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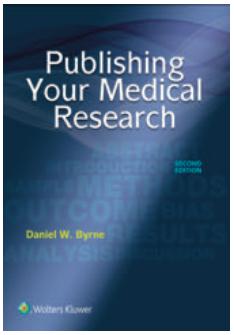

Publishing Your Medical Research (Second Edition)

Daniel W. Byrne
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Daniel Byrne has taught courses on biostatistics and medical writing at Vanderbilt University since 1999. He wrote the first edition of *Publishing Your Medical Research* in 1998 to provide clinicians with practical information and advice on how to write a publishable paper. The second edition has the same general aims and consists of 34 chapters divided into five main sections: Planning, Observing, Writing, Editing, and Revising.

The Planning section (Chapters 2 to 12) focuses on tips and advice for designing and running clinical studies. The rationale is that journal editors and reviewers are looking for best practice in how trials are conducted and written up – and this is best addressed by not designing flaws into the research. I was tempted to skim through these chapters as not being very interesting to medical writers, but I'm glad that I didn't. As a freelance medical writer, I don't have any influence on the design of clinical studies but the finer points of trial design and how a flawed study design can be avoided, is good background information to understand. The chapters are meticulously written and include some useful and interesting tables. I particularly liked the panels containing the personal views of journal reviewers on what constitutes a "good" or "bad" paper.

The Observing section deals with the collection and analysis of data. I am no statistician and approached the chapters on statistical tests (Chapters 15 to 19) with some trepidation. I was pleasantly surprised (and relieved): these chapters are quite short, easy to follow, and informative. I now have a better understanding of some of the issues that investigators and study statisticians find so frustrating when discussing how the results of a trial should (or can) be presented. These chapters provide information on which statistical tests should be used in particular circumstances and which are not appropriate, together with the reasons why. Chapter 19 considers multivariate analysis: this chapter is more detailed and explains how this form of analysis can be used to control for confounding factors in clinical trials. For this reason, selecting multivariate analysis alongside univariate analysis can enhance research papers. Byrne also points out that as statistics is a subject that is evolving and developing, investigators must ensure that they are using up-to-date statistical methodology.

Chapters 20 to 27 focus on writing the paper, with separate chapters devoted to the preparation of the title page, abstract, introduction, methods, results, discussion, and references. As in the early chapters, Byrne provides examples of feedback from reviewers and editors to highlight potential weaknesses in writing. Chapter 24 (Results) provides more guidance on presenting statistical results and advice on presenting clear and concise figures and tables. There is some excellent advice in Chapter 25 on how to set out the discussion. I particularly liked the list of eight questions that Byrne suggests should be answered in the course of the discussion – from pointing out the novelty in the research, to discussing the strength of the data set, the rationale for the choice of analysis, and how and why the findings might alter clinical practice.

While I agree with most of what Byrne has written in Chapters 20 to 27, I found some areas that were less satisfactory. While the meticulous attention to detail was a strength of the early chapters, here the level of detail in some chapters just seems to add to their length without providing correspondingly greater insight. This is particularly true when the author reiterates information usually covered in a journal's instructions to authors. The need to check that the manuscript complies with the journal guidelines prior to submission is highlighted in a later chapter and means that this level of detail is unnecessary here. Personally, I did not find Tables 24.1 and 24.2 (providing preferred "terms" for pejorative or problematic "terms" for patients) helpful: Byrne covers the most important advice about describing patients and their disease in the text of Chapter 24, and I would have preferred it to have been left at that.

> I wholeheartedly agree with Byrne's comments on clarity and readability and with his advice concerning internal peer review of the paper.

Byrne has included the International Committee of Medical Journal Editors' (ICMJE's) Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals in Appendix A, and I think that he needs to reflect on whether the advice he gives about authorship in Chapter 20 (Title Page) is entirely in line with ICMJE recommendations. The absence of any mention of good publication practice (GPP) guidelines in Chapter 27 (Industry Publications) is, I feel, a major flaw. Although clinicians – the target audience for this book – were not the primary focus for the original GPP guidelines, in my opinion, Chapter 27 is inadequate in its current form and should be revised in future editions to include information on GPP.

I did not think that a separate chapter on references (Chapter 26) was necessary. Byrne provides good advice in this chapter, but for me this is so integral to the writing process that it should have been included in Chapter 22 (Introduction).

The Editing section (Chapters 28 to 31) focusses on final preparations for submission of the manuscript. I wholeheartedly agree with Byrne's comments on clarity and readability and with his advice concerning internal peer review of the paper. The checklist for internal review produced by Vanderbilt University that he reproduces in Appendix B is very interesting, and I can certainly see its usefulness in editing and subsequently revising a first draft. Table 30.1 – advice from editors and reviewers on how to improve writing style for impact – is also very useful and to the point, but I was not convinced

of the value of many of the other tables in this chapter (14 tables in total). A particular criticism is that Byrne has not taken sufficient account of differences between UK and US English in all of his suggestions.

The final section (Revising) is very short. Chapter 32 covers proofreading and layout: the advice is all good and the tables and figures are informative, but there is overlap with the writing section. Chapter 33 gives advice on writing a persuasive cover letter – once again, Byrne includes feedback from journal editors to add weight to his guidance. He also reiterates advice from journal editors to make a presubmission enquiry to ascertain the journal's interest in publishing a particular paper. Chapter 34 contains useful advice on responding to reviewers' comments as well as insight about the peer review process and how the decision to publish is made.

The book includes two further appendices (Appendix C provides a sample data collection form and Appendix D is a copy of the World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects), a bibliography, and an index.

This book covers a vast amount of material in relatively few pages, although (as I mentioned earlier) some detail could be removed from some chapters. I would also question the idea of having more than 250 principles in a book designed to help people through an extended and complex process: Readers can't possibly hold all of these in their heads to prompt their next action, and I would suggest using numbered subsections instead.

The book is not intended for professional medical writers and editors, and, in my opinion, it is not a book that this group needs to read from front to back. Nevertheless, the Planning and Observing sections may be of interest to people without a background in clinical trials, and the Writing, Editing, and Revising sections could provide a gentle introduction for new medical writers and editors. For these reasons, medical writing departments in pharmaceutical companies and contract research organisations, as well as medical communications companies, may benefit from keeping a copy on their bookshelves.

Reviewed by
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Journal Watch

Journal Watch is based on the French-language blog *Rédaction Médicale et Scientifique* by Hervé Maisonneuve available at www.redactionmedicale.fr.

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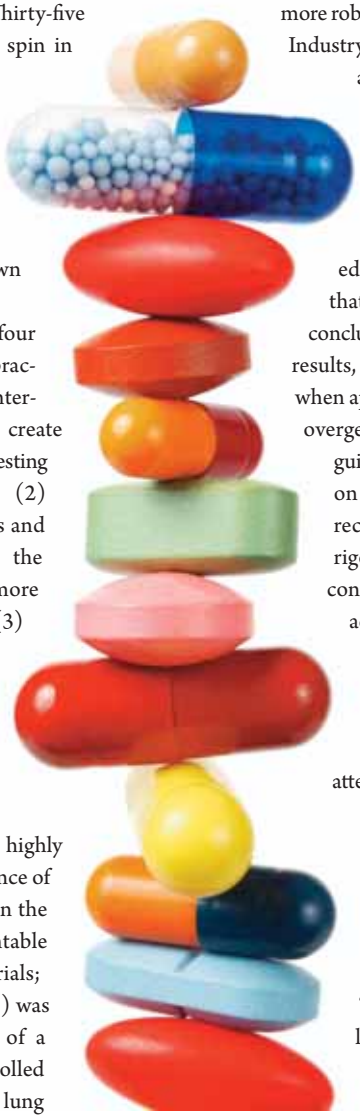
"The highest (but also greatest) variability in the prevalence of spin was present in trials."

"In the scientific literature, spin refers to reporting practices that distort the interpretation of results and mislead readers so that results are viewed in a more favourable light." The above title and first sentence are from a systematic review that aimed to study the nature and prevalence of spin in the medical literature. Thirty-five reports, which investigated spin in clinical trials, observational studies, diagnostic accuracy studies, systematic reviews, and meta-analyses, were included. This systematic review was well conducted by a known Australian team.

Spin was classified in four categories: (1) reporting practices that distort the interpretation of results and create misleading conclusions, suggesting a more favourable result; (2) discordance between results and their interpretation, with the interpretation being more favourable than the results; (3) attribution of causality when study design does not allow for it; and (4) overinterpretation or inappropriate extrapolation of results.

The prevalence of spin is highly variable. The highest prevalence of spin (100%) was observed in the main text of 10 implantable cardioverter defibrillator trials; the lowest prevalence (9.7%) was measured in the abstracts of a sample of randomized controlled trials of systemic therapy in lung cancer. Nineteen of the 35 reports investigated the practices that researchers used to spin results. Four categories of spin practices were identified: inappropriate interpretation given study design; inappropriate extrapolations or recommendations for clinical practice; selective reporting; more robust or favourable data presentation. Industry sponsorship was not significantly associated with spin.



Further research is needed to better identify and classify spin; we don't know the impact of spin on decision-making. Peer reviewers and journal editors should check to make sure that abstract and manuscript conclusions are consistent with the study results, that causal language is used only when appropriate, and that results are not overgeneralised. Clinical practice guidelines should be developed based on systematic reviews to ensure that recommendations are founded on rigorous data and not misleading conclusions. Structural reforms within academia are needed to change research incentives and reward structures that emphasise "positive" conclusions, including the pressure to publish and media attention.

Reference:

Chiu K, Grundy Q, Bero L. 'Spin' in published biomedical literature: A methodological systematic review. PLoS Biol. 15(9):e2002173.