	20	3	0	...	**23** (11)
Poor methods	6	2	1	...	**9** (4)
Side effects	12	1	0	...	**13** (6)
External group problem	9	1	0	...	**10** (5)
Controversy	0	3	2	...	**5** (2)
Unknown or blank	5	26	1	5	**37** (18)
Total No. (%) of RCTs	**74 (36)**	**102 (50)**	**23 (11)**	**5 (2)**	**204†**

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†Does not include 34 completed unpublished trials by one author.

significant results. When only studies that reported the statistical significance of the outcome were counted, these percentages were 61%, 76%, and 40%, respectively. Sommer found that the best predictor of publication status of the study was prior publication by the responding investigator. Investigators with only one study under their belts tended not to publish (76%), while those with two or more usually had one or more published studies (67%). Furthermore, if their first study was published, investigators were more likely to perform subsequent studies (68%) than were investigators who had not published their first study (35%).

In addition, several studies concerned with the complete publication of studies initially published as abstracts have been reported.[20-24] Data from these studies have been remarkably consistent, showing that only 30% to 60% of results published in abtracts are ultimately published in full. McCormick and Holmes[23] found that pediatric abstracts submitted but not accepted for presentation reach subsequent full publication just 13% to 22% of the time, while 49% to 54% of selected abstracts achieved full publication. This may be an indication that the selected articles represent studies of better quality, but it could just as easily indicate greater editorial interest in the findings presented in selected articles. Chalmers et al[24] followed up summary reports that were contained in the Oxford Database of Perinatal Trials and published between 1940 and 1984. Search of the database, using authors' names, revealed that approximately 37% were subsequently published in full. Neither study quality, as judged from the abstracts, nor study results were associated with final publication status. As this design

Table 5.—Characteristics of Drug Trials by Publication Status[27]

Trial Characteristics	Nonpsychotropic Drugs (n=69)		Psychotropic Drugs (n=234)	
	Published	Unpublished	Published	Unpublished
% Controlled	47	26	47	52
% "Good" quality	23	46	35	37
% That had information regarding adverse effects	43	83	56	77
Mean sample size	62	48	83	76

does not provide any information about the process between data analysis and the decision to publish, the results do not necessarily indicate the absence of publication bias.

It is difficult to estimate, even crudely, the size of the problem of publication bias, given the available information. When data from investigations of the problem are used, the ratio of published to unpublished studies ranges from 128:1[13] to 1:1,[17] with the majority of the ratios falling between 10:1 and 1:1.[1,9,13,17-19] We are currently conducting a prospective study at The Johns Hopkins University, Baltimore, Md, that should provide a better estimate of the size of the problem. The project is designed to follow up studies approved in 1980 by institutional review boards at our institution and clinical trials funded by the National Institutes of Health, Bethesda, Md, in 1979, to see whether publication bias exists and, if so, what the risk factors are. Potential risk factors are study design characteristics, such as sample size, type of control group, and number of collaborating centers; investigator characteristics; funding source; and strength of study findings.

The Role of Journal Editors

How has publication bias come about? There has been an assumption in medical literature that the bias for publishing striking results starts with the journal editors. There is some basis for this belief. The *British Medical Journal* stated in 1980 that their ideal article described "findings that will affect clinical practice, . . . and findings in a common disease that either improved prognosis or simplified management . . . ."[25] A 1983 piece in the "Views" section of the same journal gave advice that "those who seek rapid publication of a paper (especially negative results)" should submit the article to a pay journal. They finished, ". . . as to how many people will then see it . . . well, negative results have never made riveting reading."[26]

This situation has prompted discussion as to whether it makes sense to have a journal of negative results: "The scientific need for a publication of negative or null-difference results is apparent and the 'Journal of Negative Results' has been bandied about for many years as an almost sick joke. Such a journal would not only be decidedly dull but also a financial catastrophe."[12]

Maxwell[12] went on to suggest that at least editors should provide a register of negative results, listing the subject, authors' names and addresses, and title of the study, accessible by *Index Medicus*. This is an equally unsatisfactory solution to the problem.

Edward Huth, editor of the *Annals of Internal Medicine*, has stated that an electronic medical journal could be published at a lower cost than printed journals, and thus might be in a better position to publish negative or nil results. However, he warned, "it ought to be quite clear in the title or in the abstract that the paper arrived at a negative conclusion, lest the authors or researchers think they are getting positive data" (*New York Times*. April 29, 1986:C1, C7).

The Journal of the American Medical Association once had a section entitled "Negative Results" that a quick perusal of *JAMA* volumes indicates was included as a somewhat regular feature, approximately once a month, from 1962 through 1968. The articles were 1 1/2 to 2 pages long. Unfortunately, there is no information available regarding the rationale for the start-up or continuation of this section of the journal, despite attempts to learn more (E. Knoll, PhD, personal communication, March 1988).

The Role of Study Quality

So far, the potential role of the direction of study findings on the publication of results has been emphasized. There are other potential risk factors for nonpublication, most prominently quality, sample size, and the funding source of trials.

In 1980, Hemminki[27] described the quality of information submitted to drug licensing authorities and related this to publication status (Table 5). Applications for the licensing of psychotropic drugs in Finland and Sweden for 1965, 1970, 1974, and 1975 and for a random sample of nonpsychotropic drugs in Finland were reviewed. For all years, 39% and 44% of the trials included in applications in Finland and Sweden, respectively, were not published. Unpublished reports related to trials of psychotropic drugs more often contained information regarding patient selection and exclusion criteria than did published reports, although this was not so for unpublished studies of nonpsychotropic drugs. Overall, the quality of the published and unpublished reports seemed about equal. This study provides evidence that the quality of a clinical trial funded by a pharmaceutical company is not a factor in publication decisions.

The Role of Sample Size

Study size may play a part, either directly or indirectly, in publication decisions. The aforementioned study by me and my colleagues[18] found that unpublished trials performed by a specific group of authors had a median sample size of 24, whereas the "index" randomized, controlled trials (a sample of published randomized, controlled trials used to generate the list of authors surveyed) had a median sample size of 68. Chalmers and coworkers[24] found that of 176 abstracts that described perinatal trials, those with a sample size greater than the median were more likely to be published in full than those with a sample size less than the median. (If finer strata were used to categorize sample size, however, the association between sample size and publication was not significant.) It is reassuring in some ways that smaller studies may not be published as often, because sample size can be an indicator of a study's quality. However, small sample size may lead to an underpowered study that incorrectly fails to reject the null hypothesis. If publication bias operates, the study would go unpublished because of nil results. These data support this hypothesized continuum.

Berlin and Begg,[28,29] in a review of 246 published trials of treatments for cancer, found a strong association between sample size and treatment effect: studies with smaller sample sizes had larger treatment effects. The trend is most dramatic in randomized, as opposed to nonrandomized, studies. This implies that small trials with large effects tend to be published preferentially, while large trials are likely to be published regardless of the outcome.

The Role of Funding Source

Davidson[30] reviewed 107 trials published in 1984 and classified them based on the direction of the results (favoring

Table 6.—Direction of Results of Clinical Trials Published During 1984 in Selected Journals

Journal	No. (%) Favoring New Treatment	No. (%) Favoring Standard Treatment	Total No. (%)
Annals of Internal Medicine	12 (86)	2 (14)	**14 (100)**
Archives of Internal Medicine	11 (79)	3 (21)	**14 (100)**
Lancet	30 (75)	10 (25)	**40 (100)**
New England Journal of Medicine	18 (67)	9 (33)	**27 (100)**
American Journal of Medicine	5 (42)	7 (58)	**12 (100)**

new therapy vs favoring the standard therapy) and the source of funding (pharmaceutically supported vs "generally" supported). Seventy-six (71%) of the 107 trials favored the new therapy and 31 (29%) favored the standard therapy. Of those that favored the new therapy, 33 (43%) were pharmaceutically supported, while of those that favored the traditional therapy, only 4 (13%) were pharmaceutically supported. This translates into 89% (33/37) of the pharmaceutically supported studies and 61% (43/70) of the generally supported studies favoring the new treatment. The proportion of articles that favored the new vs the traditional therapies varied considerably, depending on the journal evaluated (Table 6). Davidson concluded: "While it seems unlikely that conspiracies to suppress unfavorable results of clinical trials exist, a de facto exclusion of negative results may be occurring." The prospect of conspiratorial suppression of results has also been raised[31] and refuted.[32]

The possibility that funding may affect the way in which study results are communicated extends beyond the clinical trial setting.[29] Because of concern about this issue and others having to do with conflict of interest, full disclosure of financial support is now required by many journals, including *JAMA*, for all published reports.

COMMENT

It is probably not in our best interest to develop ways to "cure" the problem of publication bias. For example, retrieval of unpublished data from trials requires a great deal of effort and may not be unbiased. Although this cure and others[29] can provide useful additional information for those evaluating the published literature, they are not very good remedies for publication bias.

A measure somewhere between cure and prevention is to insist that the scientific community mend its ways. Investigators should report the results of all studies undertaken. Journal editors should formalize editorial policy stating that the decision to publish will be based on issues of quality and logical reasoning by the authors and not the direction and strength of study results.[33] Although this is the simplest approach to the problem of publication bias, its universal implementation is not likely to be realized.

The most effective measure to prevent publication bias is the registration of all trials, perhaps all research studies, undertaken. Registers exist for several research areas,[34] most notably the perinatal,[35] cancer,[36] and acquired immunodeficiency syndrome[37] fields. The Oxford Database of Perinatal Trials[35] is one of the best developed and has been used as a basis for methodological research and hundreds of meta-analyses.[38] Although prospective trial registration is a considerable task, it is the logical imperative for the electronic age in which we live. Prevention, not cure, is the direction in which we should move.

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